National Sustainable Agriculture Coalition

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Food and Drug Administration
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Rockville, MD 20852

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RIN 0910-AG35

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Re: Comments on the proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

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 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. 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

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ACKNOWLEDGEMENTS

The National Sustainable Agriculture Coalition's (NSAC) comments on the proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption 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:

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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 Produce 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 Produce 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 Produce 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 Produce Rule, in the order in which they appear in the comments below, is as follows:

- FDA must retain its "integrated approach."
- 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 release a second proposed rule for public comment before issuing a final rule.
- FDA must revise the definition of "farm" and the supporting definitions of "facility" to reflect activities that many farms do, and thus limiting the scope of the term "facility," consistent with FSMA.
- FDA must retain the $25,000 exemption but base it on sales of covered produce and not all food.
- FDA must clarify coverage in Subpart A by revising the definition of "you," creating a definition of "covered farm," and reorganizing certain subsections.
- FDA must amend the modified requirements so that only the average annual value of covered produce and not all food applies when determining whether a farm is eligible for the modified requirements.
- FDA must not rely on flawed and limited alternative options to provide sufficient flexibility to rigid requirements, and should work with farmers and research institutions and agencies to conduct research needed to support alternative practices that are relevant and appropriate to the wide range and diversity of farming systems.
- FDA must completely revise Subpart E on agricultural water to meet the requirements of FSMA and establish a process for developing a science- and risk-based standard.
- FDA must completely revise the pre-harvest intervals between application of biological soil amendments of animal origin and harvest of covered produce in Subpart F so that they do not proscribe sustainable farming systems and do not exceed the pre-harvest intervals in the National Organic Program.
- FDA must not require insulation of compost as part of an acceptable composting process.
- FDA must incorporate the concept of co-management and sustainable conservation practices directly into the regulatory text.
- FDA must not imply that there should be a nine-month interval between grazing of a field by domesticated animals and harvest of covered produce from that field.
- FDA must make clear that product from exempt and qualified exempt farms cannot de facto be considered "adulterated."
- FDA must completely revise the process for withdrawing a qualified 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 exempt 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 THE REGULATORY FRAMEWORK

Summary

NSAC makes comments and recommendations on FDA's regulatory framework in the proposed Produce Rule. Specifically, we comment on:

- Our support for the "integrated approach";
- The deficiency of the Qualitative Assessment of Risk to establish an adequate scientific and risk basis;
- The inconsistency of the approach with existing "continuous improvement" food safety regimes; and
- The inappropriateness of requiring food safety plans or farm registration.

Comments

A. An integrated approach to the Produce Rule is the correct approach.

In the proposed Produce Rule, FDA has appropriately implemented the requirement from FSMA to "minimize, as appropriate, the number of separate standards that apply to separate foods."[19] Specifically, FDA has taken an "integrated approach" and has not set forth separate standards for separate foods (with the sole exception of sprouts) in the proposed Produce Rule. FDA is tentative in its determination to use an integrated approach rather than a commodity-specific approach, and the agency specifically requests additional comment on this approach.

In 2009 when the legislative process that led to FSMA was just getting underway and the House of Representatives was crafting its food safety bill, NSAC initially supported a highly targeted approach to federal food safety legislation that focused on the highest risk of commodity/processing combinations, such as fresh-cut produce. Such a focused approach would have channeled limited resources to addressing the highest risks in the food supply that were not already subject to federal regulations and oversight. This approach was rejected by other stakeholders and by the agency, and Congress therefore went on to craft legislation that gave FDA broad authority – within a flexible, scale- and supply-chain appropriate framework – to regulate produce production. It was then that NSAC fully moved to support what the agency has termed an "integrated approach."

An integrated approach is a critical component of making the produce regulations work for diversified farmers and of fulfilling the FSMA mandate 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."[20] Commodity-specific standards would be extremely burdensome for farmers with highly diversified operations and would fail to provide the flexibility mandated by FSMA. Diversified farmers grow dozens of varieties of fruits and vegetables, and requiring separate standards for each type of produce would be totally unworkable for diversified farmers.

[19] Food, Drug, & Cosmetic Act § 419(c)(1)(D)
[20] Food, Drug, & Cosmetic Act § 419(a)(3)(A)

In the preamble discussion about the integrated approach and the consideration of differing risk of different commodities and practices, FDA also "tentatively conclude[s] that we should not…use market channels as a basis of risk categorization in this proposed rule"[21] other than through the statutorily mandated qualified exemption. In deciding not to use market channels as basis of risk categorization, FDA states that the agency is "not aware of any data that would enable us to compare the likelihood of contamination" of "produce that is sold directly…as compared to that of produce that is sold into other commercial channels."[22] Given the developing but incomplete scientific understanding of how risk is amplified or diminished through different practices, including supply chain practices and characteristics, it is critical for the agency to support research and data collection efforts that compare the risks of different types of supply chains.

Recommendation: In the final Produce Rule, FDA should retain its "integrated approach" and should not take a commodity-specific approach. FDA should also support research and data collection that compares the risks of different types of supply chains, including direct-to-consumer supply chains and supply chains with multiple "touch points."

B. The Qualitative Assessment of Risk is limited and is not sufficient to establish a risk- and science-based approach to the Produce Rule.

Underpinning FDA's proposed Produce Rule is a Qualitative Assessment of Risk (QAR) that does not adequately establish a risk or scientific basis for the proposed standards. FDA makes "some important conclusions" based on the QAR despite the fact that there are significant data limitations.[23] FDA states, "data and information available to us at this time permitted us to conduct only a qualitative (not quantitative) assessment."[24] The lack of a quantitative assessment due to limitations in data and information is significant and emphasizes the difficulty in establishing an adequate scientific and risk basis for the Produce Rule. NSAC provides specific comments on the lack of adequate scientific and risk basis in our comments on the option to establish alternatives through § 112.12, on Subpart E—Standards Directed to Agricultural Water, and on Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste below in sections VII, IX, and X below.

C. The Produce Rule is fundamentally inconsistent with the "continuous improvement" approach in existing farm food safety regimes.

Cooperative Extension agencies, farmer-based organizations, industry associations, and private consulting firms have worked to train farmers and farm workers in the family of food safety certifications broadly referred to as Good Agricultural Practices (GAPs). The foundational document for GAPs program development is FDA's 1998 "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables."

The essential feature of those public and private variations of GAP certification is that they are intended as tools for continuous quality improvement in safety risk management. They are systems

[21] 78 Fed. Reg. at 3527

[22] 78 Fed. Reg. at 3527

[23] 78 Fed. Reg. at 3522

[24] 78 Fed. Reg. at 3522

that recognize the inherent uncertainty of the effectiveness of a food safety intervention. GAP inspection programs necessarily leave the farm a margin for error to reflect the farm's best practical efforts as the best answer to that uncertainty, and allow farm operators to prioritize the most cost-effective strategies for maximizing risk reduction in the execution of their food safety programs. A number of NSAC members work with farmers to support this kind of continuous food safety program, and have developed training programs and materials that have proven effective in preparing farms to succeed in pursuing GAP certification without drastic capital investments or changes in essential farming practices, including organic practices.

The proposed Produce Rule does not reflect the continuous improvement approach of the GAPs regime. The rule establishes a mandate for absolute compliance with all standards, regardless of the relative importance of any standard to actually reducing risk.

Recommendation: In the final Produce Rule, FDA should adopt the continuous improvement approach used in GAPs certifications that supports continuous quality improvement in a farm's food safety performance, and that provides a margin for error between achieving all the specific components of a set of safety standards, and achieving substantial risk reduction to the best of the farm's ability. Enforcement of the Produce Rule should also allow for farms to take the cost-effectiveness of any of the rule's requirements into account, in relation to each requirement's proven impact on improving food safety performance, without risking penalty.

D. Requiring farm food safety plans is inconsistent with FSMA.

In the preamble to the proposed Produce Rule, FDA requests comment on whether the agency "should require, in a final rule, some or all covered farms to perform operational assessments and/or develop a food safety plan, and any criteria that should be employed to determine which farms should be subjected to such a requirement."[25]

FSMA does not authorize FDA to require farms to perform operational assessments or develop food safety plans. While some farms may perform operational assessments or have food safety plans, and farms may benefit from food safety plans, requiring that all covered farms perform operational assessments or develop food safety plans is outside of the scope of FSMA. Codifying this requirement via regulation would be inconsistent with the statute and would increase costs of compliance for covered farms, would further decrease the flexibility of the regulations, and would risk applying a "one-size-fits-all" approach that Congress clearly rejected.

There are several non-governmental organizations, farm groups, and private businesses that are working with farmers on appropriate food safety planning, including many NSAC member organizations. NSAC supports appropriate food safety planning but that work should be allowed to continue outside of the scope of federal regulations.

Recommendation: In the final Produce Rule, FDA should not require farms to perform operational assessments or develop food safety plans. This work should remain outside the scope of federal regulation.

[25] 78 Fed. Reg. at 3619

E. Requiring farm registration is inconsistent with FSMA and unreasonable.

In the preamble to the proposed Produce Rule, FDA requests comment on whether the agency "should require, in the final rule, that covered farms, as described in proposed § 112.4(a), register with FDA."[26]

FSMA does not authorize FDA to require farms to register with FDA. In the preamble, FDA fails to establish how requiring farms to register would contribute to improved food safety outcomes in produce production. Without a robust justification, and with no legal basis for requiring registration, FDA cannot require farms to register.

Recommendation: In the final Produce Rule, FDA should not require farms to register with FDA.

[26] 78 Fed. Reg. at 3619

IV. COMMENTS ON THE 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 preliminary economic impact analysis to the Produce Rule;
2. FDA's scoping notice on the intent to prepare an EIS; and
3. FDA's failure to meet Tribal consultation responsibilities.

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

Comments

A. 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 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.[27] 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.[28]

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:

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

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

- 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 Produce 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 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."[29]

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."[30]

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.

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

[30] Ibid. Page 4.

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.[31] 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 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

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

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 Produce 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 Produce Rule.

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

a. The public health benefits of the Produce Rule are likely more limited than the EIA suggests.

i. The EIA overstates the benefits of the Produce Rule.

FDA bases its estimate of the public health benefit of the proposed Produce Rule on sparse evidence. FDA maintains that society's ability to track foodborne illness is so limited that only about five percent of the foodborne illnesses that occur can be documented. Within the possible universe of foodborne illnesses, the agency does not know whether these illnesses occurred in connection with foods that are already regulated by USDA or FDA. Given the broad scope of those regulatory portfolios, it is certain that a large percentage of the universe of foodborne illnesses occur within the already regulated community. It is very difficult to predict, therefore, what outcomes or benefits could emerge from enlarging the scope of the regulatory regime to the new contexts that the new Produce Rule now proposes to cover. This has important implications for determining the benefits of the proposed rule.

One scholar argues that the analysis estimating the extent of foodborne illness in the US relied upon in the EIA overestimated the scope of the problem, due to an abnormal incidence of norovirus (a foodborne pathogen that may cause diarrhea and vomiting but seldom requires medical care) during the years in which the study was made.[32] That study's authors, Scallan et al., also point to possible overestimation; 58 percent of the foodborne illnesses reported in the study were attributed to norovirus. The authors conclude, "the proportions [of illnesses] that spread person-to-person (e.g., norovirus) may be higher among institutionalized elderly persons. Because a higher proportion of cases are reportedly associated with hospitalization or death in these vulnerable groups, we may have overestimated the total contribution of foodborne transmission for these outcomes."[33] This conclusion also serves as a reminder that *where* a given food is eaten may be as important as *which food* is eaten, and underscores the concern that FDA cannot measure with sufficient precision the actual incidence and causes of foodborne illness.

In calculating the estimated number of illnesses due to raw agricultural commodities (RACs), FDA makes a significant error in attributing the illnesses related to fresh-cut produce as if these were caused on the farm, when in fact, most evidence points toward contamination during processing

[32] Hedber, C. "Foodborne illness acquired in the United States." *Emerging Infectious Diseases* 17: 1338-1340 (2011).

[33] Scallan, E. et al. "Foodborne illness acquired in the United States – major pathogens." *Emerging Infectious Diseases* 17: 7-15 (2011). Page 14.

beyond the farmgate. This suggests that the issue should be a concern (and cost item) taken up in reference to the Preventive Controls Rule, not the Produce Rule.[34] In fact, FDA states that it has no evidence showing how much contamination of fresh-cut produce may be attributable to activities governed by the Produce Rule.[35] Given that the transformation of RACs into fresh-cut products is unquestionably a processing activity that is governed by the Preventive Controls Rule, the FDA estimate of 753,958 foodborne illnesses identified with fresh-cut produce[36] should be deleted from the Produce EIA cost/benefit estimates.

Table 1: Calculation of different scenarios based on different assumptions made by FDA
See explanations in text.

Scenario	**Estimated annual foodborne illness**	**Illnesses attributable to produce covered by this rule**	**Illnesses prevented**	**Proposed benefits ($ millions)**
FDA estimate	3,150,782	2,703,144	1,750,826	$1,036.5
Omit fresh-cut	2,396,824	2,056,302	1,331,867	$788.5
Adjust further for Scallan *et al.*	1,078,499	925,274	599,300	$354.8
Adjust further by omitting unidentified illnesses	206,980	177,574	115,015	$68.1

If this deletion is made, the total number of foodborne illnesses attributable to produce (2,314,715)[37] and sprouts (82,109)[38] would be 2,396,824, only 76 percent of the 3,150,782 illnesses claimed by FDA.[39] Following the methodology pursued by FDA, this revised total should then be reduced by 14.2 percent[40] to get the illnesses attributable to produce covered by the Produce Rule.[41] This yields 2,056,302 illnesses. If, as in Table 26 in the EIA, this number is multiplied by 64.77 percent to get the estimated number of illnesses that could be prevented through this rule, under FDA estimates, we are left with 1,331,867 prevented illnesses. Since FDA puts the cost of each of these illnesses at $592, this is a total benefit of $788.5 million – 76 percent of the $1.036 billion estimate published by FDA.[42]

There are further uncertainties to consider as well. FDA acknowledges that its estimate of foodborne illness is higher than that made by Scallan et al. FDA asserts that the share of illness

[34] U.S. Food and Drug Admin. "Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Pages 63-64.

[35] Ibid. Page 63

[36] Ibid. Table 19, Page 64

[37] Ibid. Table 17, Page 63

[38] Ibid. Table 19, Page 64

[39] Ibid. Page 64

[40] Ibid. Page 65

[41] Ibid. as for Table 26, Page 69

[42] Ibid. Page 79

attributable to unidentified pathogens is 91.4 percent,[43] while Scallan et al. estimate this to be 80 percent.

Using Scallan et al.'s data, FDA estimates that there are 797,112 illnesses attributable to unidentified pathogens. This is only 37.7 percent of the 2,115,417 illnesses listed by FDA.[44] Combining this with the 199,278 illnesses it attributes to known causes,[45] FDA proceeds to state that the total number of foodborne illnesses caused by microbial contamination of FDA-regulated produce RACs other than sprouts would be 996,390. This would be 43 percent of FDA's estimate of 2,314,715. If this figure then is added to the estimated illnesses from sprouts (82,109), and if illnesses from fresh-cut are omitted as above, only 1,078,499 illnesses are tallied. Reducing this figure by 14.2 percent, as above, yields 925,274 illnesses, of which 64.77 percent are considered by FDA to be reducible by the Produce Rule. This yields a total of 599,300 illnesses that FDA considers preventable, for a total benefit of $354.8 million, calculated by multiplying by $592 (cost per illness) as per the FDA estimate. This is only 34 percent of the benefits computed by FDA in the EIA. **Moreover, it amounts to fewer benefits than the proposed cost of the program ($460 million).**

Table 2: Comparison of proposed benefits under scenarios above with FDA estimates of costs and benefits.

Scenario	Proposed benefits ($ millions)	Percent of FDA estimated benefits	Net benefits if annual costs are $460 million
FDA estimate	$1,036.5	100%	$576
Omit fresh-cut	$788.5	76%	$328
Adjust further for Scallan *et al.*	$354.8	34%	-$105
Adjust further by omitting unidentified illnesses	$68.1	7%	-$392

The uncertainty goes even deeper than this. If FDA is not certain whether there are 2,115,437 unidentified illnesses or 797,112, then perhaps the calculation of unidentifiable illnesses itself is flawed in the FDA methodology. For one thing, if the source of an illness has not been identified – even to the point of not knowing the pathogen involved – then it is impossible to trace that illness back to the farm. If an illness cannot be traced to a farm, then there is no evidence to suggest that addressing food safety at the farm level will prevent that illness. The immense uncertainty surrounding these estimates further suggests that federal regulatory policy should not be made on the basis of tallies such as these.

What would the FDA cost calculation look like if these unidentified illnesses were omitted as being too speculative? If, once again, we also omit fresh-cut illnesses (as above), we are left with a total of 199,278 illnesses attributable to RACs, calculated, as above, from Table 17 on p. 63, with another 7,702 attributed to sprout production (once again removing unidentified illnesses). This is a total of 206,980 illnesses. If this figure is subjected to the same methodology as above (reduced by 14.2

[43] Ibid. Page 62

[44] Ibid. Table 17, Page 62-63

[45] This sum is calculated from FDA's listed data, since it was not included in the Table by FDA.

percent) to get 177,574, of which 64.77 percent (115,015) are considered preventable under this rule, by multiplying by a cost of $592 per illness we arrive at a total benefit of $68 million, only 7 percent of FDA's estimate. **This benefit would be only 15 percent of the proposed cost of the rule.**

In the benefits calculation section of the EIA, the benefits of the 199,278 identified foodborne illnesses attributable to RACs are listed at $910 million (calculated from Table 20, p. 66), or $4,568 per case, considerably more than the per-case value listed earlier in the report. Sprout production is considered the cause of another $36.6 million in benefits, or $446 per case. This leads to a total of $947 million in proposed benefits, or $3,365 per case. (Note: It is not clear why this FDA-derived value is lower than the $1.0365 billion FDA figure referenced in the table above.)

FDA estimates the total cost of the new Produce Rule at $460 million. Clearly, under many of the reasonable scenarios presented above, the rule fails the cost-benefit test. It should be noted that all of these scenarios could be considered realistic, using the methodology outlined by FDA. There is no reason, therefore, to choose one scenario as being more plausible than another. It is not wise to frame regulatory policy around such a high level of uncertainty.

With respect to the benefits estimate for the rule, an additional confounding factor is that FDA cannot prove that farmers currently fall short in addressing food safety. In fact, FDA cites evidence that most producers of major commodities already have access to food safety training programs and that 50 GAP training programs already exist.[46] Studies referenced by FDA show that more farmers comply with safe food practices than are required to do so.[47] FDA also states that it does not know how many US farms are currently following safe food handling practices.[48] This means the FDA analysis of the problem is necessarily somewhat speculative and thus, the proposed "benefit" of the rule cannot be precisely measured. It is also quite possible the cost level is underestimated, which, combined with entirely plausible scenarios that arrive at much lower benefit levels, would mean costs may exceed benefits by an even wider amount than shown in the table above.

ii. There is great uncertainty about whether Produce Rule requirements will actually result in significant reductions in foodborne illness.

FDA recognizes there is uncertainty in its ability to track foodborne illness.[49] There is also uncertainty in tying contamination to farm practices. Studying an outbreak of hepatitis A associated with green onions, investigated by a team of USDA scholars, Calvin et al. conclude that "Even growers with the best food safety practices may still have contaminated product—all sources of risk cannot be controlled."[50]

FDA makes the assumption that a percentage reduction in pathogen levels will be associated with an identical reduction in illness. Yet this is only an assumption, as Crutchfield and Allshouse point out:

> "The relationship between human exposure to microbial pathogens and any resultant illness

[46] Produce EIA, Pages 37-38

[47] Ibid. Pages 31, 36

[48] Ibid. Pages 37-38

[49] 78 Fed. Reg. at 3512

[50] Calvin, L. et al. "The economics of food safety: The case of green onions and Hepatitis A outbreaks." U.S. Dep't of Agric. Economic Research Service (2004). Page 2.

> is very complex. A number of factors influence whether a person, once exposed, becomes ill, and the severity of the illness. Factors include the level of pathogens in the food, the way the consumer handles the product before cooking, the final cooking temperature, and the susceptibility of the individual to infection. In addition, the relationship between pathogen levels and disease varies across pathogens. Some, such as *E. coli* O157:H7, are infective at very low doses, while others require ingestion of higher doses to cause illness."[51]

As Calvin concludes, "Because most fresh produce is grown in a natural environment, it is vulnerable to microbial contamination. No set of practices would eliminate all risk."[52]

In the absence of clear evidence of contamination, and given the inherent difficulties of tracking the source of contamination, or proving a connection between contamination and illness, the science of foodborne illness necessarily relies upon considerable estimation. This uncertainty in tracking foodborne illness, when combined with the uncertainty of FDA's calculations of proposed economic benefits attributable to the Produce Rule, starkly illustrates the inherent uncertainty in this realm of regulation.

An effective food safety protocol must recognize this uncertainty, and spread risk among all parties – but cannot, ultimately, be risk-free.

b. The EIA understates the costs to farms of complying with the Produce Rule.

i. Many farms will now be subject to FDA oversight and regulatory costs.

Farms of all sizes will incur substantial costs under the proposed Produce Rule. FDA estimates that all produce farms combined will spend $198 million in the first year they fall under the new Produce Rule, simply to learn the rule. This is the single largest one-time cost farms are expected to assume, amounting to 28 percent of total first-year costs. Not only would exempt farms face $54 million in costs to learn about the Produce Rule, FDA estimates that farms selling less than $250,000 will shoulder $64 million in costs to learn about the rule, while farms selling more than that level but less than $500,000 will take on $29 million of costs. The largest farms are expected to carry $51 million of first-year costs as they learn about the rule. This alone suggests that the complexity of the rule creates a significant burden on farms.

Table 1 and Table 2 on page 18 of the EIA contain information about the number of not covered and exempt farms by sales class. We note that this information is not based on publicly available data sets available from USDA, making them difficult to verify or analyze. A more transparent reporting process is required if the public is to understand the impacts of the Produce Rule.

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[51] Crutchfield, S. and J. Allshouse. "The economics of improving food safety." U.S. Dep't of Agric. Economic Research Service (1999). Page 58.

[52] Calvin, L. "Outbreak linked to spinach forces reassessment of food safety practices." U.S. Dep't of Agric. *Amber Waves* 5 (2007). Page 25.

Table 3: FDA's Table 132: Covered Farms in the Proposed Rule

Sales category	**<$250,000**	**<$500,000**	**$500,000+**	**Total**
	"very small"	*"small"*	*"large"*	
Number of farms covered	26,947	4,693	8,571	40,211
Percent of farms covered	67%	12%	21%	100%
Percent of acres covered	9%	8%	83%	100%
Ave. annual monetary value of food	$ 75,279	$ 320,696	$ 2,638,384	$656,108

Table 3 shows that the small farms selling less than $500,000 per year make up 31,640 (79 percent) of the 40,211 US farms that FDA estimates will be subject to the new Produce Rule. Yet, these farms account for only 17 percent of the acreage that is to be covered by the new Rule. Their average sales are about $111,680 per year (calculated by multiplying average sales by the number of farms for each of the two categories, very small farms and small farms, adding these two totals, and dividing by the number of farms in the two categories). As discussed below, very small and small farms will shoulder 43 percent of the costs of the new rule – far out of proportion to their 17 percent share of acres in production.

ii. FDA makes unrealistic assumptions and, therefore, understates important costs.

FDA "estimate[s] that very small and small farms operate 3 months per year where the harvest period is 45 days, and that large farms operate for 6 months per year where the harvest period is 90 days (non-consecutive)."[53] The agency states that it bases this assumption on USDA planting data (Reference 2 of the report). Yet the data referenced cover Washington State only, and are dated 2004. This is hardly a representative sample of US farms.

Several regions in the South, and in California and Arizona, can harvest year-round, and many farmers in northern regions have adopted high tunnel, greenhouse, or other season extension technology. Northern farmers also have field duties year-round (e.g., starting plants in a greenhouse, pruning orchards, building soil fertility, etc.) that have food safety implications. Thus, it would make sense for FDA to increase its season estimates for all farms, small, mid-size, and large, to six to 12 months, depending on region.

As researcher Shermain Hardesty noted in comments to FDA on the Produce Rule EIA, "Production periods are the same regardless of farm size."[54] She continued by stating that the growing season for California farms should be considered 9-12 months.

If this season estimate were lengthened, it would increase the proposed costs for several expense items, notably: Health and Hygiene, Agricultural Water, Growing and Harvesting Activities, Equipment, Personnel Qualifications & Training, and Recordkeeping.[55] If the costs for each of these activities would approximately double in cost if the season were twice as long as the agency had assumed, or triple if the season were extended to nine months, then the total costs would increase by 33 percent, from $459 million to $609 million or by nearly 50 percent, from $459 million

[53] Produce EIA Statement Page 10

[54] Hardesty, S. Memo to FDA Re: Analysis of Economic Impacts of the draft FSMA Rules (2013).

[55] Produce EIA Statement Table 123, Page 294

to $867 million, respectively. In both instances, small and mid-sized farms would shoulder the greatest cost burden of the new proposed rule.

The Hardesty comment further noted that the FDA estimate for worker training "grossly underestimates worker training costs." She suggested using a value of eight hours of additional training in food safety, rather than the 0.64 hours used by FDA. This is 12 times higher than FDA's estimate; if a similar ratio were applied to worker training costs on Table 114 of the EIA[56] it could easily lead to $50 million of additional costs (assuming the $3.2 million of costs estimated to be incurred by farms already engaged in food safety training for their personnel were multiplied by 5 to $16 million, and the $3.3 million of costs to be incurred by farms with no prior experience of food safety training were multiplied by a factor of 10, to $33 million – both cautious estimates that do not take into account a longer growing season).

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

All told, according to FDA, the first-year cost of the Produce Rule will be about $700 million, with an added $365 million per year in recurring costs, for annualized costs of $460 million. [57] Since 4,473,575 acres of production land are projected by FDA to be covered under the Produce Rule, these start-up costs in the first year would amount to more than $150 per acre, based on FDA calculations.

FDA estimates the average cost burden of the rule per farm for the 31,640 farms selling less than $500,000 (the agency's definition of a "small farm") to be $12,972 per farm, a burden of 4 percent of average sales (assuming this to be $320,696, as FDA estimates). [58]

Relative costs for very small farms, however, are even higher. The agency estimates that farms selling less than $250,000 will shoulder average costs of $4,697 when the rule is implemented. This is six percent of the average sales of $75,279 that FDA reports for this category. FDA estimates that these very small farms would shoulder average costs of $8,260 in their first year. Such costs would place *any* of the 26,947 farms the FDA considers very small farms at severe risk. Since this is 67 percent of all farms that are to be covered by the Produce Rule, two of every three covered farms would be at risk of shut down.

This leads to FDA's unsettling analysis that:

- "Some small entities might determine that their new expected costs are likely to exceed their revenues";
- "We believe that some farms will choose to switch farming operations, but that choice depends on many variables that make the quantification intractable at this time: regional geography (including soil nutrients and climate), capital requirements, supply chain,

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[56] Page 268

[57] Ibid. Page 51. "Annualized" costs distribute total costs over a seven-year period, assuming (in this example) a 7 percent interest rate for borrowing money to pay these costs. This is meant to approximate the average annual costs should a farm depreciate the costs it assumes for adopting food safety practices.

[58] Ibid. Pages 294, 312

alternative produce market elasticity, and acreage requirements, as well as land prices";

- "Farm operators may decide to increase their off-farm income (that is, income coming from a source other than the farm, for example, if the farm operator has an additional occupation) in order to provide more total income to the farm operation"; and
- "The regulatory costs of this proposed rule may discourage at least some new small entities from entering the industry. The agriculture industry is characterized by substantial entry of small entities. Although we cannot quantify how much that will change, we expect that the rate of entry of very small and small businesses will decrease."[59]

The concern about costs was echoed by Calvin in an investigation of the potential impacts of new food safety practices instituted following an outbreak of disease from *E. coli* O157:H7 that had been traced back to a California spinach grower. While Calvin concluded that it was not clear that the new food safety procedures would actually reduce contamination, or prevent disease, the study found it easier to predict was that the new procedures will "undoubtedly raise costs and could bring structural change to the leafy green industry, as some growers find themselves with relatively higher costs than others."[60]

In an earlier study addressing international food safety, Calvin argued that increased costs will be pervasive, and are not limited to those who may be considered responsible for contamination incidents: "Food safety standards and costs tend to increase for everyone growing the implicated crop, not just those associated with the contamination."[61]

While the Produce Rule is estimated to make produce growing more expensive, it will not raise farmgate prices because farmers do not have the marketing power to sell at a price that will cover increased costs for food safety procedures. Thus the rule places farmers in a tight squeeze.

The EIA shows that small farms would endure the greatest burden from the Produce Rule, despite the fact that FDA has no research data showing the relative importance of large versus small farms in causing foodborne illness.[62] FDA's analysis shows that small farms would assume $197.5 million (43 percent) of the annualized $459.6 million of costs associated with the proposed Rule; average first-year costs for instituting compliance would be higher, at $372.9 million (53 percent of first-year costs).[63] This is a disproportionate burden on small farms, given that they farm only 17 percent of the acreage that FDA estimates will be to be covered by the regulation. Large farms, by contrast, will shoulder 57 percent of the costs of the new Rule, very low considering that they account for 83 percent of the acreage that FDA proposes to cover. As an additional example of the cost burden to small farms, the EIA indicates that 71 percent of the new costs of the proposed agricultural water provisions ($34.5 million of $48.6 million) will be carried by small farms, even under the unrealistic assumption that small farms have only a three-month growing season.[64]

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[59] Ibid. Pages 312-314

[60] Calvin, L. 2007.

[61] Calvin, L. "Response to U.S. foodborne illness outbreaks associated with imported produce." *USDA Agriculture Information Bulletin* 789 (2004). Page 1.

[62] Produce EIA Statement Pages 65

[63] Ibid. Pages 294

[64] Ibid. Table 123, Page 295

Even the FDA's cost accounting practices reflect a failure to consider the actual situations facing small farm businesses. When the agency calculates economic costs on the basis of a seven-year depreciation cycle, it fails to evaluate the fact that depreciation cycles are irrelevant to farmers who do not have sufficient income to write off costs against revenues – a situation many small farms find themselves in. Moreover, even if small farmers earn enough income to consider filing depreciation schedules, they may not actually have the cash on hand to implement a required procedure. The average cost over a seven-year period may not seem prohibitive in itself, but actually acquiring the capital to pay for new procedures on the front end may be prohibitive.

Thus, based on FDA's own evaluation, corroborated by the analysis of agricultural economists, it is plain that FDA has not met its statutory requirement to provide less burdensome alternatives for small businesses, nor to provide sufficient flexibility for small business.

B. FDA must incorporate the findings of the EIS into the final rule.

When it first released the proposed Produce Rule, FDA made the "determination that there are no extraordinary circumstances which raise the potential for this rule to individually or cumulatively have a significant effect on the human environment."[65] After publication of the Produce Rule, FDA determined that its implementation may significantly affect the quality of the human environment, and accordingly the National Environmental Policy Act (NEPA) required the agency to conduct an environmental analysis (EIS) before issuing the final rule.[66] FDA published a notice of intent to prepare an EIS (the Scoping Notice or Notice) in the Federal Register on August 19, 2013, and it sought comments on the issues, alternatives, mitigation measures, and other information FDA should include. NSAC provides comments on the Scoping Notice filed separately and attached hereto in Appendix II.[67]

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

In the proposed Produce 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
2. Rules with Tribal implications that preempt tribal law.

Consultation is important on the proposed requirements of the Produce 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 Produce Rule, the

[65] 78 Fed. Reg. at 3616

[66] 78 Fed. Reg. at 50358, 50359

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

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 Produce Rule, FDA must meet its Tribal consultation responsibilities.

D. The scope and magnitude of the problems in the proposed Produce Rule requires the promulgation of a second proposed rule for public comment.

FDA's proposed Produce Rule fails to meet a substantial number of the significant requirements of FSMA. FSMA requires FDA to establish "minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks."[68] Additionally, FSMA requires FDA to "provide sufficient flexibility to be applicable to various types of entities engaged in 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."[69]

The proposed produce standards are not sufficiently supported by adequate scientific evidence or quantitative risk assessment to be considered either science-based or risk-based. Additionally, a number of the standards are very prescriptive and do not provide sufficient flexibility; in fact, some of the proposed requirements would severely limit certain types of production, particularly sustainable agricultural systems, including certified organic production. Foundational terms such as "farm" are fundamentally flawed and need significant revision to reflect the realities of farming and not inappropriately regulate many farms as facilities. We provide details on all of these points in the comments on the proposed standards below.

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 engaged in produce production. Given the scope and magnitude of the problems in the proposed Produce 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 Produce Rule, the agency should release a second proposed rule for public comment and not an interim final rule.

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[68] Food, Drug, & Cosmetic Act § 419(b)(1)

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

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 Produce 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).[70] Congress passed BTA to "prevent, prepare for, and respond to bioterrorism and other public health emergencies" in the post-9/11 era.[71] 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."[72]

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."[73] 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.'"[74] 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.[75] These confusing definitions have led to a lack of clarity around when a farm also

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[70] P.L. 107-188

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

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

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

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

[75] 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.[76] 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"[77];
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"[78]; 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."[79]

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.

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

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

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

[79] 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.[80]

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

[80] *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."[81] 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.[82] 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."[83] 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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[81] 78 Fed. Reg. at 3541 and 3680

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

[83] 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."[84] 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)[85] 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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[84] U.S. Dep't of Agric. "Exploring Alternative Farm Definitions: Implications for Agricultural Statistics and Program Eligibility." Economic Research Service 2009.

[85] 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."[86] 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."[87] 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,"[88] 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.[89]

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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[86] 78 Fed. Reg. at 3686

[87] 78 Fed. Reg. at 3686

[88] 78 Fed. Reg. at 3686

[89] 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.[90] 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.

[90] 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[91] 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."[92] 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.[93] 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.[94] 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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[91] 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

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

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

[94] 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.[95]

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.[96] 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.[97] 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 our comments on the proposed Preventive Controls Rule,

[95] 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.

[96] Barham, J. et al. 2012

[97] 78 Fed. Reg. at 3801

it is important to note here that FDA has 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.[98]

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

[98] 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.[99]

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[100] or outreach materials[101] 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."[102] 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."[103]

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

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

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

[102] 78 Fed. Reg. at 3677

[103] 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~~).

***

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.

***

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~~.

***

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.

***

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.

***

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 COVERAGE ISSUES IN SUBPART A—GENERAL PROVISIONS[104]

Summary

NSAC makes comments and recommendations on coverage issues in Subpart A. We comment on the $25,000 exemption, and the need to clarify coverage to identify who is responsible for complying with the requirements, and the need to clarify different requirements for different types of coverage under the rule. We provide recommended languages changes to the definitions at the end of the section.

Comments

A. The $25,000 gross sales exemption must be fixed to apply solely to covered produce as provided by FSMA.

When writing FSMA, Congress rejected a "one-size-fits-all" approach, and provided FDA with flexibility to ensure that the Produce Rule worked for a diversity of farming operations. Specifically, FSMA requires FDA to "provide sufficient flexibility to be applicable to various types of entities engaged in 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."[105]

In its proposed Produce Rule, FDA proposes to exempt farms with an average annual monetary value of food sold during a previous three-year period of $25,000 or less. In the preamble to the rule, FDA tentatively concludes that "farms with $25,000 or less in sales do not contribute significantly to the produce market" and that they account for "only 1.5% of covered produce acres."[106]

The exemption for farms with $25,000 or less in gross sales is consistent with Congress' mandate to create risk-based requirements that reflect the diversity of the farming systems. The farms eligible for this exemption represent a tiny fraction of the food supply and should not be regulated under the Produce Rule.

Instead of focusing the exemption on the gross sales of all food, however, FDA should focus the exemption on the value of covered produce. This distinction will provide some flexibility in the rule for beginning farmers, non-produce farmers who are trying to diversify their production, and family farmers who have diversified operations.

In § 112.3(c), "food" is defined as "food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts." Section 201(f) of the FD&CA, in turn, defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." The definition of food is very broad

[104] We make comments to other areas in Subpart A, particularly § 112.3 on definitions, in other sections throughout our comments. The comments on this section are not the only comments we are making on Subpart A.

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

[106] 78 Fed. Reg. at 3549

and encompasses food that is not covered by the Produce Rule. This will be a problem for producers that have part of their operation growing non-covered food (such as corn and soybeans, or wheat and barley) and another part growing covered produce. According to the way the proposed Produce Rule is written, if the producer's sale of food (both non-covered food and covered produce) exceeds $25,000, the producer will be subject to the Produce Rule even if the sales from covered produce are less than $25,000. By changing the word "food" to "covered produce," FDA would allow producers that may have other "food" operations not covered by the Produce Rule to remain excluded from the Produce Rule if their covered produce operation is small.

Nothing in FSMA restricts FDA from focusing the $25,000 outright exemption to covered produce instead of "food." Doing so is consistent with the fact that this is, after all, a produce rule and also consistent with FSMA mandate for sufficient flexibility in the produce standards.

Recommendation: FDA should retain the $25,000 exemption in the final Produce Rule but should base it on the value of produce covered by the Produce Rule (i.e., "covered produce") produced on the farm and not the value of all food, as defined in § 201(f) of the Federal Food, Drug, and Cosmetic Act and referenced in § 112.3(c) of the proposed Produce Rule, sold by the farm.

B. FDA needs to make changes to Subpart A to clearly define coverage under the Produce Rule.

The proposed Produce Rule is unclear on the following issues that determine and define coverage under the rule:

1. Who is responsible for complying with the requirements; and
2. The difference between not covered, covered, and covered-but-exempt categories.

Much of the confusion can be addressed through additional clarifying text and definitions, and some reorganization of certain sections and subsections. NSAC makes recommendations on these points below.

1. FDA should more clearly link a covered farm to a person who is responsible for complying with the requirements of the part.

In the proposed Produce Rule, it is unclear how "you" is related to a covered farm. FDA defines "you" as "a person who is subject to some or all of the requirements in this part" and then proceeds to link "you" to a farm that may or may not be covered under the Produce Rule in § 112.4, but nowhere is the relationship between "you" and the farm covered under the rule clear. As it reads now, the proposed rule links coverage to a person who is then described as a farm. One of the problems is that the definition of "farm" is a place-based definition, not a definition tied to a person (see additional comments on that problem in section V). Additionally, there is no definition of a "covered farm" outside of § 112.4, and as it is currently written, § 112.4(a) implies that all farms above the $25,000 exemption are covered, not just farms growing covered produce.

All of this is very confusing because there are many ways that a person may be connected to a farm, including, for example, through direct ownership of that farm, through rental agreements, or through unique land transfer arrangements between beginning farmers and retiring or other farmers. This latter category is important to stress because lack of clarity around who must comply and how

coverage is determined may significantly jeopardize a beginning farmer's eligibility for $25,000 outright exemption and the qualified exemption in § 112.5. Examples of these unique land transfer arrangements include, but are not limited to, the following:

a. A beginning farmer is renting land on a larger operation and is running his/her own operation. Land and water are shared, but production and marketing are done independently.
b. A beginning farmer is part of an incubator farm project, where multiple small beginning farmer operations are sharing land and equipment/other overhead. In some cases they are sharing just land, water access, and large equipment, and in some cases they are sharing marketing as well.
c. A beginning farmer is co-operating a farm operation with another farmer (sharing not only land, but actually producing together) and then harvesting separately for different markets and operating as separate DBAs.
d. A beginning farmer is renting land to run an operation from a landowner who owns land that is bringing in other income for the owner (i.e., haying or grazing). The beginning farmer is running a completely independent business, but the owner (who is being paid as per a rental agreement) is making more than $500,000 in income from agricultural land.
e. A beginning farmer has entered into a business partnership with a wealthy patron who has other agricultural income (i.e., a landowner who is making more than $500,000 in income from other agricultural land). The beginning farmer's operation is run independently of other land operations, but the business partner has that larger income.
f. A family farm situation, where a family member (i.e., a child of the farm owner) wants to start a separate business on the farmland. For example, someone on a large cattle operation wants to start a small vegetable operation. The new business is a separate DBA, but it is on family land, and sharing family equipment and buildings.
g. A beginning farmer enters into a land-use agreement with a municipality, school, or other institution. The operation is an independent DBA. This may be a simple case where the institution will be viewed as a lessor, but there could be a more complicated agreement, such as one where the beginning farmer is providing food or interactivity (i.e., with schoolchildren) in exchange for rent.

In each of these cases, if covered produce were being grown, who would be responsible for ensuring compliance with the Produce Rule? In scenarios d and e, would the beginning farmer be eligible for the qualified exemption in § 112.5?

NSAC proposes that FDA clarify who is responsible for complying with the Produce Rule by revising the definition of "you" and creating a definition of "covered farm."[107] With the above scenarios in mind, our goal is to ensure that coverage is clear and that farmers, including beginning farmers, who should be eligible through their own businesses for the outright $25,000 exemption and the qualified exemption in § 112.5 are eligible for those exemptions. Our goal is also to make clear that not all farms above the $25,000 exemption are covered under the Produce Rule.

NSAC proposes that FDA link the definition of "you" directly to the "owner, operator, or agent in charge of a covered farm." This is consistent with terminology FDA uses in Subpart R and in Part

[107] Elsewhere in these comments, NSAC makes recommendations to the "farm" definition.

117. NSAC proposes a definition of "covered farm" that incorporates the focus on covered produce in the rules and incorporates the outright exemption of $25,000.

Recommendation: In the final Produce Rule, FDA should in § 112.3 clarify the definition of "you" so that is it linked directly to the "owner, operator, or agent in charge" and create a new definition of "covered farm."

1. Specifically, FDA should define "you" as (language to add is underlined and language to delete is ~~struck-through~~):

   You means ~~a person who is~~ the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements in this part.

2. Specifically, FDA should define "covered farm" as (language to add is underlined and language to delete is ~~struck-through~~):

   Covered farm means a farm with an average annual monetary value of covered produce sold during the previous 3-year period of more than $25,000.

2. FDA must clearly articulate the difference between not covered, covered, and qualified exempt categories.

In the proposed Produce Rule, FDA has implicitly created three separate categories of coverage: covered, not covered, and qualified exempt. Proposed § 112.4 should be revised to reflect consistency in the use of terms indicating coverage by the Produce Rule. "Covered," "not covered," and "qualified exempt" refer to very different states under the Produce Rule. Farms making over $25,000 doing covered activities to covered produce are covered by the Produce Rule. Farms eligible for the $25,000 outright exemption are not covered (meaning not subject to any provisions under the Produce Rule). Farms that are eligible for the qualified exemption are covered but qualified exempt (because they are still required to comply with certain requirements under the Produce Rule).

The Produce Rule purports to only cover farms and farm mixed-type facilities with annual sales of food over a certain amount, but Subpart A is confusing because it does not clearly state which requirements apply under which coverage status, and needs to be clarified. Proposed § 112.4 currently reads as follows:

> (a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of food (as "food" defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a "covered farm" subject to this part. If you are a covered farm subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on covered produce.
>
> (b) You are not a covered farm if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the requirements of Subpart R of this part.

The language used to describe which size farms are covered by the Produce Rule and which size farms are not covered by the Produce Rule is confusing. The proposed rule only expressly states that qualified farms are not covered; there is no explicit provision stating that farms eligible for the $25,000 exemption are not covered. FDA uses exclusionary language (i.e. "except as provided in paragraph (b)") and then defines covered farms as those making over $25,000 a year during the previous three-year period. In paragraph (b), which describes which farms are "not covered," there is no mention of farms making less than $25,000. According to paragraph (b), the only way you are "not a covered farm" is if you are eligible for a qualified exemption in § 112.5 (based on average monetary value of all food sold and direct farm marketing). One has to infer that farms making less than $25,000 a year during the previous three-year period are not covered. Producers should not have to infer that farms that make less than $25,000 are also not covered.

Unlike farms and farm mixed-type facilities that have a qualified exemption that can be withdrawn, if a farm is not covered at all, it will never be subject to the provisions of the Produce Rule. The fact that farms below the $25,000 threshold cannot be subject to any "withdrawal," and may never be asked to come into compliance with the Produce Rule, is not expressly stated in the proposed rule. The issue is not clear due to the reference in § 112.4(b) to non-covered farms, defined in subparagraph (b) as those farms subject to an exemption.

Additionally, the Produce Rule should make explicit the substantive requirements that are applicable to qualified exempt farms, which are subject to: (1) compliance and enforcement; (2) exemption withdrawal provisions; and (3) certain labeling or point-of-sale information requirements. FDA could help clear up confusion by including these subpart titles when cross-referencing, which makes the Produce Rule much clearer to process for any readers less versed in regulatory language or structures.

In addition to the recommendations on the "you" and "covered farm" definitions discussed above, a number of these issues can be addressed through some reorganization of current text and additional text.

Recommendation: In the final Produce Rule, FDA should clarify the status of farms covered, not covered, and qualified exempt by:

1. In § 112.4(a), deleting the first sentence and adding a new first sentence that says that you are subject to the requirements of this part if you are a covered farm (as defined in the recommendation above);

2. In § 112.4(b), striking the reference to qualified exempt farms and referencing instead farms that are eligible for the outright $25,000 exemption. Consistent with the adjustment for inflation reference to 2011 for the qualified exemption, we also recommend including a sentence in § 112.4(b) that includes an adjustment for inflation for the $25,000 exemption and references 2011 as the baseline year for calculating the adjustment for inflation;

3. Creating a new § 112.4(c) that makes clear that qualified exempt farms are covered but exempt from the requirements for subparts B through P; and

4. In § 112.6, making a few adjustments to the text so that it is clear which requirements qualified exempt farms are subject to.

NSAC provides specific recommendations below to changes needed in the language of Subpart A dealing with coverage issues discussed in this section. Our recommendations on other parts of Subpart A, including definitions, are also made elsewhere in our comments.

C. Recommended language changes pertaining to coverage issues in Subpart A—General Provisions

We have indicated below the changes that we recommend FDA make directly to Subpart A to incorporate our comments from this section. We indicate proposed new language (underlined) and language to delete (~~struck-through~~).

§ 112.3 What definitions apply to this part?

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Covered farm means a farm with an average annual monetary value of covered produce sold during the previous 3-year period of more than $25,000.

***

You means ~~a person who is~~ the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of this part.

***

§ 112.4 Who is subject to the requirements of this part?

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

(b) You are not a covered farm if you ~~satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the requirements of subpart R of this part~~ have an average annual monetary value of covered produce sold during the previous 3-year period of $25,000 or less, adjusted for inflation. The baseline year for calculating the adjustment for inflation is 2011.

(c) You are a covered farm but exempt from the requirements of subparts B through P if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the provisions of Subpart R of this part.

***

§ 112.6 What modified requirements apply to me if I am eligible for a qualified exemption in accordance with § 112.5?

~~(a)~~ If you are eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:

~~(1)~~ (a) This subpart A (General Provisions); ~~and~~

~~(2) Subparts Q and R of this part.~~ (b) Subpart Q (Compliance and Enforcement)

(c) Subpart R (Withdrawal of Qualified Exemption)

~~(b) In addition, you are subject to~~ (d) ~~t~~The following modified requirements pertaining to labeling:

(1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

(3) The complete business address that you must include in accordance with the requirements of paragraph ~~(b)~~(d)(1) or ~~(b)~~(d)(2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

VII. COMMENTS ON §§ 112.5 AND 112.6—MODIFIED REQUIREMENTS FOR QUALIFIED EXEMPT FARMS

Summary

NSAC makes comments and recommendations on the modified requirements for qualified exempt farms set forth in §§ 112.5 and 112.6. We recommend that FDA calculate the sales based on covered produce and not all food, and comment on certain aspects of the modified requirements.

Comments

A. FDA's modified requirements for qualified exempt farms in § 112.5 and § 112.6 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 Produce Rule worked for a diversity of farms, 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 § 419 of Federal Food, Drug, and Cosmetic Act (FD&CA):

- A number of provisions to support small and very small businesses, including the requirement to define "small business" and "very small business,"[108] longer compliance periods,[109] and the option to exempt or create modified requirements for small and very small businesses that produce and harvest low-risk produce commodities[110];
- 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"[111]; and
- 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."[112]

It was within this broader scale-appropriate framework that Congress also specified certain modified requirements for farms involved in direct marking through FD&CA § 419(f). To be qualified for those alternative requirements – instead of the full produce standards – a farm must 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

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

[109] Food, Drug, & Cosmetic Act § 419(b)(3)

[110] Food, Drug, & Cosmetic Act § 419(a)(1)(B)

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

[112] Food, Drug, & Cosmetic Act § 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.

farm or within a 275-mile radius of the farm. FDA refers to these farms as "qualified exempt" farms.

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 farm'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, 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 Produce Rule and Preventive Controls Rule upholds Congressional intent and supports a robust option for qualified exempt farms.

In the proposed Produce Rule, FDA sets forth modified requirements for qualified exempt farms in § 112.5 and § 112.6. FDA seeks comments on some of these requirements and makes tentative conclusions about others. While there are many other provisions in the Produce Rule that impact the success of the modified requirements that need significant revisions (see sections V and XIII), FDA's modified requirements for qualified exempt farms 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 Produce Rule, FDA must maintain and strengthen the modified requirements in § 112.5 and § 112.6.

B. FDA should amend § 112.5(a)(2) to calculate sales based on the average annual monetary value of covered produce, not all food.

NSAC is aware of the statutory language in § 419(f)(1)(B) stating that the "average annual monetary value of all food sold" 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 Produce Rule and not to all food regardless of whether it is regulated by the Produce Rule. Specifically, Congress required FDA 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."[113]

The definition of food is very broad and encompasses food that is not covered by the Produce Rule. This will be a problem for producers that have part of their operation growing non-covered food (such as corn and soybeans, or wheat and barley) and another part growing covered produce. According to the way the proposed Produce Rule is written, if the producer's sale of food (both non-covered food and covered produce) exceeds $500,000, the producer will be subject to all of the requirements of the Produce Rule even if the sales from covered produce are significantly less than

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

$500,000. By changing the word "food" to "covered produce," or by amending "all food" to read "all food covered by part 112," FDA would allow producers that may have other "food" operations not covered by the Produce Rule to qualify for the modified requirements if their covered produce operation is small.

The agency recognizes the need to distinguish between all food and covered produce in the preamble discussion about the modified requirements. When discussing the proposed notification requirements for a sign or packaging label on food that would otherwise be covered produce sold by a qualified exempt farm, FDA says that the notification requirements "apply[] only to food that would otherwise be covered produce but for the qualified exemption. We tentatively conclude that this interpretation is reasonable because applying these consumer notification requirements to food that would not otherwise be covered produce would mean applying requirements to food that bears no relationship to the subject of this rulemaking (e.g., to milk from a farm that also grows and harvests produce and that meets the criteria for the qualified exemption from this proposed rule)."[114] This reflects the reality that a farm that grows covered produce may also grow non-covered food that should not be regulated under the Produce Rule, and should not count in determination of whether a farm qualifies for the modified requirements.

Additionally, FDA has identified and addressed this very problem 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 "it intends to only include the sale of food for animals and not the sale of human food in determining whether a facility meets the requirements in those cases where a facility sells both."[115] Implied in the agency's proposal and analysis is the fact that if the agency 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. Applied to the Produce Rule, if a farm grows hay or other animal food, the sales from the animal feed side of the operation will count in determining whether the farmer qualifies for the modified requirements if he or she grows produce.

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 Produce Rule, in § 112.5 FDA should limit the average annual value of food sold during the previous three-year period to the sales of food regulated by the Produce Rule (i.e., covered produce), and not "all food."

C. Notification requirements should only apply to food that would otherwise be covered produce.

The modified requirements for qualified exempt farms entail notification to consumers of the name and business address of the farm, either through a packaging label or through a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business. In the preamble, FDA says that the notification requirements "apply[] only to food that would otherwise be covered produce but for the qualified exemption. We tentatively conclude that this

[114] 78 Fed. Reg. at 3550

[115] 78 Fed. Reg. at 64757

interpretation is reasonable because applying these consumer notification requirements to food that would not otherwise be covered produce would mean applying requirements to food that bears no relationship to the subject of this rulemaking (e.g., to milk from a farm that also grows and harvests produce and that meets the criteria for the qualified exemption from this proposed rule)."[116] This specification is reflected in §§ 112.6(b)(1) and (2). NSAC agrees with this conclusion because it is consistent with FSMA.

Recommendation: In the final Produce Rule, FDA should retain its conclusion to apply the notification requirements in § 112.6(b) only to food that would otherwise by covered produce.

D. It would be inconsistent with FSMA to require qualified exempt farms to establish and maintain records in accordance with subpart O.

In the preamble, FDA "request[s] comment on whether we should require farms to be able to provide adequate documentation, as needed to demonstrate the basis for the qualified exemption. Specifically, we request comment on whether we should do this by requiring records to be established and maintained in accordance with the requirements of proposed subpart O, or if there is an alternative strategy by which we could require retention of and access to such records (such as by requiring farms only to retain records kept in the normal course of their business bearing on the criteria for the qualified exemption that they use to determine their eligibility and requiring FDA access to such records upon request)."[117]

FDA rightly notes that § 419 of FD&CA "does not explicitly require farms that meet the criteria for the qualified exemption to establish and maintain documentation of the basis for their exemption."[118] This is an important point to emphasize. The modified requirements through § 419 are less onerous than those through § 418, which require qualified facilities to submit certain documentation to FDA. The Tester amendment explicitly included documentation submission requirements for qualified facilities and explicitly excluded such requirements for qualified farms. Congress determined that the notification to consumers was sufficient for qualified farms.

NSAC recognizes that having documentation to support a qualified farm's status may be useful for FDA. However, we also note that according to FDA, the recordkeeping requirements are the fifth costliest aspect of the proposed Produce Rule.[119] The qualified exemptions were designed specifically to decrease this type of burden on small businesses and FDA must not require more than what is absolutely necessary.

To that end, NSAC does not support requiring qualified exempt farms to establish and maintain records in accordance with the requirements of subpart O. We do support the alternative that farms not be required to retain records that are not kept in the normal course of business. However, we do not support including recordkeeping or documentation requirements in the rule itself. We think the better option is for FDA to issue guidance, for public comment, that would establish guidelines for the type of documentation qualified farms should keep that supports their

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[116] 78 Fed. Reg. at 3550

[117] 78 Fed. Reg. at 3551

[118] 78 Fed. Reg. at 3550

[119] Travis Minor, presentation at FDA Public Meeting, Washington, DC.

status. In such guidance, it is very important that the guidelines established protect a farm's privacy, especially with respect to financial records.

Recommendation: In the final Produce Rule, FDA should not require qualified exempt farms to submit documentation to FDA. FDA should not require qualified exempt farms to establish and maintain records in accordance with Subpart O. FDA should set recordkeeping guidelines for qualified exempt farms in guidance for public comment, not in the rule itself. Those guidelines should not require qualified farms to establish and maintain documents or records that are not kept in the normal course of business.

E. FDA's request for comment on the labeling provisions is unclear.

In the preamble discussion about labeling provisions in § 112.6(b), FDA "seek[s] comment on the feasibility of the labeling provisions in proposed 112.6(b), *particularly in the case of consolidating produce from several farm locations*."[120] It is not clear what types of activities the agency is referring to as "consolidating" and it is not clear whether "several farm locations" refers to multiple locations under the same ownership or not. On the first point, we are confused by the agency's use of the term "consolidating"; FDA does not use this term in its discussion of the activities in the "farm" definition elsewhere in the preamble. Consolidation of produce implies aggregation activities, such as packing and holding of raw agricultural commodities from multiple places. On the second point, given the agency's current "farm" definition, we assume that FDA is referring to several farm locations under the same ownership.

Presumably, if produce from multiple farm locations is being packed or held at one farm location to then be brought to market, then, for the purposes of the business address discussion, the address that applies is the address of the business, i.e., the farm business. The fact that the produce may be coming from multiple farm locations – which it almost certainly will, given that different fields that are part of the same farm are in different locations – should not make a difference in the discussion about labeling and business address notification.

We provide a complete discussion of issues concerning the "farm" definition in section V above.

Recommendation: The business address that is required to be displayed in the modified requirements should be the business address of the qualified farm.

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

In § 112.5(b), FDA establishes 2011 as the baseline year for calculating the adjustment for inflation "because 2011 is the year that FSMA was enacted into law."[121] NSAC agrees with FDA's determination that 2011 should be the baseline year for inflation.

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

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[120] 78 Fed. Reg. at 3550; emphasis added

[121] 78 Fed. Reg. at 3549

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 419(f)(2)(A) demonstrates Congress' intent to require the farm's full address, including the street address or P.O. box to appear on labels or other required notifications when the farm qualifies for the exemption in section 419(f) of the FD&C Act."[122] NSAC agrees with the agency's interpretation on the meaning of "business address."

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

[122] 78 Fed. Reg. at 3550

VIII. COMMENTS ON ALTERNATIVES IN § 112.12

Summary

NSAC makes comments and recommendations on the option for alternative practices set forth in § 112.12. The alternatives are flawed and not practical enough to provide adequate flexibility.

Comments

A. The alternatives established in § 112.12 are flawed and are not practical enough to provide adequate flexibility.

FSMA requires FDA to provide sufficient flexibility in the Produce Rule 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"[123]; and
- "Practicable for all sizes and types of businesses, including small businesses such as a small food processing facility co-located on a farm."[124]

This requirement for a flexible regulatory framework that is applicable and practicable to all types of farms must underpin the produce regulations.

In the proposed Produce Rule, FDA proposes prescriptive, inflexible standards that prohibit or create significant barriers to the use of practices that many different types of farms engaged in produce production currently use. Specifically, FDA proposes requirements in Subpart E on agricultural water and Subpart F on biological soil amendments of animal origin that would be costly, impractical, and unworkable for many farms (for our complete comments on these subparts see sections IX and X).

As a way to provide flexibility to certain rigid requirements in Subparts E and F, FDA proposes to allow the use of alternative practice in §112.12. While we appreciate the agency's attempt to provide some flexibility through the use of alternatives, as currently proposed the option for alternative practices would not provide the flexibility necessary to comply with the mandate from Congress to establish flexible, applicable, and practicable standards. We detail the reasons for this below and then provide a recommendation based on these points.

1. The alternatives apply to only a small subset of Produce Rule requirements.

The option to use an alternative practice applies narrowly to one requirement in Subpart E and to three requirements in Subpart F. These are all requirements that include a specific numerical

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

[124] Food, Drug, & Cosmetic Act § 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.

standard or interval. Yet, the option for an alternative does not apply to other numerical requirements in the Produce Rule, such as the frequency of water testing requirements in § 112.45 and requirements for agricultural water in § 112.44(a). The narrow focus of the alternatives to only certain requirements in the proposed Produce Rule limits the flexibility the option is meant to provide.

2. The standard for establishing an alternative practice is too high.

To establish an alternative practice, a farmer must show that there is "adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part."[125] This requirement means that FDA is requiring the science supporting an alternative practice to address public health risks generally. This is an enormous task that research aimed at agronomic practices tailored to a specific production system, climate, or region cannot reasonably be expected to accomplish.

In point of fact, FDA itself has not been able to assess the public health risks of the standards it is proposing in the Produce Rule and has had to rely on limited data. The body of scientific literature on the role and risks of farm practices in food safety is limited at best and rapidly evolving. Neither FDA in its proposed standards nor a farmer trying to use an alternative practice would be able to show that practices provide an equivalent level of public health protection because the base level of public health protection has not been established.

3. The research required to support an alternative practice is too costly for small and mid-sized farmers.

In the preamble, FDA recognizes that more research is needed; we completely agree. There are many topics concerning on-farm practices and their role in food safety that merit scientific study and investigation. (We provide a list of research topics for biological soil amendments of animal origin in our comments on Subpart F in section X.)

It is important for federal and other public research institutions to work directly with farmers on food safety research questions, because farmers, and especially small and mid-sized farmers and local farm groups, are not able to themselves fund the long-term research that would be required to establish alternative practices. As an organization that has long advocated for and supported investments in on-farm research and extension, NSAC strongly supports on-farm food safety research, but we are also acutely aware of the limited resources that farmers have to invest in research and support long-term research studies. It is critical to ensure that farmers are actively involved in setting the research agenda and engaged as partners in the research process, but they cannot shoulder the expense of the research needed to establish the general public health risks of farming practices.

Recommendation: In the final Produce Rule, FDA must ensure sufficient flexibility by improving the requirements in Subparts E and F and establishing practical and applicable requirements. Additionally, FDA should ensure flexibility by allowing alternatives to other requirements of the Produce Rule, such as the frequency of water testing requirements in § 112.45 and requirements for agricultural water in § 112.44(a). Finally, FDA should work with farmers and research institutions

[125] § 112.12(b)

and agencies to conduct research needed to support alternative practices that are relevant and appropriate to the wide range and diversity of farming systems impacted by the Produce Rule.

IX. COMMENTS ON SUBPART E—STANDARDS DIRECTED TO AGRICULTURAL WATER

Summary

NSAC makes comments and recommendations on Subpart E—Standards Directed to Agricultural Water. Proposed Subpart E fails to meet the requirements of FSMA for a science- and risk-based approach and must be thoroughly revised.

Comments

A. Proposed Subpart E fails to meet the requirements of FSMA for a science- and risk-based approach and must be thoroughly revised.

The proposed Subpart E—Standards Directed to Agricultural Water (Subpart E) fails to meet the requirements of FSMA. Specifically, FSMA requires FDA to:

- Establish "minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks"[126];
- "Provide sufficient flexibility to be applicable to various types of entities engaged in 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"[127];
- "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"[128];
- Not "conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990"[129]; and
- "Not require a business to hire a consultant or other third party to identify, implement, certify, compliance with these procedures, processes, and practices."[130]

FDA's proposed Subpart E fails to meet the requirements of FSMA because the standard contains requirements that:

1. Are not science- or risk-based;
2. Are rigid, prescriptive, and inflexible;
3. May harm conservation and the environment;
4. May conflict with requirements of the National Organic Program (NOP) established under the Organic Foods Production Act of 1990;
5. May require the use of a third party for compliance with the procedures.

[126] Food, Drug, & Cosmetic Act § 419(b)(1)
[127] Food, Drug, & Cosmetic Act § 419(a)(3)(A)
[128] Food, Drug, & Cosmetic Act § 419(a)(3)(D)
[129] Food, Drug, & Cosmetic Act § 419(a)(3)(E)
[130] Food, Drug, & Cosmetic Act § 419(c)(1)(E)

Proposed Subpart E fails to meet these requirements primarily because of the testing requirements in § 112.44, the requirements concerning the frequency of testing in § 112.45, and the agricultural water treatment requirements in § 112.43.

FDA seeks comment on its "proposals and approach related to agricultural water."[131] NSAC expands on each of these points in the comments below and then provides a recommendation at the end of this subsection based on these points.[132]

1. Proposed Subpart E fails to meet the requirements of FSMA because it is not science-based or risk-based.

FDA's proposed agricultural water standard fails to meet the FSMA requirement for science-based standards because of the microbial standard used for testing and the testing frequencies required.

FDA adopts the Environmental Protection Agency's (EPA) recreational water standard and applies it to agricultural water. Based on this standard, proposed Subpart E would require a farmer to "immediately discontinue use of that source of agricultural water" if there are "more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water."[133] FDA acknowledges that this standard was "developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers."[134] The type and intensity of exposure experienced by swimmers who are immersed in the water for extended periods and may accidentally swallow several ounces thereof, is far greater than, and qualitatively different from, the exposure resulting from water's use in crop irrigation. In addition, the standard was developed by EPA to address primarily viral gastrointestinal illnesses, and there is no scientific basis developed for the standard's use in produce production as an appropriate test for food pathogens.[135]

FDA is proposing to adopt this standard in the absence of other appropriate existing standards for irrigation water. In the preamble of the Produce Rule, FDA acknowledges the drawbacks of relying on a generic *E. coli* standard, including that "generic *E. coli* does not always reliably predict the presence of pathogens despite fecal pollution being a known source of pathogenic microorganisms," and that "generic *E. coli* monitoring serves as a measure to assess the potential for fecal contamination, not to directly predict the presence of pathogens."[136] FDA notes a number of benefits, including that it is "most closely associated with incidents of fecal contamination" and the existence of "multiple test methods, commercial kits, and formats available at relatively low cost."[137] While the proposed standard might be the best option currently available, this is not a sufficient scientific basis for requiring farmers across the country to comply with it.

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[131] 78 Fed. Reg. at 3561

[132] NSAC, Scoping Notice Comments, at 5-6, 9-13.

[133] § 112.44(c)

[134] 78 Fed. Reg. at 3563

[135] Suslow, T. "Standards for Irrigation and Foliar Contact Water." Produce Safety Project Issue Brief, Georgetown University (2010).

[136] 78 Fed. Reg. at 3560

[137] 78 Fed. Reg. at 3560

In addition to the lack of scientific basis for the application of EPA's recreational water standard to water used in produce production, it is unclear what the scientific basis is for the testing frequencies proposed in § 112.45. FDA states that a routine sampling and microbial testing program is a "fundamental component in assessing the adequacy of water for its intended use," but that studies that quantify pathogens on a monthly basis "do not specifically address the impact of water quality on produce safety." [138] FDA must therefore make assumptions about what the appropriate testing frequencies should be in the context of agricultural water, but those frequencies – especially the frequency for untreated surface water that is from any source where a significant quantity of runoff is likely to drain into the source – do not have an adequate scientific basis.

Additionally, FDA does not adequately establish a risk-based approach in Subpart E and instead mandates testing requirements to the EPA's recreational water standard regardless of risk. FDA has not quantified the risks of using different types of water (e.g., surface or groundwater) in different parts of the country and in different farming systems. In the preamble, FDA acknowledges that it is an "extremely difficult task" to "quantify[] risks associated with the use of agricultural water as a function of water source, time of application, irrigation method, and commodity type"[139] Additional considerations in a risk assessment include climate, soil type and soil biological activity, location (proximity to known or likely sources of contamination), and farming system. It is certainly understandable that quantifying the risks is a challenging task, but the solution FDA has proposed to that challenge is a rigid standard that assumes, without relevant evidence, significant risk and that does not account for risk factors that vary according to source, climate, soil type, farming system, timing, etc. As currently proposed, FDA establishes a prescriptive standard applied to every farm that must comply with the Produce Rule standards regardless of critical risk factors.

2. Proposed Subpart E fails to meet the requirements of FSMA because it is not sufficiently flexible.

Because the standard is prescriptive and applies regardless of risk, climate, soil type and conditions, location, farming system, or water source, the standard also fails to meet the FSMA mandate to be flexible. Specifically, the standard is inflexible because it requires farmers to ensure that their agricultural water meets EPA's recreational water standard through regular testing.

It is probable that most surface waters in the US will fail to meet the proposed standard at least periodically, and in some areas of the country, the surface waters may frequently fail to meet the standard. According to available water quality data reported by the States to EPA under Section 305(b) and 303(d) of the Clean Water Act (CWA), there are 41,531 impaired waters in the US. Over 10,000 of those 303(d) impaired waters may at times fail the proposed standard while simultaneously passing EPA-approved State standards for use as agricultural water. As a more targeted example of the likely failure of farms being able to meet the standard, in Pennsylvania, a two-year study of smaller farms with multiple types of surface-water sources for irrigation found that many farms would fail the generic *E. coli* tests, although O157:H7 and Salmonella were not detected, and

[138] 78 Fed. Reg. at 3561

[139] 78 Fed. Reg. at 3560

Salmonella could be found occasionally when irrigation water would have passed the tests.[140] The study also showed that the way in which samples were chilled and iced for transport to an accepted laboratory could greatly affect results and, therefore, consequences of the testing.

When the agricultural water fails to meet the proposed standard, the farmer "must immediately discontinue use of the source of agricultural water and/or its distribution system."[141] With no EPA chemical treatments for irrigation water available to producers, the farmer's only options are either to eliminate the source of contamination, or switch to a different water source, such as groundwater. Since the source of contamination is almost always located upstream and outside of the farm's control, and changing the source entails installing new infrastructure such as a well, the farmer would effectively lose access to irrigation, at least until generic *E. coli* levels in the current water source subside below thresholds, and quite possibly for the remaining duration of the current cropping cycle. In semiarid and Mediterranean climates (such as AZ and CA), the loss of irrigation would probably result in a complete crop loss; even in humid climates, severe yield reductions may result in the event of drought. With farm profit margins often razor-thin, one crop failure can result in significant financial loss for many farms.

While FDA has allowed for "alternatives" for certain requirements in the water standard, the limited scope and requirements for an alternative make them untenable for farmers to use. The alternatives apply very narrowly and not to the entire standard; there is an option to follow an alternative practice to the requirement of testing to the EPA recreational water standard and then the requirement to take actions based on the results of that test in § 112.44(c), but there is no alternative to the frequency of water testing.

Additionally, the burden of proof is on the farmer to have adequate scientific data or information to show that the alternative would "provide the same level of public health protection as the applicable requirement" in the proposed standards.[142] In other words, FDA is placing the burden on farmers and groups of farmers to conduct research on public health risks generally – a task that FDA has been unable to fulfill. Many very small and small farmers or groups of small farmers will not be able to afford to conduct this type of research because it is costly and requires a sustained investment.

If FDA assumes that States will seek an alternative on behalf of in-State farmers, it is unclear why the proposed standard, which requires all agricultural water to meet the same microbial standard, is the appropriate approach to begin with; in this scenario it would make more sense to have States responsible for the standards and testing protocols.

It is inappropriate to place such a significant and very costly burden on farmers and farmer groups and then claim to be offering flexibility. As currently proposed, the option for alternatives and for corrective action in the event of a non-passing water test result would not provide true additional flexibility in the water standards. NSAC provides more complete comments on the alternatives option in section VIII above.

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[140] Draper, A. "Microbial survey of Pennsylvania water used for specialty crop irrigation and development of sampling, handling and shipping procedures for surface water testing." MS Thesis, Food Science, Pennsylvania State University (2012).

[141] § 112.44(c)

[142] § 112.12(b)

3. Proposed Subpart E fails to meet the requirements of FSMA because it may harm the environment.

Because of the testing requirements in Subpart E, FDA is creating a significant incentive for increased groundwater depletion, which is a major and growing environmental concern. In FDA's Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, FDA acknowledges that the proposed water standard may lead to increased groundwater depletion because the application of the standard to surface water supplies in some regions is unworkable.[143] Additionally, proposed Subpart E creates an incentive for treating water, even in the current absence of EPA-approved irrigation water treatments, because there is no requirement to test water when it is treated according to the requirements in § 112.43. These are both significant concerns that point to the inappropriate nature of the standard and that must be addressed in the final rule. NSAC addresses this issue and other issues more fully in our comments on the scoping notice, which are incorporated herein.[144]

4. Proposed Subpart E fails to meet the requirements of FSMA because the treatment requirements will likely conflict with NOP requirements.

Proposed Subpart E includes requirements in § 112.43 to treat agricultural water "if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use." FDA gives the example of an EPA-registered antimicrobial pesticide product as a type of product that may be acceptable for water treatment even though FDA notes that "at the present time, no such registration for chemical treatment of irrigation water exists."[145] While this is an issue in and of itself, and there is a significant environmental issue with treatment of water (see above), there is also the significant issue of whether such treatment products will be permissible under NOP regulations for certified organic production.

There are a limited number of antimicrobial pesticides allowed under NOP regulations for limited uses and under limited circumstances.[146] Adding a substance like EPA-registered antimicrobial pesticide to the NOP National List of Allowed and Prohibited Substances would be a lengthy, multiyear process that would not necessarily result in the product's approval because of the environmental criteria that must be met for a pesticide to be allowed. It is very likely that organic farmers will not be able to use whatever treatment product does become available, and the requirement to treat agricultural water would then conflict with NOP requirements.

5. Proposed Subpart E fails to meet the requirements of FSMA because it would require the use of a third party for compliance with procedures.

The testing requirements in §§ 112.44 and 112.45 will conflict with FSMA because they require the farmers to use a third party to implement and comply with requirements. Farmers will have to regularly collect water samples and send those samples to a certified lab, which will almost certainly be a third-party, to be analyzed. Most farmers do not have the capacity to analyze water samples on-

[143] 78 Fed. Reg. at 50359

[144] NSAC, Scoping Notice Comments, at 9-13.

[145] 78 Fed. Reg. at 3567

[146] 7 C.F.R § 205.601

farm and most will send those samples to a lab for analysis.[147] This is directly and completely contrary to Congress' intent in FSMA to not require farmers to substantially rely on a third party for compliance with the standards.

Recommendations: In the final Produce Rule, FDA must substantially revise Subpart E so that it is a reasonable, science- and risk-based approach to agricultural water that allows farmers to respond to specific risks in their water systems. Specifically:

1. FDA should not include inappropriate numerical thresholds for presence of pathogens or pathogen indicators (i.e., generic *E. coli*) in agricultural water.

2. FDA should come up with a process for developing a science- and risk-based agricultural water standard that includes conducting sufficient research to develop an appropriate, science-based standard, which might vary according to the region, farming system, and other variables, and seeking comments and input from the public on the results and implications of this research.

3. Once sufficient research has been conducted and public comment has been collected to inform the development of an appropriate, science-based standard, it is imperative that the standard be included in guidance for public comment, not in the regulation itself. This allows for the standard to be updated if new research becomes available about appropriate agricultural water standards.

4. FDA should not require weekly water testing for surface waters; FDA should instead require farmers to collect monthly baseline information about their water systems in the first growing season and to base future actions and testing frequencies on those results.

5. FDA should not increase pollution and decrease the safety of the food supply by encouraging treatment of irrigation water with chemicals, nor should it encourage the depletion of groundwater aquifers

B. The requirement in Subpart E to inspect and adequately maintain the agricultural water system is consistent with FSMA, but farmers should not be responsible for circumstances out of their control that may affect water.

NSAC supports the requirement in § 112.41 that "all agricultural water must be safe and of adequate sanitary quality for its intended use" and the requirements in §§ 112.42(a), (b), and (c) that a farmer must inspect and maintain the agricultural water system under his/her control. These requirements are consistent with a risk-based, flexible approach set forth by Congress in FSMA. However, we

[147] FDA's economic analysis highlights the assumption that a lab will be required: "Per-sample microbial water testing costs include the time required to obtain a sample from each farm water source, and the costs of the laboratory to analyze the sample to detect the particular microbes of interest. Farms may either hire a sample collector from the laboratory or collect water samples themselves. Farms will choose to collect the water sample themselves and ship it to a laboratory for analysis if the cost of doing so is less than the cost of having a sample collected and analyzed by the laboratory or another party." U.S. Food and Drug Admin. "Produce Rule Preliminary Economic Impact Analysis." Page 132.

generally object to the implication that farmers are responsible for circumstances beyond their control that may affect their agricultural water systems.

Although there are some cases in which agricultural water becomes contaminated from sources on the farm or over which the farmer has some control, the source of water contamination is often outside of the control of the produce farmer whose irrigation water is affected. Examples include contamination from concentrated animal feeding operations (CAFOs) or poorly managed pastures upstream (e.g., livestock allowed to enter and defecate in streams), or improperly functioning sewage treatment plants or septic systems from municipalities or dwellings located upstream. In these situations, the only options available to the farmer would appear to be to switch to a different water source, treat the water once there is an EPA-approved treatment, or stop irrigating altogether. These are not feasible or desirable options, and may reduce the supply of fresh produce in the US to the degree that farmers' irrigation water fails to meet the proposed FDA standard owing to upstream conduct or conditions beyond the farmer's control.

While it is beyond the jurisdiction of FDA to regulate or reform livestock production practices (such as CAFOs), FDA must take into account the fact that these problems with agricultural water quality need to be addressed at a societal and systemic level, and not expect farm-by-farm enforcement to correct the situation. The requirements of Subpart E must not result in produce farmers shouldering the burden of a problem for which they are not directly responsible and over which they have no control.

Recommendation: In the final Produce Rule, FDA should retain the requirement to inspect and adequately maintain the agricultural water system, but should establish an approach to the water standards that does not result in farmers shouldering the burden of ensuring the quality of agricultural water when the source of water contamination is off-farm.

C. FDA must clarify that farmers are not required to fence on-farm water sources such as ponds.

In the preamble discussion of Subpart E, FDA includes two contradictory statements about practices that impact conservation and wildlife:

1. FDA "do[es] not propose that vegetation surrounding an on-farm pond be cut back and/or removed or that fencing must be used to prevent access to a pond by wildlife and domestic animals"[148]; and
2. FDA states that "[p]roperly maintaining a farm pond that is used for irrigation using a direct application method, with respect to keeping it free from domesticated animals, could mean fencing the pond if you keep domesticated animals in the area such that they would otherwise have access to the pond."[149]

These are contradictory statements that are confusing and that will likely result in farmers taking measures to exclude domesticated and wild animals from on-farm water sources, or treating the water since FDA states that "if you treat the water before use in this way, you may not need to take

[148] 78 Fed. Reg. at 3560

[149] 78 Fed. Reg. at 3565

steps to prevent access of domesticated animals to the pond."[150] This is inconsistent with other statements in the preamble, the requirements in Subpart I, and the intent of Congress in FSMA around taking into consideration conservation and environmental efforts at other agencies. For a more detailed discussion about conservation and wildlife, see section XI.

Recommendation: In the final Produce Rule, FDA should not imply that farmers should fence on-farm water sources such as ponds to limit access from domesticated and wild animals. Additionally, FDA should not imply that farmers who do not fence on-farm water sources should then treat those sources to comply with the requirements of Subpart E.

D. FDA should clarify that treatment is not the only option if there is reason to believe that the agricultural water is not safe and of adequate sanitary use.

While we express concerns about water treatment above and in our comments on the EIS scoping notice,[151] there are contradictory statements about treatment in Subpart E. From the way that § 112.43(a) is written, FDA implies that a farmer must treat the agricultural water if the farmer "know[s] or ha[s] reason to believe that the water is not safe and of adequate sanitary quality for its intended use." This conflicts with the statement in § 112.42(d) that specifies that if there is a reason to believe that there is a problem with the agricultural water system, a farmer must discontinue use of the water and has the option of *either* making necessary changes and testing to determine if the changes were effective, *or* treating the water in accordance with the requirements of § 112.43. In the preamble[152] and in FDA outreach materials,[153] it seems like farmers do have the option to *either* make the necessary changes and test, *or* treat to deal with a problem and that FDA is not requiring that they *must* treat if there is a problem. A simple revision of § 112.43(a) would clarify this issue.

Recommendation: In the final Produce Rule, FDA should clarify that if there is a reason to believe that a farmer's agricultural water system is not safe and of adequate sanitary quality for its intended use, the farmer has the option to meet the requirement in *either* § 112.42(d)(1) *or* (2), and that a farmer is not required to treat the agricultural water according to § 112.43 if the farmer opts to meet the requirements in § 112.42(d)(1). Specifically, FDA should revise § 112.43(a) so that is reads (language to add is <u>underlined</u> and language to delete is ~~struck-through~~):

> (a) You must treat any agricultural water that you use (such as with an EPA-registered antimicrobial pesticide product) if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use <u>and you choose not to comply with § 112.42(d)(1)</u>.

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[150] 78 Fed. Reg. at 3565
[151] NSAC, Scoping Notice Comments, at 9-11.
[152] 78 Fed. Reg. at 3566
[153] U.S. Food and Drug Admin. FSMA Facts: "More on the Proposed Agricultural Water Standards – FDA's Proposed Rule for Produce Safety." Available at: http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM360242.pdf

X. COMMENTS ON SUBPART F—STANDARDS DIRECTED TO BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE

Summary

NSAC makes comments and recommendations on Subpart F—Standards Directed to Biologicla Soil Amendments of Animal Origin and Human Waste. The proposed pre-harvest intervals violate the requirements of FSMA. FDA does not provide sufficient evidence for a sufficient public health benefit to justify the serious environmental and economic impact these proposed pre-harvest intervals will have.

Comments

A. The proposed pre-harvest intervals in Subpart F violate the requirements of FSMA.

The proposed Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste (Subpart F) fails to meet the requirements of FSMA. Specifically, FSMA requires FDA to:

- "Provide sufficient flexibility to be applicable to various types of entities engaged in 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"[154];
- "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"[155];
- Establish "minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks"[156]; and
- Not "conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990."[157]

FDA's proposed Subpart F fails to meet the requirements of FSMA because the standard:

1. Does not provide sufficient flexibility to be applicable to the diversity of produce farms;
2. Does not take into consideration conservation and environmental practice standards;
3. Does not have an adequate scientific basis; and
4. Directly conflicts with the requirements of the National Organic Program (NOP) established under the Organic Foods Production Act of 1990.

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

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

[156] Food, Drug, & Cosmetic Act § 419(b)(1)

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

Proposed Subpart F fails to meet these requirements primarily because of the intervals between application and harvest of covered produce set forth in § 112.56. Specifically, in § 112.56 FDA proposes a nine-month restriction between the application of an untreated biological soil amendment of animal origin that is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and harvest of covered produce. FDA is proposing a 45-day interval between the application of a biological soil amendment of animal origin that is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) and is applied in a manner that minimizes the potential for contact with covered produce during and after application, and harvest of covered produce. FDA seeks comment on the "appropriateness of the proposed application period intervals."[158]

If included in the final rule unchanged, the proposed intervals would effectively eliminate the use of untreated biological soil amendments of animal origin (including raw manure, aged manures, and cool-composted amendments with any ingredients of animal origin) in most production systems, and create significant barriers to the use of compost. The use of these types of biological soil amendments is a fundamental and foundational practice in sustainable production systems, and is a critical aspect of soil, nutrient, fertility, water-holding capacity, and pest management in sustainable and organic agriculture. In Subpart F, FDA is proposing to greatly and significantly restrict the use of a major nutrient source that is as old as agriculture itself, and by doing so force farmers into greater reliance on costly agrichemicals that serve as major contributors to agricultural pollution and run-off and that are subject to reduction and control efforts through both regulation and substantial taxpayer-financed incentives. These synthetic chemicals also have a deleterious effect on soil health and degrade soil quality.

NSAC expands on each of these points in the comments below and then provides a recommendation at the end of this subsection based on these points.

1. Proposed Subpart F fails to meet the requirements of FSMA because it is not sufficiently flexible.

Proposed Subpart F includes rigid requirements for agricultural production, including intervals between the application of biological soil amendments of animal origin and the harvest of covered produce. These requirements severely restrict practices that are widely used by farmers – especially sustainable and organic farmers – for soil, nutrient, fertility, and pest management.

Farmers need to use fertilizer to grow crops, and there are two main types of fertilizers: chemical fertilizers and biologically based fertilizers (including most importantly on-farm resources). Sustainable and certified organic farmers choose to use – and in the case of certified organic production, must use – biologically based fertilizers as the major nutrient sources in crop production. As an example of the widespread use of these amendments, USDA's National Agricultural Statistics Service 2008 Organic Production Survey (OPS), which surveyed all types of organic growers and not just produce, found that 65 percent of certified organic farms use green or animal manures, and that 51.3 percent of certified organic farmers use organic mulch or compost.[159] These practices are fundamental and foundational aspects of sustainable and organic production

[158] 78 Fed. Reg. at 3583

[159] US Dep't of Agric. "NASS 2008 Organic Production Survey."

systems that cannot simply be replaced by the use of synthetic inputs. Biologically based fertilizers serve multiple functions in a production system, including, but not limited to providing fertility; synthetic fertilizers do not provide these other functions and are not an adequate replacement for biologically based fertilizers such as manure and compost.

The intervals between application and harvest proposed will severely restrict the use of untreated biological soil amendments of animal origin such as manure. A nine-month interval between application and harvest of covered produce means that, for farmers who use manure in produce production in nearly all areas of the country, *the interval between application and harvest will be longer than the growing season overall and the growing season for individual crops*.

This issue was raised during the interagency review process when the proposed interval was one year. The interagency review process found that "if a full year was required, many growers that utilize raw manure would be forced to fallow fields for the full year, thus only allowing them to grow produce in alternating years, instead of every season. This was viewed as a significant potential economic impact."[160] The same potential impact applies with a nine-month interval. There is little or no practical difference between the two standards.

For a number of regions of the country, a nine-month interval would mean that both application and harvest would occur during winter and, hence, outside of the growing season. If those growers wanted to do the application or harvest during the growing season, under these proposed regulations, those growers would be forced to fallow the field for an entire growing season. Even in regions with long growing seasons such as southern California and the Gulf Coast states, the nine-month interval would seriously disrupt crop production schedules and rotations, because vegetable growers in these regions commonly grow two, three, or even four crops in succession.

Also, while the growing season overall may be shorter than the nine-month interval, the growing season for individual crops is certainly shorter than nine months, unless the crops are perennials. Each crop requires tailored nutrient management based on characteristics such as when the crop most needs nutrients to grow. Requiring a nine-month interval would significantly disrupt the nutrient management of individual crops.

Additionally, FDA's determination of what constitutes an "untreated amendment" is broad. In addition to fresh manure, chicken litter, and slaughterhouse or fishery wastes, the proposed Produce Rule classifies any biological soil amendment with animal-derived components that have not met the requirements of § 112.54(c) and § 112.55(b) as an "untreated" amendment. For example, any compost that is based in part on manure or other animal byproducts and has undergone an extended warm phase of 110-125°F, followed by six months curing with no re-contamination, could still not be applied less than nine months prior to harvest. For this and other reasons mentioned above, the nine-month interval is an entirely inflexible approach that conflicts with established produce production practices.

For farmers who use compost, enactment of the proposed 45-day interval would severely limit crop rotations for short-season crops and significantly restrict the use of compost during the growing season for side-dressing. Mesclun and other salad mixes, spinach, radishes, arugula, and salad turnips are often harvested as soon as 20 to 45 days after planting; all of these crops are relatively

[160] Produce Rule Reference 34, Mahovic, M, FDA Memorandum to the Record June 2011.

heavy feeders that typically require compost during growth to provide satisfactory yield and quality. In addition, summer squash, zucchini, and cucumbers typically begin yielding within 40 days of being transplanted into the field or high tunnel. Finally, some producers side-dress with compost as a part of their integrated pest management plan, with the goal of enhancing soil biological activity and thereby improving nutrient availability and suppressing certain crop diseases. As with manure, this proposed interval is an entirely inflexible approach that conflicts with established produce production practices.

While FDA has allowed for "alternatives" to certain requirements in Subpart F in accordance with § 112.12, the limited scope and unclear, burdensome requirements for an alternative do not make them a realistic option for farmers. The alternatives apply very narrowly and not to the entire standard. Additionally, the burden of proof is on the farmer to have adequate scientific data or information to show that the alternative would "provide the same level of public health protection as the applicable requirement" in the proposed standards.[161] In other words, FDA is placing the burden on farmers to conduct research on public health risks generally – a research and investigative task that even FDA has been unable to fulfill. Many small farmers, or groups of small farmers, will not be able to afford to conduct this type of research because it is costly and requires a sustained investment.

Due to the unscientific nature of the proposed pre-harvest application intervals (discussed in detail below), it is impossible for a farmer to demonstrate that an alternative biological soil amendment approach would provide the "same level of public health protection" – because FDA cannot prove a level of public health protection that results from its proposed intervals. Farmers thus do not have any clear information against which to measure their proposed alternative. It is inappropriate for FDA to place such a significant burden on farmers and private entities and then claim to be offering flexibility. As currently proposed, the option for alternatives would not provide true additional flexibility in the biological soil amendment standards. NSAC provides more complete comments on the alternatives option in section VII.

2. Proposed Subpart F fails to meet the requirements of FSMA because it does not take into consideration conservation and environmental efforts.

Because of the restrictions in proposed Subpart F on biological soil amendments of animal origin, FDA is creating a significant incentive for the use of chemical fertilizers; these are products that have been widely shown to result in significant environmental impacts, including agricultural run-off and pollution, and the degradation of soil biological health. In FDA's Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, FDA acknowledges that the biological soil amendment standard requirements as proposed "are expected to result in changes in current use of treated and untreated biological soil amendments of animal origin or potentially greater use of synthetic fertilizers."[162]

NSAC addresses this issue and other issues more fully in our comments on the scoping notice, which are incorporated herein.[163]

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[161] § 112.12(b)

[162] 78 Fed. Reg. at 50359

[163] NSAC Scoping Notice Comments, at 13-24.

Given the scope of agricultural pollution from synthetic fertilizers, other government agencies, such as USDA's Natural Resources Conservation Service (NRCS), have established initiatives and developed specific conservation practices – including nutrient management and compost facilities – with the goals of decreasing agricultural pollution and minimizing run-off and erosion, as well as supporting efforts to encourage more ecologically sound, biologically based fertility practices.[164] NRCS spends considerable public funds to provide technical assistance and financial incentives to decrease agricultural pollution caused by the overreliance on purchased synthetic chemical fertilizers. Proposed standards that encourage a shift from biologically based fertilizers to synthetic fertilizers would undermine existing and significant efforts at other agencies, agricultural organizations, and educational institutions to mitigate agricultural pollution and, as such, would fail to meet the requirements of FSMA to coordinate with other agencies on conservation and environmental issues. Rather than showing coordination, the proposed rule directly contradicts the activities and expenditures of other conservation and environmental agencies.

3. Proposed Subpart F fails to meet the requirements of FSMA because it does not have an adequate scientific basis for the proposed intervals.

a. There is a lack of a scientific basis for the nine-month interval.

FDA's proposed nine-month interval for untreated biological soil amendments of animal origin fails to meet the FSMA requirement to be science-based. There has been very little research conducted on many of the topics related to the application waiting periods for raw manure and there is not substantial evidence to support a nine-month interval over other intervals between application of an untreated biological soil amendment of animal origin and harvest of covered produce. In the preamble, FDA recognizes that "pathogen survival and die-off time in soils amended with raw manure are extremely varied" and that "it is unclear in the existing literature at what point the population is low enough to minimize the potential for contamination of covered produce."[165] Despite this recognition, FDA is proposing to require this excessive and arbitrary nine-month interval.

The references that FDA cites to support a nine-month interval fail to establish a basis for the standard. For those pathogens that are more commonly associated with fresh produce outbreaks, such as *E. coli* O157:H7 and *Salmonella* spp., several of the references cited by FDA are not appropriately interpreted: abnormally high rates of pathogens were used for inoculation, measurements of pathogen survival were made in manure rather than soil (when growers use manure in produce production, they almost always incorporate it into soil), and sterile soil was used that lacked the diverse populations of pathogen-suppressing microorganisms typically found in soil. Additionally, FDA discusses studies that focused on pathogens such as *Cryptosporidium*, *Giardia*, and *Ascaris* (roundworms); these pathogens are not commonly associated with the contamination of fresh produce by untreated biological soil amendments of animal origin. Table 1 provides further critique of the references FDA cites to support the nine-month interval.

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[164] Examples of such initiatives include NRCS's Mississippi River Basin Healthy Watersheds Initiative: http://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/national/programs/farmbill/initiatives/?cid=stelprdb1048200; and NRCS's Soil Health Initiative: http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/soils/health/

[165] 78 Fed. Reg. at 3582

In our review of the literature, NSAC found numerous studies where *E. coli* O157, *Salmonella* spp., *Campylobacter* spp., and *Listeria* spp. persisted for fewer than 120 days (the interval required by the National Organic Program regulations; see below). Table 2 provides more details about these particular studies.

FDA chose to justify the nine-month interval between the application of untreated manure and harvest based on too few relevant studies, and on a worst-case scenario. Contamination from untreated soil amendments is a real concern, but FDA's approach to minimizing the risk is not sufficiently science-based and is far too extreme to be practical.

Additionally, FDA requests comment on "whether and how, as an additional requirement for the application of untreated biological soil amendments of animal origin, the time period when the soil is frozen should count toward the proposed application interval" and on the "impact that freeze-thaw cycles may have on use of biological soil amendments of animal origin."[166] Given the findings of the study[167] that FDA cites in its discussion of the impact of freeze-thaw cycles showing that such cycles "may cause more rapid die-off rates of pathogens present in soils,"[168] NSAC supports counting the time period when the soil is frozen toward any application interval. We do so so that farmers who are applying manure in the fall are not penalized. We do not support the application of manure to frozen ground and we do not think that is an acceptable practice. Nothing in this comment is intended to indicate support for the nine-month interval in proposed Subpart F.

[166] 78 Fed. Reg. at 3582

[167] FDA cites Natvig et al. "*Salmonella enterica* serovar Typhimurium and *Escherichia coli* contamination of root and leaf vegetables grown in soils with incorporated bovine manure." *Applied Environmental Microbiology* 68: 2737-2744 (2002).

[168] 78 Fed. Reg. at 3582

Table 1. Critique of FDA references supporting a nine-month interval between application of an untreated biological soil amendment of animal origin and harvest of covered produce.

Pathogen Persistence	**Pathogen**	**Relevant Details**	**Critique**	**Authors**
154 – 196 days	*E. coli* O157:H7	Used high concentration (10^7 cfu g^{-1}) of pathogen in inocula	The concentration used (10^7 cfu g^{-1}) is far greater than what would typically be found in an agricultural field	Islam et al. 2005[169]
154 – 217 days	*E. coli* O157:H7	Used high concentration (10^7 cfu g^{-1}) of pathogen in inocula	The concentration used (10^7 cfu g^{-1}) is far greater than what would typically be found in an agricultural field	Islam et al. 2004[170]
184 days (a), 332 days (b), and 405 days (c)	*Salmonella*	(a) days in manure, (b) days in manure-amended nonsterilized soil, and (c) days in manure-amended sterilized soil	Longest pathogen survival occurred in sterilized soil, providing evidence that the final Produce Rule should *not* favor sterilized soil amendments of animal origin over finished compost that meets the requirements of § 112.54(c) and is not heat- or chemical-treated	You et al. 2006[171]
226 days	*E. coli* O157:H7	Used high rate (10^7 cfu g^{-1}) of pathogen and placed manure in sterile soil	The pathogen persisted this long because the manure was inoculated with a high pathogen level, and it was put in autoclaved soil that did not support diverse microorganisms antagonistic to the pathogen. Pathogens declined more rapidly in non-autoclaved soil	Jiang et al. 2002[172]

[169] Islam, M. et al. "Survival of *Escherichia coli* O157:H7 in soil and on carrots and onions grown in fields treated with contaminated manure composts or irrigation water." *Food Microbiology* 22: 63-70 (2005).

[170] Islam, M. et al. "Persistence of *Salmonella enterica* serovar Typhimurium on lettuce and parsley and in soils on which they were grown in fields treated with contaminated manure composts or irrigation water." *Foodborne Pathogens and Disease* 1: 27-35 (2004).

[171] You, Y. et al. "Survival of *Salmonella enterica* serovar Newport in manure and manure-amended soils." *Applied and Environmental Microbiology* 72: 5777-5783 (2006).

[172] Jiang, X. et al. "Fate of *Escherichia coli* O157:H7 in manure-amended soil." *Applied and Environmental Microbiology* 68: 2605-2609 (2002).

1 year	*Cryptosporidium*		This pathogen is primarily transmitted to humans through water rather than soil	Peng et al. 2008[173]
<1 year	*Giardia* and *Cryptosporidium*		These pathogens are primarily transmitted to humans through water rather than soil	Sorber and Moore 1987[174]
21 months	*E. coli* O157:H7		Detected in a manure pile, not in soil that had a manure application	Kudva et al. 1998[175]
15 years	*Ascaris* (roundworm)		Biological soil amendments of (non-human) animal origin are not a likely vector for this pathogen	Wichuk and McCartney 2007[176]

[173] Peng, X. "Evaluation of the effect of temperature on the die-off rate for *Cryptosporidium parvum* oocysts in water, soils, and feces." *Applied and Environmental Microbiology* 74: 7101-7107 (2008).

[174] Sorber, C. and B. Moore. "Project Summary, Survival and Transport of Pathogens in Sludge-Amended Soil: A Critical Literature Review." 1987.

[175] Kudva, I. et al. "Analysis of *Escherichia coli* O157:H7 survival in ovine or bovine manure and manure slurry." *Applied and Environmental Microbiology* 64: 3166-3174 (1998).

[176] Wichuk, K. and D. McCartney. "A review of the effectiveness of current time-temperature regulations on pathogen inactivation during composting." *Journal of Environmental Engineering and Science* 6: 573-586 (2007).

Table 2. References that support a 120-day interval between the application of untreated manure and harvest.

Pathogen Persistence	**Pathogen**	**Relevant Details**	**Commentary**	**Authors**
7 days	*Salmonella*	*Salmonella* in land applied manure was found to survive for 7 days when sampled at 2 cm depth		Gessel et al. 2004[177]
14-21 days	*Salmonella*	Pig slurry containing *Salmonella* was incorporated into the soil		Baloda et al. 2001[178]
25-96 days	*E. coli* O157:H7	Fallow fields and fields planted with cover crops were amended with manure contaminated at a rate of 10^6 cfu/g of pathogen		Gagliardi and Karns 2002[179]
28 days	*E. coli* O157:H7	*E. coli* was not detected on plant shoots after seven days but did survive in soil for up to 28 days		Patel et al. 2010[180]
<31 days*	*Salmonella*, *Campylobacter*, *Listeria*, E. coli* O157:H7	Manure inoculated at levels of 2-5 log CFU/g spread on land	*Listeria* survived longer than the other pathogens	Nicholson et al. 2005[181]

[177] Gessel, P. et al. "Persistence of zoonotic pathogens in surface soil treated with different rates of liquid pig manure." *Applied Soil Ecology* 25: 237-243 (2004).

[178] Baloda, S. et al. "Persistence of *Salmonella enterica* serovar Typhimurium DT12 clone in a piggery and in agricultural soil amended with *Salmonella*-contaminated slurry." *Applied and Environmental Microbiology* 67: 2859-2862 (2001).

[179] Gagliardi, J. and J. Karns. "Persistence of *Escherichia coli* O157:H7 in soil and on plant roots." *Environmental Microbiology* 4: 89-96 (2002).

[180] Patel, J. et al. "Persistence of enterohaemorrhagic and nonpathogenic *E. coli* on spinach leaves and in rhizosphere soil." *Journal of Applied Microbiology* 108: 1789-1796 (2010).

[181] Nicholson, F. et al. "Pathogen survival during livestock manure storage and following land application." *Bioresource Technology* 96: 135-143 (2005).

32-110 days	*E. coli* O157:H7	Survival time varied with soil type		Ma et al. 2011[182]
43 days	*Listeria*	Initial inoculation level of 5-6 log CFU/g in manure		Jiang et al. 2004[183]
50-70 days	*Salmonella* and *E. coli*	Multi-year field study in sandy loam soil, also found no contamination of vegetables		Cote and Quessy 2005[184]
56 days	Fecal bacteria	Poultry litter at 15 or 30 t/ac	Recommended application rates for poultry litter typically range from 2 to 5 t/ac	Zhai et al. 1995[185]
>56 days	*E. coli* O157:H7	Crisphead lettuce was grown in soil fertilized with manure inoculated at 4 log CFU/g	No contamination of lettuce observed	Johannessen et al. 2005[186]
60 days	*E. coli* O157	Pathogen prevalence and densities were modeled probabilistically through the primary production chain of lettuce (manure, manure-amended soil and lettuce).		Franz et al. 2008[187]
64-128 days	*Listeria*, *Salmonella, Campylobacter,*	Initial inoculation of 6 log CFU/g	Most pathogens were not recoverable after 64 days, but *Listeria* sometimes	Hutchison et al. 2005[188]

[182] Ma, J. et al. "Persistence of *Escherichia coli* O157:H7 and its mutants in soils." *PLOS One* 6 (2011).

[183] Jiang, X. et al. "Fate of *Listeria monocytogenes* in bovine manure-amended soil." *Journal of Food Protection* 8: 1676-1681 (2004).

[184] Cote, C. and S. Quessy. "Persistence of *Escherichia coli* and *Salmonella* in surface soil following application of liquid hog manure of production of pickling cucumbers." *Journal of Food Protection* 68: 900-905 (2005).

[185] Zhai, Q. et al. "Mortality rates of fecal bacteria in subsoil amended with poultry manure." *Bioresource Technology* 54: 165-169 (1995).

[186] Johannessen, G. et al. "Potential uptake of *Escherichia coli* O157:H7 from organic manure in crisphead lettuce." *Applied and Environmental Microbiology* 71:2221-2225 (2005).

[187] Franz, E. et al. "Modeling the contamination of lettuce with *Escherichia coli* O157:H7 from manure-amended soil and the effect of intervention strategies. *Journal of Applied Microbiology* 105: 1569-1584 (2008).

	Cryptosporidium, E. coli O157		persisted up to 128 days	
69-92 days	*E. coli* O157:H7	3 log CFU/g *E. coli* present at day 19; no E coli recovered from radishes harvested at day 69 or from soil at day 92		Mukherjee et al. 2006[189]
90 days	*Listeria*	Time required for a 7 log reduction		Girardin et al. 2005[190]
98 days	*Salmonella* and *E. coli* O157:H7	Tropical conditions		Ongeng et al. 2011[191]
>99 days	*E. coli* O157:H7	Soils amended with manure inoculated at rate of 10^8 to 10^9 cfu g^{-1} and then spread on grassland	Even though a high concentration of pathogens was used, they did not survive a long time on grassland because of the biological activity in the soil, including diverse microorganisms antagonistic to *E. coli*.	Bolton et al. 1999[192]
105 days	*E. coli* O157	Samples of soil and sheep feces were collected from the campsite and tested for the presence of *E. coli* O157.		Ogden et al. 2002[193]

[188] Hutchison, M. et al. "Analyses of livestock production, waste storage, and pathogen levels and prevalences in farm manures." *Applied and Environmental Microbiology* 71: 1231-1236 (2005).

[189] Mukherjee, A. et al. "Soil survival of *Escherichia coli* O157:H7 acquired by a child from garden soil recently fertilized with cattle manure." *Journal of Applied Microbiology* 101: 429-436 (2006).

[190] Girardin, H. et al. "Behavior of the pathogen surrogates *Listeria innocua* and *Clostridium sporogenes* during production of parsley in fields fertilized with contaminated amendments." *FEMS Microbiology Ecology* 54: 287-295 (2005).

[191] Ongeng, D. et al. "Survival of *Escherichia coli* O157: H7 and *Salmonella enterica* serovar Typhimurium in manure and manure-amended soil under tropical climatic conditions in Sub-Saharan Africa." *Journal of Applied Microbiology* 110: 117-1022 (2011).

[192] Bolton, D. et al. "The survival characteristics of a non-toxigenic strain of *Escherichia coli* O157:H7." *Journal of Applied Microbiology* 86: 407-411 (1999).

[193] Ogden, I. et al. "Long-term survival of *Escherichia coli* O157 on pasture following an outbreak associated with sheep at a scout camp." *Letters in Applied Microbiology* 34: 100-104 (2002).

b. There is a lack of scientific basis for the 45-day interval.

For compost, the agency has failed to show how the literature it cites on the 45-day interval supports its conclusion that the interval is scientifically justified.

FDA overstates the risk associated with properly managed compost, and neglects scientific research indicating the important role diverse microbial populations in compost play in suppressing pathogens. FDA's proposed standards would excessively restrict the use of compost and push farmers towards sterilized soil amendments that, because of their lack of biological diversity, would be more vulnerable to pathogen regrowth than properly managed compost.

As FDA acknowledges, composting is widely recognized as an effective process to kill pathogens and produce a hygienic product from potentially contaminated waste.[194] This is based on a wealth of studies confirming that composting to accepted time and temperature standards inactivates pathogens, even when they have been inoculated into the source waste at high levels.[195] Various studies of commercial compost support the claim that properly managed compost is fully safe for use on covered produce. Miller et al.[196] tested 103 organic fertilizers from across the United States and found no *Salmonella*, *Listeria moncytogenes*, or *E. coli* O157:H7, while Brinton et al.[197] concluded, "compost that is hygienic by common standards can be produced."

FDA establishes a microbial standard for animal waste treatment processes while acknowledging that any treatment process, including both heat treatment and composting, may "not always result in complete elimination of pathogens."[198] FDA chooses, however, to extend the consequences of this uncertainty only to its regulation of composted animal waste: Subpart F establishes a pre-harvest application interval for compost in 112.56(a)(4)(i) that is not applied to physically or chemically treated animal waste in 112.56(a)(3), even though both are treated to the same microbial standard. By adopting a worst-case scenario approach for composted waste that is not adopted for otherwise treated waste, FDA creates a double standard that is not scientifically supported and will place an undue burden on sustainable and organic farmers.

Furthermore, FDA neglects the substantial body of scientific literature on the pathogen suppressing effects of the naturally occurring, diverse microbial communities in compost (see Table 3). The preamble to the proposed rule calls for a "multiple hurdle" approach to compost safety[199]; suppression/competition by compost microflora provides the second hurdle. Thus FDA's requirement that compost be treated to time and temperature standards followed by adequate

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194 78 Fed. Reg. at 3579

195 E.g., Wiley, B. and S. Westerberg. "Survival of Human Pathogens in Composted Sewage." *Applied Microbiology* 18: 994-1001 (1969); Lung, A. et al. "Destruction of *Escherichia coli* O157:H7 and *Salmonella enteritidis* in cow manure composting." *Journal of Food Protection* 64: 1309-1314 (2001); Erickson, M. et al. "Inactivation of *Salmonella* spp. in cow manure composts formulated to different initial C:N ratios." *Bioresource Technology* 100:5898-5903 (2009.

196 Miller, C. et al. "Analyzing indicator microorganisms, antibiotic resistant *Escherichia coli*, and regrowth potential of foodborne pathogens in various organic fertilizers." *Foodborne Pathogens and Disease* 10: 520-527 (2013).

197 Brinton, W. et al. "Occurrence and levels of fecal indicators and pathogenic organisms in market-ready recycled organic matter composts." *Journal of Food Protection* 72: 332-339 (2009).

198 78 Fed. Reg. at 3579

199 78 Fed. Reg. at 3577

curing, which will allow diverse pathogen-suppressing microbial populations to become fully established, already provides multiple hurdles without any need for an unfounded and burdensome pre-harvest application interval.

Table 3. References that support the pathogen-suppressing ability of biologically active vs. sterile compost.

Pathogen	**Relevant Details**	**Commentary**	**Authors**
Salmonella	Established coliform populations suppressed pathogen regrowth.		Millner et al 1987[200]
Salmonella, Listeria, Enterococcus	Pathogens did not survive when inoculated into stabilized compost but showed minimal die-off in sterilized compost.	Used strains isolated from compost	Paniel et al 2009[201]
Salmonella, Listeria, E. coli O157:H7	Pathogens inoculated into sterilized composts at low levels showed rapid population growth. No pathogen regrowth was detected in non-sterilized composts.		Kim and Jiang 2010[202]
E. coli O157:H7	Sterilized compost supported pathogen regrowth, while compost with active microbial communities left intact did not.		Kim et al 2011[203]
E. coli O157:H7	Dramatic reduction in *E. coli* levels when introduced in untreated compost; autoclaving or chemically treating compost improved *E. coli* survival.		Puri and Dudley 2010[204]

Because of the pathogen-suppressing effect of compost microflora, biologically active compost is much more resilient to potential recontamination by pathogens than materials treated with physical or chemical processes that leave behind a biological vacuum (see Table 3). This makes FDA's decision to treat sterilized waste as safer than composted waste – by establishing a pre-harvest application interval for the latter but not the former – all the harder to justify on the grounds of science or risk management. FDA has identified recontamination of previously treated waste as a

[200] Millner, P. et al. "Microbially mediated growth suppression and death of *Salmonella* in composted sewage sludge." *Microbial Ecology* 14: 225-265 (1987).

[201] Paniel, N. et al. "Assessment of survival of *Listeria monocytogenes*, *Salmonella* Infantis and *Enterococcus faecalis* artificially inoculated into experimental waste or compost." *Journal of Applied Microbiology* 108: 1797-1809 (2010).

[202] Kim, J. and X. Jiang. "The growth potential of *Escherichia coli* O157:H7, *Salmonella* spp. and *Listeria monocytogenes* in dairy manure-based compost in a greenhouse setting under different seasons." *Journal of Applied Microbiology* 109: 2095-2104 (2010).

[203] Kim, J. et al. "Impact of indigenous microorganisms on *Escherichia coli* O157:H7 growth in cured compost." *Bioresource Technology* 102: 9619-9625 (2011).

[204] Puri, A. and E. Dudley. "Influence of indigenous eukaryotic microbial communities on the reduction of *Escherichia coli* O157:H7 in compost slurry." *FEMS Microbiology Letters* 313: 148-154 (2010).

major concern for the safety of biological soil amendments of animal origin,[205] and biologically active composted waste is less vulnerable to such recontamination than waste treated by a sterilization process which leaves behind a biological vacuum. FDA acknowledges this at several points when discussing recontamination in the preamble,[206] but then dismisses the well-established pathogen suppressing capabilities of biologically active compost as unreliable without providing any scientific justification for doing so.

The repeatedly demonstrated pathogen suppressing effects of naturally occurring microbial communities even extend to the soil, with van Elsas et al.[207] finding an inverse relationship between soil microbial diversity and survival of *E. coli* O157:H7. *Listeria* and *E. coli* 0157:H7 inocula have been shown to decline more quickly in soils with their native microfloras intact than in sterilized soils,[208] while Vidovic et al.[209] found that native soil microflora inhibited *E. coli* 0157:H7. Given the variety of potential sources of contamination other than soil amendments, FDA should regard biologically active compost as an additional line of defense against pathogens rather than as a hazard.

FDA should not treat composted waste as riskier than waste treated in other ways to the same microbial standard. It should allow composted waste produced according to accepted standards to be used without a minimum pre-harvest application interval.

4. Proposed Subpart F fails to meet the requirements of FSMA because it would cause certified organic producers to be non-compliant under National Organic Program regulations.

Congress was very clear in FSMA that nothing in the proposed Produce Rule should undermine organic production practices, yet FDA has ignored this mandate. NSAC agrees with FDA that "organic production practices and food safety are not cross-competing goals"[210] but the intervals that FDA has proposed would severely compromise the ability of certified organic producers to comply with the requirements of the National Organic Program (NOP) regulations, particularly with regard to providing and managing crop nutrients in ways that build and maintain soil and plant health, and that do not contaminate water resources.

In the preamble to the proposed Produce Rule, FDA "tentatively conclude[s] that compliance with the provision of this proposed rule would not preclude compliance with the requirements for organic certification in 7 CFR part 205"; FDA "seek[s] comment on this tentative conclusion."[211] FDA argues that there is not a conflict between the proposed Subpart F intervals and the NOP regulations because "[a]ny minimum application interval that you use can be concurrent with any

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[205] 78 Fed. Reg. at 3576

[206] 78 Fed. Reg. at 3576-3577

[207] Van Elsas, J. et al. "Microbial diversity determines the invasion of soil by a bacterial pathogen." *Proceedings of the National Academy of Sciences* 109: 1159-1164 (2012).

[208] Jiang et al. 2002; Goberna, M. et al. "Pathogenic bacteria and mineral N in soils following the land spreading of biogas digestates and fresh manure." *Applied Soil Ecology* 49: 18-25 (2011).

[209] Vidovic, S. et al. "Effect of soil composition, temperature, indigenous microflora, and environmental conditions on the survival of *Escherichia coli* O157:H7." *Canadian Journal of Microbiology* 53: 822-829 (2007).

[210] 78 Fed. Reg. at 3574

[211] 78 Fed. Reg. at 3574

application intervals that you are already required to, or voluntarily, apply."[212] The agency argues that because the interval is concurrent and not consecutive, there is no conflict. FDA bases this tentative conclusion on a very narrow interpretation of NOP standards, reflecting a limited understanding of the multiple functions that soil amendments perform in organic systems.

The intervals between application and harvest that FDA is proposing – specifically the nine-month interval on untreated amendments and the 45-day interval for compost – are in direct regulatory conflict with the National Organic Program (NOP) regulations. With respect to manure, NOP allows farms to use raw manure fertilizer if it is applied 120 days before harvest if the crop's edible portions come into contact with the soil directly, or 90 days before harvest if the edible portions do not come into contact with the soil. In the proposed Produce Rule, FDA proposes a nine-month restriction when the covered produce does not come into contact with the amendment during application, but may come into contact with an untreated biological soil amendment of animal origin, such as raw manure, after application (§ 112.56). FDA is proposing a zero-day interval if the untreated amendment does not come into contact with the covered produce during or after application. With respect to compost, NOP regulations do not set an interval between application of manure treated by a composting process that is consistent with NOP composting standards and harvest; FDA is proposing a 45-day restriction (§ 112.56). NOP regulations also do not require insulation of compost (§ 112.54; see comments below on insulation).

FDA claims that the proposed standards "would not jeopardize [] compliance with the requirements of the National Organic Program" because for certified organic farms, the application intervals required by NOP and the produce standards would "run concurrently…rather than consecutively."[213] This reasoning shows a lack of understanding for how organic systems work, the multiple standards that organic farmers must comply with to be certified, and the fundamental role that biological soil amendments of animal origin play within the entire system of production. As proposed, the intervals would result in regulatory conflict between NOP requirements and the requirements of Subpart F because requiring these intervals will fundamentally alter the ability of organic farmers to meet NOP requirements and could cause a number of organic farmers to be found in non-compliance with NOP and, therefore, to risk losing their organic certification. Congress specifically sought to avoid this situation when it prohibited FDA's produce standards from conflicting with the requirements of NOP.[214]

In FSMA, Congress saw a risk of the new produce regulations conflicting with existing NOP regulations. This reflected the experience of private food safety regimes that made it more difficult for organic farmers to use NOP-approved fertility systems by placing onerous restrictions on the use of organic fertility treatments such as manure and compost to the point where as a practical matter farmers were unable to use those materials. Congress therefore took care to direct FDA to avoid any such regulatory conflict. Yet FDA adopts a logic in which, however it constructs the rules, there is no conflict. If it imposes lower standards than NOP, there is no conflict because by following NOP farmers are also complying with FSMA; yet somehow FDA also maintains that there is no conflict in setting a stricter standard than NOP, because by complying with FSMA farmers will also be complying with NOP (although as we explain below, that is not true). This has the effect of

[212] 78 Fed. Reg. at 3584

[213] 78 Fed. Reg. at 3519

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

rendering Congress's language meaningless and undoing the protections they sought for organic producers.

The Organic Trade Association (OTA) and the Washington State Department of Agriculture (WSDA) conducted a survey in late summer/early fall 2013 of certified organic producers to investigate the effects of the pre-harvest intervals in Subpart F on organic production.[215] The survey results show that 94 percent of organic producers surveyed indicated use of compost or manure as a soil fertility input on covered produce.

The responses showed that the intervals in Subpart F create regulatory conflict with NOP requirements and would result in adverse action by organic certification agencies. For example, seventy-three percent of the organic growers who use compost surveyed by OTA and WSDA said that FDA's proposed regulation of compost under FSMA would negatively affect their ability to include crop rotation or biological diversity in their farming operations as mandated by NOP standards. Thirty-seven percent said the proposed waiting period between application of compost and harvest, established in 112.56(a)(4)(i), would completely prevent their operation's ability to rotate crops or introduce biological diversity. This means implementation of the proposed rule would effectively force these farmers out of compliance with NOP standards, violating Congress's directive that FDA create rules under FSMA that do not conflict with organic standards. This is because the proposed intervals will severely restrict the ability of organic farmers to rotate crops as part of preventive pest and disease control, and will result in non-compliance with the following standards set forth in NOP regulations:

- Soil fertility and crop nutrient management practice standard;[216]
- Crop rotation practice standard;[217] and
- Crop pest, weed, and disease management practice standard.[218]

The OTA/WSDA survey indicated that specific examples of regulatory conflict include, but are not limited to:

- For untreated manure:
    - For diversified livestock and crop farms, early season covered produce could not follow a late harvested feed crop;
    - For intensively managed mixed vegetable operations, rotations between various plant families (cucurbits, brassicas, etc.) would be severely restricted; and
    - The nine-month interval necessitates the application of untreated manure at times when the risk of runoff, nutrient loss, and damage to soil quality are the greatest.
- For compost:
    - For short season greens (lettuce, spinach, arugula, etc.), rotations would be severely restricted if not impossible;

[215] Washington State Department of Agriculture and Organic Trade Association. "Impact of FDA's Proposed Application Intervals on Organic Fertility and Crop Rotation Requirements." 30 August 2013 to 4 October 2013. http://www.ota.com/regulatory/foodsafety.html

[216] 7 C.F.R. § 205.203

[217] 7 C.F.R. § 205.205

[218] 7 C.F.R. § 205.206

- Side dressing heavy feeders and leafy greens during the growing season (summer squash, kale, chard) would be severely restricted, if not eliminated, and growers would need to seek out alternative fertilizers; and
- For smaller diversified operations in short season northern climates, the number of crops that could be grown would be severely limited if they were to accommodate the 45-day application interval and follow an adequate crop rotation cycle.[219]

All of these areas of conflict with existing practices would also be the case for non-organic diversified operations using manure and compost.

The results of the OTA/WSDA survey plainly show that it is not just a question how the intervals match with existing intervals required in organic production, but how the intervals proposed in Subpart F would fundamentally alter organic production such that farmers would no longer be in compliance with NOP regulations.

If FDA adopts these intervals in the final rule and does not change these intervals to align with NOP requirements, then FDA will be forcing organic farmers out of compliance with NOP regulations and actively discouraging farmers from becoming certified organic, in violation of Congress' clear instructions. Farmers would then have to find alternatives to manure and compost, but the alternatives would be more synthetic fertilizers that are more costly, degrade soil health and the environment, and do not perform the multiple functions that manure and compost perform in production systems (e.g., soil, nutrient, fertility, and pest management). The synthetic alternative is not a desirable or viable option for sustainable and organic farmers.

Recommendation: In the final Produce Rule, FDA must thoroughly revise the intervals in Subpart F to meet the requirements of FSMA. FDA must align its biological soil amendments of animal origin standards with the National Organic Program requirements and on-farm practices widely used in diversified, sustainable, and conservation-based production systems. The proposed intervals in Subpart F must not exceed the intervals in NOP regulations. Specifically, FDA should change the minimum application intervals in § 112.56(a) to require:

- In § 112.56(a)(1)(i), a four-month interval (120 days) between the application of an untreated biological soil amendment of animal origin that is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application; and
- In § 112.56(a)(4)(i), a zero-day interval for a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of §112.54(c) to meet the microbial standard in § 112.55(b).

[219] Washington State Department of Agriculture and Organic Trade Association. "Impact of FDA's Proposed Application Intervals on Organic Fertility and Crop Rotation Requirements." 30 August 2013 to 4 October 2013. http://www.ota.com/regulatory/foodsafety.html

B. Insulation of compost should not be required as part of an acceptable treatment for composting processes.

FDA requests comments on the treatment approach, and a problematic area in proposed Subpart F is the requirement for insulation of compost as part of adequate curing in a scientifically controlled composting process in § 112.54(c). FDA correctly identifies proper curing as an important part of safe composting practices.[220] Curing provides time for the natural compost microbiome to establish itself and complete the process of pathogen exclusion. FDA's requirement for insulation during the curing process, however, would disrupt farmers' ability to properly manage their compost.

Insulation would negatively affect compost safety and efficacy by interfering with farmers' abilities to manage carbon dioxide and moisture levels in their piles and potentially disrupting carbon to nitrogen ratios in the pile. In addition to potentially making the compost less effective as a soil amendment, all of these disruptions could have a negative impact on compost safety. In the preamble, FDA says that insulation "usually consist[s] of around one foot of insulating material, *e.g.*, hay, straw, finished compost."[221] During the curing process, which can take up to three months, the compost may need to be turned many times because the carbon dioxide could increase to unacceptable levels, or the compost could become too dry and require that water be mixed into it. If a foot-thick layer of hay or straw is on the compost that needs turning, it will change the carbon-to-nitrogen ratio of that turned produce and require the whole pile or windrow to be re-composted.

If the composter does not allow for re-composting, a high nitrogen source mixed in such as alfalfa hay insulation could cause anaerobic conditions unfavorable to antagonistic processes that reduce the levels of pathogens. Too much nitrogen added back into the compost can also cause the production of ammonia, which is a potent greenhouse gas, and kills off many beneficial microorganisms. Mixing a high carbon source of insulation, such as straw, back into the compost could tie up the nitrogen availability and stress the crop. If the compost is re-composted, and then another insulation layer is reapplied during the curing process, the same problem could occur where the compost needs turning, leading to an unending situation of re-composting/insulating/turning.

With static composting, the insulation could cause the compost to become anaerobic, causing problems unfavorable to the reduction of pathogens, as mentioned above.

If insulation were required, the best choice of insulating material would be finished compost because it would have the least impact on the composting process and would help inoculate the pile with desirable organisms. However, for both static and turned compost, using finished compost would increase the cost and likely be impractical. Special machinery for putting on the layer of insulation and taking it off would also increase the cost of making compost, as would additional turnings.

The preamble also mentions that insulation "serves as a layer of protection from external influences (e.g., … wild animal encroachment)."[222] If the compost was contaminated with wildlife feces, the composter could remove and dispose of those feces, just as they would if the feces were found in a produce field. The same steps would occur if the insulation on top of the compost were contaminated. Otherwise, trying to rake or in some other way remove all the insulation could cause

[220] 78 Fed. Reg. at 3580

[221] 78 Fed. Reg. at 3580

[222] 78 Fed. Reg. at 3580

further contamination. Therefore, the use of insulation would not be the best way to reduce wild animal feces contamination. Furthermore, by excluding beneficial microorganisms as well as potentially harmful ones, the insulation would not clearly benefit food safety and could be counterproductive.

Finally, the National Organic Program regulations do not require insulation of compost as part of the soil fertility and crop nutrient management practice standard.[223] Any standard that would require organic farmers to insulate compost during the composting process would be in conflict with NOP requirements, which FSMA expressly prohibits.

Recommendation: In the final Produce Rule, to align with current best management practices as well as with NOP regulation, FDA must not require insulation of compost as part of an acceptable treatment process for compost. Specifically, FDA should strike the phrase, "which includes proper insulation" from § 112.54(c)(1) and (2).

C. The Produce Rule should not regulate biological soil amendments that are not of animal origin.

In the preamble, FDA states that it does "not propose treatment or timing restrictions for biological soil amendments that do not contain any animal waste product or human waste (such as would be case with yard waste, purely vegetative matter, or shrub trimmings, or agricultural teas made from such materials)."[224] FDA adds that "[u]nless otherwise specifically noted, chemical soil amendments, physical soil amendments, and biological soil amendments that are not of animal origin … are not covered by this rule"; FDA "encourage[s] comment" on this issue.[225]

FDA correctly identifies biological soil amendments that do not contain any animal or human waste products as low-risk products that need not be subject to the same regulations as the amendments covered in proposed Subpart F. Given the low likelihood of contamination of plant feedstock by human pathogens, the likelihood that any such contamination would be at a low level, and the general effectiveness of the composting process at eliminating and suppressing pathogens, FDA correctly does not propose to regulate biological amendments that do not contain any animal or human waste.

For chemical and physical soil amendments, FDA cannot ignore the environmental and human health impacts associated with the increased use of these amendments. NSAC addresses this issue and other issues more fully in our comments on the scoping notice, which are incorporated herein.[226]

Recommendation: In the final Produce Rule, FDA should retain its position that biological soil amendments that do not contain any animal waste product or human waste should not be regulated or covered by the Produce Rule. Moreover, the final Rule should avoid creating preferences for the use of chemical fertilizers over biologically based fertilizers that include components of animal origin.

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[223] 7 C.F.R. § 205.203

[224] 78 Fed. Reg. at 3574

[225] 78 Fed. Reg. at 3576

[226] NSAC Scoping Notice Comments, at 13-17, 21-24.

D. Standards directed to animal feces are outside of the scope of Subpart F.

In the preamble, FDA states that "[s]tandards directed to animal feces deposited by domestic or wild animals that are not part of your planned growing activities (*e.g.*, by working animals, by animals that graze or encroach into your growing areas) are proposed to be included in subpart I."[227] Given that animal feces deposited outside of the planned growing activities is covered in Subpart I, and given that feces dropped by animals acts differently from manure added as a soil amendment, NSAC supports the regulation of such feces in Subpart I. NSAC provides comments on Subpart I elsewhere in this document (see section XI).

Recommendation: In the final Produce Rule, FDA should retain its current decision to include standards directed to animal feces deposited by domestic or wild animals in a separate subpart of the rule

E. Documentation from commercial compost operations

In the preamble, FDA "tentatively conclude[s] that the most reliable and least burdensome proposal regarding the use of purchased treated biological soil amendments of animal origin is to require growers to obtain certain documentation (such as a Certificate of Conformance) from the treating operation that validated treatment methods were utilized, the treatment process is periodically verified through testing, and good handling practices were followed," and requests comment on this proposed requirement, "including periodic verification through testing."[228]

Since commercially produced compost is disseminated to many farms, we understand the need for additional scrutiny through process verification that may include testing. However, FDA should take care to clarify these requirements so that they do not unduly burden farmers or manufacturers of compost and other biological soil amendments.

FDA should clarify the sampling procedures and protocols for compost that is purchased from suppliers. What are FDA's expectations for sampling? What verification program for compost suppliers is acceptable FDA? Does FDA seek a validated process(es) for a specific pathogen(s)? Which pathogen(s)? What laboratory accreditations are acceptable to FDA for purposes of compost tests? FDA should also clarify that the responsibility for process verification, including testing, falls on the manufacturer of the soil amendment and not on the farmer. In clarifying these questions, FDA should ensure that sampling procedures and protocols are not economically impractical. Compost manufacturers are often small businesses or local or state government agencies, and they are critical to agricultural systems.

Recommendation: In the final Produce Rule, FDA should minimize the burden of and clarify the requirements of process verification in compost. FDA should clarify that the responsibility for process verification, including testing, is not the responsibility of the farmer purchasing the amendment.

F. Agricultural teas

[227] 78 Fed. Reg. at 3576

[228] 78 Fed. Reg. at 3575

The proposed Produce Rule requires that biological materials used to make agricultural tea must be processed, and that the water used for the tea meets the requirements of § 112.44(a). However, if the water is used to subirrigate the crop, then it is not by definition "agricultural water." If the compost has been processed, then an agricultural tea made with the compost and applied using methods that minimize or do not contact edible portions of the crop should be allowed using non-agricultural water. FDA should clarify this point.

Recommendation: In the final Produce Rule, FDA should clarify that the water used to make agricultural tea needs to meet the agricultural water requirements only with water that fits the definition of "agricultural water."

G. Much more research is needed to develop scientifically based standards on the use of biological soil amendments of animal origin in produce production.

Much more research is needed to develop scientifically based standards for the use of biological soil amendments of animal origin in produce production. Topics for research in the use of biological soil amendments of animal origin in produce production include:

- Monitor and document foodborne pathogen presence/survival in soil and pathogen presence/absence on greens, root crops, and fruiting vegetables (solanaceous and cucurbit families) grown after application of raw, aged, and cool (<130F) composted cattle, horse, swine, and small-ruminant manures, and poultry litters, applied at realistic rates compatible with good management. (Suggest up to 15 tons/ac mammalian manures; up to 5 tons/ac poultry litters).
- Monitor and document foodborne pathogen occurrence and survival in soils amended with (a) a high quality finished compost (with manure component) made in a way that meets the requirements of § 112.54(c); (b) a finished compost (with similar manure content) made at lower temperatures but with adequate curing period to appear "finished"; (c) raw or aged manure; and (d) synthetic fertilizers.
- Repeat that last experiment with the addition of foodborne pathogens introduced equally in all treatments at a realistic rate.
- Examine how different species and mixes of cover crops interact with the presence of pathogens in soils.
- When there are foodborne outbreaks, determine not only what soil amendments were used, but also how the soil was managed for the past several years, the level of soil microbial diversity present, the levels of *stable* carbon and nitrogen, the soil's tilth (well-aerated vs. compacted).
- Examine the presence of antibiotics in root crops grown with biosolids versus those grown with finished compost.
- Examine the transmission of pathogens present in soil and soil amendments at reasonable rates to produce grown in that soil. This will help determine at what contamination level pathogens in soil become a hazard to food safety.
- Examine how the microbiome of finished compost develops, and how this microbial community is able to exclude and suppress pathogens.

- Examine how the presence of an insulation layer in compost affects the re-inoculation from biologically active soils and plant communities near the composting operation.
- Further examine the efficacy of composting under field conditions at killing and excluding pathogens.
- Examine which microbiological, physical, or chemical characteristics of finished compost reliably correlate to a pathogen-free end product.

The aforementioned research should be conducted:

1. Using realistic rates of pathogens, and
2. Using real agricultural practices that simulate the conditions of or occur on working farms.

Recommendation: FDA should work with research and educational institutions, farmer organizations, and other agencies to conduct research that addresses the research needs listed above to develop a scientific basis for standards directed to biological soil amendments of animal origin.

XI. COMMENTS ON NATURAL RESOURCE CONSERVATION ISSUES

Summary

NSAC makes comments and recommendations on natural resource conservation issues in the proposed Produce Rule. The proposed Produce Rule fails to comply with FSMA by not adequately supporting conservation practices and co-management of conservation, environmental, and public health considerations. We provide recommended languages changes in this section.

Comment

A. FSMA and recent experience support a proactive approach to natural resource conservation, wildlife conservation, and environmental protection in the Produce Rule.

In FSMA, Congress directed FDA to be proactive with respect to natural resource conservation, wildlife conservation, and environmental protection. Specifically, FSMA requires FDA to:

- "Take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environment agencies"[229];
- Not "conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990…"[230]; and
- "Provide sufficient flexibility to be applicable to various types of entities engaged in 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."[231]

Congress made these protections for on-farm and natural resource conservation because in recent years, conservation practices – particularly those that encourage wildlife – have been viewed as a potential threat to food safety without a sufficient scientific basis. After an outbreak of *E. coli* O157 was traced back to a farm on California's central coast in 2006, many individual produce buyers created their own food safety requirements and collectively the industry developed the California Leafy Greens Marketing Agreement (CALGMA). While it was never unequivocally determined how the spinach became contaminated, non-native feral pigs, contaminated irrigation water, and adjacent cattle operations were all considered as possible sources. All wildlife and the habitat they occupied became scrutinized by the leafy greens industry. Some produce buyers would not purchase leafy greens when wildlife were present, or from fields within 450 feet of rivers or wildlife habitat.[232] This incentivized farmers to destroy wildlife and their habitat.

CALGMA initially also encouraged producers to remove conservation practices they had implemented on their farms – including those installed with government assistance and

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

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

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

[232] Schmit, J. "Fresh express leads the pack in produce safety." *USA Today*. 23 Oct 2006.

encouragement through voluntary conservation programs.[233] Six months after the spinach *E. coli* O157 outbreak, growers managing 140,000 acres on California's Central Coast responded to a survey conducted by the Resource Conservation District (RCD) of Monterey County.[234] They indicated that they had adopted environmentally destructive measures in order to comply with food safety audit requirements and keep their markets. Eighty-nine percent of respondents reported that they had actively removed conservation practices for water quality or wildlife habitat. The survey found that respondents now use the following practices:

- Bare ground buffers;
- Trapping;
- Poisoned bait stations; and
- Fencing.

Wild Farm Alliance (WFA) documented the destruction of a mile of Salinas River habitat 100 feet wide in 2008 due to misguided food safety requirements.[235] This mature riparian habitat provided nesting for migratory bird species and shade for the survival of the South Central Coast Steelhead, a species federally listed as threatened. Farmers in the Salinas Valley put up tall deer fences adjacent to the river, and installed rodent bait or trap stations alongside, which can still be seen today when driving along the major 101 highway. Fencing impedes wildlife movement to and from important riparian habitat to uplands. During major flooding, wildlife may be trapped. Photos depicting these changes and others, including the removal of windbreak and a pond, are available on the WFA website.[236]

Unfortunately, in response to the 2006 outbreak, scientists estimated that "13.3% of remaining riparian habitat was eliminated or degraded" and that if the practices were implemented statewide across all crops, that "up to 40% of riparian habitat and 45% of wetlands in some counties would be affected."[237]

The pressure farmers faced severely constrained conservation advances addressing environmental concerns in the region. Over half of the 66 growers interviewed in a UC Santa Cruz study found they had adopted at least one conservation practice designed to improve and protect water quality before the spinach contamination.[238] This researcher also reported that policy and market changes in food safety requirements have led to a significant loss of participation in conservation efforts.[239]

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233 Wild Farm Alliance and Community Alliance with Family Farmers. "Farming with Food Safety and Conservation in Mind." 2013. http://caff.org/wp-content/uploads/2010/07/WFA-CAFF_Food_Safety-Conservation.pdf

234 Resource Conservation District of Monterey County. "A grower's survey: Reconciling food safety and environmental protection." August 2007.

235 Wild Farm Alliance. "Environmental Destruction in the Salinas Valley: 'Food Safety' Requirements to Remove Habitat Make Leafy Greens Less Safe." 2008.
http://wildfarmalliance.org/resources/WFA%20FS%20EnvDestruct2.pdf

236 Wild Farm Alliance website. http://www.wildfarmalliance.org/resources/photos_of_destruction.htm

237 Gennet, S. et al. "Farm practices for food safety: an emerging threat to floodplain and riparian ecosystems." *Frontiers in Ecology and the Environment* 11: 236-242 (2013).

238 Stuart, D. "Coastal Ecosystems and Agricultural Land Use: New Challenges on California's Central Coast." *Coastal Management* 38: 1, 42-64 (2010).

239 Stuart, D. and S. Gillon. "Scaling Up to Address New Challenges to Conservation on U.S. Farmland." *Land Use Policy* 31: 223-36 (2013).

To this day, conservationists who work with growers in the region are finding them reluctant to implement new conservation practices.[240]

As the scientific basis for on-farm food safety practices develops, industry practices are evolving, including with respect to wildlife management. Earlier this summer, CALGMA announced a change to its standards dealing with animal intrusion in fields.[241] The change shifted the standards from requiring growers to take measures to prevent animals thought to be of significant risk from entering into fields, to allowing growers to assess and mitigate risk from animal intrusion specific to their operations. Co-management practices – i.e., practices that simultaneously achieve conservation goals and reduce pathogens hazards associated with food production – are becoming a key part of food safety regimes and auditor trainings (see below).

While the improvement in CALGMA standards represents a step forward, past experience and FSMA requirements make it critical that the Produce Rule proactively protect against other unfounded industry requirements that undermine on-farm and natural resource conservation. NSAC provides comments on this issue below.[242]

B. The proposed Produce Rule fails to comply with FSMA by not adequately supporting conservation practices and co-management of conservation, environmental, and public health considerations.

In the proposed Produce Rule and in proposed Subpart I, FDA does not require farmers to take any extreme measures to prohibit the presence of wild and domesticated animals in fields of covered produce. However, FDA fails to protect against farmers being required by buyers to take extreme actions referenced above. Given past experience, it is critical to ensure that buyers do not unjustifiably require the removal of beneficial conservation practices in the name of food safety. Specifically, the proposed Produce Rule does not protect against these situations because it:

- Does not incorporate supportive concepts about conservation from the preamble into the rule itself;
- Does not include the concept of co-management, including in Subpart I and Subpart C; and
- Is not sufficiently consistent with existing conservation practice and certified organic practices required by National Organic Program (NOP) regulations.

In the proposed Produce Rule, FDA does include a few important conservation considerations, including basing actions on monitoring and the decision not to establish a list of "animals of concern," a decision that NSAC supports.

FDA requests comments on a number of conservation-related issues in the proposed Produce Rule, and NSAC details its comments and recommendations on these issues below.

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[240] Sam Earnshaw of Hedgerows Unlimited, Watsonville, CA. Personal Communication. November 8, 2013.

[241] Andrews, J. "California's LGMA Changes Standards on Animal Intrusion Into Fields." *Food Safety News*. 30 August 2013.

[242] Also, see generally NSAC, Scoping Notice Comments.

Recommendation: In the final Produce Rule, FDA must be proactive about on-farm conservation and natural resource conservation to fulfill FSMA requirements and protect against unfounded buyer-driven food safety requirements to remove conservation practices.

C. The Produce Rule must incorporate the concept of co-management and sustainable conservation practices directly into the regulatory text.

Overall, FDA needs to more strongly support on-farm conservation practices by incorporating the positive concepts and statements made in the preamble to the Produce Rule into the regulatory text itself. The preamble does not have the same force as the regulatory text, and it is important to include stronger statements about on-farm conservation in the regulatory text to ensure that the standards support the FSMA mandate to take into consideration conservation practice standards and ensure sufficient flexibility for different farming systems subject to the rule, and to protect against buyer-driven requirements that are detrimental to conservation.

In the preamble, FDA includes important text on the interplay between food safety and conservation. Specifically, in the preamble FDA:

- Encourages "the application of practices that can enhance food safety, including sustainable conservation practices"[243];
- States that the "proposed rule would not require the destruction of habitat or the clearing of farm borders"[244];
- "Do[es] not propose that vegetation surrounding an on-farm pond be cut back and/or removed or that fencing must be used to prevent access to a pond by wildlife and domestic animals"[245]; and
- Notes that "wild animals are likely to have access to production fields. The presence of animals in a production field of covered produce, in and of itself, is not a significant food safety risk."[246]

Additionally, in the preamble, FDA "note[s] … that we do not intend the phrase 'under the circumstances' in these proposed requirements to suggest that farms alter their surrounding environment in order to reduce the chances of animal intrusion, such as by clearing farm borders around outdoor growing areas or drainages."[247] FDA seeks comment on this issue. By explicitly incorporating co-management into the Produce Rule and actively protecting conservation practices, FDA will be making clear its intentions stated in the preamble but missing from the regulatory text.

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[243] 78 Fed. Reg. at 3586

[244] 78 Fed. Reg. at 3586

[245] 78 Fed. Reg. at 3560; this statement comes from the preamble discussion about Subpart E—Standards Directed to Agricultural Water. In the same discussion a few pages later, FDA states that "[p]roperly maintaining a farm pond that is used for irrigation using a direct application method, with respect to keeping it free from domesticated animals, could mean fencing the pond if you keep domesticated animals in the area such that they would otherwise have access to the pond" (78 Fed. Reg. at 3565). These are conflicting statements that must be clarified.

[246] 78 Fed. Reg. at 3587

[247] 78 Fed. Reg. at 3587

The preamble statements are all strong statements in support of on-farm conservation, but the support falls short of meeting FSMA requirements because the statements of support in the preamble are not included in the regulatory text – which is what matters when farmers are determining what they must or must not do to comply with the regulations. Given the history of buyers encouraging the removal of conservation practices, it is imperative to protect against those types of requirements by strongly incorporating the concept of "co-management" into the Produce Rule regulatory text.

Below, NSAC first discusses how co-management is becoming part of food safety regimes, and then discusses conservation practices supported through conservation programs and the National Organic Program requirements. NSAC then makes recommendations based on these discussions.

1. Co-management is becoming part of food safety regimes.

Co-management practices – i.e., practices that simultaneously achieve conservation goals and reduce pathogen hazards associated with food production – are becoming a key part of food safety regimes as the scientific understanding of the role of farm practices, and in particular on-farm conservation practices, develops. Co-management is being incorporated into third-party food safety certification regimes and into auditor trainings.

LGMA requirements include a definition of co-management, and encourage growers to seek support from conservation and environmental agencies before making changes that could affect environmental resources. The Produce Safety Alliance is in the process of developing a training module on co-management.[248] The "On Farm Food Safety Project" addresses co-management in their online food safety planning process.

Recently developed co-management training scenarios by Wild Farm Alliance, with help from NSAC and its members, are available online for USDA GAP and third party auditors.[249] These scenarios are to be used alongside Produce GAPs Harmonized Food Safety Standards, and USDA auditors who review them can receive continuing education units. Since 2008, the Farm Food Safety Conservation Network, based on the Central Coast of California, has produced co-management forums for farmer and auditor audiences, and the last two provided continuing education units for USDA auditors. UC Davis published a "Co-management of Food Safety and Sustainability" brochure and offers auditors more information on specific conservation practices.[250] Wild Farm Alliance and Community Alliance with Family Farmers have published two documents for farmers

[248] Produce Safety Alliance. Working Committee Four. Core Curriculum/Hazards & Preventive Controls — "*Production*: *Special emphasis on Co-Management and NOP related issues*." http://producesafetyalliance.cornell.edu/

[249] Wild Farm Alliance. **"**Training Scenarios for USDA and Third Party Auditors on the Co-management of Food Safety and Conservation as well as Small and Mid-Size Farm Concerns." October 2013. http://www.wildfarmalliance.org/resources/FS_Training_Scenarios.htm

[250] UC Davis. Co-Management of Food Safety and Sustainability. http://ucfoodsafety.ucdavis.edu/Preharvest/Co-Management_of_Food_Safety_and_Sustainability/

on co-management: *Farming with Food Safety and Conservation in Mind* [251] and *A Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions.*[252]

An excerpt from this latter document points out the co-management benefits of vegetation:

> "Vegetation can help reduce the movement of pathogens across the farm by filtering pathogens, increasing infiltration of water into the soil, and serving as a structure for biological competition to take place. Grasses[253] and other types of vegetative buffers[254] filter pathogens in runoff before they reach a pond or stream. The vegetation also slows surface water flow which allows for increased infiltration rates.
>
> "Wetlands decrease pathogen levels[255] due to increased oxygen levels in the water, antagonistic root exudates, and the fostering of antagonism in biofilms. [256] These processes that act to reduce pathogens in water work best when the water has a long residence time – it moves slowly through the vegetation – a proper hydraulic loading rate – the volume of water flowing through is suited to the size of the planted vegetation, and appropriate settling rates of suspended sediments.[257]

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[251] Baumgartner, J. and D. Runsten. "Farming with Food Safety and Conservation in Mind." Updated 2013. http://producesafetyalliance.cornell.edu/PSA-Mat/conf/Baumgartner_WFA-CAFF_brochure.pdf

[252] Baumgartner, J. "A Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions." Wild Farm Alliance and Community Alliance for Family Farmers. October 2013. http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm

[253] "Relative to a 0.1-m buffer, we found 0.3 to 3.1 log(10) reduction in *E. coli* discharge per additional meter of vegetative buffer across the range of residual dry vegetation matter levels, land slope, and rainfall and runoff conditions experienced during this project."

Tate, K. et al. "Significant *Escherichia coli* attenuation by vegetative buffers on annual grassland." *Journal of Environmental Quality* 35:795-805 (2006).

[254] Presence of a buffer zone had a protective effect.

Strawn, L. et al. "Risk Factors Associated with *Salmonella* and Listeria *monocytogenes* Contamination of Produce Fields." *Applied Environmental Microbiology*. September 2013.

[255] "[Constructed] wetland treatment of influent wastewater resulted in effective removal of various microbial populations during the 2-year study, with removal efficiency slightly enhanced (approximately 0.5 log) for most microbial groups in the presence of vegetation."

Hench et al.. "Fate of physical, chemical and microbial contaminants in domestic wastewater following treatment by small constructed wetlands." *Water Research.* 37: 921-927 (2003).

[256] Aquatic plants and algae may increase oxygen levels in the water, making undesirable conditions for pathogens. Root exudates from aquatic plants may be toxic to some pathogens.

Vymazal, J. "Removal of enteric bacteria in constructed treatment wetlands with emergent macrophytes: A review." *Journal of Environmental Science and Health Part A-Toxic/Hazardous Substances & Environmental Engineering* 40: 1355-1367 (2005).

[257] Long residence time and low loading rates may improve wetland function, which may result in increased pathogen die-off rates. Conversely, short residence time and high loading rates decrease wetland function, which results in decreased pathogen die-off rates.

Diaz, et al. "Efficacy of constructed wetlands for removal of bacterial contamination from agricultural return flows." *Agricultural Water Management* 97: 1813-1821 (2012); Vymazal (2005); Knox et al. "Efficacy of natural wetlands to retain nutrient, sediment and microbial pollutants." *Journal of Environmental Quality* 37: 1837-1846 (2008).

> "Windbreaks can intercept dust that may be carrying pathogens.[258, 259] When dust trapped on the leaves of a windbreak is exposed to sunlight and other desiccation effects, pathogens can be destroyed.[260]"

Co-managing wildlife corridors for food safety helps to keep animals in the habitat they prefer and away from production fields. In an unpublished Wild Farm Alliance survey, a farmer of a mid-sized operation reported, "We maintain ample setbacks from streams. We also have created wildlife migration corridors on our main ranch. This dramatically reduces pressure from wildlife – especially deer." [261]

Co-management benefits of managing farm soils for diverse microbial populations and using compost that help to reduce pathogen persistence are described in NSAC's comments on Subpart F and in NSAC's comments on the EIS scoping notice.[262] Clearly, co-management is an important aspect of food safety.

2. Co-management practices are supported by federal conservation programs.

In addition to food safety benefits, co-management practices are consistent with current on-farm conservation practices supported through federal conservation programs and including co-management in the rules would support the FSMA mandate to take these practices into consideration. FDA "tentatively conclude[s] that the provisions of proposed subpart I are consistent with existing conservation and environmental practice standards while providing for enforceable public health protection measures."[263] While FDA is not requiring farmers in Subpart I to take extreme measures, the requirements would be more fully consistent with existing conservation and environmental practices if co-management were incorporated directly.

Many farmers participate in voluntary federal conservation programs such as the Conservation Stewardship Program (CSP) and the Environmental Quality Incentives Program (EQIP). These programs provide financial and technical assistance to farmers to implement conservation practices and incorporate those practices into their farming systems. For example, CSP provides comprehensive conservation assistance through support for activities such as wildlife habitat

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[258] *E. coli* O157:H7 was transferred by wind to spinach plants.

Berry, E. "*Escherichia coli* O157:H7 in bioaerosols from cattle production areas: evaluation of proximity and airborne transport on leafy green crop contamination." *A Practical Guide to the Scientific Research Presented at The Center for Produce Safety's 2012 Research Symposium*. R. Whitaker and H. Giclas.

[259] Exposure to UV radiation both damages and dries pathogens and typically leads to quick die-off.

Beattie, G. and S. Lindow. "The secret life of foliar bacterial pathogens on leaves." *Annual Review of Phytopathology* 33: 145-172 (1995).

Newsham, K. et al. "Ultraviolet-B radiation influences the abundance and distribution of phylloplane fungi on pedunculate oak (Quercus robur)." *New Phytologist* 136: 287-297 (1997).

[260] Vegetative buffers (that function like windbreaks) were placed between poultry houses and preliminary results showed no aerial transfer of microbial organisms.

Burley, H. et al. "The potential of vegetative buffers to reduce dust and respiratory virus transmission from commercial poultry farms." *Journal of Applied Poultry Research* 20: 210-222 (2011).

[261] Wild Farm Alliance. Unpublished California farmer survey conducted in September 2013.

[262] NSAC, Scoping Notice Comments, at 17-32.

[263] 78 Fed. Reg. at 3586

enhancements, including pollinator habitat, enhanced vegetative cover, and riparian forest buffers. EQIP supports the installation and maintenance of riparian buffers, field borders, hedgerows, windbreaks, and wetland and upland wildlife habitat plantings, all of which consist of perennial grasses, forbs, shrubs, and trees.

Farmers use conservation practices for a variety of reasons. Some need more pollinator services and plant hedgerows to attract them. Pollinators help one third of the world's crop production and they are in decline. Many farmers rely on conservation practices like field borders to provide food sources for predatory and parasitic insects that attack pest insects, thereby reducing the need for pesticides. The Dust Bowl days serve as a reminder that our soils are valuable and need to be protected from erosion, which many practices in CSP and EQIP program do. They also help to protect soil and water quality and conserve water and energy.

All of these practices help farmers to grow produce while conserving not just their farm's resources, but our public resources as well. In the Produce Rule, FDA needs to protect farmers' ability to use these conservation practices and to ensure that the massive public investment of taxpayer dollars into farm conservation over the past eight decades is not put in jeopardy by food safety rules.

3. Co-management practices are required by the National Organic Program.

In the preamble to the proposed Produce Rule, FDA "tentatively conclude[s] that the provisions of proposed subpart I do not conflict with or duplicate the requirements of the National Organic Program."[264] FDA "seek[s] comment on the interactions of the proposed rule with the National Organic Program."[265]

Organic growers implement a wide array of conservation practices, including practices that co-manage for food safety and conservation goals. Conservation practices are foundational to certified organic production; the definition of organic is explicit in this regard: "organic production" is defined in NOP regulations as a "production system that is managed … to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."[266] To implement this charge, NOP regulations require that "[p]roduction practices … must maintain or improve the natural resources of the operation, including soil, and water quality."[267] The definition of natural resources includes soil, water, wetlands, woodlands and wildlife. [268] NOP regulations also require farmers with perennial cropping systems to employ means such as alley cropping, intercropping, and hedgerows to assist with pest control by introducing biological diversity in lieu of crop rotation.[269] If FDA does not protect the ability of organic growers to use practices that co-manage for conservation and food safety, then FDA will be actively constraining growers from becoming certified organic and risk impairing the ability of existing organic growers to stay certified. The current proposed Subpart I does not sufficiently protect this fundamental aspect of organic and sustainable production systems.

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[264] 78 Fed. Reg. at 3586

[265] 78 Fed. Reg. at 3586

[266] 7 C.F.R § 205.2

[267] 7 C.F.R § 205.200

[268] 7 C.F.R § 205.2

[269] 7 C.F.R § 205.205

Directly incorporating these concepts and aspects of on-farm food safety and resource conservation practices would fulfill the FSMA mandate, would be consistent with current modernization of food safety regimes, and would protect against harmful, unjustified requirements from buyers that require or provide incentives for the removal of conservation practices.

Recommendations: In the final Produce Rule, FDA must more strongly support conservation in the final Produce Rule by incorporating statements and concepts from the preamble into the regulatory text, in the definitions, training requirements, and domesticated and wild animal standards. Specifically, FDA should (language to add is underlined and language to delete is ~~struck-through~~):

1. Include in § 112.3 the following definition of "co-management": Co-management means farm system management approaches that respond to site-specific conditions by integrating cultural, biological and mechanical practices that promote ecological balance and public health by conserving and improving biodiversity, soil, water, air, energy, and other natural resources, while also reducing pathogen hazards associated with food production.

2. Include under § 112.22(a) a new subsection (4) regarding minimum requirements for training personnel who conduct a covered activity: (4) The importance of the co-management of food safety and conservation, including recognizing that sustainable conservation practices can enhance food safety and not taking measures to destroy wild animal habitat, take endangered species, or exclude all wild animals from the farm.

3. Include under § 112.83 new subsections (c) and (d) regarding animal intrusion:

> (c) If significant wild animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction occurs, you should focus on very targeted measures to exclude only those specific animals and not all animals. You should avoid:
>
> (1) Destroying wild animal habitat;
>
> (2) Clearing farm borders around outdoor growing areas, ponds, or drainages, particularly where such action would contribute to increased nutrient flow into waterways or increased soil erosion;
>
> (3) Harming migratory birds; and
>
> (4) Taking an endangered species.
>
> (d) To the maximum extent practicable, you should use co-management and sustainable conservation practices that can enhance food safety.

D. The Produce Rule must support diversified crop-livestock farming systems and clarify grazing.

In the preamble, FDA states that the "proposed rule would not prohibit the use of on-farm domesticated working animals."[270] This is critical because some farms that grow produce covered by the Produce Rule rely on domesticated animals, such as draft horses, to produce their crops, and many farmers graze animals in fields that are later used for produce production. Grazing animals or poultry are often allowed into produce fields after harvest of one crop and before planting the next,

[270] 78 Fed. Reg. at 3586

for the purposes of weed, pest, and crop disease management, as well as for parasite control and to enhance biological diversity. Livestock and poultry may be similarly used in orchards and other perennial fruit to control weeds, or immediately after harvest to remove drops and culls, and crop pests and diseases therein.

Proposed § 112.82(a) would require an "adequate waiting period between grazing and harvesting for covered produce." FDA provides additional guidance on that waiting period in the preamble and states that the agency "would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval we propose for use of raw manure as a soil amendment."[271] In addition to the serious issues with the nine-month waiting period between the application of raw manure and harvest (see comments on Subpart F in section X), FDA should not imply that an "adequate" waiting period is nine months because there is no scientific basis for that assumption.

Grazing animals leave feces on the surface of the soil, exposing them to sunlight. This allows ultraviolet (UV) radiation and desiccation from the sunlight to reduce the survival time of pathogenic organisms. More research on this topic is needed. Additionally, under most conditions, grazing animals do not leave the same amount of feces on a field as when raw manure is applied as a soil amendment. The parallel between feces dropped during grazing and raw manure applied as a fertilizer is weak at best, and certainly not strong enough to argue for a similar interval and risks confusing farmers looking for guidance on what FDA means by "adequate" in proposed § 112.82(a).

Additionally, when asked about the statement in the preamble that nine months may be an adequate waiting period between grazing and harvest at the FDA public meeting in Portland, OR, FDA replied that the nine-month interval did not apply to grazing.[272] It is important to clear up any confusion caused by the statement in the preamble by removing the statement entirely.

Recommendations: In the final Produce Rule, FDA should remove the sentence from the preamble that states that the agency "would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval we propose for use of raw manure as a soil amendment."[273]

E. As part of a proactive approach to conservation and food safety, NSAC supports FDA's approach based on monitoring in Subpart I.

While NSAC makes comments above on how to take a more proactive approach to fulfill the FSMA mandate and protect against unjustified buyer-driven requirements to remove conservation practices, we believe that FDA's monitoring-based approach, coupled with additional strong protections for conservation, is the right approach.

In the preamble, FDA "acknowledge[s] that when covered produce is grown in an outdoor environment, wild animals are likely to have access to production fields. The presence of animals in a production field of covered produce, in and of itself, is not a significant food safety risk."[274] NSAC fully agrees with this statement. It is only when there is significant risk that there is a problem, which can be avoided with the Produce Rule's requirement for monitoring.

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[271] 78 Fed. Reg. at 3587

[272] Transcript of FDA Public Meeting in Portland, OR, Day 1, pages 201-202

[273] 78 Fed. Reg. at 3587

[274] 78 Fed. Reg. at 3587

Although pathogens of concern in foodborne disease have been identified in the feces of wild animals, research conducted so far has indicated that native wildlife in the US have a low relative prevalence.[275, 276, 277] Given the nature of outdoor produce production, and the limited information available about the prevalence of pathogens in wild animal populations, it would be unscientific to impose more stringent requirements regarding the presence of animals in the growing field, and as such, violate FSMA's requirement to establish science-based rules.

Recommendation: In the final Produce Rule, FDA should retain its monitoring-based approach in Subpart I and couple it with strong protections for conservation discussed above.

F. The Produce Rule should not establish a list of "animals of concern."

In the preamble of the proposed Produce Rule, FDA tentatively concludes that "current scientific evidence on the extent to which specific animals present the greatest risk for pathogens is inadequate to develop such a list."[278] FDA's conclusion is correct; FSMA does not require such a list and to include one would be unscientific and, therefore, a violation of FSMA's requirement to establish science-based rules.

Any animal that leaves feces in a crop field or damages a crop may be a source of contamination. The type of animal does not matter and a list of animals of concern would result in certain animals being targeted over others. Deer, which were on the CALGMA list until recently, were no more of a food safety risk than rodents on some farms. Yet since deer were on the list, environmentally destructive measures that included fencing and destroying deer habitat were used to control them, even when they may have not been causing any food safety problems.

Recommendation: In the final Produce Rule, FDA should retain its current conclusion and should not develop a list of "animals of concern."

G. Standards directed to manure are outside of the scope of Subpart I.

In the preamble, FDA states that "[p]roposed subpart I would not be directed to the potential for biological hazards from manure that may be used as a soil amendment."[279] Given that manure as a soil amendment is covered in Subpart F, and given that feces dropped by wild or domesticated animals acts differently than manure added as a soil amendment, FDA is correct to limit provisions regulating NSAC manure to Subpart F. NSAC provides comments on Subpart F elsewhere in section X.

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[275] Gordus, A. et al. "Wildlife survey for E. coli O157:H7 and Salmonella in the central coastal counties of California." Center for Produce Safety Research Symposium (2011).

[276] Jay, M. et al. "*Escherichia coli* O157:H7 in feral swine near spinach fields and cattle, central California coast." *Emerging Infectious Diseases* 13: 1908-1911 (2007).

[277] Lowell, K. et al. "Safe and sustainable: Co-managing for food safety and ecological health in California's Central Coast region." The Nature Conservancy of California and the Georgetown University Produce Safety Project (2010).

[278] 78 Fed. Reg. at 3586

[279] 78 Fed. Reg. at 3586

Recommendation: In the final Produce Rule, FDA should retain its current decision to address manure applied as part of growing practices for covered produce in a separate subpart of the rule. This distinction should be made clear in any guidance documents as well so that it cannot be interpreted that feces dropped by domesticated or wild animals are regulated in the same way as manure applied as part of growing practices.

XII. COMMENTS ON SUBPART Q—COMPLIANCE AND ENFORCEMENT

Summary

NSAC makes comments and recommendations on Subpart Q—Compliance and Enforcement. The proposed Produce Rule must make clear that product from exempt and qualified exempt farms will not de facto be considered "adulterated."

Comments

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

FSMA § 105(a) added a new section to the FD&CA that states that the regulations for on-farm food safety must set forth "procedures, processes, and practices" that "provide reasonable assurances that the produce is not adulterated under § 402 [of the FD&CA]."[280] In the proposed Produce Rule, FDA does not change the definition of adulterated directly, but in Subpart Q 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 Subpart Q states that:

> The criteria and definitions in this part apply in determining whether a food is adulterated:
>
> (a) 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 grown, harvested, packed, or held under such conditions that it is unfit for food; or
>
> (b) 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)."

Through proposed Subpart Q, FDA is adding the words "grown, harvested, packed, or held" to determine whether produce is "unfit for food." This is new language in the FDA's regulation of adulterated foods. This new language causes some confusion around whether FDA is changing the definition of "adulterated" because it adds language that establishes criteria for determining *how* a food can become "unfit for food," resulting in the expansion of the agency's interpretation of what can make a food "unfit for food."

[280] FD&CA § 419(c)(1)(A)

Creating further confusion, however, the agency asserts in the Produce Rule that the words "prepared, packed, or held" expressly listed in the "injurious to health" portion of the FD&CA definition of adulteration impliedly include "growing, harvesting, packing, or holding."[281] The agency explains, "The common meaning of 'prepare,' as represented by the dictionary definition is, in relevant part, 'to make ready beforehand for some purpose, use, or activity… to put together.' Growing and harvesting are operations that make food ready for use as food. In addition, growing and harvesting at times involve holding of food."[282] FDA, therefore, is asserting that the method under which produce is grown (e.g., on-farm practices) now can be considered when the FDA is making a determination of adulteration under FD&CA.

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.[283] Theoretically, then, if FDA uses a violation of the Produce 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.[284] 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 the safety of the food (such as recordkeeping rules), could face a risk that FDA would deem their food adulterated. However, Subpart Q 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 $25,000 exemption and the qualified exemption are included in the "criteria and definitions" used in making a determination of adulteration. Given that the qualified exemption and the $25,000 exemption are 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 exempt and qualified exempt farms are selling adulterated food because they are by definition exempt from all or parts of the Produce Rule. However, this is unclear because of the added language to FDA's regulation of adulterated food discussed above. Making the assumption that product from exempt and qualified exempt farms 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 Produce Rule, FDA must be very clear in Subpart Q that compliance with the Produce Rule through the modified requirements for qualified exempt farms is not sufficient grounds for a determination of adulterated food. Said the other way, it must be abundantly clear that if a farm is in compliance with the Produce Rule's modified requirements because it is a qualified exempt farm, 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 Produce Rule. For farms that are eligible for the $25,000 exemption, it should be equally

[281] 78 Fed. Reg. at 3611

[282] *Ibid.*

[283] 21 U.S.C. § 350(l) (2012).

[284] 78 Fed. Reg. at 3644

clear that not implementing the requirements of the Produce Rule – which they are, by definition, not required to do – is not sufficient grounds for an adulteration determination.

XIII. COMMENTS ON SUBPART R—WITHDRAWAL OF A QUALIFIED EXEMPTION

Summary

NSAC makes comments and recommendations on Subpart R – Withdrawal of a Qualified Exemption. NSAC finds that Subpart R 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. Subpart R is woefully inadequate and must be significantly rewritten to establish a clear and fair process for withdrawing a farm's qualified exemption.

In the proposed Produce Rule, FDA establishes a process for the withdrawal of a qualified exemption in Subpart R. In Subpart R, FDA sets forth two circumstances under which a qualified exemption may be withdraw: "in the event of an active investigation of a foodborne illness that is directly linked to your farm; or [i]f we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm." Subpart R 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 farmer must take if he or she receives an order, the option to appeal an order, and the appeals process. Subpart R includes circumstances under which an order to withdraw can be revoked. If a farm's qualified exemption is withdrawn, the farm is required to come into compliance with all of the requirements of the Produce Rule.

In the proposed Produce Rule, FDA seeks "comments on the proposed process for withdrawal of a qualified exemption"[285] and tentatively concludes that "it is appropriate to be transparent about the process we would use to withdraw a qualified exemption and that we should include the process in the proposed rule."[286] While we support FDA's tentative conclusion to be transparent about the process for withdrawing a qualified exemption, there are significant problems with proposed Subpart R, 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 exempt farms.

Proposed Subpart R is woefully inadequate and must be significantly revised. As it is currently proposed, Subpart R fails to satisfy Congressional intent, is extraordinarily vague, is silent on a number of important issues, and does not provide adequate protections for farmers from false accusations and unfounded allegations. Subpart R places the burden on the qualified exempt farm

[285] 78 Fed. Reg. at 3613

[286] 78 Fed. Reg. at 3611

to be familiar with the details of the produce 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 R fails to establish a fair and clear process for withdrawing a farm's qualified exempt status.

Although FSMA stipulates that farms eligible for the qualified 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 and qualified exemptions 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 qualified exemptions, and likely lead to the collapse of the flexible, scale-appropriate framework Congress intended. Congress was clear in FSMA that farmers eligible for a qualified exemption would only have to implement modified requirements and would be exempt from the majority of the Produce Rule's requirements. FDA estimates that the proposed requirements have significant compliance costs for very small, small, and large producers.[287] Withdrawal of a farm's qualified exempt status would subject very small and small producers to unexpectedly high compliance costs that could put them out of business. Making a clear and fair process around the withdrawal of a qualified exemption is critical to a having a robust scale- and supply-chain appropriate regulatory framework.

The importance of the qualified exemptions to the viability of small and very small businesses cannot be stressed enough – for many of these farms, 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 exempt farm 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 farms disproportionately to the risk or the actual public harm that might be created by their farming practices.

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 I). It is important to have a fair and clear process so that farmers are protected from inspectors who may use the authority to withdraw a farm's qualified exempt status as a way to threaten the farm.

Recommendation: Proposed Subpart R fails to establish a fair and clear process for withdrawing a farm's qualified exempt status and FDA must substantially revise Subpart R in the final Produce Rule to ensure a flexible, scale- and supply-chain appropriate regulatory framework mandated by FSMA. We provide our detailed recommendations below.

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[287] US Food and Drug Admin. "Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Page 313. http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf.

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

In FSMA, Congress stipulated that farms eligible for the qualified 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 farm 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 farm that are material to the safety of the food produced or harvested at such farm."[288] This creates two standards with high thresholds that FDA must meet before contemplating the withdrawal of a farm's qualified exempt status: direct linkage and necessity. These high thresholds limit FDA's authority to broadly interpret the option to withdraw a farm's qualified 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."[289] This expressed limit on FDA's inspection authority under this subsection further limits the scope of the withdrawal authority. Given that FDA's inspection authority for farms is based on preventing adulterated and misbranded food from entering into commerce,[290] this statement continues to limit FDA's inspection authority to situations of adulterated and misbranded food and expressly does not grant FDA new powers to inspect qualified exempt farms (see section D below).

These limitations support a narrow interpretation of the circumstances that would lead to the withdrawal of a farm's qualified exempt status. While Congress set forth the framework under which a farm's qualified 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 Produce Rule fails to clarify the circumstances under which FDA would withdraw a qualified exemption, resulting in the possibility of broad interpretation of the circumstances and abuse of power by FDA over when a farm may lose its qualified exempt status. The proposed Subpart R is extremely vague and appears to give FDA broad authority to withdraw a qualified exemption without adequate evidence of an actual harm or likely severe problem from the farm'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.

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

[289] Food, Drug, & Cosmetic Act § 419(f)(3)(B)

[290] U.S. Food and Drug Admin. "Guide to Produce Farm Investigations." Posted 3 May 2006, Accessed 12 November 2013 at http://www.fda.gov/iceci/inspections/inspectionguides/ucm074962.htm#purpose

FDA does not clarify or define a number of the terms used in Subpart R that form the basis for withdrawing a qualified 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, especially given the lack of clarity around how violations come to the attention of FDA. The definitions of 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 farm's qualified exemption could be withdrawn. "Directly" is defined as "in a direct manner," "in immediate physical contact," or "in the manner of direct variation."[291] "Linked" is defined as "marked by linkage and especially genetic linkage" or "having or provided with links."[292] The inclusion of "directly" means that an outbreak cannot be merely "linked" to a farm 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 farm 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 farms and classes of farms cannot be held accountable for environmental conditions that are not the result of their own farming practices and that are external to them, nor for activities occurring at other farms. This change is critical to ensure that no farm will have its qualified exemption inappropriately withdrawn due to some broad, general linkage that is not a direct link to an on-farm activity in the control of the farmer or farm employees.

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

Recommendation: In the final Produce Rule, FDA should add a definition of "directly linked" in § 112.3 to preclude the possibility that any actions by upstream or downstream actors or any other circumstances outside the control of the farmer or farm employees – unrelated to the actual conduct and practices of the subject produce farm – will result in a change to that farm's qualified exempt status. There should be concrete and specific evidence required to establish a direct link between a foodborne illness outbreak and a farm. 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 farm and provide specific examples of direct linkage to an outbreak. In that guidance, FDA should clarify that individual farms and classes of farms cannot be held accountable for environmental conditions that are not the result of their own farming practices and

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

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

that are external to them, nor for activities occurring at other farms, and that those environmental conditions or activities at other farms cannot form the basis for the withdrawal of a qualified exemption. In that guidance, FDA should provide a concrete list with examples of situations in which a farm may be directly linked to an outbreak. The list need not be exhaustive, but it would give farmers 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 § 112.3. The concept of "necessary" is commonly associated with being inescapable or required.[293] 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 Produce Rule, FDA should add a definition of "necessary" in § 112.3 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 on a specific farm. 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 farmers 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 farm meets the threshold for having its qualified exempt status withdrawn under proposed § 112.201(b) is "associated." The broadly understood definitions of the verb "associate" include "to join or connect together" and incorporates the concept of combining.[294] 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 farmer or farm employees – unrelated to the actual conduct and practices of the farm in question – cannot endanger that farm's qualified exempt status.

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

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

Additionally, it should be formal policy that the general conditions of the watershed in which a farm operates cannot establish that "conduct or conditions… material to the safety of food" are actually associated with a particular farm. FDA should also clarify that merely because a particular crop or product, or a crop or 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 farm's qualified exemptions.

Recommendation: In the final Produce Rule, FDA should add a definition of "associated" in § 112.3 to prevent possible broad misinterpretation of the term "associated" to encompass undocumented linkages between farms 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 farm in question cannot be the basis for establishing an association between a farm and a safety concern that would jeopardize a farm's qualified 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 farm that are material to the safety of the otherwise covered produce," 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.[295] 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.[296]

In the preamble to the proposed Produce 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

[295] 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.).

[296] 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).

417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a farm that grew, harvested, packed, or held the food…[and] our investigation finds conduct or conditions associated with the farm that are material to the safety of the food…(for example, conduct or conditions that likely led to the contamination of the food)."[297]

Second, there is the case where "during a routine inspection of a farm to which the qualified exemption in proposed § 112.5 applies, 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."[298] We address the issue of FDA's authority to conduct a routine inspection of a qualified farm section D below.

Both of these examples necessarily accept that the action to withdraw exemption would be based on actual, documented conduct and conditions on the farm. 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 farm would negatively affect public health absent a specific finding of significant risk arising from that farm'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 farms, 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.[299] A standard built around connection to contamination also provides additional, although insufficient, clarity for farms.

The common usage definition of the term "material" includes "having real importance or great consequences" and emphasizes a relational aspect.[300]

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

Recommendations: In the final Produce Rule, FDA should add a definition of "material to the safety of food" in § 112.3 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

[297] 78 Fed. Reg. at 3612

[298] 78 Fed. Reg. at 3612

[299] 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.).

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

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 § 112.201(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 § 112.201(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 outbreak of foodborne illness. We provide our specific recommendations to changes needed to the language of Subpart R in section F 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 farmers information about what types of activities would trigger a withdrawal process from FDA based on conduct or conditions material to the safety of food.[301]

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

In the proposed Produce 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."[302] 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 farm 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.

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[301] 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.

[302] § 112.203(c)

Currently, the mere requirement that the triggering conditions be associated with the farm 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.

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 Produce Rule, FDA should increase the evidentiary standard for withdrawing a qualified exemption, including evidence that shows direct linkage to a problem on a specific farm, 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 § 112.201(b) so that it specifies that the determination must be supported by credible and substantial evidence related to an individual farm, and never to a group or class of farms. We provide our specific recommendations to changes needed to the language of Subpart R in section F 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 farm'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 farms 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 farm that was initially thought to be directly linked to an outbreak no longer is because a different commodity or contamination pathway is implicated. In many produce outbreak incidents, FDA has erroneously implicated farms in outbreaks and later determined that both the product and the farms involved were different from the ones the agency initially took action against. Without protection from false allegations in the case of active investigations of foodborne illness, even for farms that may be "directly linked" to an active investigation, FDA must not go directly to the withdrawal order option.

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 qualified exemptions 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 Produce Rule could be devastating for farms. A three-tiered approach would keep that flexibility while also addressing the identified problem.

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

1. FDA must first issue a warning letter to a qualified exempt farm 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."[303] 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."[304] Because FDA already uses warning letters for facilities to remedy violations,[305] there seems to be no reason why warning letters could not be used in the farm context. 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 Produce Rule, FDA should be required to first issue a warning letter to a qualified exempt farm before resorting to exemption withdrawal proceedings. In the warning letter, FDA should identify the conduct or conditions in question, or how FDA believes the farm is directly linked to an active investigation of a foodborne illness outbreak, and outline how the farm can remedy the situation. FDA should give the farm 15 calendar days to identify how it will remedy

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[303] 21 U.S.C. § 336 (2013).

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

[305] 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.

the issue before issuing an order to withdraw the qualified exemption. Specifically, FDA should add a new § 112.202 that addresses what actions FDA must take before issuing an order to withdraw an exemption. The new § 112.202 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 farm that:

1. Identifies the material conduct or conditions in question or how the farm is directly linked to an active investigation of a foodborne illness outbreak;
2. Includes information for how the farm can remedy the situation; and
3. Notifies the farm 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 R in section F 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 farm is directly linked to an active investigation of a foodborne illness outbreak, and outline how the farm can remedy the situation.

This option would last six months and allow the farmer 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 on the farm 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 farm. This type of targeted approach could be tailored to the farm's directly linked issues or to the conduct/conditions associated with the farm. This way, small businesses can seek targeted solutions as needed without falling under all the substantive, costly provisions of the Produce Rule, which could prove ruinous.

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

Recommendation: In the final Produce 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 farm is directly linked to an active investigation of a foodborne illness outbreak, and outline how the farm 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 on a farm. FDA should also provide technical assistance to the farmer. FDA should specify this in the new section § 112.202 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 R in section F 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 Produce 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 farm. Because conditions on a farm can 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 Produce 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 farm 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 R in section F below.

b. FDA should send the order to withdraw through certified mail with confirmation of delivery to ensure the farmer 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 farm'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 Produce Rule, FDA must require confirmation of the delivery and receipt of an order to withdraw by the farm 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 farm 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 R in section F 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 § 112.203. Currently in proposed Subpart R, 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 farm; or
> >
> > (2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm; . . . [306]

The language of proposed § 112.203(c)(2) does not match the language in proposed § 112.201(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 farmer meet the requirements of proposed § 112.206(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 farm relies." Without more specific information required in the withdrawal order, it is unreasonable to expect that a farmer 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 farm 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 Produce Rule, FDA must modify in the language in proposed §

[306] § 112.203

112.203(c) (new § 112.204(c)) so that the brief, general statement of the reasons for the order include:

1. Whether the order is based on 112.201(a) or 112.201(b);
2. The evidence on which the order is based;
3. If the order is based on 112.201(a), evidence linking the active investigation of a foodborne illness outbreak directly to the farm;
4. If the order is based on 112.201(b), measurable evidence that has been collected using generally accepted scientific standards indicating the presence of pathogens on the farm 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 R in section F below.

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

In proposed § 112.203, FDA does not explicitly state that the farm 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."[307] Without an explicit statement of a farm's options, the order to withdraw is confusing and unclear about what a farm'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 Produce Rule, FDA must specify in proposed § 112.203 (new § 112.204) that an order to withdraw a farm's qualified exemption must include a statement that the owner, operator, or agent in charge of the farm 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 R in section F 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 Produce Standards, and not always a total withdrawal triggering a requirement that the farm comply with all subparts of the Produce Standards. The partial withdrawal could be tailored to the farm's issues or conduct/conditions associated with the farm. This way, small businesses can seek targeted solutions as needed without falling under all the substantive, costly provisions of the Produce Rule, which

[307] § 112.203(f)

could prove ruinous.

Recommendation: In the final Produce Rule, FDA should authorize the use of a partial withdrawal and modify proposed § 112.203 (new § 112.204) to include a statement that indicates whether the withdrawal order is for a partial or total withdrawal. If the withdrawal is partial, FDA should indicate which subparts of the rule the farm must comply with. We provide our specific recommendations to changes needed to the language of Subpart R in section F below.

f. FDA should specify that a farmer'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 farmer receiving the order to "[a]ppeal the order within 10 calendar days of the date of the order."[308] Given that proposed Subpart R is silent on how the order is communicated to the farm in question, it is entirely possible that the farm 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 farm would receive the order after the ten-day timeframe, especially if the farm is located in a remote area. A far more reasonable approach would be to start a farmer's timeframe for taking action once the order has been received.

Recommendation: In the final Produce Rule, throughout Subpart R as appropriate, FDA must specify the owner, operator, or agent of the farm 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 farm in question. We provide our specific recommendations to changes needed to the language of Subpart R in section F below.

g. FDA should align the timeframe for compliance with the requirements of the Produce 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 one year after the effective date of the final regulation to come into compliance with the Produce Rule, and that very small businesses had two years.[309] 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 Produce Rule, FDA is defining very small business as a that has an average annual monetary value of food sold during the previous three-year period of $25,001-$250,000, and a small business as one that has $250,001-$500,000. A qualified exempt farm would fall under one of these two definitions, by definition.

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[308] § 112.204(b)

[309] Food, Drug, & Cosmetic Act § 419(b)(3)

In proposed Subpart R, FDA proposes to require a farm that receives an order to withdraw to comply with the full requirements of the Produce Rule within 60 calendar days or at the start of the next growing season if operations have ceased for the season.[310] This 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 exempt farm that has had its exemption withdrawn would be coming into compliance with the full Produce Rule for the first time, FDA should change the timeframes in Subpart R so that they align with the timeframes in FSMA for compliance with very small and small businesses.

Recommendation: In the final Produce Rule, FDA should align the timeframes for compliance with the Produce Rule in proposed §§ 112.203(d), 112.204(a), and 112.205(b) (new §§ 112.204(e), 112.205(a), and 112.206(b)) 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 two years, and for small businesses should be one year. We provide our specific recommendations to changes needed to the language of Subpart R in section F 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 exemption.

For farms 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 farm relies."[311] It would be unfair and inconsistent with FSMA for FDA to require qualified exempt farms to refute the claims made in a withdrawal order with records FSMA does not require those farms to keep. While we provide comments in section VII on FDA's request for comments on whether the agency should "require farms to be able to provide adequate documentation, as needed, to demonstrate the basis for the qualified exemption,"[312] we provide our comments on record requirements during a withdrawal proceeding here.

FDA should accept, for purposes of a qualified exempt farm's appeal of a withdrawal order, records that those farms typically keep in the normal course of business. Documents kept in the normal course of business include:

- Records about the type, amount, or dates of soil amendment applications;
- Records about the type, amount, or dates of spray applications;
- Water test results, even when such tests are not conducted as frequently as FDA requires of non-exempt farms;
- Soil test results, occasionally done either once or on an as-needed basis, but in some cases done annually;
- Timesheets of employees; and
- Field schedules of what is planted where.

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[310] § 112.204(a)

[311] § 112.206(a)(2)

[312] 78 Fed. Reg. at 3551

According to FDA, the recordkeeping requirements are the fifth costliest aspect of the proposed Produce Rule.[313] Additional recordkeeping requirements for qualified exempt farms to defend themselves against unwarranted withdrawals of their exemptions would increase the costs of compliance that these farms would face and directly contravene Congress' intent in establishing FSMA's flexible, scale- and supply chain-appropriate regulatory framework.

Recommendation: FDA should not require farmers submitting a written appeal to provide documents that they do not keep in the normal course of business. 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.[314]

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 farm or farm mixed-type facility exemption.

In the proposed Produce 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.[315] 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 farms to regain their exempt status after correcting a problem, and outlines the criteria for such a course of action.

In the proposed Produce Rule, FDA is completely silent on the issue of how a farm that has had its qualified exemption withdrawn can regain its status as a qualified exempt farm. 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."[316] FDA has a history of providing opportunities for facilities

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313 Travis Minor, presentation at FDA Public Meeting in Washington, D.C., 28 February 2013.

314 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.

315 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). 78 Fed. Reg. at 3646 (Sub. R § 112.211(a–d)).

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

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 farms that have a qualified exemption to fix the problems leading to the order to withdraw the exemption.

In developing a process to reinstate a farm'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).[317] Similar to the proposed Produce 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.[318] 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.[319] 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."[320] After the hearing on the suspension, if FDA determines that the registration should be reinstated, the registrant is required to submit a "corrective action plan" that outlines how the registrant is going to fix the problem that led to the suspension.[321] 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.[322]

The process for reinstating a facility's registration can be applied in the context of a farm regaining its qualified exemption; in both cases, FDA has reason to believe the food produced on such a farm or facility may cause some significant harm. If FDA makes such a finding, it has the authority to withdraw a facility's registration.[323] If a facility's registration is suspended, that facility is not permitted to introduce food from that facility into commerce.[324] Under the proposed Produce Rule, if a farm with a qualified exemption is directly linked to a foodborne illness outbreak or FDA finds conduct or conditions associated with the farm that are material to the safety of the food and merit action to prevent or mitigate a foodborne illness outbreak, that farm can have its qualified exemption withdrawn. If a qualified exemption is withdrawn, the farm becomes subject to the full requirements of the proposed Produce Rule. Given the history and likelihood of foodborne illness investigations that erroneously attribute the cause of outbreaks to certain farms 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 farm's qualified exemption when the ultimate conclusion of an investigation establishes that that farm was not in fact responsible for the investigated outbreak.

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

318 21 U.S.C. § 350d(b)(1) (2013)

319 21 U.S.C. § 350d(b)(2) (2013)

320 21 U.S.C. § 350d(b)(2) (2013)

321 21 U.S.C. § 350d(b)(3)(A) (2013)

322 21 U.S.C. § 350d(b)(3)(B) (2013)

323 21 U.S.C. § 350d(b)(1) (2013)

324 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)

FDA should provide a process by which a farm 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 Produce Rule, FDA must provide for a process to regain a farm's exempt status like the process used to reinstate a facility's registration. FDA should add a new § 112.213 that details how a farm can regain its qualified exempt status. Specifically, FDA should:

1. Allow a farm to regain its qualified exempt status before the compliance deadline passes. In this situation, FDA would be required to reinstate the farm's qualified exempt status if the owner, operator, or agent in charge of the farm demonstrates that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved.
2. Allow a farm 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 farm an opportunity for an informal hearing during which the owner, operator, or agent in charge of the farm 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 farm's exemption.
3. Automatically reinstate a farm's qualified exemption if FDA concludes an active investigation of a foodborne illness and finds that the farm in question was not directly linked to the foodborne illness outbreak. In this situation, FDA should provide notice to the farm of the reinstatement.

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

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

In proposed Subpart R, 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."[325] In justifying this decision, FDA states that the circumstances that would lead to a withdrawal merit "prompt action" and that a farm has the opportunity for "judicial review in accordance with § 10.45."[326] This is not a sufficient argument for justifying the removal of the option to file a motion for reconsideration or stay.

Qualified exemption from any particular subparts of the Produce 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 on a farm regardless of whether it is a qualified exempt farm or a non-exempt farm operating in compliance with the standards, that give rise to a foodborne illness concern. Staying the decision as to a farm's exempt status therefore would not necessarily prevent "prompt action" to address an actual foodborne illness concern on the subject farm.

[325] § 112.208(c)(6)

[326] 78 Fed. Reg. at 3615

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 farmers that operate on tight margins.

Recommendation: In the final Produce Rule, FDA must allow the option for a qualified exempt farm to file a motion for reconsideration or stay. Specifically, FDA should amend proposed § 112.208(c)(6) (new § 112.209(c)(6)) to specify that the qualified exempt farm shall have that right. We provide our specific recommendations to changes needed to the language of Subpart R in section F below.

D. The proposed Produce Rule creates the power for FDA to "routinely inspect" qualified exempt farms that FSMA does not grant FDA and that, therefore, must be removed from the rule.

In the preamble discussion of the Subpart R, FDA states that it may withdraw a qualified exemption if "during a *routine inspection* of a farm to which the qualified exemption in proposed § 112.5 applies, 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."[327] FSMA does not give FDA new authority to "routinely inspect" farms, especially qualified exempt farms.

FSMA requires FDA to increase the inspection of facilities,[328] and while certain farms may have facilities that may be subject to inspection, FSMA does not give new FDA the authority to routinely inspect farms, including qualified exempt farms. FSMA expressly states that, in the subsection about withdrawals of exemptions, "[n]othing in this subsection shall be construed to expand or limit the inspection authority of the Secretary."[329] Despite these clear restrictions from FSMA, FDA is saying in the preamble to the proposed Produce Rule that it may start to routinely inspect qualified exempt farms.

Recommendation: In the final Produce Rule, FDA should not state in the preamble or elsewhere in the proposed Produce Rule that it plans to routinely inspect farms, including qualified exempt farms. No less importantly, FDA should also provide clear guidance and training to all of its staff and contracting entities, including state and local entities, that they have no such power or authority.

E. FDA is correct to apply the withdrawal standard to food that would otherwise be covered produce and not food generally.

In the preamble to the proposed Produce Rule, FDA "tentatively conclude[s] that the food to which this standard applies is food that would otherwise be covered produce, because that is the food that would be subject to this proposed rule if a qualified exemption is withdrawn."[330] We agree with FDA's tentative conclusion that Subpart R applies to covered produce and not all of the food produced on a farm. This is consistent with the FSMA mandate to establish standards for produce safety of "fruits and vegetables, including specific mixes of categories of fruits and vegetables, that

[327] 78 Fed. Reg. at 3612, emphasis added

[328] Food, Drug, & Cosmetic Act § 421

[329] Food, Drug, & Cosmetic Act § 419(f)(3)(B)

[330] 78 Fed. Reg. at 3612

are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death."[331]

Recommendation: In the final Produce Rule, FDA should retain its decision to apply Subpart R to food that would otherwise be covered produce.

F. Recommended changes to § 112.3 and to Subpart R—Withdrawal of Qualified Exemption

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

Recommended Language Changes to §112.3:

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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.

***

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.

***

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 R:

Subpart R—Withdrawal of Qualified Exemption

[331] Food, Drug, & Cosmetic Act § 419(a)(1)(A)

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

We may withdraw your qualified exemption under § 112.5:

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

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

§ 112.202 What 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 farm that:

(1) Identifies:

(i) If the determination is based on § 112.201(a), how the farm is directly linked to an active investigation of a foodborne illness outbreak; or

(ii) If the determination is based on § 112.201(b), the conduct or conditions in question;

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

(3) Notifies the farm 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 § 112.202(a), FDA determines that the issue persists, FDA shall issue a temporary conditional withdrawal before issuing an order to withdraw under § 112.203.

(1) The temporary conditional withdrawal must identify:

(i) If the determination is based on § 112.201(a), how the farm is directly linked to an active investigation of a foodborne illness outbreak; or

(ii) If the determination is based on § 112.201(b), the conduct or conditions in question;

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

(iv) Notifies the farm 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 on the farm that needs to be remedied; and

(ii) Provide referrals to sources of technical assistance that may assist the farm in question to remedy the issue, including through training on on-farm 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 § 112.202(b)(3) expires, FDA may renew the temporary conditional withdrawal for one additional period that automatically expires after 6 months.

§ 112.20~~2~~3 What procedure will FDA use to issue an order to withdraw an exemption?

(a) If, after taking the actions in § 112.202, FDA determines that the issue persists and a qualified exemption applicable to a farm under § 112.5 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 farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve or deny an order to withdraw 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 farm.

(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 farm within 5 calendar days after the FDA District Director or official senior to such Director makes the determination under § 112.203(c).

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

§ 112.20~~3~~4 What information must FDA include in an order to withdraw a qualified exemption?

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

(a) The date of the order;

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

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

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

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

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

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

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

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

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

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

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

(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 farm must comply with subparts B through O of this part on the date that is 60 calendar days after the date of the order;~~ A statement that the owner, operator, or agent in charge of the farm 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 § 112.207.

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

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

(i) If the farm is a very small business, within 2 years of the date the order was received; or

(ii) If the farm is a small business, within 1 year of the date the order was received.

(2) If the withdrawal is total, the statement shall indicate that the farm must comply with subparts B through O of this part:

(i) If the farm is a very small business, within 2 years of the date the order was received; or

(ii) If the farm is a small business, within 1 year of the date the order was received;

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

~~(f)~~ (g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.20~~8~~9;

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

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

§ 112.204~~5~~ What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

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

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

(1) If the farm is a very small business, within 2 years of the date the order was received; or

(2) If the farm is a small business, within 1 year of the date the order was received; or

(b) Appeal the order within 10 calendar days of the date ~~of~~ the order was received in accordance with the requirements of § 112.20~~6~~7.

§ 112.20~~5~~6 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

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

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

(1) If the farm is a very small business, within 2 years of the date the order was received; or

(2) If the farm is a small business, within 1 year of the date the order was received.

§ 112.20~~6~~7 What is the procedure for submitting an appeal?

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

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, 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 farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.20~~7~~8.

§ 112.20~~7~~8 What is the procedure for requesting an informal hearing?

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

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206~~7~~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 farm explaining the reason for the denial.

§ 112.208~~9~~9 What requirements are applicable to an informal hearing?

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

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

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

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

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

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

(3) Section 112.2~~09~~10, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

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

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208~~9~~9(c)(4) are part of the administrative record.

(6) ~~No party~~ A qualified exempt farm 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 § 112.20~~8~~9(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.20~~9~~10 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.21~~0~~1 What is the timeframe for issuing a decision on an appeal?

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

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

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.20~~8~~9(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.

§ 112.21~~1~~2 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 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 farm 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 farm 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 farm 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.

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

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

(a) If, after an order to withdraw a qualified exemption has been issued under § 112.201(b) (and confirmed upon appeal, if applicable) and the date by which the farm is required to come into compliance with the provisions of this part has not passed as per § 112.206(b), the owner, operator, or agent in charge of the farm demonstrates to FDA that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved, FDA shall reinstate the farm's qualified exemption status.

(b) If a farm has had its qualified exemption withdrawn under § 112.201(b) and the date by which the farm is required to come into compliance with the provisions of this part as per § 112.206(b) has passed, the Secretary shall provide the owner, operator, or agent in charge of the farm an opportunity for an informal hearing, upon request of said owner, operator, or agent, to be held as soon as possible but not later than 10 business days after the request, on the reasons the farm's qualified exemption should be reinstated.

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

(2) The Secretary shall reinstate a farm's qualified exemption under §§ 112.4(b), 112.5, and 112.6 of this part if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue to withhold the farm's exemption status.

(c) If, after an order to withdraw a qualified exemption has been issued under § 112.201(a), FDA concludes the active investigation of a foodborne illness outbreak and FDA finds that the farm in question was not directly linked to the foodborne illness outbreak, the Secretary shall automatically reinstate the farm's qualified exemption and notify the farm of the reinstatement.

XIV. 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.[332] 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 I and reference them here to emphasize the importance of

[332] 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.

XV. APPENDIX I – 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.

XVI. APPENDIX II – NSAC COMMENTS ON THE EIS SCOPING NOTICE

National Sustainable Agriculture Coalition

November 15, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

Docket No. FDA-2011-N-0921
RIN 0910-AG35
Submitted electronically via http://www.regulations.gov

Re: Comments on Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

On behalf of the represented member organizations[1] of the National Sustainable Agriculture Coalition (NSAC), I submit the following comments on the Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. 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. NSAC recognizes that the comment period has just been extended to March 15, 2014, and we may file supplemental comments at that time.

Sincerely,

Ariane Lotti

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 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption 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 on the proposed rules, 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 detain on specific issues, including on the FDA's Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

The following people were part of the EIS subcommittee:

NSAC members:

Jo Ann Baumgartner, Wild Farm Alliance
Roger Noonan, New England Farmers Union
Dave Runsten, Community Alliance with Family Farmers
Mark Schonbeck, Virginia Association for Biological Farming

NSAC partners:

Mindy Goldstein, Edward Ezekiel, and Helen Jubran, Turner Environmental Law Clinic at Emory University School of Law

NSAC staff: Ferd Hoefner

Scoping Notice Comments

on

FDA Produce Rule

Submitted by

National Sustainable Agriculture Coalition

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

November 15, 2013

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I. INTRODUCTION

The National Sustainable Agriculture Coalition (NSAC)—an alliance of grassroots organizations that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities—submits these comments on the scope of the Environmental Impact Statement (EIS) for the Food and Drug Administration's (FDA) proposed rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Rule or Rule).[1] NSAC has also concurrently submitted comments on the Rule itself (the NSAC Rulemaking Comments),[2] which support and explain the comments set forth in this document. Those comments are incorporated herein by reference.

A. FACTUAL BACKGROUND

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA).[3] Among other requirements, FSMA requires the FDA to regulate the production of produce.[4] Specifically, it requires the agency to "establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death."[5] FDA proposed such standards—the Produce Rule—on January 16, 2013.[6]

After publication of the Produce Rule, FDA determined that its implementation may significantly affect the quality of the human environment, and accordingly the National Environmental Policy Act (NEPA) required the agency to conduct an environmental analysis (EIS) before issuing the final rule.[7] FDA published a notice of intent to prepare an EIS (the Scoping Notice or Notice) in the Federal Register on August 19, 2013, and it sought comments on the issues, alternatives, mitigation measures, and other information FDA should include in the EIS.[8] NSAC's detailed comments are set forth below.

The Scoping Notice gives very little information regarding FDA's current thinking about the appropriate scope of the Produce Rule EIS. According to the Notice, the purpose of the

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[1] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3,504 (proposed Jan. 16, 2013) (to be codified at 21 CFR pts. 16, 112) ("Produce Rule"). The docket number for the Rule is FDA-2011-N-0921 and the Regulatory Information Number (RIN) is 0910-AG35.
[2] NSAC, *Comments on the Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, submitted in Docket No. FDA-2011-N-0921, on Nov. 15, 2013.
[3] 21 U.S.C.A. § 350h (2013).
[4] *Id.*
[5] *Id.*
[6] 78 Fed. Reg. 3,504.
[7] Notice of Intent to Prepare an EIS for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 50,358, 50,359 (Aug. 19, 2013) ("Scoping Notice").
[8] *Id.*

scoping process is "to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives, and the extent to which those issues and impacts will be analyzed in the EIS."[9] But contrary to FDA and Council on Environmental Quality (CEQ) regulations, the Notice does not adequately identify the "alternatives" and "impacts" that the EIS will evaluate.

Given these deficiencies, NSAC requested FDA withdraw the Scoping Notice and republish a more complete notice.[10] NSAC contended that FDA had violated NEPA and FDA's implementing regulations by failing to identify alternatives and impacts. Without identifying these key components, the Scoping Notice failed to give the public sufficient information on which to develop comments on the appropriate scope of the EIS. To date, FDA has ignored the request to withdraw the Scoping Notice.

NSAC again requests that FDA withdraw the deficient Scoping Notice and republish a more complete notice. The failure of FDA to set forth alternatives and impacts hinders NSAC's ability to provide meaningful comments on the scope of the EIS. With nothing more on which to rely than its own speculation and hypotheses of FDA's intent, NSAC has prepared these comments. Of course, the opportunity for meaningful public comment on alternatives and impacts to be considered in the forthcoming EIS should rest upon a more solid foundation.

B. LEGAL BACKGROUND

When a federal agency proposes regulations that will "significantly affect[] the quality of the human environment," NEPA requires the agency to consider these impacts in an EIS.[11] As part of the EIS process mandated by NEPA, the agency must take a "hard look" at all impacts of and potential alternatives to the proposed action.[12] While the standard "hard look" cannot be defined with complete precision, courts have found it to "encompass[] a thorough investigation into the environmental impacts of an agency's action and a candid acknowledgment of the risks that those impacts entail."[13]

According to the FDA and CEQ regulations regarding NEPA, as a first step in the process, the agency must determine the appropriate scope and the significant issues to be analyzed in depth in the EIS.[14] The key component of this scoping process is the agency's determination of the range of actions, alternatives, and impacts to be considered in the EIS.[15] With regard to alternatives, agencies must consider the no-action alternative, other reasonable

[9] Scoping Notice, 78 Fed. Reg. at 50,359.
[10] Letter from Mindy Goldstein and Helen Jubran to Leslie Kux, Docket ID No. FDA-2011-N-0921-0216 (Sep. 4, 2013).
[11] National Environmental Policy Act of 1969. 42 U.S.C. § 4321 *et seq.* (1970).
[12] 42 U.S.C. § 4332(2)(C); *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976)).
[13] *Nat'l Audubon Soc'y v. Dep't of Navy*, 422 F.3d 174, 185 (4th Cir. 2005); *see also Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) ("the adverse environmental effects of the proposed action [must be] adequately identified and evaluated"); *Hughes River Watershed Conservancy v. Johnson*, 165 F.3d 283, 288 (4th Cir. 1999).
[14] 21 C.F.R. § 25.42; 40 C.F.R. § 1501.7.
[15] 40 C.F.R. § 1508.25.

courses of action, and mitigation measures to the proposed action.[16] Regarding impacts, the agency must give a hard look to both the direct and indirect impacts of a proposed rule.[17] Agencies must also consider the cumulative impacts of small actions that may be insignificant alone, but when added together, become significant.[18] Impacts to be evaluated may be ecological, aesthetic, historic, cultural, economic, social, or health-related in nature.[19]

Agencies bear the burden of complying with NEPA, and agencies may not unfairly shift this burden to concerned citizens or environmental groups.[20] When commenting on a proposed action, the public need not conduct a study or intensive research on potential environmental impacts. Instead, it is the agency's job to study and consider the potential impacts suggested by the public.[21] If the agency conducts an insufficient environmental analysis, concerned parties may enforce the obligations of NEPA by judicial remedy.[22]

II. COMMENTS

A. FDA MUST CONSIDER ALTERNATIVES AND MITIGATION MEASURES IN THE EIS.

FDA must take a hard look at the no action alternative, other reasonable alternatives, and mitigation measures to the Produce Rule in its EIS. The requirement to analyze alternatives is the "linchpin"[23] of an EIS, and FDA's analysis must include a rigorous and objective evaluation of all reasonable alternatives.[24] This analysis should compare the net benefit of the proposed action to the environmental impacts presented by alternative courses of action.[25] FDA should also prepare a formal cost-benefit analysis that monetizes the cost and benefits of the proposed action and its alternatives. A cost-benefit analysis would aid FDA in choosing among alternatives with different environmental impacts.[26]

If FDA identifies the current proposed Rule as its preferred alternative, it must consider and discuss mitigation measures that offset the environmental impacts.[27] Mitigation measures include:

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[16] *Id.*
[17] *Id.*
[18] 40 C.F.R. § 1508.7.
[19] 40 C.F.R. § 1508.8.
[20] *E.g.*, *Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 559 (9th Cir. 2000) ("Compliance with NEPA is a primary duty of every federal agency; fulfillment of this vital responsibility should not depend on the vigilance and limited resources of environmental plaintiffs.") (quoting *City of Davis v. Coleman*, 521 F.2d 661, 666 (9th Cir. 1975)).
[21] *See id.* at 558–59.
[22] *See, e.g.*, *W. Watershed Projects v. Bennett*, 492 F.Supp.2d 1271, 1225, 1228–29 (D. Idaho 2005).
[23] *Monroe County Conservation Council, Inc. v. Volpe*, 472 F.2d 693, 697-98 (2nd Cir. 1972) (internal citations omitted).
[24] *See also*, 40 C.F.R. § 1502.14 (describing the alternatives requirement as the "heart" of the EIS).
[25] *Natural Resources Defense Council, Inc. v. Morton*, 458 F. 2d 827 (D.C. Cir. 1999).
[26] 40 C.F.R. § 1502.23
[27] 40 C.F.R. § 1502.14(f)

a. Avoiding the impact altogether by not taking a certain action or parts of an action.
b. Minimizing impacts by limiting the degree or magnitude of the action and its implementation.
c. Rectifying the impact by repairing, rehabilitating, or restoring the affected environment.
d. Reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action.
e. Compensating for the impact by replacing or providing substitute resources or environments.[28]

FDA's deficient Scoping Notice hinders NSAC's ability to meaningfully comment on the alternatives to the proposed Rule and relevant mitigation measures, and NSAC again renews its request that FDA withdraw the deficient notice and re-publish a complete scoping notice. Notwithstanding the deficiency, NSAC attempts to provide meaningful comments on the scope of the EIS and proposes the following alternatives and mitigation measures for consideration in the EIS.

1. FDA Must Consider the No-Action Alternative.

FDA must take a hard look at the no-action alternative. In this instance, the no-action alternative is the decision to refrain from issuing the proposed Produce Rule. Instead of issuing the proposed Produce Rule, however, FDA could issue guidance documents that establish science-based standards for the safe growing, harvesting, packing, and holding of produce, in order to satisfy the mandates of Congress set forth in FSMA.

2. FDA Must Consider Other Reasonable Alternatives and Mitigation Measures.

a. FDA Must Consider Reducing the Number of Farms Subject to the Rule.

FDA must take a hard look at the impacts associated with reducing the number of farms subject to the Produce Rule in its EIS. FDA must weigh the impacts of the proposed Rule against the impacts of this narrowed scope. In conducting this comparison, FDA may consider the costs and benefits of each approach.

As currently drafted, the Rule does not apply to farms whose average annual monetary value of all food sold during a previous three-year period is $25,000 or less.[29] Instead, FDA should consider covering farms based on a calculation of sales of only those foods covered by the Rule, rather than calculating sales based on all foods sold. *See further,* NSAC Rulemaking Comments at 44-45 (explaining in more detail this alternative). Because the number of farms subject to the Rule relates directly to the magnitude of all environmental impacts, covering more farms will create more environmental impacts. Conversely, excluding more small farms from the Rule's coverage will create fewer environmental impacts. FDA must take a hard look at and compare the impacts of such an alternative.

[28] 40 C.F.R. § 1508.20.
[29] Produce Rule, 78 Fed. Reg. at 3,549 (§ 112.4(a)).

b. FDA Must Consider Expanding the Number of Farms Exempt From Most of the Rule's Requirements.

FDA must also take a hard look at the impacts associated with expanding the number of farms with qualified exemptions to the proposed Rule. Again, FDA must weigh the impacts of the proposed Rule against the impacts of this alternative regulatory approach. In conducting this comparison, FDA may consider the costs and benefits of each approach.

The Rule as drafted would exempt certain farms and facilities from the scope of most of the Rule's provisions. Farms qualify for the exemption if they meet a two-prong eligibility test: during the previous three-year period preceding the applicable calendar year, the average annual monetary value of food sold directly to qualified end-users exceeded the average annual monetary value of the food sold to all other buyers; and the average annual monetary value of all food sold during that three-year period was less than $500,000.[30] Although the Rule would still apply to these farms, because their average annual gross sales exceed $25,000, the Rule would provide an exemption from most provisions.[31] An alternative approach would be to apply the $500,000 threshold only to sales of produce covered by the Produce Rule, rather than sales of all food sold. *See further,* NSAC Rulemaking Comments at 52-53 (explaining in more detail this alternative). The scope of the qualified exemptions relates directly to the number of farming operations that will be subject to the majority of the Rule's provisions and an expanded scope of exemptions would decrease the magnitude of all environmental impacts. FDA must take a hard look at and compare the impacts of exempting more farms from most of the Rule's requirements.

c. FDA Must Consider Adopting an Alternative Water Quality Standard.

FDA must take a hard look at the environmental impacts of using an alternative water standard in its EIS. In doing its alternatives assessment, FDA must acknowledge the defects of its proposed standard—EPA's 1986 Recreational Water Quality Criteria (1986 RWQC)—and take a hard look at the environmental impacts which result from its implementation. In conducting this comparison, FDA may consider the costs and benefits of each approach.

As explained in NSAC's Rulemaking Comments, FDA's proposed water quality standard is defective because it fails to meet two requirements of FSMA.[32] *See further,* NSAC Rulemaking Comments at 60-67. First, FDA failed to establish risk-based and science-based minimum standards for agricultural water when it adopted the 1986 RWQC. FSMA requires FDA to establish "minimum science-based standards for … raw agricultural commodities, based on known safety risks."[33] FDA's adopted standard, however, is not a science-based standard

[30] *Id.* at 3,549 (§ 112.5(a)).
[31] Farms that qualify for the exemption are subject to only three subparts of the Rule and certain labeling requirements. *Id.* at 3,550 (§ 112.6).
[32] FDA's proposed water quality standard is also defective because EPA's 1986 RWQC is outdated. In 2012, the EPA updated its recreational water quality criteria and made several significant changes. *See* "2012 Recreational Water Quality Criteria," 77 Fed. Reg. 71191. For example, EPA's 2012 RWQC provides two sets of recommended criteria, it no longer recommends multiple 'use intensity' values, it consists of both a geometric mean (GM) and a Statistical Threshold Value (STV), and it is comprised of a magnitude, duration, and a frequency of excursion for the GM and STV. *Id.*
[33] 21 U.S.C.A. § 105(a)(b)(1) (2013).

developed to protect human health from consumption of produce. In its proposed Rule, FDA acknowledges, "the EPA recreational water standards were developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers (Ref. 136), *rather than to consumption of produce.*"[34] Additionally, FDA's adopted standard does not adequately establish a risk-based approach. As currently proposed, FDA's standard applies to every farm that must comply with the Rule standards regardless of critical factors such as risk, climate, location, farming system, and water resource.

Second, FDA failed to provide sufficient "flexibility" to farmers, as required by FSMA.[35] As noted above, FDA's water quality standard is inflexible because it applies regardless of risk, climate, location, farming system, or water system.

FDA must take a hard look at the following alternative water quality standards and their impacts:

1. Using a new science-based water quality standard developed from research correlating the risks of gastrointestinal illness from agricultural water to consumption of produce, which might vary according to the region. For any such new standard FDA must take a hard look at the impacts from including such a standard in guidance, not in the regulation itself. This allows for the standard to be updated if new research becomes available about appropriate water quality standards. *See further*, NSAC Rulemaking Comments at 60-67 (explaining that FDA must consider creating a new water quality standard).

2. Using an alternative risk-assessment process. Specifically, FDA should require farmers to collect monthly baseline information about their water systems in the first growing season and base future actions and testing frequencies on those results, instead of requiring weekly water testing. *See further*, NSAC Rulemaking Comments at 60-67 (explaining that FDA must consider a more flexible water quality standard).

3. Using the World Health Organization's ("WHO") *E. coli* water quality standard. As FDA notes, the WHO standard is less-restrictive than FDA's proposed standard.[36] Conversely, the 1986 RWQC *E. coli* standard is overly-restrictive,[37] encourages farmers to use chemically treated water, municipal water, and groundwater, and

[34] Produce Rule, 78 Fed. Reg. at 3.569 (§ 112.44(c)) (emphasis added).
[35] 21 U.S.C.A. § 105(a)(a)(3)(A) (2013) (requiring FDA to "provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables that are raw agricultural commodities).
[36] "The proposed standard is more stringent than the WHO standard." *Id.* at 3,569 (§ 112.44(c)); *See also* World Health Organization and United Nations Environmental Programs, *WHO Guidelines for the Safe Use of Wastewater, Excreta and Greywater*, Geneva, Switzerland: WHO Press, 2006 (concluding that the minimum microbial quality for water used on root crops that are eaten raw is 1,000 CFU generic E. coli per 100 ml and 10,000 CFU generic E. coli per 100 ml in leaf crops).
[37] The 1986 RWQC, as used in the Produce Rule, prohibits farmers from using agricultural water that contains more than 235 colony forming units (CFU) generic E coli. per 100 mL for any single sample or a rolling geometric mean of more than 126 CFU per 100 mL of water. Produce Rule, 78 Fed. Reg. 3,504 (§ 112.44(c)).

causes numerous environmental effects. FDA must take a hard look at the WHO standard in its EIS and evaluate its environmental effects. FDA must then compare those effects to the effects of the 1986 RWQC.

d. FDA Must Consider Aligning Soil Amendment Standards with those of the National Organic Program.

FDA must take a hard look at the impacts associated with aligning the Rule's soil amendment standards to those used in the U.S. Department of Agriculture's (USDA) National Organic Program. FDA must weigh the impacts of the standards proposed in the Rule against the impacts of this alternative approach. In conducting this comparison, FDA may consider the costs and benefits of each.

FDA's proposed standards require significant waiting periods between the application of an untreated biological soil amendment of animal origin and harvest of covered produce, under certain conditions.[38] Alternatively, FDA could align its biological soil amendments of animal origin standards with those standards for the use of manure and compost in the National Organic Program. For example, FDA could reduce section 112.56(a)(1)(i)'s nine-month required interval between application of untreated manure and harvest to the four-month (120-day) interval required by the National Organic Program. Similarly, FDA could reduce section 112.56(a)(4)(i)'s 45-day required interval between application of compost and harvest to a zero-day interval, if the compost is treated by a process in accordance with the requirements of section 112.54(c) to meet the microbial standard in section 112.55(b). FDA must take a hard look at and compare the impacts associated with each of these alternatives, as set forth in more detail in the recommendations in NSAC's Rulemaking Comments. *See further,* NSAC Rulemaking Comments at 81-84.

e. FDA Must Consider Ways to Mitigate the Environmental Impacts Caused by Certain Provisions and Preferences in the Proposed Rule.

In addition to considering the alternatives listed above, FDA must consider ways to mitigate environmental impacts that result from the provisions and preferences of the Rule as proposed. As discussed in detail below, the Rule's provisions and preferences create substantial and varied environmental impacts to water, land, air, animals, and human health. Specifically, in its EIS, FDA should consider ways to mitigate the environmental impacts caused by:[39]

- The preference for chemical water treatment (see Section II.B.1. of these comments);
- The preference for use of municipal and public water supplies (see Section II.B.2. of these comments);
- The preference for use of groundwater supplies (see Section II.B.3. of these comments);
- The preference for use of synthetic fertilizers (see Section II.B.4. of these comments);
- The preference for treatment of biological soil amendments of animal origin (see Section II.B.5 of these comments);

[38] *See* section II.B.4.-7. of this document for description.
[39] This is not an exhaustive list.

- The restrictions on use of raw manure and composting (see Section II.B.6. of these comments);
- The preference for conventional growing methods[40] (see Section II.B.7. of these comments);
- The preference for use of new packing materials (see Section II.B.8. of these comments);
- The preference for domestic animal confinement (see Section II.B.9. of these comments);
- The preference for the exclusion of wild animals from cropland (see Section II.B.10. of these comments);
- The requirement to monitor for and exclude pests from buildings (see Section II.B.11. of these comments);
- The aggregate human health impacts of the Rule (see Section II.B.12. of these comments).

B. FDA MUST CONSIDER DIRECT AND INDIRECT ENVIRONMENTAL IMPACTS IN THE EIS.

In its EIS, FDA must take a hard look at the direct, indirect, and cumulative impacts to the environment caused by its proposed Rule.[41] This analysis is necessary so that FDA can evaluate the benefits of the proposed action in light of its environmental impacts.[42] In its EIS, FDA must also consider unquantified environmental amenities and values.[43]

Direct effects are effects caused by the agency action and occur at the same time and place.[44] Indirect effects are defined as effects that are caused by the agency action and are later in time or farther removed in distance, but are still "reasonably foreseeable."[45] Cumulative effects are incremental environmental impacts of the action added to other past, present, and reasonably foreseeable future actions, regardless of what agency undertakes such other action.[46] Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.[47]

FDA's deficient Scoping Notice hinders NSAC's ability to meaningfully comment on the environmental impacts of the proposed Rule, and NSAC again renews its request that FDA withdraw the deficient notice and re-publish a complete scoping notice. Notwithstanding the

[40] Conventional farming includes industrial methods that rely on monocultures and purchased synthetic chemicals and other non-sustainable or non-organic practices.
[41] 42 U.S.C.A. § 4332(C)(i). *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) (agencies must take a "hard look" at environmental consequences in its EIS) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976)); *see also* 40 C.F.R. § 1508.8 (agencies must consider and discuss the direct, indirect, and cumulative effects to the environment in its review of the environmental consequences of its action).
[42] *Natural Resources Defense Council, Inc. v. Morton*, 458 F. 2d 827 (D.C. Cir. 1999).
[43] 42 U.S.C.A. § 4332(B).
[44] 40 C.F.R. § 1508.8.
[45] *Id.*
[46] 40 U.S.C.A. § 1508.7.
[47] *Id.*

deficiency, NSAC attempts to provide meaningful comments on the scope of the EIS. The following comments are based on NSAC's best efforts to anticipate and evaluate the environmental impacts of the proposed Rule.

The following sections describe preferences that the Produce Rule creates for certain agricultural production practices. In each section, preferences are accompanied by the environmental impacts they create to water, land, air and energy, animals, or human health. FDA must take a hard look at each of these environmental impacts in its EIS.

1. FDA Must Consider the Water, Animal, and Human Health Impacts Created by the Preference for Chemical Water Treatment.

a. Preference for Chemical Water Treatment

The Produce Rule likely encourages farmers to use chemically treated water in two ways. First, the FDA's use of the 1986 RWQC discourages farmers from using untreated surface water. Second, the Produce Rule exempts farmers that chemically treat their surface water from extensive requirements.

The Rule discourages farmers from using untreated surface water. Section 112.44(c) of the Produce Rule requires farmers to meet EPA's 1986 RWQC during growing activities. [48] Farmers must ensure any water that is directly applied to produce contains no more than 235 colony forming units (CFU) of *E. coli* per 100 ml.[49] In many parts of the country, surface water cannot meet this criterion without chemical water treatment.

The Produce Rule also discourages farmers from using untreated surface water by creating inspection, monitoring, modification, and testing requirements for farmers that use it. Farmers that use untreated surface water during growing activities in a manner that directly contacts covered produce must:

- Ensure that the water meets water quality standards borrowed from the Environmental Protection Agency's 1986 RWQC;[50]
- Discontinue use, re-inspect, make necessary changes, and retest any time testing shows that they violate these microbial standards;[51]
- Test their water at the beginning of each growing season;[52]
- Test their water at least every 7 days during the growing season if the surface water is from any source where a significant amount of runoff is likely to drain into the source, such as a river or a natural lake;[53]
- Keep additional records.[54]

[48] Produce Rule, 78 Fed. Reg. 3,568 (§ 112.44(c)).
[49] *Id.*
[50] *Id.*
[51] *Id.* at 3,567-68 (§ 112.44(b)-(c)).
[52] *Id*. at 3,570 (§ 112.45(a)).
[53] *Id*. at 3,571 (§ 112.45(b)(1)).
[54] *See id.* at 3,572 (§ 112.50(b)(2), (4), and (5)).

Taken together, these requirements clearly discourage farmers from using untreated surface water. In some cases, these requirements may prohibit farmers from using it altogether.

The Rule then encourages farmers to use chemically treated surface water by *exempting* farmers that use it from all of the requirements listed above. Farmers that use chemically treated agricultural water are exempt from testing their agricultural water at the beginning of the growing season or any time thereafter, they automatically meet microbial water quality criteria, and they are exempt from numerous reporting requirements. The Rule specifically clarifies that chemical treatment is a form of acceptable water treatment.[55] Thus, the Rule likely discourages farmers from using untreated surface water and creates a clear preference for farmers to use chemically treated agricultural water.

b. Preference for Chemical Water Treatment Creates Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water of creating a preference for chemical water treatment.[56] FDA should take a hard look at which chemicals farmers are most likely to use and how those chemicals will likely impact water quality. For example, FDA should take a hard look at the likely environmental impacts to water resources and aquatic animals that result from agricultural runoff and leachate containing chemically treated irrigation water. If chemically treated agricultural water leaches into groundwater, community drinking water might be affected.

ii. Animals

FDA must take a hard look at the environmental impacts to animals caused by a preference for chemical water treatment. Agricultural runoff that contains chemically treated water may harm aquatic life and livestock or terrestrial wildlife that drinks from affected waterways. Harm to aquatic life likely includes fish and wildlife kills and food source contamination.

iii. Human Health

FDA must take a hard look at the human health impacts caused by a preference for chemical water treatment. These impacts may include negative health conditions due to the

[55] *See id.* at 3,566 (§ 112.43(b)).

[56] FDA alleges that the Produce Rule's chemical water treatment requirements are dependent on EPA certification, and it may try to rely on this certification process to relieve it of its NEPA duties. Produce Rule, 78 Fed. Reg. 3,504 (§ 112.43(b)) ("any chemicals used in the treatment of water would require EPA registration under the [FIFRA] before they can be lawfully used"). Any such reliance would be misplaced. First, no certification for chemical treatment of irrigation water currently exists. *Id.* at 3,566 (§ 112.43(b)). Additionally, and more importantly, encouraging farmers across the United States to use chemical water treatment will likely create substantial direct, indirect, and cumulative effects on water resources. FDA must consider these effects in its EIS now, regardless of what actions EPA may take in the future. Therefore, EPA's registration process under FIFRA simply does not excuse FDA from evaluating the impacts of chemical water treatment on water resources.

increased use of chemicals in the water treatment process. Humans are likely to encounter these chemicals directly through drinking water, produce consumption, working on farms, or agricultural runoff.

2. FDA Must Consider the Water and Animal Impacts Created by the Preference for Use of Municipal and Public Water Supplies.

a. Preference for Municipal and Public Water Supplies

The Produce Rule likely encourages farmers to use municipal water and public water supplies over any other water source. The proposed Rule creates this preference in two ways. First, the proposed *E. coli* standard places a burden on farmers that use other sources of surface water. As discussed above, farmers that use other sources of surface water are required to test the water or chemically treat it in order to comply with this standard.

Second, the Rule exempts farmers that use municipal or public water from these testing and treatment requirements.[57] It is likely that some farmers will pay for municipal or public water in order to avoid of the higher costs of testing and treating other sources of water in compliance with the proposed *E. coli* standard. Thus these exemptions likely create a preference for farmers to use municipal or public water.

b. Preference for Municipal and Public Water Supplies Creates Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water of creating a strong preference for municipal water and public water. For example, the FDA should consider the environmental impacts of creating an increased demand on already-stressed municipal waters,[58] construction of new water treatment facilities, and construction of new water supply reservoirs to accommodate the increased water supply need.[59]

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[57] *See id.* at 3,570 (§ 112.45 ("The standard in § 112.44(a) is derived from the EPA drinking water standard … we are not aware of anything suggesting a need for additional testing at its delivery point to the farm"); *id.* at 3,571 ("Under the sampling, testing, and reporting requirements of 40 CFR 141, we tentatively conclude that additional actions by the grower to assure its safety are unwarranted").

[58] Water scarcity is a well-known problem in many metropolitan areas, including Los Angeles, California. *See* Hilda Blanco et al., *Water Supply Scarcity in Southern California: Assessing Water District Level Strategies* 1–10 (2013), *available at* http://sustainablecities.usc.edu/research/publications.html. For situations in which farmers were previously using groundwater, the increased demand on municipal water supplies will be particularly noticeable.

[59] Increased demands for water, including water used for irrigation, put stress on water management systems. *See* Herman Bouwer, *Integrated Water Management: Emerging Issues and Challenges* 45 Agric. Water Mgmt. 217, 218 (2000). If agricultural demands were made on municipal water supplies, the effects could be very significant, given current growth in demand for municipal water. A 2006 EPA survey showed that 52.6% of capital investments made by public and private water supply companies were directed toward system expansion, such as new facilities and transmission systems. U.S. EPA, *2006 Community Water Survey* 28–31 (2009), *available at* http://water.epa.gov/infrastructure/drinkingwater/pws/upload/cwssreportvolumeI2006.pdf.

ii. Animals

FDA must take a hard look at the environmental impacts to animals caused by a preference for municipal and public water supplies. Municipal and public water sources are already subject to several competing uses and pollution sources. Encouraging farmers to use municipal and public water will likely decrease minimum flows and therefore harm aquatic life.[60]

3. FDA Must Consider the Water and Animal Impacts Created by the Preference for Use of Groundwater Supply.

a. Preference for Use of Groundwater Supply

The Produce Rule likely encourages farmers to use groundwater over surface water. The Rule creates this preference by adopting an overly-restrictive *E. coli* water quality standard, which encourages farmers to avoid costly testing and treatment requirements by switching to groundwater.

First, the Rule encourages farmers to use groundwater by placing costly testing requirements on surface water. Farmers that use untreated surface water must test the water at the beginning of each growing season and every three months thereafter.[61] Farmers that use untreated surface water must additionally test it at least every seven days during the growing season, if it is exposed to significant quantities of runoff.[62] Farmers that use groundwater, however, are only required to test their water once every month during the growing season.[63]

Second, the Rule encourages farmers to use groundwater by placing costly treatment requirements on surface water. As discussed above, FDA's *E. coli* standard will also likely eliminate entire sources of untreated surface water from agricultural use. Farmers will be forced to either conduct chemical water treatment, or switch to groundwater sources. [64] A significant number of farmers across the nation will likely switch from surface water to groundwater sources in order to avoid water treatment requirements. The Rule therefore burdens farmers who use untreated surface water and thus creates a preference for the use of groundwater sources. *See further,* NSAC Rulemaking Comments at 60-67.

[60] *Flow 101*, U.S. EPA, http://water.epa.gov/scitech/datait/models/dflow/flow101.cfm.
[61] Produce Rule, 78 Fed. Reg. at 3,570 (§ 112.45(a)).
[62] *Id.* at 3,571 (§ 112.45(b)(1)).
[63] *Id.* at 3,504 (§ 112.45(b)(2)) ("any source where underground aquifer water is transferred to a surface water containment").
[64] Farmers are likely to use groundwater because groundwater sources are far less likely to be contaminated with *E. coli* than surface water sources. *See id.* at 3,561 ("water obtained from a public water source is least likely to be a vehicle for pathogen contamination of produce, followed by water obtained from deep underground aquifers, shallow wells, and surface water, in that order").

b. Preference for Use of Groundwater Supply Creates Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water of creating a preference for the use of groundwater supplies. This preference will increase reliance on already-strained groundwater resources and will force some farmers to relocate farming activities.

FDA must take a hard look at the environmental impacts to water of potentially dramatically increasing dependency on groundwater supplies. According to the USDA, in 2007 three-fourths of irrigated agriculture in the United States took place in seventeen western states. Across these states, 52 percent of the water sources used were surface water sources.[65] Forcing farmers to consider using groundwater is likely to exacerbate already competing demands for water resources,[66] and in turn substantially impact the environment. These impacts might include extreme drops in groundwater levels and possible depletion of groundwater resources in some areas. Other potential environmental impacts to water include reductions in streamflow, harm to terrestrial ecosystems, and destruction of wildlife habitat.[67]

FDA must also take a hard look at the environmental impacts to water (and land, air and energy, animals, and human health) of forcing some farmers to shift farming activities to new regions as a result of this preference. In some cases, groundwater may not be available as an alternative to untreated surface water. Farmers in these areas will likely be forced either to re-locate entire farms, at tremendous cost, in search of a new water sources, or to stop farming altogether.

ii. Animals

FDA must take a hard look at the environmental impacts to animals caused by a preference for groundwater supplies. Potential environmental impacts associated with competition for groundwater resources include harm to aquatic life.[68]

4. FDA Must Consider the Water, Land, Air, Animal, and Human Health Impacts Created By the Preference for Synthetic Fertilizers.

a. Preference for Synthetic Fertilizers

The Rule, taken as a whole, will likely create a preference for farmers to use synthetic fertilizers as opposed to biological soil amendments. The Rule creates this preference by

[65] Glenn D. Schaible & Marcel P. Aillery, USDA, *Water Conservation in Irrigated Agriculture: Trends and Challenges in the Face of Emerging Demands*, at ii (2012), *available at* http://www.ers.usda.gov/media/884158/eib99.pdf.
[66] The USDA goes on to examine future supply and demand issues associated with irrigated agriculture, finding that threats to groundwater supply and quality are growing with the expansion of biofuels, global climate change, the growing popularity of hydrofracking, and an increase in crop irrigation across the eastern states. *See id.* at 8–13.
[67] William M. Alley, et al., USGS, *Sustainability of Ground-Water Resources* 34 (1999).
[68] *Id.*

distinguishing between biological and non-biological soil amendments and imposing additional requirements on the use of biological soil amendments.[69] These requirements govern handling, conveying, storing, treatment, microbial standards, application method and minimum intervals, and reporting.[70] Because of the restrictions proposed on biological soil amendments of animal origin, FDA creates a significant incentive for farmers to use synthetic fertilizers, which have been widely shown to result in significant environmental impacts. Indeed, FDA acknowledges in the Scoping Notice that the proposed biological soil amendment requirements "are expected to result in changes in current use of treated and untreated biological soil amendments of animal origin *or potentially greater use of synthetic fertilizers*."[71]

For example, the Rule requires minimum application intervals for soil amendments, based upon the type of amendment used.[72] Biological soil amendments of animal origin, if untreated, require a minimum application period of nine months, in addition to other application restrictions.[73] Biological soil amendments of animal origin that are treated by a composting process in accordance with the requirements of section 112.54(c) require a 45-day interval between application and harvest.[74] Synthetic fertilizers, however, have no minimum interval for application.

Additionally, the Rule prescribes a method of application of soil amendments, based upon the type of amendment used.[75] Biological soil amendments of animal origin, when untreated, must be applied in a manner that does not contact produce during application and minimizes the potential for contact with produce after application, in order to reduce contamination.[76] In contrast, synthetic fertilizers are not subject to restrictions on the method of application. By virtue of the limitations imposed on biological amendments, the Rule burdens farmers who use biological soil amendments and thereby creates a very strong preference for synthetic fertilizers. *See further,* NSAC Rulemaking Comments at 68-72 (explaining the incentives for farmers to rely on chemical fertilizers instead of biological amendments).

b. Preference for Synthetic Fertilizers Creates Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water of encouraging farmers to use synthetic fertilizers. Increased use of synthetic fertilizers is widely shown to lead to agricultural runoff and pollution. Correspondingly, the impacts of this preference include nutrient pollution, eutrophication, and contamination of drinking water.

Nitrogen-based soil amendments are often applied as nitrate, ammonium, and/or urea; the latter two are rapidly converted to nitrate by soil life. Because nitrate is highly soluble and

[69] Produce Rule, 78 Fed. Reg. 3,504 (§ 112.3(c)).
[70] *See id.* at 3,577-85 (§§ 112.52, 112.54, 112.55, 112.56, and 112.60).
[71] Scoping Notice, 78 Fed. Reg. at 50,359 (emphasis added).
[72] Produce Rule, 78 Fed. Reg. at 3,581-84 (§ 112.56).
[73] *Id.* at 3,581 (§ 112.56(a)(1)).
[74] *Id.* at 3,583 (§ 112.56(a)(4)(i)).
[75] *Id.* at 3,581-84 (§ 112.56).
[76] *Id.* at 3,581 (§ 112.56(a)(1)).

mobile, its use can lead to nuisance growth of algae, mostly in downstream estuaries, and cause contamination of drinking water.[77] The use of nitrogen-based synthetic soil amendments is also linked to degradation of nitrogen and carbon resources naturally occurring in soil, which further increases reliance on synthetic soil amendments to maintain crop yields.[78] Such reliance is dangerous, in part, because excess fertilizer application contributes to eutrophication and dead zones in waters, which is harmful to water resources and aquatic life.[79]

Phosphorus is applied to soil as phosphate, and phosphate runoff can also lead to nuisance algae and plant growth, often in freshwater streams, lakes, and estuaries, including critically impaired waters such as the Chesapeake Bay and the Gulf of Mexico.[80]

Because of the preference for synthetic fertilizers, less untreated or composted animal manure and poultry litter will be used for crop production. The reduced use of these wastes will result in increased accumulation of wastes on livestock farms and at the sites of animal feeding operations (AFOs), including concentrated animal feeding operations (CAFOs) and poultry houses. Such waste accumulation contaminates both surface and groundwater resources with nutrients and pathogens.

ii. Land

FDA must take a hard look at the environmental impacts to land of creating a preference for synthetic fertilizers. For example, the use of nitrogen-based soil amendments is linked to

[77] Nitrate pollution in drinking water supplies can cause serious illness or death. *Basic Information About Nitrate Pollution in Water*, U.S. EPA, http://water.epa.gov/drink/contaminants/basicinformation/nitrate.cfm (last updated May 21, 2012).

[78] R.L. Mulvaney et al., *Synthetic Nitrogen Fertilizers Deplete Soil Nitrogen: A Global Dilemma for Sustainable Cereal Production,* 38 J. Envtl. Quality 2295, 2307–08 (2009). Specifically, synthetic soil amendments fail to support soil health and nutrient content, which indicates that using synthetic soil amendments is a less sustainable farming practice. Paul Hepperly et al., *Compost, Manure and Synthetic Fertilizer Influences Crop Yields, Soil Properties, Nitrate Leaching and Crop Nutrient Content*, 17 Compost Sci. & Utilization 117, 125 (2009).

[79] *See Nutrient Pollution*, U.S. EPA, http://www2.epa.gov/nutrientpollution/ (last updated Mar. 25, 2013) (providing, throughout the website, explanations of the sources and effects of nutrient pollution).

[80] *Fertilizer Applies for Agricultural Purposes: What Are the Trends in Chemicals Used on the Land and Their Effects on Human Health and the Environment*, U.S. EPA, http://cfpub.epa.gov/eroe/index.cfm?fuseaction=detail.viewInd&lv=list.listByAlpha&r=216629&subtop=312 (last visited Mar. 28, 2013). Mining phosphorous for phosphate fertilizers also releases radionuclides like uranium and radium-226. *About Phosphogypsum*, U.S. EPA, http://www.epa.gov/radiation/neshaps/subpartr/about.html (last updated July 31, 2012). Some studies indicate that a "peak phosphorous" phenomenon could occur, as mining of phosphate rock increases and resources become scarcer. *E.g.*, Patrick Déry & Bart Anderson, *Peak Phosphorous*, Energy Bull., Aug. 13, 2007, *available at* http://www.resilience.org/stories/2007-08-13/peak-phosphorus. As the U.S. Geological Survey succinctly explains, "There are no substitutes for phosphorous in agriculture." U.S. Geological Survey, *Mineral Commodity Summaries 2013*, at 119 (2013). In the future, if U.S. sources of phosphate soil amendments are depleted, farmers could be compelled to import phosphate fertilizers.

degradation of nitrogen and carbon resources naturally occurring in soil, which further increases reliance on synthetic soil amendments to maintain crop yields.[81]

Again, the reduced use of untreated or composted animal manure and poultry litter for crop production will result in increased accumulation of these wastes on livestock farms and at the sites of AFOs, including CAFOs and poultry houses. This accumulation will likely lead to greater nutrient and pathogen overloads in concentrated areas, and less input of manure at rates that would otherwise enhance soil fertility and quality over much larger areas of cropland.

iii. Air and Energy

FDA must take a hard look at the air and energy impacts caused by a preference for synthetic fertilizers over biological soil amendments. These impacts may include additional emissions and energy expenditure to produce synthetic fertilizers. During and after application, the use of synthetic fertilizers also creates air impacts. In addition, the formation and release of nitrous oxide (N_2O, a greenhouse gas 300 times as potent as CO_2) during wet soil conditions is aggravated by the presence of high concentrations of soluble nitrogen, as occur after synthetic fertilizer application. Slow-release nitrogen sources, such as compost, are less likely to release large amounts of N_2O. Impacts may also include increased transportation emissions, due to many farmers obtaining synthetic fertilizer from another source and transporting it to their farms.

iv. Animals

FDA must take a hard look at the environmental impacts to animals caused by a preference for synthetic fertilizers. The eutrophication and dead zones in waters—caused by synthetic fertilizer application—harm aquatic life. See the Water section above for more detail.

v. Human Health

FDA must take a hard look at the human health impacts caused by a preference for synthetic fertilizers over biological soil amendments. These impacts may include an increase in chronic and acute health conditions due to the increased use of chemical fertilizers.[82] Humans may come in contact with these fertilizers directly from produce consumption, working on farms, or through agricultural runoff. These impacts may also include increased human exposure to pathogens in irrigation water. Nitrates can lead to growth of algae in water. Some kinds of pathogenic bacteria survive longer when attached to algae.[83] UV penetration in water, important

[81] R.L. Mulvaney et al., *Synthetic Nitrogen Fertilizers Deplete Soil Nitrogen: A Global Dilemma for Sustainable Cereal Production,* 38 J. Envtl. Quality 2295, 2307–08 (2009). Specifically, synthetic soil amendments fail to support soil health and nutrient content, which indicates that using synthetic soil amendments is a less sustainable farming practice. Paul Hepperly et al., *Compost, Manure and Synthetic Fertilizer Influences Crop Yields, Soil Properties, Nitrate Leaching and Crop Nutrient Content*, 17 Compost Sci. & Utilization 117, 125 (2009).

[82] Nitrate pollution in drinking water supplies can cause serious illness or death. *Basic Information About Nitrate Pollution in Water*, U.S. EPA, http://water.epa.gov/drink/contaminants/basicinformation/nitrate.cfm (last updated May 21, 2012).

[83] Y.A. Pachepsky et al., *Irrigation Waters As a Source of Pathogenic Microorganisms in Produce: A Review*, Advances in Agronomy 113 (2011).

in reducing pathogens, is diminished with the presence of algae.[84] Therefore, increasing nitrate runoff from fields may increase algae and pathogens in irrigation surface water.[85]

5. FDA Must Consider the Land and Air Impacts Created by the Preference for Treatment of Biological Soil Amendments.

a. Preference for Treatment of Biological Soil Amendments of Animal Origin

The Rule, taken as a whole, creates a preference for treating biological soil amendments of animal origin (as opposed to leaving such amendments untreated) due the additional requirements imposed upon untreated biological soil amendments of animal origin. These additional requirements include restrictions on handling, conveying, storing, application intervals, and method of application.

The Rule requires farmers to determine the status of any biological soil amendments of animal origin, which are divided into categories of treated or untreated, based on several parameters.[86] Once sorted, the Rule provides specific instructions for handling, conveying, and storing treated amendments so they do not get contaminated with untreated amendments.[87] In order to avoid taking these precautions against contamination, farmers may treat all or most animal-based amendments. Treatment of biological soil amendments of animal origin must be conducted according to acceptable processes.[88] Treatments are generally physical (heating) or chemical, which FDA acknowledges require large amounts of energy.[89]

The Rule also requires minimum application intervals and prescribes a method of application for untreated biological soil amendments of animal origin, compared to satisfactorily treated biological soil amendments of animal origin.[90] Untreated amendments require a minimum application period of nine months if the produce is likely to contact the soil after application.[91] Amendments that have been physically or chemically treated to satisfaction, however, have no waiting period or minimum application period.[92] Regarding method of application, untreated biological soil amendments of animal origin must be applied in a manner that does not contact produce during application and minimizes the potential for contact with produce after application, in order to reduce contamination.[93] Satisfactorily treated biological soil amendments of animal origin, on the other hand, do not have any application restrictions and may come in

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[84] *Id.*
[85] *See* J.D. Brookes, J. Antenucci et al., *Fate and Transport of Pathogens in Lakes and Reservoirs*, 30 Environment International 741-759 (2004); J.A. Baumgartner, *Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions*, Wild Farm Alliance and Community Alliance for Family Farmers (2013), *available at* http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm.
[86] Produce Rule, 78 Fed. Reg. at 3,576-77 (§ 112.51).
[87] *Id.* at 3,577 (§ 112.52).
[88] *Id.* at 3,578 (§§ 112.54, 112.55).
[89] *Id.* at 3,578-79 (§ 112.54(a)-(c)).
[90] *Id.* at 3,581-84 (§ 112.56).
[91] *Id.* at 3,581 (§ 112.56(a)(1)).
[92] *Id.* at 3,581-82 (§§ 112.54(a), 112.56(a)(2)).
[93] *Id.* at 3,581 (§ 112.56(a)(1)).

contact with produce during growing and harvesting.[94] Again, farmers are likely to treat all or most biological soil amendments to avoid these limitations.

b. Preference for Treatment of Biological Soil Amendments of Animal Origin Creates Impacts to:

i. Land

FDA must take a hard look at the environmental impacts to land of a preference for treatment of biological soil amendments of animal origin. Biological soil amendments make a key contribution to healthy soil life, by providing a great diversity of microorganisms. Biologically active soils deliver plant nutrients more efficiently (thereby reducing or eliminating the need for synthetic fertilizers), reduce the risk of nutrient leaching or runoff, and make the soil less hospitable to foodborne pathogens.[95] Eliminating these microorganisms from soil amendments may negatively impact soil health.[96] FDA should consider the environmental impacts to land of imposing physical and chemical treatment processes on soil amendments, rather than allowing the use of untreated biological amendments.

ii. Air and Energy

FDA should take a hard look at environmental impacts to air and energy that result from a preference for treatment of biological soil amendments of animal origin. FDA should take a hard look at the energy expenditure required of the treatment process. FDA should also consider the air impacts that will result from the transportation required to obtain treated soil amendments. FDA acknowledges that conducting physical or chemical treatments onsite may be impracticable for many farms,[97] which may require farms to import treated amendments and export untreated amendments. FDA should therefore take a hard look at the air impacts of transportation emissions, due to increased imports and exports.

6. FDA Must Consider the Water, Land, Air, and Human Health Impacts Created by the Restrictions on Use of Raw Manure and Composting.

a. Restrictions on Use of Raw Manure and Composting

Certain provisions of the Rule discourage the use of raw manure as a soil amendment. The Rule's limitations on untreated biological soil amendments of animal origin essentially

[94] *Id.* at 3,581-82 (§§ 112.54(a), 112.56(a)(2)).
[95] For instance, the high populations and diversity of non-pathogenic microorganisms in soil managed organically with biological soil amendments may shorten survival of foodborne pathogens in soil. A.V. Semenov et al., *Estimating the Stability of Escherichia Coli O157:H7 Survival in Manure-Amended Soils with Different Management Histories*, 10 Envtl. Microbiol. 1450-59 (2008);
X.P. Jiang et al., *Fate of Escherichia Coli O157:H7 in Manure Amended Soil*, 68 Appl. Envtl. Microbiol. 2605-09 (2002); X.P. Jiang et at., *Fate of Listeria Monocytogenes in Bovine Manure-Amended Soil,* 67 J. Food Prot. 1676-81 (2004).
[96] J.D. van Elsas, P. Hill, et al., *Survival of Genetically Marked Escherichia coli O157 : H7 on Soil As Affected by Soil Microbial Community Shifts*, 1 Isme Journal 204-14 (2007).
[97] Produce Rule, 78 Fed. Reg. at 3,579 (§ 112.53)

prohibit farms from using raw manure for any period less than nine months before harvest, if the produce is likely to contact the soil after application.[98] FDA imposes this requirement because it finds "the use of raw manure at a time close to harvest, during organic or conventional production, presents a significant likelihood of contamination of covered produce if produce is reasonably likely to contact the soil."[99] In parts of the country, the nine-month waiting period will be longer than the growing season. To comply with the waiting period, farmers applying raw manure during a growing season will be forced to fallow the field for that entire growing season and harvest in the following year. The extended waiting period, even for farms with longer growing seasons, presents a serious impediment to the use of raw manure. The impediments of the waiting period are likely to discourage farmers from using raw manure as a soil amendment. *See further,* NSAC Rulemaking Comments at 69-71 (explaining the impacts of the Rule's restrictions on use of manure).

In addition, the Rule taken as a whole likely discourages farms from composting materials such as manure, table scraps,[100] and other materials of animal origin for use as soil amendments because it requires additional treatment measures. Because FDA does not consider composting alone to be a pathogen-elimination step,[101] the Rule requires additional treatment processes to be undertaken.[102] Under the Rule, material must be composted to at least 131 degrees Fahrenheit for a minimum of 3 days for a static aerated pile and a minimum of fifteen days for a turned pile, and then cured with proper insulation. After treatment, the compost must be applied to crops at least 45 days before harvest.[103] The treatment process and waiting period impose additional burdens on farmers using compost that will discourage the composting of manure or other material of animal origin. *See further,* NSAC Rulemaking Comments at 79-81 (explaining the impacts of the Rule's treatment and insulation requirements on the use of composting).

In addition, FDA's proposed standards for compost are misinformed and are likely to push farmers using compost toward sterilized soil amendments. As FDA acknowledges, composting is widely recognized as an effective process to kill pathogens and produce a hygienic product from waste. Indeed, a substantial body of scientific literature supports the pathogen-suppressing effects of the naturally occurring microbial communities in compost. *See generally,* NSAC Rulemaking Comments at 72-81 (explaining more fully the importance of biologically-active compost).

[98] Produce Rule, 78 Fed. Reg. at 3,581-82 (§ 112.56(a)(1)(i)).
[99] *Id.* at 3,574.
[100] The Rule classifies post-consumer waste, or table waste, such a plate scrapings, as "animal waste" for the purposes of the definition of biological soil amendments of animal origin. *Id.* at 3,574. Therefore, in order to be applied to produce, table scraps require the same level of treatment as biological soil amendments of animal origin, such as manure.
[101] *Id.* at 3,579-80 (§ 112.54(a)-(c)).
[102] *Id.* at 3,580 (§ 112.54(c)).
[103] *Id.* at 3,583 (§ 112.56(a)(4)(i)).

b. Restrictions on Use of Raw Manure and Composting Create Impacts to:

i. Water

FDA must take a hard look at the water impacts caused by the Rule's restrictions on use of raw manure and composting. Restrictions on the use of manure will likely cause an excess of animal waste that farmers may accumulate in manure stockpiles. Excess animal waste contaminates runoff and can degrade water resources, such as groundwater and surface water. Animal waste contains significant levels of phosphorus and nitrogen, which enter the water and contribute to low levels of dissolved oxygen and cause fish kills.[104] Decomposing organic matter in the water can contribute to toxic algae blooms.[105]

ii. Land

FDA must take a hard look at the land impacts caused by the Rule's restrictions on use of raw manure and composting. FDA must consider the impacts of decreased nutrient loads in soil and potential pathogen overload that may result from these restrictions.[106]

As described above, biological soil amendments such as manure contribute to healthy soil life by providing a great diversity of microorganisms. Biologically active soils deliver plant nutrients more efficiently and reduce the risk of nutrient leaching or runoff. Compost's suppressive capacity also helps to reduce plant pathogens in the following plants: beetroot, bean, apple, eggplant, cauliflower, and tomato.[107] Reducing the use of raw manure and compost in soil amendments may negatively impact soil health. FDA must take a hard look at the environmental impacts to land of restricting the use of raw manure and compost in soil amendments. For example, FDA must consider the likely increase in plant pathogens resulting from reduced use of compost.[108]

In addition, the restrictions on use of raw manure are likely to cause more accumulation of untreated or composted animal manure and poultry litter at or near livestock farms and at the sites of AFOs, including CAFOs and poultry houses. This accumulation will likely lead to greater nutrient and pathogen overloads in concentrated areas, and less input of manure at rates that would otherwise enhance soil fertility and quality over much larger areas of cropland.

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[104] *How Do CAFOs Impact the Environment?*, EPA Region 7, http://www.epa.gov/region07/water/cafo/cafo_impact_environment.htm (last accessed Oct. 24, 2013).
[105] *Id.*
[106] *See* A.V. Semenov et al., *Estimating the Stability of Escherichia Coli O157:H7 Survival in Manure-Amended Soils with Different Management Histories*, 10 Envtl. Microbiol. 1450-59 (2008); X.P. Jiang et al., *Fate of Escherichia Coli O157:H7 in Manure Amended Soil*, 68 Appl. Envtl. Microbiol. 2605-09 (2002); X.P. Jiang et at., *Fate of Listeria Monocytogenes in Bovine Manure-Amended Soil,* 67 J. Food Prot. 1676-81 (2004).
[107] V. Stan et al., *Waste Recycling and Compost Benefits*, 37 Notulae Botanicae Horti Agrobotanici Cluj-Napoca (2009)
[108] H.A.J. Hoitink and M.E. Grebus, *Status of Biological Control of Plant Disease With Composts*, 2 Compost Sci. and Utilization 6-12 (1994); M. Pugliese, B.P. Liu, et al., *Microbial Enrichment of Compost With Biological Control Agents to Enhance Suppressiveness to Four Soil-Borne Diseases in Greenhouse*, 118 J. Plant Diseases and Prot. 45-50 (2011).

iii. Air and Energy

FDA must take a hard look at the air and energy impacts caused by the Rule's restrictions on use of raw manure and composting. This restriction likely creates excess manure and food scraps because smaller quantities of those biological materials will be composted for crop application. The impacts from this preference may include air emissions caused by anaerobic decay of large concentrations of these wastes. The impacts also likely include increased transportation emissions, because farmers will need to dispose of manure, bedding materials, and table scraps offsite that otherwise would have been composted onsite and applied to crops. Increased transportation emissions may also result if farmers import fertilizer or soil amendments, instead of using a ready-source of composted material. Transporting compost could have greater transportation impacts than transporting synthetic fertilizer. Additional impacts may include increased air pollution, due to stockpiles of unused manure that otherwise would have been composted and applied to crops.

iv. Human Health

FDA must take a hard look at the human health impacts caused the restrictions on composting. Excess animal waste, due to limitations on composting, may create impacts such as an increase in chronic and acute health conditions, due to the air and water pollution that results from excess manure stockpiles. This accumulation of waste will also likely increase human exposure to foodborne pathogens. Also, reduced inputs of raw manure and compost due to the Rule's restrictions will lower microbial diversity in the soil and will likely increase pathogen survival.[109] Farmworkers may encounter these pathogens directly on the farm.

7. FDA Must Consider the Water, Land, Air, Animal, and Human Health Impacts Created by the Preference for Conventional Growing Methods.

a. Preference for Conventional Growing Methods

The soil amendment preferences, in aggregate, create a preference for farmers to grow produce using conventional methods, as opposed to using more sustainable methods,[110] including but not limited to growing according to USDA National Organic Program standards. The legislation authorizing the proposed Rule, however, prohibits FDA from creating any provisions that directly conflict with the National Organic Program[111] and accordingly, FDA "tentatively"

[109] Microbial diversity helps to reduce pathogen survival. Non-pathogenic beneficial microbes usually prevail if diverse populations are present, by outcompeting the pathogens for food, water, and space by killing and consuming the pathogens, and by generally making conditions unfavorable to the pathogens. *See* J.A. Baumgartner, *Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions*, Wild Farm Alliance and Community Alliance for Family Farmers (2013), *available at* http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm.

[110] While this section discusses organic methods, the preferences and implications discussed apply much more broadly to other sustainable growing methods as well.

[111] "[I]n the case of production that is certified organic, [the proposed rulemaking shall] not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990, while providing the same level of public health

concludes that compliance with the Rule will not preclude compliance with organic certification.[112] In practice, however, the Rule may create a preference for conventional growing due to its restrictions on raw manure and compost application, and the Rule's corresponding preference for synthetic fertilizers. These preferences will severely compromise the ability of certified organic producers to comply with the National Organic Program regulations.

As discussed above, the Rule prohibits the application of raw manure to crops where the produce is likely to contact the soil after application, for any period less than nine months (270 days) before harvest.[113] The National Organic Program, however, sets the minimum threshold for application of raw manure at only 120 days before harvest, if application will contact the edible portion of crops, or 90 days before harvest if the edible portions will not contact the soil.[114] Regarding composting, the proposed Rule requires a 45-day waiting period after application of compost.[115] In contrast, the National Organic Program regulations do not set a minimum waiting period for the application of manure treated by a composting process.[116]

The Rule restricts practices that sustainable and organic farmers rely upon for soil, nutrient, fertility, and pest management. Namely, the extended waiting periods imposed by the Rule may completely deter the application of manure and compost to cropland, and will at least deter application at appropriate rates and consistent with good nutrient management. For instance, farmers who use manure and observe the nine-month interval between application of raw manure and harvest will realize a lower efficiency of nutrient capture and utilization by the crop than would be realized with the 120-day interval currently required by the National Organic Program. Yet, the application of biologically based fertilizers such as manure and compost are foundational practices in sustainable and organic farming. In addition, the proposed intervals will significantly limit the ability of organic farmers to rotate crops as part of preventive pest and disease control, which will conflict with the National Organic Program's requirements of crop rotation or biological diversity.[117] These restrictions imposed by the Rule are likely to make it more difficult for farmers to grow produce using organic methods. *See generally,* NSAC Rulemaking Comments at 68-89 (explaining in more detail the Rule's conflicts with soil amendment practices of organic methods), and at 97-98 (explaining in more detail the Rule's conflicts with the conservation practices of organic production).

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protection as the requirements under guidance documents, including guidance documents regarding action levels, and regulations under the FDA Food Safety Modernization Act." 21 U.S.C.A. § 350h(a)(3)(E).

[112] Produce Rule, 78 Fed. Reg. at 3,519, 3,574.

[113] *Id.* at 3,581-82 (§ 112.56(a)(1)(i)).

[114] 7 C.F.R. § 205.203(c)(1).

[115] Produce Rule, 78 Fed. Reg. at 3,583 (§112.54).

[116] 7 C.F.R. § 205.203(c)(2).

[117] *See* 7 C.F.R. § 205.205. The National Organic Program natural resources standard requires organic farmers to maintain or improve the natural resources of their operation, including soil, water, wetlands, woodlands, and wildlife. The definition of organic production includes biodiversity conservation, and the rotation standard requires that perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation, to assist with pest control. Failure to implement crop rotation as part of a preventive pest management program will force organic producers out of compliance with current USDA organic regulations and may prompt organic certifiers to pursue adverse action.

Farmers need to use fertilizer to grow crops and the burdens on use of manure and compost may require more farmers to rely on synthetic fertilizer out of necessity. However, synthetic fertilizers are not permitted in organic growing methods. As such, the extended waiting periods will interfere with the organic practices of farmers that currently grow according to the standards of the National Organic Program. As a result, some farmers may be pushed to adopt conventional growing methods and to abandon the National Organic Program altogether. *See further,* NSAC Rulemaking Comments at 81-84.

b. Preference for Conventional Growing Methods Create Impacts to:

i. Water

FDA must take a hard look at the environmental impacts to water caused by a preference for conventional growing methods and a tension with the National Organic Program. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides, synthetic fertilizer, and chemical treatment of agricultural water.[118] Pesticides and synthetic fertilizers both accumulate in agricultural runoff. The environmental impacts from agricultural runoff containing pesticides and excessive nitrate and phosphate include direct harm to aquatic life and the generation of algae blooms, resulting in reduced levels of dissolved oxygen as well as release of toxins harmful to other life forms. Impacts to water from chemical water treatment may include decreased water quality, disrupted ecosystems, and damage to aquatic life.

ii. Land

FDA must take a hard look at the environmental impacts to land caused by a preference for conventional growing methods and a tension with the National Organic Program. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides and synthetic fertilizer. Impacts likely include decreased soil fertility, decreased biodiversity above and below ground, increased soil compaction, and increased erosion. The reduction in organic inputs to the soil will further degrade soil quality and leave the soil more erodible. For instance, organic practices, such as use of biological soil amendments, provide a great diversity of microorganisms in soil and contribute to healthy soil life.[119] Soils under long-term organic management have improved physical, chemical, and biological properties.[120] In addition, organic practices may reduce foodborne pathogens.[121] Eliminating these microorganisms from soil amendments may negatively impact soil health.

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[118] *See also* Section II.B.1.b. of these comments for the environmental impacts that are likely to accrue from an increase in the chemical treatment of agricultural water.

[119] *See* Section II.B.5.b.i. and II.B.6.b.ii of these comments for the environmental impacts to land that are likely to accrue from restrictions on the use of untreated biological soil amendments, such as raw manure.

[120] C. Kremen, A. Miles, *Ecosystem Services in Biologically Diversified Versus Conventional Farming Systems: Benefits, Externalities, and Trade-Offs*, 17 Ecology and Soc'y (2012).

[121] A.V. Semenov et al., *Estimating the Stability of Escherichia Coli O157:H7 Survival in Manure-Amended Soils with Different Management Histories*, 10 Envtl. Microbiol. 1450-59 (2008); X.P. Jiang et al., *Fate of Escherichia Coli O157:H7 in Manure Amended Soil*, Appl. Envtl. Microbiol. 68:2605-2609 (2002); X.P. Jiang et at., *Fate of Listeria Monocytogenes in Bovine Manure-Amended Soil,* 67 J. Food Prot. 1676-81 (2004).

FDA should consider the environmental impacts to land of discouraging organic practices that incorporate biological soil amendments.

iii. Air and Energy

FDA must take a hard look at the air and energy impacts of a preference for conventional methods. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides and synthetic fertilizer. Impacts may include additional air emissions and energy expenditure to produce synthetic fertilizers and petroleum-based pesticides, as well as increased nitrous oxide emissions from soils amended with synthetic nitrogen fertilizer. In addition, lower soil quality can lead to increased wind erosion and associated airborne particulates.

iv. Animals

FDA must take a hard look at the impacts to animals of a preference for conventional methods. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides and synthetic fertilizer. Pesticides and synthetic fertilizers both accumulate in agricultural runoff, where they may generate algae blooms, disrupt ecosystems, and damage aquatic life. Some pesticides are also harmful to terrestrial wildlife and bird populations. Lower soil quality resulting from reduced organic inputs can also compromise livestock health.

v. Human Health

FDA must take a hard look at the human health impacts of a preference for conventional methods. A shift away from organic growing practices in favor of conventional growing practices will likely produce greater use of pesticides and synthetic fertilizer. Impacts may include health problems resulting from pesticide exposure of farmworkers and those who consume produce. Negative health effects may include neurologic, endocrine, and psychological problems, cancer, and other diseases. Nitrate in drinking water from agricultural runoff is another threat to human health. Finally, reduced use of organic soil amendments will result in reduced soil microbial diversity and biological activity, and thereby may prolong the half-life of foodborne pathogens in soil.

8. FDA Must Consider the Land and Air Impacts Created by the Preference for Use of New Packing Materials.

a. Preference for Use of New Packing Materials

The Rule creates a preference for farmers to use new packing materials, rather than recycling and using reusable packaging. The Rule requires operations to either use new packing materials or ensure that reusable packaging is clean and sanitized, in order to harvest and transport produce.[122] Farming operations may use new packing materials in order to avoid the requirements imposed on reusable packing materials.

[122] Produce Rule, 78 Fed. Reg. at 3,589 (§ 112.116).

b. Preference for Use of New Packing Materials Creates Impacts to:

i. Land

FDA must take a hard look at the land impacts caused by a preference for new packing materials over reused or recycled packing materials. Such a preference will likely lead to an increased consumption of new materials, shorter useful life of packing materials, and additional waste. Therefore, the impacts may include a greater use of landfills, due to increased disposal of packaging materials.

ii. Air and Energy

FDA must take a hard look at the air and energy impacts caused by a preference for new packing materials over reused or recycled packing materials. Such a preference will likely lead to an increased consumption of new materials, shorter useful life of packing materials, and additional waste. The increased manufacturing of new packing materials will likely produce air impacts, in the form of increased emissions. Impacts may also include increased air emissions due to the need to transport and dispose of more packing materials.

9. FDA Must Consider the Water, Land, Air, Animal, and Human Health Impacts Created by the Preference for Domestic Animal Confinement.

a. Preference for Domestic Animal Confinement

The Rule, taken as a whole, creates a preference for animal confinement because the Rule places restrictions on domestic animal grazing in produce fields and domestic animal contact with agricultural water sources. If animals are allowed to graze in fields where produce is grown and there is a reasonable probability that grazing will contaminate the produce, farmers must use a waiting period between grazing and harvest.[123] Therefore, if domestic animals are allowed to graze in produce fields, crop harvesting will be delayed for a period of time. FDA provides that the agency "would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval [proposed] for use of raw manure as a soil amendment."[124] FDA thereby implies that feces left from grazing animals is of similar risk as manure applications, which require a nine-month interval. *See further*, NSAC Rulemaking Comments at 98-99. The Rule also requires famers to keep all agricultural water sources free from domestic animals.[125]

FDA claims that these requirements will not impact the environment because the Produce Rule does not expressly prohibit grazing by domesticated animals.[126] However, the requirement for an "adequate" waiting period—which FDA implies is nine months—will likely create pressure for farmers to prevent (or at least reduce) domesticated animals from grazing and will impact the environment by compelling farmers to find alternative ways to feed domesticated animals, including purchasing livestock feed.[127] Further, if farmers do not allow animals to

[123] *Id.* at 3,587 (§ 112.82).
[124] *Id.*
[125] *Id.* at 3,565 (§ 112.42(b)).
[126] *Id.* at 3,586.
[127] *See* Don Ball et al., Grazing Lands Conservation Initiative, *Extending Grazing and Reducing Stored*

graze, they may feed livestock in CAFOs. Confinement is likely to be a solution that some farmers adopt to separate domestic animals and agricultural water sources, and to prevent animals grazing in crop fields. The restrictions on domestic animals, therefore, create a preference for animal confinement, which farmers may deem to be an attractive alternative to otherwise burdensome limitations.

Despite FDA's claims that the requirements do not prohibit grazing, FDA is required to consider in its EIS all impacts that are not "remote and speculative." So, even if some farmers may not increase confinement of domestic animals, if it is reasonable to conclude that some may, then consideration of the environmental impacts of taking such measures is required.

b. Preference for Domestic Animal Confinement Creates Impacts to:

i. Water

FDA must take a hard look at the water impacts caused by a preference for domestic animal confinement over pastured practices. Confined animals living on CAFOs produce tremendous amounts of concentrated waste. Excess animal waste contaminates runoff and can degrade water resources, such as groundwater and surface water. Animal waste contains significant levels of phosphorus and nitrogen, which enter the water and contribute to low levels of dissolved oxygen, cause fish kills,[128] and contribute to toxic algae blooms.[129] Severe weather events can aggravate these problems by causing spillage of animal waste from CAFO manure lagoons. For example, in 1999, flooding by Hurricane Floyd resulted in catastrophic regional water contamination and livestock deaths throughout the tidewater region of North Carolina.[130] In addition to the waste issue, CAFOs require a significant amount of water for operation. Therefore, the preference may create additional water impacts, such as increased pollution and a strained water supply.

ii. Land

FDA must take a hard look at the land impacts caused by a preference for domestic animal confinement over pastured practices. These impacts may include deforestation and habitat destruction for animal grazing, raising feed crops, and soil erosion from conversion of pasture or prairie to row crops for feed grain production. Impacts may also include increased soil contamination if chemicals and pathogens are deposited on land in the vicinity of CAFOs. The enormous amount of animal waste generated by CAFOs is also likely to cause impacts.[131]

Feed Needs 1 (2008), *available at* http://agebb.missouri.edu/mfgc/2009extgraz.pdf (explaining that, as farmers are able to use grazing less, they rely more on livestock feeds).

[128] *How Do CAFOs Impact the Environment?,* EPA Region 7, http://www.epa.gov/region07/water/cafo/cafo_impact_environment.htm (last accessed Oct. 24, 2013).

[129] *Id.*

[130] *See* S. Wing et al., *The Potential Impact of Flooding on Confined Animal Feeding Operations in Eastern North Carolina*, 110 Envtl. Health Perspect. 387-91 (2002) (explaining the potential impact of flooding on confined animal feeding operations in eastern North Carolina).

[131] *See* section II.B.6.b.iv. of this document.

Moreover, farmers typically apply animal waste to fields, as manure. FDA should consider the land impacts due to stockpiles of animal manure that can no longer be composted or land-applied. The Rule itself contemplates animal excreta and requires farmers to locate manure piles away from locations where covered produce is grown or packaged.[132] However, when farmers allow manure on CAFOs to accumulate, the manure can contribute to the growth of dangerous organisms like Pfiesteria piscicida.[133] One way to more effectively manage manure in CAFOs is to compost and sell the manure, but as discussed above, the Produce Rule discourages composting.

iii. Air and Energy

FDA must take a hard look at the air and energy impacts caused by a preference for domestic animal confinement over pastured practices. These impacts may include increased air emissions due to the need to produce and import livestock feed and the need to transport away and dispose of animal waste. Impacts may also include air emissions resulting from the production of the petroleum-based pesticides used to grow additional livestock feed. The effects of transporting these crops to farms across the country are also likely to produce emissions. Finally, impacts are likely to include air pollution due to toxic releases from CAFOs, such as methane emissions, hydrogen sulfide, ammonia, and pathogen-laden dust.

iv. Animals

FDA must take a hard look at the impacts to animals caused by a preference for domestic animal confinement over pastured practices. These impacts may include restricting animals to a grain-fed diet, poor sanitation and disease, and the inability to express natural animal behaviors. Impacts may also include harm to aquatic life. Agricultural runoff containing phosphorus and nitrogen from animal waste may deplete oxygen levels in water and lead to fish kills.

v. Human Health

FDA must take a hard look at the human health impacts caused by a preference for domestic animal confinement over pastured practices, including:

- Human disease that is more virulent and difficult to treat, due to an increase in antibiotic-resistant bacteria and the transmission of pathogens from domestic animals to humans;[134]
- The transmission of antibiotic-resistant genes to soil bacteria where food is grown;[135]
- Increased respiratory problems and lung disease among farmworkers and neighbors due to dust and odors generated by CAFOs;[136]

[132] Produce Rule, 78 Fed. Reg. at 3,594 (§ 112.134).
[133] *See* Michael A. Mallin, Lawrence B. Cahoon, *Industrialized Animal Production—A Major Source of Nutrient and Microbial Pollution to Aquatic Ecosystems*, 24 Population & Env't 369, 378–79 (2003).
[134] Mary Gilchrist et al., *The Potential Role of Concentrated Animal Feeding Operations in Infectious Disease Epidemics and Antibiotic Resistance*, 115 Envtl. Health Perspectives 313 (2007).
[135] S. Jechalke, C. Kopmann, et al., *Increased Abundance and Transferability of Resistance Genes After Field Application of Manure From Sulfadiazine-Treated Pigs*, 79 Appl. Envtl. Microbiol. 1704-11 (2013).
[136] *How Do CAFOs Impact the Environment?,* EPA Region 7, http://www.epa.gov/region07/water/cafo/cafo_impact_environment.htm (last accessed Oct. 24, 2013).

- Increased incidence of heart disease, diabetes, and other degenerative diseases animals from increased consumption of CAFO-raised meat. Meat from animals raised in CAFOs likely have a less healthful balance of fatty acids than meat from grass-fed animals;
- Increased exposure of humans to pathogens for three reasons. First, pathogen survival increases with a field history of artificial fertilizer compared with manure and compost.[137] Second, a USDA comprehensive review indicates that *E. coli* is higher in cattle that are fed grain diets in CAFOs.[138] Third, more people encountering wastes and pathogens in their drinking water due to contamination of water resources.

10. FDA Must Consider the Land, Animal, and Human Health Impacts Created by the Preference for Wild Animal Exclusion.

a. Preference for Wild Animal Exclusion

The Rule, taken as a whole, creates a preference for farmers to exclude wild animals from outdoor growing areas because farmers may be unable to harvest affected produce where wild animal intrusion occurs and because it fails to protect conservation practices. The Rule requires farmers to monitor areas for animal intrusion and if intrusion occurs, evaluate whether produce can be harvested.[139] FDA's provisions for animal monitoring are triggered when the circumstances of the farm suggest it to be necessary (i.e., when animal excreta or other evidence of animal intrusion is present). FDA states that this provision "should not be construed to require the 'taking' of an endangered species, as the term is defined in the [ESA]" or to require farms to take measures to exclude animals from outdoor growing areas or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.[140]

To avoid the animal monitoring requirements of the Rule, farmers are likely to take actions that prevent animal intrusion, such as destroying habitat and clearing farm borders. These measures are likely to conflict with conservation efforts and the USDA Natural Resources Conservation Service's (NRCS) Conservation Practice Standards.[141] Farmers experiencing

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[137] E. Franz, A. V. Semenov et al., *Manure-Amended Soil Characteristics Affecting the Survival of E-Coli O157 : H7 In 36 Dutch Soils*, 10 Envtl. Microbiol. 313-27 (2008).
[138] *Id.*
[139] Produce Rule, 78 Fed. Reg. at 3,587 (§ 112.83).
[140] *Id.* at 3,587 (§ 112.83).
[141] *See* Natural Resources Conservation Service, Constructed Wetlands (#656); Wetland Restoration (#657); Wetland Creations (#658); Wetland Enhancement (#659); Fencing (#382) Prescribed Grazing (#528); Stream Habitat Improvement and Management (#395); Mulching (#484); Animal Trails and Walkways (#575); Restoration and Management of Rare and Declining Habitats (#643); Wetland Wildlife Habitat Management (#644); Upland Wildlife Habitat Management (#645); Shallow Water Development and Management (#646); Tailwater Recovery System (#447); Tillage Management Practices (#329, 344, 345, 346); Roof Runoff Structure (#558); Well Water Testing (#355); Monitoring Well (#353); and Integrated Pest Management (#595) *available at* http://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/national/technical/?cid=nrcs143_026849; *See also* J.A. Baumgartner, *Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions*, Wild Farm Alliance and Community Alliance for Family Farmers, http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm (2013) (depicting many conservation practices NRCS provides).

significant intrusion of wild animals may take control measures that exclude or destroy *all* wild animals and their habitat, instead of only excluding those pest animals. Therefore, the monitoring requirements and threats to harvest create a preference for animal exclusion, which farmers may regard as preferable to monitoring. *See generally,* NSAC Rulemaking Comments at 90-98 (for more detailed discussion of wild animal exclusion).

Food safety policy and market changes may intensify habitat destruction and the loss of participation in conservation efforts.[142] Some farmers may be pressured to adopt these measures in response to purchasers and third-party auditors requiring habitat destruction. Purchasers that do not require habitat destruction may refrain from purchasing produce grown within hundreds of feet of wildlife habitat or conservation plantings. This practice, which currently occurs in the Salinas Valley, may further encourage farmers to destroy habitat. Personal interviews conducted with growers after the spinach contamination indicate that, in many cases, growers face serious ethical dilemmas and feel pressured by large processing and retail firms to adopt measures they find environmentally destructive and unethical.[143]

Despite FDA's claims that the Rule does not require farmers to take animal exclusion measures, FDA is required to consider in its EIS all impacts that are not "remote and speculative." So, even if some farmers may not take these measures, if it is reasonable to conclude that some may, then consideration of the environmental impacts of taking such measures is required.

b. Preference for Wild Animal Exclusion Creates Impacts to:

i. Land

FDA must take a hard look at the land impacts caused by a preference for wild animal exclusion. In the past, farmers have reacted to similar food safety requirements by taking measures that threaten habitat and wild animal populations. For example, a 2007 survey conducted by the Resource Conservation District of Monterey County in California's Central Coast region found that 89% of surveyed growers had adopted at least one measure to actively discourage or eliminate wild animal intrusion because of food safety concerns.[144] Examples of these measures include: removal of non-crop vegetation, elimination of conservation practices, bare ground buffers, fencing, trapping, poison bait traps, hunting, removal of water bodies, changing crop types, and changing crop locations. Farmers reported that some of their efforts resulted in the clearing of vegetation along stream corridors and other water bodies. These reports were corroborated by an aerial photography study of the Central Coast region conducted by the Nature Conservancy, which identified areas where habitats adjacent to water bodies were

[142] *See* D. Stuart and S. Gillon, *Scaling Up to Address New Challenges to Conservation on U.S. Farmland*, 31 Land Use Policy 223-36 (2013).
[143] D. Stuart, *Constrained Choice and Ethical Dilemmas in Land Management: Environmental Quality and Food Safety in California Agriculture*, 22 J. Agric. & Envtl. Ethics 53-71 (2009).
[144] Resource Conservation District of Monterey County, *A Grower's Survey: Reconciling Food Safety and Environmental Protection* (2007); M. Beretti, and D. Stuart, *Food Safety and Environmental Quality Impose Conflicting Demands on Central Coast Growers*, 62 California Agriculture 68-73 (2008); The Nature Conservancy, *Comments for FDA Docket (FDA-2010-N-0085)*, at 10 (July 23, 2010).

replaced by bare or sparsely vegetated ground. It is likely that farmers will engage in these measures in response to the Produce Rule.

Removing non-crop vegetation may create significant impacts to the environment, due to destruction of flora and fauna.[145] For instance, if non-crop vegetation is replaced with bare ground or crop vegetation not equivalent to the original non-crop vegetation, physical changes to the soil could occur, including increased erosion.[146] The removal of non-crop vegetation may also increase nutrient runoff, decrease soil fertility, and attract pests.[147] In addition, bare ground has been found to facilitate the movement of pathogenic organisms into nearby waterways[148] and certain vegetative buffers have been shown to reduce certain pathogens by at least 95 percent.[149]

ii. Animals

FDA must take a hard look at the impacts to animals caused by a preference for wild animal exclusion. Farmers taking wild animal exclusion measures will likely harm wild animals (including endangered animals) through the use of traps, poisoning, and hunting.[150] In addition, the fencing of fields may eliminate wild animal habitat to the extent that wild animals directly utilize fields for food, shelter, and breeding and are unable to do so after the imposition of fencing. Fencing may also indirectly eliminate wild animal habitat by restricting movement.[151] The removal of non-crop vegetation and the creation of bare ground buffers may have a similar effect on wild animal habitat by directly eliminating opportunities for food, shelter, and breeding and indirectly limiting the movement of species that need non-crop vegetation to travel.[152] These

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[145] *See* Robert J. Naiman et al., *The Role of Riparian Corridors in Maintaining Regional Biodiversity*, 3 Ecological Applications 209 (1993).
[146] *See* Kevin D. Reid et al., *Runoff and Erosion in a Piñion-Juniper Woodland: Influence of Vegetation Patches*, 63 Soil Sci. Soc'y of Am. J. 1869, 1876 (1999) (finding distinct runoff and erosion properties for different vegetative and bare ground patches).
[147] *See generally* Wei Zhang et al., *Ecosystem Services and Dis-services to Agriculture*, 64 Ecological Econ. 253, 255 (2007) (describing the use of non-crop vegetation in increasing soil fertility and in pest control). Many farmers use non-crop vegetation to improve soil fertility and to attract pests away from crops, or grow complementary crops to enhance crop yields. *See* David Tillman, *Global Environmental Impacts of Agricultural Expansion: The Need for Sustainable and Efficient Practices*, 96 Proc. Nat'l Acad. Sci. 5995, 5999 (1999) (explaining the positive effect of species diversity on agricultural productivity).
[148] *Food Safety Considerations for Conservation Planner: A Field Guide for Practitioners,* Resource Conservation District of Monterey County (2009), www.rcdmonterey.org.
[149] Gerald M. Sapers et al., *The Produce Contamination Problem: Causes and Solutions,* Academic Press 87 (2009); Kenneth W. Tate et al., *Significant Escherichia Coli Attenuation by Vegetative Buffers on Annual Grasslands*, 35 J. Envtl. Quality (2006): doi10.2134/jeg2005.0141.
[150] The Nature Conservancy, *Comments for FDA Docket (FDA-2010-N-0085)*, at 11 (July 23, 2010) (indicating that some farmers engaged in hunting and shooting, used poison to kill rodents, and trapped wildlife out of concern for food safety).
[151] *See* David K. Person & David H. Hirth, *Home Range And Habitat Use of Coyotes in a Farm Region of Vermont*, 55 J. Wildlife Mgmt. 433, 437 (1991) (finding seasonal use of open agricultural land by coyotes).
[152] *See* David N. Cherney, *Securing the Free Movement of Wildlife: Lessons from the American West's Longest Land Mammal Migration*, 41 Envtl. L. 599, 603 (2011) (discussing problems encountered by some migratory land animals due to fencing).

actions may have a disproportionate effect on wild animals that utilize riparian land.[153] In addition, substantial food safety management changes may impact regional water quality and the wildlife that depends upon it.[154] Because farmers have reported that conserving a wildlife corridor "dramatically reduced the pressure from wildlife—especially deer," on the crop, the destruction of wildlife corridors may increase contamination of produce by wildlife.

iii. Human Health

FDA must take a hard look at the human health impacts caused by a preference for wild animal exclusion. The impacts of clear-cutting or destruction of habitat may have negative public health effects. For instance, conservation buffers that serve as habitat can help with water purification,[155] flood control,[156] more available water, and the plentiful supply of food due to good pollination.[157] Vegetation[158] and grasses,[159] wetlands,[160] and windbreaks[161] can also reduce

[153] *See* Andrew F. Bennett et al., *Corridor Use and the Elements of Corridor Quality: Chipmunks and Fencerows in a Farmland Mosaic*, 68 Biological Conservation 155, 155 (1993) (finding the use of wooded fencerows adjacent to agricultural land by chipmunks for both residential habitat and movement corridors but identifying no such use for grassy land adjacent to agricultural land).
[154] D. Stuart, *Coastal Ecosystems and Agricultural Land Use: New Challenges on California's Central Coast*, 38 Coastal Management 42-64 (2010).
[155] Koelsch et al., *Vegetative Treatment Systems for Management of Open Lot Runoff: Review of Literature*, 22 Applied Engineering In Agriculture 141-153 (2006).
[156] Richard Lowrance et al., *Water Quality Functions of Riparian Forest Buffers in Chesapeake Bay Watersheds*, 21 Envtl. Mgmt 687-712 (1997).
[157] A. Brittain Klein, A et al., *Wild Pollination Services to California Almond Rely on Semi-Natural Habitat*, 49 J. Applied Ecology 723-732 (2012).
[158] Vegetation can help reduce the movement of pathogens across the farm by filtering pathogens, increasing infiltration of water into the soil, and serving as a structure for biological competition to take place. J.A. Baumgartner, *Farmer's Guide to Food Safety and Conservation: Facts, Tips, and Frequently Asked Questions*, Wild Farm Alliance and Community Alliance for Family Farmers (2013), *available at* http://www.wildfarmalliance.org/resources/FS_Facts_Tip_FAQ.htm.
[159] Grasses and other types of vegetative buffers filter pathogens in runoff before they reach a pond or stream. The vegetation also slows surface water flow and allows for increased infiltration rates. Tate et al., *Significant Escherichia Coli Attenuation by Begetative Buffers on Annual Grassland*, 35 J. Envtl. Quality 795-805 (2006).
[160] Wetlands decrease pathogen levels due to increased oxygen levels in the water, antagonistic root exudates, and by fostering antagonism in biofilms. These processes that act to reduce pathogens in water work best when the water has a long residence time—it moves slowly through the vegetation—a proper hydraulic loading rate—the volume of water flowing through is suited to the size of the planted vegetation, and appropriate settling rates of suspended sediments. Hench et al., *Fate of Physical, Chemical and Microbial Contaminants in Domestic Wastewater Following Treatment by Small Constructed Wetlands*, 37 Water Research. 921-27 (2003); Diaz et al., *Efficacy of Constructed Wetlands for Removal of Bacterial Contamination From Agricultural Return Flows*, 97 Agric. Water Mgmt. 1813-21 (2012); Knox et al., *Efficacy of Natural Wetlands to Retain Nutrient, Sediment And Microbial Pollutants* 37 J. Envtl. Quality 1837-46 (2008).
[161] Windbreaks can intercept dust that may be carrying pathogens. When dust trapped on the leaves of a windbreak is exposed to sunlight and other desiccation effects, they help to destroy pathogens. H.K. Burley et al., *The Potential of Vegetative Buffers to Reduce Dust and Respiratory Virus Transmission From Commercial Poultry Farms*, 20 J. Appl. Poultry Research 210-22 (2011).

human exposure to pathogens.[162] The destruction of conservation buffers eliminates these beneficial public health functions.

11. FDA Must Consider the Animal Impacts of the Rule's Pest Control Requirements.

FDA must take a hard look at the animal impacts that result from the Rule, on its face, related to pest control. The Rule requires farmers to monitor for and exclude pests from fully-enclosed buildings, and prevent them from becoming established in partially-enclosed buildings.[163] This requirement may lead farmers to use pesticides or rodenticides to prevent animal intrusion. First and second generation rodenticides are typically used exclusively as control agents around structures, often having side effects of poisoning predatory wildlife. Of the 492 California non-target animals analyzed between 1995 and 2011, approximately 75% had residues of one or more rodenticide, and the overwhelming majority were from at least one second generation anticoagulant rodenticide.[164] Many species of raptors and four-footed predators have died, including the endangered San Joaquin kit fox,[165] the California fisher (a candidate for listing under the federal Endangered Species Act),[166] and the protected mountain lion. FDA must take a hard look at the impact of these pest-control requirements on wildlife, and potentially endangered or threatened species.

12. FDA Must Consider the Human Health Impacts of the Rule as a Whole.

FDA must take a hard look at the human health impacts of the Rule, taken as a whole. For instance, FDA should consider generally the Rule's impacts to food security or availability of fresh produce and the relationship to human health. By FDA's own admission, implementation of the Produce Rule as currently proposed will likely discourage the entry of new farmers into production, and will likely slow the growth of local food systems. Independent analysis and farmer testimony indicate that some current producers of vegetables, fruits, and value-added products would go out of business. This will likely reduce the availability of fresh produce to consumers, especially low income and senior citizens, and those who live in historically underserved areas (e.g., food deserts). Reduced consumption of fresh produce may aggravate the epidemics of childhood obesity, degenerative disease of elders, and type-2 diabetes at all ages. These effects may disproportionately impact the food-insecure. Thus, any regulation that makes it harder for farmers and food entrepreneurs to provide fresh produce and quality value-added foods will adversely impact the public health.

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[162] Rodent control efforts that potentially reduce biodiversity may also increase pathogen exposure. *See* C. Kilonzo et al., *Fecal Shedding of Zoonotic Food-Borne Pathogens by Wild Rodents in a Major Agricultural Region of the Central California Coast*, 79 Appl. Envtl. Microbiol. 6337-44 (2013).
[163] Produce Rule, 78 Fed. Reg. at 3,592 (§ 112.128).
[164] D. Daniels, *Second Generation Anticoagulant Rodenticides Memorandum*, Calif. Dept. of Pesticide Regulation (Sep. 19, 2012).
[165] S. McMillin *Anticoagulant Rodenticides: Secondary Poisoning of Wildlife in California*, California Department of Fish and Game, Powerpoint presentation (2012).
[166] M.W. Gabriel et al,, *Anticoagulant Rodenticides on our Public and Community Lands: Spatial Distribution of Exposure and Poisoning of a Rare Forest Carnivore*, 7 PLoS ONE: e40163. doi:10.1371/journal.pone.0040163 (2012).

In addition, FDA should consider the human health impacts from air pollution emissions generated by the additional energy expenditure that the Rule promotes (e.g., energy expenditure for soil amendment treatment). Similarly, FDA should consider the human health impacts from air pollution generated by the additional transportation that the Rule promotes (e.g., transportation of synthetic fertilizers).

C. FDA MUST CONSIDER CUMULATIVE IMPACTS IN THE EIS.

FDA must take a hard look at the cumulative impacts of the Rule to the environment in its EIS. The cumulative impacts of the Rule include the direct and indirect impacts of the Rule to the environment together with impacts caused by other agencies' actions, FDA's other pending actions, and the actions of private individuals. FDA should place special consideration on the Rule's cumulative impact to impaired resources and endangered animals across different regions of the United States. The scope of this analysis is broad because the Rule impacts farms across the United States and internationally.

1. FDA Must Consider the Cumulative Impacts to Water, Land, Air, Animals, and Human Health.

FDA must take a hard look at reasonably foreseeable cumulative impacts of the Rule to water, land, air, animals, and human health in its EIS, together with impacts caused by the following:

- Pollution from point and nonpoint sources such as municipal wastewater discharges, industrial and agricultural storm water discharges, CAFOs, and industrial and agricultural runoff;
- Impacts to 303(d) impaired waters where discharges already exceed the waters' assimilative capacity to absorb pollution;
- Brownfield contamination, habitat destruction and deforestation, land degradation, soil contamination, and litter and waste disposal;
- Groundwater depletion;
- Climate change; and
- Impacts to endangered species across different regions of the United States.

2. FDA Must Consider the Preventive Controls Rule.

FDA must take a hard look at the cumulative impacts to water, land, air, animals, and human health from the Rule, together with impacts caused by implementation of its Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Rule (Preventive Controls Rule).[167] 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. *See further,* NSAC Preventive Controls Rulemaking Comments.[168]

[167] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3,646-01 (proposed Jan. 16, 2013) (to be codified at 21 CFR pts. 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211).
[168] NSAC's Preventive Controls Rulemaking Comments, submitted in Docket No. FDA-2011-N-0920, on Nov. 15, 2013.

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 impacts to greenhouse gas emissions from additional reliance on foods sourced more than 275 miles from the point of consumption.

FDA must consider the incremental 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 the additional environmental degradation imposed by the Produce Rule on top of any environmental impacts already imposed by the Preventive Controls Rule.

3. FDA Must Consider International Impacts.

FDA must take a hard look at the environmental impacts of foreign farms complying with the Produce Rule. The cumulative effects of foreign farms complying with the Produce Rule could be significant and potentially impact the United States as well as the global commons.

III. CONCLUSION

The Produce Rule will change farming practices across the United States and will necessarily have environmental impacts. Therefore, FDA must take a hard look at alternatives and mitigation measures to the proposed Rule in its EIS. Additionally, FDA must take a hard look at the direct, indirect, and cumulative impacts of the proposed Rule, as required by NEPA.