Food Safety Modernization Act
Sample Farmer Commenting Template

Make Your Voice Heard: Submit a Comment to FDA Today!

The Food and Drug Administration will accept comments submitted online or through the mail. You can use the sample materials below to get started! It is important to personalize your comment – FDA will read every single submission, and unique comments have the most impact.

> ***Step 1 –*** *Get informed and determine how you may be affected by the rules – some farmers and processors may be eligible for exemptions or modified requirements, but even if so, the rules could still impact you! http://sustainableagriculture.net/fsma/who-is-affected/*
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> ***Step 2*** *– Customize the comment below for yourself! There are guiding questions to help you tell your story effectively to FDA. Remember that there is more detailed information online about each of the 10 issues here: http://sustainableagriculture.net/fsma/learn-about-the-issues/. You can pick and choose – feel free to include in your comment letter whichever issues below are most important to you – all ten or just a few.*
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> ***Step 3*** *– Submit your comment in TWO places – to the Produce Rule (http://bit.ly/fsma-pr) and to the Preventive Controls Rule (http://bit.ly/fsma-pcr). This is important because these issues affect both rules. You can get extra help, along with instructions for using regulations.gov and for mailing a comment here: (http://sustainableagriculture.net/fsma/speak-out-today/).*
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> ***Step 4*** *– Take a stand publicly and sign our FSMA petition! (http://sustainableagriculture.net/fsma) You can also find materials online to share via social media like Facebook to help spread the word!*

Sample Farmer Comment

Re: Preventive Controls Rule: FDA-2011-N-0920, Produce Standards Rule: FDA-2011-N-0921

I am a ___ [farmer, entrepreneur, processor, parent…].
[Customize your comment with your story: What is the name and location of your farm? What do you grow? How long have you been in operation? Where do you sell your products and how do you already ensure their safety?]

I am writing because I am concerned about the impact that FDA's proposed FSMA rules will have on [my farm / business operation, the practices I use on my farm, other farmers in my community, the farms that I buy food from, etc…]. I ask you to ensure that new regulations do not put safe farms out of business, harm farmers' soil, water, and wildlife conservation efforts, or shut down the growth of local and regional healthy food systems!

Because of all of the specific issues described below, I urge FDA to publish a second round of draft rules for public comment before finalizing the produce safety and preventive controls regulations. I am specifically concerned about the following issues:

Comments Specific to the Proposed Produce Rule:

1. ***Issue: Manure and Compost –*** The Produce Rule directly conflicts with established federal organic standards around using manure and compost – making it effectively impossible for farmers to use manure and creating barriers to the use of compost.

[***Help FDA understand why this matters*:** *Do you use biological soil amendments of animal origin in your farming system? If yes, what kind? Will these requirements discourage you from using manure or compost that includes animal waste? If you are a certified organic farmer, how will these requirements conflict with year practices?*]

> ***Recommendation to FDA***: In the final produce safety regulations, FDA must align its standards for the use of manure and compost with the National Organic Program (NOP) regulations. Specifically:
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> a. The interval between application of untreated manure and harvest should be four months, not the nine months proposed by FDA.
> b. For compost, there should be no interval between application and harvest if the compost is treated consistently with NOP or similarly rigorous composting standards.
> c. To align with current best management practices, insulation of compost should not be required as part of an acceptable treatment process for compost.

2. ***Issue: Conservation Practices –*** The Produce Rule fails to protect and promote on-farm conservation practices that help protect our soil, water, and wildlife habitat and places arbitrary restrictions on integrating grazing animals into farm fields.

[Help FDA understand why this matters: *Do you use conservation practices on your farm? What kind? Have those practices helped you address a food safety issue? Is nine months too long a waiting interval between grazing animals in a field and harvest? Have you had to remove conservation practices to comply with industry or buyer food safety requirements? How can FDA make these standards better support diversified farming systems and biodiversity?]*

> ***Recommendation to FDA:*** FDA must incorporate stronger support for on-farm conservation that supports food safety and protects our soil, water, and wildlife habitat. Specifically:
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> a. FDA should state support sustainable conservation practices in the final regulations and should prohibit the destruction of conservation practices as a condition of complying with food safety rules.
> b. As part of the personnel training standards in the Produce Rule, FDA should include requirements to train on-farm personnel on how conservation practices support food safety goals.
> c. FDA should not treat grazing like manure application and should not restrict grazing through unrealistic intervals, such as nine months, between grazing a field and harvest of a crop.
> d. FDA should conduct a full Environmental Impact Statement and subsequently incorporate the findings into a new set of proposed rules.

3. ***Issue: Agricultural Water –*** The Produce Rule includes costly, burdensome, and unscientific standards for irrigation water – including water testing and treatment requirements.

[Help FDA understand why this matters: *Do you test your water? If yes, what do you test for, how*

often do you test, what method do you use to test, and what does testing cost you? If no, what do you do to monitor the quality of your water? Will these standards conflict with the way you use water on your farm?]

Recommendation to FDA: FDA must take a reasonable, risk-based approach to agricultural water that allows farmers to respond to specific risks in their water systems. Specifically:

- In the final regulations, FDA should not include inappropriate numerical thresholds for presence of pathogens or pathogen indicators (i.e., generic *E. coli*) in water. This information should be included in guidance after sufficient research indicates what is an appropriate numerical standard, which might vary according to the region.
- FDA should not require weekly water testing; 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.
- FDA should not encourage or allow treatment of irrigation water with chemicals.

4. ***Issue: Diversified Farming Systems –*** This is a good issue that FDA **needs to retain, not change** - the Produce Rule acknowledges the importance of diversified farming systems by taking an "integrated" approach to the standards that does not set separate requirements for each kind of fruit and vegetable.

[Help FDA understand why this matters: *If you are a farmer, how many different types of fruits and vegetables do you grow? Which of these would be covered by the proposed Produce Rule? If FDA chooses a commodity-specific approach, how will that impact the type of farming that you do and your costs of complying with food safety regulations?]*

Recommendation to FDA: FDA should adopt this integrated approach in the final regulations.

Comments Specific to the Proposed Preventive Controls Rule:

5. ***Issue: Value-Added Processing –*** Farmers adding value to their crops through low-risk on-farm processing should not be subject to the same regulations as high-risk processors. The Preventive Controls Rule includes a good initial list of low-risk processing activities done on-farm, but FDA fails to include additional activities like making pickles and salsa that are already considered low-risk by many states.

[Help FDA understand why this matters: *Do you process your own fresh produce using any of the low-risk methods below? If so, which ones? Are your processing activities already regulated at the state or county level for food safety? How would additional regulation impact your operation?]*

Recommendation to FDA: FDA should include a fuller range of low-risk on-farm processing activities in the final regulations, including:

- Acidifying, pickling, and fermenting low-acid fruits and vegetables made in compliance with existing Good Manufacturing Practices
- Baking activities involving grain products
- Roasting grains for animal feed
- Extracting oils from seeds
- Extracting virgin olive oil
- Making molasses from sugarcane and sugar beets

- Making syrups from sorghum, rice, and malted barley

6. ***Issue: Direct-to-Consumer Marketing –*** The rules fail to clarify that Community Supported Agriculture (CSAs) and other direct-to-consumer businesses are not facilities subject to regulations for food facilities, despite clear instructions from Congress in FSMA to do just that. Without this clarification, CSAs and other direct farmer-to-consumer farms that do light processing activities or include produce from another farm in their boxes will be subject to inappropriate, excessive regulations designed for industrial food facilities.

[***Help FDA understand why this matters:*** *Do you operate a CSA, farmers' market, or other direct-to-consumer outlet? Do you aggregate or otherwise include produce from multiple farms in your CSA box? What measures do you already take to ensure the safety of this food? How might being subject to additional regulation as a facility impact your operation?]*

Recommendation to FDA: In the final regulations, FDA must clarify in the Preventive Controls Rule that CSAs, roadside stands, and other direct-to-consumer vendors fall under the definition of a "retail food establishment" and are not facilities that must register with FDA and, therefore, are not subject to the Preventive Controls Rule.

7. ***Issue: All Food vs. Regulated Food –*** Even though not all food produced on farms is governed by the rules, the value of everything produced on a farm counts toward exemptions and modified regulations – which will make it hard for mid-size farms to diversify their operations.

[Help FDA understand why this matters: *Do you have a variety of income streams from farming? What are they? Do you gross more than $500,000 in food other than produce or processed food? If yes, do you also grow produce or process food? If no, would you like to diversify into produce or processing? How will the "all food" sales threshold affect you?]*

Recommendation to FDA: FDA should count the value of only covered (or regulated) product or produce and not "all food" when:

- Determining whether a farm or facility is eligible for the modified requirements through the Tester-Hagan provisions,
- In the exemption from the Produce Rule for farms grossing less than $25,000, and
- In the definition of "very small business" in the Preventive Controls Rule

8. ***Issue: Definition of "Very Small Business"*** **–** The rules set modified requirements for small and very small businesses, but FDA has not settled on a definition for "very small business" and most of their options are unrealistic. Without a realistic definition, many very small businesses will be regulated like big facilities.

[Help FDA understand why this matters*: If you operate a processing facility, food hub, or do processing on your farm, which option for the definition of "very small business" would you fall under, if any? If FDA calculated the definition of "very small business" not based on all food but based on processed food, how would that change your status, if at all?]*

Recommendation to FDA: FDA should adopt the $1,000,000 threshold for a very small business and make sure that it is based on the value of regulated product, not the value of all food. This would focus the full regulations on big businesses that produce the vast majority of covered farm and food products, while focusing modified requirements on smaller farms and businesses that represent the majority of producers but only minority of product in the food supply.

Comments Covering Both the Proposed Preventive Controls Rule and the Produce Rule:

9. ***Issue: Loss of Protections for Local Food (Exemptions and Modified Requirements) –*** FDA has the unlimited ability to take away the exemptions and modified requirements certain farmers and facilities are eligible for and subject them to the full weight of the regulations if they think there is a food safety problem on the farm – but the rules do not require FDA to have proof of a problem, and there is no way to get that status back once FDA revokes it.

[Help FDA understand why this matters: *Are the modified requirements feasible? Do you anticipate significantly increased costs in complying with the requirements? What type of evidence of a problem should FDA include in a withdrawal order? What type of documentation do you regularly keep that could be used to appeal a withdrawal order?]*

Recommendation to FDA: In the final regulations, FDA must make a robust and fair regulatory framework for the qualified exemptions and modified requirements. Specifically:

- FDA should define "material conditions" as scientifically measurable traits that can be clearly identified in individual cases, and never by conjecture be applied to a whole class of persons, types of operations, or broad description of food being produced.
- FDA should require credible and substantial evidence to justify a withdrawal.
- FDA should establish a clear and fair process for reinstituting a farm or facility's status if that operation has had their exemption or modified requirement withdrawn.

10. ***Issue: Excessive Compliance Costs –*** The costs of compliance are substantial and put an unfair burden on smaller growers. As a result of the high costs of compliance, FDA anticipates that some farmers will go out of business, fewer people will start to farm, and more farmers will have to seek off-farm jobs to keep farming.

[Help FDA understand why this matters: *How will the estimated costs of compliance impact your operation? Will you be able to absorb these costs? What is your hourly wage? What do you pay other employees? How long is your growing season? Will you have compliance costs from both the Produce Rule and Preventive Controls Rule? Please share any cost data on food safety plans or HACCP/HARPC requirements that you have and are comfortable sharing with FDA. Please share any cost data on practices for agricultural water; soil amendments; health and hygiene; domesticated and wild animals; equipment, tools, and buildings; and training that you have and are comfortable sharing with FDA.]*

Recommendation to FDA: FDA must find ways to decrease the costs of compliance with the new rules, especially for small and very small farms. FDA must also base the costs on realistic assumptions about length of growing season, farm net income, and feasibility of water testing.

Thank you for your consideration.

Sincerely,
[Full name, business name, city and state, email address]