

Top 10 Problems

with the Food and Drug Administration's Proposed Food Safety Regulations for Farmers and Local Food Businesses

1. They're too expensive. The rules could cost farmers over half of their profits and will keep beginners from starting to farm.

The costs of compliance are substantial and put an unfair burden on smaller growers. As a result of the high costs of compliance for both the Produce and Preventive Controls Rules, 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.ⁱ Costs will be significant for farmers of all sizes but most acutely felt by small and mid-size growers – FDA's numbers show that growers with sales up to \$500,000 will spend 4-6% of their gross revenue to comply with proposed on-farm regulations.ⁱⁱ The average net income for farmers nationally was 10% of sales in 2011;ⁱⁱⁱ so for small farms subject to the rules, FSMA could consume more than half of those modest profits. **Learn more about the cost of compliance issue:**

- Details on Produce Rule costs: <http://sustainableagriculture.net/fsma/learn-about-the-issues/costs-to-farmers-and-consumers-produce-rule/>
- Details on Preventive Controls Rule costs: <http://sustainableagriculture.net/fsma/learn-about-the-issues/preventive-controls-rule/>

2. They treat farmers unfairly. FDA is claiming broad authority to revoke small farmers' protections without any proof of a public health threat.

Congress chose to provide modified scale-appropriate requirements to the food safety regulations for farms and food-makers selling most of their food to local customers if their revenues are under \$500,000/year.^{iv} But as currently proposed, FDA has broad authority 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 FDA thinks there may be a food safety problem on the farm – but the rules do not require FDA to have proof of a problem, and there is no defined way to get that status back once FDA revokes it. **Learn more about the modified requirements and how FDA can revoke them:**

- Details on Produce Rule modified requirements and exemptions: <http://sustainableagriculture.net/fsma/learn-about-the-issues/qualified-exemptions-and-modified-requirements/>
- Details on Preventive Controls Rule modified requirements and exemptions: <http://sustainableagriculture.net/fsma/learn-about-the-issues/modified-requirements-for-qualified-facilities/>

3. They will reduce access to fresh, healthy food. Local food distributors like food hubs could close, and new food businesses will not launch.

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 the options they present are unrealistic. Without a realistic definition, many very small businesses – including thousands of farms – will be regulated under the Preventive Controls Rule like big industrial food manufacturers. If FDA’s definition of “very small business” is not reasonable, small start-up operations – like an farmer making jam from her fruit or a food hub helping get healthy local food into schools – could be regulated well beyond their risk and with compliance costs too high for them to stay in business. We’ve seen this scenario before: industrial-scale food safety rules for meat processors in the 1990’s partially contributed to the closure of many small-scale livestock processing facilities, which today is a barrier to increasing sales of locally-produced meats.^v **Learn more about the definition of “very small business” issue:**

- <http://sustainableagriculture.net/fsma/learn-about-the-issues/definition-of-very-small-business-preventive-controls-rule/>

4. They make it harder for farms to diversify. Grain, dairy, and livestock farmers could be denied access to emerging local food markets.

Even though not all food produced on farms is subject to the new regulations, FDA proposes that the value of everything produced on a farm counts when determining whether a farm is eligible for exemptions and modified regulations. This will make it hard for mid-size farms to diversify their operations because all food grown on the farm counts toward the \$500,000 income eligibility test, including covered crops like strawberries and non-covered crops like soybeans.^{vi} For example, this means that a small u-pick strawberry operation on a 800-acre corn and soybean farm could be subject to the same expensive, burdensome requirements as California’s mega-scale packaged berry industry even if the farmer sells less than \$25,000 worth of strawberries. **Learn more about the all food vs. covered food issue:**

- <http://sustainableagriculture.net/fsma/learn-about-the-issues/all-food-covered-product/>

5. They will over-regulate local food. The rules could consider farmers markets, roadside stands, and community-supported agriculture programs “manufacturing facilities” subject to additional regulation.

The Preventive Controls Rule fails 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.^{vii} 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. For example, if a CSA also packs a few apples from a neighbor’s farm into their CSA boxes, they will become a ‘food processing facility’ and subject to an additional level of regulation.^{viii} **Learn more about the direct to consumer marketing issue:**

- <http://sustainableagriculture.net/fsma/learn-about-the-issues/direct-to-consumer-marketing-preventive-controls-rule/>

6. They treat pickles like a dangerous substance. The rules fail to protect a host of low-risk processing activities done by smaller farms and processors.

Farmers adding value to their crops through low-risk value-added processing should not be subject to the same regulations as high-risk processing activities by large corporations. The Preventive Controls Rule includes a good initial list of low-risk processing activities, but FDA fails to include additional activities like making pickles and salsa that are already considered low-risk by many states. The list of low-risk value-added processing needs to be comprehensive. **Learn more about the value-added processing issue:**

- <http://sustainableagriculture.net/fsma/who-is-affected/on-farm-processors/>

7. They make it nearly impossible to use natural fertilizers like manure and compost. Farmers will be pushed to use chemicals instead of natural fertilizers.

The proposed Produce Rule standards for using manure and compost would make it effectively impossible for farmers to use manure and create barriers to the use of compost – in direct contradiction with established federal organic standards and the public interest in promoting the use of these natural soil amendments instead of chemicals. Under the USDA organic standards, for crops that come in contact with the soil, farms can use raw manure for fertilizer if it is applied at least four months prior to crop harvest^{ix}. For those same crops, FDA increases the waiting period to nine months,^x making application of manure fertilizer impossible in a normal growing season on both organic and conventional farms. Congress ordered that that FSMA produce safety rules should not conflict with the National Organic Program^{xi}, but FDA is ignoring this mandate. **Learn more about the manure and compost issue:**

- <http://sustainableagriculture.net/fsma/learn-about-the-issues/manure-and-compost/>

8. They require excessive water testing on farms. Farmers using water from streams and lakes will be required to pay for weekly water tests regardless of risk or cost.

The proposed Produce Rule includes costly, burdensome, and unscientific standards for irrigation water – including water testing and treatment requirements. Farms using water from creeks, streams, and rivers on produce crops will have to test their water every 7 days if the water touches the edible parts of a crop.^{xii} That's much more often than farmers are asked to test now, and FDA estimates the typical cost for one water test is \$87.30 – which could add up to thousands of dollars for farmers each year.^{xiii} **Learn more about the agricultural water issue:**

- <http://sustainableagriculture.net/fsma/learn-about-the-issues/agricultural-water/>

9. They could harm wildlife and degrade our soil and water. The rules could force farmers to halt safe practices that protect our natural resources and wildlife.

The proposed 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. Because the rules don't explicitly protect practices like installing native plant buffers for pollinator habitat – that in fact benefit both wildlife and food safety – inspectors would have free reign to require farmers to tear them out regardless of any proof of a problem.^{xiv}

- <http://sustainableagriculture.net/fsma/learn-about-the-issues/conservation/>

10. Bonus: there's at least one good thing about the rules. The rules take an 'integrated', not a 'commodity-specific' approach – meaning farmers won't face over 30 separate rules for each kind of fresh produce they grow.

The proposed 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. This is a good decision that FDA should retain, not change, despite agribusiness demands to the contrary! The rules don't require separate rules for each kind of fresh produce – meaning a grower who raises tomatoes, lettuce, and peaches won't need to follow separate and different food safety rules for each type crop but rather will be able to take a whole-farm approach – which is much less complicated and less costly for farmers! (I can add citation from issue page)

- <http://sustainableagriculture.net/fsma/learn-about-the-issues/integrated-approach-vs-commodity-specific-approach/>

LEARN MORE ABOUT THE ISSUES AND TAKE ACTION:

<http://sustainableagriculture.net/fsma/>

Citations

- i FDA. "Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Page 313-314. <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf>
- ii FDA Analysis of Economic Impacts – Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. Page 313. <http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf>
- iii USDA: ERS Farm Balance Sheet Data
- iv Public Law 111-353: FDA Food Safety Modernization Act. (2011). <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.
- v Muth MK, Karns SA, Wohlgenant MK, Anderson DW. Exit of Meat Slaughter Plants During Implementation of the PR/HACCP Regulations. *Journal of Agricultural and Resource Economics* 27(1): 187-203 2002. <http://ageconsearch.umn.edu/bitstream/31073/1/27010187.pdf>
- vi Public Law 111-353: FDA Food Safety Modernization Act. (2011). <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.
- vii Public Law 111-353: FDA Food Safety Modernization Act. (2011). <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.
- viii** Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food <https://www.federalregister.gov/articles/2013/01/16/2013-00125/current-good-manufacturing-practice-and-hazard-analysis-and-risk-based-preventive-controls-for-human#p-504>
- ix USDA AMS National Organic Program Final Rule. Crop Products. <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087165>
- x Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. <https://www.federalregister.gov/articles/2013/01/16/2013-00123/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-234>
- xi Public Law 111-353: FDA Food Safety Modernization Act. (2011). <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.
- xii Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. <https://www.federalregister.gov/articles/2013/01/16/2013-00123/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-1501>
- xiii FDA. "Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Page 137. <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf>
- xiv <http://sustainableagriculture.net/fsma/learn-about-the-issues/conservation/>