



### **Extension Small Farms Program**

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Thank you for the opportunity to comment on the proposed rule for produce safety. We appreciate the extension of the comment period to allow more farmers to engage in the comment process.

The Oregon State University Extension Small Farms Program provides education and technical assistance to small, sustainable farmers and ranchers in Oregon. Our state has a vibrant small-scale, sustainable agriculture sector, with innovative farm and food businesses providing high quality food into local and regional markets.

We recognize the importance of food safety practices for all farms, regardless of size. We appreciate that the Food Safety Modernization Act explicitly requires FDA not to take a “one size fits all” approach to food safety but to take a risk-appropriate approach. We also appreciate that the Act explicitly requires that the rules not conflict with the National Organic Program or conservation practices. In our comments, we discuss our concerns about areas of the draft rule that appear to contradict these intentions and requirements of the Act and/or create unnecessary economic hardship for small-scale, local farmers and food systems.

### **Agricultural Water**

The farmers we work with are deeply concerned that the proposed agricultural water standards will impose significant costs on them for testing, treatment, and maintenance but are (a) based on inadequate (or no) science and (b) will not actually reduce food-borne illness.

#### No Clear Scientific Basis

First, as FDA itself has acknowledged, there is no clear scientific basis for using the U.S. Environmental Protection Agency (EPA) Recreational Water standards. Scientific research has shown, on the contrary, that generic E.coli is a poor indicator of water quality.

Before FDA imposes potentially cost-prohibitive requirements on farms – especially the many small to mid-sized farms that will not qualify for an exemption – the Agency must assure that its standards are scientifically justified.

### Testing Frequencies

In addition, FDA has not provided scientific justification for the proposed testing frequencies, particularly for the weekly testing for farms using certain sources. We recommend that water testing frequency requirements be decreased to once every four months for groundwater and once every six weeks for surface water sources. After two or four years of data collection at those frequencies (two years for groundwater and four years for surface water), farms should be allowed to set a testing frequency that reflects the risk at that farm. Farms should be required to keep records that demonstrate and support their specific risk assessment and testing frequency. In addition, farms should not be required to test irrigation water outside the irrigation season.

### Systems Approach to Water Quality

Second, many farmers have little control over their irrigation water supply but are being asked to shoulder the responsibility and cost. In public meetings, FDA has responded to this concern by saying it does not have jurisdiction over irrigation districts, only farmers.

We recommend that FDA coordinate with federal, state, and local regulatory agencies with jurisdiction over irrigation districts and other water suppliers to assure that water quality is being adequately managed system-wide.

In addition, FDA should, in the produce rule, allow a regional approach to water quality testing, to let irrigation districts and other water service providers (a) determine optimum sampling locations throughout the system to monitor water quality, and (b) submit to FDA testing plans for their systems with a requirement to report water quality issues to system users. Such an approach is likely to be more effective than farm-by-farm water testing in situations where water is delivered by an irrigation district or other water service provider.

### Treatment

If farmers must rely on treatment, it will likely lead to a significant increase in application of chlorine and other antimicrobial agents. We are deeply concerned about the impact of these chemicals on groundwater and surface water quality, soil health, beneficial microbial organisms in both water and soil, and human health, especially for farmworkers. Large-scale use of chlorine will also cause corrosive damage to farm equipment and may reduce the effect of biological pesticides. This issue must be addressed in the environmental impact statement (EIS) process that FDA began this fall – and without which, the draft rules must not be finalized. Ultimately, FDA's water standards should not require large-scale chemical treatments and chlorination. Farmers will need access to affordable non-chlorine alternatives for irrigation water treatment.

In addition, FDA should assess the relative value of chlorinating an irrigation source over a period of months versus only chlorine-treating water within 2-4 weeks of harvest versus only using chlorine treatment during post-harvest washing and handling. Such an assessment may require additional scientific research.

### Compliance Timeline

Long lead times that FDA has proposed for implementation and enforcement are necessary not only for farmers but for much-needed scientific research to be done and translated into practical applications.

### Scope

The scope of the water standards should not be broader to include water that does not directly contact produce.

### Standards into Guidance with Stakeholder Involvement

Finally, FDA has made it clear since issuance of these draft rules that it invites science-based alternatives to this water standard. This approach is welcome. However, the standards as written should not be included in the final rules. We tentatively agree with proposals to put much of the water standards, including the actual metrics, into guidance instead of rules, though we are concerned that this will offer far less opportunity for public scrutiny and input in the future. We strongly encourage FDA to establish a process to involve stakeholders – including small and mid-sized farmers – in writing and revising such guidance as new science is available.

### **Biological Soil Amendments of Animal Origin**

The proposed manure and compost standards conflict with National Organic Program regulations, contrary to the Act. The standards are more restrictive than the NOP – and therefore more burdensome to farmers – in two specific ways:

1. The NOP allows the application of raw manure 3-4 months before harvest depending on the risk of soil contact; the draft produce rule requires 9 months;
2. The NOP does not require an interval before applying composted manure (minimizing contact with produce), but the draft produce rule requires a 45 day interval.

In both cases, FDA should amend the rule to match NOP regulations, which rest on a solid scientific foundation. For example, the NOP time and temperature standards for applying compost with no harvest interval are based on research that informed EPA's Title 40 standards for biosolids. A great deal of evidence shows that composting is a robust PFRP (process to further reduce pathogens).

Research into effective pre-harvest intervals is not entirely conclusive, but peer-refereed research tentatively supports 3-4 month harvest intervals for uncomposted manure, for example:

- Baloda, S.B., L. Christensen and S. Trajcevska (2001). Persistence of a *Salmonella enterica* serovar Typhimurium DT12 clone in a piggery and in agricultural soil amended with *Salmonella*-contaminated slurry. *Applied Environmental Microbiology* 67:2859-2862.
- Ingham, S.C., M.A. Fanslau, R.A. Engel, J.R. Breuer, J.E. Breuer, T.H. Wright, J.K. Reith-Rozelle and Jun Zhu (2005). Evaluation of fertilization-to-planting and fertilization-to-harvest intervals for safe use of noncomposted bovine manure in Wisconsin vegetable production. *Journal of Food Production*, 68(6):1134-1142.

- Tannock, G.W. and J.M.B. Smith (1972). Studies on the survival of *Salmonella typhimurium* and *Salmonella bovis-morbificans* on soil and sheep feces. *Research in Veterinary Science* 13:150-153.
- Van Donsel, D.J., E.E. Geldreich and N.A. Clarke (1967), Seasonal variations in survival of indicator bacteria in soil and their contribution to storm-water pollution. *Applied Microbiology* 15:1362-1370.

To our knowledge, there are no documented cases of foodborne illness linked to manure used as a soil amendment 3-4 months before harvest. The fact that this practice is quite common in organic fruit and vegetable production, as regulated by the USDA National Organic Program implemented in 2001, is strong evidence that it should be allowed under FSMA.

In addition, the draft rule contains a curing or covering requirement for compost that is not required by the NOP. Curing is not needed for field application because adequate pathogen suppression occurs during the thermophilic phase. Curing is not necessary for pathogen reduction when compost is field applied. Longer term composting that includes curing can further reduce plant available nitrogen in amendments such as chicken manure that have met PFRP without curing.

The draft standards as written will also likely increase the use of synthetic fertilizers, for which there is no interval; this is likely to lead to declines in soil health and water quality due to nitrogen and phosphorus runoff. In Oregon and other states with wet winters, 9 month pre-harvest intervals will also encourage application of raw manure in the fall when the risk of nutrient leaching over winter months is high. This leaching would contaminate water with nutrients and pathogens, thereby increasing the risk of foodborne illness from irrigation water, as well as eutrophication of U.S. waterways.

### **Alternatives to Certain Requirements**

We appreciate that FDA has proposed to allow alternatives to specific requirements, (water testing and treatment, composting treatment, and application intervals for certain soil amendments) under some conditions, as long as farmers can present scientific evidence that these alternatives work. The Agency says it will accept scientific data and information “developed by you,” the farmer, but FDA should be more specific about what type of evidence it will accept. The agency has done this to some degree in its fact sheets but must also provide clarification in the rule itself.

### **Qualified Exemptions**

The Tester-Hagen amendments to the Act require that the rules be risk-appropriate and recognize that food safety can be adequately assured in short, local and regional supply chains through clear traceability from farm to fork. However, the treatment of exemptions in the draft rule combined with FDA comments in public meetings (e.g., Eugene, OR, April 17, 2013) have together led many small farms and farm advocates to conclude that FDA may not honor the Act’s exemptions in practice. We hope the Agency will clarify in the rule, in public meetings, and in informational materials its intention to honor the exemptions as the Act requires.

We have two main concerns about the current language related to qualified exemptions: the income thresholds and the process by which farms may lose exemptions.

#### Income thresholds

Income thresholds for qualified exempt status for farms are based on the value of all food produced, including animal feed, not just food covered by the rule. For example, if dairy or small grain farmers want to grow and sell a very small amount of produce at a roadside stand during the summer months, their total “food” income may exceed the threshold, even if their produce sales are small in volume and direct to consumer. This should be changed so that the income threshold is based only on food covered by the rule.

We also wish to point out that the \$500,000 gross income threshold does not account for the low net income associated with produce farming. Vegetables and fruits may yield high gross income but have high production costs, resulting in low net income. \$1 million would be a more reasonable threshold for farms that would otherwise qualify for an exemption because they sell primarily to local and regional qualified end users.

#### Losing and Regaining Exemptions, i.e., “Withdrawal of Modified Requirements”

The draft rule lacks critical information about how qualified exempt farms might lose and regain their exemptions. The draft rule states that qualified exempt farms can lose their exemptions and be required to comply with all requirements if FDA finds:

1. A direct link to an active investigation of an outbreak, or
2. Material conduct or conditions: If FDA “determines it is necessary to protect public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility/farm that are material to the safety of food produced or manufactured, processed, packed, or held at such facility or farm.”

We do not suggest that farms that are causing real foodborne illness should be allowed to continue doing so without penalty, including the loss of a qualified exemption. However, much about the language above is still unclear, and we ask that FDA provide additional detail on the following:

1. What actual conditions will trigger a withdrawal (loss of exemption)? FDA should define “material,” “associated,” and “direct link.”
2. Can exemptions be withdrawn for all farms growing an entire category of produce, even for farms not involved in an outbreak or “material conditions”?
3. What is the withdrawal process? FDA should provide detail on the timeline and farmer notification requirements.
4. Can exemptions be regained? Under what conditions?

In addition, both the exemptions and the additional information requested above should remain in the final rule as the law requires and not be relegated to guidance.

Finally, we are concerned that some small and mid-scale farms selling primarily into local and regional markets will not qualify for the exemptions because the definition of a qualified end user does not include local produce brokers who connect farms with local markets. Oregon has many small and mid-sized, diversified produce farms that sell to local and regional retailers and restaurants through a produce broker. These farms meet the spirit of the qualified exemptions – short supply chains backed by clear traceability – but will be excluded from them, at a high cost.

### **Additional Comments**

Clarification and consistent definitions are needed in many areas of the draft rule, to help farmers and mixed-type facilities understand which rules and standards apply to them:

- Clear, consistent definitions of “farm” v. “facility”;
- Clear, consistent definitions of “small” and “very small” for farms and facilities;
- Clarity about how the two draft rules interact.

We strongly recommend that FDA change the definitions of “farm,” “facility,” and “manufacturing/processing” – in both the produce rule and the preventive controls rule – to align with common-sense, long-accepted practice: the basic packing, handling and storing activities that farms have traditionally performed in preparing intact fruits and vegetables for marketing should be within the “farm” definition and are not food “manufacturing” or “processing.”

Wooden bins for produce harvesting: FDA should clarify in the rule that wooden bins are acceptable for produce harvesting and the initial stages of food processing. The rule should state that bins must be kept clean or that bins and storage containers should be stored and handled so as to limit microbial contamination. The rule as written would require wooden bins to be replaced with plastic bins. The cost to do this far outweighs potential food safety risks associated with wooden bins. Wooden bins can last up to 40 years, while far more expensive plastic bins may last only five to seven years.

Grazing animals: Proposed § 112.82(a) requires farmers “to implement an adequate waiting period between grazing and time of harvest.” This appears to give farmers the discretion to decide what is adequate for their specific circumstances. However, later on in this section, FDA notes, “we would not expect it to be necessary for such time periods to exceed 9 months.” As written, this is likely in practice to become a requirement, not a suggestion. While 9 months may in fact be prudent for some farms, it is unreasonable for all farms and will cause unwarranted economic hardship for diversified, integrated livestock-crop farms. FDA should state clearly that a shorter interval is acceptable and that 9 months is not the required interval.

Training and capacity building to help farms and facilities comply with the rule will be critical. The Act recognizes this, for example, by authorizing a new competitive grants training program. However, USDA has not yet provided funding for it. FDA will need to find resources to fund training and capacity building done by university cooperative extension, state departments of agriculture, and other entities that will provide local outreach and training.

In addition, the lack of scientific basis for many parts of the proposed rule makes it clear that a great deal of research is still needed on how best, and most cost-effectively, to assure food safety on farm. FDA should provide support for the research necessary to provide a strong scientific basis for the rules it promulgates under FSMA.

Economic impact analysis: FDA was required to analyze the economic impact of the rule on farms and facilities. However, that analysis contains insufficient consideration of the economic impact on local and regional food systems (e.g., CSA, food hubs, farm-to-school/institution, and other innovative marketing channels).

Conservation practices are acknowledged as valuable (in the Act itself and the Preamble to the draft rule), but they are not explicitly protected in the actual rule. We are concerned that the proposed language in the rule regarding animal intrusion will discourage producers from maintaining wildlife habitat. Reducing habitat near streams and along fields is very likely to jeopardize efforts to protect and restore threatened and endangered fish and wildlife populations. The removal of streamside vegetation is also likely to reduce water quality by removing shade and filtration for pollutants in runoff.

We are glad that FDA has initiated the EIS process and will be watching to make sure that the EIS adequately addresses this issue. FDA should also include explicit language in the produce rule – not just the preamble – to assure farmers that conservation buffers, wildlife habitat, and other co-management practices to protect wildlife habitat and biodiversity are not prohibited.

**Another draft rule is needed.**

Given the extent of the revisions FDA will have to make to the proposed rule, we strongly agree with the National Association of State Departments of Agriculture that FDA must publish another set of draft rules for public comment. As they note, “food safety will be better advanced by getting the rules right,” and taking the time needed to establish “a workable federal, state and local integrated food-safety system.” This effort is too consequential to be unduly rushed.

Thank you for the opportunity to comment.

Sincerely,



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