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Food and Drug Administration
5639 Fishers Lane, rm. 1061
Rockville, MD 20852

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Regulatory Information Number RIN 0910-AG36 FIX

Thank you for the opportunity to comment on the proposed Preventive Controls Rule for Human Food. We appreciate the extended comment period to allow more farmers, food businesses, and food system stakeholders to engage in the comment process.

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

We recognize the importance of food safety practices for all farms and manufacturing/processing facilities, 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. In our comments, we discuss our concerns about areas of the draft rule that appear to conflict with this requirement and/or create unnecessary economic hardship for small farms and facilities without improving food safety for consumers.

**Farmers’ Markets and Community Supported Agriculture**

FSMA contains provisions that require that farm stands, farmers’ markets, and Community Supported Agriculture (CSA) will be defined as “retail food establishments” (not “facilities”) and thereby will not be subject to the preventive controls rule. The draft rule did not follow the Act and makes these innovative marketing approaches, which typically involve produce from more than one farm, subject to the rule. Similarly, the current “packing” and “holding” definitions would also make these innovative local food aggregators subject to the rule, contrary to the Act.

We appreciate that FDA has publicly acknowledged this discrepancy and provided assurances that CSAs, farmers’ markets, and farm stands will be explicitly defined as retail food establishments in the final rule. FDA must now follow through on these assurances.

**Exemptions**

The Act requires 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. 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, food businesses, and farm advocates to conclude that FDA may not honor the Act’s exemptions in practice. We hope
the Agency will clarify in this rule, in public meetings, and in informational materials that it will honor the exemptions as the Act requires. We have multiple comments related to the exemptions:

1. Income Thresholds
Income thresholds for qualified exempt status for facilities and “farm mixed-type facilities” are currently based on the value of all food produced, not just food covered by the rule. The income threshold should be based only on food covered by the rule. If a facility manufactures animal feed, that should not be included in the calculation.

2. Additional Exemption for Facilities with Sales of Less than $25,000
Subjecting firms of this size to additional regulations is unlikely to improve food safety but very likely to stifle cottage food industries. We agree with the Oregon Department of Agriculture’s recommendation that FDA exempt from the entire preventive controls rule facilities meeting the definition of a qualified facility who also have an average annual value of food sold during the previous three-year period of $25,000 or less. Tester-type limits on sale (distance and qualified end users) could also apply.

3. Simplify and Clarify the Exemptions
We understand that FDA was asked to create rules for multiple exemption categories based on different factors. However, as currently proposed, the exemptions are extremely difficult to understand and will be difficult for firms to interpret. In particular, FDA must be clear about which activities and circumstances are considered farming and which activities and circumstances are considered processing and manufacturing, to help farmers understand whether they are, in fact, farm mixed-type facilities. This clarification should be done both in the rule itself and in associated guidance and educational materials.

4. Packing and Holding
Low-risk packing and holding activities should be explicitly exempt from subpart C of the proposed rules. The FDA could include these in the definition of “low-risk activities” or farm activities regulated under the produce rule.

5. Remove Farming Activities from Definition of Facility
FDA should revise several definitions to make low-risk farm mixed-type activities exempt from the preventive controls rule. FDA should change the definitions of “farm,” “facility,” and “manufacturing/processing” – in both the preventive controls rule and the produce rule – to recognize as “farming” the basic packing, handling and storing activities that farms have traditionally performed in preparing intact fruits and vegetables for marketing.

As FDA itself recognizes in the Preamble to the proposed Produce Rule, activities such as washing, waxing, fumigating, coloring, drying in order to store or transport, hydro-cooling, packing, refrigerating, removing leaves, stems and husks, shelling, activities that only isolate or separate out foreign objects or other non-food parts of the plant, and otherwise treating crops in their unpeeled natural state do not constitute manufacturing or processing: the crop is still a raw agricultural commodity.

FDA should remove these activities from the definitions of “manufacturing/processing” at 21 CFR Secs. 1.227, 112.3(c), and 117.3. These revisions will protect consumers while minimizing the regulatory burden on farm mixed-type facilities and recognizing modern agricultural business practices. Farms and farm-mixed type facilities are better regulated under the produce rule, and compliance with one regulation is more streamlined and much more economically feasible for small owner-operated businesses.
6. Documentation Associated with State Cottage Food Laws

We appreciate that FSMA appears not to override cottage food laws regulated at the state level. Under the proposed rules, farms that make and sell certain low-risk products, like jams and preserves, and qualify as “small” or “very small” businesses would qualify (per the Sanderson amendment) for an exemption from the HARP-C requirements. Farms that make and sell products like pickles and salsa but still qualify as “small” or “very small” and meet the conditions of the Tester amendment would be exempt but have to comply with modified requirements, which could be satisfied by submitting evidence of compliance with applicable non-federal law.

In Oregon, our Farm Direct cottage food law exempts farms from licensing requirements, as long as they meet certain conditions, including traceability through labeling and point of sale materials. FDA should include in the rule that a copy of a state’s relevant regulations and a letter from the farm stating compliance with those regulations are acceptable evidence of compliance with applicable non-federal law. FDA could also address this by exempting qualified facilities from submitting documentation (see below).

We also ask FDA to reconsider the registration requirement for farms that make small batches of pickles or preserves for direct sales but otherwise operate entirely as farms, doing farming activities. For them, the requirement to register as a facility with FDA seems excessive and unnecessary, when the state cottage food law already includes strict and direct traceability requirements.

7. Reduce the Burden for Qualified Facilities

Because “qualified facilities” are limited in both sales and distribution, they are intended to be subject to a reduced level of regulation. However, as written, qualified facilities are the only facilities required to submit documentation to the FDA under the proposed rules. Other exempt facilities and even facilities subject to subpart C are not required to submit any documentation.

In accordance with the intent of the Tester Amendment, qualified facilities should be exempt from subpart C as long as they have adequately identifying and controlling hazards in accordance with existing state law. They should not have to submit documents to FDA. If FDA insists on this, facilities should be allowed to decline the qualified facility exemptions all together and comply with subpart C or qualify under a different exemption, thereby avoiding documentation submittal.

8. Small and Very Small Business Exemption:

FDA has asked for comment on the income threshold to define a “very small” business for the qualified exemption: $250,000, $500,000, or $1 million. We encourage FDA to adopt the $1 million threshold gross revenue. These businesses normally have high production costs and relatively low net income.

However, given that equal exemptions are provided for small and very small businesses, it appears that the definition of a small business (<500 employees) makes the very small business exemption irrelevant. FDA should create a simple and broad small business exemption for any small business (defined by a firm with less than 500 employees) conducting “low-risk activities,” the combined lists under 117.5(g) & 117.5(h).
9. Due Process Regarding Loss and Recovery of Exemptions

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

- A direct link to an active investigation of an outbreak, or
- 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 facilities 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:

- What actual conditions will trigger a withdrawal (loss of exemption)? FDA should define “material,” “associated,” and “direct link.”
- Can exemptions be withdrawn for all facilities that process or manufacture an entire category of produce, even for facilities not involved in an outbreak or “material conditions”?
- What is the withdrawal process? FDA should provide detail on the timeline and facility notification requirements.
- 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.

Allergen Testing: Clarify Expectations on Testing and Acceptable Levels

We understand that FDA must require food allergen controls and prevention of allergen cross-contact. However, allergen cross-contact can adequately be controlled through standard sanitation operating procedures, and FDA should clarify that allergen testing in finished product is not required. In the annex and preamble to the proposed rule, FDA makes many suggestions about testing, sampling, and verification related to allergens.

FDA should clarify that these are only recommendations and are not required, to prevent them being interpreted (i.e., by FDA inspectors) as law. We also encourage FDA to establish set standards at which cross contact is deemed to have occurred. A simple presence or absence test may be unreasonable. Finally, FDA should clarify that Tester-exempt facilities are not required to submit to FDA evidence of compliance with GMPs.

Food Processing Study

We are concerned that the food processing study done by FDA as required by FSMA to inform rulemaking relies on very limited data and did not adequately survey small food facilities or farms that would qualify as farm mixed-type facilities. FDA’s estimate that only 1,673 farms nationally will qualify as facilities is likely a serious underestimate. If those farms are also
subject to the proposed Produce Rule, then they will have two sets of compliance costs to absorb. We recommend that this study be redone to inform the rewrite of the rules.

**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 of compliance on farm mixed-type facilities and, more broadly, on local and regional food systems (e.g., CSA, food hubs, farm-to-school/institution, and other innovative marketing channels). This study should also be redone to inform the rewrite of the rules.

**Support for Ongoing Education and Outreach**
FDA must provide ongoing education, training, and outreach for previously regulated firms, newly regulated firms, regulators that will be responsible for implementing the rules, and educators who will help farmers and facilities understand and manage the new requirements. It will be an enormous task to educate agriculture and food businesses about the preventive controls rules. The proposed rule will affect many firms that have not previously had preventive controls in place and would also affect a significant number of firms that have never been subject to food safety inspection all together. This is particularly true for on-farm mixed-type facilities.

In order for FSMA to succeed in improving food safety while minimizing economic hardship, a major education and training effort will be required to reach out to these facilities to make sure they understand and can comply with the requirements. FDA must make available adequate resources to support outreach and technical assistance delivered by state regulatory agencies as well as Cooperative Extension programs and non-governmental organizations that work directly with farmers and facilities.

**Ongoing Stakeholder Input**
We agree with the Oregon Department of Agriculture in strongly recommending that FDA establish a national advisory committee to provide ongoing input as FSMA implementation begins. The committee could include membership from states, industry stakeholders and the scientific community. FSMA implementation will undoubtedly raise many questions and problems that FDA, states, farmers, and processors have not yet identified. An advisory committee can flag and give feedback on emerging issues, propose changes to regulations and guidance, and provide a formal vehicle for dialogue between FDA, states, industry stakeholders, and the scientific community.

Such a committee must include representation for the small and very small farms and facilities that may qualify for exemptions, as well as educators and associations that work with and represent local and sustainable farming and food systems.

**Research Needs**
FDA must continue to set aside funds to support research on minimizing the risk of food-borne illness while maximizing regulatory flexibility and economic viability of agriculture and food production.
Another Draft Rule Is Needed.

Given the extent of the revisions FDA will have to make to an already complex proposed rule, we strongly agree with the National Association of State Departments of Agriculture that FDA must publish another draft rule and invite another round of public comment before publishing a final rule. FSMA represents an enormous shift in food safety regulation. To assure that the final rules are effective and workable for all parties, this effort must not be unduly rushed.

Thank you for the opportunity to comment.

Sincerely,

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