

OTA Talking Points on FDA's Revised Food Safety Rule

Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard and Analysis and Risk Based Preventive Controls for Human Food

For OTA Members Only

Comment Deadline: Monday, December 15, 2014

Mixed-Type Facilities and Covered Farms

FDA's Revision: Regarding the packing and distributing provisions for mixed-type facilities (operations that grow, pack, and/or process on the farm) described in the proposed produce safety rule, FDA's announcement supports a collaborative approach to local and regional agriculture. It clarifies the rules and reduces unwarranted burdens for operations that pack and distribute produce on their own farms as well as produce from neighboring farms.

- A farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities grown on another farm under a different ownership. FDA proposes to define such packing and holding as a traditional farming activity.
- In general, on-farm packing and holding of produce would be subject to the proposed produce safety rule, not the human food preventive controls rule.
- Farms that conduct additional processing or manufacturing may be subject to the preventive controls rule for those activities.

OTA Talking Points for Comments:

- **Definition of a "farm":** <Business name> agrees with FDA's revised definition of a "farm." We recognize, however, that a farm may have multiple sites located in "one general physical location" and one or more of these sites may be designated for packing operations. <Business name> requests that FDA issue guidance to clarify the boundaries intended by the phrase "one general physical location," and clarify the extent to which this would apply to holding or packing operations located within close proximity of a farm and under its ownership, but not on the farm itself.
- **Farms that pack or hold food from other farms:** <Business name> supports FDA's revisions to the following definitions: "farm," "harvesting," "holding," and "packing." Specifically, we agree that a farm should not be required to register as a food facility merely because it packs or holds raw agricultural commodities (RACs) grown on another farm under a different ownership. We agree that on-farm packing and holding of produce should be subject to the Proposed Produce Safety Rule, not the Preventive Controls Rule, provided RACs are not transformed into a processed product. Farms that conduct additional processing or manufacturing should be subject to the preventive controls rule for those activities. FDA's revision supports a collaborative approach to local and regional agriculture. It clarifies the rules, and reduces unwarranted burdens for farming operations that pack and distribute produce on their own farms as well as produce from neighboring farms.
- **Operations that pack and hold produce but are not growing produce:** <Business name> recognizes that many off-farm produce operations pack and hold produce but they do not grow the produce. The activities carried out by such operations are no different than the post-harvest activities described

under the proposed definition of a “farm” and the definitions of “packing” and “holding.” The only difference is that the off-farm operation is devoted to packing and holding rather than growing produce. Regardless, as the proposed rule is now written, the off-farm operation would be subject to the Preventive Controls Rule for Humans, and would therefore be subject to additional requirements that a farm performing the same activities would not. This creates an un-level playing field and causes unnecessary burden to the off-farm operation. <Business name> suggests that off-farm operations that perform the same post-harvest activities (packing and holding) as an on-farm operation be subject to the Preventive Controls Rule for Humans (and therefore required to register under the Bioterrorism Act), BUT only be subject to requirements that are consistent with packing and holding activities described under the Produce Safety Rule.

Product testing and environmental monitoring

FDA’s Revision:

- While these potential provisions were referenced in the preamble of the proposed rule, they were not included in the regulatory text. FDA is now providing an opportunity for input on specific language and seeking comment on whether to include it in the final rule. FDA is seeking comment on whether the preventive controls for human food should require:
 - A facility, as appropriate to the facility, the food, and the nature of the preventive control, to conduct product testing to verify implementation and effectiveness of preventive controls.
 - A facility, as appropriate to the facility, the food, and the nature of the preventive control, to conduct environmental monitoring to verify implementation and effectiveness of preventive controls if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard.

OTA’s Talking Points for Comments:

- <Business name> agrees with FDA that environmental and product testing are important verification measures to ensure that preventive controls are effectively controlling hazards.
- Environmental and product testing may be appropriate in certain instances as verification activities, but they do not constitute a **control step**, and should not be included in the rule itself. Guidance on this matter would be more appropriate.
- <Business name> believes that FDA should continue to express the importance of testing as an effective part of a food safety plan, and focus on providing useful guidance to industry on best practices and methods for monitoring and testing protocols.

Supplier Approval and Verification

FDA’s revision:

- Supplier controls are proposed when the receiving facility’s hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient from a supplier.
 - If these provisions were to be included, the facility would have flexibility to determine the appropriate verification activity (such as onsite audit, sampling and testing) unless there is reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.

- In that instance, an annual onsite audit of the supplier would be required unless the facility can show that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

OTA's Talking Points for Comments:

- Supplier approval and verification programs can be important parts of a preventive approach to food safety. The role and need for supplier approval and verification vary depending on the type of facility and type of food.
- Given the flexibility built into this supplemental proposed rule, <Business name> supports the addition of supplier verification requirements into the rule itself.
- <Business name> supports FDA's proposed approach of providing each facility with the flexibility to determine the appropriate verification activity (e.g., onsite audit; sampling and testing of the raw material or ingredient, review of the supplier's food safety records, or other appropriate verification activity). We strongly recommend, however, that FDA issue guidance that can be adapted to each operation.