OTA Talking Points on FDA's Revised Food Safety Rule

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
(Produce Safety Rule)

For OTA Members Only

Comment Deadline: Monday, December 15, 2014

Biological Soil Amendments of Animal Origin (Manure and Compost)

FDA's Revision:

- FDA is removing the 9-month proposed minimum-time interval between the application of untreated biological soil amendments of animal origin (including raw manure) and crop harvesting. The agency is deferring its decision on an appropriate time interval until it pursues certain actions. These include conducting a risk assessment and extensive research to strengthen scientific support for any future proposal, and working with the U.S. Department of Agriculture and other stakeholders. FDA expects this process will take at least five years.
- At this time, FDA does not intend to take exception to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.
- FDA is proposing to eliminate the previously proposed 45-day minimum application interval for compost (also known as humus), including composted manures. Properly treated and handled compost is safer than raw manure from a public health standpoint, and this change to the proposal would help facilitate its use while still providing an appropriate level of public health protection.

OTA Talking Points for Comments:

- <Business name> is particularly pleased to see the revisions made to the proposed requirements for manure and compost. The Organic Trade Association's extensive surveys of organic producers showed the importance of compost and manure in organic production, and demonstrated the conflict between the proposed produce safety rule and the organic regulations.

- <Business name> is pleased to see that the supplemental proposed rule recognizes the regulatory conflict with organic regulations and the lack of scientific support for a 9-month minimum application interval following the use of untreated manure.

- FDA proposes to defer a final decision on proper waiting times for untreated manure for 5 to 10 years until research and risk assessment focused on pathogen persistence provide a scientific basis for a specific interval. In the interim, organic producers will continue to comply with organic standards which require either 90 or 120 days minimum application interval following untreated manure use depending on the crop's contact with the soil. We recognize the concern expressed by others that deferring a decision on a minimum application interval for untreated manure will not restrict non-organic producers' use of this material and may pose an unacceptable risk to public safety. To address these concerns, FDA could consider suggesting an interim standard based on USDA's Good Agricultural Practices guidelines, which require a 120-day minimum application interval.

- <Business name> applauds FDA for eliminating the 45-day minimum application interval for properly made compost and for FDA's recognition of the importance of compost in sustainable agriculture. However, we remain concerned that FDA has not proposed revisions to the requirement that compost piles be insulated during curing. This is not typical industry practice at either commercial or on-farm composting facilities, and we urge FDA to align its composting procedure requirements with current industry standards and state regulations, which do not require an insulating layer on curing piles.

- The organic sector is eager to support FDA in its effort to conduct research on pathogen persistence in soils from untreated manure. We offer our network of organic farmers and partners at land-grant universities to participate in the study. It is critical for FDA to evaluate pathogen persistence on both conventional and organic operations, since certified organic farmers must implement practices that maintain and improve soil health and grow their crops on biologically active soils. Biological activity in soils may have effects on pathogen persistence, and this factor should be factored into any risk assessment research FDA conducts.

Water Quality Standard and Testing

FDA's Revision: The initial proposed requirements under this section prescribed frequent water testing (every three months and up to every seven days for surface water) as well as treatment to ensure that agricultural water (including irrigation water) meets proposed microbiological limits based on recreational water use rather than agricultural use.

- FDA is proposing various revisions to the microbial standard for water directly applied during the growing of produce (other than sprouts). The agency is updating the microbial quality standard to reflect data that support the 2012 Environmental Protection Agency recreational water quality criteria.
- Farmers with agricultural water that does not initially meet the proposed microbial standard would have additional means by which they could meet the standard and then be able to use the water. These options include establishing a sufficient interval of days between last irrigation and harvest to allow time for potentially dangerous microbes to die off. They could also apply an interval of days between harvest and the end of storage using appropriate microbial die-off or removal rates, provided there is adequate supporting data. And there is an option to calculate and apply appropriate pathogen removal rates for activities such as commercial washing.
- A number of commenters felt that FDA should allow for microbial die-off that occurs naturally in the field before the crop is harvested. This provision provides that flexibility. However, any of these options would have to provide the same level of public health protection and not increase the likelihood that the covered produce will be adulterated.
- Recognizing that water sources have different levels of contamination risk, FDA is proposing a tiered and more targeted approach to testing each source of untreated water that will be less burdensome on farmers while still protective of public health. The revisions reduce how often the water is tested, with the frequency depending on the water source (i.e., surface or ground water) and on the results of prior tests.

OTA Talking Points for Comments:

- <Business name> agrees that a farm must assess the agricultural water system, identify hazards, and take appropriate steps to correct the situation so the water is safe.

- <Business name> agrees that testing water sources when agricultural water is used during growing activities for covered produce is only necessary when there is a reasonable likelihood of direct water contact of the harvestable portion of covered produce. We also strongly support FDA's proposed die-off provision, but we believe this belongs in guidance with the proposed microbial standard.
- <Business name> agrees no water testing is necessary if the water source is municipal (and municipal records of water quality are available) or treated (and records of chemical testing are available).
- <Business name> agrees with FDA's proposed revisions to provide for the use of a pathogen die-off rate as a mechanism for farmers to mitigate food safety risk from utilizing water that may exceed the established or recommended microbiological thresholds.
- <Business name> agrees that an operation should initially test the quality of each water source to determine its baseline quality. Testing requirements should reflect the level of risk for each unique operation. The revised water testing frequency requirements are an improvement. However, they are still overly prescriptive and do not allow enough flexibility for the diversity and range of operations across the nation. Farms and water sources—surface or ground—with an established good history and a food safety plan that addresses water quality should be required to test less frequently than those identified at higher risk. Testing should be determined according to a risk-assessment conducted by each farm and recommended testing frequencies should be available to growers in guidance.
- <Business name> does not support including prescribed metrics ***in the regulation itself*** unless those metrics are scientifically based and proven to be appropriate for any given situation. Science may never provide "the right answer" to the question of how much testing is required to adequately ensure the safety of agricultural water used on produce. Because of this, we emphasize that the proposed microbial water quality standard and proposed testing frequencies belong in guidance. More research specifically targeted at agricultural use is needed. We encourage FDA to work with EPA and other appropriate research organizations to develop a scientifically valid agricultural water standard for fresh produce that appropriately addresses foodborne pathogens. This will allow FDA to effectively and efficiently facilitate updates as new science is developed.

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.

- FDA is proposing that farms or farm mixed-type facilities with an average annual monetary value of **produce** sales of $25,000 or less will not be covered. The original proposed rule defined that monetary threshold in terms of all **food** sales. The FDA is also proposing corresponding changes to the definitions of "very small business" and "small business" to base those monetary thresholds on **produce** sales rather than **food** sales. The monetary threshold for the qualified exemption with modified requirements, however, would not change because that exemption is defined by statute.
- The definition of "farm" would be revised; a farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities (RAC) grown on another farm under a different ownership. FDA is proposing that such activities would be subject to the produce safety rule rather than the preventive controls rule for human food.

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 the 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.

Domesticated and Wild Animals

FDA's Revision: In the preamble of the proposed rule, FDA asserts that in general, carrying out the regulation would not require total exclusion of animals from outdoor growing areas, or the destruction of animal habitats near growing areas, or the clearing of farm borders, or any action that would violate environmental laws or regulations.

- FDA states in the proposed revisions that the proposed produce regulation does not authorize or require farms to take actions that would constitute the "taking" of a threatened or endangered species in violation of the Endangered Species Act. There were concerns expressed that growers would interpret the original proposed rule in ways that would harm wildlife, including taking measures to exclude animals from outdoor growing areas or destroying animal habitats. This clarification is intended to relieve those concerns.
    - This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

OTA Talking Points for Comments:

- FDA states in the proposed revisions that the proposed produce regulation does not authorize or require farms to take actions that would constitute the "taking" of a threatened or endangered species in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

- Organic producers must manage their farms in a manner that supports biodiversity, and a misinterpretation of FDA's intent behind the proposed rules could jeopardize organic farmers' full compliance with NOP regulations. By including this language in the regulation, FDA clarifies its intention and alleviates the concern for potential regulatory conflict. <Business name> commends FDA for including this language in the rule itself, and for communicating the agency's commitment to environmental stewardship and resource conservation.