Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

The Organic Trade Association (OTA) Talking Points on FDA's Proposed Produce Safety Rule

General Comments

- The organic industry takes food safety seriously. We fully embrace FDA's efforts and the intended outcome of a safer food supply. We believe that **every** food producer has a legal obligation to supply safe food to the public.
- FDA's has the legal responsibility to establish science-based and risk-based minimum standards that will minimize the risk of serious adverse health consequences or death.
- The Food Safety Modernization Act (FSMA) mandates that FDA develop rules that do not duplicate or conflict with existing organic regulations.
- The proposed produce safety rule for the most part takes an integrated and common sense approach focusing on common actions that will be effective in achieving the goal of safe produce. This approach, rather than attempting to establish a unique standard for each type of agricultural commodity, will best help in the development of *preventive controls* to ensure food safety.
- Many growers currently use and understand voluntary auditing programs such as the USDA GAP and GHP (Good Agriculture Practices and Good Handling Practice) programs. FDA can enhance the goals of FSMA by re-evaluating the proposed rules, compare them with existing programs, and identify where current programs may be adequate and where programs need upgrading.
- Considering the number of questions asked in the preamble of the proposed rule and the number of tentative conclusions, the quality and legitimacy of a final rule would be improved if FDA were to consider and respond to the extensive comments received and issue a second proposed rule. We expect there will be many substantive changes made to the proposed rule that will necessitate an additional public comment opportunity.

Biological Soil Amendments of Animal Origin

Background

- Current USDA organic regulations require either a 90- or 120-day waiting period between untreated manure application and crop harvest depending on whether the edible portion of the crop comes in contact with soil. Compost is not subject to any waiting period following application regardless of crop.
- Proposed FDA regulations would require a 9-month waiting period following untreated manure applications and a 45-day waiting period following compost application for all crops covered by the produce safety rule (referred to as "covered crops").
- FDA has tentatively concluded that nine months may be more than is needed under certain circumstances. FDA also explains on Page 3575 of the preamble that "FDA is collaborating with partners on research that may provide scientific support for specific alternatives to this proposed application interval."

Regulatory Conflict and Ramifications

- A recent survey conducted by the Washington State Department of Agriculture (WSDA) and OTA received responses from over 300 of the approximately 8,100 certified organic producers in the USA. This level of response equals a confidence level of 95% and a confidence interval of 5.51%.
- Results indicate that FDA's proposed waiting periods between application and harvest for compost and untreated manure will restrict organic producers' ability to rotate crops as part of preventive pest and disease control and to comply with the established UDSA organic regulations at 7 CFR 205.205 (Crop rotation practice standard).
- Failure to implement crop rotation as part of a preventive pest management program will force organic producers out of compliance with current USDA organic regulations and prompt organic certifiers to pursue adverse action.

Scientific Evidence

- The scientific justification for a 9-month application interval for untreated manure is based on one or two papers that present the worst-case scenario. Numerous other studies on pathogen persistence in soil align more with the current USDA organic regulations (90/120 days depending on soil contact).
- The cited literature doesn't clearly indicate how FDA decided upon a 45-day waiting period as necessary to mitigate the risk of pathogen exposure from compost.

- The use of selective science from worst-case scenarios for assessing pathogen risk from manure and the establishment of seemingly arbitrary waiting periods for compost are inconsistent with FDA's mandate that it develop science-based produce safety rules.

Solutions for Safe Organic Produce

- The proposed 9-month waiting period following untreated manure applications for all produce should be brought into alignment with USDA's organic regulations by implementing a waiting period of 120 days for covered crops in contact with the soil (i.e. potatoes) and 90 days for covered crops not in contact with the soil (i.e. apples).
- The proposed 45-day waiting period following compost applications should only be applied to crops in contact with the soil or compost, and alignment with USDA's organic regulations (no waiting period) should be applied to crops not in contact with the soil.
- Additionally, the 45-day waiting period following compost applications should be removed entirely from compost that has been managed in accordance with time and temperature requirements **AND** tests free of the specific disease causing pathogens outlined in 21 CFR 112.55(a).

Water Requirements

- The proposed requirements for **agricultural water** will place undo economic hardship on organic producers and other producers across the United States by requiring extensive and potentially unnecessary testing in order to ensure water is safe according to water quality criteria that is not proven to be applicable to consumed produce.
- FDA's proposed testing requirements are not appropriate for many operations throughout the U.S. and will significantly increase producer's cost of maintaining a water supply. Testing protocols should be determined according to a risk-assessment conducted by each farm.
- EPA's Recreational Water Standards should not be applied to a food safety regulation since there is no scientific basis as it relates to produce production. Further analysis and scientific justification are needed regarding the indicator organisms used and the microbial limits being set, particularly for irrigation water.
- Prescribed metrics should not be included *in the regulation itself* unless those metrics are scientifically established and proven to be appropriate for any given situation.
- The establishment of alternatives in the regulation will provide some flexibility. However, in addition to the alternatives available to required microbial testing standards, we urge FDA to also allow alternatives for any required testing frequency that may be included in the final rule.
- FDA should provide additional clarification on acceptable forms of scientific data and documentation that would support an alternative practice developed by a farm based on its own research.
- The final rule should be written to allow flexibility within the agricultural water section to allow a risk-based modeling approach when an appropriate model has been designed.

Standards Directed to Domesticated and Wild Animals

- In the Preamble, FDA asserts that in general, carrying out the regulation by minimizing risks to food safety would not require the 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. These principles, however, were not captured in the regulatory text of the proposed rule. The principles so clearly expressed in the expressed in the Preamble should become part of the actual text of the regulation.

Record Keeping

- OTA recognizes the value for farms to conduct operational assessments and develop written food safety plans. We believe that the most effective approach to produce safety would be one that incorporates food safety plans developed at the operational level. We also realize that for some operations, a written food safety plan may be unnecessary. OTA agrees with FDA's decision to not require a written food safety plan. However, we urge FDA to outwardly recommend operational assessments and written food safety plans and to do so through guidance.