

## Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food

The Organic Trade Association's (OTA's) Talking Points on FDA's Preventive Control 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 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.
- As written, the rule will have significant impact on all facilities and, in particular, mixed-facilities throughout the country. 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.

### Proposed Regulations on Hazard Analysis and Preventive Controls

#### *Background*

- The preamble to the proposed rule makes it clear that these new requirements would be based largely on Hazard Analysis and Critical Control Point (HACCP) principles, a systematic, scientifically based approach to food safety developed in the 1960s.
- Operations subject to FDA's juice or seafood HACCP regulations are exempt from the preventive control rule.
- Many handlers/processors currently use and understand voluntary auditing programs such as HACCP and Global Food Safety Initiative (GFSI). Handlers will likely not stop requesting these audits because it is what customers and produce buyers recognize and markets currently demand.
- FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing Section 103 of FSMA. However, FDA also explains that there are significant differences between a HACCP plan and a preventive controls plan. For example, a HACCP plan applies controls at critical control points (CCPs), and each CCP has a critical limit (*i.e.*, a maximum or minimum value to which a biological, chemical, or physical parameter must be controlled in order to prevent, eliminate, or reduce a hazard to an acceptable level).

#### *FDA should formally recognize existing food safety programs that satisfy the requirements of the proposed rule*

- The differences between the proposed preventive rule and HACCP are insignificant. HACCP programs clearly focus on identifying preventive measures for hazards of concerns, and satisfy the proposed requirements for a food safety plan and the specific components therein.
- OTA urges FDA to recognize operations that have an established HACCP Program and HACCP Plan.
- FDA can enhance (or further the goals of) FSMA by building on the existing HACCP-based training programs. It is neither operationally sound nor efficient to create a separate inspection framework for FSMA programs without taking steps to provide integration with currently existing food safety programs.
- OTA recommends that FDA re-evaluate the proposed rules, compare them with existing programs, and identify where current programs may be adequate and where programs need upgrading. We suggest creating a list of recognized training programs prior to the issuance of the final rule.

### Mixed-Type Operations

#### *Background*

- FDA's proposed rule defines "mixed-type facility" as an establishment that engages in activities that are within and outside the definition of a farm. Such operations are subject to the Produce Safety Rule and the Preventive Control Rule.
- FSMA mandates that FDA issue regulations clarifying on-farm manufacturing, processing, packing, and holding activities that would trigger the requirement to register under Section 415 of the FD&C Act. Facilities required to register with FDA are subject to the Preventive Control Rule.
- FDA's proposed rule clarifies that "manufacturing/processing" occurs when a Raw Agricultural Commodity (RAC) is transformed into a processed food. FDA's proposed rule also amends the definition of "manufacturing/processing" to provide that "for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or

holding” unless packing or holding activities are performed on produce not grown on the farm or another farm under the same ownership.

- Accordingly, under FDA’s proposal, a farm or farm mixed-type facility that places others’ RACs into consumer containers would be subject to the Preventive Control Rule because the activity would now be classified as “manufacturing/processing.”

#### *Focus on “risk” rather than “farm ownership”*

- A farm or farm mixed-type facility that places others’ RACs into consumer containers should NOT be subject to the Preventive Control Rule provided the activity does not change the “status” of the RAC into a processed product.
- Foodborne pathogens do not care whether they are grown on the farm or another farm under different ownership.
- Placing a farm’s own RACs or a neighbor’s RACs into consumer containers that contact the food (e.g., a strawberry farm placing strawberries in clamshell packages, an egg farm putting eggs in cartons, an apple farm placing apples into bags) should be considered “packing” within the “farm” definition.
- A farm operating in compliance with the Produce Safety Rule will be able ensure the safe production, harvesting **and packing** of raw fruits and vegetables regardless of the ownership of the farm the produce was grown on.
- The risk and concern is whether the produce received from a farm under different ownership was grown and harvested in a safe manner. Farms should be required to assess their suppliers and accept produce from farms under different ownership provided they are receiving produce that was grown and harvested under the Produce Safety Rule or a similar food safety program.

## **Environmental and Product Testing**

### *Background*

- The proposed rule would not mandate any requirements for testing (e.g., testing of raw materials or ingredients, finished product testing, environmental monitoring). FDA is requesting comments on whether to include such a requirement in the final rule.
- The role and need for product testing and environmental monitoring vary depending on the type of products and processing operation. It should be the facility’s responsibility to determine the testing needed to verify that its preventive controls are effective.
- It is generally acknowledged that testing, especially microbiological, is in most cases not a practical preventive control or critical control point. It is typically used as a verification tool.
- In the preamble, FDA makes very clear that it believes testing is an essential part of an effective food safety plan for many facilities.

### *Environmental testing is a verification tool that should be emphasized in guidance*

- Testing is an important verification measure to ensure that preventive controls are effectively controlling hazards. More so, 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.
- FDA should focus on ensuring that preventive measures are properly designated and effective, instead of relying on environmental or finished product testing.
- 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**

### *Background*

- The proposed rule would not mandate any requirements for approval or verification of suppliers. However, FDA believes that a supplier approval and verification program can be an important part of a preventive approach to food safety.

### *Supplier approval and verification is best addressed in guidance*

- The role and need for supplier approval and verification vary depending on the type of facility and type of food.
- Rather than mandating supplier verification, we recommend that FDA issue guidance that can be adapted to each operation.