



FSMA RULES HIGHLIGHTS OF WG COMMENTS

BOTH RULES

Although food safety programs may differ widely in their content, it is our strong assertion that preventive practices have a place in every setting in the fresh produce supply chain regardless of the size of the farm, the length of the supply chain or the commodity that is produced.

There are numerous areas of the *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* Rule (Produce Rule) where the simple act of handling product from a different owner results in a shift out of the proposed Produce Rule to the proposed *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* (Preventive Controls Rule). “Ownership” of product should not be a determining factor for which Rule an operator is subject to. In fact, the complexity of the FDA proposals in this area may work against food safety by confusing preventive practices for farms with controls more applicable to facilities.

PRODUCE RULE

Western Growers recognizes that there are significant data and research gaps regarding on-farm produce safety preventive controls which make finalization of the FDA produce safety standards in several areas difficult. While Western Growers supports the use of metrics as a means of evaluating the integrity and safety of key inputs, we believe that more research is needed before numerical preventive standards are imposed and producers are held liable to meet those standards. Western Growers suggests that the numeric standards proposed in the rule be reviewed prior to the associated effective dates for producers.

The proposed Produce Rule is appropriately focused on practices and every fresh produce supplier (and receiver) should review the potential for these practices to introduce contamination into their system and products and tailor their programs accordingly.

The proposed Produce Rule provides much flexibility for operators to tailor their preventive practices but Western Growers believes additional flexibility is needed in the Rule to allow producers to target their limited resources toward preventive efforts in the areas most necessary for their unique setting, practices and commodity characteristics.

To increase the flexibility within the proposed Produce Rule, the FDA should allow broader application of both the “alternative approach” and “variance” mechanisms. If a program is offered by or on behalf of a producer, packer, harvester or other party subject to the Rule, the FDA should evaluate that program for its preventive practices, and as long as it is at least as protective as the proposed standard, it should be approved for use by those individuals in that setting.

PREVENTIVE CONTROLS

We are supportive of the FDA's proposed provisions for revising current requirements in part 110 and for incorporating hazard analysis and preventive controls into food safety plans for food manufacturing/processing facilities. We assert that a preventive and practical final Rule should provide clear standards that are based on fundamental food safety principles and accompanied by guidance as needed to provide individual operators with a pathway to tailor programs to their unique risks.

Hazard Analysis and Risk-based Preventive Controls (HARPC) provides a flexible framework to formulate a food safety plan and utilize the best available technologies and scientific information to implement the most effective monitoring activities. While environmental testing is one of several appropriate tools to verify that preventive practices are effectively minimizing or preventing identified hazards, it is not itself a preventive practice. Similarly, the merits of product testing are also recognized by the produce industry as a tool to verify preventive practices. However, finished product testing presents a unique set of challenges and concerns for the fresh produce industry including the time and cost to confirm a positive result, the disruptions within the commercial pipeline and the statistical reliability that does not ensure the safety of fresh produce prior to sale/distribution. We encourage the FDA to exclude environmental and product testing from the final Rule.

Western Growers supports the FDA's intent of aligning any potential requirements for a Supplier Approval and Verification Program (SAVP) in the Preventive Controls Rule with the requirements in the currently proposed rule addressing *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals* (FSVP). We recommend that a risk-based framework is used if any requirements to evaluate suppliers and conduct verification are included in the proposed Rule to allow facilities to maximize the use of their resources and determine the need for these activities. Domestic facilities that source from both domestic and international suppliers should not have to follow two distinct sets of requirements to satisfy this Rule and the FSVP.

Collecting information about the company size and type, products manufactured/handled, employee number, and operational schedule may be helpful to the FDA in prioritizing inspections to maximize their resources. Other components of a company's food safety plan (e.g., hazard identification, preventive controls, third-party audits, and employee training) may change frequently or may include proprietary information with collection and entry imposing a significant burden for fresh produce facilities. The FDA should evaluate a company's hazard analysis and preventive controls within the context of an operation and with consultation with on-site food safety personnel.