

FDA expands farm definition and exemptions

Here's what you need to know about the Food Safety Modernization Act's Preventive Controls for Human Food final rule.

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On September 17, the U.S. Food and Drug Administration (FDA) published the Preventive Controls for Human Food final rule in the Code of Federal Regulations (CFR). There are two major features of the rule: 1) requirements for hazard analysis and risk-based preventive controls and 2) revision to the existing Current Good Manufacturing Practice requirements. All these new features will be placed in 21 CFR Part 117 titled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food." For the Florida citrus industry, this rule has the potential to impact fresh fruit packers. Juice processors who already fall under the Juice HACCP (Hazard Analysis and Critical Control Point) final rule are exempt.

FDA hosted a conference call on September 15 for more than 1,000 stakeholders to discuss the range of facilities that will be covered by the Food Safety Modernization Act's Preventive Controls for Human Food final rule. In the earlier proposal and comment periods, FDA received considerable stakeholder feedback, particularly regarding the regulation of farm operations with activities that overlapped proposed versions of both the Preventive Controls rule and the Produce Safety rule. During the call,

representatives from FDA stated their intent to streamline grower compliance by minimizing the number of different regulations that an individual operation needs to follow. To address these concerns, FDA has expanded the farm definition to reflect the complex reality that many farming operations do undertake activities beyond simply growing and harvesting crops.

Farms are not covered by the final Preventive Controls rule. Thus, the regulatory requirements for many producers will be streamlined by their inclusion within the expanded farm definition. In the proposed rule, there was a distinction made between "on-farm" and "off-farm" packinghouses/facilities. Thus, there were many possible scenarios where growers would need to comply with multiple regulations (e.g., Produce Safety rule for "on-farm" activities and Preventive Controls for Human Food rule for "off-farm" activities). The expanded "farm" definition now includes some of the "off-farm" but "farm-owned" packing facilities that would have previously fallen under the Preventive Controls rule.

The Preventive Controls for Human Food final rule expands the farm definition to include 1) primary production farms and 2) secondary activities farms. Regardless of the distinction made between primary

production farms and secondary activities farms, both are considered farms and neither will be covered under the Preventive Controls final rule or required to register as a food facility.

PRIMARY PRODUCTION FARM

A primary production farm is defined as an *operation under one management in one general, but not necessarily contiguous, location that is devoted to the growing of crops, the harvesting of crops, the raising of animals or any combination of these activities*. This definition was expanded by replacing "facility" with "operation" and "ownership" with "management."

In previous proposals, stakeholders expressed concern that the definition excluded cooperatives and operations divided by a road, for example. The revised wording still lacks some clarity regarding what FDA will consider as *one general location*, which stakeholder participants were quick to point out. FDA is working to resolve the many nuances in this definition and expects to issue further guidance in the near future, but reiterated its desire to streamline regulatory requirements for all farming operations.

In addition to growing and harvesting crops, primary production farms can also pack or hold raw agricultural commodities (RACs) *regardless of who grew them*. Primary production farms can also perform limited processing functions such as drying grapes to produce raisins or treating produce with ethylene gas. Further processing, such as slicing, is not allowed on a farm and must occur in a registered food facility following the Preventive Controls for Human Food rule.

SECONDARY ACTIVITIES FARM

A secondary activities farm is an *operation not located on a primary production farm (i.e., where crops are grown) that is devoted to harvesting, packing and/or holding RACs*. In previous iterations, these secondary

activities farms would have fallen under the Preventive Controls rule, but this expanded farm definition allows for an exemption for these operations as long as *the primary production farm(s) that grow, harvest and/or raise the majority of those RACs must own or jointly own a majority (i.e., 51 percent or more) interest in the secondary activities farm.*

The discrepancy between ownership requirements of RACs on primary production farms vs. secondary activities farms is a nuance that stakeholders are seeking further guidance on, especially considering the vagueness of the “one general location” provision that distinguishes between what even constitutes a secondary activities farm.

FACILITIES COVERED

The facilities that *are* covered under the Preventive Controls final rule, generally, include facilities that manufacture, process, pack or hold food. These are the facilities that are required to register with FDA, and this does not include farms or retail establishments. There are some exemptions and modified requirements for certain facilities that are detailed in the final rule. FDA will issue additional guidance documents. 🍊

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For More Information

- Read the full final rule online: www.fda.gov/fsma
- Contact the U.S. Food and Drug Administration about the Food Safety Modernization Act and find the new online form for submitting questions: www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm



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