

The on-farm readiness review resource document addresses preharvest, harvest and postharvest requirements of the Produce Safety Rule.

# On-farm readiness reviews help growers with Produce Safety Rule

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he Produce Safety Rule (PSR) was published by the U.S. Food and Drug Administration (FDA) in the Federal Register in November 2015 as one of seven major new regulations under the Food Safety Modernization Act (FSMA). The PSR covers activities related to the growing, harvesting, packing and holding of fresh-market produce, with a few specific exemptions.

#### GROWER TRAINING AND TOOLS

A requirement of the PSR is that at least one person from each farm attend a Produce Safety Alliance (PSA) grower training course or receive other equivalent training. PSA grower trainings by University of Florida Institute of Food and Agricultural Sciences (UF/ IFAS) Extension have been ongoing in Florida since October 2016. This oneday course covers and expands upon good agricultural practices and highlights the key PSR requirements related to worker training, health and hygiene; biological soil amendments of animal origin; wildlife and domesticated animals; agricultural water quality; sanitation; and recordkeeping.

More information is available at sc.ifas.ufl.edu on upcoming grower training courses.

After attending a PSA course and developing awareness of the key PSR requirements, many growers still have questions about different ways that the PSR requirements might be met in their operations. To bridge this critical gap, the National Association of State Departments of Agriculture (NASDA) — in partnership with FDA, state departments of agriculture and Extension from across the United States — received funding to develop and deliver an on-farm readiness review (OFRR) tool.

The OFRR will be used by most states to ensure technical assistance and educational on-farm engagement by the state departments of agriculture and Extension. The tool will be used on an individual farm or operation to help align practices with the regulatory requirements. Another goal of the OFRR process is to help establish a conversational dialogue between growers, regulators and Extension before inspections begin.

As opposed to a third-party audit or regulatory inspection, the OFRR assessment is a high-level overview of the operation and is focused on farm activities, with no formal record review, although the few records that are required under the PSR are discussed. Participating in an OFRR is voluntary, is initiated by a grower/ harvester/packer and takes place at the grove/packinghouse.

In Florida, the OFRR team of assessors will typically consist of two to three people from the Florida Department of Agriculture and Consumer Services and UF/IFAS. The entire OFRR process is intended to take two to four hours. The OFRR tool presents the PSR requirements in the general sequence of farming activities: preharvest, harvest and postharvest. This structure allows assessors and participants to sort out the sections of the OFRR tool that are relevant to a specific operation and quickly identify the associated PSR regulatory require-

### The on-farm readiness review program is voluntary and there is no fee to participate.

ments. For example, many citrus growers do not conduct any postharvest activities as part of their operation. In that case, the postharvest sections of the OFRR tool would not be needed. Similarly, the harvesting sections may apply to a contracted harvester.

#### MODULES ADDRESS REQUIREMENTS

The OFRR toolkit contains several parts, including an exemption questionnaire to determine if any or all parts of the operation could be excluded from the PSR (e.g., if all of the fruit goes to make juice). The OFRR also includes a PSR decision tree to determine the sections of the tool that pertain to the operation, FSMA factsheets, and the OFRR resource document. This document consists of 12 modules that refer to each requirement of the PSR. The modules are:

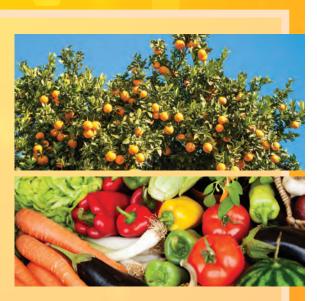
- Worker Health and Hygiene
- Preharvest Water
- Preharvest Sanitation
- Preharvest Worker Training
- Preharvest Wildlife and Domestic Animals
- Preharvest Soil Amendments (of Animal Origin)
- Harvest Water
- Harvest Sanitation
- Harvest Worker Training
- Postharvest Water
- Postharvest Sanitation
- Postharvest Worker Training

Within each module, there is information on the regulatory requirement for each section, examples of possible activities that may lead to compliance

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August 15–16 Lee Civic Center North Fort Myers, Florida with each regulatory requirement, and ways that someone who comes onto your operation may evaluate compliance with each requirement (what they're looking for), including if a record is required. Every grower participating will receive a copy of the full OFRR tool at the time of the visit.

#### WHAT TO EXPECT FROM ASSESSORS

After conducting the OFRR through discussion and observation of relevant growing, harvesting, packing and holding activities, the assessors will conduct a final meeting to highlight both positive aspects of the operation and high-priority areas for improvement. The assessors will address any remaining questions, review use of the OFRR tool, discuss potential followup technical assistance, and explain the current regulatory approach and potential changes related to the PSR provisions on agricultural water and soil amendments.

No documentation of the OFRR is

kept by the assessors; any notes taken during the OFRR will be left with the grower/harvester/packer. After completing a PSA training, voluntarily participating in an OFRR, and following up with any additional technical assistance, your operation should be ready for a regulatory inspection. Inspections are anticipated to begin in spring 2019.

A significant amount of effort has gone into minimizing the risk to the grower/harvester/packer, should an egregious condition be found during an OFRR. Egregious conditions are defined by FDA as a practice, condition or situation on a farm or in a packinghouse that is reasonably likely to lead to serious adverse health consequences or death from the consumption of or exposure to covered produce; and/or an imminent public health hazard is posed if corrective action is not taken immediately. If an egregious condition is found, assessors have been trained in a course of actions to follow with the grower/packer. If product has not

entered commerce, and the issue can be immediately addressed, no further action will be taken.

The OFRR program is voluntary and there is no fee to participate as federal funding (through cooperative agreements to the states) to provide this service to growers was mandated under FSMA. To sign up for an OFRR in Florida, visit freshfromflorida.com/ FSMA. NASDA also intends to make the tool publicly available online after the formal launch of the OFRR program in spring 2018.

More information can be found online at fda.gov/fsma about the PSR.

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