PRODUCE SAFETY RULE INSPECTIONS AND THIRD-PARTY AUDITS

Extension Legal Services Initiative
FSMA Fact Sheet

NECAFS
The Northeast Center to Advance Food Safety

VERMONT LAW SCHOOL

AGRICULTURE & FOOD SYSTEMS

Produce growers have asked about the difference between produce audits and FSMA PSR inspections, particularly regarding any legal protections or obligations that result as a consequence of being found in or out of compliance during a FSMA PSR inspection, or from succeeding or failing to meet an audit's acceptance criteria. This factsheet helps to distinguish between audits and inspections, and discusses how they may impact a producer's liability.

WHAT IS THE FSMA PSR?

The Food Safety Modernization Act's Produce Safety Rule (FSMA PSR) sets mandatory standards for growing, harvesting, packing, and holding produce for human consumption.

Thank you to Andrew Chamberlin, UVM Extension, for many of the photos in this factsheet.

Why do we have both audits and inspections?

In 1998, FDA released the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, a non-binding set of best practices known as Good Agricultural Practices (GAPs) for produce farms. Adopting GAPs is voluntary. However, many buyers require the implementation of GAPs, verified through a third-party audit, as a buying requirement, essentially making GAPs mandatory for those accessing certain markets. Between 1998 and 2011, buyer requirements and the produce industry drove the implementation of GAPs and voluntary third-party audits on the farm.

The enactment of FSMA in 2011, and subsequent issuance of the FSMA PSR in 2016, led to the first-ever mandatory national standards governing the growing, harvesting, and holding of produce for human consumption (the FSMA PSR). Compliance with the FSMA PSR is verified through routine inspections, which began in 2019.

Inspections may not be occurring on an annual schedule for covered farms, or at all for exempt and qualified exempt farms, so buyers may still require voluntary audits as a purchasing requirement. Therefore, with FSMA PSR inspections underway and buyers still requiring third-party audits as a purchase requirement, the produce safety landscape now contains a range of voluntary audit standards and regulatory requirements.

What is the difference between an inspection and an audit?

FSMA PSR INSPECTION

An inspection is a **mandatory** review of a farm's food safety practices to confirm compliance with the FSMA PSR. An inspection is a review of all covered crops and covered activities on a farm, and is conducted by either an FDA or state agency official, depending on the state. To set up a *routine* or *pre-announced* inspection, the inspector calls to coordinate scheduling. However, FDA has outlined that its unannounced inspections may occur under any of the following circumstances: if an operation does not respond to a routine inspection request within 5 days; as a follow up to prior unresolved produce safety issues; or in response to a complaint, recall, or foodborne illness outbreak.

States conducting routine inspections can follow the same criteria as the FDA or may have their own criteria. For more information on PSR inspections, please visit the Produce Safety Inspections page of the FDA's website at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/produce-safety-inspections.

THIRD-PARTY FOOD SAFETY AUDIT

An audit is a **voluntary** review of a farm's food safety practices to confirm compliance with the audit's produce safety standards. Produce buyers may ask their supplying farms to pass an audit as a purchasing requirement. An audit only reviews the crop(s) requested by the producer, so a farm may have an audit to review only a portion of its total crops grown.

There are a range of food safety audit standards available and they are conducted by accredited entities, such as the U.S. Department of Agriculture, a state agency, or a third party, depending on the audit standard. To set up an audit, the farm or their buyer calls the auditing entity to initiate the process. Common audit standards include, but are not limited to:

- Good Agricultural Practices (GAP); and Good Handling Practices (GHP);
- Harmonized GAP (HGAP);
- GLOBALG.A.P.; and
- state accreditation programs, such as the California Leafy Greens Marketing Agreement.

DIFFERENT STANDARDS ARE REQUIRED FOR AUDITS VS. INSPECTIONS

While going through an audit or an inspection on the farm may appear similar in process, it is important to know that they are different in more ways than just an inspection being mandatory and an audit being voluntary. An inspection verifies all covered crops and all covered activities based on the standards established in the FSMA PSR. Audits, on the other hand, range in what crops and activities they verify and can be based on a variety of different audit standards. Some audits have been matched or benchmarked to the FSMA PSR in order to meet buyer interest in having an audit that demonstrates practices aligned with the PSR; however, an inspection and an audit are separate processes. A producer that has both a PSR inspection and an audit will need to pass both independently. Successful passage of one does not guarantee successful passage of the other.

What does passing an audit or being found in compliance mean for liability?

FSMA PSR INSPECTION

Being found in compliance during an inspection indicates that a farm is satisfying its obligations under the FSMA PSR. In terms of market access, buyers may consider accepting compliance with a FSMA PSR inspection in lieu of an audit. However, FDA does not intend to issue certificates following a FSMA PSR inspection, nor do most states, so an inspection may not be a feasible audit alternative in most cases.

Being found in compliance during a FSMA PSR inspection does not automatically protect a producer from liability if a foodborne illness is traced back to their operation. However, demonstrating compliance could reduce their civil or criminal liability (for more information, see our fact sheet on liability).

THIRD-PARTY FOOD SAFETY AUDIT

Passing an audit indicates that the farm is in compliance with the audit's produce safety standards.

Audits may be used to grant market access for a producer, and may address other, non-food safety, standards. However, FDA has suggested that successfully passing an audit will be part of the consideration for prioritizing inspections.

Moreover, in some states, passing an audit could reduce an operation's civil liability if it is implicated in a foodborne illness outbreak.

How does noncompliance following an inspection or failing an audit impact a producer's liability or market access?

FSMA PSR INSPECTION

If a farm is found out of compliance during a FSMA PSR inspection, there are a variety of actions that could result. These actions range from education and an opportunity to implement immediate corrective action to administrative responses to criminal enforcement.

The FDA has expressed that it intends to examine each noncompliance on a case-by-case basis and exercise flexibility when considering its response.

Administrative responses could include corrective actions, a warning letter, an order to halt sales. Criminal enforcement could result in fines or incarceration.

THIRD-PARTY FOOD SAFETY AUDIT

A producer will not face any legal implications for simply failing an audit. However, if a foodborne illness is traced back to their farm, then both civil and criminal actions may be brought against them, and the failure of the audit could be used as evidence in the case.

Additionally, when an agent of the US government is conducting an audit, there is a potential legal obligation to disclose to FDA any risks of serious adverse health consequences or death observed during the audit.

Because audits are generally a requirement of produce buyers, failing an audit may limit the number of buyers willing to purchase from a farm.

This document is for educational purposes only. It is not intended to serve as legal advice. Each operation and situation is unique, and state laws may vary. Accordingly, for legal assistance, you should contact an attorney licensed in your state.

This fact sheet is part of a series on legal topics related to compliance with the FSMA PSR. To access additional resources, go to go.uvm.edu/fsmafactsheets. If you would like to view the legal research and citations that inform this fact sheet, please contact CAFS@vermontlaw.edu.

We also encourage readers to visit the FDA's website for additional information: www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety

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