

Produce Safety Rule Inspections and Voluntary USDA Audits

Guidance to Help Understand the Differences and Commonalities



Produce safety affects all fruit and vegetable growers and consumers. Growers may fall under the Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) and be subject to regulatory inspections depending on commodities grown, covered activities performed, and the dollar amount of sales over a three-year average. Some growers may also have a market driven buyer requirement for an audit. The term inspection and audit are commonly confused.

The purpose of this document is to help explain the differences between mandatory requirements of the PSR and the requirements within market driven buyer specific audits. The chart below will help to explain differences and commonalities between PSR inspections and United States Department of Agriculture (USDA) audits. In some cases, growers may need both an inspection to satisfy the regulatory requirement and an audit to meet a market driven buyer requirement.

What is FDA? The FDA is a federal agency of the Department of Health and Human Services (DHHS). The FDA is responsible for protecting and promoting Public Health through the control and supervision of food safety such as produce safety, seafood, milk products, tobacco products, medical products, and other food products regulated by FDA. FSMA, signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by strengthening the food safety system. FSMA required the FDA to establish science-based minimum standards under 21CFR112 (PSR) for the safe growing, harvesting, packing, and holding of fresh produce for human consumption.

PSR Inspections will be conducted either by FDA inspectors or state inspectors under state regulatory authority and are required (not voluntary). Covered farms that are not exempt or qualified exempt will be subject to a mandatory inspection under the PSR. Inspections will evaluate the farm's compliance with the PSR and have a preventative focus to reduce foodborne illness with regards to public health. Farms should determine if they are covered, exempt, or qualified exempt by reviewing the [FDA Decision Tree](#).



What is USDA? The USDA is made up of twenty-nine agencies and offices with nearly 100,000 employees who serve the American people at more than 4,500 locations across the country and abroad. In January 2002, USDA Agricultural Marketing Service (AMS) formally implemented the USDA Good Agricultural Practices (GAP) audit verification program. The program verifies the participant has taken pro-active measures to

reduce the risk of contamination by adhering to generally recognized industry best practices.

Audits are voluntary, market driven by the buyer, and focus on the use of best agricultural practices to verify that fresh fruits, vegetables, and nuts are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial food safety hazards. There are several different types of audits and each has specific requirements and associated fees.

[USDA GAP Audit Programs](#) offered include the USDA GAP (formerly the USDA GAP&GHP), Harmonized GAP, and Harmonized GAP Plus+ audits. The USDA GAP audit is USDA's foundational GAP audit aligned with the FDA Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. The USDA Harmonized GAP audit is aligned with the Produce GAP Harmonization Initiative and the FSMA Produce Safety Rule, in addition to industry best practices. The USDA Harmonized GAP Plus+ audit builds upon the USDA Harmonized GAP audit by including additional requirements which have allowed the program to be recognized by the Global Food Safety Initiative (GFSI) Technical Equivalence process.

The following chart only focuses on differences and commonalities of PSR inspections, USDA GAP audits, and USDA Produce GAPs Harmonized audits. There are many other GAP audit schemes available with additional requirements that are not covered in this document. Additionally, some third-party companies conduct other types of audits based on certain market driven buyer standards and matrices.

	FSMA PSR Inspections	USDA GAP Audit	USDA Harmonized GAP/Harmonized GAP Plus+ Audit
Are farmers required to participate?	Yes. Inspections are mandatory for any <u>covered</u> farm/operation that grows, harvests and packs <u>covered</u> produce under the rule. This is determined by a three-year gross sales average and the threshold increases with inflation (See FDA Decision Tree to determine coverage and exemptions).	No. Audits are a voluntary service. Farms/operations may be required by a buyer/market to pass an audit to sell their produce.	No. Audits are a voluntary service. Farms/operations may be required by a buyer/market to pass an audit to sell their produce.
Who is the governing authority?	FDA and/or State	USDA	USDA
Is Farm Registration required?	Varies by state or governing authority.*	No.	No.
Who performs the service?	State and/or FDA inspector	USDA auditor or USDA-licensed state auditor	USDA auditor or USDA-licensed state auditor
Is there a fee or cost for this service?	No.	Yes. Fees are hourly and based on several factors. Hourly rates increase periodically. (See Fresh Fruits and Vegetables-Audit Verification Services-Federal and State)	Yes. Fees are hourly and based on several factors. Hourly rates increase periodically. (See Fresh Fruits and Vegetables-Audit Verification Services-Federal and State)
What is the frequency?	Varies by state or governing authority based on numerous factors such as commodities, risks, and previous inspection results.*	Initial annual audit, and operations may also be subject to unannounced visit(s) depending on length of growing season during the one-year certification and the scope of the audit.	Initial annual audit, and operations may also be subject to unannounced visit(s) depending on length of growing season during the one-year certification and the scope of the audit.
What is the final outcome or determination?	In compliance or not in compliance.	Meets or does not meet. Minimum of 80% must be scored on each scope of the audit conducted to “pass” the audit. In addition, no “automatic unsatisfactory” conditions can be present.	Meets or does not meet. Minimum of 80% must be scored on each scope of the audit conducted to “pass” the audit. In addition, no “immediate action required” conditions can be present.

	FSMA PSR Inspections	USDA GAP Audit	USDA Harmonized GAP/Harmonized GAP Plus+ Audit
Commodities Inspected or Audited?	Raw Agricultural Commodities (Covered crops) as specified in the PSR (See Subpart A—Comments on Definitions and General Provisions). (§ 112.1 (a)(b))	Most specialty crops as defined by USDA. Growers choose which products to have audited.	Most specialty crops as defined by USDA. Growers choose which products to have audited.
Commodities not Inspected or Audited?	See Rarely Consumed Raw list for produce not covered (§ 112.2 (a)(1)(2)(3)).	Algae, Forage and grain products, Mint oil and other similarly produced oils, Medicinal herbs, Sea asparagus, Seaweed, and Sprouts. (See GAP Program Scope).	Algae, Forage and grain products, Mint oil and other similarly produced oils, Medicinal herbs, Sea asparagus, Seaweed, and Sprouts. (See GAP Program Scope).
What are the scopes of activities?	Covered Activities means growing, harvesting, packing, or holding covered produce on a farm. (See definition in § 112.3 for clarification.)	General questions along with the scope(s) selected by auditee. Activities covered by a GAP audit can include growing, harvesting, (re)packing, holding, and food defense.	General questions along with the scope(s) selected by auditee. Activities covered by a GAP audit can include growing, harvesting, (re)packing, holding, and food defense.
What hazards are covered?	Biological	Biological, Physical, and Chemical	Biological, Physical, and Chemical
Is there an external training requirement?	Yes. Produce Safety Alliance Grower Training or equivalent (See Subpart C—Comments on Personnel Qualifications and Training).	No. GAP training is encouraged but not required.	No. GAP training is encouraged. If an operation is subject to the PSR they must meet the Subpart C requirements.
Are records required to be kept by the farm?	Yes. Records are required as specified under each subpart of the PSR as specified. Records are also required for qualified exempt farms (See Subpart O—Comments on Records).	Yes. Records are required as specified dependent upon scope of audit.	Yes. Records are required as specified dependent upon scope of audit.

	FSMA PSR Inspections	USDA GAP Audit	USDA Harmonized GAP/Harmonized GAP Plus+ Audit
Is a documented food safety plan required?	No.	Yes. A documented and implemented food safety plan is required for the audit to occur.	Yes. A documented and implemented food safety plan is required for the audit to occur.
Is a traceability or recall plan required?	No.	Yes. A documented traceability plan and mock recall are required.	Yes. A documented traceability plan and mock recall are required.
Are there requirements for preharvest water testing on farms?	PSR Subpart E (once finalized).	Yes, preharvest as directed by risk assessment. Minimally: Municipal water - annual report or test. Well water - one test during the growing season. Surface water - three tests during the growing season.	Yes, preharvest as directed by risk assessment. Minimally: Municipal water - annual report or test. Well water - one test during the growing season. Surface water - three tests during the growing season.
Is periodic commodity sampling or environmental sampling required?	No. The only exception would be for sprouts as specified under Subpart M.	No.	No.

*Please contact your state produce program for more information.

(<https://www.afdo.org/directories/dslo/results/?q=&loc=All&a083j00001hmr0LAAQ=on>)

Accessory Documents

FDA-PSR

- FDA Decision Tree <https://www.fda.gov/media/94332/download>
- PART 112 – Standards for the growing, harvesting, packing, and holding of produce for human consumption <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-112>
- Frequently Asked Questions on FSMA: Produce Safety Rule <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma#Produce>
- What to Expect of a Regulatory Inspection <https://www.fda.gov/media/124328/download>
- Draft Guidance for Industry: Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-evaluating-alternate-curricula-standards-growing-harvesting-packing-and>

USDA

- Good Agricultural Practices (GAP) Audit Program Scope <https://www.ams.usda.gov/sites/default/files/media/GAPProgramScope.pdf>
- Fresh Fruits and Vegetables, Audit Verification Services- Federal and State <https://www.ams.usda.gov/services/grading/fees#fresh>

- Good Agricultural Practices and Good Handling Practices Audit Verification Program User's Guide [GAPGHP Audit Program User's Guide.pdf](https://www.ams.usda.gov/sites/default/files/media/GAPGHP_Audit_Program_User's_Guide.pdf)
- Produce GAPs Harmonized Food Safety Standard https://www.ams.usda.gov/sites/default/files/media/Harmonized_GAP_Standard_Version2.pdf
- Harmonized GAP Plus+ Standard https://www.ams.usda.gov/sites/default/files/media/Harmonized_GAP_Plus_Standard_Version3.pdf
- USDA Aligns Harmonized GAP Program with FDA Food Safety Rule <https://www.ams.usda.gov/sites/default/files/media/FAQsUSDAGAPFSMAProduceSafetyRuleAlignment.pdf>
- USDA Harmonized GAP Audit-What One USDA Audit Can Do for You [GAP Suite of Services 2018 - one pager \(1\).pdf](https://www.ams.usda.gov/sites/default/files/media/GAP_Suite_of_Services_2018_-_one_pager_(1).pdf)
- Produce GAPs Harmonized Food Safety Audit Program https://www.ams.usda.gov/sites/default/files/media/Produce_GAPs_Harmonized_Auditor_Manual.pdf
- USDA Harmonized GAP Plus+ Audit Service Questions and Answers <https://www.ams.usda.gov/services/usda-harmonized-gap-plus-audit-service-questions-and-answers>

Extension Resources

- Produce Safety, Audits, and Regulations: A Few Short Questions and Answers to Help Fruit and Vegetable Growers <https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Audits-and-regulations.pdf>
- Produce Safety Rule Inspections and Third-Party Audits <https://elsi.necafs.org/psr-inspections-third-party-audits>
- Southern University Agricultural Research and Extension Center (SUAREC) Comparison of Produce Safety Rule and Good Agricultural Practices [SUAREC PSR - GAP Comparison 2021.pdf](https://www.suarec.org/wp-content/uploads/2021/03/SUAREC-PSR-GAP-Comparison-2021.pdf)

References

- Association of Food and Drug Officials-Produce Safety https://www.afdo.org/resources_category/produce-safety/
- Food and Drug Administration Produce Safety Rule <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>
- United States Department of Agriculture Good Agricultural Practices Audits <https://www.ams.usda.gov/services/auditing/gap-ghp>
- Produce Safety Alliance <https://producesafetyalliance.cornell.edu/>

The Association of Food and Drug Officials is the international leader and trusted resource for building consensus and promoting uniformity on public health and consumer protection issues related to the regulation of foods, drugs, devices, cosmetics and consumer products.

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