



Agricultural Marketing Service

Frequently Asked Questions

USDA Aligns Harmonized GAP Program with FDA Food Safety Rule

AMS/Specialty Crops Program
June 5, 2018

What action did USDA take?

The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) have aligned USDA's voluntary Harmonized Good Agricultural Practices (GAP) Audit Program with the FDA's Food Safety Modernization Act Produce Safety Rule.

This alignment is the first step the federal government will take to streamline the complex regulatory and market requirements for America's specialty crops sector. Once auditors, inspectors and stakeholders are educated on the alignment, the alignment will help ensure the voluntary, user-fee funded USDA H-GAP Program continues to advance preventive food safety practices and facilitate market access for the specialty crops industry.

With this alignment, USDA Harmonized GAP audits are now an additional tool that farmers can use to demonstrate to buyers that they are implementing the requirements set forth in the Produce Safety Rule. While the USDA audits are not a substitute for FDA or state regulatory inspections, the alignment helps farmers by allowing them to assess how ready they are to comply with the rule. The alignment also streamlines complex regulatory requirements for the U.S. specialty crops sector and facilitates market access for the specialty crops industry.

Does this mean the requirements for the USDA Harmonized GAP audit and the Produce Safety Rule are identical?

No. The requirements of the USDA Harmonized GAP audit and the Rule are not identical, but the alignment means that all relevant technical components in the Rule are covered in the USDA Harmonized GAP Program, and that the metrics used in the USDA program meet the Rule's ultimate goals of increasing food safety.

Why did USDA align its GAP audit program with the FSMA Produce Safety Rule?

USDA took this action to provide a practical solution to help grow markets for America's specialty crops sector and to help them keep our nation's food supply safe. This action is the initial step that helps ensure that USDA's voluntary, user-fee funded USDA Harmonized



GAP Program continues to advance preventive food safety practices and facilitate market access for the specialty crops industry.

Once auditors, inspectors and stakeholders are educated on the alignment, the alignment will help ensure the voluntary, user-fee funded USDA H-GAP Program continues to advance preventive food safety practices and facilitate market access for the specialty crops industry.

How does the USDA Harmonized GAP Audit and FDA regulatory inspections compare?

USDA Harmonized GAP Audit	Produce Safety Rule Inspection
<p>Market Access Audit</p> <p>USDA Harmonized GAP audits are a way to demonstrate to buyers that you have met the requirements of the Harmonized GAP Initiative and essentially implemented the requirements of the Produce Safety Rule.</p>	<p>Regulatory Inspection</p> <p>Regulatory inspections are a way to demonstrate to Federal or State regulators that you are complying with the requirements of the Produce Safety Rule.</p>
<ul style="list-style-type: none"> - Confirms compliance with Produce Harmonized GAP Standard - Aligns with Produce Safety Rule technical requirements 	<ul style="list-style-type: none"> - Confirms compliance with Produce Safety Rule
<ul style="list-style-type: none"> - Voluntary 	<ul style="list-style-type: none"> - Mandatory
<ul style="list-style-type: none"> - Annually upon request 	<ul style="list-style-type: none"> - No predetermined frequency
<ul style="list-style-type: none"> - Fee for service 	<ul style="list-style-type: none"> - No cost to producer
<ul style="list-style-type: none"> - USDA-licensed auditor 	<ul style="list-style-type: none"> - Regulatory inspector
<ul style="list-style-type: none"> - USDA certification of meeting audit standard and acceptance criteria 	<ul style="list-style-type: none"> - Documentation provided
<ul style="list-style-type: none"> - Result on USDA website 	<ul style="list-style-type: none"> - Significant deficiencies recorded for correction

How does this alignment help me as a producer?

The alignment of USDA’s premier food safety verification program for fruits and vegetables with the requirements of the FDA’s Produce Safety Rule provides growers with an opportunity to better understand how their operations align with FDA’s complex regulatory requirements for America’s specialty crops sector, and gives America’s specialty crops sector a new tool for delivering safe products to consumers and growing markets for their products.

The USDA Harmonized GAP audit program is an audit that was developed as part of the Produce GAP Harmonization Initiative, an industry-driven effort to develop food safety GAP standards and audit checklists for pre-harvest and post-harvest operations. The initiative will continue to serve the platform for ensure that all stakeholders are involved in the next implementation steps needed to properly educate and train auditors, inspectors and production facilities.



How does this alignment help me as a buyer?

The alignment allows buyers to use a single audit – the USDA Harmonized GAP audit – both to demonstrate compliance with the Produce Harmonized GAP Standard AND the relevant technical components in the Produce Safety Rule. The metrics in USDA’s Harmonized GAP audit will provide you with metrics that help you meet the Rule’s ultimate goals of increasing food safety.

What is a USDA Harmonized GAP audit?

The USDA Harmonized GAP audit program is an audit that was developed as part of the Produce GAP Harmonization Initiative, an industry-driven effort to develop food safety GAP standards and audit checklists for pre-harvest and post-harvest operations. The Initiative is a collaborative effort on the part of growers, shippers, produce buyers, audit organizations, and government agencies, including USDA.

The USDA Harmonized GAP audit, in keeping with the Initiative’s goals, is applicable to all fresh produce commodities, all sizes of on-farm operations, and all regions in the United States.

What is the difference between a regulatory inspection and a GAP audit?

A regulatory inspection is an action taken by a Federal or State regulatory agency to verify compliance to a law. In the case of regulatory inspections related to the Produce Safety Rule, the FDA will determine when and how frequently regulatory inspections will be conducted to ensure adherence to the requirements of the Rule. Regulatory inspections only address what is outlined in the law – in this case the Food Safety Modernization Act. They do not assess compliance to company specifications or industry best practices.

A USDA GAP audit is a market access tool used when a buyer requires its supplier(s) to undergo an annual food safety/GAP audit to ensure specific food safety practices are being followed based on buyer specifications and/or industry best practices. In addition to market access, the USDA Harmonized GAP Audit, one of our suite of GAP services, also provides the producer with the ability to demonstrate their conformance with the technical requirements of the Produce Safety Rule.

If I get a USDA Harmonized GAP audit, do I still have to undergo a Food and Drug Administration regulatory inspection to ensure my compliance to the Produce Safety Rule?

Yes. The USDA Harmonized GAP audit is a market access tool – it is not a regulatory inspection. Because of the alignment, successful completion of a USDA Harmonized GAP audit provides you with certification that you are in compliance with the Produce Harmonized GAP Standard and also provides you with important information and metrics that demonstrate that you are conforming to the relevant technical components in the Produce Safety Rule.



At this time, the FDA is finalizing their strategy for ensuring compliance to the Produce Safety Rule, including how and when they will carry out regulatory investigations related to the Rule. If an FDA or State regulatory inspector contacts you to schedule an inspection, be sure to communicate your USDA Harmonized GAP audit status for them to consider.

Why should I pay for a USDA GAP audit when a regulatory inspection is free?

You should determine what type of audit you need. If you're looking for market access – an audit that meets your buyer's needs – then a USDA GAP audit is an option for you. Retail, wholesale, and institutional buyers require GAP audits to ensure conformance to a specific set of company specifications and/or industry best practices. In many cases, buyers require a third-party GAP audit as a term of their contracts with their suppliers. A regulatory inspection is designed to assess adherence to a law, and may not meet the needs of a buyer.

Are all USDA GAP audits aligned with the Produce Safety Rule?

No. Only the USDA Harmonized GAP audit is aligned with the Produce Safety Rule requirements. In addition to the USDA Harmonized GAP audit, USDA offers a suite of GAP services to meet the specialty crops industry's unique needs, including audits for specific commodities such as mushrooms, tomatoes, leafy greens and cantaloupes; the basic USDA GAP audit; and GroupGAP, which allows producers of all sizes to attain GAP certification.

What is the Produce Safety Rule?

The Produce Safety Rule, which went into effect on January 26, 2016, establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. The goal is to reduce the presence of potentially dangerous biological hazards in the food supply and illnesses caused by contaminated produce. It is part of the FDA Food Safety Modernization Act.

What is the Food Safety Modernization Act?

The Food Safety Modernization Act, signed into law in 2011, shifts the focus for addressing food safety from responding to foodborne illness to preventing it. The Act is predicated on the understanding that preventing foodborne illness and its consequences improves public health and the economic well-being of the food system.

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