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What the Harmonized GAP FSMA Alignment Means for Growers

June 13, 2018 By [Chelsea Matzen](#) Blog



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On June 5, FDA Commissioner Scott Gottlieb, M.D., and U.S Secretary of Agriculture Sonny Perdue [announced](#) a joint effort to simplify produce safety requirements for farmers by aligning the USDA Harmonized Good Agricultural Practices (GAPs) Audit Program with the requirements of the FDA Food Safety Modernization Act's (FSMA's) Produce Safety Rule.

The [Harmonized GAP Audit Program](#) is a third party audit administered by USDA and developed with industry to verify food safety standards in pre-harvest and post-harvest operations. It verifies that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible. Harmonized GAP is applicable to all fresh produce commodities, all sizes of on-farm operations, and all regions in the United States.

What does this mean for produce farmers? In short, it means that farmers who participate, and successfully pass, the new FSMA aligned Harmonized GAP audit will have had the opportunity to assess their food safety practices in regards to compliance with the Produce Safety Rule. Additionally, as [Secretary Perdue stated](#), “Specialty crop farmers who take advantage of a USDA Harmonized GAP audit now will have a much greater likelihood of passing a FSMA inspection as well.” So – if you’ve passed the Harmonized GAP audit you should pass a FSMA inspection.

It’s important to note that while there is now recognized alignment between the Harmonized GAP Audit and the FSMA Produce Safety Rule these are still not the same programs. Harmonized GAP is **NOT** a replacement for a FSMA inspection. An **AUDIT** and an **INSPECTION** are two different things. The aligned Harmonized GAP **AUDIT** is a voluntary program, just like all audits. It can be performed annually upon request and costs the grower or buyer a fee to perform. Harmonized GAP can only confirm that you’re meeting the standards set out in the Produce Safety Rule. The FSMA Produce Safety Rule regulatory **INSPECTION** is mandatory for all farms that don’t meet an [exemption or qualified-exemption](#) status. There is no predetermined frequency at which inspections will occur and there is no cost to the producer for an inspection. Only a regulatory inspection can confirm you’re compliant with the FSMA Produce Safety Rule. The chart below from a FSMA aligned Harmonized GAP Program [FAQ](#) highlights some of the differences between these two programs.

USDA Harmonized GAP Audit	Produce Safety Rule Inspection
Market Access Audit	Regulatory Inspection
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.	Regulatory inspections are a way to demonstrate to Federal or State regulators that you are complying with the requirements of the Produce Safety Rule.
- Confirms compliance with Produce Harmonized GAP Standard	- Confirms compliance with Produce Safety Rule
- Aligns with Produce Safety Rule technical requirements	
- Voluntary	- Mandatory
- Annually upon request	- No predetermined frequency
- Fee for service	- No cost to producer
- USDA-licensed auditor	- Regulatory inspector
- USDA certification of meeting audit standard and acceptance criteria	- Documentation provided
- Result on USDA website	- Significant deficiencies recorded for correction

Why get a Harmonized GAP Audit? Even if your operation is exempt from the FSMA Produce Safety Rule, it is important to make sure that your operation is following proper food safety practices. An audit, such as the Harmonized GAP, can also increase market access for a grower. Many buyers require some form of third party audit to show that farms are following a certain level of food safety standards. A Harmonized GAP audit is one way to show buyers that you are taking steps to be compliant with FSMA regulations, and that you and your farm are taking extra steps to ensure your products are as safe for human consumption as possible.

It is important to note here that the aligned Harmonized GAP Audit has additional mandatory requirements to those found in the FSMA Produce Safety Rule. These requirements make it *a tougher, more stringent, and more time consuming standard* to meet than just the FSMA Produce Safety Rule standards. Many small growers may want to consider other routes to show FSMA Produce Safety Rule compliance if that's all their buyer is requiring. Clear and open communication with your buyers will help determine your best route.

If a Harmonized GAP Audit is a good option for your operation there is one more added benefit. Those operations that pass the audit will be lower on the FSMA regulatory inspection list. While the largest farms had to be in compliance with the Produce Safety Rule in January of 2018, inspections will not begin until 2019. It is the intent of this alignment and coordination to prioritize the farms that will need inspections when those begin. Farms who have passed the FSMA aligned Harmonized GAP Audit will be lower on the list for FSMA regulatory inspections than farms who have not taken or passed the audit.

More information on the formal agreement between USDA and FDA can be found [here](#). Be sure to check out LFSC's [resources](#) page for more information on tools and programs that you can use to ready your farm or operation for FSMA.

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