

How do GAP and GMP Certifications compare to FSMA’s Produce Safety (PS) Rule?

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This document provides a general comparison between GAP and GMP certifications that produce operations have been undergoing for the past decade and the new requirements set by FSMA’s Produce Safety Rule. Despite the fact that the Produce Safety Rule was published on November 27, 2015 there are guidance documents and inspection guidelines that are being developed at the time of this publication and therefore do not allow for a full comparison of the Rules.

GAP and GMP Certifications	FSMA- Produce Safety Rule
<p>All the Good agricultural practices (GAPs) and Good Manufacturing Practice (GMPs) audits that produce farms have undergone up to this point have been buyer-driven. After passing an audit, the farm receives a GAP and/or GMP Certification.</p> <p>For the past decade, farms selling primarily wholesale have been required to pass a third party audit annually in order to sell to a specific outlet.</p> <p>GAP Audits often include a field and harvest crew audit. GMP audits cover packinghouses and if any produce is processed the facility is often required to have a HACCP plan.</p>	<p>The Produce Safety Rule is a federal law that requires all segments of the industry to grow, harvest, pack and hold produce in such a way that minimizes the risk of causing food borne illness.</p> <p>The PS Rule has set the requirements for a regulatory program that is based on inspections, not audits. An audit will not replace an inspection.</p> <p>The PS Rule is based on Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs).</p> <p>The PS Rule will come into effect starting in 2017 for sprout growers and 2018 for all other operations. (See compliance dates for the PS Rule).</p>
<p>There are numerous companies that offer auditing services; each one has a slightly different scheme (guidance documents, auditing guidelines and fees). Examples of companies include: Primus labs, SQF and USDA.</p>	<p>The Food and Drug Administration (FDA) and the North Carolina Department of Agriculture & Consumer Services/Food and Drug Protection Division regulate the PS Rule. FDA has published the requirements, but the inspection guidelines are forthcoming.</p>
<p>If a grower currently sells to different buyers the farm may be doing audits with different companies.</p>	<p>FDA and NCDA&CS/Food and Drug Protection Division inspectors will conduct inspections. The frequency of the inspections is not outlined in the Rule.</p>
<p>The grower pays for the cost of the audits. Cost share is available to offset some of the costs.</p>	
<p>An audit is only conducted after a grower has requested the service, set a date and paid the fees. The fees are non-refundable if the farm fails the audit.</p>	<p>Inspections may be unannounced. A farm legally has 24 hours to provide records if FDA or NCDA&CS/Food and Drug Protection Division inspectors request these.</p>
<p>Audits have changed the way many farms operate. Many farms have adopted a food safety culture, but audits are only a snapshot of what happened that day at the farm and/or packinghouse.</p>	<p>It will be much easier for a farm that is already following a food safety plan and passing audits to comply with the PS Rule. Records to comply with the PS Rule do not need to be duplicated, just supplemented with any additional requirements.</p>

<p>Audits usually cover the whole operation: adjacent areas, wildlife intrusion, employee hygiene, compliance with city, state and federal laws regarding labor laws, compliance with all pesticide laws and applications, fertilizer (synthetic and organic) applications and laws, harvest practices, water testing and inspection of the water sources, tool inventory, all chemicals used in the operation, maintenance of equipment, pest control, harvest practices, inventory of all the materials supplied, post harvest handling, safe transport, trace back and recall protocols, pre inspection audits by the farm, records and training for all employees that handle the crop.</p> <p>Depending on the audit, there may be more or less requirements.</p>	<p>The PS Rule covers the following:</p> <ul style="list-style-type: none"> - Training - Agricultural water - Biological soil amendments of animal origin - Domesticated and wild animals - Equipment, tools, building and sanitation - Sprouts <p>The rule does not cover aspects of the operation that are already being regulated by other agencies (such as pesticide and fertilizer laws).</p> <p>The rule does not require a farm to have a food safety plan.</p>
<p>Audits require growers to prove they have attended training during the year and to train their employees.</p>	<p>The Rule requires all farms that grow covered produce and do not meet the guidelines to be exempt or qualified exempt to have a supervisor or representative for the farm attend a Produce Safety Alliance Grower training. This is a one-time requirement.</p> <p>In addition, training requirements for employees is very similar in the PS Rule and audits.</p>
<p>Any crop can be audited, as long as the grower requests it.</p>	<p>The PS Rule covers crops that are considered raw agricultural commodities (RACs) and that will not receive commercial processing.</p> <p>The PS Rule provides exemptions and qualified exemptions, so not all operations have to comply with the rule in its entirety. Become familiar with the exemptions and the requirements for these farms if your farm is eligible as there are some record keeping and labeling requirements that will still apply.</p>
<p>In the event of a food safety outbreak, all documents used to build a food safety plan are legally binding, regardless of the fact that FDA does not regulate audits.</p>	<p>In the event of a food safety outbreak, all records must be provided to FDA within 24 hours of a formal request made by the agency to any operation that is being investigated for a possible food safety outbreak.</p>