

A Guide to Food Safety Certification for Food Hubs and Food Facilities



A Guide to Food Safety Certification for Food Hubs and Food Facilities

Created by

Grace Perry,
Community Alliance with Family
Farmers (CAFF)

Kali Feiereisel,
Community Alliance with Family
Farmers (CAFF)

Gwenaël Engelskirchen,
University of California Sustainable
Agriculture Research and Education
Program (UC SAREP)

Acknowledgements

Thank you to our reviewers who
graciously contributed their time and
expertise to this publication:

Jacob Guth,
California Certified Organic Farmers
(CCOF)

Phil Britton,
Fresh Systems, LLC

Patricia Tripp,
Artisan Food Solutions, LLC

Nina Foy

This guide emerges from a Specialty Crop Block Grant project to address barriers and enhance pathways for institutional sourcing from regional farms, particularly small and mid-scale farms. The project is led by Dr. Frederick J. Meyers, Director of UC Davis Health, Center for Precision Medicine & Data Sciences and professor of internal medicine, in close collaboration with UC Health, Food & Nutrition Services and UC SAREP.

Funding for this project is made possible by the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service through grant AM200100XXXXG032. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the USDA.

This information is provided by the authors in good faith, but without warranty. It is intended as an educational resource and not as advice tailored to a specific food hub operation or a substitute for actual regulations and guidance from the US Food and Drug Administration (FDA) or other regulatory agencies. We will not be responsible or held liable directly or indirectly for any consequences resulting from use of information provided in this document.



UNIVERSITY OF CALIFORNIA
Agriculture and Natural Resources

Sustainable Agriculture Research and
Education Program

UC DAVIS
HEALTH

Center for Precision Medicine
and Data Sciences

Table of Contents

Introduction	4
Landscape of the Audit Industry	4
<i>Table: Food Safety FAQs</i>	5
How to Get Started	7
Determine Your Buyer’s Expectations	7
Assess the Risk Level of Your Commodities	10
Assess the Risk Level of Your Activities	10
Determine the Hub’s Capacity to Follow Through with Certification (and Recertify Annually).....	11
Consider Your Hub’s Long-Term Goals	11
Consider the Hub’s Food Safety Requirements for Suppliers (Farms).....	12
Determine if Your Hub Needs to be in Compliance with the FSMA Preventive Controls for Human Food (PC) Rule.....	15
If Your Hub is Certified Organic by CCOF, Consider Both Audits with the Same Certifier	15
So, You Decided to Pursue a Food Safety Certification. What Now?	15
<i>Table: Comparison of Four Common Food Safety Audits</i>	16
Tips for Success	19
Preparing for an Audit	19
What to Expect During an Audit	21
What to Expect After an Audit.....	22
Recertification.....	22
Unannounced Inspection	22
Failing an Audit.....	22
Continual Improvement.....	23
Conclusion	23

Introduction

This guide is written for food hubs and other food facilities seeking information about how to navigate food safety questions from buyers and pursue a third-party food safety audit. The first part of the guide begins with a brief overview of the food safety audit industry and introduces key considerations for food facilities to review prior to pursuing an audit. For food hubs who decide to pursue a third-party food safety audit, the guide concludes by comparing four common food safety audits for food hubs and offers tips for success gleaned from interviews with practitioners and food safety consultants.

Landscape of the Audit Industry

With the prevalence of nationwide foodborne illness outbreaks linked to various commodities throughout the produce industry, more and more buyers require their suppliers to adhere to independent standards for safety and quality. Most buyers verify a supplier's food

safety program by requiring a food safety audit performed by a **Third-Party Certification Body (CB)**, or auditing company. These audits evaluate a supplier's food safety program and can occur at many levels throughout the food supply chain, including distributors, growers, packers, processors and manufacturers of food. Food businesses who pass a third-party audit receive a certification that can be provided to their buyer upon request. Certifications are only valid for one year requiring facilities to undergo an audit annually.¹

Unlike the federal law, the Food Safety Modernization Act (FSMA), or state and local health department regulations that some food businesses must comply with, third-party food safety certifications are **voluntary** and utilized as a marketing tool to help establish new business with larger buyers. For example, institutions and national grocery retailers may require food safety certification.

Note: Full URLs for in-text website links can be found in the footnotes.



1 In emergency situations, annual certifications can be extended to provide time for the auditee or auditor to conduct the next year's annual audit.

Food Safety FAQs

	Good Manufacturing Practices (GMPs)	Good Agricultural Practices (GAPs)	FSMA Produce Safety Rule (PSR) and Preventive Controls for Human Food (PC) Rule	Third-Party Food Safety Audits
What is it?	The US Food and Drug Administration (FDA) regulations published in Title 21 of the Code of Federal Regulations, Part 110 (21 CFR 110) that outline standards that facilities must follow for sanitary food processing. Also referred to as Current Good Manufacturing Practices (cGMPs).	Voluntary guidelines for produce farmers to reduce the risk of microbial contamination related to food borne illnesses on their farms. The guidelines are based on the FDA's Guide to Minimizing Microbial Food Safety Hazards for Fresh Produce . ¹	Required food safety practices for farmers and food facilities covered by federal law. Exemptions may apply depending on the size of the operation.	Voluntary verification of food safety practices used for marketing purposes and potentially increasing access to markets. May be required by some buyers. Also known as GAP audits.
Who is in charge of establishing the standard?	FDA	FDA	FDA	Several standards exist; standards are established by both private and public entities.
How is it enforced?	All food manufacturers are required to follow cGMPs, but not all food manufacturers will be inspected by the FDA for compliance. Food hubs must maintain and monitor GMPs internally unless subject to the PC Rule.	GAPs are voluntary guidelines. Enforcement depends on local or state regulations that might require compliance with GAPs practices.	FDA or State Departments of Agriculture and State Departments of Public Health inspect farms and food facilities to ensure compliance with FSMA.	Both private companies and public agencies offer third party audits.

Table notes:

1. To learn more about the FDA's guidelines in the Guide to Minimizing Microbial Food Safety Hazards for Fresh Produce: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables>



There are several types of **food safety audits, or “schemes,”** available; each audit is based on a **standard** that is owned by a public or private entity.² For example, the United States Department of Agriculture (USDA) owns the Harmonized GAP Plus+ audit standard and the audit is conducted by trained and licensed federal or State Department of Agriculture employees on behalf of the USDA. Audit standards are accompanied by an **audit checklist**,³ which contain the evaluation criteria used during the audit.

Audit standards can contain multiple **modules**⁴ and **scopes**,⁵ that correspond to different aspects of an operation, including but not limited to the farm, harvest, packing house,

processing and storage, and distribution. Depending on the audit, food hubs can choose which modules apply to the scope of their operation. For example, if a food hub only performs storage and distribution activities, they would complete the module(s) that correspond to those activities. Depending on the services provided to the food hub’s buyer, the buyer may specify the required scope of the audit based on their internal safety and quality standards.

With many audits to choose from, the **Global Food Safety Initiative (GFSI)** benchmarking helps ensure consistency and reliability among the certification options. Because of this, many buyers require their suppliers to go through a GFSI recognized certification program; however, this level of certification is not always appropriate for every scenario. GFSI is an independent organization that benchmarks and approves different auditing standards as meeting their criteria; GFSI does not own an audit standard. Audit standards that successfully undergo this process are recognized as GFSI-benchmarked. PrimusGFS and GLOBALG.A.P. are two audit standards that are GFSI-benchmarked. Although not fully GFSI benchmarked, the USDA Harmonized GAP Plus+ standard is considered a GFSI Government Equivalent Benchmarked Standard and is more widely accepted by buyers today. To learn more about GFSI-benchmarked audits, visit the [GFSI-Recognised Certification Programme Owners](https://mygfsi.com/how-to-implement/recognition/certification-programme-owners) website.⁶

-
- 2 Audit standards are requirements developed by audit owners with complete and detailed information about the audit.
 - 3 Audit checklists are the evaluation criteria used during the audit.
 - 4 Audit modules are the part of the audit standard that applies to the audit scope.
 - 5 Audit scopes are the parts of the operation that will be audited, e.g., farm, harvest crew, packinghouse, etc. The scope can be limited to certain fields on the farm, certain areas of the packinghouse, certain high tunnels, etc.
 - 6 To learn more about GFSI-benchmarked audits: <https://mygfsi.com/how-to-implement/recognition/certification-programme-owners>.

How to Get Started

Navigating the bounty of information found on the internet related to food safety audits can be a daunting task. The following key considerations intend to help food hubs and facilities determine their food safety certification goals based on a myriad of factors: 1) buyer expectations; 2) risk assessments; 3) internal capacity; and 4) long-term goals. We recommend reviewing this section as you enter into a conversation about food safety with your buyer and prior to deciding whether to pursue a third-party food safety audit.

Determine Your Buyer's Expectations

If your buyer is asking questions about your hub's food safety practices, don't panic. Questions do not necessarily mean your buyer will request a food safety audit and having a conversation with your buyer about food safety will likely benefit your hub in the long term. If this situation arises, ask your buyer questions to understand what is behind their interest in your food safety practices. It could be just for their own knowledge, it could be because they have regulations requiring them to do so, or something entirely different.



Questions to ask your buyer

- Why do they want to learn more about your food safety practices?
- Do they want documentation of food safety practices? In what form?
- Do they want to conduct a site visit?
- Are they requiring an audit?
- Would they accept a copy of your food safety plan on file in lieu of a third-party certification?
- Is the buyer being asked about the food safety practices of their suppliers by some other entity?

If your buyer requests a food safety audit, ask:

- Do you require a specific audit?
- Which modules of the audit do you need?
- Which audit schemes will you accept from small operations?
- Can you email me your supplier food safety requirements?
- How much time do we have to prepare for and pass an audit?

Mini Case Study

A food hub in California, serving approximately 100 wholesale customers - 50 active accounts and another 50 occasional/seasonal buyers - shares how they respond to buyer questions about food safety practices.

We do not get asked food safety questions very often. If buyers do ask food safety questions, we respond with the information we can provide. If we (the food hub) are asked for a third-party audit specifically, we respond with the following:

- *Letter of Continued Guarantee*
- *Current Food Safety Plan*
- *Preventive Controls Qualified Individual (PCQI) certificates*
- *Copies of producer Organic Certifications*

If your buyer does not request a specific audit, you are free to choose. Consider the tips below when making your decision, keeping the risk level of the commodities you sell in mind, as well as potential future buyers. For example, if your 3-year goal is to sell to a certain buyer with specific certification requirements, start working toward that goal now.

Hub Tips

- **Ensure your expectations are aligned with your buyer by determining if they require specific modules be completed within the audit standard. For example, modules that apply to your packing facility and cooler facility, or Hazard Analysis and Critical Control Points (HACCP) add-on.⁷**
- **It helps to receive answers from your buyer in writing so that they can be referenced as needed.**
- **Often buyers can be flexible, so approach expectation-setting as a conversation. They want to see that your hub takes food safety seriously. If your hub is just starting out with food safety certifications, consider starting with an entry-level audit and negotiating more time for a more complex audit over a few years. For example, perhaps your buyer will accept a working Food Safety Plan for the first year or so, which will give your food hub time to start incorporating necessary additions, like Standard Operating Procedures (SOPs).**

⁷ Hazard Analysis and Critical Control Points (HACCP): a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product; commonly used in food processing and handling operations.



Does your buyer have other food safety requirements aside from an audit?

Make sure that you are clear on ALL the requirements to be able to sell to a buyer (sometimes there are more than just the audit). For example, they might also want documentation that your food hub is in compliance with the PC Rule. Some audit standards are aligned with that law (see pg. 15 of this guide for more information).⁸ They might also want to see that you have general product liability insurance for a certain minimum dollar amount, typically ranging between \$1 million and \$4 million. [Farm Commons](#) has great resources related to farm insurance if you are looking for more information on this topic.⁹

Hub Tip

If it doesn't make sense financially for your food hub to start with an audit, negotiate with your buyer. Ask: will sales to this particular buyer be consistent enough in the long-term to justify the time and expense for your hub? For example, will the ROI on an expensive and difficult food safety audit for higher risk crops (e.g., lettuce) be worth the volume of lettuce you sell them? Some buyers may be willing to cover some of your audit costs depending on the relationship and products you offer.

⁸ Audit standards today are aligned with the FSMA Produce Safety Rule and Preventive Controls Rule. Completing an aligned standard is not a substitute for FDA inspection but can help food hubs assess their readiness to comply with the regulation. To learn more: <https://www.ams.usda.gov/sites/default/files/media/FAQsUSDAGAPFSMAProduceSafetyRuleAlignment.pdf>.

⁹ To learn more about Farm Commons: <https://farmcommons.org/collections/insurance-and-liability/>.

Assess the Risk Level of Your Commodities

Biological, chemical and physical contamination risks are the primary focus of any food safety audit. Foodborne illnesses are caused by biological hazards such as viruses, parasites, and bacteria. Commodities have various risk levels based on the consumption of biologically contaminated food and the illnesses that have resulted. Examples of commodities that are generally considered higher risk: fresh berries, leafy greens, fresh herbs, lettuce, romaine,



spinach, microgreens, and melons. If your food hub primarily distributes commodities that are higher risk, extra care needs to be taken to reduce food safety risks, such as monitoring facility temperature and strengthening sanitation practices.

Risk assessments will be part of any food safety audit, so assess your risk level accordingly when deciding which third-party food safety audit to pursue; however, higher risk does not necessarily mean you need a more complex audit. Hubs can add to their food safety program to cover their risk (e.g., environmental monitoring) instead.

Assess the Risk Level of Your Activities

Is your food hub holding,¹⁰ packing,¹¹ processing,¹² distributing, or a combination of all four? Holding and packing activities are less risky than processing. If your food hub conducts processing activities (e.g., milling flour or shredding cabbage), be sure to select an audit standard that certifies processing activities.¹³ Washing produce or any addition of water in a food facility also elevates the food safety risk of a product.

-
- 10 Definition of “holding”: holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets) but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
 - 11 Definition of “packing”: packing means placing food into a container and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food.
 - 12 Definition of “processing”: processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients (e.g., baking, canning, cutting, drying/dehydrating, labeling, milling, washing, etc.).
 - 13 Processing can be outside the scope of third-party audits and involves working with your State Department of Agriculture or Public Health Department to obtain a license for processing fresh vegetables.

Determine the Hub's Capacity to Follow Through with Certification (and Recertify Annually)

Developing a food safety culture at your food hub means food safety is valued and prioritized, and practices are implemented throughout every level of the organization. A food safety culture is imperative to ensure your hub is distributing safe food for consumers. In business terms, developing a food safety culture also reduces the risk that your business would be connected to a food safety incident.

Answering questions can help determine your hub's current capacity to follow through with and pass a certification.

Questions to assess your hub's capacity:

- What is the food safety culture at your food hub?
- Do you have a food safety plan in place?
- Are employees trained to follow the food safety protocols?
- How financially prepared is your hub to make food safety improvements?
- Are you already following an audit standard but aren't yet certified?
- Are you certified in one audit, but your buyer is asking you for another?
- Will your buyer to accept your current certification while you work towards another?

Preparing for and passing your first food safety audit is just one step of the process. After passing the first audit, your hub will need to maintain its food safety standards - remaining "audit ready" at all times - and recertify once annually to maintain certification.

Keep in mind that certification will result in new expenses, and a more complex audit could



lead to even greater expenses. For example, an audit might elevate the need to replace equipment or implement more robust pest management practices.

Hub Tips

- **Get specific on what percentage FTE (annual, full-time employee) you are able to earmark for audit prep and maintenance. If this is the first time your hub is preparing for an audit, you will likely need at least a 0.5 FTE whose job is dedicated to food safety.**
- **Check with your current and prospective buyers prior to recertification to confirm acceptance of the current certification.**
- **Reviewing the audit checklists and asking peers in your business could help you get a sense of the requirements and the financial impacts of a particular standard.**

Consider Your Hub's Long-Term Goals

Is your hub currently only holding and packing, but plans to include processing activities in the future? Plan your certification goals around the food hub's strategic plan.

Processing activities present a greater food safety risk and could result in more stringent food safety requirements from buyers and



state and local governments. For example, some audit standards do not cover complex processing, slicing and dicing, or any post-harvest activities like drying, which could necessitate your food hub pursuing a more complex audit that verifies all relevant activities, as well as complying with applicable state and local regulations.

A food hub's activities can also impact their status under the PC Rule. For example, the PC Rule provides full and partial exemptions for facilities, as well as modified requirements for some operations. One of these exemptions, the "Secondary Activities Farm Exemption" only allows packing, holding and "low-risk"

processing activities (e.g., dehydrating but not slicing). If your food hub plans to include processing activities in the future, [Demystifying the Food Safety Modernization Act's Preventive Controls Rule](#) can help determine how your food hub's activities would impact compliance with the PC Rule.¹⁴

Consider the Hub's Food Safety Requirements for Suppliers (Farms)

Some buyers require that the hub's suppliers be third-party food safety certified and require proof of this, while some accept the food hub certification in lieu of farm-level certification. Clearly describing your food hub's food safety requirements for suppliers may satisfy your buyer's requirements instead of farm-level food safety certifications.

During an audit, expect to receive questions from your auditor about the farms, or suppliers, you source from.^{15, 16, 17, 18} Hubs must have a procedure explaining their food safety requirements for suppliers and how suppliers' food safety practices are verified. Hubs will need to demonstrate their procedure according to the audit requirements (e.g., through a written policy and/or records).

When establishing your requirements, consider the level of food safety risk among the farms you purchase from. For example, do their activities include field packing or processing? Do they produce commodities that are

14 To learn more about compliance with the PC Rule, see the [Demystifying the Food Safety Modernization Act's Preventive Controls Rule](https://caff.org/pc-rule-supplier-verification-guide/) guide: <https://caff.org/pc-rule-supplier-verification-guide/>

15 In the USDA Harmonized GAP Plus+ standard, these questions appear in the General Questions, Postharvest and Logo Use sections: https://www.ams.usda.gov/sites/default/files/media/HarmonizedGAPPlus%2BStandardVersion4.0_0.pdf

16 In the USDA GMP standard, these questions appear in the Supply Chain section: <https://www.ams.usda.gov/sites/default/files/media/GMPAuditStandard.pdf>

17 In the PrimusGFS v3.2 standard, these questions appear in Module 1 - Food Safety Management System Requirements: <https://primusgfs.com/wp-content/uploads/2022/01/PGFS-ND-020-R2-PrimusGFS-v3.2-General-Regulations.pdf>

18 In the GLOBALG.A.P. PHA Standard, these questions appear in the Supplier Approval section: https://www.globalgap.org/content/galleries/documents/200715_GG_CPCC_PHA_V1_2_en.pdf



Mini Case Study

A wholesale distributor of fresh fruits and vegetables in Northern California, serving approximately 2,000 customers, shares their food safety requirements for suppliers.

Suppliers that are growing, harvesting, packing and/or holding fruits or vegetables need to have a current GAP certified program in place that is audited by a third-party like USDA or Primus. If a supplier does not have a current third-party GAP certificate, which is common among small local farms that we are interested in partnering with, we want to see the implementation of an effective GAP program and a commitment to become third-party certified in the future. To some extent, our requirements vary depending on the supplier. For example, our temperature requirements for small local growers that harvest, pack and deliver their products to us on the same day. In those scenarios we do not require a certain temperature threshold be met because the products have not yet entered into a holding or refrigeration status.

We onboard new suppliers by sending them a food safety questionnaire and a list of documents we would like to review, if they are available. Based on the initial answers from

the questionnaire we decide if an onsite farm visit is needed. This is usually not necessary for operations with food safety certifications. For operations without food safety certifications, we conduct a phone interview or contact via email to better understand the operation and how it applies food safety and GAPs. Then, an onsite visit will be conducted so that we can observe operations and review any documentation. During these visits we discuss how the farm can start a GAP program or improve upon what they are already doing. After an onsite visit, more email communication may take place to answer basic food safety questions and provide links to resources. To verify our suppliers' food safety practices, documentation pertaining to individual farmers is collected, updated and stored in hard copy and digitally.

The process of establishing an effective food safety program will require time and energy. We find that investing in food safety is worth it to better uphold our commitment to provide our partners with wholesome and safe produce, and also to open up new opportunities with partners that require third-party certified suppliers.



consumed raw or cooked? Higher risk activities and crops should have higher standards.

Be sure that your food hub can verify its suppliers' food safety practices (e.g., by reviewing a food safety plan and records, or conducting a site visit) and document that the verification has occurred.

Buyers care about traceability, so be sure that your hub has and follows a traceability system for its suppliers.

Note: *GroupGAP is a USDA program that allows farmers, food hubs, and marketing organizations to achieve USDA GAP certification as a group, which might be an attractive option for your suppliers, or even your food hub. More information about GroupGAP can be found at the USDA GroupGAP Food Safety Program website.¹⁹*

Hub Tip

Depending on the audit and your buyer's food safety requirements, food hubs may be able to establish the food safety requirements for their suppliers. For example, a food hub does not have to require their suppliers be food safety certified (e.g., pass a third-party audit). Instead, a food hub could require their suppliers to have a food safety plan, conduct water tests or be in compliance with the FSMA PSR or audit standard without certifying.

19 To learn more about the GroupGAP Food Safety Program: <https://www.ams.usda.gov/services/auditing/groupgap>

Determine if Your Hub Needs to be in Compliance with the FSMA Preventive Controls for Human Food Rule (PC Rule)

Some audits offer an add-on module to assess the operation's PC Rule plan and serve as a guide for PC Rule compliance.²⁰ This add-on module does not require a separate written plan to comply with the PC Rule. Any additional requirements can be added to your hub's current program.

For more information about the PC Rule, see [Understanding FDA's FSMA Rule for Food Facilities](#) from the National Sustainable Agriculture Coalition.²¹ For help determining your facility's status under the PC Rule, see [Demystifying the Food Safety Modernization Act's Preventive Controls Rule](#) from Farm Commons, CAFF, and the University of California Extension.²²

If Your Hub is Certified Organic by CCOF, Consider Conducting Both Audits with the Same Certifier.

California Certified Organic Farmers (CCOF) provides both organic certification and food safety certifications in the United States, Canada, and Mexico. CCOF only provides food safety certifications to operations who have certified organic production/handling (either issued by CCOF or another accredited certification agency) or to those who are verified as in transition to organic. As long as part of a facility is certified or in transition to organic, the food safety certification can apply to both the organic and non-organic portions of the operation.

Note: CCOF also offers a "pre-assessment" service whereby CCOF evaluates your facility to the audit standard but does not decide whether your facility complies with the standard, and no certificate is issued. Some buyers may only require a pre-assessment and determine whether to buy your products themselves.

So, You Decided to Pursue a Food Safety Certification. What Now?

It's time to choose the certification right for your operation. On the following pages, we compare four common audits for food hubs, including tips for success and tips about the process



20 The PC Rule portion of food safety audits will not guarantee legal compliance with FSMA as only the FDA can provide approval for regulatory compliance.

21 To learn more about the FSMA PC Rule: <https://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-FACILITIES-FINAL-.pdf>

22 To learn more about compliance with the PC Rule: <https://caff.org/pc-rule-supplier-verification-guide/>

Comparison of Four Common Food Safety Audits

	USDA Harmonized GAP Plus+	USDA Good Manufacturing Practices (GMP)	PrimusGFS Good Manufacturing Practices (GMP) Modules 1, 5 and 6	GLOBALG.A.P Produce Handling Assurance (PHA)
	Audit Standard and Checklist ¹			
	Version 4.0 ²	Version 1.0 ³	Version 3.2 ⁴	Version 1.2-1 ⁵
Description of audit standard and scope	<p>USDA offers multiple food safety audits. The Harmonized GAP Plus+ audit is the only USDA GAP audit acknowledged as a GFSI Government Equivalent Benchmarked Standard. This audit Standard is applicable to the following operations:</p> <ul style="list-style-type: none"> ✓ On-farm packing-houses for fresh fruits, vegetables, and other specialty crops other specialty crops ✓ Packinghouses for fresh fruits, vegetables, and other specialty crops ✓ Wholesale distribution centers and terminal warehouses distributing Raw Agricultural Commodities (RACs), including operations that distribute fresh-cut produce^{6,7} ✓ Repack operations⁶ <p>This audit Standard is not applicable to the following operations:</p> <ul style="list-style-type: none"> ✗ Fresh-cut processing operations⁷ ✗ Fresh-cut repack operations⁷ 	<p>This newly established audit is administered by the USDA and will replace the current section of the USDA GAP and Good Handling Practices (GHP) audit that applies to distribution centers. This audit Standard is applicable to the following operations:</p> <ul style="list-style-type: none"> ✓ Produce distribution centers, aggregators and processors ✓ Fresh-cut processing operations 	<p>The PrimusGFS certification program covers both pre- and post-farm gate production activities and is divided into seven modules including the PC Rule compliance module. The audit Standard is applicable to the following operations:</p> <ul style="list-style-type: none"> ✓ Storage and distribution ✓ Packinghouse ✓ Cooler and cold storage ✓ Processing 	<p>A certification for stand-alone packing-houses that require a GMP audit and certificate. The PHA program covers pre-process production steps after crop harvest, and includes HACCP principles. Individual and multi-site operations may apply for this certification. The audit standard is applicable to the following activities:</p> <ul style="list-style-type: none"> ✓ Cooling ✓ Packing ✓ Re-packing ✓ Handling ✓ Storage <p>This audit Standard is not applicable to the following activities:</p> <ul style="list-style-type: none"> ✗ Complex processing that that significantly transform crops from the original whole state ✗ Slicing and dicing ✗ Post-harvest activities <p>See the GLOBAL-G.A.P. PHA covered activities¹⁰</p>

Table notes: See page 18

Continued on next page

Comparison of Four Common Food Safety Audits, continued

	USDA Harmonized GAP Plus+	USDA Good Manufacturing Practices (GMP)	PrimusGFS Good Manufacturing Practices (GMP) Modules 1, 5 and 6	GLOBALG.A.P Produce Handling Assurance (PHA)
	Audit Standard and Checklist ¹			
	Version 4.0 ²	Version 1.0 ³	Version 3.2 ⁴	Version 1.2-1 ⁵
Modules that apply to food hubs and must be completed for certification	<ol style="list-style-type: none"> 1. General Questions 2. Post-Harvest 3. Logo Use for operations who intend on using the USDA GAP logo on packaging or promotional materials 	All	<ol style="list-style-type: none"> 1. Module 1 - Food Safety Management Systems 2. Module 5 - GMP 3. Module 6 - Hazard Analysis and Critical Control Point (HACCP) 	This certification technically does not have modules. All components of this audit standard are required.
Certifiers in California	Select the office closest to the facility that needs to be audited, from the list of Local Specialty Crops Inspection Division audit offices ⁹	Select the office closest to the facility that needs to be audited, from the list of Local Specialty Crops Inspection Division audit offices	Certification Bodies for PrimusGFS certification ¹⁰	Certification Bodies for GLOBALG.A.P. certification. ¹¹ Refine your search to find CBs who administer the PHA.
Financial cost ¹²	Annual \$250 certification fee plus the current audit rate (\$132/hour), which covers the auditors travel time, travel expenses, time to review, approve, certify an post audit results	The current audit rate (\$132/hour), which covers the auditors travel time, travel expenses, time to review, approve, certify an post audit results	<p>Depends on your Certification Body.</p> <p>Estimates from CCOF Certification Services¹³ (pg. 7-8), vary depending on your operation.</p> <p>One time application fee of \$50 + annual certification fee of \$350 + flat rate audit fee of \$2,000 per packinghouse, \$1,500 for cooler.</p> <p>Additional fees or special pricing may apply if you are an existing CCOF organic client.</p>	<p>Depends on your Certification Body.</p> <p>Estimates from CCOF Certification Services¹⁴ (pg. 9), vary depending on your operation. GLOBALG.A.P. Facility registration fee of \$200 + CCOF Annual Facility fee of \$540 + variable inspection fees.</p> <p>Additional fees or special pricing may apply if you are an existing CCOF organic client.¹⁵</p>
GFSI-benchmarked/ Technically Equivalent	Yes	No	Yes	Yes

Table notes: See page 18

Continued on next page

Comparison of Four Common Food Safety Audits, continued

	USDA Harmonized GAP Plus+	USDA Good Manufacturing Practices (GMP)	PrimusGFS Good Manufacturing Practices (GMP) Modules 1, 5 and 6	GLOBALG.A.P Produce Handling Assurance (PHA)
	Audit Standard and Checklist ¹			
	Version 4.0 ²	Version 1.0 ³	Version 3.2 ⁴	Version 1.2-1 ⁵
Aligned with FSMA	Yes, the Produce Safety Rule	Yes, the Preventive Controls for Human Food Rule	Version 3.2 includes a focus on the Preventive Controls for Human Food Rule. Facilities can also choose to complete Module 7, the PC Rule Addendum.	Yes, the Produce Safety Rule and the Preventive Controls for Human Food Rule
Optional Add-ons	Tomato Audit Protocol for Open-field Production and Harvesting, Packinghouse, Greenhouse, Repack and Distribution	A Food Defense audit standard may be added to the GMP audit if requested. This standard includes the requirements of the Food Drug Administration Food Safety Modernization Act (FSMA) Mitigation Strategies to Protect Food Against Intentional Adulteration, 21 CFR Part 121.	Module 7 - PC Rule compliance is optional	None

Table notes:

- Audit standards are revised periodically and updated standards receive a new version number. Be sure the audit standard used to prepare for an audit is the same standard used to evaluate your operation during an audit.
- USDA Harmonized GAP Plus+ Version 4.0 Audit Documents: <https://www.ams.usda.gov/services/auditing/gap-ghp/harmonized>
- USDA GMP Version 1.0 Audit Documents: <https://www.ams.usda.gov/services/auditing/gmp>
- PrimusGFS GMP Version 3.2 Audit Documents: <https://primusgfs.com/pgfs-v3-2/>
- GLOBALG.A.P. PHA Version 1.2-1 Audit Documents: https://www.globalgap.org/uk_en/for-producers/globalg.a.p./produce-handling-assurance-pha/
- These operations are not covered by the scope of recognition for GFSI technical equivalency. See more details in the USDA GAP Program Scope, pg. 3: <https://www.ams.usda.gov/sites/default/files/media/GAPProgramScope.pdf>
- For fresh-cut produce, it is important that only operations that distribute fresh-cut produce are audited using USDA GAP audit services. When fresh specialty crops are processed into fresh-cut products, this process falls under the FDA regulation for GMPs. If an auditee would like to be audited for the processing of fresh-cut produce, the USDA Plant Systems Audits (PSA) would be the appropriate audit protocol. See more details in the USDA GAP Program Scope, pg. 3: <https://www.ams.usda.gov/sites/default/files/media/GAPProgramScope.pdf>
- To learn more about activities covered by the GLOBALG.A.P. PHA: <https://www.globalgap.org/permalink/a3ef5ab1-b8c6-11eb-9b1b-6805ca037347.pdf>
- Local Specialty Crops Inspection Division Audit Offices: <https://www.ams.usda.gov/services/auditing/groupgap/state-contacts>
- PrimusGFS Certification Bodies: <https://primusgfs.com/certification/>
- GLOBALG.A.P. Certification Bodies: https://www.globalgap.org/uk_en/what-we-do/the-gg-system/certification/Approved-CBs/index.html
- The cost can vary depending on which scheme is used, which Certification Body you go through, and how complex your food hub is. Estimates for food hubs start around \$1,500 and tops out around \$3,000.
- CCOF PrimusGFS Certification Manual: https://www.ccof.org/sites/default/files/2022-06/CCOF_PrimusGFS_Program_Manual.pdf
- CCOF GLOBALG.A.P. Certification Manual: https://www.ccof.org/sites/default/files/2022-06/CCOF_GLOBALG.A.P._Program_Manual.pdf
- CCOF fees for the GLOBALG.A.P. PHA audit are slightly cheaper than their fees for the PrimusGFS facility audits

Tips for Success

- Start the conversation with a Certification Body (CB) as early as possible, before you're ready for an audit. Some CBs have an onboarding process or a readiness assessment that your hub may choose to go through.
- Say what you do, do what you say. If you say you're going to clean the restroom weekly, an auditor will be looking for the log that shows you really did clean it every week. You're not just held to what the audit standard requires, but you're held to your own procedures as well, so do what is attainable for your hub and set yourself up for success.
- If you know of another food hub that successfully completed a specific audit, reach out to them to learn about their process



- For a new auditee, most audit standards require a minimum of 30 days of records to demonstrate the food safety plan is being followed. Check with your CB to verify their specific record keeping requirements.
- Audit standards are revised periodically, and updated standards receive a new version number. Be sure the audit standard used to *prepare* for an audit is the same standard used to evaluate your operation *during* an audit.

Preparing for an Audit

How long does it take to prepare for an audit?

Estimates range from 3 months to 9 months from start to finish. This depends on the food hub's food safety culture, personnel availability, financial capacity and recordkeeping practices.

1. After choosing which certification to pursue, review the audit standard and checklist:

– Audit Standards:

- USDA Harmonized GAP Plus+: https://www.ams.usda.gov/sites/default/files/media/HarmonizedGAPPlus%2BStandardVersion4.0_0.pdf
- USDA Good Manufacturing Practices (GMP) Audit: <https://www.ams.usda.gov/sites/default/files/media/GMPAuditStandard.pdf>
- PrimusGFS: <https://primusgfs.com/pgfs-v3-2/>
- GLOBALG.A.P. PHA: https://www.globalgap.org/content/galleries/documents/200715_GG_CPCC_PHA_V1_2_en.pdf

– Audit checklists:

- USDA Harmonized GAP Plus+: <https://www.ams.usda.gov/sites/default/files/media/HarmonizedGAPPlusChecklist4.0.pdf>
- USDA Good Manufacturing Practices (GMP): <https://www.ams.usda.gov/sites/default/files/media/GMPChecklistV1.pdf>
- PrimusGFS, view by Module: <https://primusgfs.com/pgfs-v3-2/>
- GLOBALG.A.P. Produce Handling Assurance (PHA): https://www.globalgap.org/content/galleries/documents/200715_GG_CPCC_PHA_V1_2_en.pdf

2. Create or update a food safety plan for your food hub. Tailor templates to your operation and to ensure they meet the audit standard.

- Food hub-specific resources are available at no cost from UC SAREP: <https://sarep.ucdavis.edu/fs/supply/foodhubs/safety>

3. Contact your desired CB to schedule your audit.

- How do I request an audit?
 - USDA Harmonized GAP Plus+ and Good Manufacturing Practices (GMP), scroll down to 'How to Request an Audit':
 - <https://www.ams.usda.gov/services/auditing/gap-ghp>
 - PrimusGFS, GLOBALG.A.P and other private audits: depends on your CB; reach out to them directly for more information about requesting an audit.

4. Perform a self-audit:

Most food safety standards require you to perform a “self-assessment” using the specific checklist prior to the audit. Performing a full self-audit on your operation(s) using the audit checklist (above) will allow you to detect potential non-conformances, implement corrective actions before a formal audit and improve your performance on the day of the audit. If possible, have another person knowledgeable on food safety (ideally from another food hub or a consultant) shadow you during the self-audit to provide any tips based on what they see.



Hub Tips

- Talk to your CB and apply for the certification well in advance of your desired audit date. This gives time for both you and your Certification Body to prepare and assign an audit efficiently. For example, CCOF suggests applying 3 months before you expect to need or have your audit.

- Auditors need to see your operation in action to verify your food safety practices, so schedule your audit when the food hub is fully operational and commodities included in the scope of the certification are present. If some steps do not occur at the time of the audit (e.g., in the middle of your slow season), it can affect the operation's certification, and your hub will likely need a follow-up visit.

- If your food safety plan is finalized and your auditor will allow it, send them a copy before your audit. This way they can familiarize themselves with your operation before arriving onsite.

What to Expect During an Audit

How long is the audit?

Duration will depend on the complexity of your food hub operation. The audit duration includes the time required to perform the documentation review and the visual inspection for each operation included in the certification. You can expect the audit to take 4-9 hours to go through everything with the auditor.

More information from PrimusGFS and GLOBALG.A.P.:

- PrimusGFS Audit Duration Tables: <https://primusgfs.com/wp-content/uploads/2022/03/PGFS-ND-026-R0-PrimusGFS-v3.2-Appendix-7-Audit-Duration-Tables.pdf>
- PrimusGFS Certification Process: <https://primusgfs.com/wp-content/uploads/2020/07/PGFS-R-005-R2-PrimusGFS-Certification-Process-Flow-Chart.pdf>
- GLOBALG.A.P. PHA General Regulations: https://www.globalgap.org/content/galleries/documents/211001_GG_GR_PHA_V1_2-1_en.pdf

How much will an audit cost?

The cost can vary depending on which scheme is used, which CB you go through, and how complex your food hub is. Estimates for food hubs are around \$1,500-\$3,000. See the table on page 16-17 for more detail.

How do auditors assess conformance with the audit standard during the audit (i.e., how is my food hub scored)?

Each audit standard has its own evaluation criteria used to verify conformance and determine certification. See the links below for specific information about each standard.

- USDA GAP Audit Program Evaluation Criteria and Scoring, pg. 12-13 and 17-18: <https://www.ams.usda.gov/sites/default/files/media/HarmonizedGAPProgramManual.pdf>



- PrimusGFS Evaluation Criteria and Scoring, pg. 17-20: <https://primusgfs.com/wp-content/uploads/2022/01/PGFS-ND-020-R2-PrimusGFS-v3.2-General-Regulations.pdf>
- GLOBALG.A.P. Certification Process, pg. 10-12: https://www.globalgap.org/content/galleries/documents/211001_GG_GR_PHA_V1_2-1_en.pdf

Hub Tip

Auditors understand that change is difficult, and it takes time for employees to adjust to the new policies and procedures, so during an audit, a food hub may be allowed to make real time corrective actions to address non-conformance issues. For example, if an employee is improperly wearing a hair net or beard net, the food hub representative should immediately ask the employee to adjust their hair or beard net.



What to Expect After the Audit

After an audit, expect to continue communicating with your auditor regarding your certification and any follow up actions.

In order for an audit to move to the certification phase, a food hub may be required to make corrective actions after their audit within a period of time determined by the CB.

Recertification

Each facility undergoes a minimum of one announced audit per year. An additional audit may be required if major changes occur within the operation.

In order to recertify one year from the date of certification, your food hub must be able to demonstrate that your food safety program has been maintained throughout the year based on their program requirements.

In all cases, a food hub is responsible for scheduling their annual audit in a timely manner to prevent a lapse in their certification. Make sure to reach out to your certifier a couple months before the certification expiration date to schedule the next audit.

Unannounced Inspection

After a food hub receives certification, CBs have the authority and generally are required to conduct unannounced inspections at any time and of a certain percentage of their certified clients. For example, GFSI requires CBs to perform unannounced inspections of 10% of their certification operations per year. The protocol for unannounced inspections varies depending on the CB, and auditees will be made aware of any specifics necessary during the audit opening or closing meeting.

Failing an Audit

What happens if a food hub fails an audit?

If you receive a low score or are not in compliance with certain questions in the audit checklists, the audit will result in an automatic failure.

If an operation does not meet the audit standard requirements, the operation has the option to address the issues and schedule a new audit to show compliance. For some audit standards, there is a wait time prior to undergoing a follow-up audit where the previous audit resulted in failing the audit.

Continual Improvement

Continual improvement is an integral part of a successful food safety program. A food facility may find deficiencies within the program during the first year, and years after, that will need to be addressed. A hub's food safety program is designed to improve as the program is implemented.

For example, some standards require that a corrective action be submitted for any non-compliance identified during the audit in order to receive certification. This is part of the continual improvement process.

Conclusion

While third-party food safety audits can help verify a food hub's food safety practices, they are not the only route to implementing food safety practices at the food-hub level. The following list of resources can help if your food hub or food facility is looking for additional support with food safety audits or food safety topics not covered in this guide.

General Food Safety Resources:

- Community Alliance with Family Farmers can help answer questions about food safety: <https://caff.org/food-safety/>
- UC SAREP's CA Food Hub Network listserv is a learning network to coordinate technical assistance, collaborative learning and information sharing for and among food hubs in California: <https://sarep.ucdavis.edu/fs/supply/foodhubs>
- Food hub food safety templates available at no cost from UC SAREP: <https://sarep.ucdavis.edu/fs/supply/foodhubs/safety>
- A guide to Good Manufacturing Practices for Making Low-Risk Foods for Small-Scale Farms and Food Businesses from Carolina Farm Stewardship Association: https://www.carolinafarmstewards.org/wp-content/uploads/2018/11/GMPmanual_v07_0818-Final-for-Web.pdf

Third-Party Audit Resources for Food Hubs:

- Food Safety Consultants can help guide operations through the third-party audit process: <https://www.ccof.org/page/consultants-ag-advisors>
- GroupGAP certification information for buyers is available from the USDA: <https://www.ams.usda.gov/services/auditing/groupgap>
- A GroupGAP Case Study from the Wallace Center: <https://foodsysteinsleadershipnetwork.org/wp-content/uploads/2021/04/Four-Corners-GroupGAP.pdf>
- CCOF's PrimusGFS Certification Program Manual with detailed information about the PrimusGFS Audit: https://www.ccof.org/sites/default/files/2022-06/CCOF_PrimusGFS_Program_Manual.pdf
- CCOF's GLOBALG.A.P. Certification Program Manual with detailed information about the GLOBALG.A.P. Audit: <https://www.ccof.org/resource/globalgap-certification-program-manual>

Third-Party Audit Resources for Farmers:

- A Farmer's Handbook to the USDA Harmonized GAP Standard from Carolina Farm Stewardship Association: https://www.carolinafarmstewards.org/wp-content/uploads/2019/06/HGAPmanual_v09-web-printable.pdf
- Fundamentals of On-Farm Food Safety: Audit Tips and Strategies for Small and Mid-scale Produce Operations from Carolina Farm Stewardship Association: https://www.carolinafarmstewards.org/wp-content/uploads/2019/07/CFSA_2019-FoodSafetyManual_Final.pdf
- GroupGAP certification information for growers is available from the USDA: <https://www.ams.usda.gov/services/auditing/groupgap>
- Removing Barriers to USDA GAP Programs Grower Toolkit: <https://www.nasda.org/gap-overview>



UNIVERSITY OF CALIFORNIA
Agriculture and Natural Resources

UC DAVIS
HEALTH

Center for Precision Medicine
and Data Sciences



CAFF
COMMUNITY ALLIANCE
with **FAMILY FARMERS**