

Assessing On-Farm Produce Safety Risks: Preparing for GAP Certification

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Overview

As consumption of fresh fruits and vegetables in the United States has increased, so have foodborne disease outbreaks and recalls associated with fresh produce (Callejón 2015; Painter 2013). In addition to compliance with regulations such as the Food Safety Modernization Act (FSMA) Produce Safety Rule, the marketplace has become stiffer in terms of on-farm produce safety requirements. Growers selling to larger buyer channels and institutions are often required to obtain Good Agricultural Practices (GAP) food safety certification. While growers selling through direct market channels including farmers markets and roadside stands do not typically need certification, they may have on-farm produce safety standards to achieve. Regardless of the market outlet channel and/or size of the farm, the potential for produce contamination exists. Thus, understanding on-farm produce safety risks is essential for all farms who grow, harvest, pack, hold and/or ship fruits and vegetables. This publication is the seventh in a series of seven factsheets assisting growers in developing and implementing best practices to reduce risks and reduce potential produce contamination, and provides guidance for tying all the pieces together in preparation for a third-party food safety audit (Figure 1).

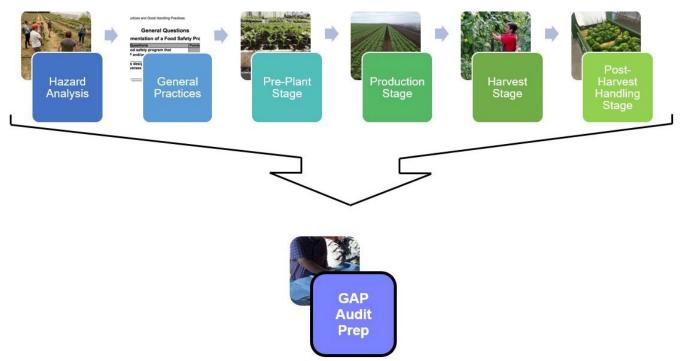


Figure 1. This series is designed to provide produce operators with the knowledge and tools to develop and implement Good Agricultural Practices (GAP). The final publication provides guidance for tying all the pieces together in preparation for a third-party food safety audit.

To Be or Not to Be GAP Certified

Best practices are always important for the integrity and safety of your product. Understanding how to assess risks and implement practices to mitigate them should be an integral part of every produce operation, regardless of size or buyer. While food safety should be a top priority on your farm, do you need to become a GAP-certified farm? Ultimately, the decision to become GAP certified is market-driven, so you should always consider your current and potential markets (Figure 2). Large retailers, institutions, or wholesalers often require a food safety audit to sell to them, while other buyers such as restaurants (typically not including big chains), schools, or direct to consumer sales (roadside stands or farmers markets) generally do not. Be sure to ask your buyers or potential market outlets what their expectations are regarding food safety programs and verification of your practices. If the buyers require a third-party food safety audit, discuss which ones they require.



Figure 2. Important questions to discuss with current and prospective buyers to determine what their food safety requirements are.

While all produce food safety audits address hazards, identify routes of contamination, implement good agricultural practices, and document activities, there are different levels of complexity and stringency between audits. Much is driven by market pressures and trends in the produce industry (Vallotton et al. 2017). For some markets, where requirements are less rigorous, obtaining a basic level certification like the U.S. Department of Agriculture (USDA) GAP audit is an acceptable option (Vallotton and Strawn 2017). In markets that have stiffer requirements, like wholesale or institutions, audits like the USDA Harmonized GAP (HGAP) and HGAP Plus+ can suffice. Additionally, in certain states some commodities like leafy greens or tomatoes are seen as higher risk and may have specific food safety programs. Examples include the California Leafy Greens Marketing Agreement or Florida's Tomato GAPs program. In other cases, some buyers might require complex third-party food safety certification schemes, such as Primus, Safe Quality Food (SQF) Program, GlobalG.A.P., etc. (GFSI 2021). Ultimately, it is vital to talk with your buyers so you know what audits will satisfy their food safety requirements.

Since the marketplace is moving toward more stringent food safety requirements such as USDA Harmonized GAP (HGAP) or HGAP Plus+ audits, we encourage you to consider seeking one of these audits to open more

market possibilities. These audits typically cost less than other audit schemes. The USDA HGAP and HGAP Plus+ standards incorporate a risk-based framework and are closely aligned with the Food Safety Modernization Act's Produce Safety Rule language and intent. Further, the USDA Harmonized GAP Plus+ is an audit program that has been acknowledged as achieving the Global Food Safety Initiative (GFSI) Technical Equivalence Requirements (GFSI 2021) and can be a good audit option to pursue. For these reasons, the remainder of this factsheet will focus on obtaining a USDA HGAP and HGAP Plus+ certification.

Becoming Familiar with Audit Checklists

Now that you have determined you need to obtain a Harmonized GAP audit, you are ready to begin the preparation process! First, access the checklist for the USDA Harmonized GAP or HGAP Plus+ audit. The checklist is available on the USDA AMS website (USDA 2021). The audit is divided into four sections, or "scopes." Each of these scopes focus on a different aspect of your farming operation and contain further sections. The four scopes are General Questions, Field Operations and Harvesting, Post-Harvest Operations, and Logo Use.

The General Questions (G) scope is required for every audit, and includes questions related to demographics, food safety managerial designations, worker health and hygiene, and traceability. Depending on your operation and post-harvest activities, you will complete one or both Field Operations and Harvesting (F) scope and Post-Harvest (P) scope. If you intend to use the official USDA GAP & GHP logo on packing and promotional materials, then you will need to complete the Logo Use (L) scope. The HGAP and HGAP Plus+ Checklists denote when documents, records, policies, written plans, or assessments are required to satisfy a specific question. There are also HGAP and HGAP Plus+ Standards that detail what an auditor is looking for to satisfy each question on the checklists (USDA 2021).

In the checklists for each section within a scope you will see two columns with the headers DOC and MAN. The DOC column tells you if certain documentation is required. In the DOC column you may see WP, R, or A. If WP is present, a written policy, procedure, and/or plan is required. Policies are high-level guidance that describes general goals and procedures; procedures are specified ways to carry out a process; and plans outline actions that will be taken to mitigate risks. You may also see R, which means a record is required. This is a document that states results achieved or provides evidence of activities performed. Examples include logs, test reports, certificates of analysis, chemical labels, receipts, invoices, and other supporting documents. An A means a risk assessment is required. Risk assessments identify potential hazards and should be documented in the manner which best represents the operation and the type of risk assessment required. Within the MAN column, a \bullet indicates a requirement that is mandatory and must either be assessed as compliant or not applicable to meet USDA Acceptance Criteria (USDA 2021).

Preparing Your Food Safety Manual

Basic Manual Set-Up

Once you familiarize yourself with the checklist questions, you can begin to prepare your food safety manual or plan. The manual is your primary written food safety plan that addresses the checklist questions found in each scope relevant to your farming operation. It includes responses to the questions along with all the necessary documentation to comply with the audit standard criteria. To simplify the process, Virginia Cooperative Extension (VCE) has developed HGAP and HGAP Plus+ manual templates that can be edited to your farm and practices. Given the complexity of the preparation process, we urge you to work with VCE so they can assist you. For guidance, please complete the "Request for VCE Food Safety Audit Materials and Assistance" form (Edwards and Vallotton 2021). If you are in a state other than Virginia, reach out to your local cooperative extension service for their assistance and resources. The process described here may differ from their approach, but the general information is still relevant.

Manual Components

The manual is laid out by sections separated by notebook dividers. Each section or scope includes the following:

- Table of Contents
- Checklist Questions ordered sequentially by sub-sections
- Assessments
- Standard Operating Procedures (e.g., Standards)
- Records (Logs)
- Supporting Documents

Table of Contents

Each scope begins with a detailed table of contents. The contents match the numbering of the checklist questions and is a handy tool to use as you compile and assemble each section of your manual. For example, if you complete the G and F scopes, the manual will have a G section and an F section, each with their own table of contents (Figure 3).

PRODUCE GAPS HARMONIZED FOOD SAFETY STANDARD:		I	PRODUCE GAPS HARMONIZED FOOD SAFETY STANDARD:	
Version 2 (2021)			Version 2 (2021)	
Comonal	Questions (G)			
General G-1	Management Responsibility	Field Op	erations and Harvesting (F)	
G-1.1	Food Safety Written Policy	F-1	Field History and Assessment	
G-1.1 G-1.2	Food Safety Written Policy Food Safety Management Policy with Contacts	F-1.1-1	Land Use History, Adjacent Land Use, and Storage Structure Standard	
		F-1.1-2	Initial Land Use History, Adjacent Land Use, & Storage Structure Assessm	
-1.3-1	Food Safety Violation Policy	F-1.1-3	Annual Land Use, Adjacent Land Use, & Storage Structure Assessment	
	Food Safety Violation Log	F-2	Agricultural Chemicals/Plant Protection Products	
i-2	Food Safety Plan	F-2.1-1	Agricultural Chemicals/Plant Protection Products Standard	
-2.1-1	Written Food Safety Plan & Products Covered		Agricultural Chemical Use spray records, Agricultural Chemical Labels, and	
-2.1-2	Maps and Diagrams	F-2.1-2	SDSs	
-2.2	Food Safety Plan Annual Review Policy and Log	F-2.1-3	Agricultural Chemicals/Plant Protection Products Spill Log	
-2.3	Approved Supplier List; Production Input List (see G-6.1)	F-2.3-1	Applicator License/Certificate	
-2.3.a	Approved Supplier Program Standard	F-2.3-2	Worker Protection Standard Training Log	
-3	Documentation and Recordkeeping	F-2.4	Water System Risk Assessment (see F-4.1)	
-3.3	Yearly Labeled Binders with Previous Years' Supporting Documents and Logs	F-3	Water Used in Growing Activities	
-4	Worker Education and Training	F-3.1-1	Water System Description	
-4	Worker Education and Training Standards	F-3.1-2	Water System Maps, Diagrams, and photos	
4.1	Employee Food Safety Training Log, Certificates, and Handouts	F-3.1-3	Water System Check Log	
4.2	Food Safety Manager Training Log, Certificates, and Handouts	F-3.2	Water System Risk Assessment (see F-4.1)	
4.3-1	Contracted Personnel Training - On Farm Food Safety	F-4	Water System Risk Assessment	
-4.3-2	Contracted Personnel Food Safety Training Log, Certificates, and Handouts	F-4.1	Water System Risk Assessment	
-5	Sampling and Testing	F-5	Water Management Plan	
-5.1	List of Certified Water Testing Labs and GLP documentation	F-5.1	Water Management Plan Standard; Approved List Labs (see G-5.1)	
	Lab Sampling Protocol Documents (from Respective Lab(s)), Microbiological	F-5.2	Lab Protocols (see G-5.2)	
	Sampling Standard (see G-5.4), Copy of F-5.1 Water Management Plan	F-5.3-1	Water Testing and Corrective Actions Log	
5.2	Standard	F-5.3-2	Water Test Results	
	Microbiological Sampling Test Results; Copy of Microbial Quality Testing Log	F-5.4-1	List of Approved Chemical Water Treatments with Supporting Reference	
	(F-10.2); Copy of Water Testing & Corrective Actions Log (F-5.3-1) and Water	F-5.4-2	List of Other Water Treatments	
-5.3	Test Results (F-5.3-2)	F-5.5	List of Approved Postharvest Handling Practices with Supporting Referen	
	Copies of List Approved Water Treatments with Supporting References (F-	F-5.6	Alternative Approach Supporting References	
-5.4	5.4-1 and F-5.4-2)	F-6	Animal Activity	
6	Traceability	F-6.1	Animal Activity Risk Assessment	
6	Traceability Standards with Supporting Documents	F-6.2	Animal Monitoring & Mitigation Measures Log	
6.1	Production Input List- Trace Back with Supporting Documents	F-6.3	Animal Activity Standard	
6.2	Trace Exercise Log w/ Supporting Documents; Recall Contact List (see G-7.1-3)	F-7	Soil Amendments	
7	Recall Program	F-7.1-1	Soil Amendment Risk Assessment w/ Amendment Records	
7.1-1	Recall Program Standard	F-7.1-2	Soil Amendment Standard w/Supporting References	
7.1-2	Recall Report Log with Supporting Documents	F-7.2-1	Compost Process Log	
7.1-3		r-1.2-1	Compost Flocess Log	

Figure 3. Table of Contents for G and F scopes of the Virginia Cooperative Extension Version 2 USDA Harmonized GAP audit template.

Checklist Questions

Immediately following the table of contents, you will find a checklist of questions for that scope. The questions are divided into sub-sections coinciding with the checklist numbering (Figure 3). For example, the HGAP F section contains numbered sub-sections F-1, F-2, F-3...F-14. Within each sub-section, questions generally follow numerically. For example, checklist questions pertaining to sub-section F-3 are numbered F-3.1, F-3.2, and F-3.3 (Figure 4). Each of the sub-sections of the checklist are immediately followed by standards and any records or supporting documents that support those questions. Organizing the manual in this linear way simplifies the process and speeds up an audit, saving you time and money.

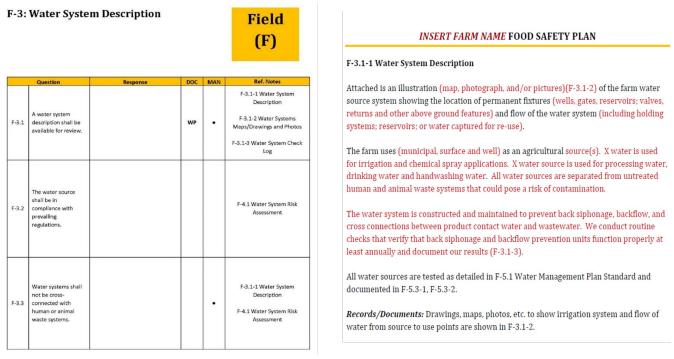


Figure 4. Virginia Cooperative Extension sub-section F-3 of the Harmonized GAP F scope template. The left image is the sub-section checklist questions. The right image is a description that provides part of the documentation to support checklist question F-3.1.

Assessments

The HGAP and HGAP Plus+ audits require assessments in the G, F, and P scopes. The assessments are an excellent way to focus in on specific areas that are highlighted in the checklist. Examples include food defense, water systems, soil amendments, animal activity, etc., and are used to better develop policies, procedures, and corrective actions. The preceding factsheets in this series provide a strong foundation for understanding risks and developing practices to address those identified risks (Bardsley et al. 2021a-c; Vallotton et al. 2021a-c). If an Assessment is required, you will see an A in the DOC column.

Standards

In the Virginia Cooperative Extension HGAP and HGAP Plus+ manual templates, Standard Operating Procedures are called "Standards". Standards detail the concern (relevance), policies, procedures (step-by-step description of how to perform specific operations or activities), corrective actions (if needed), associated records and supporting documents, as well as any helpful additional resources. If a standard is required, you will see a WP in the DOC column.

Records

Records provide evidence of activities performed or results obtained. An example of a record would include water test results or a log sheet documenting the cleaning of restroom facilities. Log sheets and appropriate records help you to prove you do what you say you will do. If a record is required to satisfy a question, you will see an R on the checklist table beside that question.

Some tips to make recordkeeping easy may include using technology as appropriate, such as the use of apps or other computer programs, or even posting logs on clipboards where they will be filled out. If you choose to use paper logs, active logs that are currently being filled out may be kept in the location where they are being used. It may be helpful to attach a pen and use plastic sleeves if the logs may get wet. We suggest removing logs after they are completed and storing them in a safe location, preferably in your plan of action manual or in a separate notebook kept in your farm office. It is important to develop a routine time for completing logs that are documenting repetitive activities since that will make it easier for you and your employees to do it.

Supporting Documents

Supporting documents are used to help validate a response to a checklist question. Examples include farm assessment notes, traceability system field maps, flow of food maps, pesticide logbooks, pesticide labels, training certificates, and any other supporting documentation related to specific practices. Loose supporting documents can be placed into a plastic sleeve and labeled so they can be inserted into your manual binder notebook directly behind the corresponding checklist question. Other supporting documents, like your pesticide record books or pesticide labels and Safety Data Sheets (SDS), should be kept in a location where they are readily available when needed.

Assembling Your Manual

Now that you have a framework for the different components of the manual, you can work methodically through the sections you need to complete. Start with the G section. The first and second factsheet in this series should be helpful (Bardsley et al. 2021a, b), especially in developing a flow of product diagram and basic hazard analysis. The publications in the factsheet series complement the templates so as you move into the F and/or P sections, you can use any of the relevant risk assessments from the pre-plant, production, harvest, and post-harvest stages to make sure you address all identified food safety risks (Bardsley et al. 2021c; Vallotton et al. 2021a-c). In addition to answering the checklist questions and assembling the pieces into the manual binder, make sure to document and collect any appropriate supporting records (e.g., water test results, training logs) as you implement your plan and monitor the effectiveness of your food safety practices.

Bringing the Pieces Together

On-Farm Implementation

Now that your written manual is developed, it is important that you implement your plan and ensure that food safety practices are being performed. This includes any on-the-ground changes to infrastructure and product flow, as well as incorporating practices into the daily activities. Complete records at the appropriate times, follow all cleaning and sanitizing procedures at their scheduled intervals, conduct water sampling and record the results. Document any corrective actions that need to be taken. While having a well-completed plan of action is great, it is the follow-through that makes your food safety plan successful in mitigating risks. Always do what you say you will do — and not what you wish you would do!

Conducting a Pre-Audit Walkthrough

To make sure you have addressed the checklist questions and have everything in place prior to your audit, conduct a pre-audit walkthrough or "mock audit" with your Virginia Cooperative Extension agent (Figure 5). Together, take the audit checklist and work through each question, making sure that each question is addressed in your plan. Make sure your logs and other records are easily accessible and organized. Then, walk through your operation and ensure the questions are also addressed in all production and packing areas and that there are no corrective actions that need to be taken to meet the requirements. Walk through each of your fields and monitor your workers. Are they following the food safety protocols they learned in training? Are your animal mitigation measures working? Do you notice any issues with your water system? Was your water of appropriate microbial quality after testing, and if not, are your water treatment measures successful? How clean is your packing shed and/or packing facility? Have you conducted a mock recall (e.g., trace exercise) to test the effectiveness of your traceability program? Do you have all required documentation needed to support your activities? Is signage posted where needed? A documented self-audit procedure is a requirement for the audit, so doing a mock audit can satisfy that requirement. The checklist at the end of this factsheet has been developed to help you and follows the Harmonized GAP and HGAP Plus+ audit formats.



Figure 5. A VCE agent conducting a pre-audit walkthrough with a farmer prior to his audit. During the walkthrough, the agent discusses all aspects of the food safety plan as it relates to on-farm practices with workers, production, irrigation water, harvesting, and post-harvest transport. (Amber Vallotton, Virginia Cooperative Extension)

Filing Audit Paperwork and Scheduling the Audit

Once your manual is complete, all standard operating procedures are written and being followed, and applicable records are kept, you should request an official audit. New applicants must first submit the USDA SC-430 vendor form, then they may submit the SC-237A USDA Agricultural Marketing Service Request for Audit Services Form. Work with your auditor to schedule your audit date and time. In Virginia, the Harmonized GAP audit is administered through the Virginia Department of Agriculture and Consumer Services Division of Marketing. VDACS inspectors act on behalf of the USDA to perform the official audit as an independent third party. If possible, check with other nearby farms to see if you could coordinate multiple farms' audits during the same trip. This can help reduce cost since audit costs include travel as well as audit time (Vallotton and Bowen 2019).

After the initial farm audit, an unannounced visit is possible within the remainder of the growing season. If the auditor left you with any areas that required corrective action, it is important that you address these areas so that you are ready for any follow-up visits. Previous manuals and records must be retained for three years. It may be helpful to store previous records in separate binders and label by year. Your plan of action manual is what we call a "living document," and may be updated as you make changes during season and from year to year. Be sure that any changes are appropriately documented.

Summary of Audit Preparation Steps

While there is no one "right" way to proceed, it is helpful to create a schedule and figure out your audit time frame. The process takes time and effort, so it is best to start planning earlier rather than later. If the growing season has already started, it is a lot harder to find ample time to work on the manual and any implementation steps. Being organized and making a solid commitment to the work will make for a smoother process.

Although the road to Harmonized GAP or HGAP Plus+ certification contains a lot of steps, Virginia Cooperative Extension has developed numerous tools to simplify this process and will work with you along the way. Be sure to reach out to your local Extension Agent for guidance as you work through the assessments, manual templates, and on-farm practices. A mock audit conducted with your extension agent prior to your audit will help ensure you are ready.

A strong farm food safety program will not only improve the safety and security of our food supply, but will hopefully help you to become a stronger, more organized operation! Take pride in your food safety program and what you do! The following checklist has been put together to help you ensure you are addressing each important step to prepare you for a successful audit.

Final Pre-Audit Walkthrough Checklist

Check boxes for all items <u>you have completed</u> as a part of your on-farm food safety program. For items that do not apply to your operation, write N/A next to item.

General Practices (applicable to all stages)

- □ All workers, including family members, have been trained in proper health, hygiene, and produce handling practices and policies for any of the stages they are involved in.
- □ Visitors are instructed in expectations, especially if they are allowed in any production and packing areas.
- □ Appropriate signage is posted to remind workers and visitors of food safety practices and policies.
- □ Portable restrooms or indoor restrooms are readily available, and wash stations are available and appropriately stocked.
- □ All workers and visitors wash hands after using the restroom and at other specified times as stated in training/policy.
- □ Eating is only permitted in designated eating areas.
- Drinking water is provided and only allowed in production and handling areas where containers are not breakable.
- □ Smoking, if permitted, is never allowed in production and handling areas.
- Anyone who is exhibiting signs of an infection, sickness, or has an accident knows to report to the supervisor and not work around produce until authorized to do so.
- □ A first aid kit and emergency contact numbers are readily available.

Pre-Plant Stage

- Any known risks associated with each crop grown have been identified (i.e. netted rind, stem scars on fruit, or high-risk crop in terms of related outbreaks, etc.).
- □ Plant material used for plant propagation (i.e. seeds, transplants, bulbs, tubers, rootstocks) is maintained and stored appropriately prior to planting.
- □ Flats of seed starts and transplants are clean and not a source of contamination.
- Prior to field preparation, including protected culture (i.e. greenhouses, high tunnels), it has been determined that the prior land history does not pose contamination risks to current production areas. This includes:
 - Previous flood events
 - Septic system drain field areas
 - Chemical spills or dump sites
 - Previous early 1900s orchards
 - Concentrated livestock operations
- □ Where possible, production fields are not located where there is a potential for runoff from livestock or grazing areas.

Production Stage

- □ Any equipment and tools used for field preparation are not a source of contamination.
- □ Soil amendments such as manure or biologically-based compost have been applied 120 days prior to harvest.
- □ For any purchased composts used, there is a certificate of analysis which provides information about the different inputs used to make the compost, the composting process, and contact information for the manufacturer.
- \Box Any bulk fertilizers and plant protection products are stored in a way that prevents contamination.
- □ For protected culture systems, steps are taken to reduce risks:
 - Channels, containers, and rafts are regularly cleaned and sanitized between rotations.
 - Overhead lights are protected to prevent breakage.
 - Acids used for lowering pH are stored so as to prevent accidents and contamination.
- □ Production water (irrigation, frost protection, plant sprays) is tested for generic *E. coli* annually for groundwater sources, and at the beginning of season, at peak use, and at harvest for surface water sources.

- □ Production areas are monitored for evidence of animals such as animal tracks, feces, droppings, trails, and damaged crops.
- \Box Measures are taken to exclude or deter wildlife.
- Domesticated animals are not allowed in production and packing areas.
- □ Outdoor and indoor spaces are kept clean to reduce rodent habitat and refugia.

Harvest Stage

- □ Harvesting tools, bins, and totes are cleaned and sanitized prior to use.
- □ Harvest wagons and machinery are in good repair and lights are protected to prevent glass breakage.
- $\hfill\square$ Harvest equipment is not a source of cross contamination.
- □ When harvesting, any produce showing signs of visible contamination is either not harvested or discarded.

Post-Harvest Handling Stage

- □ Harvested produce brought from fields or protected culture areas is handled so as to prevent cross contamination.
- □ In open pole barn structures, measures have been taken to prevent bird roosting, as well as live traps set for rodents.
- □ For indoor packing areas, non-baited, live rodent traps are used and regularly checked.
- □ Light fixtures are protected to prevent glass from shattering over product.
- □ Food contact surfaces are made of construction materials that can be cleaned and sanitized prior to use.
- □ Prior to repacking, all dirt, mud, and other debris is removed from produce.
- □ All post-harvest water is tested annually to ensure it meets the standard of zero generic E. coli. Water test results are kept on file.
- \Box If a sanitizer is added to wash water, it is monitored to make sure it is working.
- □ Boxes and containers used for re-packing are stored to prevent cross-contamination.
- □ Cardboard boxes are new, or if re-used, are free from soil or debris and always lined with new plastic.
- □ A traceability program is in place and at least one mock recall has been performed.
- □ Packaged product has identifiable traceback codes to provide a traceability system.
- □ Storage coolers are kept clean, maintained, and do not contain both produce and non-produce items (such as meat).
- □ Produce in coolers is kept at appropriate holding temperatures, which are monitored.
- □ When produce is put on ice, the water used to make the ice contains zero detectable generic E. coli.
- □ Transport vehicles are clean and well maintained to maintain cold chain to the marketplace.

Name

Signature

Date

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