



2nd Edition

Bridging the GAPs

FARM GUIDE

**Good Agricultural Practices and
On-Farm Food Safety for Small,
Mid-Sized, and Diversified Fruit
and Vegetable Farms**

Based on the USDA Good Agricultural
Practices/Good Handling Practices
(GAP/GHP) Audit Program Standards
and the Food Safety Modernization Act
(FSMA) Produce Safety Rule

A publication of the Washington State Department of Agriculture

2018 • 2nd Edition

Bridging the GAPs

FARM GUIDE

**Good Agricultural
Practices and
On-Farm Food Safety
for Small, Mid-Sized,
and Diversified Fruit
and Vegetable Farms**

Based on the USDA Good Agricultural Practices/
Good Handling Practices (GAP/GHP) Audit Program
Standards and the Food Safety Modernization Act
(FSMA) Produce Safety Rule



Second Edition Authors

Laura Raymond, Karen Ullmann, and Ele Watts

First Edition Authors

Tricia Kovacs and Sue Davis

AGR PUB 307-412 (R/9/18)

Contributors to the Second Edition of this Guide

WSDA Regional Markets Program

Laura Raymond
Ele Watts

WSDA Produce Safety Program

Karen Ullmann

WSDA GAP/GHP Audit Staff

Lonnie Marlin

WSDA Communications Office

Hector Castro
Kathy Davis
Karla Salp
Becca Sotelo

Publication Design

Robyn Ricks

Contributors to the First Edition of this Guide

GAP/GHP Audit Staff, WSDA

Chuck Dragoo
Ken Frazier
Lonnie Marlin

Office of Compliance and Outreach, WSDA

Claudia Coles
Katie Lynd
Betsy Levy

Communications Office, WSDA

Kathy Davis

Organic Program, WSDA

Brenda Book

Photography

Meryl Schenker

Spanish Language Translation

María Natalia Carrillo

Thanks to the following farms that allowed us to photograph their best practices for this guide

Full Circle Farm, North Bend
Imperial's Garden, Wapato
Ralph's Greenhouse, Mt. Vernon
Skagit Flats, Mt. Vernon
Tahoma Farms, Orting
WSU Puyallup Research & Extension Center, Puyallup

Bridging the GAPs Project Acknowledgements

Farm Walk Host Farms

Alvarez Organic Farms	Skagit Flats Farm
Imperial's Garden	Viva Farms
Local Roots Farm	Williams Hudson Bay Farm
Pheasant Fields Farm	

Auditors, Trainers, and Partners at Workshops and Events

WSDA Staff

Tricia Kovacs	Chuck Dragoo
Sue Davis	Ken Frazier
Patrice Barrentine	Darla Lindemeier
Sherryl Stoltenow	Lonnie Marlin
Claudia Coles	Epifanio Rodriguez
	Ken Tuttle

GAP/GHP Audit Staff, USDA

Todd Mattos
Greg McNair

Washington State University Faculty and Staff

Andy Bary, WSU Puyallup Research & Extension Center
Colleen Donovan, WSU Small Farms Program
Malaquias Flores, WSU Small Farms Program
Doug Collins, WSU Center for Sustaining Agriculture and Natural Resources
Amy Moreno-Sills, WSU Puyallup Research & Extension
Holly Thompson, WSU Snohomish County Extension
Pat Munts, WSU Spokane County Extension
Jenelle Ottmar, WSU Grant-Adams Area Extension

Other Partner Organizations

Bainbridge Graduate Institute
Cascade Harvest Coalition
Organicology
Seattle Neighborhood Farmers Market Association
Tilth Producers of Washington
Washington State Farm Bureau

Project Web Support

Jill Kunz, WSDA

Other Project Support

Billy Campbell



The Second Edition of the Bridging the GAPs Farm Guide was published in September, 2018.

The Bridging the GAPs project and this publication was made possible through two grants from the WSDA Specialty Crop Block Grant program, awarded in 2011 and 2015.

Funding for this publication was also made possible, in part, by Grant Number U18FD005913 through the Food and Drug Administration funding program PAR-16-137. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the FDA.

You may request a copy of this guide, at no cost, by calling the WSDA Regional Markets program at 206-256-6150 or by emailing GAPedu@agr.wa.gov. You may also download a digital copy of the guide from the WSDA website, by going to agr.wa.gov and searching for "Bridging the GAPs."

This guide was developed as a resource to assist farms as they implement good agricultural practices on their farms, and prepare for GAP/GHP audits and FSMA Produce Safety Rule inspections. Writing a food safety plan using the resources and templates provided is a good place to start, though it does not guarantee a successful audit or inspection. The GAP/GHP audit standards and FSMA Produce Safety Rule guidance may be adjusted over time. Please refer to the GAP/GHP web page and the Produce Safety Program page on the WSDA website for current information, at agr.wa.gov.

Contents

Introduction	1	The GAP/GHP Audit	35
About This Guide	1	What is GAP/GHP and Why is it Valuable for a Farm?	35
FSMA and GAP/GHP Overview	3	Different GAP/GHP Audits	36
How to Use This Guide	4	USDA GAP/GHP Audit Programs	36
How This Guide is Organized	5	How to Meet the Standard.....	38
Features of This Guide	6	GAP/GHP Documentation Requirements.....	39
Food Safety Basics	9	Policies, Procedures, and Records	39
Why Care About On-Farm Food Safety?.....	9	The GAP/GHP Audit.....	43
Managing Business Risk	10	Your Food Safety Plan	43
Buyer Demands for Food Safety Assurance	10	How to Get a GAP Audit.....	44
Regulatory Requirements.....	11	Requesting an Audit.....	45
How to Approach On-Farm Food Safety.....	11	During the Audit.....	46
Understand the Objective of a Food Safety Program	12	Automatic Failure.....	47
Learn to Identify Risks on Your Farm	12	After an Audit.....	48
Understand Common Food Safety Risks	13	Costs of an Audit.....	49
Basic Steps to Get Started	14	General Questions	51
FSMA Produce Safety Rule	17	Implementation of a Food Safety Plan	51
What is the Produce Safety Rule?.....	17	Traceability and Mock Recall	52
Understanding FSMA: Background Information	18	Recall Plan	53
Overview of the 7 Rules That Make Up FSMA	19	Mock Recall	53
Does the Produce Safety Rule Apply to You?	20	FSMA Food Safety Program Implementation	55
Determine If You are a Farm	20	Food Safety Plan and Traceability / Mock Recall.....	55
Exemptions Based on Farm Size or Products	23	Employee Training.....	55
Modified Requirements for Qualified Exempt Farms	27	Designated Food Safety Person.....	56
What Does the Produce Safety Rule Include?	28	Worker Health and Hygiene	56
Recordkeeping Requirements of the Produce Safety Rule	30	Potable Water.....	56
What Records are Required?	30	Worker and Visitor Training and Practice	56
Records Must Contain Certain Information.....	30	Handwashing.....	57
How and How Long to Keep a Record.....	31	FSMA Handwashing Requirements	57
Compliance and Enforcement	32	Restrooms and Field Sanitation Units.....	59
Role of the WSDA Produce Safety Program.....	32	Designated Eating and Smoking Areas	59
Compliance Timelines.....	33	Worker Health	60
Evolving Agricultural Water Standards.....	33	Personnel Applying Pre- or Post-Harvest Materials	60
Produce Inspections.....	33	Visitors on the Farm	61

Part 1: Farm Review63

Farm Map..... 63

Water Usage.....66

 Water Testing.....67

 How to Take a Water Sample68

 Making Decisions Based on Water Test Results69

FSMA Requirements for Production Water70

 System Monitoring and Maintenance70

 Water Quality Testing70

 Corrective Actions for Production Water72

 Recordkeeping.....72

 Testing Compliance Timeline.....73

Sewage Treatment75

Animals/Wildlife/Livestock 75

 Livestock and Poultry Adjacent to Growing Areas.....75

 Intentional Interaction Between Livestock and Production Fields75

 Animal Disturbances76

 Avoiding Cross-Contamination from Animals77

FSMA Requirements For Animal Management78

Manure and Municipal Biosolids79

FSMA Standards for Biological Soil Amendments80

Soils81

Traceability.....81

Part 2 : Field Harvest and Packing83

Pre-Harvest Assessment84

FSMA Requirements For Pre-Harvest Assessments85

Field Sanitation and Hygiene85

Field Harvesting and Transportation87

 Harvest Containers.....87

 Harvest Practices that Minimize Cross-Contamination.....88

 Harvest Using Cleaned and Sanitized Tools.....88

 Glove Use90

 Harvest Equipment and Machinery90

 Transportation from Field to Storage and Processing..... 91

Post-Harvest Water Usage92

Product Packing94

Traceability.....95

Part 3: House Packing Facility97

Washing/Packing Line98

Receiving98

FSMA Requirements for Harvest and Post-Harvest Water.....99

 System Monitoring and Maintenance99

 Water Quality Standard99

 Water Quality Testing100

 Corrective Actions for Harvest/Post-Harvest Water100

 Monitoring Requirements for Re-Circulated Water100

 Recordkeeping.....101

 Sanitizing Agents for Post-Harvest Produce Water103

 Sanitizer List for Produce103

Worker Health and Hygiene.....103

General Housekeeping105

FSMA Requirements for Buildings, Tools, and Equipment107

Pest Control.....108

FSMA Requirements for Animals In/Near Buildings.....108

Traceability.....109

Part 4: Storage and Transportation111

FSMA Requirements for Storage and Transportation112

Storage Areas, Product Containers, and Pallets112

 Work Spaces.....112

 Cleaning Up Spills or Accidents.....114

 Clean Packing Boxes, Pallets and Storage Bins.....114

 Preventing Contamination from Non-Food Substances115

Pest Control.....116

Ice and Refrigeration117

 Ice and Cold Water Used for Cooling Produce117

 Cold Storage118

Transportation and Loading.....119

Worker Health and Personal Hygiene.....119

Traceability.....120

Templates and Resources123

Reference Docs for the FSMA Produce Safety Rule125

Reference Docs for the USDA GAP/GHP Audit.....127

Introduction

About This Guide

This guide is part of Washington State Department of Agriculture's (WSDA) Bridging the GAPs project, which seeks to facilitate adoption of good practices for on-farm food safety by providing education, outreach, and technical assistance to small and mid-sized diversified farms.

WSDA staff developed this project in response to farmer requests for information regarding evolving food safety requirements in the marketplace and new regulations. Washington fruit and vegetable growers are seeking affordable ways to adapt their farms to meet these standards. As the Food Safety Modernization Act (FSMA) goes into effect, farmers continue to request support in understanding the changing landscape of food safety standards.

The main goal of the Bridging the GAPs project is to identify and share best practices relating to on-farm food safety for small and mid-sized diversified fruit and vegetable farms. WSDA engaged growers throughout the project by soliciting questions, concerns, and examples of successful solutions.

This chapter introduces the Bridging the GAPs project, and explains how to use this guide to prepare for a USDA GAP/GHP audit and the FSMA Produce Safety Rule.



The first phase of the WSDA Bridging the Gaps project focused specifically on developing guidance and resources for farms preparing for United States Department of Agriculture (USDA) Good Agricultural Practices (GAP) and Good



WSDA GAP auditors and educators have spent extensive time at farm walks on small, diversified farms in order to clarify how to manage these farms for GAPs implementation and audit.

Handling Practices (GHP) audits, as well as for farms simply seeking best on-farm food safety practices without the intention of being audited. The first edition of this guide was published in 2014 as a part of that effort.

With the passage of FSMA and the implementation of its Produce Safety Rule, demands on farms to understand and

implement good on-farm food safety practices have only increased. For small and mid-sized diversified farms, understanding the intersection of regulatory requirements under FSMA, the marketplace expectations for GAP/GHP audits, and the desire to adopt best practices can be complex to understand and navigate.

This second edition includes information about the FSMA Produce Safety Rule and how its legal requirements compare to the voluntary standards of the basic USDA GAP/GHP. This updated publication hopes to bridge the gap between voluntary and regulatory standards — and to bridge any knowledge gaps for farms preparing to meet those standards, or simply improve their on-farm food safety practices.

In addition to this publication, WSDA coordinates workshops and tools for the farming community to share examples of safe growing practices that meet the USDA GAP/ GHP certification standards and that will prepare farms to comply with the FSMA Produce Safety Rule. The Bridging the Gaps team also aims to help WSDA GAP auditors and WSDA FSMA Produce Safety inspectors better serve small and diversified farming operations with education about small and diversified farm operations. WSDA's licensed USDA GAP/GHP auditors, experts on standards for large-scale and single crop production, receive hands-on education, tools, and resources to help them understand the challenges of smaller-scale diversified producers and recognize recordkeeping and food safety solutions that work for these farms. Similarly, WSDA Produce Safety educators and inspectors are developing guidance on Produce Safety Rule implementation that is relevant for small scale and highly diversified farms.

The intent of this guide is to be a helpful resource for any small or mid-sized farm to gain an understanding of basic food safety concepts for produce farms and to begin improving their on-farm food safety practices. New information in this edition provides readers with an overview of both the GAP/GHP audit and the FSMA Produce Safety Rule and how they are similar and different — and where to go for additional information beyond the scope of this guide. Finally, for those farmers who are interested, the guide is designed to walk them through the process of preparing for a basic USDA GAP/GHP audit.

A brief overview of the FSMA Produce Safety Rule and the USDA GAP/GHP audit program

	FSMA Produce Safety Rule	USDA GAP/GHP Audit
Year Started	2015	2002
Required by	Federal governmental regulation	Some buyers
Can I get an exemption?	Mandatory federal law, but some exemptions and exclusions exist.	GAP certification is voluntary, but some buyers may require it.
Federal agency responsible	U.S. Food and Drug Administration	USDA Agricultural Marketing Service
Administered in Washington by	WSDA Produce Safety Program will conduct inspections in coordination with FDA.	WSDA Fruit and Vegetable Inspection Program conducts audits in Washington, under contract with USDA. Many private companies conduct GAP audit programs as well.
What does it cover?	Basic on-farm produce safety: worker health and hygiene, wild and domestic animals, soil amendments, water, post-harvest handling and sanitation. Clarification on a few specific standards has been deferred to a future date.	Basic on-farm produce safety: water, soil amendments, animals, personnel, equipment, worker training, and record keeping.
Documentation required?	Certain records are required. A food safety plan is not required, but it can be a helpful tool.	A food safety plan with specific components and records is required.
How do evaluations happen?	Inspection protocol is yet to be developed.	Point-based audit checklist. Farmer chooses parts or “scopes” of audit and which products to have audited.
When do evaluations happen?	WSDA inspections will likely occur during harvest season beginning in Spring 2019, starting with larger farms.	Audits happen during the harvest season at the request of the farmer.
Evaluation frequency	Inspection frequency currently unknown.	Farm must be audited every year that they are certified.
What happens if you fail an evaluation?	Unknown at this time.	You can make corrections and get audited again.
Cost	No cost for farms covered by the rule. (Fee for exempt or qualified exempt farms that request a voluntary inspection. Cost for voluntary inspection unknown at this time.)	\$108 per hour for WSDA auditor time, plus auditor mileage. There is an additional cost for USDA processing time. (Fees current at time of publication, but subject to change.)

Adapted with permission from “GAPS certification/FSMA Produce Safety rule comparison” by Londa Nwadike, PhD, Kansas State University / University of Missouri Extension Consumer Food Safety Specialist

How to Use This Guide

This guide is intended to assist fruit and vegetable growers as they begin to implement and document good agricultural practices for on-farm food safety – and to help them prepare for a third-party audit or inspection of those practices. The information in this guide is based on the USDA Good Agricultural Practices and Good Handling Practices (GAP/GHP) Audit standards. In order to provide accurate, useful information, the WSDA team has worked closely with WSDA auditors, who conduct the audits in Washington State through a cooperative agreement with USDA, and with educators and inspectors in the WSDA Produce Safety Program, which is responsible for implementing the FSMA Produce Safety Rule in Washington State through a cooperative agreement with the U.S. Food and Drug Administration (FDA).

WSDA's Bridging the GAPs project worked with auditors and educators to identify tips and best practices that will be cost-effective on small and mid-sized diversified farms, including those with livestock and other farm animals. This guide aims to provide information that will help growers implement good on-farm food safety practices and provide auditors with a basic guide for issues of most concern to growers with smaller, diversified farms.

This second edition of the guide is updated to include information about the FSMA Produce Safety Rule. Many of the fundamental concepts and practices of the Produce Safety Rule are rooted in Good Agricultural Practices and Good Handling Practices audit standards. Therefore, the specific information about the FSMA Produce Safety Rule in this guide focuses on the areas where there are notable differences in the requirements of the two food safety standards.



For a high level overview of the FSMA Produce Safety Rule and the basic USDA GAP/GHP audit see the table on page 3. Later chapters go into further detail about the specific organization and standards of the two food safety programs.

How This Guide is Organized

The guide begins with a chapter on Food Safety Basics to provide an understanding of the food safety concepts that form the foundation of good agricultural practices for fruit and vegetable farms. This overview should provide a framework for understanding the reasons behind the recommendations and requirements of the specific food safety standards. This section should equip farmers with the food safety principles they will use to think through food safety and recordkeeping approaches that respond to the particular circumstances on their own farms.

The Overview of the FSMA Produce Safety Rule chapter provides a brief history and summary of the federal regulation, including what businesses and products are covered, excluded, or qualify as exempt from the rule; required records; and compliance and enforcement information, with as much detail as is available at the time of publication.

The following chapter, Overview of the USDA GAP/GHP Audit, explains the different types of audits available, the basic structure and required components of a USDA GAP/GHP audit, and what to expect throughout the audit process.

The remainder of the guide generally follows the flow and structure of the basic USDA GAP/GHP Audit Checklist: General Questions, Part 1, Part 2, Part 3, and Part 4. The audit checklist provides a comprehensive look at the kinds of risks you should consider when creating a food safety plan tailored to your farm. The checklist will be the guiding document followed by an auditor when conducting a GAP/GHP audit.



Each chapter provides details and best practices for a different section of the audit. By following the guidance and using the resources collected in the Templates and Resources section at the end of this guide, you can create a working draft of a food safety plan. Consider drafting your policies, standard operating procedures (SOPs), and corrective actions plans as you make your way through the guide. Working through the guide in this way will get you started on a draft food safety plan that will be helpful, whether it is intended for a USDA GAP/GHP audit, FSMA Produce Safety Rule compliance, or simply to use as a best practices guide on your farm.

The Templates and Resources section is a collection of sample records templates (that you may use as-is, or adapt for use on your farm) and information resources on a variety of topics you may wish to delve deeper into. The FSMA Produce Safety Rule reference section provides the full text of the regulation so you can look up the exact legal language of the regulation. In the GAP/GHP Audit reference section, you will find the complete GAP/GHP Audit Checklist and related documents. All of the records templates and reference documents are available in digital format on the thumb drive attached to this guide.

It is important to remember that the FSMA Produce Safety Rule is a law that establishes mandatory practices for some farms. In contrast, all GAP/GHP audits are voluntary. Most growers who seek a GAP/GHP audit do so to meet requirements of a particular buyer or to enter a new market that requires or prefers a third-party food safety certification. Growers have flexibility to select specific parts, or “scopes” of the audit, they would like. Growers with smaller-scale operations that have modest infrastructure are most likely to choose to be audited for General Questions (required for all audits), and Parts 1, 2, 3, and/or 4. Many small farms will only need General Questions and Parts 1 and 2, based on common practices on most small, diversified farms. The GAP/GHP Audit Checklist scopes that are most relevant for small diversified farms are treated in detail in this publication:

- ✦ General Questions
- ✦ Part 1: Farm Review
- ✦ Part 2: Field Harvest and Packing
- ✦ Part 3: House Packing Facility
- ✦ Part 4: Storage and Transportation

The remaining parts of the audit checklist (Part 6: Wholesale Distribution/Terminal Markets; and Part 7: Preventative Food Security Procedures) are not covered here, as they generally apply only to larger farms or wholesaler/distributors, and are outside the scope of the Bridging the GAPs project. (Part 5: Traceability has been incorporated into all sections of the audit, and is no longer a separate scope.)

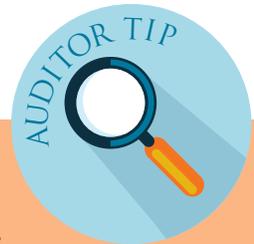
Features of This Guide

Best practice examples, photographs, and sample policy language are included in this guide to provide insight on strategies other Washington farms are using to meet the standards, and help guide development of your food safety plan. You may wish to model your farm’s policies on some of these. However, each farm is unique, and you must follow recommended procedures for risk assessment in order to develop policies that reflect your farm’s unique risk profile.

Some other special features you will find throughout this guide include:



Farmer Question boxes appear throughout the guide to answer frequently asked questions



Auditor Tips from GAP/GHP auditors offer practical suggestions for developing your food safety plan and preparing for an audit



On-Farm Examples illustrate ways that Washington farmers are using good agricultural practices on their operations



These green GAP/GHP Audit Checklist icons highlight the specific question(s) in the GAP/GHP audit that the adjacent section of this guide refers to. You can look up the cited question(s) in the complete GAP/GHP Audit Checklist provided in the GAP/GHP Audit reference section of this guide.



These red FSMA Produce Safety Rule icons highlight the specific section(s) in the Produce Safety Rule that the adjacent section of this guide refers to. Sections are indicated by the § symbol. You can look up the exact legal language in the cited sections(s) of the regulation in the full text of the FSMA Produce Safety Rule and the FSMA Regulatory Reference Table provided in the Produce Safety Rule reference section of this guide.

You will notice sections that appear in maroon font, such as this, throughout the guide. These sections highlight important areas where the FSMA Produce Safety Rule has a specific requirement, or where the Produce Safety Rule standard differs significantly from the GAP/GHP standard.

To assist you in developing your farm's unique food safety plan and SOPs, worksheets and templates relevant to each audit scope are included in the Templates and Resources chapter at the end of this guide. We provide a Standard Operating Procedures worksheet and examples, sample recordkeeping logs, and other documentation that can be used as-is or be adapted as needed for your own use. To find a specific document, refer to the table of contents listing the templates and resources provided, located at the beginning of the Templates and Resources chapter. The documents are organized in the same general order that they are discussed in the guide. The table of contents indicates which part(s) of the GAP/GHP Audit each document pertains to, as well as its relevance to the Produce Safety Rule. So that they are easily available for you to use and adapt, these sample policies, worksheets and templates are included in Word or Excel format on the flash drive included with the hard copies of this publication. They are also available on the WSDA website (agr.wa.gov; search for "Bridging the Gaps").

The reference materials in the final two chapters of this guide are provided so you can easily access the original documents of the food safety standards this guide refers to: the USDA GAP/GHP Audit Checklist, and the FSMA Produce Safety Rule itself.

The record templates and information resources are organized in the same general order as they are referenced in this guide. For documents that relate to more than one section of this guide (such as the SOP worksheet), only one copy is provided, rather than multiple duplicates. A table of contents in the Templates and Records section will help you find the document you want, and indicate which section(s) in this guide the specific document pertains to.

Food Safety Basics

Why Care About On-Farm Food Safety?



At its core, food safety is about keeping people who consume your products safe from foodborne illnesses. Everyone along the supply chain, from farm to fork, plays a role in the safety and quality of food. For farmers, maintaining good agricultural and food handling practices will help keep your customers healthy and it is also an important element of managing your risk as a farm business.

For a combination of reasons, there is increasing awareness about the role that good food safety practices at the farm level play in reducing risk of serious outbreaks of foodborne illnesses. In recent years, there have been a number of high-profile outbreaks of serious foodborne illnesses linked to produce. This has raised public concern and awareness about food safety in general. Many shoppers have new questions about the origins and the safety of their produce and it

This chapter describes the principles of on-farm food safety and some basic components of on-farm food safety programs.



is now common for produce buyers to request information and assurances from farms about their on-farm food safety practices. In the past, regulation and management of food safety was primarily reactionary and focused on response to outbreaks. Now the shift is towards a preventive approach focused on reducing the possibilities for pathogens to contaminate food at all points from farm to plate.

While there's no question that eating fresh produce is good for health, it's also true that produce has some special considerations when it comes to food safety concerns. If produce becomes contaminated, permeable surfaces and crevices on fruits and vegetables provide places for pathogens to harbor and infiltrate produce. Once produce is contaminated with a pathogen, it is hard to remove; simply washing produce is often not enough to adequately reduce their presence. Produce eaten fresh does not go through a "kill step" like cooking.

The combination of all these factors has resulted in marketplace demands and new regulatory requirements for produce farms. Understanding and implementing good on-farm food safety practices can help you gain or maintain markets that are important to you.

Food Safety and Managing Business Risk

Good Agricultural Practices (GAP) and Good Handling Practices (GHP) are commonly thought of as audit standards or certifications, but they are also the generic terms used to refer to the steps that a farm takes to protect their produce from the risk of microbial, physical, or chemical contamination.

Using GAPs/GHPs is an important way you can reduce your business risk as a farm. When a food product is related to an illness outbreak or other health concern, a recall is often the response.

Recalls can be costly in terms of product loss and expenditures of time and funds to manage the product recall and related communications. Good on-farm food safety practices and having a food safety and recall plan in place can both reduce the likelihood of a need for a recall in the first place, and reduce the business impacts if there is a public health concern.

During a 2018 outbreak, *E.coli*-contaminated lettuce from Yuma, Arizona was tied to hundreds of reported illnesses and several deaths. The Wall Street Journal reported that prices for whole romaine heads plummeted as much as 60% in one month, illustrating that produce safety issues can have broad economic impacts. Being prepared and communicating about your on-farm food safety practices with your customers can help you to maintain customer confidence in your farm products, even when there may be broader concerns about the safety of certain types of produce.

Buyer Demands for Food Safety Assurance

With consumer attention focused on produce safety and businesses concerned about limiting risks related to food safety, farms face increasing expectations to assure buyers that they are following safe growing and handling practices. Many wholesale buyers such as grocers, produce distributors, and some institutions like schools and hospitals require that farms provide information about their on-farm food safety practices. In some cases, buyers may simply expect farms to have a food safety plan in place and be able to speak about it. In other cases, buyers have developed their own food safety program, checklist, or protocol that their farm suppliers must comply with. More and more frequently, buyers require a third-party assurance of good agricultural practices, such as through a formal GAP/GHP audit program, like the basic USDA GAP/GHP program this guide is focused on.

All GAP/GHP programs are voluntary audit certifications. While they are not required by law, for a farm that needs a GAP/GHP certification in order to maintain or expand their markets, it may feel mandatory.

Regulatory Requirements

With the implementation of the FSMA Produce Safety Rule, there are now regulatory requirements for produce farms. The Produce Safety Rule is a mandatory federal regulation. With this rule, some produce growers will be facing regulation of their businesses for the first time. Other farms may be exempt from the Produce Safety Rule based on their products, markets,

and size of business. Whether or not your farm is required to adhere to these federal food safety standards, having a general awareness and understanding of current regulatory requirements, guidelines, and best practices is important for both business and public health reasons.

Though there are differences between the Produce Safety Rule and the voluntary GAP/GHP audit, the fundamental principles are similar. For that reason, many farmers look to implementing GAPs as a good way to prepare for compliance with the Produce Safety Rule.

How to Approach On-Farm Food Safety

Most on-farm food safety standards, including both mandatory regulations and voluntary certifications, are written with an open-ended approach to implementation. In other words, the standards may not specify how to meet the requirements. This is because there is usually more than one way to effectively implement a food safety solution. GAP/GHP and the Produce Safety Rule both require farms to identify the risks related to their individual operations and then take actions to reduce or remove those risks. The lack of specific guidance can be frustrating, but it also provides flexibility for you to make your own decisions. Agricultural operations are so diverse that no one approach to food safety would work for all.

That being said, there are several basic on-farm food safety concepts that are recognized across standards. You should have a basic understanding of food safety and how contamination occurs and be able to apply this information to your unique circumstances. Farms with a successful food safety program are continually learning and becoming accustomed to actively monitoring and responding to risk. Establishing a food safety program into daily practice may take time, but the following concepts can help you get started.



My farm is certified organic. How does this interact with GAP certification? Do I need both? Are they compatible?

The two programs have different goals and requirements, and your need for each is determined by your market decisions and business model. It is certainly possible to successfully meet both standards on your farm.

As with organic certification, GAP is based on a system plan or implementation of standard operating procedures and requires thorough recordkeeping. While organic standards require operations to prevent contamination of organic crops from prohibited input materials and prevent commingling of organic and nonorganic products, GAP certification ensures that the operation is following practices to minimize the risk of microbial contamination of crops. Both regulations cover practices from planting through harvest, packing, storage and transportation. More specific information in response to this question is provided in the WSDA Organic / GAP Comparison Fact Sheet in the Templates and Resources section of this guide.

Understand the Objective of a Food Safety Program

The three main categories of food safety hazards are physical, chemical, and microbial contamination. In fresh produce, the biggest food safety hazard is contamination by pathogenic microbes such as bacteria, viruses, and parasites that cause disease or illness in humans. Most foodborne illness outbreaks are caused by the bacteria *Escherichia coli* (*E. coli*), *Salmonella*, and *Listeria monocytogenes*. Farms are rich in microorganisms of many types, and many are beneficial. The emphasis of on-farm food safety programs is on reducing or eliminating the introduction and spread of human pathogens to your products. No farm environment is totally pathogen-free, so the risk of microbial contamination cannot be totally eliminated. Rather, the goal is to grow and handle produce in ways that minimize the risk of contamination.

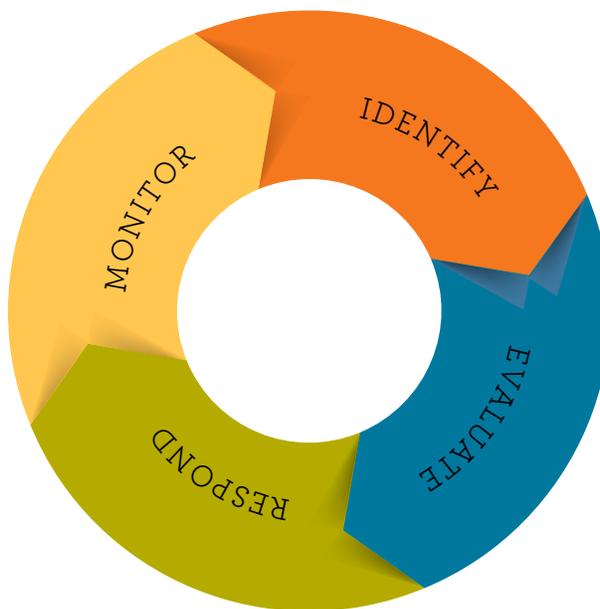
Physical and chemical risks are less common forms of contamination, but you should still consider them and work to reduce the likelihood of contamination. For example, broken glass, chipped machinery, oil spills, and improper use



of sanitizers could contaminate produce or cause a choking or injury hazard if comingled with harvested product, in addition to posing a risk to worker safety.

Learn to Identify Risks on Your Farm

The root of food safety is being able to identify and respond to risks present on your farm. The basic steps of a risk assessment are:



Risk assessment is an on-going practice of identifying problems or potential risks, and fixing the issue. It can be used to address a variety of food safety concerns on the farm.

- ❖ **Identify** the risk
- ❖ **Evaluate** the severity
- ❖ **Respond** accordingly
- ❖ **Monitor** the effectiveness of your response

A classic example is the case of a spilled sanitation unit such as a port-a-potty. Using the risk assessment model above:

- ❖ The risk is the spill and possible crop contamination from human waste.
- ❖ The evaluation is assessing the location, timing, and amount of the spill, and determining which crops might be contaminated as well as the potential for spreading the impact through cross-contamination via tools, equipment, movement of people and animals, etc.



Some farms use field sanitation units on wheels so they can be hitched to a tractor or other vehicle and pulled to the various harvest locations. If using wheeled sanitation units, it is important to carefully plan where they will be located and have a written plan for what will be done in case of tipping or leakage.

- The response is to prevent contact between the waste and your crops, and safely cleaning up the mess. You should also record the issues and steps you took to correct the problem.
- The monitoring step may include making a plan to prevent future incidents, such as moving the unit to a different spot, or redesigning the response plan for quicker clean up.

Farmers may have different ways of resolving the risks that occur on their farms, but the solutions should be practical and appropriate for the situation.

Understand Common Food Safety Risks on Farms

Because on-farm food safety programs are focused on microbial contamination risks, it is important for your farm risk assessment to consider how to minimize the growth and spread of pathogens. Pathogens are most likely to persist in environments where the growing conditions are favorable. Growing conditions vary based on available nutrients, acidity, time, temperature, and oxygen and moisture in the environment. Most bacteria favor warm, moist environments in hard-to-reach spots, such as a crack in a harvest bin on a hot day. (Proper cleaning, storage, and equipment maintenance can help reduce risk in that situation.) Cold storage tends to slow the growth of bacteria and the decay of produce; however, some bacteria, including *Listeria*, can persist even at low temperatures. No farm environment can ever be entirely pathogen-free, but you can minimize their growth and progression.

It's important to understand the common sources of pathogens, where pathogens tend to live, and how they multiply and move. Consider these features on any farm: humans, animals, soil,

Common ways contamination is introduced and spread on farms

Humans	Animals	Soil amendments	Water	Tools
Workers and visitors	Domestic and wild animals	Amendments from biological sources such as compost and manure	Production and post-harvest water	Production and post-harvest tools and equipment
<ul style="list-style-type: none"> • Hands • Clothing • Boots • Jewelry • Gloves • Illness • Injury 	<ul style="list-style-type: none"> • Feces on crops, tools, boots, or in storage areas • Hoof traffic • Drinking water • Crop damage 	<ul style="list-style-type: none"> • Previous and adjacent land use • Soil amendment <ul style="list-style-type: none"> • Inputs • Treatment • Application • Storage • Transportation 	<ul style="list-style-type: none"> • Source quality • Water system (irrigation pipes, etc.) • Treatment • Intended use • Contamination issues (flooding, animals, environmental runoff) 	<ul style="list-style-type: none"> • Harvest tools • Wash and pack equipment • Food packing materials • Buildings • Machinery • Equipment storage • Ice and refrigeration

water, and tools. Each of these can be a source or a vehicle for spreading pathogens on the farm. This can occur as easily as a worker forgetting to wash their hands after using the bathroom, or putting a piece of produce with bird droppings on it into a dunk tank with other produce. Your aim is to reduce the instances and conditions when a contaminant could come into contact with produce.



This feels overwhelming. Where do I start?

It's likely that you are already following some good agricultural practices required by GAP/GHP and FSMA, because they are based on common sense principles that align with good farm management and attention to product quality. You may only need to make small adjustments, or take the next step to document what you are already doing. Here are some examples of good food safety practices that align with both GAP/GHP and FSMA Produce Safety Rule standards:

- Provide accessible and well-maintained bathrooms and handwashing facilities.
- Train employees on basic health and hygiene practices (e.g. handwashing, reporting injuries).
- Consider your timing and method of soil amendment application.
- Try to deter wild animals from the crop production area.
- Do not harvest produce that has animal feces on it.
- Test your irrigation water at least once annually.
- Use potable water during any harvest and post-harvest activities.
- Keep harvest bins off the ground during harvest and post-harvest activities.
- Maintain or replace equipment that is in poor condition or difficult to thoroughly clean.
- Set a cleaning and sanitizing schedule for tools and equipment.

Cross-contamination is the spread of pathogens from one place to another. Each farm has unique cross-contamination considerations depending on the location and flow of activities on the farm. A general rule of thumb is to maintain some distance between activities, while keeping topography and climate factors in mind. For instance, it would make sense to keep untreated manure downhill from the crops where runoff is likely. Another example is keeping livestock away from surface water used for irrigation. The following chapters will provide many more examples of how to manage a variety of scenarios.

Basic Steps to Get Started

Many food safety programs — whether GAP/GHP, the Produce Safety Rule, or other buyer-required schemes — share similar, overarching components. In some food safety programs, they are required elements; in other cases they are recommended as best practices. In later chapters, this guide covers specific requirements of the USDA GAP/GHP audit and the FSMA Produce Safety Rule. Here, we provide a brief description of these common elements and why they are important.

Designate a food safety person

Both the USDA GAP/GHP standard and the Produce Safety Rule require that each farm designate a food safety lead. The food safety lead is the point of contact when the farm is audited or inspected. On a day-to-day basis, this person is responsible for understanding and applying the appropriate food safety standards on the farm and conducting on-going risk management assessments. The food safety lead may help develop and update the farm's food safety plan, train or supervise other workers in food safety practices, and help model and enforce a culture of food safety.

For very small farms, the food safety person might be the owner or farm manager; on larger operations, a staff member or team may be solely dedicated to food safety. Regardless of who is selected, your food safety person should have the training, experience, and authority necessary for the role. All employees must contribute to food safety on the farm, but it is important to have one person who is responsible for ensuring that the farm successfully carries out its food safety program.

Conduct employee training

Employee training is a critical component of any food safety program, helping ensure that workers understand and do their part to carry out the farm's food safety practices. At a minimum, all staff should have a basic understanding of good health and hygiene practices such as knowing proper hand washing technique, and when to report illness or injury. Beyond this, food safety training should be relevant and specific to each employee's work duties. For example, the harvest crew may learn different safe handling practices than the pack crew, if those roles and tasks are done by different people. Generally speaking, training should be accessible to workers (in terms of language, delivery method, and so on) and occur as needed, at least annually. Additional information about employee training requirements under GAP/GHP and the Produce Safety Rule is provided in later chapters.

Keep records and make a plan

Many farmers are already following basic food safety practices, some without recognizing it, but fewer document their efforts. Recordkeeping is an important (and in specific cases, required) element in any food safety program because without documentation, there is no way to verify what has happened. Records are a form of proof for auditors and inspectors that you are following your food safety program outside of their brief visit.

Records do not need to be complicated and can be adapted to your work style. For example, some farmers prefer paper records located near the activity or in a centrally-located binder, while others opt to input data on a computer or mobile app. More information on the specific records required under GAP/GHP and the Produce Safety Rule, as well as examples of how to keep good records, are in later chapters. In the Templates and Resource section of this guide, you will also find records templates that help clarify what is important to track, and which you can adapt and use on your farm.

A food safety plan is a comprehensive document that outlines practices a farm will use to reduce food safety risks. One benefit of food safety planning is that it is an opportunity to take a step back and analyze your whole system for improvements, including work flow and processes, time management, tools and equipment, staff and training, and more. Writing a food safety plan can help you focus on the essential tasks of your operation, document how you've assessed the food safety risks on your farm, and define your plans to reduce those risks in an organized way. A food safety plan may also include farm policies and standard operating procedures, and serve as a place to store relevant records. Some farms use their plan to set goals for the food safety improvements they would like to make over time, such as infrastructure improvements or investments in new equipment.

A food safety plan is required under the USDA GAP/GHP audit. While a food safety plan is **not** required under the Produce Safety Program, it is recommended as a best practice. The most sustainable way to adopt on-farm food safety is to make it manageable, realistic, and tailored to your operation.

FSMA Produce Safety Rule

What is the Produce Safety Rule?



Note: This guide is not intended to be a comprehensive manual on the FSMA Produce Safety Rule, and should not be the sole information source on preparing your farm for compliance with FSMA. Instead, this guide should help you understand the ways the FSMA Produce Safety Rule aligns or differs from the USDA GAP/GHP audit requirements. Where possible, the guide includes references to the relevant section of the Produce Safety Rule or additional resources for further information about the Produce Safety Rule requirements.

Many farmers, even those experienced with GAP/GHP or other food safety standards, are eager to understand the FSMA Produce Safety Rule. As a new, mandatory federal regulation, FSMA imposes new requirements on some farms, and impacts the overall landscape of food safety standards. This chapter provides a general overview of the FSMA Produce Safety Rule in order to familiarize you with the regulatory framework, as well as information about the criteria used to determine whether a farm is subject to the rule, or partially or fully exempt from it. Later chapters will go into greater detail about specific guidelines and requirements of the Produce Safety Rule. In many cases, GAP/GHP standards align with the Produce Safety Rule standards; where there is a significant difference between the two, we make note of the specific FSMA requirements.

This chapter provides general information about the FSMA Produce Safety Rule, including the criteria for coverage / exemption status.

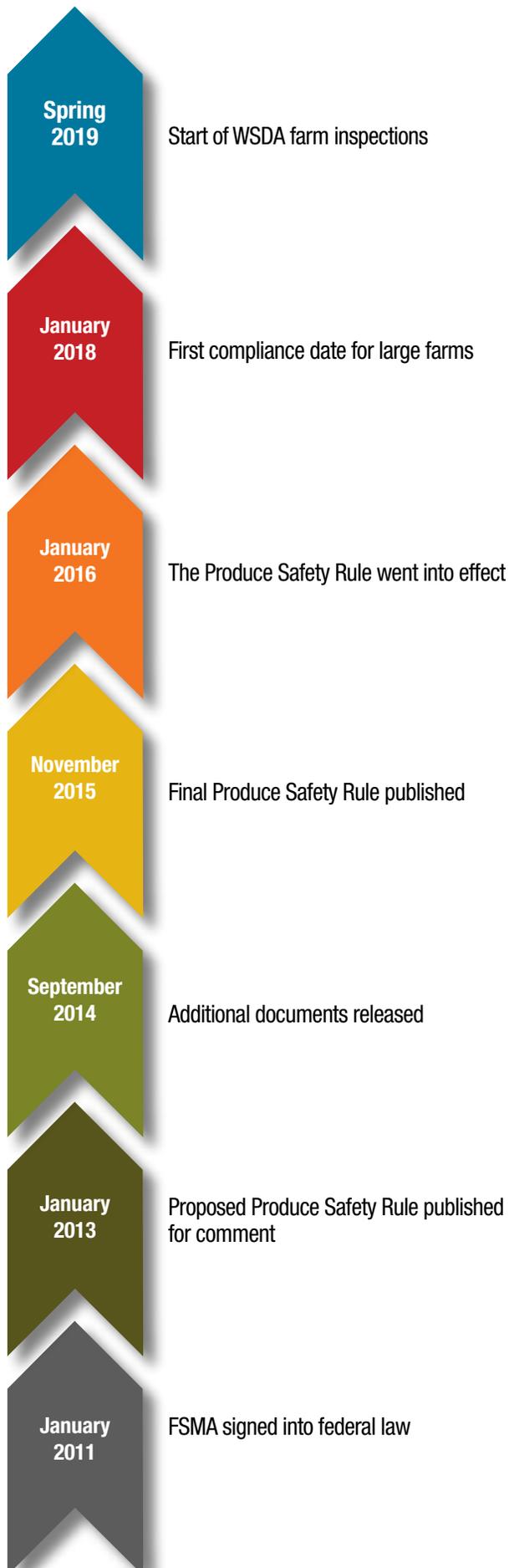


Understanding FSMA: Background Information

The Food Safety Modernization Act (FSMA) is the largest update to federal food safety law in 70 years. When FSMA was signed into law in 2011, it authorized the FDA to take a preventive – rather than reactive – approach to food safety. The FDA took five years to research, solicit and incorporate stakeholder input, and ultimately finalize the food safety rules that regulate farms and food businesses along the supply chain.

FSMA is made up of seven rules, one of which is the Produce Safety Rule (#7). The overview on the next page briefly describes each of the rules to provide context for where the Produce Safety Rule exists in a regulatory framework. Depending on your business, you may or may not need to comply with other FSMA rules. For many small and mid-size produce and diversified farms, only the Produce Safety Rule will apply.

Since FSMA was signed into law in 2011, the FDA developed an initial and then final version of the Produce Safety Rule. Stakeholder input was key in shaping the final rule. WSDA will begin farm inspections in Spring 2019.



Overview of the 7 Rules That Make Up FSMA

- 1** Current Good Manufacturing Practice, Hazard Analysis and Risk-Based **Preventive Controls for Human Food**. *Facilities that manufacture and/or process food must establish and implement a food safety system that will identify and minimize hazards.*
- 2** Current Good Manufacturing Practice, Hazard Analysis and Risk-Based **Preventive Controls for Animal Food**. *Facilities that manufacture and/or process animal food must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls.*
- 3** **Foreign Supplier Verification Program** for Importers of Food for Humans and Animals. *Requires importers to verify their food has been produced in a manner that provides the same level of public health protection.*
- 4** **Accredited Third-Party Certification** to Conduct Food Safety Audits and to Issue Certifications. *Establishes an accreditation program for third-party auditors to conduct audits and issue certifications of foreign facilities.*
- 5** **Sanitary Transportation** of Human and Animal Food. *Requires sanitary practices for shippers, receivers, loaders and carriers who transport food.*
- 6** Mitigation Strategies to Protect Food Against **Intentional Adulteration**. *Domestic and foreign facilities must implement preventive measures against adulteration intended to cause large-scale public harm.*
- 7** Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (AKA **The Produce Safety Rule**). *Establishes science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms.*

In most cases, FSMA simply updates existing food safety regulations. However, the Produce Safety Rule is the first regulation that sets food safety standards for the growing, harvesting, packing, and holding of fresh produce. Prior to FSMA, the only food safety law that applied to produce farms was the general FDA regulation against the selling of adulterated food. This means that farms that have never been specifically regulated before will now be required to comply with federal food safety regulations.

Some multi-faceted farm businesses that conduct value-added processing, or significant storage, handling, and shipping activities, may need to have a permit from the state or their local health jurisdiction, depending on their activities, in addition to complying with the Produce Safety Rule for their growing, harvesting, and packing activities. These permits include the WSDA Food Processor License, the WSDA Food Storage Warehouse License, and a retail food permit issued by the local health jurisdiction. The requirements for these licenses and permits are being updated by their respective administrators

to align with applicable regulations in other FSMA rules, namely the Preventive Controls for Human Food Rule, the Preventive Controls for Animal Food Rule, or the Sanitary Transportation Rule. Therefore, if you are in compliance with these licenses and permits, you should be in compliance with the applicable FSMA rules.

Farm businesses that are required to have a WSDA Food Processor License or WSDA Food Storage Warehouse License should work with the WSDA Food Safety Program to ensure they are meeting the applicable parts of other FSMA rules through their licensing process. You can contact the program at (360) 902-1876 or foodsafety@agr.wa.gov. Farm businesses that have a retail food permit should contact their local health jurisdiction for the same.

Does the Produce Safety Rule Apply to You?

There are several questions to answer to determine if the Produce Safety Rule applies to you. This section will walk you through them.

Determine If You are a Farm

The FDA defines a “farm” in order to clarify which FSMA rules apply to various operations. According to the FDA definition, the key activities of a farm are growing, harvesting, packing, and holding. Do you conduct any of those activities? Most small to mid-sized, diversified farms will meet the FDA’s definition. To dig a little deeper, see the following table for more examples.

You may notice that the harvesting, packing, and holding definitions do not include any activities that change produce from its raw or natural state. Drying/dehydrating is allowed so long as no additional processing steps, such as slicing, occur. Packing, labeling, and fumigation for the purpose of ripening produce are also allowed if no additional manufacturing or processing occurs. Processing activities, such as slicing, cooking, canning, baking, and freezing, which modify produce from its raw or natural state, are subject to a different set of laws and regulations. The farm definition distinguishes farms from food processors and manufacturers who are required to register with the FDA as a “food facility” under FSMA. Farms do **not** have to register with the FDA.

Definition of activities subject to the Produce Safety Rule



§112.3

Harvesting

- Cutting edible portion from plant
- Cooling
- Field coring
- Filtering
- Gathering
- Hulling
- Removing stems and husks
- Shelling
- Sifting
- Threshing
- Trimming outer leaves
- Washing

Packing

- Sorting
- Culling
- Grading
- Weighing or conveying

Holding

- Fumigating produce during storage
- Drying / dehydrating without further processing
- Blending of the same product
- Breaking down pallets
- Storing food

More examples are provided in the FDA draft guidance, “Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processes for Farms and Facilities: Guidance to Industry.”



What if I grow and process food?

Operations that grow and process food, such as a large berry farmer that grows, freezes, and sells frozen strawberries direct to consumers, are considered “mixed facilities” and may be subject to both the Produce Safety Rule and the Preventive Controls for Human Food Rule. Remember that various food licenses are being updated to align with FSMA standards, so as long as you maintain compliance with those licenses, you should be in compliance with the applicable FSMA rules. In this example, the farmer would likely need a WSDA Food Processor License to make the frozen berry product, and a WSDA Food Storage Warehouse License to store it; these licensure processes should ensure that the farmer is meeting the necessary FSMA regulations.

For questions about what other FSMA rules (other than the Produce Safety Rule) may apply to your business, and how to meet those requirements, contact the WSDA Food Safety Program at (360) 902-1876 or foodsafety@agr.wa.gov.

If you exclusively conduct farm activities — growing, harvesting, packing, or holding — and you meet the FDA’s definition of a farm, you are exempt from the other FSMA Rules (including the Preventative Controls for Human Food, Preventative Controls for Animal Food, and the Sanitary Transportation rules). See the full FDA farm definition below:

- A **Primary Production Farm** is an operation:
 - Under one management;
 - In one general physical location (that may include multiple non-contiguous parcels); and
 - Devoted to growing or harvesting crops, or raising animals.

In addition, a primary production farm may:

- Pack and hold Raw Agricultural Commodities (RACs);
- Dry / dehydrate RACs to create a distinct product with no other processing (e.g. drying grapes to make raisins); and
- Artificially ripen RACs (e.g. pears treated with ethylene gas).

- A **Secondary Activities Farm** is an operation:
 - Not located on a primary production farm;
 - Devoted to harvesting, packing and/or holding RACs, but may also conduct the same activities as a primary production farm;
 - Majority-owned by the operator of a primary production farm; or by multiple primary production farm operators together; and
 - Where the primary production farm(s) provide the majority of the RACs handled by the secondary activities farm.

The FDA definition of a farm includes “secondary activities farms” in order to include more complex business models such as farmer co-ops, on-farm packinghouses co-owned by multiple growers, food aggregators, and some types of food hubs. The definition also encompasses businesses that conduct some farming activities but not others, such as seasonal harvest crew companies that harvest produce but do not grow it. While the two-part definition is broader, some food hubs and packinghouses that conduct farm activities still may not fit neatly into the definition due to questions about how the FDA interprets ownership structure and other packing and holding activities.

Food hubs that operate primarily as a shipper / handler / distributor, and have certain business structures, may not meet the FDA definition of a farm (and therefore will not be subject to the Produce Safety Rule) but may be required to follow other FSMA rules, such as the Sanitary Transportation Rule.

The specific and technical nature of the FDA farm definition means that there is not necessarily a single blanket response to the question, “Is my business a farm?” Instead, each operation should consider their activities against the farm definition on a case-by-case basis. You can contact the WSDA Produce Safety Program with questions about whether your business meets the FDA farm definition. If you are interested in obtaining a legal response from the FDA regarding your particular situation, you can submit your question through the FSMA Technical Assistance Network (TAN). See the FSMA Technical Assistance Network fact sheet in the Templates and Resources section for information on how to do this.

In 2018, the FDA announced it would exercise discretion in enforcement for businesses that conduct farm-related activities, but do not meet the farm definition. This means the FDA will delay enforcement of certain FSMA regulations for specific types of businesses until additional rulemaking and clarification can be completed. For more information, see the FDA Enforcement Discretion for Certain FSMA Provisions document in the Templates and Resources section of this guide.



Remember:

When a farm, activity, or produce is referred to as “covered” it means that action or thing is required to follow the Produce Safety Rule.

Determine If Any Exemptions Apply to You Based on Farm Size or Products

If you have determined that your operation meets the FDA definition of a farm, continue with this section to see if any exemptions apply to your business. The decision chart and accompanying descriptions will take you through the process of determining which, if any, parts of the rule you are exempted from.

Exemptions are based on operation size, types of products, and market channels. This reflects stakeholder input the FDA received during the rulemaking process, as well as the FDA’s assessment that small and direct marketing farms contribute a relatively smaller volume of produce into the overall marketplace and tend to have fewer degrees of separation between the farm and the end consumer. Therefore, they pose less public health risk in terms of potentially introducing contaminated product into our food supply. The small farm exclusions and exemptions are outlined here and explained in more detail below.

A **full exclusion** from the Produce Safety Rule applies to small farms that gross less than \$25,000 per year in *produce* sales, based on an average of the previous three year period, adjusted for inflation. (This threshold figure is stated in 2011 dollars; see the table in section **2** for inflation adjustments.)

Farms that sell more than \$25,000 but less than \$500,000 in average annual *food* sales, and sell primarily direct to consumers or local businesses, *may* be eligible for a **qualified exemption** (see more details in section **6**). Qualified exempt farms need to comply with modified parts of the Produce Safety Rule, which are substantially less intensive than the full requirements for covered farms.

Additional exemptions are granted for specific produce items that are deemed lower risk due to how they are processed, handled, or consumed. The **product-based exemptions** are discussed in sections **3, 4, and 5**.

You do not need to apply for exemptions, but you must keep documentation that verifies your status, such as sales records, or written assurance of food processing from your buyer. You may need to provide this documentation to authorities upon request.

1 Are you a produce farmer? **NO** → Your farm is **not covered** by the Produce Safety Rule
↓
YES
↓

2 Does your farm have \$25,000 or less in annual produce sales? **YES** → Your farm is **not covered** by the Produce Safety Rule
↓
NO
↓

3 Is your produce one of the crops identified as “rarely consumed raw”? **YES** → This product is **not covered** by the Produce Safety Rule
↓
NO
↓

4 Is your produce for personal or on-farm consumption? **YES** → This product is **not covered** by the Produce Safety Rule
↓
NO
↓

5 Is your produce intended for commercial processing with a “kill step”? **YES** → This product is **eligible for an exemption** from the Produce Safety Rule, with appropriate documentation
↓
NO
↓

6 (a). Does your farm sell less than \$500,000 in annual food sales*?
and
(b). Is a majority of your food (by value) sold directly to a “qualified end-user”*?
YES to both → Your farm is **eligible for a qualified exemption** from the Produce Safety Rule. This means you must comply with some, but not all, requirements of the Produce Safety Rule.
NO to one or both → **You are covered by the Produce Safety Rule.** This means you are required to follow the Produce Safety Rule.

(*Important: see definitions)

1

Are you a produce farmer?

The Produce Safety Rule §112.3 regulates only produce, meaning fruits and vegetables. Food grains, such as barley, corn, oats, rice, rye, wheat, quinoa, and oilseeds, that are primarily grown to be processed into flour, baked foods, cereals, and oils, are not considered produce, and therefore they are not covered by the Produce Safety Rule.



§112.3

2

Does your farm have \$25,000 or less in annual produce sales?

Small farms that sell less than \$25,000 in average annual produce sales over the previous 3-year period, adjusted for inflation (see table) are not covered by the Produce Safety Rule.



§112.4(a)

Threshold value of gross annual produce sales to meet full exemption, adjusted for inflation

Full exemption

Baseline value for cut-offs (2011)	\$25,000
Value in 2016	\$26,956
Value in 2017	\$27,433

The value for years 2018 and beyond will be published online by the FDA when they become available at www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm. Click the drop-down menu for Produce Safety to see the threshold value of produce sales for a “not covered farm.”

3

Is your produce one of the crops identified as “rarely consumed raw”?

Produce considered “rarely consumed raw” by the FDA is not covered by the Produce Safety Rule. The FDA has determined the items in the following list are commonly cooked before being eaten, and therefore go through a “kill-step” that reduces the risk of microbial contamination. The FDA provides a complete list of produce items that are not covered by the rule due to this rarely consumed raw classification:

- Asparagus
- Beans: kidney, lima, navy, pinto, black, and great northern
- Beets (roots and tops)
- Cashews
- Chickpeas
- Cocoa beans
- Coffee beans
- Collards
- Cranberries
- Dates
- Dill (seeds and weed)
- Eggplants
- Figs
- Ginger
- Hazelnuts
- Horseradish
- Lentils
- Okra
- Peanuts
- Pecans
- Peppermint
- Potatoes
- Pumpkins
- Sour cherries
- Sugar beets
- Sweet corn
- Sweet potatoes
- Water chestnuts
- Winter squash



§112.2(a)(1)

4

Is your produce for personal or on-farm consumption?

Produce grown for personal or on-farm consumption is not covered by the Produce Safety Rule. Food safety laws are concerned with public health. If produce is not entering the general marketplace, its potential impact on public health is minimal.



§112.2(a)(2)

5

Is your produce intended for commercial processing with a “kill step”?

Produce that will be commercially processed in a way that reduces microbial contamination is exempt from the Produce Safety Rule, provided you maintain the



§112.2(b)

proper documentation. Examples of this type of processing include canning tomatoes, refining sugars and oils, and distilling beer and wine. Note that fresh-cut processing (such as slicing fresh fruit or shredding lettuce) does not satisfy this processing requirement, because there is no kill step involved in fresh-cut processing.

In order to claim this exemption for processed foods, growers need to keep documentation that the produce is appropriately processed. This includes annual written assurances from your buyer (or a subsequent buyer in the distribution chain) validating that their processing methods adequately reduces pathogens. If this scenario applies to your business, be sure to review §112.2(b) for a complete set of recordkeeping requirements.



What if I grow many types of produce that are both covered and not covered by the Produce Safety Rule?

It may be easier from a management and efficiency perspective, and lower your cross-contamination risk, to treat all of your produce with the same production and handling practices.



§112.111

If that is not practical for your operation, the Produce Safety Rule has two requirements:

- i. Keep covered produce and produce that is not covered separated, except when placed in the same container for distribution (e.g. a CSA box).
- ii. Clean and sanitize any food contact surfaces (including gloves, tools, harvest bins, sorting tables, etc.) between uses for covered produce and produce that is not covered.

While crops on the FDA’s “rarely consumed raw” list are not covered under the Produce Safety Rule, keep in mind that sales from those products still count towards your total produce and food sales, which can change your exemption status.

At the time of publication of this guide, the FDA is delaying enforcement related to the requirement for farms to obtain written assurances from customers about processing practices (this delay in enforcement regarding written assurances applies across all FSMA rules). The reason for this delay is due to the complexity of various supply chain relationships and the resources required to meet the requirements as written; the FDA is considering additional rulemaking on this topic. See the FDA Enforcement Discretion for Certain FSMA Provisions document in the Templates and Resources section of this guide for more information.

6

Qualified exempt farms must meet both requirements (a) and (b).

Farms that gross between \$25,000 and \$500,000 in annual food sales (adjusted for inflation) and sell the majority of their products directly to consumers or to regional businesses may be eligible for a qualified exemption. Qualified exempt farms are subject to a substantially modified set of requirements, described later in this section.



§112.5

(a). Does your farm sell less than \$500,000 in annual food sales?

Food sales include not only produce, but also sale of all food products including dairy products, eggs, meat, animal/pet feed, food ingredients or additives, beverages including alcoholic beverages, live food animals, baked goods, canned foods, candy and snacks. See the FDA Food Drug and Cosmetic Act §201(f) for further detail.

The \$500,000 sales threshold is adjusted for inflation; see the following table.

Threshold value of gross annual food sales to meet qualified exemption, adjusted for inflation each year

	Qualified Exemption
Baseline value for cut-offs (2011)	\$500,000
Value in 2016	\$539,121
Value in 2017	\$548,654

The value for years 2018 and beyond will be published online by the FDA when they become available at www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm. Click the drop-down menu for Produce Safety to see the threshold value of food sales for a “Qualified Exemption.”

and

(b). Is a majority of the food (by value) sold directly to a “qualified end-user”?

A “qualified end-user” is either:

- **The consumer of the food** (not a business); or
- **A restaurant or retail food establishment** (including grocery stores, convenience stores, and farm-operated businesses selling food directly to consumers as their primary function) that is located in the same state or Indian reservation as, or within 275 miles from, the farm that produced the food.



Does a food hub count as a qualified end-user?

It depends on the business structure of the specific food hub, and whether it meets the FDA definition of a retail food establishment. It matters who owns the produce along the supply chain and what type of customers the food hub sells to (individual consumers versus other businesses).

Each food hub should be considered on a case-by-case basis. You can contact the WSDA Produce Safety Program at producesafety@agr.wa.gov for assistance determining whether your food hub can be considered a qualified-end user.

Modified Requirements for Qualified Exempt Farms

Qualified exempt farms must follow a modified (and reduced) set of requirements of the Produce Safety Rule, and are exempted from all other aspects.

Qualified exempt farms must:

1. Keep sales records and annually verify and document their qualified exempt eligibility status. You can find a Qualified Exemption Review Template from the Produce Safety Alliance in the Templates and Resources section of this guide.

This recordkeeping requirement went into effect January 2016.
2. Prominently label their products with the name and complete business address of the farm where the food was grown. If a food packaging label is required, the farm name and address must be printed on the label. If there is no packaging label (for example, selling loose produce items at a farmers market), the farm name and address must be displayed at the point of purchase, such as on a banner, sign, invoice, etc.

This labeling requirement goes into effect January 1, 2020.

Qualified exempt farms may transition out of this status in any given year if their average annual food sales exceed the \$500,000 threshold, or their sales channels shift away from a majority of qualified end-users. Once a farm loses its qualified exempt status, it is immediately responsible for being in compliance with the full set of requirements of the Produce Safety Rule.

The FDA retains the right to remove a farm’s qualified exempt status if it determines the farm poses a significant risk to public health, for example by being identified as the source of a foodborne illness outbreak. This is anticipated to be a rare occurrence.

What Does the Produce Safety Rule Include?

The Produce Safety Rule is made up of 18 subparts, labeled Subparts A through R. Each subpart covers a different topic or set of on-farm practices. The list below gives you a high level overview of the whole Produce Safety Rule, by subpart. If you have a question about a Produce Safety Rule requirement, this at-a-glance guide can help you identify where to locate the specific information you're looking for within the law. You can find the full text in the Produce Safety Rule reference section of this guide.

A – General Provisions

Subpart A focuses on the FDA definitions used throughout the Produce Safety Rule and establishes provisions for what produce is covered and not covered, including qualified exemption requirements.

B – General Requirements

Subpart B sets the public health precedent for farms to take appropriate measures to ensure their covered produce is safe for the public to eat. It also describes how farms can apply alternatives for implementation of the agricultural water requirements given adequate scientific data and documentation.

C – Personnel Qualifications and Training

Subpart C establishes mandatory training requirements for all personnel, visitors, and employees. Section 112.22(c) requires at least one person on every farm to take a FDA-approved food safety training course. Farms must keep training records.

D – Health and Hygiene

Subpart D defines basic hygiene practices including general cleanliness, working with animals, hand washing, glove and jewelry use, and the limitations on eating and smoking during covered activities. The subpart describes how to prevent ill or injured employees and visitors from contaminating produce.

E – Agricultural Water

Subpart E sets specific microbial quality criteria requirements for production water (e.g. irrigation) and post-harvest water (e.g. produce washing) based on tests for the indicator microorganism, generic *E. coli*. This subpart requires general maintenance and annual inspection of agricultural water sources. It also provides corrective actions for managing hazardous issues or water quality concerns.

F – Biological Soil Amendments of Animal Origin (BSAAO) and Human Waste

Subpart F focuses on regulating soil amendments with animal waste or animal byproducts including, but not limited to, raw manure, fish emulsions, bone meal, and table waste. The subpart establishes standards for when to apply BSAAO based on treatment types and how they are applied. Certain aspects of this subpart are on hold for further research and review.

G and H – [Reserved]

I – Domesticated and Wild Animals

Subpart I sets requirements for grazing animals, working animals, and wild animal intrusion. This subpart makes clear that nothing in the regulation authorizes the “taking” of threatened or endangered species as defined by the Endangered Species Act (16 U.S.C. 1531-1544).

J – [Reserved]

K – Growing, Harvesting, Packing, and Holding Activities

Subpart K spans several aspects of on-farm food safety production practices. It discusses measures farms must take immediately prior to (alternatively called “pre-harvest risk assessment”) and during harvest, and how to handle and pack produce, including what kind of food-packing material is allowable. This subpart describes how to manage the comingling of covered and excluded produce.

L – Equipment, Tools, Buildings, and Sanitation

Subpart L covers equipment and tool cleaning, sanitizing and maintenance requirements. Requirements are set for food contact surfaces and non-food contact surfaces such as tractors or forklifts. Building maintenance includes pest and domestic animal control, toilet and hand washing facility maintenance, and disposal of trash and sewage.

M – Sprouts

Subpart M outlines specific requirements for sprouts, as they are considered an especially high-risk food. Sprouts have different compliance timelines and testing requirements that go beyond the scope of this guide. Sprout growers should consult the Sprout Safety Alliance (SSA) at www.ifsh.iit.edu/ssa for more guidance and training information.

N – Analytical Methods

Subpart N determines which testing methods the FDA allows for agricultural water, and which methods the FDA approves for the environmental testing for sprouts.

O – Records

Subpart O outlines general recordkeeping requirements for what details are required, how long records must be retained, what requirements apply for making records available, and so on.

P – Variances

Subpart P establishes that a state, federally recognized tribe, or foreign country may request a variance from the Produce Safety Rule if their local growing conditions justify an exemption without compromising public health risk. It describes permissible types of variances and how the petition process works.

Q – Compliance and Enforcement

Subpart Q sets general criteria for what it would mean to fail compliance under the Produce Safety Rule. The FDA commits to coordinating education and enforcement activities with state, territorial, tribal, and local officials.

R – Withdrawal of Qualified Exemption

Subpart R describes the conditions under which the FDA can withdraw a qualified exemption from a farm. The Produce Safety Rule requires the FDA to follow formal protocols for revoking that status and procedures for notifying businesses. The subpart also sets an appeal and reinstatement process for businesses.

Recordkeeping Requirements of the Produce Safety Rule

Recordkeeping is an important element in any food safety program, because records help verify what has happened. Records show inspectors that you are following your produce safety program outside of their brief visit.

What Records are Required?

All farms, even those exempt or not covered by the rule, must keep sales records in order to document their coverage or qualified exempt status.

A few specific records are required for farms fully covered by the Produce Safety Rule. For example, farms must conduct and document employee training. Farms must also document how and when they clean and sanitize equipment used for harvesting, packing, and holding activities.

The Templates and Resources section of this guide includes sample recordkeeping templates. Templates marked with a [•] symbol in the reference table indicate records that are required, if applicable. If a farm does not conduct an activity which requires a record, the record keeping requirement does not apply to that farm. For example, if a farm does not use treated soil amendments on their covered produce, then they do not have to keep treatment records.

In some cases, the Produce Safety Rule does not explicitly require a record for required activities. For example, farmers must monitor for and take measures to exclude pests from buildings used for activities covered by the rule. While pest control is required, there is no explicit requirement to record when and how a farmer responds to pest intrusions. However, you may find it useful to record your monitoring and actions as a way to validate your food safety practices. Existing GAP/GHP audit templates, in this case the Pest/Rodent Control Log, could be a useful guide in that circumstance. In the Templates and Resources section of this guide, we have marked GAP/GHP templates with a [o] symbol in the reference table to indicate that they are relevant to the Produce Safety Rule, even if they are not explicitly required.

Records Must Contain Certain Information

Subpart O contains general requirements for what to include in records and how to maintain them. Unless otherwise stated, all records must include, as applicable:

- The name and location of the farm
- The date and time of the activity being documented
- A description of the produce (e.g. the produce name, specific variety, brand name, or lot number)
- The location of the growing area or other area (e.g. field number, packing shed)
- Actual values and observations taken during monitoring process (e.g. temperature of compost, water pH)

In addition, records should be accurate, legible, indelible (permanent), and created at the time of the activity. In some circumstances the records should be dated and signed or initialed by the person who performed the activity.

If you want to look up the specific recordkeeping requirements, those can be found by topic in the last section of each subpart of the rule. Only the following subparts have recordkeeping requirements:

- ❖ Subpart A - General Provisions
- ❖ Subpart B - General Requirements
- ❖ Subpart C - Personnel Qualifications and Training
- ❖ Subpart E - Agricultural Water
- ❖ Subpart F - Biological Soil Amendments of Animal Origin and Human Waste
- ❖ Subpart L - Equipment, Tools, Buildings, and Sanitation
- ❖ Subpart M - Sprouts (Note: Sprouts are not addressed in this guide)

How and How Long to Keep a Record

In general, records and their supporting documents should be kept for at least two years after the record date. The main exception to this is the sales records needed to verify a farm's full exclusion or qualified exemption, which are based on a three-year rolling average, so records should be kept for the three previous years.

Records may come in many forms, such as a weekly log of a completed activity like cleaning a packing shed; a diagram of your fields with dates for which soil amendments were applied to each; a record of employee training with dates and names of trained employees; or water testing results from a lab. It may be that a farm management tool you already use can also serve as a record. For example, if work tasks are assigned and tracked on a whiteboard, a photo taken with your smartphone at the end of the day could serve as a record if the photo is saved (and it contains all necessary information). You may use computer programs or mobile apps to track when they apply soil amendments to their fields; if you can pull a report from these programs or apps, that could serve as a record as well.

The point is that you can think beyond the paper form and keep records in a way that works for you. In this same vein, think about layering the uses of your records so that a record kept for one purpose might also serve as a record for your food safety program. For example, if your farm is certified organic, the lab results from your water testing needed for that certification can double as your Produce Safety Rule record. Just be sure that the single record contains all the information required by both programs.



If you track work activities on a whiteboard, you can take a photo of the board to make a record of those activities. Make sure all information required for the record is present, that the photo is dated (most phones and cameras do this automatically), and that the photo is saved somewhere where you can access it again when needed.

Compliance and Enforcement

Role of the WSDA Produce Safety Program

In partnership with the FDA, WSDA is developing and implementing a Produce Safety Program for Washington State. The goal of the program is to help farmers understand and comply with the Produce Safety Rule, and implement a consistent and uniform inspection protocol. The WSDA Produce Safety Program will conduct the Produce Safety Rule inspections, as authorized under RCW 15.135.

At the time of publication, the inspection protocol is still under development. While general compliance dates for covered farms that sell over \$500,000 in annual produce sales are in effect, the FDA and WSDA are postponing routine inspections until 2019. That decision was made to ensure farmers have the training and information they need, and to also provide states time to establish strong produce safety programs.

The WSDA Produce Safety Program makes available trainings and technical assistance, and develops guidance resources to help farms understand the Produce Safety Rule and prepare for produce inspections, including:

- Produce Safety Alliance (PSA) Grower Trainings.** At the time of publication, the PSA Grower Training is the only training that satisfies the Produce Safety Rule educational requirement. See the Templates and Resources section of this guide for a Produce Safety Alliance fact sheet with more information about the resources and services the PSA provides.



- On-Farm Readiness Reviews (OFRR).** These are free, educational, voluntary, and non-regulatory farm assessments conducted by WSDA inspectors and other subject matter experts to help you identify whether your on-farm practices meet the Produce Safety Rule. Farms of all sizes are encouraged to make use of this service. See the Templates and Resources section for a WSDA publication outlining OFRR registration information.



Business size*	General compliance date	Proposed water compliance date
Large businesses (>\$500K)	January 26, 2018	January 26, 2022
Small businesses (\$250K - \$500K)	January 28, 2019	January 26, 2023
Very small businesses (<\$250K)	January 27, 2020	January 26, 2024

* (Based on annual produce sales in rolling three-year average)

Compliance Timelines

Compliance timelines are staggered based on farm size. Small and very small businesses have extended compliance timelines to provide them additional time to implement their food safety programs, understanding that small businesses may have fewer resources to train employees, set up recordkeeping systems, or invest in new equipment.

Evolving Agricultural Water Standards

The compliance dates pertaining to agricultural water standards differ from the general compliance timeline. This is due in part to the requirement that farmers take multiple water samples over a period of time, and in part to on-going stakeholder concern that the agricultural water requirements, as written, are too complex to understand, interpret, and implement. The FDA issued a proposed extension in September 2017 to provide farms an additional two years to meet the water requirements. In the same year, the FDA announced that they are considering simplifying the agricultural water standards. The FDA is currently working on guidance, collecting more data, and coordinating with stakeholders on how to proceed.

Effectively, the proposed extension would set the date for compliance with the water standards at four years after a farm's general compliance date for all other aspects of the Produce Safety Rule. If finalized, farms must begin sampling by the proposed water compliance dates. For example, a covered "small business" would need to start sampling surface water they use for irrigation no later than January 26, 2023 (see table).

While the agricultural water section is being assessed by the FDA, you should continue with your existing water quality and monitoring practices, particularly if required by your buyers or audit program. Farms that have never tested their water before should consider conducting some initial samples. This applies to farms who are likely to be covered by the Produce Safety Rule, but it is also a recommended best practice for farms that are not covered.

Produce Inspections

The first WSDA produce safety inspections are anticipated for spring 2019, beginning with larger farms. The inspection protocol is still under development at the time of writing and so the inspection evaluation criteria, citation measures, inspection frequency, and enforcement protocol have not yet been established.

What can be predicted is that, similar to GAP/GHP audits, WSDA inspections will occur as close as possible to harvest so that inspectors can see handling practices in action.

Through a cooperative agreement and funding from the FDA, there is no cost to farmers for produce inspections of covered farms. WSDA is authorized under state law to develop a voluntary, fee-based inspection program for excluded or qualified exempt farms that wish to be inspected for compliance with the Produce Safety Rule. This voluntary inspection program will be developed if there is a demand from farms for that service.

Keep in mind that WSDA Produce Safety Program inspectors and WSDA GAP/GHP auditors work in separate programs. If both apply to your situation, the personnel visiting your farm will be different.

Visit agr.wa.gov/producesafety or contact the WSDA Produce Safety Program at producesafety@agr.wa.gov for any questions regarding education and enforcement of the Produce Safety Rule.

The GAP/GHP Audit

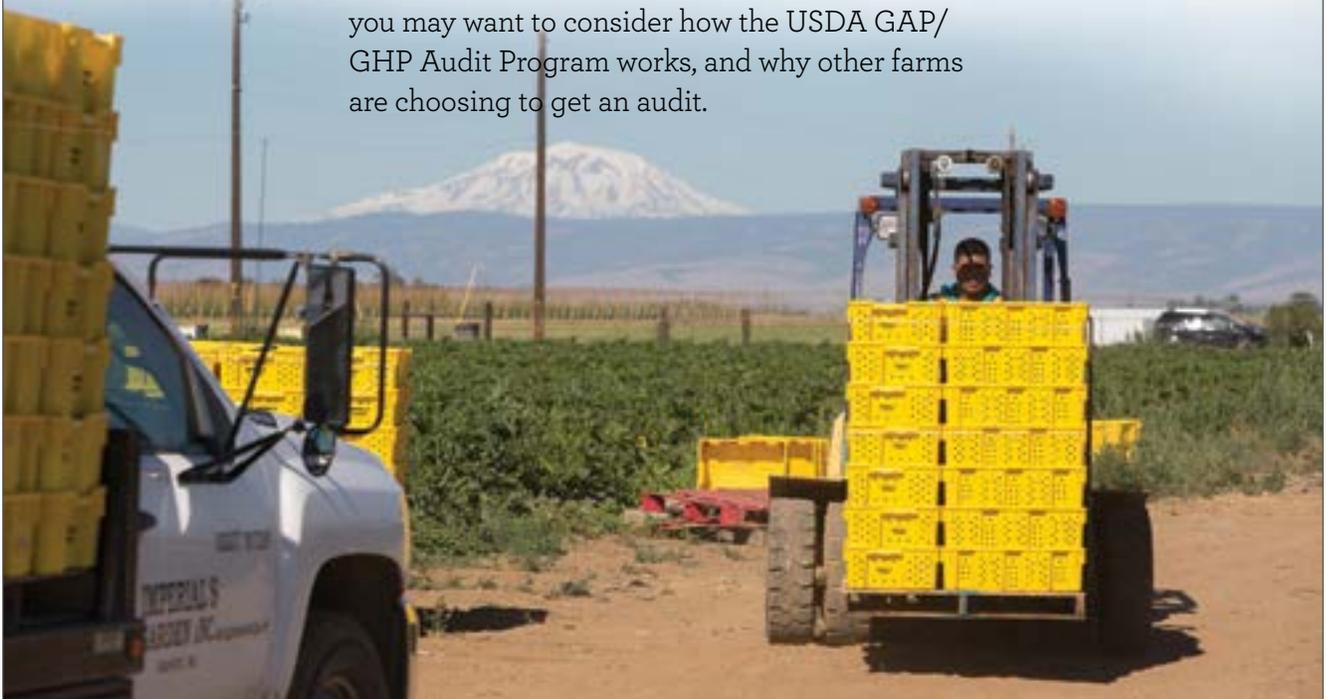


What is GAP/GHP and Why is it Valuable for a Farm?

The USDA GAP/GHP Audit Program is a voluntary food safety audit and certification program for fruits and vegetables that evaluates farm practices against standards set by the USDA to minimize risks of microbial contamination. It covers production, packing, handling, and storage. A GAP/GHP audit is valuable in a variety of marketplaces to assure buyers that risks have been assessed and effective mitigation strategies have been identified, articulated, trained to, and documented. Many farmers are interested in implementing GAP/GHP practices, with or without an audit step, in order to decrease the risk of a food safety problem and protect themselves and their customers from contaminated product.

As you make the decision about whether you need a third-party food safety audit, or whether you simply want to use this guide to help you review and improve your food safety practices, you may want to consider how the USDA GAP/GHP Audit Program works, and why other farms are choosing to get an audit.

This chapter provides information about the USDA Good Agricultural Practices and Good Handling Practices Audit Program and the audit process.



Different GAP/GHP Audits

There are several different types of GAP audit programs. They vary in their level of complexity, and by which a public entity or private certifier develops and implements the audit. It is very important that you have a discussion with your buyer(s) about their specific food safety requirements, so that you can prepare to meet their expectations, whether that is a specific audit or some other expectation.

The USDA is the main public entity that offers a range of GAP certification programs for various business types and scales that are described in greater detail below. In addition, there are a number of private food safety certifiers that each offer their own GAP standards and audit services. Examples of private industry certification programs you may hear about include Global GAP, SQF, and Primus Labs.

To maintain a general standard of equivalency between different food safety auditing schemes, the Global Food Safety Initiative (GFSI) acts as a benchmarking organization that reviews adherence to internationally-recognized requirements. GFSI-approved food safety schemes are aligned in their high standards, though may differ in their approach. Many large buyers require that their suppliers pass a GFSI-benchmarked audit. Visit www.mygfsi.com for more information.

USDA GAP/GHP Audit Programs

The **USDA GAP/GHP** audit is the USDA's most basic audit program. It is the focus of this guide because, whether seeking an audit or simply wanting to improve on-farm food safety, implementing GAPs in accordance with the USDA GAP/GHP audit checklist is a good place to start for small to mid-sized diversified farms. In addition, the USDA audit tends to be more cost-effective compared to private certifiers.

Group GAP is a USDA audit program where several farms (such as a farmer co-op or food hub membership) are evaluated as a group. This requires the group of farmers to have a shared comprehensive food safety plan, and the ability to uphold food safety standards through internal accountability mechanisms. Farms in the group are audited by a trained internal lead and then by spot-checked by a USDA auditor. Group GAPs can reduce the cost of GAP certification for individual farms, but it requires significant on-going collaboration amongst the group of farms. You can find more information in the Group GAP fact sheet in the Templates and Resources section of this guide.

Harmonized GAP, sometimes called H-GAP, is a USDA audit program that is more comprehensive than the basic GAP program. Compared to the basic GAP/GHP audit, the H-GAP has enhanced documentation standards and audit scoring criteria, and has modified scoping and numbering systems. The H-GAP standards have been generally aligned with the FSMA Produce Safety Rule; in cases where the Produce Safety Rule was more stringent, the Harmonized GAP standard was raised to meet it; where the Harmonized GAP standard was more stringent than the Produce Safety Rule, the H-GAP standard was maintained. An H-GAP audit is not a substitute for a Produce Safety Rule inspection, but the H-GAP audit checklist can help farmers assess their compliance with the FSMA Produce Safety Rule. For additional information about the Harmonized GAP standard, see the two Harmonized GAP fact sheets in the Templates and Resources section of this guide. Visit www.ams.usda.gov/services/auditing/gap-ghp/harmonized to view and download the Harmonized GAP standard and Audit Checklist at Standard and Audit Checklist; these documents are also included in the thumb drives attached to this guide.

Harmonized GAP Plus+ is a new USDA Harmonized GAP standard that achieved a Technical Equivalency rating from the Global Food Safety Initiative in 2018. This means that producers utilizing this USDA audit also meet other U.S. and international regulatory and market requirements. USDA augmented the Harmonized GAP standard in order to meet the GFSI equivalency rating, so the two standards are generally similar but the Harmonized GAP Plus+ standard has several important differences: 1) A reorganization of the requirements, 2) Changes in the documentation requirements, and 3) Changes in the acceptance (passing) criteria.

1. In order to streamline the audit scopes, reduce duplication of questions between scopes, and simplify the requirement numbering system, USDA reorganized the standard requirements. The audit requirements remain largely the same as the H-GAP standard requirements, with a few additional requirements in order to comply with the GFSI benchmarking criteria. There are four scopes in the Harmonized GAP Plus+ standard: General Questions; Field Operations and Harvesting; Post-Harvest; and GAP/GHP Logo Use. Like the basic GAP standard, all audited farms must complete the General Questions scope, but the other scopes are optional.
2. A new feature of the Harmonized GAP Plus+ standard is that the documentation requirements are now written into the standards themselves, not only in the audit checklist and manual. The Harmonized GAP+ standard also introduces a new documentation category — risk assessment — although the requirement to conduct risk assessments is not new. How an auditee records their risk assessment is flexible, though a written document is a necessary component. The three documentation categories are written policy, record, and risk assessment. Some changes to the

documentation requirements were made to bring this standard in compliance with the FSMA Produce Safety Rule documentation requirements.

3. Finally, the Harmonized GAP Plus+ standard increases the number of audit questions which must be “assessed as compliant” (i.e. passed) in order to successfully complete the audit. All Produce Safety Rule-aligned requirements must be assessed as compliant. A new column in the Harmonized GAP Plus+ standard and audit checklist (also in the Harmonized GAP standard and checklist) titled “MAN” indicates which questions are mandatory for a successful audit.

In addition to the charge for WSDA auditor time and travel and USDA staff time, which apply to any of the USDA GAP/GHP audits, there is an additional \$250 certification fee for the Harmonized GAP Plus+ audit to cover the costs of the GFSI benchmarking process.

At the time of this guide’s publication, the USDA is creating an updated “Guidance Manual” (formerly called the Auditor Manual) for the Harmonized GAP Plus+ standard, which will be available to both auditors and growers.

For more information on the Harmonized GAP Plus+ audit standard, see the Harmonized GAP Plus+ Q & A document in the Templates and Resources section of this guide. Visit www.ams.usda.gov/services/auditing/gap-ghp/harmonized to view or download the complete Harmonized GAP Plus+ Standard and Audit Checklist, as well as a Summary of Changes to the USDA GAP Harmonized Standard Checklist (differentiating the H-GAP and H-GAP Plus+ standards). The Harmonized GAP Plus+ Standard and Audit Checklist are also included in the thumb drives attached to this guide.

How to Meet the Standard

There are a wide variety of ways to meet food safety standards and secure a GAP certification. The success or failure of an audit will depend on effective identification and mitigation of the food safety risks identified around and within your specific farm operation. This guide doesn't guarantee a successful audit. Examples of innovative ways to meet requirements are distributed throughout the manual and are intended to show the spectrum of food safety planning, from the smallest alteration to a wash table, up to large hydro-coolers. These are examples of solutions to food safety challenges and represent some of the many options. In any situation, the auditor will need to determine the appropriateness of the solution your farm is using and will evaluate that strategy based on how well it mitigates the risk of contamination.

There is no single correct way to implement GAPs. Every grower's process and the resultant food safety plan will be unique to that operation. The GAP planning process requires you to anticipate your unique contamination risks and develop strategies to prevent and manage that risk. The USDA GAP/GHP Audit Checklist, and this guide, will provide you with guidance about the way the auditor will evaluate and score your plan, bearing in mind that GAP is truly an individual plan that follows consistent principles to help minimize the risk of microbial contamination of your farm's product.

Just as there are countless variations from one farm to another, so there are a variety of management practices that are appropriate in one farm setting that may not be acceptable in another. Different accommodations are used in different settings. A solution that fits with the scale and production practice at one farm may be inappropriate in a different farm setting. But that doesn't mean either is disqualified for GAP certification. In fact, a successful GAP audit doesn't require earning 100% of the possible points. The audit is pass / fail based on earning a minimum of 80% of the points in each section. A perfect score is obtainable, but not necessary. If you choose not to implement measures to gain all the points on the checklist for each section, some minimal exposure to risk is assumed. The GAP standard does not seek to eliminate all risks, but instead verifies your plan to mitigate your farm's risk.

GAP/GHP Documentation Requirements

At first glance, the GAP audit guidance documents may seem daunting. However, many growers find as they work through the checklist, the practices required for a successful audit are already in place. What often is missing, however, are the required written food safety plan and record keeping systems. This is the documentation that the GAP audit requires to clearly show the grower has considered their unique risks for contamination, developed prevention plans, and thought through the corrective actions to take if and when a prevention strategy does not work as planned.

To achieve GAP certification, the farm must demonstrate through documentation a thorough risk assessment, a plan to address the risks identified, and records showing that the plan is being implemented in an on-going manner. For the purposes of an audit, no matter how good the practices are on the farm, if you didn't record it, it didn't happen.

All farms seeking a GAP/GHP audit must have a written food safety plan to serve as your guideline or mission statement for food safety practices on your farm. As part of that, you will need Standard Operating Procedures (SOPs), which are the policies and procedures you and your workers will follow to meet the goals of your food safety plan.

In reviewing the USDA GAP/GHP Audit Checklist as you prepare for an audit, you will see that each checklist item has a spot for a description, a point value, and a document abbreviation. This "Doc" column may be blank, or have a D, P, or R. The following describes the kinds of documentation you will be required to provide during the audit, using the abbreviations listed in the USDA GAP/GHP Audit Checklist:

D - Document

When the checklist shows "D" in the "Doc" column, it means that the farm must have some form of documentation relating to that item. Specifically, the auditor will look for a written SOP in your food safety plan that outlines your policy and the actions or activities you undertake to implement the policy. If applicable, the SOP should be backed up with some form of record that documents that actions outlined have been taken and the food safety plan is being implemented as it is written.

P - Policy

When a "P" appears in the "Doc" column of the checklist, the food safety plan must include a written standard operating procedure or policy that addresses the question specifically.

R - Record

An "R" in the "Doc" column means that the farm must keep records related to the issue, showing that actions have been completed.

Policies, Procedures, and Records

Written policies and procedures are a critical component of a food safety plan. However, there can be confusion about the difference between a policy, an SOP, and supporting records, and how they interact with each other. Using our favorite example (a tipped over port-a-potty), we describe the content and purpose of each type of document and provide sample language.

A **policy** is a statement or explanation of a farm's approach to achieving a particular food safety outcome. It is the "what and why" that explains a practice on the farm. A policy does not need to be lengthy but it should be relevant to actual circumstances on your farm. Make sure that your policies are precise about who or what situations they apply to. For example, policies should define specific expectations for employees or visitors, if they are different. If the policy is vague

about who it applies to, it may be interpreted that it applies to every person who enters the farm. A policy is usually backed up by a Standard Operating Procedure and may even be incorporated as part of the SOP.

Sample policy: *Sanitation facilities that have tipped over or are in any way unusable will be dealt with in a manner that minimizes the risk of contamination of the produce.*

Standard Operating Procedures (SOPs) are step-by-step instructions for doing specific activities that are part of farm operations. The procedure is the “how” of “how will I do (the policy)?” The instructions should be detailed enough to ensure the process is done in a consistent way each time, but not so detailed that it’s difficult to follow your own procedure. For example, rather than stating “Empty boxes will be marked with a red X” you can say “Empty boxes will be clearly marked” – regardless of the color pen you have handy. Typically, a farm’s SOPs, which cover a variety of activities, are gathered together in one place as part of the farm’s Food Safety Plan. SOPs should be updated as your processes change, new equipment is acquired, and so on.

❖ **Sample SOP:** *In the event of a sanitation unit spilling, or any other septic leakage occurring in or near production fields, the following clean up steps will be taken:*

- 1. A visual assessment will be conducted to determine the boundaries of the contaminated area. The contaminated area will be marked off with string or other marker.*
- 2. Signs in all appropriate languages will be posted at the perimeter of the contaminated area, prohibiting entry.*
- 3. People and animals will be kept out of the area until it is sufficiently decontaminated.*
- 4. Any solid waste on the surface will be collected and disposed of in a covered waste bin.*
- 5. Any affected produce will be immediately disposed of in a covered waste bin.*
- 6. Any affected structures will be hosed off and disinfected with a dilute bleach solution.*
- 7. The company that provides and services the sanitation unit will be notified. The company will replace the unit and clean up the immediate surrounding area.*
- 8. The spillage event and corrective actions will be written down in the Sanitation Unit Service Log.*

A **record** is a type of proof that you are following your SOPs. An auditor will read through your SOPs, then review records and observe on-farm activities to ensure that you are following the plans you have set for yourself.

❖ **Sample record:** *The Sanitation Unit Service Log.*

This record would likely track the regular maintenance (cleaning, restocking) done to the port-a-potty, in addition to documenting the steps taken when the spill occurred. In describing the corrective actions taken, the record may include a statement like “Followed the Sanitation Unit Spillage SOP (Company X replaced unit and cleaned immediate area including solid waste. Barrier and signage put around affected area until decontaminated. No produce or structures affected.)”

Records come in many forms. A weekly log of a completed activity like cleaning a packing shed; a diagram of your fields with dates for which soil amendments were applied to each; a record of employee training with dates and names of trained employees; or water testing results from a lab, are all types of records.

It may be that a farm management tool you already use can also serve as a record. For example, if work tasks are assigned and tracked on a white board, a photo taken with your smart phone at the end of the day could serve as a record if the photo is saved in an organized way for later reference (and it contains all necessary



If you track work activities on a whiteboard, you can take a photo of the board to make a record of those activities. Make sure all information required for the record is present, that the photo is dated (most phones and cameras do this automatically), and that the photo is saved somewhere where you can access it again when needed.

information). Some farmers use computer programs or mobile apps to track plantings or when they apply soil amendments to their fields. If you can pull a report from these programs or apps, that could serve as a record as well.

The point is that you can think beyond simply creating a new paper form and keep records in a way that works for you. In this same vein, think about layering the uses of your records so that a record kept for one purpose might also serve as a record for your food safety program. For example, if your farm is certified organic, the lab results from your water tests needed for that certification can double as your GAP record. Just be sure that the single record contains all the information required by both programs.

This excerpt of the GAP/ GHP Audit Checklist shows how the information is organized.

USDA Good Agricultural Practices and Good Handling Practices
Audit Verification Checklist

General Questions
Implementation of a Food Safety Program

Questions	Points	Yes	NO	N/A	Doc
P-1 A documented food safety program that incorporates GAP and/or GHP has been implemented.					D
P-2 The operation has designated someone to implement and oversee an established food safety program. Name _____					D

Traceability

It's important to write policies and procedures that you will actually follow and that are reasonable and responsive to actual risks you have identified on your farm. If you say you are going to do something, but then don't do it — or don't keep records that document you are doing it — you may lose points on your GAP audit.



There is no one boilerplate for a food safety plan. During an audit, the farm food safety plan and its standard operating procedures will be reviewed carefully to make sure they accurately reflect the unique set of practices being used on the farm.

Watch for reminders and tips throughout this guide about what to include in your farm's SOPs related to each part of the audit.



All farms requesting an audit of Part 2: Field Harvest and Field Packing Activities, must have a documented pre-harvest assessment (GAP/GHP Audit Checklist Question 2-1), written as a policy in their SOPs and supported by records that the assessment has been done as written. The assessment should include a review for evidence of domestic or wild animal crop damage or intrusion. If the pre-harvest assessment (or other field review) indicates there is a risk from excessive rabbit intrusions into a row crop field, and that a decoy coyote is an

appropriate strategy to minimize those intrusions, the placement of the decoy and monitoring for ongoing pest intrusions is recorded in a written log (R). The log will be reviewed as part of an audit under Part 1: Farm Review (GAP/GHP Audit Checklist Questions 1-12 and 1-13). Records should show, perhaps in the form of crop maintenance reports or field review logs, that the staff is monitoring for the effectiveness of the strategy, making adjustments based on their observations, and taking corrective action whenever they find pest contamination in spite of the practice. So, for example, farm workers are trained to make sure the coyote is placed (and not, for instance, blown over in a storm), and if they find rabbit droppings on the crops, they are trained to place flags at the site of the problem. All harvest crews are trained not to harvest products within a five-foot diameter of a flag. Ideally, this staff training is also logged so that the auditor can see that it is occurring.





Review the audit checklist carefully as you prepare for your audit. Pay particular attention to the boxes that are shaded out. Where N/A is shaded, the question has to be answered Yes or NO.

The GAP/GHP Audit

During a GAP/GHP audit, the auditor will use the USDA GAP/GHP checklist to assess your farm. The auditor will use a review of your standard operating procedures, visual observations, and an interview process to determine the answer for each check-list question. The food safety plan and SOPs you write to meet the GAP standards will form the basis for the GAP/GHP audit, and will allow the GAP auditor to verify that your plan complies with the standards. Accompanying documents and records are required in order to show that your farm is following and documenting implementation of the plan.

Your Food Safety Plan

In order to pass an audit, you must have a food safety plan in place, and a written designation of the person assigned to oversee and implement the plan. Various items on the checklist require documents, records or policies, and those will be checked during the audit. Any missing documents, records or policies will result in lost points.

In order for your audit to go smoothly, and to clearly convey that you meet the GAP standards, make sure your plan:

- Includes a map that accurately represents the farm, shows the number of acres, and includes a legal description.
- Identifies any secondary crop production areas located at other parcels.
- Accurately reflects your farm's operations and practices, including training practices.

- Can be implemented as written at your farm.
- Includes SOPs that define policies and procedures to be followed on your farm.
- Designates an individual to oversee the food safety program.

The operator must also:

- Determine what to document and record, based on the checklist.
- Keep records current.
- Document any corrective actions taken to show adherence to the written plan.
- These documents will all be reviewed by the auditor during a GAP/GHP audit.

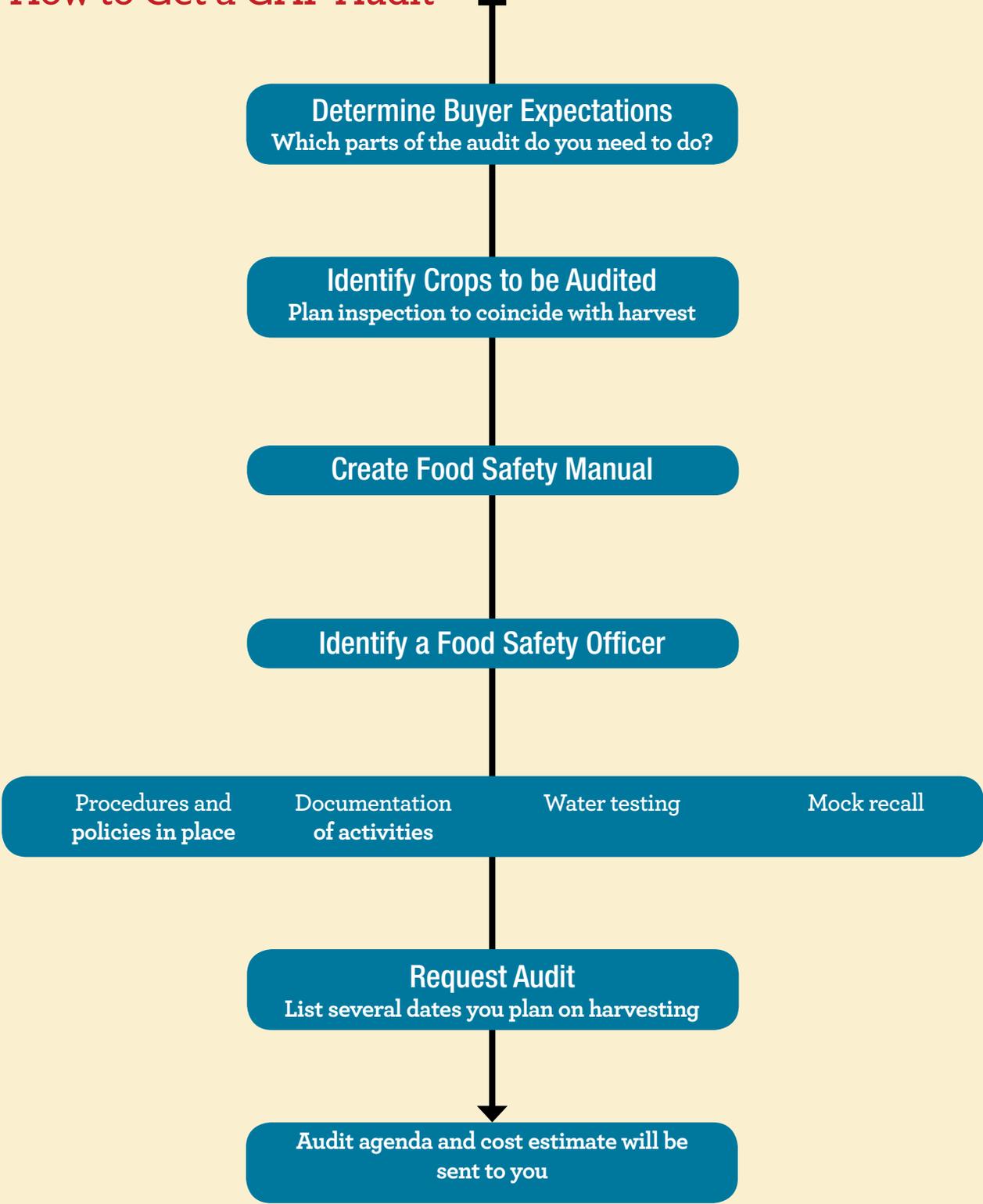


Multiple crops can be covered in a single audit. For operators of diversified farms there have been concerns that every one of their crops would have to be individually audited in order to meet the certification standard. In fact, USDA allows these farms to cover all their crops under the same audit as long as:

- All crops are declared during the initial audit.
- The food safety plan addresses the risks associated with each of the crops.
- The auditor has the opportunity to observe the growing and harvesting practices.

If some of your crops are not being harvested during the initial audit period, the auditor may need to conduct an unannounced audit to observe the harvest of additional crops, if they have different harvest practices. The auditor will call ahead to confirm it's a harvest day prior to arriving on-site to conduct an unannounced visit.

How to Get a GAP Audit



Source: Good Agricultural Practices for Small Diversified Farms: Tips and Strategies to Reduce Risk and Pass an Audit, Ben Chapman, Ph.D., Audrey Kreske, Ph.D., and Roland McReynolds, Esq. Published by Carolina Farm Stewardship Association in partnership with North Carolina State University, www.carolinafarmstewards.org. Reprinted with permission.

Requesting an Audit

GAP/GHP audits are only performed at the request of the applicant. For Washington State fruit and vegetable producers, GAP/GHP audits are conducted by staff from the WSDA Fruit and Vegetable Inspection Program. Remember, though WSDA conducts both GAP/GHP audits and Produce Safety Rule inspections, they are separate programs. WSDA GAP auditors do not perform Produce Safety Rule inspections, and vice versa.

To request an audit, call the WSDA GAP/GHP Program office nearest you to schedule a time for the auditor to visit your farm.

- Yakima District Office: (509) 249-6900
- Wenatchee District Office: (509) 662-6161

Audits are conducted during the growing / harvesting / packing season of the applicable products. You should request an audit well before the end of the season to allow time for scheduling and ensure auditor availability.

Participation in this program requires a signed Agreement for Participation in the GAP/GHP Audit Verification Program, and a completed Request for Audit Services form. Both documents can be given to the auditor at the time of the audit.



During a GAP/GHP audit, the auditor will review your food safety plan and SOPs with you or your designated food safety representative.

When you request an audit, you will need to provide the following information:

- Type of audit requested
- Name
- Phone number
- Business information such as name and address you wish to be listed on the USDA Certificate site
- Address of where to meet to perform the audit
- Crops you'd like to be included in the audit (e.g. beets, cabbage, carrots, kale, potatoes)
- First choice for audit date
- Second choice for audit date
- Please confirm that you will be harvesting that day: Y | N
- For the USDA GAP and GHP Audit, please indicate which scopes (sections) of the audit are you requesting:
 - General Questions (Necessary for any GAP/GHP audit)
 - Part 1 – Farm Review (Necessary for any GAP/GHP audit)
 - Part 2 – Field Harvest and Field Packing (This part is usually done in a GAP/GHP audit)
 - Part 3 – House Packing Facility
 - Part 4 – Storage and Transportation
 - Part 5 (No longer part of audits)
 - Part 6 – Wholesale Distribution/Terminal Markets
 - Part 7 – Preventive Food Security Procedures

Note: The General Questions section is required for any USDA GAP/GHP Audit. Parts 1 and 2 (Farm Review and Field Harvest and Field Packing) are done in most USDA GAP audits, as they cover scenarios and harvest activities that occur on all fruit and vegetable farms. Parts 3, 4, 6, and 7 are available for farms or businesses that engage in those activities. Please confirm with your buyers what parts they require so you can obtain the audit that meets their standards.



Consider organizing your Food Safety Plan, its SOPs and your supporting documents in the same order as the USDA GAP/GHP Audit Checklist. Remember that records do not necessarily need to be paper forms with handwritten information — records can also be computer files, information stored on mobile apps, saved digital photos, and so on (so long as they contain all the required information). Organizing your documents, no matter what format they are in, in the same order as the checklist, can help the audit go more smoothly and quickly, and save you money, since audits are charged by the hour.

You will also be asked if this is your first audit. If so, you may also be asked the following questions to help you confirm that you are prepared for the audit:

- Have you had an audit done before?
 Y | N
- Have you reviewed the USDA Good Agricultural Practices / Good Handling Practices Audit Verification Checklist? Y | N
- Do you have a written food safety plan with SOPs? (Required for the audit) Y | N
- Do you have policies, documents and records required in the audit checklist? (Your policies, documents and records will need to be readily available during the audit.) Y | N

During the Audit

- Opening meeting — before beginning the audit, the auditor will review the information provided on your Request for Audit Services and explain the audit process to all participants. He or she will remind you that the audit is voluntary, confirm the sections of the audit you would like them to perform, explain costs, and describe how the audit works. During this meeting, the farm representative will fill out or give to the auditor the Agreement to Participate. This form can be downloaded ahead of time. First-time auditees will need to fill out a new account form for billing purposes. At the opening meeting, you will be provided with a copy of the audit checklist so you can follow along.
- Conducting the audit — this will include:
 - Thorough review of the Food Safety Plan, including standard operating procedures, policies, documents and records.
 - Observation of processes and operation to determine adherence to your food safety plan.
 - Employee interviews.
- Auditor time to review and prepare for closing meeting — after completion of the audit itself, the auditor will take time to review findings and make clear notes to finalize the audit.
- Closing meeting — the auditor will review the audit's findings with the grower and answer questions and explain observations. You will also be informed about how to provide feedback to USDA about the quality of service during the audit.



Automatic Failure

There are several ways for the audit to be deemed an automatic failure while the audit is being conducted. An automatic fail would mean the audit stops at that point, and cannot be rescheduled until the problem has been corrected. These include:

- ✦ The farm does not have a written food safety plan in place.
- ✦ There is no one designated to oversee and implement the plan.
- ✦ An auditor finds evidence of falsified records.
- ✦ Employees are not following hygienic practices that could jeopardize the safety of the product.
- ✦ Excessive signs of insects or rodents.
- ✦ Any other situation that creates an immediate food safety risk.

What happens after an automatic fail?

- ✦ The auditor will stop the audit, explain the policy, and provide the rationale for the stop.
- ✦ If the auditor feels there is an immediate food safety risk, the auditor will notify USDA. USDA will determine if further action needs to be taken.
- ✦ The farm must complete a corrective action document for the non-conformity prior to re-scheduling the audit.

Do I have to comply 100% with all the areas of the GAP audit in order to qualify for certification?

No, you do not need a 100% score. In order to have a successful GAP audit and be certified, you need 80% of the total possible points within each section of the checklist against which your farm is being audited. Each audit must start with the General Questions section of the audit checklist and you must pass this section before moving onto any other requested section of the audit.



After an Audit

If the audit is successful:

- The audit will be sent to USDA for approval.
- Once approved the auditee will receive a copy of the completed audit and USDA and WSDA certificates.
- The audit will be posted on the USDA web site. (Only positive information is posted on the website. No negative information is posted.)
- Unannounced visits will be done as required.
- The audit or “GAP certification” is good for one year.

If an audit fails:

- The auditor will issue a corrective action report that the auditee must complete.
- The auditee can re-submit for the audit to be redone.

A variety of resources are available to help you prepare for GAP implementation and audit, many of which are referenced in this manual. This is not intended to be a comprehensive guide, but to capture the many different kinds of questions producers and advocates submitted as part of our three-year Bridging the GAPs project. The stories, pictures and inquiries recorded create a snapshot of the kinds of issues small diversified farms confront, and share some low-cost ways to address those challenges.

Some farms keep their logs and other records in binders for later auditor review. Others may post them on walls or in clipboards. You may wish to have individual logs and clipboards at their appropriate locations around the farm, and then transfer the completed log sheets and other records into binders



Costs of an Audit

The GAP audit is not free. Farms and food businesses must pay the costs of the GAP audit. The cost of the audit includes the auditor's travel time to and from the farm or food business, time spent on-site, and any preparation time needed to perform the audit; plus a reimbursement for mileage. At the time of publication the rate for WSDA's audit services was \$108 per hour per auditor. The mileage rate from the auditor's work station to and from the audit site is based on the federal mileage rate, \$0.545 per mile as of publication. Effective October 2018, there is an additional charge from the USDA to cover costs incurred by the federal agency, for reviewing, filing, and posting audit results, and covering administrative costs for the audit program.



How can I estimate the cost of the audit?

Generally you should plan for the audit itself to take between two and seven hours. The length of time needed will vary depending on the size, scope, and type of audit requested. A small owner-operated farm growing one crop might take only a couple of hours, but a large diversified farm would take significantly longer. The distance an auditor is required to travel will impact the cost as well, however that is more easily projected than the length of time an auditor would need to spend on-site in order to complete the audit.



If you know a neighboring farm is scheduling an audit, you can coordinate with the grower to request that your audits be conducted on the same or subsequent days. The ability to conform to proposed schedules like this will depend on each farm's variety of crops, seasons, harvest schedules, and other variables.

Auditors will attempt to schedule multiple audits in a single region when possible, so travel costs can be shared across several farms.

For many farms, the cost of the audit is less of a concern than the cost of staff time to prepare for the audit – from writing a food safety plan and SOPs to developing and maintaining documentation systems. This cost may be challenging to estimate and is specific to each farm. Most growers start planning for a first-time audit during the winter of the preceding year, while the fields are less busy. This guide and other resources aim to help you prepare for the audit, with a goal of reducing your time researching the standards and document requirements.

General Questions

Implementation of a Food Safety Plan

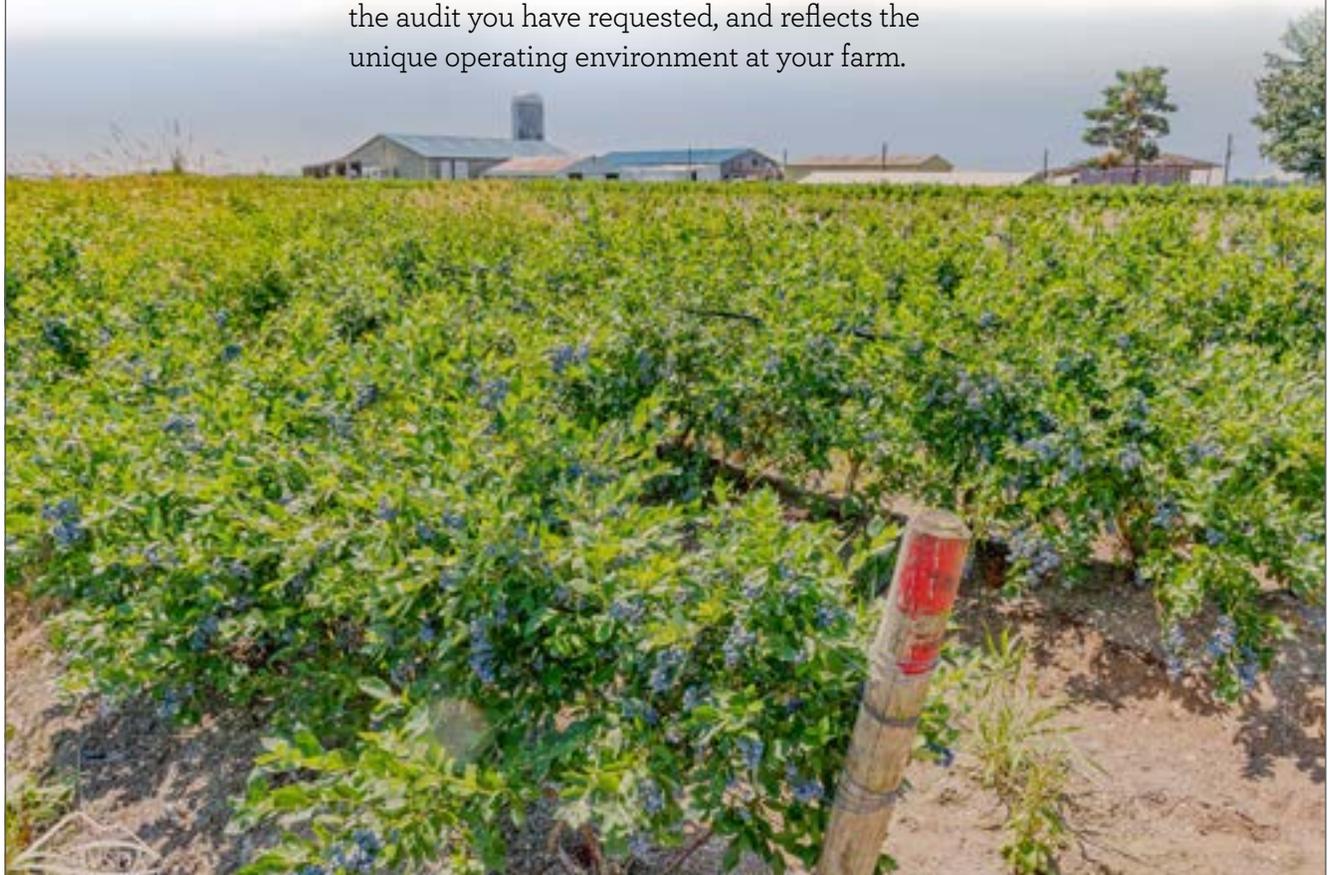


QUESTIONS
P-1 AND P-2

General Questions are always required as part of a GAP/GHP audit, regardless of the selected scope of the audit. A successful audit is one in which the farm being audited receives at least 80% of the points possible within each section, so getting 80% of this section is necessary before moving on to the following portions of your audit.

An audit begins with an on-site review of your written food safety plan to determine whether it meets the GAP/GHP food safety standards. The written food safety plan must include standard operating procedures, and supporting documents and records for the audit checklist questions that require them. Together, these will show that you have developed a GAP/GHP program on your farm that covers all of the scopes, or sections, of the audit you have requested, and reflects the unique operating environment at your farm.

This section covers implementation of a food safety plan, traceability, and worker health and hygiene.



Your farm must have a specific person designated, (in writing), to be responsible for implementation and oversight of your food safety program. The auditor will want to speak with the designated food safety representative for the farm during the audit to determine that he or she is knowledgeable and aware of all aspects of the food safety program. It makes sense that this person is the one to meet with the auditor on audit day anyway.

The audit will not go forward unless these two standards are met.

Traceability and Mock Recall

You must provide evidence that your farm has a traceability plan in place, and that you have performed a successful mock recall of the product. A traceability and recall program is essential in case recall of an adulterated product is needed — whether as a result of microbial contamination, a physical contaminant, or even a product that is mislabeled.

Of course, establishing a system for identifying the source of a product will not prevent a contamination event. But it will allow you to reduce the spread of contamination from other products grown or handled in the same batch. Also, the information gathered during a traceback exercise may identify previously missed pathways for potential contamination, so that you can address them.

A traceability plan allows you to track your harvested product one step forward and one step back. That means you need to determine who you have sold it to (one step forward), and be able to determine from which production field it was harvested (one step back).



QUESTIONS G-1 AND G-2

An on-farm traceability plan will look different at each farm, but at a minimum, should:

- Capture enough information to track the product one step forward, and one step back.
- Record whether the product came from a single field or group of fields.
- Document product held in storage before packing.
- Record grower, production area, and year.
- Include the harvest date, or group of dates.
- Document any comingling of products after harvest.
- Use crop production records, farm maps, transportation bills, weight tickets, and storage records.

In a packing house, the traceability system should incorporate the following:

- Boxes packed for shipment should be identified so that the product can be traced back to the packing house.
- If the farm has several different packing facilities, the package labels must uniquely identify from which packing house the product was shipped.
- The containers must show the date of pack, which should also be linked to the farm's traceback lot numbering system.

You will need to establish a system that corresponds to your farm's production areas, harvest and packing practices, and shipping or invoice system. This information will allow you to identify any other product from the same lot that may also have been contaminated, and help you determine if, when, and how much of your product to recall.

Recall Plan

The traceability plan must include traceback and recall procedures, recall team roles with contact information, and contacts for product destinations. Ideally, the plan should have ready-to-use documents such as traceback/recall customer contact forms (stating who was called, date and time, and the purpose of the recall), crop history records, traceability logs, etc. These forms will be used to trace the origin of a product and account for all other products distributed from that same point of origin that falls under the recall scenario.

Mock Recall

If the audit is for Farm Review and/or Field Harvest *only*, and it's the *farm's first year requesting an audit*, then a mock recall will not be required. Otherwise, a mock recall is required for all audits. You will need to perform a mock recall every year thereafter and provide evidence that you have performed a mock recall within the 12 months prior to the audit.

The more detailed traceability information you track for your produce, the less product you may need to recall in case of a food safety concern with your produce. For instance, if you only know the harvest date, you would need to recall all product from that day's harvest. If you know the field, section, or smaller area, you would only need to recall the products that came out of that area, thus reducing loss of revenue from any incident.



A mock recall is a practice exercise to determine how well your traceability system would work in the event that you need to bring your product back from the marketplace. During a mock recall, the farm takes the steps to determine where the product was shipped and whether or not it's possible to return it to the origin or remove it from the marketing chain. When performing a mock recall, you will create a scenario of a problem with a delivered product. Then follow the traceability and recall plan,

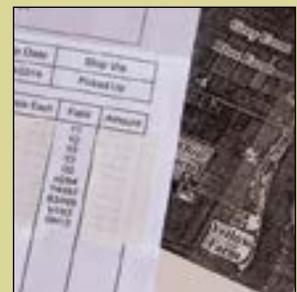
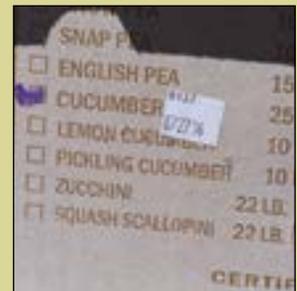


One Washington diversified farm identifies each field as a color, based on the color of buildings, gates or other identifiable features in that field. Within each field, they use numbered irrigation risers to identify field sections. So for the Blue field, the product can be traced to B1, B2, B3, etc. These numbers are kept with the product all the way through the harvest, washing, and packing process, and are then listed on the invoice when the product is delivered. That way, if a customer has a problem or receives complaints from their customers, they can contact the farm and provide the lot number from the invoice so the farm can recall product from that very specific harvest location.



Another farm gives each planting a unique number and enters it into a searchable spreadsheet. When the product in that planting is harvested, a paper identifying the planting number is kept with the produce through washing and packing. A sticker is generated from the computer

with the planting number and date and put on each delivery box. Customers can then call the farm with the planting number and date from the box if they identify a food safety concern. Then any other product from that lot can be recalled by checking the spreadsheet for other items in that lot and where they were sent.



tracking date and time of contact. The mock recall should reconcile as close to 100% of all affected product as possible. Make copies of all supporting materials to show how reconciliation occurred. **BE SURE TO WRITE OR STAMP THE PHRASE “MOCK RECALL” ACROSS ALL COPIES OF SUPPORTING MATERIALS.**

The auditor will review the written traceability and recall plan, along with your mock recall records and will evaluate how effective the plan is likely to be given the operating environment on the farm and the data and information you were able to gather from the lot numbers provided by the theoretical “buyer” in your mock recall.

Mock Recall Example

A customer notifies your farm that there is evidence of motor oil on 10 boxes of lettuce they received from you yesterday. In a mock recall you will trace the product back using the lot number provided by the buyer, to determine:

- Date of harvest — to help determine soil applications, machinery used in the field, and other specifics of the day’s work.
- Any further processing of the product, such as washing, or packing in order to identify potential contact with the contaminant.
- Potential sources for the oil — machinery, adjacent land use, packing area, transportation, storage.
- Whether other crops at your farm are impacted.
- Whether impacted product was sold to other buyers.
- Whether, when, and how to recall your product.

Recall Plan Checklist

- ✦ Create a Customer/Buyer Contact list. Be sure to update names, phone numbers, and emails annually or as needed.
 - Restaurants or buying club distributors: Two contacts in purchasing/shipping department.
 - Your own CSA: All members by email or website.
 - Farmer’s Market/Roadside stand: Website for customers to look for information, email sign up sheet, signs posted at the market or roadside stand.
- ✦ Create a Recall Contact list. This list should include names and phone numbers of media representatives, proper authorities (FDA, NCDA&CS, etc.), your insurance company and your legal counsel.
- ✦ Identify the problem (chemical, physical or microbial risks) and assess the health risks.
- ✦ Determine the products and lot numbers involved (only strawberries, or one day’s worth of all vegetables, etc.).
- ✦ Determine quantities involved (cases, boxes, etc.).
- ✦ Determine current inventory on the premises.
- ✦ Determine the amount of product in the marketplace.
- ✦ Identify the customers/buyers who have received the product.
- ✦ Collect pertinent documentation regarding the affected product.
 - Inputs and outputs of affected field associated with the lot number such as notes on flooding, wildlife activity, an ill employee, manure application, etc.
- ✦ You will need to determine:
 - The total amount of suspect product shipped/delivered.
 - The total amount of suspect product still in the buyer’s possession.
 - The total amount of suspect product the buyer has shipped.
 - Any product discarded.
- ✦ Upon completion of the mock recall, outline any issues in the recall plan and how you should change the recall plan to make it better. For example, taking longer than 2 hours and not being able to account for 100% of the product.

Source: Good Agricultural Practices for Small Diversified Farms: Tips and Strategies to Reduce Risk and Pass an Audit, Ben Chapman, Ph.D., Audrey Kreske, Ph.D., and Roland McReynolds, Esq. Published by Carolina Farm Stewardship Association in partnership with North Carolina State University, www.carolinafarmstewards.org. Reprinted with permission.

FSMA Food Safety Program Implementation

In their general approach to food safety, and in many specific requirements, GAP/GHP audit standards align with the FSMA Produce Safety Rule standards. However, there are several important differences between the two standards that you should be aware of.

Food Safety Plan and Traceability / Mock Recall

Unlike the GAP/GHP audit, the Produce Safety Rule does not require farms to write a food safety plan, or a traceability and mock recall plan. However, it is a recommended best practice for farms to develop a comprehensive food safety plan. Writing down a plan is an opportunity to take a step back and analyze your whole system for improvements, including work flow and processes, time management, tools and equipment, staff and training, and more. Writing a food safety plan can help you focus on the essential tasks of your operation and identify the most significant and efficient ways to improve food safety. The written plan documents how you've assessed the food safety risks on your farm and defines your plans to reduce those risks in an organized way.

Employee Training

The GAP/GHP audit approaches core food safety concerns by requiring a farm to have a written policy or procedure to address the risk areas. In comparison, the FSMA Produce Safety Rule emphasizes employee training, over written policies. For example, a GAP-audited farm may have a written handwashing policy that an auditor will review (and observe worker behavior for compliance). For the Produce Safety Rule, an inspector will review employee training records (and observe worker



§112.21, §112.22,
AND §112.30

behavior) to assess whether the handwashing requirements are being followed. Therefore, employee training, and recordkeeping of trainings, are critical components of compliance with the Produce Safety Rule. The regulation specifies that:

- All personnel must receive adequate training related to their specific duties, upon hiring and as needed thereafter (at least once annually)
- Training must be repeated if personnel are observed to not be in compliance with any food safety standards
- Trainings must be conducted in such a way that is easily understood by the people being trained – in the appropriate language, in an appropriate format (verbal, written, visual), and so on
- Workers must be trained in the principles of food safety, good health and personal hygiene, including how to recognize and respond to illness or injury
- You must keep records of employee trainings. See the Records Required by the FSMA Produce Safety Rule document, and the sample Worker Training Log in the Templates and Resources section of this guide

In addition to the training requirements that apply to all workers on your farm, the Produce Safety Rule also requires that at least one person from every farm (generally the designated food safety person) must complete an FDA-approved, standardized food safety training course. At the time of publication of this guide, the only training that meets FDA approval is the Produce Safety Alliance (PSA) Grower Training course. For more information on the PSA Grower Training course, including a listing of trainings being offered in Washington, please visit the Produce Safety Alliance website, producesafetyalliance.cornell.edu or see the PSA fact sheet in the Templates and Resources section of this guide.

Designated Food Safety Person

Similar to the GAP/GHP audit, the Produce Safety Rule requires each farm to designate a person who is responsible for operations to ensure compliance with the regulation. Because the Produce Safety Rule places such importance on employee training, this person may be responsible for supervising employee training related to the farm's food safety practices, overseeing the record-keeping, generally understanding and applying the appropriate food safety standards on the farm and conducting on-going risk assessments. Your food safety lead would be well-suited to respond to questions if your farm is inspected. For very small farms, your food safety lead might be the owner or farm manager; on larger operations, one staff member (or more) may be solely dedicated to food safety. Regardless of who is selected, your food safety person should have the training (see previous page) and experience necessary for the role.



§112.23

Worker Health and Hygiene

Employees and visitors can be effective vectors for transmission of microbial contamination from people to equipment or product, and then onto consumers. Operators must understand how to minimize risks, communicate those policies, and verify that the practices are followed.



QUESTIONS G-3 THROUGH G-15

Potable Water

Potable water must be available to all workers for drinking and hand-washing in order to decrease the risk of microbial contamination. The audit will require you to present documentation that shows the water available for these uses is potable. All municipal water is potable (by law), and records should be available to you through your municipality. Well water may be potable, but will need to be tested for potability by a qualified lab. Surface water should be assumed to be non-potable, but can be tested and treated in order to reach that standard.



QUESTION G-3

Worker and Visitor Training and Practice

All workers and visitors to the farm or farm stand must know and follow proper sanitation and hygiene practices.

Staff must be trained on proper sanitation and hygiene. Also documentation must be kept demonstrating that this policy is regularly reinforced and employees are evaluated to determine whether refreshers or follow-up training are required to ensure compliance. While on-site, the auditor will observe the hygiene and sanitation practices of employees and visitors as a measure of how well the food safety plan's worker health and hygiene policies are being implemented.



QUESTIONS G-4 THROUGH G-6



Below is the worker sanitation hygiene section of a Field Harvest Policy used by a diversified farm in the Yakima Valley. Each farm will have modifications that reflect their on-site practices, but this may be a useful starting place as it covers the key components of worker health and hygiene.

- Hands are to be washed and sanitized before commencing work and break, also after break and when work is completed.
- No children or infants are allowed in the fields.
- No animals are allowed.
- No food within 20 feet of the product field.
- No drugs, alcohol or tobacco use:
 - Use of any of these substances in the product field will be terminated immediately.
- No jewelry or clothing with little rocks is to be worn during harvest or general field work.
- Harvesters are not permitted to use cell phones unless:
 - Emergency.
 - Call foremen or managers to notify of possible food safety risk.

Handwashing

Of particular importance is the practice of handwashing prior to beginning work, or after breaks or bathroom use.

Employees returning to work after bathroom use must wash their hands thoroughly in order to minimize the risk of transmitting diseases harbored in human intestinal tracts. The farm should post signs to remind employees about handwashing, and those signs should be readily understandable, which may require accommodation for native languages other than English. The dominant native language spoken is the one in which the farm will be required to provide signs. Otherwise, for additional languages, graphic depictions of the



QUESTIONS G-7 AND G-8

instruction are sufficient. **If workers who handle produce are seen returning to work without washing their hands, and no work lead takes immediate corrective action, then the auditor will stop the audit and it will be considered an automatic unsatisfactory.**

The auditor will check that signage indicating handwashing requirements and locations of sanitation facilities are clearly posted, and that restrooms and field sanitation facilities are cleaned and properly maintained.

FSMA Handwashing Requirements



§112.32(b)

The Produce Safety Rule specifies that all workers must thoroughly wash their hands:

- ✦ Before starting work;
- ✦ Before putting on gloves;
- ✦ After using the toilet;
- ✦ Upon return to work after breaks;
- ✦ As soon as practical after touching animals or animal waste; and
- ✦ At any other time their hands may have become contaminated.

Other requirements, such as the need to use soap and potable water (hand sanitizer is not sufficient) during handwashing, and the required components of a handwashing station, generally align with the USDA GAP/GHP standard.



If my hand-wash station is outdoors, do I need to collect the water and discard it?

Water should not run freely on the ground as workers' shoes and boots can track bacteria into storage areas or any adjacent packing or production areas. A gravel drainage pad may work, as long as it has capacity to soak up the water without creating pooling. If you need to catch the waste water and dump it, the dumping area should be away from the production or packing area and not a source of contamination to the irrigation water. The waste water should be dumped in an area that workers and visitors do not walk through when coming to and from the field or packing area.

Handwashing stations may vary from rudimentary to full-service bathroom sinks, but they must all have the required basic components:

- Potable water;
- Single-use towels;
- Toilet paper;
- Hand soap; and
- Trash can with a lid.



Restrooms and Field Sanitation Units

Field sanitation units and restrooms should be maintained on a regular cleaning schedule and supplied with pump hand soap, single-use towels and potable water for handwashing. Good practices include making sure that handwashing water is prevented from pooling, which would create a risk for tracking contaminants into the production fields. Single-use towels should be discarded in a foot pedal-controlled, lidded trash bin.



Field sanitation units must include adequate handwashing facilities, whether they are in the field, or by the packing house.



QUESTIONS G-9
AND G-10

Designated Eating and Smoking Areas

Field harvest areas and packing houses must indicate with signage and through employee training which areas of the facility are designated for smoking and eating. Also, smoking and eating must be excluded from produce handling. For field harvest workers, this may mean that they are at the edges of fields or in the driveway areas away from the crops. Bottled water is an exception and is allowed in the work areas as long as it is in closed plastic containers away from the work area when not being used. The auditor will review work sites and will not award the points for this section if they see any other eating, drinking, smoking or the presence of food or tobacco in a food-handling area.



Designated areas for eating and drinking may be outside, by the side of the field, or in a room in a packing house or office.



QUESTION G-11

Pathogens often transmitted by food contaminated by infected employees

Pathogen	Symptoms
Hepatitis A virus	Fever, jaundice, vomiting
Salmonella species	Nausea, vomiting, diarrhea, fever
Shigella species	Diarrhea, fever, cramps
<i>E. coli</i> 0157:H7	Severe abdominal pain, watery diarrhea, vomiting
Staphylococcus aureus	Diarrhea, nausea, vomiting
Streptococcus pyogenes	Fever, Sore throat with fever

Reprinted with permission from Plant & Pest Advisory, Rutgers Cooperative Extension, New Jersey Agricultural Experiment Station

Worker Health

Sick workers are vectors for food-borne illness. Farm owners and operators should train staff to identify when they are sick, and either stay home or be temporarily assigned to jobs that do not put them in direct or indirect contact with produce. Managers and supervisors should be familiar with the symptoms of diarrheal disease and other infectious diseases. Other visible signs which should be cause for concern and action on the part of employee or supervisor are open lesions such as boils, sores or infected wounds, or any abnormal source of microbial contamination which could come in contact with food or food contact surfaces. The auditor may ask questions of the supervisor in order to determine their awareness and ability to recognize a sick or injured worker that should be reassigned away from direct or indirect contact with fresh produce.



QUESTIONS
G-12 THROUGH
G-14

The farm must also consider the possibility of fresh produce coming into contact with blood or other bodily fluids. The food safety plan should include a policy on how the produce will be handled and disposed of, and how the food contact surfaces will be cleaned and sanitized in the event of contact with bodily fluids.

If a worker has any kind of cut, lesion, or on-the-job injury he or she must get first aid before continuing to work. Even a small cut or scratch must be covered in order to prevent potential contamination of the product. Workers should be trained to report the injury, get first aid, and seek guidance on whether they are able to return to work with produce, or whether they need to be reassigned to a role that does not require direct or indirect contact with fresh produce.

Personnel Applying Pre-Harvest or Post-Harvest Materials

If the farm uses pre-harvest materials such as fertilizers or pesticides, or post-harvest materials such as waxes or fungicides, employees must have a working knowledge of their safe, appropriate use. The auditor will review training records, interview employees, or (in the case of restricted use materials) review the federal or state applicator licenses held by the staff using, or supervising the use of, the materials.



QUESTION G-15



QUESTIONS G-4 AND G-6

Visitors on the Farm

Your SOP should contain your policies and procedures for having visitors on the farm. These may be as simple or complex as needed for the type of farm you are running and how many and what types of visitors are expected.

Rules for visitors should include:

- ❖ Handwashing with soap and water is required before entering fields and after using the restrooms.
- ❖ No smoking or eating, except in designated areas.
- ❖ No pets allowed on the farm or in the fields.
- ❖ All u-pick buckets or harvest containers clean and sanitized before entering fields. (One farm in Washington provides sanitized buckets for picking, and visitors transfer the produce into their own containers to take home.)
- ❖ If you have other policies or procedures in your SOP, they must apply to everyone, (including visitors), unless otherwise noted.



Clearly marking areas which are public (to the right of the rope line) and areas which are reserved for the packing process is a good practice to ensure farm stand visitors do not create potential food safety problems.



During an audit, the auditor should be treated just like any other visitor, so if a visitor is required to use the handwashing station and sign in, then the auditor should be required to do the same.

Best practice examples for having visitors on the farm:

- ❖ Have all visitors enter through one farm entrance, where they must pass a sign with the rules posted, and have staff stationed there during potentially busy hours (such as u-pick hours or during events) to ensure that visitors follow the rules. You may also require visitors to sign in, and review a food safety rules list. Some farms have required visitors to watch a short video about food safety measures on the farm, including the visitor rules.
- ❖ In order to ensure that visitors are following the rules, farm staff should observe visitors throughout the day. If any appear to be breaking the rules, staff should remind them and require them to follow the posted and stated farm rules for food safety.
- ❖ Handwashing facilities and restrooms should be provided in an easily accessible location. Remember to consider the likely volume of use and be sure that portable toilets are serviced frequently and that water from outdoor handwashing facilities is adequately drained to keep water from pooling or creating a situation where foot traffic can spread any contaminants in the water.

Part 1: Farm Review



Farmer and auditor visit the field to review farming practices.

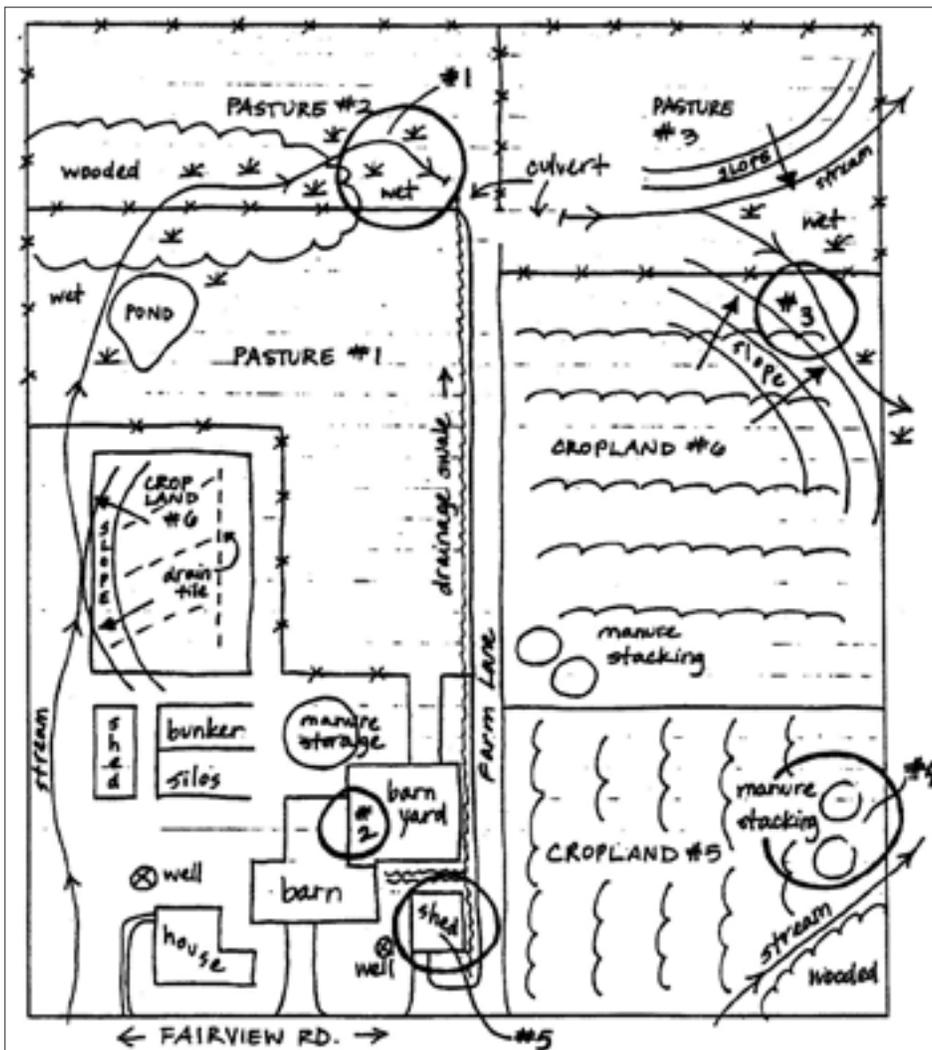
The Farm Review covers all of the activities and operations undertaken at the farm, and the auditor will personally review each production area. A passing score in General Questions is required in order for the Farm Review to proceed.

Farm Map

The best way to start planning for food safety is to map your farm. While a farm map is not listed as a requirement in the checklist, the auditor will ask to review a map or diagram of your farm. The topography of the farm and the various functions that make up the operation will influence the kinds of prevention practices you'll develop, implement, train employees on, and document. The map or diagram should indicate where potential contaminants like livestock and manure are relative to crops, and show streams and waterways, hills and valleys, fences and other natural barriers.

This section includes water usage, sewage treatment, animal/wildlife/livestock risks, manure and municipal biosolids, soils, traceability, and land use history.





A Farm Diagram Should Include:

- Cardinal directions; north, south, east, west
- Crop production fields
- Numbering system for fields (for use in your traceability system)
- Livestock barn locations and pens
- Animal waste storage/compost areas
- Buildings
- Greenhouses and high tunnels
- Hedgerows
- Fences
- Wells, ponds, and surface water sources such as canals
- Irrigation pumps
- Irrigation pipes (underground and above ground)
- Valves, gates, reservoirs, returns
- Septic systems
- Roads, driveways
- Topographic features
- Wetlands

It may also include the affects of:

- Heavy rainfall
- Flooding
- Wind
- Wildlife or domestic animal intrusion
- Adjacent land uses

Remember to note slopes and types of topography as shown in this map with arrows and notes. This will help you consider drainage and potential runoff issues. Numbered circles are a useful way to visually note the known or potential problems. You may also create a more detailed document that is coded to correspond with the numbered circles, and will describe your risk assessment and plans for preventing contamination.

A hand-drawn map can be as simple as this map of a small Washington farm, and still represent the important features present on your farm. Regardless of the way you choose to map your farm, make sure it is useful to you in predicting sources of potential contamination, and that an auditor would be able to read it easily and understand the ways the diagrammed items inform your food safety plan and SOPs.



Two examples of maps of the same farm: A satellite image, captured using maps.google.com (left); and a hand-drawn map illustrating important features of the



Water Usage



QUESTIONS 1-1
THROUGH 1-5

The GAP Farm Review checklist starts with water usage questions about all

water used on crops in the field. This includes water used for irrigation, as part of cooling and frost-control, and in chemical applications (e.g., fertilizers).

Water can be a carrier of many microorganisms, including pathogens that cause illness. Under certain circumstances even small amounts of contaminated water that has come in contact with fresh produce can result in food-borne illness. The risk of water with some level of microbial contamination damaging your saleable product will depend in part on the following:

- ❖ The crop — Does it have a large surface area or a rough texture that naturally holds onto water? Does it sit on the ground or underground, or is it grown well above the ground where drip irrigation water may not come in contact with it?
- ❖ The method of water delivery — Overhead irrigation comes in direct contact with edible portions of your crop, whereas drip irrigation largely keeps water away from the product by delivering the water directly onto soil.
- ❖ The timing of the application — How close to harvest is the water applied?

Your water risk assessment will include water testing, analysis of the findings, and careful consideration of the crops, irrigation and other water uses, to determine what practices or changes to your system may be necessary to mitigate risk of microbial contamination.



Generally, water that will be in contact with the edible portion of the crop should be better quality than water that is used where there is minimal contact with the edible portion.

Water Testing

Your planning starts with an assessment of your water quality to determine the kind and frequency of water testing needed, whether your water source is appropriate for pre-harvest application, and how it will affect your water usage practices. The assessment will include reviews of water quality testing conducted by your local irrigation district or municipality, or farm-specific tests ordered on your wells or surface water.

Generic *E. coli* is the standard test for irrigation water. *E. coli* is a common bacteria that lives in the lower intestines of animals (including humans) and is generally not harmful. It is frequently used as a marker for water contamination. Soil and water tests will often show some level of the presence of generic *E. coli*. Thresholds of acceptable levels of *E. coli* will vary, depending on each farm's unique practices.

Testing regimes vary based the water source and the way it is used in your farm. The following are general rules for municipal water, well water and surface water testing regimes.

Water source	Risk	Test	Documentation
City water/municipal	Low	Not generally required. You may want to test at your outflow however, especially if your on-site system is old, recently modified or potentially compromised.	A copy of the water quality report from the supplying municipality is sufficient.
Well water and springs	Medium	Annual test for generic <i>E. coli</i> for irrigation. (For produce wash water, which must be potable and have no presence of fecal <i>E. coli</i> , you would need to test specifically for fecal <i>E. coli</i> .)	Annual test report from a recognized lab is required. The report must include a concentration measurement of the amount of generic <i>E. coli</i> , rather than simply presence/absence of the contaminant. A presence/absence reading will not be acceptable in audit.
Surface water (ponds, streams, rivers, lakes); this includes irrigation districts that are open ditches or do not conduct regular testing	High	Test for generic <i>E.coli</i> for irrigation water. Test 3x/year: <ul style="list-style-type: none"> • Start of season • Peak use • Prior to harvest If using an irrigation district water source, the district water test is acceptable. (Test for fecal <i>E. coli</i> if considering use of the water for produce wash water.)	All three test reports are required. The reports must include a concentration measurement of the amount of generic <i>E. coli</i> , rather than simply presence/absence of the contaminant. A presence/absence reading will not be acceptable in audit. If using an irrigation district report, a copy is required at time of audit.

How to Take a Water Sample

Before Sampling Your Water Supply

- ✦ Contact your selected laboratory prior to collecting the sample to confirm the following:
 - Sample delivery times.
 - Collecting instructions.
 - Pricing per sample.
 - Testing methods available.
- ✦ Collect samples in sterile containers provided by the testing laboratory.
- ✦ Do not rinse your sample bottles prior to taking samples.
- ✦ If more than one sample is to be tested, all samples should be collected within a continuous 18 hour period.
- ✦ Always take extra bottles and sample request forms from the testing lab.

One of the tests recommended is the Colilert® method (Generic *E. coli* and coliforms) with quantitative results (not presence/absence). If funds are low, a single sample at the point of use is recommended to account for the entire irrigation system. If funds are available or you plan on participating in a cost share program, one sample should be taken from the water source (wellhead, surface water, etc) and from the point of use (end point) for irrigation and wash water. Your results will be representative of the water quality throughout your system. You will be able to identify if your water is becoming contaminated through your system, either in irrigation lines or at the wash station. If you do find an unacceptable level of contamination, you can isolate it either to the water source (i.e. cracked well casing, inflow from above due to faulty well seal, contaminated runoff, wildlife contamination, etc.) or to the above-ground (i.e. irrigation or wash station) system.

Water Sampling Procedures

Irrigation water	<ul style="list-style-type: none">• Run the irrigation system for the amount of time needed to flush the ‘hold up’ volume of the system plus an additional 5-10 minutes.• Collect samples from the sprinkler/drip system (not the intake area).
Post harvest water	<ul style="list-style-type: none">• When collecting samples from the distribution system tap make sure to remove any attachments, such as aerators.• Open the tap fully and allow the system to run for at least 10 minutes (or the time to flush out the ‘hold up’ volume) before the sample is taken.• Slowly fill the container to the line as indicated and tightly cap the container.
Transportation	<ul style="list-style-type: none">• The sample should be delivered to the laboratory as soon as possible, and no longer than 24 hours after its collection.• Samples should be placed in a cooler with ice or gel packs during transportation.• Check with specific lab for any additional procedures.

Source: Good Agricultural Practices for Small Diversified Farms: Tips and Strategies to Reduce Risk and Pass an Audit, Ben Chapman, Ph.D., Audrey Kreske, Ph.D., and Roland McReynolds, Esq. Published by Carolina Farm Stewardship Association in partnership with North Carolina State University, www.carolinafarmstewards.org. Reprinted with permission.

This farm's pumping and pressurizing equipment is secured by fencing, and the area surrounding it is kept free of contaminants like trash and debris. The water source is an open canal, and thus exposed to airborne and other contaminants. The water is tested regularly, and is pressurized and delivered via drip tape exclusively, so the water does not touch edible portions of the food.



Making Decisions Based on Water Test Results

The USDA GAP standard does not include a set level of acceptable microbial contamination for irrigation water, but instead relies on farmer analysis and decision making based on the range of practices and situations on that farm.

Each farm will have different risk scenarios early, mid and late-season, especially if more than one source of water is used. The type of crop, as well as the water delivery method, will be key components in a risk assessment. Acceptable microbial contamination levels for irrigation water vary depending on the farm's risk profile: again, the type of crop, the way the crop is irrigated and how close to harvest the water is applied.

Water testing is not the only method of assessing water quality. You may find potential sources of contamination during a pre-harvest walk-through, or in the course of regular review of farm practices.

Surface water has the highest risk of contamination — risks include everything from airborne contaminants like dust and chicken feathers, to migratory birds and other wildlife. Consider and reduce the risk of contamination of surface waters by keeping the pumping equipment and filters in good repair, and monitoring the sources for accumulations of culls, trash or debris, and signs of pests or wildlife impact. Maintain effective barriers like fences and hedgerows so that wild and domestic animals do not have access to irrigation water sources directly. Be sure to consider potential runoff issues into the water source from adjacent land, especially livestock

farms, composting activity or any septic or sewage systems.

Irrigation methods can contribute to or mitigate contamination from source water. If used in sprays or for overhead irrigation, depending on when in the life cycle of the plant it is applied, irrigation water can introduce pathogens to the edible portion of the plant. In addition to assuring that the farm's water quality is appropriate for the crop it's applied to, you may wish to consider drip irrigation or other methods that are designed to prevent water from having direct contact with the crop. Drip irrigation can decrease the risk of microbial contamination because the water is applied to the soil rather than onto the plant. However, using drip tape does not take the place of regular testing regimes as described in this manual and in other resources referenced.



In situations where well water is tested and meets potability standards, overhead irrigation is unlikely to transmit microbial contamination to the crops, even when it comes in contact with the edible portion of the plant.

FSMA Requirements for Production Water

The Produce Safety Rule sets water quality requirements for all water that is likely or intended to touch produce during growing, harvesting, packing, or holding of any produce covered by the rule. In addition to water that may or does touch produce directly, water that touches food contact surfaces, such as water used for cleaning and sanitizing tools and equipment, is also included in these standards because those surfaces are a potential cross-contamination point.

The FSMA Produce Safety Rule and USDA GAP/GHP audit standards take a similar approach to water quality monitoring that is based on a risk assessment of your unique situation. The level of risk depends on several factors including the source of the water, how and when the water is used on the farm, whether the water comes in direct contact with the produce, and the quality of the water at the time of use.

Similar to other food safety programs, the FDA divides agricultural water quality standards into two categories based on their use: (1) production water and (2) harvest and post-harvest water. This section focuses on production water, which is any water used on covered produce prior to harvest. Examples of production water include water used for irrigation, fertigation, foliar sprays, and frost protection. (See the GAP/GHP Audit Part 3 chapter in this guide for more information on post-harvest water standards for both the GAP/GHP audit and FSMA Produce Safety Rule.)



§112.41 THROUGH
§112.50

System Monitoring and Maintenance

The Produce Safety Rule requires active monitoring of agricultural water systems. You must inspect your water system — at least the parts of it under your control — at the beginning of the growing season, and as needed (at least once annually), to identify food safety hazards. You must inspect and maintain your water source and water distribution system (such as pumps, pipes, irrigation ditches, faucets, sprinklers, drip tape, etc.) as needed in order to prevent equipment malfunction, accumulation of animal and waste debris hazards, and contamination related to pooling water.

Water Quality Testing

Like the USDA GAP/GHP audit, the FSMA Produce Safety Rule requires farms to test their agricultural water quality and is more prescriptive about the requirements for that testing. The Produce Safety Rule requires testing for generic *E. coli*, as an indicator organism for fecal contamination of the water. For production water, the Produce Safety Rule requires a quantitative testing method to count the number of pathogens (rather than a presence/absence test), which is measured in Colony Forming Units (CFU) or Most Probable Number (MPN).

The FDA created a list of water testing methodologies allowed under the Produce Safety Rule; you can review these in the Equivalent Testing Methodologies for Agricultural Water fact sheet in the Templates and Resources section of this guide. (Note: The first page of the fact sheet pertains to production water; the second page pertains only to post-harvest water.) The Washington State Department of Ecology maintains a searchable database of accredited environmental labs at <https://fortress.wa.gov/ecy/laboratorysearch/>; or go to ecology.wa.gov and search for “laboratory.” The WSU Food and



§112.42

Produce Safety Extension team also maintains a map of labs at foodsafety.wsu.edu. You can search for labs by location and desired testing method(s). Check with your local lab about what tests they offer and make sure that they accept public samples.

Testing frequency

The Produce Safety Rule requires initial water testing to establish a baseline Microbial Water Quality Profile (MWQP), and then an annual testing protocol thereafter for



§112.46

on-going water quality monitoring. The Produce Safety Rule requires a higher frequency of initial tests than the USDA GAP/GHP audit. Produce Safety Rule testing frequencies are outlined below based on type of water source.

Microbial Water Quality Profile Standard

Unlike the USDA GAP/GHP audit, the Produce Safety Rule sets a specific, numerical water quality standard, and requires farms to establish a MWQP. A MWQP is a long-term water quality



§112.44(b)

management strategy tool based on a set of calculations using figures from water testing results. As new water quality tests are done, the results are analyzed to provide a running measure of water quality. If at any point the calculation results are outside of the standards listed below, the farmer knows there is a water quality concern that needs to be looked into and corrective actions need to be taken to address the issue.

Agricultural production water must meet both of the following standards:

- **Geometric Mean (GM):** ≤ 126 colony forming units (CFU) or most probable number (MPN) in generic *E.coli* per 100 mL of water
- **Standard Threshold Value (STV):** ≤ 410 colony forming units (CFU) or most probable number (MPN) in generic *E. coli* per 100 mL of water

There are many resources available online to help you develop your water quality profile and compute the GM and STV. The University of Arizona Fresh Produce Safety website provides a list of online tools at cals.arizona.edu/fps/node/57/ and the Produce Safety Alliance has online calculators and a longhand calculation worksheet on their website at producesafety-alliance.cornell.edu/resources/general-resource-listing/.

Water source	Initial baseline survey	Annual testing requirement
Surface	20 or more samples over a period of 2 to 4 years	5 or more samples rolled into profile every year after initial survey, if results continue to meet the microbial quality criteria
Ground	4 or more samples during the growing season or over the period of a year	1 or more samples rolled into profile every year after initial survey, if results continue to meet the microbial quality criteria
Public	No testing required, if farmer can document public water system results or a current water supply certificate of compliance	

Corrective Actions for Production Water

In the event that water used for agricultural production does not meet the required microbial

standards given above, the Produce Safety Rule lists three corrective actions that farmers can take, which must be followed as soon as practicable, and no later than the following year from when non-compliance is detected:

1. Apply a time interval between (1) last irrigation and harvest; or (2) harvest and the end of storage and/or activities such as commercial washing. Microbial die-off occurs over time due to factors including desiccation (drying out), sunlight (UV radiation), temperature, humidity, and crop type. An effective time interval is one in which these factors will have enough time to lower the microbial level to within the standards. A log reduction calculation can be used to assess if a time interval will be an effective corrective measure. For produce, a microbial die-off rate of 0.5 log per day, or another scientifically-validated rate, can be compared to agricultural water testing results to determine if a time interval is a feasible means to reduce your water quality to an acceptable level. There are tools online to help you calculate microbial die-off rates. The University of Arizona Fresh Produce Safety website provides a list of online tools at cals.arizona.edu/fps/node/57/, and the Produce Safety Alliance has online calculators and a longhand calculation worksheet on their website at producesafetyalliance.cornell.edu/resources/general-resource-listing/.



§112.45(b)

2. Re-inspect the entire affected agricultural water system, identify and correct the likely hazard(s), and take adequate measures to ensure the changes were effective and that the water quality is acceptable before using that source again.
3. Treat your agricultural water with a physical treatment device or an antimicrobial pesticide product that is registered by the U.S. Environmental Protection Agency (EPA).

Recordkeeping

There are several record-keeping requirements related to agricultural water in the Produce Safety Rule, including:

- The findings of your water system inspections;
- Results of water quality testing from an accredited lab (or documentation from a public water authority if using public/municipal water);
- Results of your water treatment monitoring, if treatment is conducted; and
- Documentation of corrective actions taken if tested water does not meet the numerical quality standard, if applicable

Additional documentation may be required in certain circumstances, for example if you opt to use alternative testing methodologies, die-off rate calculations, or sampling frequencies. For more information on the recordkeeping requirements for agricultural water and sample templates, see the Records Required by the FSMA Produce Safety Rule document in the Templates and Resources section of this guide.



§112.50



Testing Compliance Timeline

The compliance dates for agricultural water standards differ from the general Produce Safety Rule compliance timeline. In 2017, the FDA issued a proposed extension to provide farms an additional two years to meet the water requirements; this means compliance dates are expected to be 2022, 2023, or 2024, depending on your farm's size (larger farms have earlier compliance dates). If finalized, farms must begin their initial survey by the proposed water compliance dates. See the Overview of the FSMA Produce Safety Rule chapter in this guide for more information on compliance timelines. (Please remember that sprouts have many different requirements under FSMA, including different compliance dates, which are not addressed in this publication. Washington sprouts growers should contact the WSDA Produce Safety Program directly for guidance.)

The FDA also announced in 2017 that they are considering simplifying the agricultural water standards, due to stakeholder concerns that the agricultural water requirements, as written, are too complex to understand, interpret, and implement. The FDA is currently working on guidance, collecting more data, and coordinating with stakeholders on how to proceed. While the agricultural water standards are being assessed by the FDA, farms are advised to continue with your existing water quality and monitoring practices, until more is known about the potential changes to the regulatory requirements. This is particularly true for farms with requirements from buyers or a voluntary audit program. Farms that have never tested their water before should consider conducting some initial samples. This applies to farms who are likely to be covered by the Produce Safety Rule, but it is also a recommended best practice for farms that are not covered.

What if my farm floods?

Flooding caused by storms or other natural disaster can have significant food safety impacts on crops. There are two types of flooding, which pose different risks. Flooding caused by heavy rain that saturates the ground and causes pooling may damage or kill plants, but generally does not cause contamination of the crop. More severe flooding, caused by surface water runoff overflowing into production fields, can spread unknown chemical and/or biological hazards onto your produce. Under the U.S. Federal Food, Drug and Cosmetic Act, if any of the edible portion of a crop is exposed to contaminated flood waters, the produce is considered adulterated and should not enter the human food supply. There is no practical method to recondition the contaminated produce to provide a reasonable assurance of food safety.

Each flooding event should be considered on a case-by-case basis. To assess whether your crop is safe or not, you must evaluate the type of flooding that occurred, and whether the edible portion of the crop came into contact with the flood waters. Even if the flood waters did not entirely cover your entire crop, you must still assess whether any splashing may have occurred, and what a suitable buffer zone might be for harvesting adjacent crops that were not under water.

Before cleaning up or destroying any product, you should work with your local crop insurance program, university extension program, state department of agriculture, and your local FDA office to consider all possible types and routes of contaminations before determining whether a particular crop is adulterated.

For more information, see the Food Safety for Flooded Farms sheet in the Templates and Resources section of this guide.



Your farm's SOPs should specify the steps to be taken should your water test results indicate levels of unacceptably high levels of microbial contamination (interpreted on the basis of the crop grown, or the way the water is being delivered and applied) or if you identify other sources of contamination. Those steps must be documented, and the results recorded. For example:

- ❖ Stop using that water source.
- ❖ Investigate the source of the problem. Your farm map and initial risk assessment will help determine the potential sources of contamination.
 - Is this a systemic problem such as upstream contamination or seasonal changes in the water quality?
 - Is this a one-time contamination event? You should inspect for: cracks in the well structures including the well head, casing and seal; signs of animal contamination; possible contaminated run-off from heavy rainfall or flooding; contamination from an on-site or adjacent property septic or compost storage system.
- ❖ Implement mitigation strategies based on your SOPs.
 - If systemic or out of your control, consider adjusting irrigation methods, chemically treating your water, or changing the source of your water.
 - If a one-time contamination event, consider adjusting equipment or otherwise removing the source of contamination. Make sure to record the steps taken in your written log.
- ❖ Re-test the water prior to resuming usage. You will need to show the auditor the results of tests after the contamination event, or concerning water test results, with evidence that the mitigation strategy was effective and the water is microbially safe for the crop, delivery method and usage.

If I have a pond that serves as a watering hole for my livestock, can I use that water for irrigation?

No, you cannot use the same source of water as both watering hole for livestock and irrigation for food crops. Irrigation water must be protected from contact with livestock.



If necessary, irrigation water can go through a filter step to make it microbially safe for its intended use. In some systems, there is also the option to add an antimicrobial solution to the irrigation water before it is used on crops. The antimicrobial solution must be identified for use on fruit and vegetables and the amount used must be documented and monitored to show it meets label directions.

Sewage Treatment

The farm's septic or sewage treatment system must be documented to be functioning properly. Also, no municipal or commercial landfill or sewage treatment plant should be adjacent to the farm.

If your farm has housing or a shop with indoor plumbing, your risk assessment map should include the buildings and clearly indicate where the drain field and septic tank are located. The auditor will ask to see the map to determine its proximity to the farming location and whether it may pose a potential risk. The auditor will look at the location of the drain field and septic tank for any signs of leaking or any surface discharge.



QUESTIONS 1-6
AND 1-7

Animals/Wildlife/ Livestock

Animals can play important roles on farms. Domestic cats and birds of prey can be beneficial in controlling rodent populations. Grazing animals can be excellent sources of fertility. Even with good planning and monitoring of exclusion strategies, a farm will never realistically be 100% free of impact from wild animals such as migratory birds, deer, and elk. However, animal waste in soil or irrigation water can represent a food safety risk. Growers must take appropriate risk assessment and prevention steps to exclude animals from crop production areas and have mitigation plans in order to comply with GAP standards.



QUESTIONS 1-8
THROUGH 1-13

Livestock and Poultry Adjacent to Growing Areas

Creating and maintaining adequate protection from animal contaminants on adjacent lands or from sources on your own farm is essential. Your crop production fields should be located at a safe distance from sources of animal contamination such as dairy, livestock or fowl production facilities, or manure lagoons. When planning where to locate animals and production areas, consider potential runoff issues and prevailing winds that could blow dust or feathers onto crops, and how heavy rains or dry dusty winds may affect these. Berms, tree rows, and other barriers can reduce runoff and airborne animal contaminants. A careful farm review will identify whether or not barriers are needed and what distances are appropriate. Your risk analysis should consider the consequences of a flood event, or a leaking manure lagoon on your crop production fields, and the corrective actions to take should this kind of contamination occur.

Intentional Interaction Between Livestock and Production Fields

Diversified farms that include livestock often have natural fertility in the form of animal manure. They may use a system of moveable pens to allow livestock or poultry to graze in rotation with crops across seasons, or have sheep, goats, or pigs clean up a field or tree fruit orchard after harvest. The fertility is useful, and the animals can forage for un-harvested product, as well as feed on the remaining grasses and weeds.

When given enough waiting time on a field, this can be part of a sustainable system that minimizes the need to buy commercial fertilizer. Managing raw and composted manure properly is a key component of an auditable food safety plan. Growers must observe appropriate waiting periods from the presence of the animals in the fields to the time for workers to re-enter, raw manure to be incorporated into the soil (minimum 2 weeks) before planting, and harvest

to be done (not less than 120 days from when animals were removed and raw manure stopped being deposited on the field). The SOPs should also address preventing animal droppings on the ground from contaminating equipment or being transferred out of the field through foot traffic.

Farms that use livestock as work animals, such as draft horses, oxen, or mules, will need to address possible sources of contamination and have a plan and documentation of remediation steps.

Animal Disturbances

It is impossible to entirely exclude animals, wild or domestic, from your fields, but the GAP standard requires that farms evaluate their risks for animal contamination and act to lessen risk where signs of animal intrusion are found. Each farm will need to do an analysis of the likelihood of intrusion from different kinds of animals, plan for reducing the risk, and monitor the fields for evidence of intrusion. Your SOPs will detail how to watch for signs of animal intrusions such as game trails, crop damage, or feces, and what corrective actions to take when signs are found. Note: food crops with evidence of animal urine or feces must not be harvested.



Livestock are an integral part of many farms. Determining the best site for animal areas in relationship to crop areas requires consideration of topography and winds that may create food safety hazards.

An important strategy for minimizing the risk of animal intrusions is to eliminate attractions such as cull piles, standing water and nesting materials. You can also use techniques such as noise cannons, reflective tape and well-built fences without destroying any wildlife habitat around the farm. Before taking steps to remove habitat, check with your regional Conservation District for suggestions on appropriate habitat management strategies.

For the audit you will be asked to show records of the monitoring activities you've determined are necessary to prevent wildlife or domestic animal intrusion, as well as records showing that you're implementing the strategies.





A simple way to indicate that product must not be harvested due to contamination is to place flags at the contaminated area. One Washington farm in a river valley has experienced an increasing problem with elk and beavers. Their SOP indicates that any product with visible contamination is to be flagged, and the crops within a five-foot radius of the flag will not be harvested. Workers are trained to place the flags upon seeing evidence of animal contamination, and harvesters are trained to leave crops unharvested within a five foot radius when they encounter flags in the field. This past year, the farm manager noted that some of their romaine lettuce had the tops chewed off. Initially, she put in flags to mark the chewed plants, and advised workers (per their training) not to harvest there. Eventually, the problem became widespread enough that she chose to mark an entire section

of the field as unharvestable, and advised workers not to enter that field. Kale fields in the same area were being raided by beavers from the nearby river, and the decision was made to flag that area, as well.



Avoiding Cross-Contamination from Animals

When farm workers regularly work with both animals and produce, best practice is to have a system to clean and sanitize boots between uses, or to have two pairs of boots. This must be in your SOPs, and be included in worker training. Both the policy and the training must be documented, and the auditor will look to see if workers are following the designated practice.



One farmer identified his short boots as his “animal boots” and his tall ones as his “vegetable boots,” and was careful to change them when switching tasks.



FSMA Requirements For Animal Management

FSMA highlights the risk of cross-contamination of produce and food contact surfaces by animals (including wildlife, livestock, working animals, or any animal waste). The Produce Safety Rule requires that all workers must wash their hands as soon as practical after touching animals or animal waste; and that workers must assess all relevant areas of the farm for potential animal contamination prior to harvest (such as observing animal presence, feces, or crop destruction), and take measures to avoid harvesting contaminated product.



§112.32, §112.83,
AND §112.84

While the Produce Safety Rule recommends farmers take measures to deter wildlife from contaminating crops through non-invasive means such as fencing or scare tape, it does not authorize the “taking” (killing, harming, or harassment) of threatened or endangered species, as defined by the Endangered Species Act. Further, the Produce Safety Rule does not require farms to exclude animals from outdoor production areas, destroy animal habitat, or otherwise clear farm borders.



Elk or deer fences may be a useful strategy for animal exclusion for small orchards and farms, but are not required and may not be feasible on larger farms. In the Yakima Valley, farms located near wooded areas or nearby rivers or creeks have much greater exposure to intrusion from deer. The farms situated in fields that are in open, flat stretches of the valley are naturally less attractive to deer because there is little water and very little protection from predators. In these areas, investing in building and maintaining deer fencing doesn't make sense. In the upper part of

the valley, which is planted with more orchards and thus has more natural cover, deer are a significant problem and the orchards are almost all deer-fenced (though not as a food safety precaution, but rather to protect their harvest). Operators of row crop farms in those areas can take a cue from their neighboring orchardists and monitor carefully for evidence of deer intrusions in their production fields.

A farm has a large rabbit population, and has placed two-dimensional wooden cutout decoy coyotes in the field to scare off the rabbits.



Manure and Municipal Biosolids

Farms with integrated livestock production will naturally have a source of some quantity of raw manure. Other farms may buy raw manure from nearby dairies or other livestock operations. This animal waste can be part of a farm's fertility management program, and used as a soil amendment either in its raw form, or after composting it according to established guidelines to bring pathogen concentrations to a safe level. In the GAP audit standards for manure and municipal biosolids, farm practices are different depending on the uses. The following categories will determine which audit checklist items apply to your farm:

Option A: Raw manure or a combination of raw and composted manure is used as a soil amendment.

Option B: Only composted manure and/or treated biosolids are used as a soil amendment.

Option C: No manure or municipal biosolids of any kind are used.

Option A

Choose this option if your farm's soil amendments include any raw manure, whether alone or in combination with treated manure. If you choose this option, do not address questions 1-18 through 1-22.

GAP standards specify a waiting period of a minimum of two weeks for planting into a field where raw manure has been incorporated into the soil. Raw manure cannot be applied to crops that will be harvested less than 120 days from the date of the manure application. If the 120-day waiting



QUESTIONS 1-14
THROUGH 1-22

period is not feasible for whatever reason, you should only use composted manure. Composted manure must be treated appropriately to reduce pathogen levels. You must also evaluate your manure storage system to minimize the risk of contaminating crop production areas resulting from heavy rainfall, flooding, containment-system failure or other scenarios that would release manure from its storage area.

Your SOPs must contain your written policies and procedures for use of manure and compost. Good records showing dates of application, planting and harvest must be available for auditor review.

Note that the National Organic Program standards, which guide WSDA's certified organic program and certification, provide standards for the use of raw and composted manure, but that they specifically prohibit the use of biosolids. For additional information on how GAP certification standards relate to organic certification standards, refer to The WSDA Organic Program fact sheet, included in the Resource Section following the GAP/GHP Audit Chapter of this guide.

Option B

Choose this option if your farm uses only composted manure or treated biosolids as soil amendments. If you choose this option, do not address questions 1-14 through 1-17, or 1-22.

Your SOPs should clearly state that only properly composted manure or biosolids will be applied as soil amendments. The auditor will review your compost application records to verify that only composted manure or biosolids are used. If records show that any raw manure is used, the auditor will use the questions for Option A.



QUESTIONS 1-14
THROUGH 1-17



QUESTIONS 1-18
THROUGH 1-21



If you're composting the manure yourself, you will need to develop and be able to show the auditor your documented composting process. Commercial compost that is purchased for use on the farm must also have documentation of the compost process and test results showing that pathogens of concern have been effectively controlled.

If you are storing composted manure or treated biosolids for future use, they must be stored in a way that reduces risk of contamination to growing areas or recontamination of the compost itself. Even fully composted manure may still contain some pathogens. Barriers or containment systems such as concrete block containers or soil berms can reduce risk of runoff, leaching or wind depositing contaminants onto crop areas. Open outdoor compost piles should be at a reasonable distance and situated downhill from growing areas so runoff goes away from growing areas. Consider whether heavy rains can result in excessive leachate, and decide whether covering your manure piles is necessary, or whether you wish to collect the leachate for disposal. Leachate or manure tea may be used on crops, but should be handled using good agricultural practices that maximize time between application and harvest.

Option C

Choose this option if your farm applies no manure or biosolids at all.



QUESTION 1-22

If the farm does not apply raw or composted manure or biosolids to soils, then having a written policy to that effect included in the Food Safety Plan is sufficient to meet the GAP requirements for Manure and Municipal Biosolids.

FSMA Standards for Biological Soil Amendments of Animal Origin

It is common to use soil amendments that contain ingredients derived from animals, such as manure, bone meal, feather meal, and blood meal. The Produce Safety Rule has a specific definition of “biological soil amendments of animal origin” (BSAAO) and maintains standards for treatment, storage, handling, application, and minimum harvest intervals of BSAAO on the farm. It is important for farms to be familiar with these specific requirements which are detailed in sections §112.51 through §112.60 in the Produce Safety Rule reference section of this guide. Another useful resource is the FDA Fact Sheet on Biological Soil Amendments in the Templates and Resources section of this guide.



§112.51 THROUGH
§112.60





Soils

Previous land uses can have significant impacts on your food safety planning. An assessment of your site should consider:

- ✦ Is there evidence of dumping or industrial waste?
- ✦ Have contaminants been deposited by past flood events, runoff or drift?
- ✦ Is this a previous building site?
- ✦ Is there concentrated animal production nearby? If so, how would wind or water carry the waste?

Conducting a previous land use risk assessment on your soil provides a more detailed look at the likelihood that any portion of the soil may be contaminated. Unless there are signs of contamination or recent uses that cause concern, soil testing will not be required as part of the GAP audit. Signs that an auditor will look for to indicate soil contamination include recent flooding, evidence of past dumping, indications of misuse of animal waste, or historical use of the land in concentrated feeding operations of livestock and any abandoned buildings. If there are signs of contamination, soil testing for harmful pathogens will be required and those results must be available to the auditor. If soil contamination has occurred, the food safety plan must specify how contact with that soil will be minimized or prevented.

If your fields have been flooded they may have been contaminated by pathogens off-site, so the soil should be tested prior to use for growing crops. If the soil samples show no potential contaminants, there is no timeframe or waiting period before planting on the land. In the case of flood contamination, annual crops harvested the same season are at greater risk than perennial crops that will be planted but not harvested in the same season. Root crops are at a greater risk than crops that will grow above the ground. However, the basic rule is that soil should be sampled on previously flooded crop lands.

QUESTIONS 1-23
THROUGH 1-25



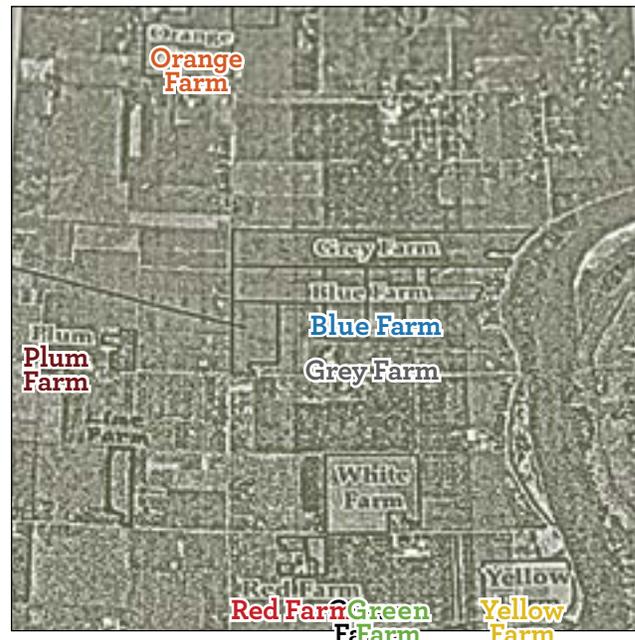
Traceability

Your farm records should always include an up-to-date map that shows the crops grown in each field or production area. This will allow you to better identify the source of any potentially contaminated product in the case of a food safety concern reported by a customer or identified in your packing process after harvest.

One step forward and one step back is the general rule for traceability, so you must have recorded enough information to know from which field a product was harvested, and to which buyer it was sold. You can use your existing farm map to create a lot numbering system which will uniquely identify the product for you in case you need to address a customer concern or initiate a recall. Your unique lot number will be recorded on the packing box delivered and/or the invoice sent to the customer.

QUESTION 1-26

Traceability and recall is covered in more detail in the General Questions section of this Guide under Questions G-1 and G-2.



A farm map, such as the one shown with color-coded fields, could be paired with a season-specific crop list of what is planted within each color-named field. This farm also uses a system of numbering irrigation risers to more closely identify the area of a field. For example, O3 would be Orange farm, Riser 3. (Orange farm is named for the orange gate.)

Part 2 : Field Harvest and Packing



Whether it's done exclusively by hand, with mechanical harvest equipment, or a combination of both, all growers interested in meeting Good Agriculture Practices need to understand and implement best practices for field harvest and packing to minimize the risk of contamination.

This section includes field sanitation and hygiene as well as field harvest and transportation.





QUESTION 2-1

Your Food Safety Plan and SOPs Should Address:

- ✦ A pre-harvest assessment to identify contamination risks that are unique to your farm.
- ✦ Appropriate placement of field sanitation units (port-a-potties) and handwashing stations.
- ✦ Access to potable water for employees.
- ✦ Cleaning and sanitizing of harvest tools and harvest totes.
- ✦ Maintaining and inspecting mechanical harvest equipment to prevent broken headlights, windshields or fluids from contaminating product.
- ✦ Applying only microbially safe water to the product at or after harvest.
- ✦ Protecting product by covering it during transportation.
- ✦ Proper storage and use of packing containers.
- ✦ Traceability.

Pre-Harvest Assessment

An environmental assessment of the production fields and surrounding area should be done before harvest to evaluate for potential sources of contamination and readiness for safe planting and eventual harvest. The assessment can be as simple as a checklist or written description to guide a walk-through of the farm's growing areas and review of harvest equipment. It may include a review of:

- ✦ Proper location and number of toilets and wash facilities.
- ✦ Availability of potable water for workers.
- ✦ Harvest containers – availability, location, cleanliness.
- ✦ Condition of harvest equipment.
- ✦ Evidence of crop damage from domestic or wild animals.
- ✦ Signs of physical contamination in the crop production area.
- ✦ How fuel and other chemicals are stored to prevent contact with crop areas.
- ✦ Systems to isolate contaminated fields with “no-harvest” indicators.



- ❖ Evidence of physical contaminants such as manure, debris, trash piles, or standing water.
- ❖ Whether crop transportation equipment is clean and in good repair.

Your farm's SOPs for pre-harvest assessment should be written to reflect the unique practices and potential risks on your farm, with the goal being prevention of contamination. The farm's SOPs should include a policy clearly stating the remediation steps to take if initial or ongoing assessment strategies identify contamination. Should contamination occur, your SOPs will guide you and your staff in the appropriate steps to correct the problem and prevent your buyers from consuming or selling adulterated product. Both the assessment itself and the steps taken in the event of contamination, require you to keep records documenting that they occurred.

A pre-harvest assessment should be done at least once each harvest season, before harvest begins. You may choose to do it more frequently, or periodically during the growing and harvest season.

Whatever method and frequency you choose, it must be written in your SOPs and then implemented and documented according to the policy. Best practice is to keep a log so that growers and workers can document any signs of concern throughout the season, along with the remediation action taken. Also, document walk-throughs that show no signs of concern. This will show the auditor that someone is doing an assessment as often as the policy states. During an audit, the auditor will verify the fact that assessments and corrective actions are being done in accordance with the policy. The auditor will not interpret the pre-harvest assessment itself, nor what you or your workers find and document during an assessment.

FSMA Requirements For Pre-Harvest Assessments



§112.22(b); AND
§112.112 THROUGH
§112.114

The Produce Safety Rule addresses food safety practices during harvest by requiring that workers who conduct harvest activities are trained to identify, report, and appropriately respond to certain food safety risks, including dropped produce, animal contamination of the crop and inspecting harvest containers. Documentation of employee training is required. For the full list of training requirements related to pre-harvest assessments and harvest time activities, refer to §112.22(b) and §112.112 through §112.114 in the Produce Safety Rule reference section of this guide.

Field Sanitation and Hygiene



QUESTIONS 2-2
THROUGH 2-5
Related worker sanitation
and hygiene topics address-
ed in General Questions
G-3 through G-15

Properly placed and maintained toilet and handwashing facilities that are easily accessible to workers are essential to prevent contamination of the product from human waste.

Guidelines for field sanitation units (port-a-potties) are detailed in the Occupational Safety and Health Act (OSHA) 29CFR, Part 1928.110. Farms must provide one field sanitation unit, and one handwashing station per 20 employees, or as per applicable regulations. Also they must be no more than ¼ mile walk from where a hand-laborer is working in a field. Smaller farms (with fewer than 12 employees working in the field on any given day) or farms where employees work three hours or less during the day (including travel time) are

not required to provide field sanitation units, per federal OSHA regulations. In that case, a toilet facility and handwashing station are still required to be readily available to workers. If that facility is in a home, the auditor will need to see it during the audit.

If using field sanitation units, deciding where to locate each unit should include consideration of prevailing wind that could tip the unit over in a storm, any slope of the ground on which it is sited which could allow the unit to be accidentally or deliberately overturned, and whether any crop or produce storage areas are downhill of the unit in case of a spill. Each unit should be easily accessible for maintenance, so nearness to



Some farms use field sanitation units on wheels so they can be hitched to a tractor or other vehicle and pulled to the various harvest locations. If using wheeled sanitation units, it is important to carefully plan where they will be located and have a written plan for what will be done in case of tipping or leakage.



A field handwashing station can be very simple, and made from easily obtained components. See GAP/GHP AUDIT Questions G-7 through G-9 covered on pages 57-59 of this guide. This unit is designed to be easily moved to the various sites where field crews are working. This is convenient for harvest crews who may have lunch or smoke breaks off to the side of a field, rather than going in to a lunch or break room.

a road should also be considered in selecting the location. Your farm map will be useful for this step. Sewage and grey water must be properly disposed of and the facilities serviced regularly, and with records for audit review reflecting dates of service in accordance with your SOP.

Your SOPs must include a written policy and clean-up plan for what to do in case of a sanitation unit spill. This will include what will be done to clean up the spill and what will be done with any contaminated product.

All handwashing facilities must use potable water, and documentation of that potability is required. If water is supplied with the unit as part of the sanitation facilities service, the farm still must provide documentation to verify that the vendor has had the water source tested to confirm that it meets the safe drinking water standards. If you're using municipal water, provide a water quality report from the municipality. This documentation must be available for review at the time of the audit.

Sample Port-a-John Spill Response Plan

- ✦ Any affected produce is immediately disposed in a covered waste bin.
- ✦ The contaminated area will be marked off with caution tape or string.
- ✦ Signs in appropriate languages will be posted at the perimeter prohibiting entry to the contaminated area.
- ✦ People and animals will be kept out until the port-a-john is sufficiently decontaminated.
- ✦ Any solid waste still resting on the surface will be shoveled up and removed to the waste bin.
- ✦ Any affected permanent structures will be hosed off and disinfected with a dilute bleach solution.
- ✦ The sanitation unit will be cleaned up and replaced by the company providing the units and maintenance services.

Good Agricultural Practices for Small Diversified Farms: Tips and Strategies to Reduce Risk and Pass an Audit, Ben Chapman, Ph.D., Audrey Kreske, Ph.D., and Roland McReynolds, Esq. Published by Carolina Farm Stewardship Association in partnership with North Carolina State University, www.carolinafarmstewards.org. Reprinted with permission.

Field Harvesting and Transportation

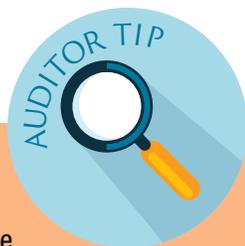


Regardless of whether the farm's field workers are packing into totes going to a packing shed, or directly into the final shipping box, the food safety plan should contain guidelines for staff to follow in order to minimize the risk of physical, microbial and chemical contamination of the product in the field, and to respond in case of accidental contamination.

This section covers best practices for field harvest, both hand-harvested and mechanical, whether the product is field packed or delivered to a packing house for washing and packing.

Harvest Containers

Harvest produce into clean, lined, or single-use packing totes or bins. Bulk harvesting containers and re-useable totes or bins should be cleaned and/or sanitized before first use and then kept as clean as practical thereafter. This needs to be monitored after each load is delivered and before reuse. They should be stored to minimize risk of contamination from birds or rodents, and should be cleaned and sanitized before harvest. Your SOP will need to include a policy and schedule for use and cleaning of harvest and packing containers, and implementation documentation is required. This can be a log of scheduled cleaning and sanitizing.



Different scales of hydro-coolers, which can be used to remove field heat from produce, can also be used to clean and sanitize harvest totes.

QUESTION 2-6
THROUGH 2-14, AND
2-16 THROUGH 2-18

QUESTIONS 2-6, 2-8,
2-14 AND 2-16



Simple logs tailored to record your specific practices, are necessary to document that SOPs related to container washing and sanitizing are followed on a regular basis.

Containers used for harvesting, transporting and shipping fresh produce should be specifically designated for that purpose, and should not be used for other purposes. Workers should be instructed not to use harvesting totes to carry their food, tools or clothing, or any other non-produce items. Of course, no container that has held hazardous chemicals or other contaminants should ever be used for food. If you have containers similar to harvest or food storage containers that you want to use for chemical storage or other non-food uses, they should be CLEARLY marked so they do not get re-used for food harvest or storage, and workers should be instructed accordingly.



There are many ways to clean and sanitize harvest totes. It is also helpful to scrub bins before the sanitizing step, to remove heavier dirt or caked mud. Whether using a larger produce wash system or a small homemade bin washer attached to pressure hoses, or the pressure hose system directly, you can make a system into which you can inject a chlorine solution can be injected to sanitize bins.

Containers should be checked for damage, and any containers with damage should be repaired or discarded.

Harvest Practices that Minimize Cross-Contamination

During harvest, workers should keep both the crop and containers as clean as possible, and remove excessive dirt and mud from produce.



Harvest containers and packing boxes should be stored off the floor or ground, on pallets, carts or shelves, to avoid contamination from standing water or dirt.



QUESTION 2-16



QUESTION 2-7

Harvest Using Cleaned and Sanitized Tools

Your SOP should contain a clear policy

and procedure for making sure that harvesting tools are cleaned and sanitized on a regular basis, along with documentation that the plan is being followed. Best practice is to keep harvest tools on the farm, rather than letting workers take them home or keep them in their vehicles, so that they cannot be used for other purposes or accidentally contaminated off-site. This also allows them to be collected for cleaning and sanitizing as part of the daily work plan, and checked off on a log to document the process.



A farm in western Washington has a clear and detailed policy and procedure for harvest knives. They gather the tools at the end of the work day to clean and sanitize them. In the morning, clean knives are given to workers. Over the lunch break, harvest workers put their knives into a bucket with a bleach water solution for sanitizing. For workers who wish to use specific tools, it is easy to mark them in some way that allows them to identify their tools when it's time to go back to work. Harvest tools with plastic handles are easier to clean and sanitize than wooden handled tools.



Growers use a variety of strategies to prevent contamination of the product after it leaves the field.



One option for clean harvest is to harvest into boxes or totes on the ground, but transport them in a single layer to the washing or packing shed, rather than stacking.



If stacking is necessary to your farm, then there are options for keeping harvest totes off the ground. On some farms, a tractor pulls a cart with bins directly into the field to serve as a mobile packing station.



Another solution is to build or purchase a wheeled cart that straddles the rows, though it does require an investment of time and/or money up front.



For some products, it may work to harvest them into clean buckets and then transfer the produce into clean boxes or totes that can be stacked.



Harvest crews could also use extra totes or other barrier under the harvest tote. If an extra tote method is used, a different color tote designated “not for harvest use” would be recommended. Even a clean piece of tarp could be used to keep produce and harvest totes off the ground. Tarp or other plastic barrier would be lightweight to carry to field, easy to clean between uses, and sturdy enough for repeated uses. Each farm can tailor a solution that meets the needs of the specific situation.

Root crops, like carrots, come out of the ground covered in soil. Best practice is to remove as much loose dirt from the products as possible before packing into bins. Loose dirt can transmit pathogens to other products in the bin or between bins if they are stacked.





Glove Use

Follow glove usage policy if you have one. If gloves are required or are being used on the farm, then you should have a glove use policy in place and have supplied proper training to ensure that the gloves are not a possible risk for contamination. One concern is that gloves taken off the premises could be used for another purpose, or could easily become contaminated by multiple uses without a schedule for cleaning and sanitizing. The following are recommended components for an SOP for glove usage:

- ❖ Gloves are not a substitute for handwashing; hand-sanitizers are not a substitute for handwashing.
- ❖ Policy should cover use, maintenance, and disposal.
- ❖ Gloves shall not be removed from the work area during breaks.
- ❖ Reusable gloves shall not be taken home for cleaning and sanitizing OR, if employees may take their gloves home to clean them, the SOP must indicate that this is allowed and that they will be checked prior to the start of each work day to verify that they are clean.

The auditor will review the glove usage SOP, if you have one, and examine records of performance, and verify that use is consistent with the SOP.



Clean and Well-Maintained Harvest Equipment and Machinery

Harvest containers, including truck beds or bulk containers, and other harvest equipment and machinery used in the fields should be kept in good repair so that they do not become a source of contamination.



QUESTIONS 2-8
THROUGH 2-13



Regular inspection and repair of trucks, tractors and harvest equipment will help minimize risk of contamination from broken parts or leaking fluids

When machines are used in the harvesting process, your pre-harvest assessment should include checking for potential leaks of hydraulic fluids, oils and grease from the machinery to the field. Cleaning and sanitizing the machinery must be done prior to the start of the season or as scheduled. If a tractor is used in a field that has been dressed with raw manure, or that has been affected by other livestock manure, it must be cleaned and sanitized prior to being used in a food production field that is within 120 days of harvest. All light lenses must be covered or maintained to prevent glass or plastic from contaminating the product.

You must have SOPs with detailed instructions for response in case of possible contamination during harvest. You will need to have a policy for breakage of glass or plastic and one for spills or other contamination from chemicals, petroleum, pesticides or other materials.

You must also prevent and inspect for any rocks, glass, metal or other foreign objects being introduced to the product from your harvest machinery.

Transportation from Field to Storage and Processing Areas

Clean hauling vehicles regularly. If you're putting produce directly into a vehicle for bulk hauling, that vehicle should be cleaned and/or sanitized in the same way harvest bins would be. For vehicles or flatbed trailers used to move product from field to storage areas or processing areas, the



QUESTIONS 2-17
AND 2-18

surface needs to be cleaned regularly and kept free of debris, to reduce risk of cross-contamination from boxes put in the truck. Remember, if harvest bins have been on the ground, they should not be stacked on top of each other for transport.

Cover produce during transport. GAP standards require that you have a policy in place that harvested produce being moved from field to washing, packing or storage areas is covered. This is to reduce risk of contamination by other vehicles, from birds or overpasses, or from airborne oils and dust. Produce in closed boxes or cartons is not considered covered. Tarps or enclosed trailers are examples of recommended practice. The auditor will determine whether the policy is being met by observation and by talking with employees on-site.

When transporting produce in from the field, stacked bins (that have not been in contact with the ground) should be covered to reduce contact with airborne dust and other contaminants during the trip.



Post-Harvest Water Usage



QUESTION 2-15

The GAP/GHP audit requires that water applied to harvested product must be “microbially safe” but does not define what that means. The FSMA Produce Safety Rule does define the standard for water used in post-harvest activities: the water must be potable, that is, it must have no detectable generic *E. coli*.



§112.44(a)

Municipal water systems provide potable water, and therefore municipal water meets the quality standard for post-harvest water. Farmers must request and keep records of the public authority’s water testing results, or a current water supply certificate of compliance. Water from other sources must be tested for the presence of generic *E. coli* by a laboratory, and these water quality records must be retained. Please refer to Water Usage GAP/ GHP Checklist Questions 1-1 through 1-5 for information on the kind and frequency of testing needed to determine whether a farm’s water meets the microbially safe standard. If the water used for post-harvest activities does not meet this standard – if there is detectible *E. coli* found in the water – then you must treat the water with anti-microbial agents prior to use. You may use appropriate chemical treatment or secondary filtration to treat the water. You must document the timing, process, and results of the actions. Note that surface water, taken from rivers, irrigation canals, or holding ponds, is likely to require filtration and/or chemical treatment to bring it to the microbially safe standard.

For additional information on produce wash water, and FSMA Produce Safety Rule standards for post-harvest water quality, see pages 99 - 101 of this guide.

Water at first use must be microbially safe, as discussed above. The challenge with post-harvest produce water is avoiding contamination and reuse of water that may contaminate the produce. One option is to use spray tables or other single use water systems, which will then require adequate drainage of large quantities of water. This way any microbial contamination is washed off the produce and discarded, rather than reused for washing subsequent produce batches.



Spray tables are a safe way to wash produce without reusing the water and introducing pathogens from one batch to the next.



What are the requirements for draining or containing water that has been used for produce washing, bin cleaning, etc. in a field packing shed?

Water that has been used for field packing and produce washing must be drained out of the packing area and other high-traffic areas. The drainage must not create areas where water pools for long periods of time or where foot traffic could possibly contaminate the fields and/or other work areas. You must also make sure that the water being drained does not come into contact with un-harvested crops and does not affect your irrigation water source.

Many farms wash produce in dunk tanks, often made from repurposed bathtubs or water troughs. This presents challenges under the GAP standard because the buildup of particulates and microbes can easily cause cross-contamination of products washed in the same water.

If produce wash water is re-used, whether in dunk tanks or spray wash lines, antimicrobial agents can be added to keep the water at microbially safe levels. When using antimicrobial agents, you must develop a standard and a schedule for testing the water to keep that antimicrobial agent's levels in the water at an effective level.



Produce wash water must either come from a potable source, or be determined to be microbially safe. If re-used, water quality must be maintained to minimize the risk of cross-contamination and to ensure that the water is microbially safe.

Product Packing



QUESTIONS 2-19
AND 2-20

The GAP standard requires new and/or cleaned and sanitized containers for packing and delivering produce. Reuse of boxes is allowed only if they can be cleaned and sanitized between uses. It is not a good practice to reuse cardboard boxes that have been out of your control (i.e. with CSA customers or others), because you cannot be certain how the box has been used or what it's come in contact with during the time it was out of your control. Waxed cardboard boxes cannot be cleaned and sanitized without causing breakdown of the cardboard, though they could be reused with new, unperforated plastic liners. Many farms invest in reusable plastic containers for transporting product to farmers markets or to buyers, or for their CSA customer deliveries. These are meant to be reused, and then clean and sanitized before each use. Whatever packing system is used, the practice must be written into your SOPs and cleaning and sanitizing records or logs are necessary.



Packing fruits and vegetables into new boxes reduces risk of contamination. A piece of paper adds an extra protection from dust or dripping water coming into the top of the box during storage or shipping.

All packing materials and containers should be stored so that they cannot be damaged or contaminated by pests, water, dirt or chemical spills. If they are stored outside, they should be covered. The auditor will observe whether this standard is being met.



Simple systems can be designed to meet your farm's needs. This farm has built an overhead box staging system that keeps boxes off the floor and is convenient for packing product directly from wash tanks.





What are the requirements for cleaning and sanitizing harvest or delivery containers?

Containers should be cleaned by removing dirt and debris first. Scrubbing with water will remove particles and dried-on mud. For sanitizing, you will need to use a chemical compound designed to kill microorganisms. Two of the most common compounds are chlorine bleach and quaternary ammonium compounds (quats). Mixing the appropriate amount as per the label with potable water creates a sanitizing solution.

For some products, it may be desirable to field harvest and pack without a wash step. This may be true of delicate berries or leafy greens, which do not hold up well when wet, or for produce that grows on taller plants off the ground and does not get significantly dirty. There is no GAP standard that says your produce must be washed; only that, if you do wash, it is done in ways that minimize the risk of microbial contamination.

Containers should be cleaned by removing dirt and debris first. Scrubbing with water will remove particles and dried-on mud. For sanitizing, you will need to use a chemical compound designed to kill microorganisms. Two of the most common compounds are chlorine bleach and quaternary ammonium compounds (quats). Mixing the appropriate amount as per the label with potable water creates a sanitizing solution.



Traceability

All harvested product should be marked in accordance with your traceability plan as described in the General Questions section of this guide. For field packing directly into delivery boxes, best practice is to label the box at the time of harvest so accurate information will be conveyed to customers for use in the event of a recall. For produce harvested for transport into a packing shed or other facility, picking records should identify harvested date and location so that information can be carried through into traceability practices at the next stage, according to the plan in your SOPs. The GAP audit requires that you keep documentation of harvest identification for traceback purposes, according to the system defined in your written traceback and recall plan.

QUESTION 2-21
Traceability and recall is covered in more detail in the General Questions section of this Guide under Question G-1 and G-2



Workers may harvest into clean, sanitized buckets designated for harvest, and then dump directly into new boxes. That way, the boxes can be packed in the field and then stacked and stored for later delivery without washing or repacking.

Part 3: House Packing Facility



A house packing facility audit will evaluate whether the packing facility and practices meet the standards for food safety outlined in the GAP/GHP audit checklist. Like a farm's field harvest and packing practices, every packing house operation will reflect the unique characteristics in place at the farm: scale, product grown, harvest season, markets served, transportation and more. Producers must get at least 80% of the points possible in order to pass that section of the audit, but there are various ways to go about meeting the standard.

The scope of the audit is selected by the farm, usually in response to a buyer-request. Many small, diversified farms will not consider this section, as they may be field packing product and selling to a variety of buyers without further handling. However, if a grower operates even a small, simple house packing facility, they should carefully consider contamination risks and prevention strategies to minimize those risks, even if an audit of the packing house is not required by any of the farm's buyers.

This section addresses packing house receiving, washing / packing line, worker health and hygiene, general housekeeping, pest control and traceability.





Receiving

Product coming from the field to the packing station must be staged for packing in such a way that it is protected from contamination. Good practices include protecting the product from contact with agricultural or other chemicals, assuring that there is not standing water coming into contact with containers, protecting the staged product from impact from birds or other animals, and making sure that containers are not stored on the ground. When the product is stored for longer periods of time before packing, similar protections should be in place, with additional attention to controlling the temperature at which the product is stored.



Produce should come into the packing house from the field in good, clean condition, based on field packing guidelines from Part 2 of this guide. Produce bins should be transported without stacking if the bins were on the ground during harvest, but can be stacked if they were packed into clean bins on a flatbed or another barrier was used between the bins and the ground.

QUESTIONS 3-1
AND 3-2



How do I know if my packing operation will be considered “field packing” or “house packing”?

Since the farm selects the sections of the checklist to be audited, this question can be answered in part based on how the farmer/packer views his or her operation.

Generally the difference between a field pack operation and a house pack operation is at what point the product is packed into a final shipping container. A field pack operation will pack directly into the final shipping box or pack at a staging area in or near the field. Alternatively a house packing operation will remove the product from the field, stage it for packing, and then pack into a final shipping box. A house packing operation may include washing, rinsing or cooling the product, possibly a sorting or grading line, sizing the product, and or storing the product.

Washing/ Packing Line



QUESTIONS 3-3
THROUGH 3-7

Managing water in the washing and packing operation will vary from one facility to another, but all require good water management practices to minimize the risk of contamination from water. Essential considerations include:

- ❖ Source water must be potable or microbially safe at first use. That means that after chemical treatment, the water must be microbially safe, which means it must meet the microbial requirements of the EPA drinking water standards.
- ❖ If water is re-circulated and re-used, its quality must be monitored regularly and you must treat with an antimicrobial agent prior to re-using it in your process.



Taking the field heat out of the product can be done a number of ways, including using hydro-coolers, dunk tanks, and by icing the produce.

- ❖ Processing water (dump tanks, flumes, etc.) temperature must be maintained at a temperature appropriate for the produce type. Water temperatures should be maintained within 10° F of incoming product pulp temperature to minimize water infiltration. Usually if water temperature is warmer than the product, this will be a good rule to follow.

Waste water generated in cooling, washing and packing processes, whether chemically treated or otherwise, must be managed to prevent excessive pooling, spilling, or other drainage problems that could lead to contamination risks.

As noted in previous sections, if using municipal water, your municipality is responsible to test and assure that it is potable. Well water must be tested at least once per year. Water tests or municipal reports are required documentation.

Chlorine is commonly added to water for post-harvest treatment of fresh produce at 50-200 parts per million total chlorine, at a pH of 6.0-7.5 with a contact time of 1 or 2 minutes. Chemicals used in this application must be labeled for fruit and vegetables.

FSMA Requirements for Harvest and Post-Harvest Water

The Produce Safety Rule regulates harvest and post-harvest water that is likely to or intended to contact covered produce. Examples of this include water used for washing produce, cooling produce (including ice), applying post-harvest fungicide and wax, handwashing, and cleaning and sanitizing tools and other food contact surfaces.

System Monitoring and Maintenance

The Produce Safety Rule requires active monitoring of agricultural water systems. You must



§112.42

inspect your water system — at least the parts of it under your control — at the beginning of the growing season, and as needed (once annually at a minimum), to identify food safety hazards. This includes inspecting and maintaining your water source and water distribution system (pumps, pipes, faucets, hoses, etc.) in order to prevent equipment malfunction, accumulation of animal and waste debris hazards, and contamination related to pooling water.

Water Quality Standard

The Produce Safety Rule sets a specific standard for harvest and post-harvest water. It must be potable, which means:



§112.44(a)

No detectable generic *E.coli* in 100 mL of agricultural water.

Water Quality Testing

In August 2018, FDA announced that a presence-absence test is allowable under the Produce Safety Rule for harvest and post-harvest agricultural water. (Please note: This is different than the requirement for testing of production water, or water used prior to harvest, where a quantitative test must be used. Please see the FSMA Requirements for Production Water section on pages 70-73 of this guide for more information.) The FDA created a list of water testing methodologies allowed under the Produce Safety Rule. You can review these in the Equivalent Testing Methodologies for Agricultural Water fact sheet in the Templates and Resources section of this guide. (Note: The second page of the fact sheet pertains to harvest and post-harvest water; the first page covers production water tests.)

Testing Frequency

Similar to the USDA GAP/GHP standard, the Produce Safety Rule determines required testing frequency, based on the water source and the relative risk posed by its exposure

to contamination from environmental factors. Untreated surface water cannot be used for harvest or post-harvest activities; further clarification is needed from the FDA on use of treated surface water. Water from a ground source, such as a well, requires more frequent initial testing to establish a baseline of acceptable test results. Specific Produce Safety Rule testing frequencies are outlined below:



§112.44(a) AND
§112.46



Corrective Actions for Harvest/Post-Harvest Water

§112.45(a)

If your harvest or post-harvest water does not meet standard of zero detectable *E. coli*, then you must immediately discontinue use of that water source and alleviate the hazard by taking one of the following steps:

1. Re-inspect the entire affected agricultural water system, identify and correct the likely hazard(s), and take adequate measures to ensure the changes were effective and that the water quality is acceptable before using that source again.
2. Treat your agricultural water with a physical treatment device or an antimicrobial pesticide product that is registered by the U.S. Environmental Protection Agency (EPA).

Monitoring Requirements for Re-Circulated Water



§112.48

For water that is used more than once during harvest, packing, or holding activities (such as water in dunk tanks, or other recirculation mechanisms), there are additional requirements for maintaining safe water quality standards. You must:

- ✦ Establish water-change schedules for re-circulating water;

Water source	Initial baseline survey	Annual testing requirement
Surface	Untreated surface water may not be used for any harvest or post-harvest activities	
Ground	4 or more samples during the growing season or over the period of a year	1 or more samples rolled into profile every year after initial survey if results continue to meet the microbial quality criteria
Public	No testing required, if farmer can document public water system results or a current water supply certificate of compliance	

- ✦ Visually monitor for buildup of organic material (i.e. soil or plant debris); and
- ✦ Maintain and monitor the water temperature appropriate for the type of produce and operation, in order to minimize microbial infiltration.

Recordkeeping

There are several record-keeping requirements related to agricultural water in the Produce Safety Rule, including:

- ✦ The findings of your water system inspections;
- ✦ Results of water quality testing from an accredited lab (or documentation from a public water authority if using public/municipal water);
- ✦ Results of your water treatment monitoring, if treatment is conducted; and
- ✦ Documentation of corrective actions taken if tested water does not meet the numerical quality standard, if applicable.

For more information on the recordkeeping requirements for agricultural water, see the Records Required by the FSMA Produce Safety Rule document in the Templates and Resources section of this guide. In that section, you will also find sample templates for the records mentioned above, except for the records that must be produced by a laboratory or public water authority.



§112.50

Testing Compliance Timeline

The compliance dates for agricultural water standards differ from the general Produce Safety Rule compliance timeline. In 2017, FDA issued a proposed extension to provide farms an additional two years to meet the water requirements; this means compliance dates are expected to be 2022, 2023, or 2024, depending on your farm's size (larger farms have earlier compliance dates). If finalized, farms must *begin* their initial survey by the proposed water compliance dates. See the Overview of the FSMA Produce Safety Rule chapter in this guide for more information on compliance timelines. (Please remember that sprouts have many different requirements under FSMA, including different compliance dates, which are not addressed in this publication. Washington sprouts growers should contact the WSDA Produce Safety Program directly for guidance.)

The FDA also announced in 2017 that they are considering simplifying the agricultural water standards, due to stakeholder concerns that the agricultural water requirements, as written, are too complex to understand, interpret, and implement. FDA is currently working on guidance, collecting more data, and coordinating with stakeholders on how to proceed. While the agricultural water standards are being assessed by the FDA, farms are advised to continue with their existing water quality and monitoring practices, until more is known about the potential changes to the regulatory requirements. This is particularly true for farms with requirements from buyers or a voluntary audit program. Farms that have never tested their water before should consider conducting some initial samples. This applies to farms who are likely to be covered by the Produce Safety Rule, but it is also a recommended best practice for farms that are not covered.



A careful review of your packing house in action will allow you to assess what surfaces may come into contact with produce, and identify measures to keep them clean, and develop a schedule for cleaning and sanitizing.

Food contact surfaces, including table tops, benches, sinks, conveyors and cleaning equipment like brushes can be sources of contamination by workers, produce or other processes in the packing area. These must be cleaned and maintained adequately to minimize this risk. An auditor will visually inspect the facility's processes and food contact surfaces to determine whether the surfaces are in good condition and are being kept adequately clean. Cleaning schedules must be established and followed throughout the season, with records to document.



QUESTIONS 3-8

When product is moved from one station to another, (for instance, from unloading to storage or storage to loading), the potential for contamination from surrounding structures and machinery must be considered. The auditor will observe the possible sources of contamination, such as open-mesh/steel-mesh catwalks



QUESTIONS 3-9

that might allow soil or rocks from workers' shoes to drop down onto the product. Your plan should address these and other possible sources, such as leaking pipes, condensation on ceilings, or motors without shields.

If you're cooling the product using cold water or ice made on-site, the source water must be potable. If ice is purchased from a supplier, the supplier must make, transport and store the ice in sanitary conditions. The auditor will review records and investigate the source of the water as part of an audit. Whether the ice is manufactured on-site or purchased from a vendor, the records showing water potability and a regular schedule for sanitizing the ice production, storage and transportation facilities must be provided to the auditor.



QUESTIONS 3-10
AND 3-11



What are water quality standards requirements for post-harvest produce washing facilities and packing areas?

Any water that is used for washing produce, or used in other harvest and post-harvest activities such as handwashing or washing tools and food contact surfaces in packing areas, must be potable at first use – that is, according to the FSMA post-harvest water standard, the water must have no detectable *E. coli*. If the water is reused, the water quality and/or the level of antimicrobial agents should be monitored to ensure its continued safety. The monitoring must be documented, noting the date, time, and results.

How to Add Sanitizing Agents to Post-Harvest Produce Water



Typical water sanitizers include chlorine and peroxyacetic acid (PAA), a chemical sanitizing solution which is sold under several trade names and is preferred by many certified organic producers.

When using chlorine, the chlorine must be labeled for use on fresh fruit and vegetables. A typical concentration of chlorine is 50-200 ppm of active chlorine at a pH of 6.5-7.5 with a minimum contact time of 1-2 minutes. An important point to keep in mind when using chlorine is that if the pH does not remain in this range, the chlorine will be mostly in an inactive form, so your SOP and operations should include a plan for regularly-scheduled testing of water to maintain appropriate pH levels. This information needs to be documented.

Read product labels carefully in order to apply sanitizers in the right combination of frequency and concentration for use in wash water and on food contact surfaces. Note that you must follow FDA, OSHA and EPA rules for their usage and disposal.

Post-harvest water SOPs should reflect the farm's unique production practices. The water must be sanitized and changed as often as is necessary, given the practices on the farm, to maintain microbially safe status. If the farm either re-uses potable water in its post-harvest processes, or relies on a filtration or sanitizing step to bring water to a microbially-safe standard, then it must develop a water quality testing, treating and changing SOP that prevents contamination and cross-contamination from post-harvest water.

Sanitizer List for Produce

The Produce Safety Alliance maintains a reference tool to help farmers find and choose an EPA-labeled antimicrobial pesticide (sanitizer) appropriate for their farm operations. You can find the sanitizer list on the Produce Safety Alliance's website, at producesafetyalliance.cornell.edu/resources under the "Sanitation" section.

Worker Health and Hygiene

Workers in a packing house should be trained on best practices for handwashing, bathroom, and break room practices, and should demonstrate those practices in the daily packing activities.



QUESTIONS 3-12
THROUGH 3-14

The packing house must have clean, well-maintained, easy-to-access restrooms, and clear signage about handwashing following bathroom usage, breaks for meals, smoking, and other work stoppages.

Break and eating areas should be separate from the packing area, whether that is in a separate building, or simply a cordoned off section of the same building supplied with tables and chairs. Depending on the layout of the packing area, there are several different ways of meeting the GAP standard, which is intended to ensure that workers are not eating or taking breaks directly in the produce areas.

If your SOPs specify use of hair or beard nets, or define when jewelry is/is not allowed to be worn, the auditor will check on-site practices against that written standard. If you require glove use, or if your employees are allowed to wear gloves as a personal preference, (e.g. for warmth in a packing house), your SOPs must include procedures for use, replacement, cleaning and sanitizing of gloves. In all cases employees should demonstrate knowledge of, and compliance with, the SOPs.



If your farm has a policy that requires hairnets or gloves, or prohibits jewelry, workers should be trained and consistently follow the rules. An auditor will look to see whether they are dressed in ways that meet your SOPs.



Packing House Policies

GOOD MANUFACTURING AND HYGIENE PRACTICES

The following good manufacturing and personnel hygiene practices have been established and communicated to all employees as a mandatory rule:

- ✦ Wash hands thoroughly with soap and warm water, and sanitize, before starting work, after each absence from the work station, after using the restroom, after breaks and at any other time when the hands may have become exposed to soil or contaminated.
- ✦ Maintain adequate personal cleanliness. Keep hair tied or short, trimmed and clean fingernails, and, if gloves are not used, free of nail polish.
- ✦ Smoking, eating or drinking is not allowed in work areas.
- ✦ Personal items are not allowed in work areas (bags, purses, jewelry, watches, musical device, etc.).
- ✦ The use of cell phones is not allowed or any electronic devices while working.
- ✦ Wear outer garments and remove all items from top outside pockets.
- ✦ Remove all protective and outer garments and store them in a designated area when on break and before using the restrooms.
- ✦ All minor cuts and wounds must be covered with waterproof detectable blue bandages with metal strip.
- ✦ Report any cuts and/or any illnesses that might be a contamination risk to the fresh product.
- ✦ Any person showing boils, sores, open wounds or exhibiting signs of food-borne illness must be excluded from operations involving direct and indirect food contact.
- ✦ No animals allowed.
- ✦ No children or infants allowed.
- ✦ Employees will stay at their designated area of operations.
- ✦ Produce boxes, lugs and bins are only used for produce:
 - No cross contamination.
 - Mark "X" on unused cases.
 - Non-solid plastic bins are used only for produce.
 - Boxes and lugs must be on a pallet at all times.

This packing house policy from a Washington grower provides a starting place as you plan your policies based on your own practices and risks.

WHEN IN DIRECT CONTACT TO FOOD

Wear gloves. (If gloves are taken home, employees need to discard them. Only use latex-free gloves).

- ✦ Wear hats or hairnets.
- ✦ No jewelry is allowed, except a plain wedding band.

CORRECTIVE ACTIONS

All employees must follow the GM&HP as mandatory rules. If any employee is not in compliance and breaking the food safety rules the following corrective actions must be taken by the immediate supervisor:

- ✦ Remind the employee of the rule being broken.
- ✦ Employee must correct behavior and leave the facility if not able to fulfill the food safety rules (i.e. if he has not reported he is sick).
- ✦ Verbal warning for non-complying to the food safety rules.
- ✦ If reoccurrence, a first written warning will be issued.
- ✦ If second reoccurrence, a second written warning will be issued and employee will be suspended.
- ✦ If third reoccurrence, employee will be terminated.
- ✦ In case of a non-compliance visitor or contractor, the person will receive a verbal warning and will be requested to take a corrective action according to the situation; if the person does not follow the instructions given by the Supervisor or area Manager, the person will be requested to leave the facility.
- ✦ If animal/s is found around the Packing House corrective action will be taken in accordance with 3.12.2 Field Policies.

SICKNESS REPORTS / RETURN TO WORK POLICY

When an employee has reported sick/illness, the Supervisor or area Manager must fill a sick/illness report, and the employee will be authorized to return to work if:

- ✦ Employee meets the GM&HP stated above and no signs of illness are detected, and/or employee presents a doctor's note stating that he/she can safely return to work.
- ✦ The return to work policy has been communicated to all employees as part of the GMP training program.

GENERAL RULES FOR GLASS

- ✦ All lights with the production, storage and maintenance areas are protected in some manner. Where Teflon coated bulbs have been used, copies of invoices have been retained.
- ✦ No glass items are stored in the storage, production or maintenance areas.
- ✦ Glass items are allowed in the break room only – these do enter the production, storage or maintenance areas.
- ✦ Staff is not permitted to bring glass into the storage, production or maintenance areas.
- ✦ Glass thermometers are not allowed inside the storage and production areas.
- ✦ Windows inside the production, storage and maintenance areas are either made of plastic or have been laminated.
- ✦ There are no glass skylights in the facility.

Reprinted with permission from Imperial's Garden, Wapato, WA

General Housekeeping

The packing house environment must be maintained in a sanitary way so that equipment, work surfaces, floor drains and water (including waste water) do not become risks for microbial contamination of your product. Your food safety plan should be based on a review of the packing house, the grounds around it, and its regular uses and activities to make sure there is not a significant source of litter or debris, that water used in the facility is captured and/or drained away from the facility, and that you have identified any potential sources of contamination. Your food safety plan should specify the preventive steps that will be taken to make sure problems don't arise, as well as corrective actions to address them as needed. You will also need to keep documents that the food safety plan required actions are taken.



QUESTIONS 3-15
THROUGH 3-29

If the packing house uses mechanized equipment – such as automated unloading ramps into flumes, automatic sorting or grading equipment, or automated packing lines – then the lubricants and chemicals being used on that equipment must be clearly labeled as food grade product. The auditor will ask to see either the containers of the chemicals and lubricants used, or recent receipts for their purchase.



QUESTION 3-15

If the facility uses non-food grade chemicals or lubricants for purposes like maintaining or cleaning equipment or machinery, those must be located outside the packing area or carefully segregated from contact with the packing line or any contact surfaces that may touch the produce. Food grade and non-food grade chemicals and lubricant must also be stored separately from each other.



QUESTION 3-16

This farm has a specific station for boot washing and hand washing, in a separate area of the packing house from where produce is stored and washed. The boot station allows workers to avoid tracking field dirt or other contaminants into the packing areas.

The handwashing station provides ample space for multiple workers to wash up at the beginning of a shift and after breaks. Note that the hand wash station has all the necessary elements: potable water, disposable paper towels, liquid pump soap, a trash can, and drainage away from the foot traffic area.





The spaces surrounding the packing area should be maintained so there are not significant accumulations

QUESTIONS 3-17
THROUGH 3-19

of standing water, trash, food waste, or other debris that might attract pests or be likely to get tracked back into the facility by workers. The packing house should be located at a good distance from the facility's trash/debris collection areas for the same reason.



An open-air packing shed must be kept clean and regularly monitored for wildlife, pooling water or other contamination risks.

If possible, the packing area should be an enclosed building which will minimize the risk of airborne contaminants, and those that would be carried by things such as rain, pests, and wildlife.



QUESTIONS 3-20
AND 3-21

However, simple open-air pole buildings used as packing sheds can meet the GAP standard if they are sufficiently protected from potential contaminants. In an open-air shed there must be prevention strategies in place to ensure that birds and other pests are not attracted to the area by standing water, waste product, or easy access to nesting materials such as cardboard and paper. The interior work space must be maintained in an orderly and reasonably clean way, with no obstructions of floor drains and no significant standing water.



QUESTION 3-22

Floor drains should be free of any blockages so that water does not pool and create a source of potential contamination. The auditor will likely inspect the floor drains to determine their functionality.



QUESTIONS 3-23
AND 3-24

Spaces through which product moves (e.g. from staging to packing) should be protected from possible contamination from overhead pipes, ducts, fans and ceilings.

Any glass such as light bulbs or lighting equipment that is above the product flow zone represents potential for broken glass to end up in the packed product. The facility's prevention plan might include installing shields over the glass fixture, using shatter-proof light fixtures that cover or enclose the bulb, or applying a coating that retards breakage and shattering.



QUESTION 3-25

Water not intended to be used in the packing process, such as hand-wash sink water, should be drained away from the processing area, and sanitary sewage lines should not leak.



QUESTIONS 3-26

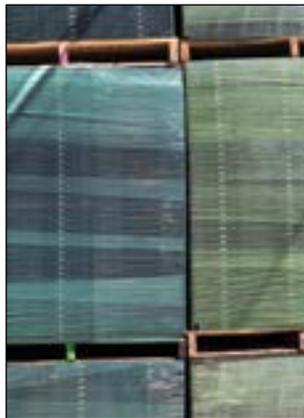
The packing house must have an SOP addressing how to manage product that has been unintentionally damaged or contaminated. This would include product opened after packing, or that has come into contact with the floor. If the farm policy states that product may be packed following contact with the floor, there must be a policy that indicates the procedures (e.g. washing)

to minimize the risk of contamination to the product prior to packing. If the policy is to dispose of the contaminated product, then the method and location of disposal should be written clearly in the policy.

Consistent with guidance provided in previous sections, the packing materials and boxes used in this phase of preparation of the product for market must either be new, single-use cardboard, or must be made of materials intended to be cleaned, sanitized and re-used. The farm's food safety plan must clearly indicate how the packing boxes, pallets and containers will be properly stored, used, and if applicable, cleaned and sanitized in order to minimize the risk of contamination.



QUESTIONS 3-27
THROUGH 3-29



Whether in a small packing shed or large scale packing house, it is important to store boxes up off the ground in a dry, clean location.

FSMA Requirements for Buildings, Tools, and Equipment



§112.121 THROUGH
§112.140

Similar to the GAP/GHP standard, the Produce Safety Rule is also concerned with the appropriateness, maintenance, and cleanliness of the buildings, equipment, and tools used on your farm. For example, the regulation states that all buildings must be suitable in size, construction, and design to ensure sanitary operation and maintenance. Buildings must have adequate plumbing, drainage, and sewage/septic systems for safe distribution of water for all necessary purposes, and disposal of wastewater. Equipment used to transport covered produce should be adequately cleaned prior to use. See sections §112.121 through §112.140 of the Produce Safety Rule reference section of this guide for the full set of requirements pertaining to buildings, tools, and equipment.

Pest Control



QUESTIONS 3-30 THROUGH 3-33

The concepts described in general housekeeping practices for the packing house will inform the development of SOPs and record-keeping for a written pest control plan. Your plan must show the steps taken to ensure that animals (including resident or family pets) and pests are excluded from the packing house. Some of the prevention strategies described above, such as holding your packing materials in a secure way so that pests cannot access them, and disposing of waste product so it doesn't become a pest attractant, are key components of a pest control plan.

In addition to implementing the prevention strategies — such as using bird deterrent tape, putting up screens, and setting traps — you must also document their implementation. You must maintain a written log with the date of inspection, results of the inspection, any corrective actions you've taken, and re-inspection of treated areas. A good practice is to flag or otherwise identify baits and traps in place, and to create a diagram of the facility showing the locations of the baits or traps. Any traps or baits that include the use of poison must be located outside the packing house. Only live traps or non-poison attractants are acceptable for use inside the packing house.

A good pest control program requires frequent monitoring in order to evaluate the effectiveness of the corrective actions taken, and to identify and correct for systemic problems if they are present. The auditor will need to review the documentation showing an adequate pest control plan is being implemented, monitored, and documented. This documentation may be hand-written log books, and could include date/time logs that are affixed to the traps with a sticker, or could be the records kept by a licensed pest control company that is contracted for the service. Service records will be required to be available for review during the audit.

The auditor will also examine the facility's interior walls, doors, floors and ceilings to ensure that, where necessary to prevent access by animals or other pests, any large cracks or crevices have been closed by appropriate blocking or repairs.

FSMA Requirements for Domesticated Animals In/ Near Buildings

In addition to the pest control measures described in this section, the Produce Safety Rule requires that you must keep domesticated animals from contaminating covered produce,



§112.127 AND
§112.134

food packing materials, equipment, or other food contact surfaces in buildings. Specifically, the regulation states that you must exclude or adequately separate (by time, location, or partition) domestic animals from indoor spaces, and have a system in place to adequately prevent contamination of produce by animal waste and litter. (Note: the Produce Safety Rule has different standards for outdoor or partially enclosed spaces; see the FSMA Requirements for Animal Management section on page 78 of this guide for more information.)



Traceability

QUESTION 3-34

The GAP standard for traceability is mandated by the Bioterrorism Act of 2002 which requires packing houses to have sufficient records in order to track produce “one step forward, one step back.”

A traceability program should reflect the unique practices of the farm and packing house. It should be included as part of the SOPs in the food safety plan, and be documented regularly so

an auditor is able to easily review the plan, how it is being implemented, and whether it is sufficient to meet the standard for traceability in the event of a recall. Some of the documents that will capture the basic information include load tickets and field harvest records for product moving from the field to a packing house, plus invoices to the buyers which also include identifying information on the products sold and either delivered or picked up. A mock recall exercise must be completed at least annually.



This farm has many barn swallows, and has developed a plan to deter the birds from entering the packing house in several ways. The entrance to the packing house has plastic strips to keep birds from flying in and out, but still allows food traffic and forklifts in and out. They also placed a decoy owl outside the packing house, along with signs that inform workers to keep doors and curtains closed to keep birds out. Note that there is also a rodent trap just outside the packing house door.



Part 4: Storage and Transportation



Part 4 is generally applicable to farms seeking a Good Handling Practices (GHP) audit, which would cover storage and transportation facilities that are near the crop production areas, or co-located at the farm, but could also be remote from the production area. This includes farms or food hubs that may receive product from other farms and distribute out from there, as well.

This section covers product containers and pallets, pest control, ice and refrigeration, transportation, worker health and hygiene, and traceability.



FSMA Requirements for Storage and Transportation

The topics covered by Part 4 of the GAP/GHP audit (storage and transportation) and discussed in this chapter, are also applicable to the Produce Safety Rule. However, many of the relevant Produce Safety Rule sections have already been addressed in other parts of this guide. For example, topics related to storage and transportation are generally included in the standards for buildings, equipment, tools, and sanitation (§112.121 – §112.140), addressed in the FSMA information in Part 3 of this guide. Rather than repeat the information, we provide the FSMA Produce Safety Rule sections here in brief for your reference:



- ❖ **Building cleanliness and maintenance:** §112.121; §112.122; §112.126; and §112.131 through §112.140
- ❖ **Packing containers and materials:** §112.115 and §112.116
- ❖ **Preventing contamination:** §112.111 through §112.113
- ❖ **Pest control:** §112.128 and §112.134
- ❖ **Ice:** Post-harvest water standards apply. See §112.41 through §112.50.
- ❖ **Cold storage:** §112.114
- ❖ **Transportation:** §112.123 and §112.125
- ❖ **Worker health and hygiene:** Includes health and hygiene standards (§112.31 through §112.33; and §112.129 through §112.130) and employee training standards (§112.21 through §112.30)

Storage Areas, Product Containers, and Pallets

Good Practices for Clean, Orderly Work Spaces

Good management for food safety in a storage facility includes keeping the work space generally free of debris, trash, waste product or other non-essential equipment or supplies. Accumulations of soil or dirt should be removed, and the facility should establish a schedule for cleaning as often as needed to accommodate the volume of product, and the day-to-day practices of the facility.



QUESTIONS 4-1
THROUGH 4-6

If there is bulk storage of product, (e.g. crops like onions or potatoes, which may be stored on the floor or ground in warehouses or cellars), the auditor will verify that records are in place showing the bulk storage area has been cleaned, and it is inspected for foreign objects or other signs of contamination before use. This would not apply to product stored in bins, totes or other kinds of packages.

The product storage area should be protected from external sources of contamination, including windblown debris, rodents, and accumulations of rainwater. The grounds around the building or shed should be free of excessive waste materials, and should not have evidence of standing water.



Whether the product is moving into or out of storage, it must be protected from contamination while in transit. Make sure to keep packed product off the ground or floor at every stage, and use temporary holding areas that are either built facilities (left) or are reasonably shaded and protected from airborne contaminants (right). Mesh coverings are good for providing shaded areas for short term storage but is not sufficient for long-term storage.

Rainfall or recent use of a hose could present evidence of standing water. Auditors will consider this when they review whether any standing water observed appears to be a one-time issue or whether it is evidence of an unresolved systemic problem. The facility supervisor should ensure that when water is spilled sufficient protection is in place (from barriers and drains) to ensure that the water does not accumulate and does not come into contact with, and potentially contaminate, the product.



This farm has a simple product transfer space that is open-air, but reasonably protected from impacts of wind and rain. The sloped gravel pad under the work space allows any waste water or rain accumulations to drain away from the work space, preventing contaminants from being tracked back into the facility on shoes and boots.



If my hand-wash station is outdoors, do I need to collect the water and discard it?

Water should not run freely on the ground as workers' shoes and boots can track bacteria into storage areas or any adjacent packing or production areas. A gravel drainage pad may work, as long as it has capacity to soak up the water without creating pooling. If you need to catch the waste water and dump it, the dumping area should be away from the production or packing area and not a source of contamination to the irrigation water. The waste water should be dumped in an area that workers and visitors do not walk through when coming to and from the field or packing area.



When you're reviewing the ways that waste water is managed on-site, remember that a good indication that there is a pattern of standing water is a greenish color to the water, indicating algae growth. This observation would cause you to review your drainage systems.

Practices for Cleaning Up Spills or Accidents

Any product that is spilled, accidentally opened, or comes into contact with the floor should be considered potentially contaminated. Just as with the House Packing section, the auditor will review your SOP on how to manage such situations. The SOP must describe the corrective action that will be taken, whether discarding the product (and how that will be done), or washing it before re-packing. The auditor will also observe whether your practices match your SOPs.



QUESTIONS 4-7

Maintaining Clean Packing Boxes, Pallets and Storage Bins

As in a packing house or field packing operation, packing containers and other packing material should be stored and properly covered to prevent the possibility of contamination from water condensation, wind, rain, birds, rodents and other outside elements. An enclosed area for storage is a good practice. However, there are circumstances under which storing packing materials outdoors will meet the standards for audit. The auditor will review the on-site storage and usage practices to determine whether materials are adequately protected and monitored to manage the risk of contamination.

Packing containers should not be stored directly on the floor. Pallets used to keep containers off the floor or ground should be in good repair and clean. There should be no foreign material present on the pallets while being used.



QUESTIONS 4-8
THROUGH 4-10



These single-use packing boxes are stored appropriately. The materials are off the ground, stacked and bundled on shelves that are not storing any other chemicals or other contaminants, and the material is protected from rain and wind. The re-useable totes shown are also an example of good practices. They are cleaned and sanitized on a regular schedule, and since the totes do not come into contact with the ground, they can be packed and stacked.



When product is not in immediate use (e.g. it's prepared for transport to a buyer) it still needs to be protected from pests, dirt, water, and other contaminants. Large, clean, plastic bags can be used to loosely cover packed product (left), while custom-fit covers can be ordered that fit snugly on totes (right).

Pallets, pallet boxes, tote bags, and portable bins must be clean, in good condition and not contribute foreign material to the product. Containers holding ready-to-eat produce should be cleaned and/or sanitized. For product that was field-packed, it is important to consider cross-contamination—if containers were on the ground in the field and have dirt from the ground, they should not be stacked for storage. Best practice for field packing is to keep containers off the ground if they are to be stacked for transport or storage.

Product staged or temporarily stored outside in totes, trucks, bins, other containers or on the ground in bulk must be covered and protected from contamination.

Preventing Contamination from Non-Food Substances

Store any substances which are non-food grade in a way that will prevent them from contaminating the product if they spill or leak. If possible, these products will be segregated from the product in a cabinet or other storage unit, but there are other ways to store these products while also ensuring that product is protected from leaks and spills. Whatever system you use, remember that it must be included in your written food safety plan.



QUESTIONS
4-11 AND 4-12

Machinery should be kept clean and well-maintained, which would include inspecting for possible fluid leaks, any broken implements, or other parts that could get deposited into the product. Machinery is assumed to get regular use, so an auditor will not consider a machine that shows signs of use as having failed the cleanliness standard. You must include an SOP and appropriate records to demonstrate cleaning practices for mechanical equipment.



Mechanical equipment will come into direct or at least close contact with the product. The machinery should be cleaned and maintained on a schedule that will keep it in good working condition.

Pest Control



QUESTIONS 4-13
THROUGH 4-16

You must establish and document a pest control program to reduce the risk of contamination from animals including rodents, birds, insects and others. The program may be run by you and your staff, or it can be provided by a commercial operator. A pest control program may include traps, screens, wind curtains, bird deterrent tape and other tools to discourage pests. When using traps and bait systems that require monitoring and maintenance, good practice is to number traps or bait stations and create a map or diagram of those, with traps identified by the code established.

Your pest control plan should include policies and procedures that prevent even your pets from accessing your storage and transportation staging areas, carts, trucks, and buildings and other enclosures.

Frequent monitoring is important to make sure your measures are effective in minimizing pests, and to identify any new pest intrusions that should be addressed. There must be a pest control log that includes dates of inspection, inspection report and steps that are taken to eliminate any problems. If you've elected to use a commercial provider of the service, the provider's records and documents showing the implementation of the established program must be available for the auditor to review.

Pests can also enter the facility through improperly maintained structures. Interior floors, ceilings and walls including doors, flooring and vents should be inspected for cracks, holes and other openings. Any identified risks should be properly blocked, repaired and/or sealed off.



A storage facility can be attractive to pests, from rodents to migratory birds, and including resident cats, dogs and other family pets. Strategies for pest prevention include ensuring buildings are properly maintained, setting bait stations and traps, and keeping spaces free of debris and waste product. The owl statue and plastic curtains are good practices for preventing insect and bird intrusions. Traps should be monitored and documented regularly. Pests can also enter the facility through improperly maintained structures. Interior floors, ceilings and walls including doors, flooring and vents should be inspected for cracks, holes and other openings. Any identified risks should be properly blocked, repaired and/or sealed off.



Ice and Refrigeration

Ice and Cold Water Used for Cooling Produce

Ice, like water, can be a carrier of many microorganisms, including pathogens that cause illness. Under certain circumstances even small amounts of contamination can result in food-borne illness. Ice or cold water used to cool the product must come from a potable water source (see Part 1 - Farm Review for information on potable water). The auditor will need to see test results on the source of water being used to cool produce or make ice (whether the ice is made on-site or is purchased from a vendor), and will need to review the testing records showing the water is potable.



QUESTIONS 4-17
AND 4-18

Ice-making equipment, tools used to handle or transport ice, and ice storage need to be cleaned and sanitized on a regular basis. Whether making ice on-site or purchasing from an outside supplier, you will need to provide records showing that there is a cleaning and sanitizing schedule for ice production, storage, and transportation. Make sure your plan includes equipment such as conveyors, belts and augers if they are used.



Making and storing ice requires that the source water be potable, and the machinery, storage, and tools are cleaned and sanitized on a regular schedule. Employee practices like washing hands and using gloves are good practices as ice is delivered to the product in the packing box. Remember to document these practices as part of your training.

Water that contacts the product after harvest must be potable at first use, and must be treated to stay at a microbially safe level if it is re-used. Hoses, tables, conveyor belts and employees' hands all assist in delivering wash and cooling water, and each touch-point must be considered carefully in order to prevent the risk of contamination of the product at this critical point.

Cold Storage

All cold storage spaces need to be monitored to ensure that they are working well and that the temperature is appropriate for the produce being stored. Your SOP should make clear what temperatures are expected for storage of different products, and you will need to maintain temperature logs to demonstrate that the standards are being met. The auditor will observe cold rooms and review your written log showing regular monitoring to ensure the temperature is maintained appropriately to minimize the survival and replication of food-borne microbes.



QUESTIONS 4-19
THROUGH 4-23



Temperature probes or thermometers must be checked or calibrated on a regular basis, and the results must be recorded.

Refrigeration systems often drip water as a result of the humidity and temperature in the room. Your food safety plan should review and anticipate this. Product should not be stored under known dripping areas. Product stored near or under refrigeration equipment must be packed and protected so that if unanticipated dripping occurs the product will not be contaminated by that water.

If packed product is stacked on shelves, make sure that any iced product is on the bottom so that as the ice melts there is not potential for cross-contamination from dripping water that has been in contact with one product and could drip onto another.



Refrigerated storage can be a valuable tool to extend the freshness and life of the crop. Cold rooms must have proper attention to temperature, humidity, and cleanliness or they can become a source of contamination of the product.

Transportation and Loading

Cleanliness, temperature control, and minimizing cross-contamination are essential to maintaining the quality of produce.

Everyone involved in transportation has a role to play to ensure that there isn't excessive risk of cross-contamination as a result of improper cleaning between loads, inappropriate combining of loads, or faulty temperature control during transportation. Communication between drivers and operators is essential to preventing contamination during transportation.

Trucks, carts, and other kinds of conveyances of the product should be regularly inspected for debris, trash, and foul odors. Transportation equipment should be cleaned on a regular schedule. Consider carefully the characteristics of the load a truck has hauled prior to your fresh product. Any contaminants left behind can be a source of contamination of your product. For example, if animals, animal products or non-food grade chemicals have been part of the previous load, ensure that cleaning regimes are sufficient to take care of residual contamination such as animal droppings, animal odors, or drips from containers. Making sure that inspection, cleaning, and sanitizing is done regularly, and the results recorded will help show the auditor that the operation is using good practices. The auditor will need to review your SOP on required cleaning of conveyances used to transport your product.

If the produce is going to be a partial load in a truck, you must ensure that the other products are not risks for contaminating your product. For instance, produce should not be shipped with meat, fish, or poultry, or with fertilizers, pesticides, or other chemicals.



QUESTIONS 4-24
THROUGH 4-27

If your product will be shipped by an outside party, you will need an SOP requiring shippers to ensure that the product is not loaded with other products that could contaminate your produce. Similarly, you must work with any transporter to ensure that temperature controls are maintained from loading to destination, appropriate to the products being shipped. Not all products require refrigeration, and it is okay for that to be part of your SOP.

Because damaged product is more susceptible to microbial contamination, loading practices should minimize the potential for damage to the product. Written SOPs must be in place indicating good loading practices to minimize product damage, including how you will convey this information to transportation partners, such as food hub operators and distributors.

Worker Health and Personal Hygiene



QUESTIONS 4-28
THROUGH 4-30

Staff lunchrooms, break rooms, and locker rooms must be clearly separated from storage, shipping, and receiving areas to prevent eating or taking breaks in the product areas. In a large facility this might be a separate room, and in a smaller operation it might just be a covered area or a designated area supplied with tables that is immediately outside the ordinary work area.

Some farms make it a policy to require hair and beard nets in order to prevent stray hair from getting into the product. If this is a written policy in their SOPs, the auditor will observe whether the policy is being followed by the staff.

There are a number of reasons that some facilities require employees to take off watches and jewelry during work hours. Watch bands and jewelry can harbor microorganisms, rings and earrings can be dropped into the product, and all could present a risk for injury depending on the kind of machinery in use in the facility. If there is a written policy in your SOPs, the auditor will review the policy and observe whether the policy is being followed.

Pathogens often transmitted by food contaminated by infected employees

Pathogen	Symptoms
Hepatitis A virus	Fever, jaundice, vomiting
Salmonella species	Nausea, vomiting, diarrhea, fever
Shigella species	Diarrhea, fever, cramps
<i>E. coli</i> 0157:H7	Severe abdominal pain, watery diarrhea, vomiting
Staphylococcus aureus	Diarrhea, nausea, vomiting
Streptococcus pyogenes	Fever, Sore throat with fever

Reprinted with permission from Plant & Pest Advisory, Rutgers Cooperative Extension, New Jersey Agricultural Experiment Station

Traceability

You must have a documented traceability system in place, and keep records of incoming and outgoing product with enough detail to allow you to trace the product “one step forward” and “one step back.” The company’s traceability plan will be written specifically to reflect the practices in place, and will be reviewed by the auditor to see that it provides sufficient detail to capture the source and the destination of the product.



QUESTION 4-31



This farm runs only product grown in its own fields through its packing facility and into its small, on-site cold storage. Products are identified by field number (e.g. “14” below), and by date, which are captured in a bar code on the sticker affixed to the outside of each packed box. During harvests of products where workers are paid by-the-piece, the identification labeling also includes who picked it. From harvest to packing, and cold storage through transportation, this numbering system makes it simple to track the product forward one step and back one step, which is required as part of a traceability plan.



Templates and Resources

This section contains sample record-keeping templates and information resources on a variety of topics. The documents are organized in the same general order that they are discussed in the guide.

The table of contents indicates which part(s) of the GAP/GHP Audit and/or the FSMA Produce Safety Rule each document pertains to. The Produce Safety Rule requires certain records. For those records that are required by the rule, if applicable to your farm, the templates are marked with a [•] symbol on the table of contents. Beyond these required records, you may find it useful to track some of your other food safety activities; certain GAP/GHP record templates can be useful in this case. Templates for records that fall into this category are marked with a [o] symbol on the table of contents.

You may use the sample record templates as-is, or adapt them for use on your farm.

All of the records templates are available in digital formats (PDF, Word, or Excel) on the thumb drive attached to this guide. The Resource numbers (R1, R2, etc.) correspond to the names of the files on the thumb drives, for easier identification of each document.

		FSMA Produce Safety Rule	GAP/GHP Audit: General Qs	GAP/GHP Audit: Part 1	GAP/GHP Audit: Part 2	GAP/GHP Audit: Part 3	GAP/GHP Audit: Part 4
Recordkeeping Templates							
R1	Records Required by the FSMA Produce Safety Rule	•					
R2	Qualified Exemption Review	•					
R3	Worker Training Record	•	•	•	•	•	•
R4	Water System Inspection Record	•					
R5	Water Treatment Monitoring Record	•			•	•	
R6	Ag Water Die-Off Corrective Measures Record	•					
R7	Compost Treatment Record	•		•			
R8	Cleaning and Sanitizing Record	•			•	•	•
R9	Standard Operating Procedure (SOP) Worksheet		•	•	•	•	•
R10	Deviations and Corrective Actions Log		•	•	•	•	•
R11	Example Traceback Log		•		•		
R12	Form 1: Sample Mock Audit Log		•				
R13	Form 2: Recall Product Information		•				
R14	Form 3: Sample Recall Contact List		•				
R15	Form 4: Recall Notification Form		•				
R16	Form 5: Recall Product Retrieval		•				
R17	Form 6: Recall Follow-Up Plan		•				
R18	Illness/Injury Report Form	○	•				
R19	Restroom Cleaning Log	○	•				
R20	Sample Soil Amendment Application Log	○	•				
R21	Water Source Testing Log			•			
R22	Water Testing Result Log			•			
R23	Septic System Inspection Log	○		•			
R24	Pest/Rodent Control Log	○		•			•
R25	Manure Application Log	○		•			
R26	Risk Assessment: Previous Land Use and Site Selection				•		
R27	Delivery Vehicle Inspection and Cleaning Log				•	•	•
R28	Equipment List				•		
R29	Sample Water Monitoring Log					•	
R30	Break Area Cleaning Log					•	
R31	Building Repair, Cleaning, and Maintenance Checklist					•	•
R32	Equipment Inspection, Cleaning, Maintenance, and Calibration						•
R33	Preventative Cleaning/Maintenance Schedule						•
R34	Cooler Temperature Log						•
R35	Thermometer Calibration Log						•
R36	Refrigerated Vehicle Temperature Monitoring						•
Information Resources							
R37	WSDA On-Farm Readiness Reviews	•					
R38	WSU Extension Produce Safety Resources	•	•	•	•	•	•
R39	Produce Safety Alliance Fact Sheet	•					
R40	FSMA Technical Assistance Network At-a-Glance Flier	•					
R41	FDA Enforcement Discretion for Certain FSMA Provisions	•					
R42	FDA Fact Sheet: Biological Soil Amendments of Animal Origin	•					
R43	FDA Fact Sheet: Equivalent Testing Methodologies for Ag Water	•					
R44	Group GAP Fact Sheet				General info		
R45	Harmonized GAPs Fact Sheet				General info		
R46	Harmonized GAP Alignment with Produce Safety Rule FAQ				General info		
R47	Harmonized GAP Plus+ Q & A				General info		
R48	WSDA Organic / GAP Comparison Fact Sheet				General info		
R49	Recall Plan Checklist		•				
R50	PSA Food Safety for Flooded Farms Fact Sheet			•			
R51	Cleaning and Sanitizing Tools and Harvest Containers				•		
R52	Sample Field Policies – Imperial’s Garden				•		
R53	Sample Packing House Policies – Imperial’s Garden					•	

Records Required by the FSMA Produce Safety Rule

K. Woods, D. Pahl, D. Stoeckel, B. Fick, G. Wall, and E.A. Bihn

**This publication has not been approved by the FDA and should not be considered legal guidance. It is provided in response to PSA training participants who asked for examples of records required by the FSMA Produce Safety Rule.*

The FSMA Produce Safety Rule (PSR) requires a few specific records. This publication summarizes the provisions requiring records and includes template records to help establish records to meet FSMA PSR requirements. Growers may want or need to keep additional records to ensure that required practices are being carried out correctly, to meet buyer requirements, and/or participate in a third party audit. Other documentation, such as Standard Operating Procedures (SOPs), may be helpful to support the implementation of practices on the farm.

Throughout this factsheet, the  icon indicates a template record is provided. Clicking on the icon will take you to an example record. The template records provided are examples of required records. They have not been approved by FDA and other formats may be used. This publication should be used in conjunction with the Produce Safety Alliance (PSA) Grower Training Curriculum and the PSR preamble and codified regulation. It should not be used as a standalone reference.

All records required by the PSR must contain certain information as outlined in § 112.161. Except as otherwise specified, all required records must include:

- The name and location of the farm
- Actual values and observations obtained during monitoring
- An adequate description of covered produce, if applicable to the record (e.g. the commodity name, or the specific variety or brand name of a commodity, and any lot number or other identifier)
- The location of a growing area or other area, if applicable to the record (e.g. a specific field or packing shed)
- The date and time of the activity documented

Records must also be created at the time an activity is performed or observed, be accurate, legible, indelible, dated, and signed or initialed by the person who performed the activity.

Records to Support a Farm's Coverage or Exemption Status

Subpart A, General Provisions, outlines what farms and commodities are covered by the Produce Safety Rule

§ 112.2 requires documentation to support an exemption from FSMA Produce Safety Rule requirements for produce undergoing a further processing step. Broadly, this includes:

- Farm documentation accompanying the produce stating that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”

Qualified Exemption Review Template	
Name and address of farm:	_____
Date:	_____
Sales receipts or records reflecting total food sales over the previous 3 years:	
Year 1 (Sales year: _____)	\$ _____
Year 2 (Sales year: _____)	\$ _____
Year 3 (Sales year: _____)	\$ _____
Average total food sales	\$ _____

- A written assurance from the customer that the produce will be processed to adequately reduce microorganisms of public health significance. This assurance must be obtained annually.

§ 112.7 requires records to establish eligibility for a qualified exemption. Records, such as receipts, must demonstrate that the farm satisfies the criteria for a qualified exemption. This includes a written record reflecting that the grower has performed an annual review and verification of the farm’s continued eligibility for the qualified exemption. Receipts must be dated, but no signature is required. The annual review verifying the farm’s qualified exemption must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Personnel Qualifications and Training (Subpart C)

§ 112.30 requires documentation of required training. Documentation must include the date of training, topics covered, and the names of persons trained. Required training topics are outlined in § 112.22. Training records must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Worker Training Record Template

Name and address of farm: _____ Date: _____

Trainer: _____ Training time: _____

Topics Covered: _____

Training materials: Please attach any printed materials related to the training. Also reference any relevant SOPs or sections of the farm food safety plan that apply.

Employee Name (please print)	Employee Signature
1. _____	_____
2. _____	_____
3. _____	_____

Agricultural Water (Subpart E)

§ 112.50(b) requires the following records that are relevant to agricultural water:

1. The findings of the inspection of the agricultural water system in accordance with the requirements of § 112.42(a). This record does not require a review but it is a best practice to have records reviewed to assure they are correct. 
2. Results of any analytical tests conducted on agricultural water to comply with FSMA Produce Safety Rule provisions. Test results are obtained from the lab and must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made.
3. Scientific data or information growers rely on to support the adequacy of the methods related to water treatment.
4. Documentation of the results of water treatment monitoring carried out under § 112.43(b). Water treatment monitoring records must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 
5. Scientific data or information relied upon to support the microbial die-off rate between harvest and end of storage or removal rate during activities such as washing, if used in accordance with § 112.45(b)(1)(ii).

Water System Inspection Record Template

Name and address of farm: _____

See farm policy for specific water distribution system inspection procedures.

Date	Time	Water Source and/or Distribution System	Observations	Corrective Actions Taken	Initials
4/22/16	7:00 AM	Well 1, north field	Well casing in good shape, backflow prevention device in place, no broken pipes	None	EAB
4/22/16	9:00 AM	Pond, south field	Significant geese presence	Introduced swan decoys. Will monitor	EAB

Water Treatment Monitoring Record Template

Name and address of farm: _____

Please see the food safety plan for overall water treatment procedures.

Date	Time	Water pH	Water Temperature	Turbidity	Sanitizer (name & rate)	Corrective Action Needed (yes or no)	Initials
10/14/16	8:35 am	8.5	65° F	25 NTU	NaOCl 75 ppm	Yes - pH was too high, added citric acid; retested - pH 7.0	EAB
10/14/16	12:00 pm	7.0	72° F	47 NTU	NaOCl 85 ppm	no	EAB

6. Documentation of corrective measures taken in accordance with § 112.45(b) if agricultural water does not meet the numerical water quality criteria in § 112.44. A template corrective measures record specifically for the die-off provision § 112.45(b)(1) is provided as a resource. This record must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Agricultural Water Die-Off Corrective Measures Record Template

Name and address of farm: _____

Water source: _____

Current calculated GM: _____ CFU/100 mL water

Current calculated STV: _____ CFU/100 mL water

Calculated Interval: _____ Days

Adjusted GM: _____ CFU/100 mL water

Adjusted STV: _____ CFU/100 mL water

EXAMPLE

Water source: Southwest pond

Current Calculated GM: 100 CFU/100 mL water

Current Calculated STV: 800 CFU/100 mL water

Calculated Interval: 1 days (0.5-log)

Adjusted GM: 80 CFU/100 mL water

Adjusted STV: 200 CFU/100 mL water

Field	Crop	Date and time of beginning of crop harvest	Date and time of end of last water application	Time interval since last water application	Harvest Supervisor Initials
2A	Cortland Apple	9/23/2016, 1:00 PM	9/21/2016, 4:00 PM	2 days	DMP
2A	Cortland Apple	9/25/2016, 10:00 AM	9/21/2016, 4:00 PM	4 days	DMP

7. Annual documentation of the results or certificates of compliance from a public water system as outlined in §§ 112.46(a)(1) or (2), as applicable. Annual records from the public water system can be obtained from the water authority.

8. Scientific data or information to support any alternative microbial water quality criteria, die-off rates, or sampling frequencies established and used on the farm in accordance with § 112.49.

9. Support for any equivalent analytical methods used in lieu U.S. EPA method 1603 (modified mTEC).

Biological Soil Amendments of Animal Origin (Subpart F)

§ 112.60(b) requires records for biological soil amendments of animal origin.

For soil amendments that growers treat and apply on their own farms, records must be kept to document that process controls (e.g., time, temperature, and turnings) were achieved. Records related to on-farm soil amendment treatment must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Compost Treatment Record Template

Name and address of farm: _____

Type of compost method: Withdraw Date piled: 9-15-2016 Date finished: _____ Row number: 2

List all ingredients added to compost: Poultry litter, kitchen scraps, dried leaves, straw

Use this record for on farm composting. Record the date piled, turning dates, and the temperatures maintained. Use one sheet for each pile or row.

Date Turned	Temp/Time Test Area 1	Temp/Time Test Area 2	Temp/Time Test Area 3	Temp/Time Test Area 4	Initials
9-25-2016	135 F/ 2:00 PM	138 F/2:01 PM	140 F/ 2:03 PM	135 F/ 2:04 PM	EAB
9-26-2016	137 F/ 2:15 PM	137 F/ 2:18 PM	138 F/ 2:19 PM	137 F/ 2:25 PM	EAB

For soil amendments received from a third party, growers must document annually that:

- The process used to treat the biological soil amendment of animal origin is a scientifically valid process that was carried out with appropriate process monitoring; and
- The biological soil amendment of animal origin has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin.

Equipment, Tools, Buildings, and Sanitation (Subpart L)

§ 112.140(b)(2) requires that growers subject to the rule establish and keep a record of the date and method of cleaning and sanitizing equipment used in covered harvesting, packing, or holding activities. This record must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Cleaning and Sanitizing Record Template

Name and address of farm: _____

List the date, time, tool or equipment name, and method for each for each cleaning or sanitizing activity.

Date	Time	List tools/equipment	Cleaned and/or Sanitized?	Method used	Cleaned By (Initials)
10/11/16	10:07 AM	Harvest tools	cleaned	See Cleaning SOP (Removed dirt with brush, washed with detergent, rinsed, air dried)	EAB
10/11/16	10:30 AM	Dump Tank	cleaned and sanitized	See Dump Tank Cleaning and Sanitizing SOP (drained tank, washed with detergent, rinsed, sanitized with 150 ppm NaOCl)	EAB

Storage of Records, Allowable Record Types, and Off-Site Storage (Subpart O)

§ 112.162 allows for the storage of records offsite if such records can be retrieved and provided onsite within 24 hours of official request. Electronic records are acceptable if they can be accessed on the farm.

§ 112.163 specifies that existing records do not need to be duplicated if they contain all of the required information. For instance, if records are kept for organic certification and they include the required information, there is no need to duplicate these records.

§ 112.164 requires that records be kept for at least 2 years past the date the record was created. Records that a farm relies on to support a qualified exemption must be retained as long as necessary to support the farm's status.

§ 112.165 requires the records be kept as original records, true copies or electronic records.

§ 112.166 outlines requirements for making records available and accessible to FDA.

- Records must be readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request. Growers have 24 hours to obtain records kept offsite, even if the farm is closed for a prolonged period.
- Records must be provided to FDA in a format that is accessible and legible.

§ 112.167 specifies that records obtained by FDA in accordance with the Produce Safety Rule are subject to the disclosure requirements under 21 CFR part 20 (Public Information). All of the templates provided in this document are marked Confidential to reduce the likelihood that farm records would be released in response to a Freedom of Information Act (FOIA) request submitted to FDA should they obtain or copy farm records.

Qualified Exemption Review *Template*

Name and address of farm: _____

Date: _____

Sales receipts or records reflecting **total food** sales over the previous 3 years:

Year 1 (Sales year: _____) \$ _____

Year 2 (Sales year: _____) \$ _____

Year 3 (Sales year: _____) \$ _____

Average total food sales \$ _____

Average food sales to qualified end users (E.g. consumers, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation) \$ _____

\$ _____ ÷ \$ _____ x 100 = _____ %

Average food
sales to qualified
end users

Average total
food sales

**Percent sales
to qualified
end users**

*Sales receipts must also be retained to support this record.

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR Reference § 112.7(b) Confidential Record

Worker Training Record *Template*

Name and address of farm: _____ Date: _____

Trainer: _____ Training time: _____

Topics Covered: _____

Training materials: Please attach any printed materials related to the training. Also reference any relevant SOPs or sections of the farm food safety plan that apply.

Employee Name (please print)

Employee Signature

1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____
6. _____	_____
7. _____	_____
8. _____	_____
9. _____	_____
10. _____	_____
11. _____	_____
12. _____	_____

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.30(b) Confidential Record

Modified from On-Farm Decision Tree Project: Worker Health, Hygiene, and Training—v14 07/16/14
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Water System Inspection Record Template

Name and address of farm: _____

See farm policy for specific water distribution system inspection procedures.

Date	Time	Water Source and/or Distribution System	Observations	Corrective Actions Taken	Initials
4/22/16	7:00 AM	Well 1, north field	Well casing in good shape, backflow prevention device in place, no broken pipes	None	EAB
4/22/16	9:00 AM	Pond, south field	Significant geese presence	Introduced swan decoys. Will monitor	EAB

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.50(b)(1) Confidential Record

Modified from On-Farm Decision Tree Project: Agricultural Water for Production—v4 07/17/2014
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.comell.edu

Water Treatment Monitoring Record Template

Name and address of farm: _____

Please see the food safety plan for overall water treatment procedures.

Date	Time	Water pH	Water Temperature	Turbidity	Sanitizer (name & rate)	Corrective Action Needed (yes or no)	Initials
10/14/16	8:35 am	8.5	65° F	25 NTU	NaOCl 75 ppm	Yes - pH was too high, added citric acid; retested -pH 7.0	EAB
10/14/16	12:00 pm	7.0	72° F	47 NTU	NaOCl 55 ppm	no	EAB

*Not all of the above factors may need to be recorded. Refer to the product's EPA label for specific use instructions.

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.50(b)(4) Confidential Record

Modified from On-Farm Decision Tree Project: Postharvest Water—v7 07/16/2014
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Agricultural Water Die-Off Corrective Measures Record Template

Name and address of farm: _____

Water source: _____
 Current calculated GM: _____ CFU/100 mL water
 Current calculated STV: _____ CFU/100 mL water
 Calculated Interval*: _____ Days
 Adjusted GM: _____ CFU/100 mL water
 Adjusted STV: _____ CFU/100 mL water

EXAMPLE

Water source: Southwest pond
 Current Calculated GM: 190 CFU/100 mL water
 Current Calculated STV: 690 CFU/100 mL water
 Calculated Interval: 1 days (0.5-log)
 Adjusted GM: 60 CFU/100 mL water
 Adjusted STV: 220 CFU/100 mL water

Field	Crop	Date and time of beginning of crop harvest	Date and time of end of last water application	Time interval since last water application	Harvest Supervisor Initials
2A	Cortland Apple	9/23/2016, 1:00 PM	9/21/2016, 4:00 PM	2 days	DMP
2A	Cortland Apple	9/25/2016, 10:00 AM	9/21/2016, 4:00 PM	4 days	DMP

* Attach documentation to support calculations (e.g. the Ag Water Excel Tool at wcfis.ucdavis.edu). If a die-off rate other than the specified 0.5 log/day in § 112.45(b)(1) is used, include documentation supporting the alternative die-off rate as required by § 112.50(b)(8).

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.50(b)(6) Confidential Record

Compost Treatment Record Template

Name and address of farm: _____
 Type of compost method: Windrow Date piled: 9-15-2016 Date finished: _____ Row number: 2

List all ingredients added to compost: Poultry litter, kitchen scraps, dried leaves, straw

Use this record for on farm composting. Record the date piled, turning dates, and the temperatures maintained. Use one sheet for each pile or row.

Date Turned	Temp/Time Test Area 1	Temp/Time Test Area 2	Temp/Time Test Area 3	Temp/Time Test Area 4	Initials
9-25-2016	135 F/ 2:00 PM	138 F/2:01 PM	140 F/ 2:03 PM	135 F/ 2:04 PM	EAB
9-26-2016	137 F/ 2:15 PM	137 F/2:18 PM	138 F/ 2:19 PM	137 F/ 2:25 PM	EAB

Proper compost production requires a minimum temperature of 131°F be maintained for 3 days using an enclosed system OR a temperature of at least 131°F for 15 days using a windrow system, during which the materials must be turned 5 times (FSMA Produce Rule. 2015. Rule 21 CFR part 112.54(b)).

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.60(b)(2) Confidential Record

Modified from On-Farm Decision Tree Project: Soil Amendments—v5 7/16/2014
 E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Cleaning and Sanitizing Record Template

Name and address of farm: _____

List the date, time, tool or equipment name, and method for each for each cleaning or sanitizing activity.

Date	Time	List tools/equipment	Cleaned and/or Sanitized?	Method used	Cleaned By (Initials)
10/11/16	10:07 AM	Harvest tools	cleaned	See Cleaning SOP (Removed dirt with brush, washed with detergent, rinsed, air dried)	EAB
10/11/16	10:30 AM	Dump Tank	cleaned and sanitized	See Dump Tank Cleaning and Sanitizing SOP (drained tank, washed with detergent, rinsed, sanitized with 150 ppm NaOCl)	EAB

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.140(b)(2) Confidential Record

Standard Operating Procedure - WORKSHEET

Below is a general outline for a Standard Operating Procedure. Please answer all of the questions with as much detail as possible. If a question does not apply to your procedure, please specify "N/A." This is not the only way to develop your Standard Operating Procedures (SOPs). There are many resources online to help in the construction of SOPs.

1.0 PURPOSE

Why do we need this procedure and what is to be accomplished?

2.0 SCOPE

To what areas will this procedure be applied?

3.0 REFERENCES

What documents are related to this procedure?

4.0 DEFINITIONS

Are there any words that require defining (acronyms, scientific terms, technical language)?

Deviations and Corrective Action Log

Instructions: List all major deviations, complaints and their related cause(s), corrective action(s), preventative measures and modified procedures. Record that employees have been trained on the new procedures.

Date/Time of Deviation or Complaint	Person Notified	Major Deviation/Complaint and Description	Corrective action	Course of action to prevent recurrence (e.g., training employee)	New/Modified Procedures	Employees Trained on New/Modified Procedures ? (✓)	Signature of trainer

Form 1: Sample Mock Audit Log

Date Conducted: 9/10/11

Lot #: 310

Conducted by: *Sam*

Product traced: *Cucumbers* Buyer Name: _____ Buyer phone: _____

Step backward	Step forward	Harvest date	Harvest Location	Harvester	Packing date	Packer	Shipping date	Customer(s) contacted	Amount of product remaining from original shipment at customer	Amount of Product Sold by Buyer
		9/10/11	<i>Field 13</i>	<i>Mary, Jon</i>	<i>9/11/11</i>	<i>Sam</i>	<i>9/11/11</i>	<i>LMNOP Distributors</i>	<i>2 Cases</i>	<i>25 cases</i>

Reviewed By: _____ Date _____

FORM 2

PRODUCT INFORMATION

Product	Lot Number/ Code/Date	Lot Quantity	Shipped To			Quantity Shipped and Requiring Recovery
			Name/Location	Date Shipped	Quantity Left On-Farm	
			TOTAL=			

Form 3: Sample Recall Contact List

Farm Name, Address, Contact person and phone number and/or Logo

Product Withdrawal: Still under the farm's control (at the warehouse, on the truck). Product has not reached the consumer.

Product Recall: In the hands of the consumers and the consumers need to be notified.

You should have a plan to handle product traceability, recovery and disposal of affected product. This may mean designating a field for disposal or a commercial landfill where it can be taken.

Farm Name

Name of Contact #1

Phone # (w)

Phone # (c)

Name of Contact #2

Phone # (w)

Phone # (c)

Buyer #1

Name of Contact #1

Phone # (w)

Phone # (c)

Name of Contact #2

Phone # (w)

Phone # (c)

Buyer #2

Name of Contact #1

Phone # (w)

Phone # (c)

Name of Contact #2

Phone # (w)

Phone # (c)

Buyer #3

Name of Contact #1

Phone # (w)

Phone # (c)

Name of Contact #2

Phone # (w)

Phone # (c)

Buyer #4

Name of Contact #1

Phone # (w)

Phone # (c)

Name of Contact #2

Phone # (w)

Phone # (c)

Other Relevant Contacts

Name of Auditor

Name of Company

Phone # (w)

Phone # (c)

Other Important Contacts

Name

Phone # (w)

Phone # (c)

To view Guidance for Industry, Product Recalls, Including Removals and Corrections, see <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>

On-Farm Decision Tree Project: Traceability—v11 8/1/2014 10

E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014

www.gaps.cornell.edu

FORM 4

RECALL NOTIFICATION

The following information is to aid you when contacting people to recall your product. Fill out one sheet for each group contacted.

This is _____ . I am calling from _____
Name of Recall Coordinator *your operation's name*
to notify you that all product _____ on _____ needs to be
lot # *date/time*

returned, destroyed, modified, etc.

I have the following questions to ask you about this recall:

1. Who do I speak to about a recall and what is their contact information?

Contact (name): _____

Phone Number: _____

Fax Number: _____

Title: _____

2. Do you have any of the product(s) being recalled? (If no, terminate questioning)

_____ YES _____ NO

If the answer to question #2 is YES, the product must be _____
returned, destroyed, modified, etc.

3. The _____ of this product will be dealt with by
return, destruction, modification, etc.

action intended

4. Have you received any reports of illness or injury related to this product?

_____ YES _____ NO

If yes, please provide details.

Thank you for your time.

Confirmation Signature: _____ **Date:** _____

FORM 5

PRODUCT RETRIEVAL

Quantity Shipped and Requiring Recovery (from Form 2)	Date/ Time (from Form 4)	Person Contacted	Quantity Recovered or Destroyed	Quantity Remaining With Contact	Action Taken and Description (e.g., picked up, returned, destroyed, etc.)	Quantity Recovered
TOTAL =						
(Total to equal the total on Form 2)						

FORM 6
FOLLOW-UP PLAN

1. Why was there a recall (i.e., what was the source of the problem)?

2. What corrective action(s) was/were taken? (*List and describe*)

3. What ongoing procedures did you put in place to prevent recurrence of the problem?

4. Identify the person(s) responsible for ensuring the above actions and procedures are monitored and implemented.

Confirmation Signature: _____ **Date:** _____

Illness/Injury Report Form^π

Completed forms will be collected and kept on file by the supervisor.

Worker Name: _____

Today's Date: _____

Person Completing Report: _____

INJURIES:

Date and Time of Injury: _____

Details of Injury: _____

Action taken (bandaged, sent to hospital, etc. Please identify which hospital if applicable):

ILLNESS:

Date and Time of First Illness Symptoms: _____

Symptoms: (check all that apply)

_____ Fever _____ Vomiting _____ Diarrhea

_____ Respiratory _____ Jaundice (e.g., yellowing of skin) _____ Nausea

_____ Sore Throat w/ Fever _____ Lesions (on exposed skin)

_____ Other (explain below)

Action taken if applicable (e.g., sent to hospital. Please identify which hospital if applicable):

Did the employee see a doctor? _____ Yes _____ No

(If yes, explain diagnosis if relevant and not confidential):

Date employee expects to return to work:

If returned to work on the same day, document if employee was assigned to fruit/vegetable handling job or a non-handling job, and for how long:

Restroom Cleaning Log

Date of Cleaning	Cleaned by	Supplies filled	Further actions necessary?

Reviewed by: _____ Date: _____

Sample Soil Amendment Application Log

Name of farm: Pleasant Valley Farm

This log should be used to record soil amendments applied to fields on your farm. Use one log for each crop for each season.

Date:	Plot:	Crop:	Quantity Used:	Type of Amendment:	Date Planted:	Date Harvested:	Application Method:	Initials:
5/2/2013	*A-1	Tomato	1.5 tons/acre	Composted manure	5/15/2013	7/1/2013	Broadcasting	ska

*This is the code name of the field/plot/row you have designated for that area (same as you will use in your traceability program). For example, A is the field and 1 is the plot within that field.

Reviewed by: _____ Title: _____ Date: _____

Water Source Testing Log

Save any document providing information on test methods and test results from your laboratory.

Test Date	Water source (surface, well)	Laboratory	Test Run / Results	Corrective actions if necessary	Initials
9/10/11	Well water	Minnesota Valley Testing Lab	Nitrites, nitrates, Total coliforms. All within normal levels	None needed	MP

Reviewed by: _____ Date: _____

Water Testing Result Log

Save any documents providing information on test methods and test results from your laboratory.

Date	Water Source (Type/ Location/Name)	Laboratory	Type of Test Performed	Results	Corrective Actions (if necessary)	Initials

Septic System Inspection Log

Name of farm: _____ Age of system: _____
 Type of system: _____

Date:	Observations of Drain field:	Tank Condition	Lid Condition	Identified by (Initials):	Corrective Actions:	Date Corrective Action Completed:	Completed by (Initials):
4-26-14	Smelly odor, soggy ground	intact	intact	ABC	Had it pumped, receipt on file. No risk to crops, located well away from growing area.	5-5-14	ALW

Reviewed by: _____ Title: _____ Date: _____

Pest/Rodent Control Log^π

Name of Operation:

Pest/Rodent Company Used* or Self	Date of Service or Action Taken	Type of Pest	Type of Control**	Location of Traps	Traps Checked (date)	Checked by (name)	Disposal Means

*If using a company for service, attach report or receipt of service for each of their visits.

**List type of control methods used such as exclusion, traps, poison, repellants, etc.

Delivery Vehicle Inspection and Cleaning Log

Date	Vehicle Description	Inspection Results	Actions Taken	Initials
9/10/11	Delivery Van	Trash in back, dog hair present	Vacuumed and removed trash	MP

Reviewed by: _____

Date: _____

Equipment List

Name of Operation: _____

Equipment Type	Brand/Model	Condition	Additional comments (if required)	Initials
Example: Tractor	John Deere 30HP	Good – no leaks	Repaired leaky gasket; 10 Dec 2010	djh

Reviewed by: _____ Title: _____ Date: _____

Sample Water Monitoring Log

Name of operation: _____

Please see the food safety plan for overall water treatment procedures.

Date	Time	Water pH	Water Temperature	Pulp Temperature (if applicable)	Turbidity	Sanitizer (name & rate)	Water Changed (yes or no)	Initials
10/14/13	8:35 am	7.0	65° F	50° F	25 NTU	NaOCl 75 ppm	No	EAB

Reviewed by: _____ Title: _____ Date: _____

Break Area Cleaning Log

Date:	Cleaned by :	Supplies filled as applicable:	Further actions necessary?

Building Repair, Cleaning, and Maintenance Checklist

Instructions: *Inspect both the interior and exterior of your buildings (e.g., packinghouse, storage areas) monthly when in use and where possible.*

Completed by: _____ **Date:** _____

Building ID #/Name: _____

Interior of Building (Permanent Structures)	Exterior of Building (Permanent Structures)
<ul style="list-style-type: none"><input type="checkbox"/> No holes/crevices/leaks in the building (e.g., walls, windows, screens)<input type="checkbox"/> Lights are shatterproof and adequate<input type="checkbox"/> No pipes or condensation leaking<input type="checkbox"/> Floor drainage is good (floor sloped, drain covers clear)<input type="checkbox"/> Floors, walls and ceilings are clean and free from garbage, spills, rodent droppings, etc.<input type="checkbox"/> Floor is free of crevices that could harbour pests or debris<input type="checkbox"/> Fans are dust-free and clean<input type="checkbox"/> Animals (wild or domestic), pests (insects, rodents, etc.) and bird nests are not present<input type="checkbox"/> All materials are in designated areas (e.g., packaging materials and product)	<ul style="list-style-type: none"><input type="checkbox"/> No holes/crevices/leaks in the building (e.g., walls, windows, screens)<input type="checkbox"/> All windows can be closed OR have close-fitting screens that are in good condition<input type="checkbox"/> ½ meter wide perimeter strip of stone or crushed gravel OR short grass around building<input type="checkbox"/> No junk piled within 3 m of building (e.g., old or unused machinery, garbage)<input type="checkbox"/> Weeds are controlled<input type="checkbox"/> Land drainage around building is good<input type="checkbox"/> Dumpsters are emptied as needed to prevent pest infestation, and surroundings are free of debris<input type="checkbox"/> All doors are close-fitting<input type="checkbox"/> Doors that can be secured (i.e., to lock storages when unsupervised)
	<p style="text-align: center;">Exterior of Building (Non-Permanent Structures)</p> <ul style="list-style-type: none"><input type="checkbox"/> Roof or cover (i.e., tarp)<input type="checkbox"/> Land drainage around structure is good<input type="checkbox"/> No areas where pests can live/feed/hide within 3 m of structure (e.g., old or unused machinery, garbage)<input type="checkbox"/> Weeds are controlled

Preventive Cleaning/Maintenance Schedule

Use this schedule to keep track of the frequency of cleaning and sanitation which covers all food and non-food contact surfaces in your packinghouse including floors, drains, walls, ceilings, transporting equipment (e.g. pallet jacks, carts, trolleys and forklifts) if applicable, cooling equipment, foreign material control devices (if applicable), food contact equipment, tools and utensils and other surfaces that may pose a contamination risk.

Area to be Cleaned/Preventative Maintenance to be Done (e.g. packinghouse floor drains, routine maintenance of conveyor belt etc.)	Frequency (daily, weekly, monthly etc)	Person(s) responsible

Cooler Temperature Log^π

Name of operation: _____

Storage Cooler number: _____ Thermometer number: _____

Please see the OFFS Project Resources section for thermometer calibration instructions at <http://onfarmfoodsafety.org/resources/risk-assessment-resources/>.

Date	Thermometer Calibrated Date	Recorded temperature		Corrective actions if necessary:	Result of corrective actions and date accomplished	Initials
		AM	PM			

^π Michele Schermann, University of Minnesota, FSP4U A Food Safety Plan (Template) for You. <http://safety.cfans.umn.edu/pdfs/FSP4U.pdf>

Thermometer Calibration Log^π

Thermometer Calibration Date:	Deviation from 32° F?	Corrective Actions (if necessary):	Result of Corrective Actions and Date Accomplished:	Initials

Refrigerated Vehicle Temperature Monitoring ^π

Name of Operation: -----

Vehicle Number: _____ Thermometer Number: _____

Please see the food safety plan for overall temperature control procedures and thermometer calibration instructions.

Date	Commodity Being Transported	Required Temperature	Actual Temperature	Corrective actions if necessary (e.g., Is vehicle pre-cooled?):	Result of corrective actions and date accomplished:	Initials



Washington State On-Farm Readiness Reviews

The Washington State Department of Agriculture (WSDA) is offering free, educational on-farm assessments to help farmers comply with the Food Safety Modernization Act's (FSMA) Produce Safety Rule.

These On-Farm Readiness Reviews (OFRR) are non-regulatory and voluntary. WSDA staff trained in the new rule will visit your produce farm to help you assess whether your produce safety practices meet the requirements of the Produce Safety Rule (PSR) and prepare you for produce safety inspections.

These voluntary farm assessments are being done in partnership with the U.S. Food and Drug Administration (FDA), Washington State University (WSU), the Washington State Tree Fruit Research Commission (WSTFRC) and other industry partners.



An OFRR is **personalized**.

Every farm is different which means the produce safety risks will vary. The results of an OFRR are customized for the needs of your farm. An OFRR is an opportunity for reviewers to observe practices in action and make tailored suggestions. Reviews should be conducted as close as possible to harvest time with each visit lasting approximately 2 hours.

During the visit, you can ask your specific food safety questions. The reviews are discussion-based between farmers and a small review team that will include WSDA staff and additional subject matter experts at the discretion of the farm.

An OFRR is **non-regulatory**.

An OFRR is an educational assessment, not an inspection or audit. The goal is to identify areas for produce safety improvement and prepare your farm for an actual inspection.

The OFRR assessment is a high-level overview of the farm operation and focuses on farm activities without a formal



record review. However, reviews could include discussion of records required to comply with the Produce Safety Rule. The assessment will give farms a better sense of what to expect from a routine inspection.

If a reviewer observes a serious, egregious condition that could pose an imminent public health hazard, the reviewer will work with you to take corrective action on-site. As long as the product has not entered commerce and the issue can be immediately addressed, reviewers will not take any regulatory action nor notify FDA or any other regulatory agency.

An OFRR is free.

OFRRs are federally funded through a WSDA cooperative agreement with FDA, so there is no cost to farmers for these assessments. Please contact the WSDA Produce Safety Program at agr.wa.gov/producesafety if you have questions about whether you have any exemptions from the PSR.



This publication was made possible by Grant Number U18FD005913 from the U.S. Food and Drug Administration funding program PAR-16-137. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the FDA.



How to request an OFRR

Farms of all types and sizes are welcome to schedule an OFRR, but priority will go to farms where at least one person has attended the PSR-required Produce Safety Alliance (PSA) Grower Training. The PSA Grower Training is the only FDA-approved produce safety curriculum that provides a foundational understanding of the regulation and will aid in the review process. For more information on the PSA training visit:

producesafetyalliance.cornell.edu
or foodsafety.wsu.edu.

To schedule an OFRR, visit agr.wa.gov/producesafety and complete the Produce Farm Inventory enrollment form, or contact Karen Ullmann at:

kullmann@agr.wa.gov
or 206-714-6125.



WASHINGTON STATE
UNIVERSITY
E X T E N S I O N

PRODUCE SAFETY RESOURCES

Washington State University's extension program is committed to providing you with support to implement the best food safety practices on your farm. Whether you are just getting started or have been farming for generations, we have programs and resources to assist you.

TRAINING

One of our strengths is providing produce safety training programs for all sizes and scales of operations. Please visit our website at <http://foodsafety.wsu.edu/training-programs/> for a comprehensive list of our training programs and to find a calendar of events. Some of the training programs available are:

- **Good Agricultural Practices grower training.** Learn the basics of implementing science-based best practices on your farm through a series of topical presentations focusing on site selection, water quality, soil amendments, wildlife control, postharvest handling, working health and hygiene, traceability and transportation. Our goal is to make food safety practical for you so that you can incorporate key principles into your farming practices. Additionally, we provide examples for food safety plan language, example standard operating procedures and monitoring logs. Training typically encompasses one day and is offered on-demand in collaboration with our county-based programs.
- **Produce Safety Alliance Grower Training.** This curriculum covers the FSMA Produce Safety Rule requirements as well as Good Agricultural Practices (GAPs) for on-farm food safety. This training is one way to meet the requirements of 21CFR Part 112.22(c) which requires that at least one supervisor or responsible party from a farm subject to the FSMA Produce Safety Rule must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration. The seven module PSA Grower Training Course was designed to be delivered in one day and is offered regionally.
- **Hazard Analysis and Critical Control Points for Fruit and Vegetable Packinghouses.** The Hazard Analysis and Critical Control Points (HACCP) workshop will help packers of fruits and vegetables learn about the HACCP principles and have an opportunity to

apply this knowledge with oversight of instructors that are experts in this field. Through hands-on learning, participants will be able to practice identifying food safety hazards, developing control measures, and determining approaches for documenting and verifying their actions. Course content and examples will be geared towards fresh fruit and vegetable packers. This 2.5 day course is offered regionally.

- Keep up with our **calendar of events** at <http://foodsafety.wsu.edu/news-and-events/> and join our email distribution list by contacting Cathy Blood at blood@wsu.edu.

ONLINE RESOURCES

Our goal is to provide you with the best resources to stay abreast of food safety best practices. We are continuously developing and updating written materials, videos and training aids that can be used to develop your on-farm programs or train employees. Here are links to our library of resources by topic:

- **Site Selection and Land Use**
<http://foodsafety.wsu.edu/produce-safety/site-selection-and-land-use/>
- **Worker Health and Hygiene**
<http://foodsafety.wsu.edu/produce-safety/worker-health-and-hygiene/>
- **Preharvest Agricultural Water**
<http://foodsafety.wsu.edu/produce-safety/preharvest-agricultural-water/>
- **Postharvest Water**
<http://foodsafety.wsu.edu/produce-safety/postharvest-water/>
- **Map of Water Testing Labs**
<http://foodsafety.wsu.edu/produce-safety/map/>
- **Soil Amendments**
<http://foodsafety.wsu.edu/produce-safety/soil-amendments/>
- **Wildlife and Domesticated Animals**
<http://foodsafety.wsu.edu/produce-safety/wildlife-and-domesticated-animals/>
- **Cleaning and Sanitation**
<http://foodsafety.wsu.edu/produce-safety/cleaning-and-sanitation/>
- **Packinghouse Management**
<http://foodsafety.wsu.edu/produce-safety/packinghouse-management/>
- **Traceability and Transport**
<http://foodsafety.wsu.edu/produce-safety/traceability-transport/>
- **Recordkeeping**
<http://foodsafety.wsu.edu/produce-safety/recordkeeping/>

CONTACT US

Please reach out to Dr. Faith Critzer, the Produce Safety Extension Specialist, at faith.critzer@wsu.edu.

Produce Safety

ALLIANCE

Providing fundamental, science-based, on-farm food safety knowledge to fresh fruit and vegetable farmers with an emphasis on small scale operations

producesafetyalliance.cornell.edu

What is the Produce Safety Alliance (PSA)?

The Produce Safety Alliance was established to help prepare fresh produce growers to meet the regulatory requirements included in the United States Food and Drug Administration's Food Safety Modernization Act (FSMA) Produce Safety Rule. The PSA is supported through a cooperative agreement funded by the USDA and the FDA.

Why is the PSA Important?

The PSA provides fundamental, science-based, on-farm food safety knowledge to fresh fruit and vegetable farmers, packers, regulatory personnel and others interested in the safety of fresh produce. This includes assessing produce safety risks, implementing Good Agricultural Practices, and how to meet regulatory demands associated with the FSMA Produce Safety Rule, as well as meet buyer requirements for food safety.

Key Details about the PSA Grower Training Curriculum

Through a four year nationwide development process, including ten Working Committees and eight grower focus groups, a seven module curriculum was developed. The curriculum includes content covering Good Agricultural Practices, co-management, and the new FSMA Produce Safety Rule requirements.

The curriculum is designed to meet grower needs. Modules 1 through 6 align with sections outlined in the FSMA Produce Safety Rule. Module 7 is focused on helping growers develop a written farm food safety plan. Even though a farm food safety plan is not required in the FSMA Produce Safety Rule, it is included in the curriculum because growers expressed a need for a plan in focus groups and as part of the Working Committees. Many growers need a written farm food safety plan in order to meet buyer demands for a third-party audit to verify produce safety practices are in place.





Produce Safety Alliance Curriculum Modules

Module 1: Introduction to Produce Safety

Module 2: Worker Health, Hygiene, and Training

Module 3: Soil Amendments

Module 4: Wildlife, Domesticated Animals, and Land Use

Module 5: *Part 1:* Production Water; *Part 2:* Postharvest Water

Module 6: Postharvest Handling and Sanitation

Module 7: How to Develop a Farm Food Safety Plan

PSA Efforts to Support Produce Grower Trainings

In order to effectively provide produce safety information, educational resources, and technical assistance to an estimated 186,000 fruit and vegetable farms across the country, the PSA currently has collaborators and trainers in all 50 states from Land Grant Universities, the produce industry, regulatory offices, and grower organizations—and our network is continually growing! The PSA has developed a two-day Train-the-Trainer Course to create a cadre of qualified trainers to support dissemination of the curriculum nationally. The PSA is also collaborating with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and other organizations to support international training programs for both growers and trainers. The PSA launched both the Grower Trainings and the Train-the-Trainer Courses in September 2016. Trainings are being conducted on a regular basis throughout the U.S. and are listed on the PSA Website!

How do I get more information about the PSA and training opportunities?

Visit our website at producesafetyalliance.cornell.edu and join the general listserv to stay up to date with the PSA's education and training activities as well as the FSMA Produce Safety Rule. In addition, the curriculum development process can be reviewed and resources can be found on the website, including links to academic collaborators, government websites, industry organizations, training events, and additional educational resources related to produce safety.

Have more questions? Do not hesitate to contact us!

Elizabeth A. Bihn, Ph.D.

Produce Safety Alliance Director

Department of Food Science

Cornell University

630 W. North Street, Jordan Hall–NYSAES

Geneva, NY 14456

Phone: (315) 787-2625 • Fax: (315) 787-2216

E-mail: eab38@cornell.edu

Gretchen L. Wall, M.S.

Produce Safety Alliance Coordinator

Department of Food Science

Cornell University

630 W. North Street, Jordan Hall–NYSAES

Geneva, NY 14456

Phone: (607) 882-3087

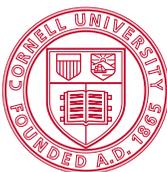
E-mail: glw53@cornell.edu



Find us online:

facebook.com/ProduceSafetyAlliance

twitter.com/Produce_Safety



Cornell University

FSMA Technical Assistance Network

At-a-Glance

The FDA Food Safety Modernization Act (FSMA) Technical Assistance Network (TAN) is now operational and providing technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. The TAN will address questions related to the FSMA rules, FSMA programs, and implementation strategies after the rules are final. We encourage stakeholders to first visit FDA's FSMA webpage at www.fda.gov/fsma, which contains detailed information on all aspects of FSMA, including implementation. The webpage includes Frequently Asked Questions about FSMA by topic area. FDA is implementing the TAN in two phases:

- Phase 1 addresses inquiries related to the publication of FSMA rules and is operational.
- Phase 2 will provide technical assistance to FDA and State staff performing inspections and supporting compliance activities; it will be implemented by 2017 when preventive controls inspections are targeted to begin.

Below are the key features of the TAN:

- Inquiries may be submitted through a web form. The web form can be accessed at www.fda.gov/fsma. Go to **Contact Us** and then **How to Contact FDA on FSMA**.
- Inquiries may also be submitted by mail if the Internet is not available at the following address:

Food and Drug Administration
5100 Paint Branch Pkwy
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: the FSMA related mailboxes (e.g. FSMA@fda.hhs.gov and FSMAfags@fda.hhs.gov) are no longer active.

- Inquiries are answered by FDA Information Specialists or Subject Matter Experts, based on the complexity of the question. Complicated questions may require more time for a response. FDA will respond to inquiries received as soon as possible. However, response times may vary, due to complexity of question and the volume of inquiries we receive.
- Once a question is submitted, the inquirer will receive notification of receipt and a case number to be referenced in future correspondence.
- Questions will be tracked and trended using a Knowledge Management System (KMS) to assist FDA in prioritizing, in part, FSMA policy, guidance, and training. Additionally, repeat questions will be addressed in Frequently Asked Question or guidance documents posted on FDA's website.
- Routine communication and data-sharing protocols with external TANs, e.g. Alliances (such as the Food Safety Preventive Controls Alliance), are vital for coordination and success.

At this time, FDA does not intend to enforce certain provisions in four regulations implementing FSMA.

Which provisions and why?

The FDA has announced that it does not intend to enforce certain provisions in four of the rules that implement the FDA Food Safety Modernization Act (FSMA). The enforcement discretion covers certain entities or activities covered by the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal food rules (PC Human Food and PC Animal Food or CGMP & PC rules), Foreign Supplier Verification Programs rule (FSVP), and the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule (Produce Safety rule).

While this enforcement policy is in place, FDA will consider the most effective and practical approaches to address issues that have been raised since the FSMA rules became final and provide long-term certainty for stakeholders.

1. CERTAIN FACILITIES CONDUCTING FARM-RELATED ACTIVITIES THAT ARE SUBJECT TO THE PREVENTIVE CONTROLS REQUIREMENTS.

Farms are exempt from the preventive controls and CGMP requirements in the CGMP & PC rules. Produce farms are typically covered by the Produce Safety rule, unless an exemption applies. The enforcement policy applies to certain facilities conducting farm-related activities. Some of these facilities also conduct activities not within the farm definition even if conducted on farms (e.g., coloring RACs).

FARM-RELATED ACTIVITIES: These are activities within the definition of “farm” if performed on farms. These activities include growing and harvesting crops and some manufacturing/processing activities: drying/dehydrating raw agricultural commodities (RACs) to create a distinct commodity, treating RACs to manipulate ripening, and packaging and labeling RACs.

RAW AGRICULTURAL COMMODITY: RACs are a food in its raw or natural state, including fruits that are washed, colored, or otherwise treated in their unpeeled form. Grains and eggs are examples of non-produce RACs.



■ Why does FDA intend to exercise enforcement discretion for certain facilities that conduct farm-related activities?

Some establishments that fall outside of the current “farm” definition conduct activities that also are typically conducted on farms. However, because those establishments are not considered farms, they are subject to the preventive controls and CGMP requirements (unless another exemption applies).

The agency intends to initiate a rulemaking that could change the way the requirements in the PC rules apply to facilities that conduct activities similar to those that occur on farms, as farms are currently defined. The FDA intends to exercise enforcement discretion for the requirements in the PC rules for these specific entities and activities until the completion of a future rulemaking related to farm activities.

■ Which facilities and activities does this enforcement discretion apply to?

TABLE 1. Summary of Enforcement Policy with Regard to Human Food

Description of facilities and activities conducted by the facilities	Does enforcement discretion apply for human food preventive controls requirements?	Does enforcement discretion apply for human food CGMPs?
<ul style="list-style-type: none"> Facilities that would qualify as Secondary Activities Farms except for the ownership of the facility 	<ul style="list-style-type: none"> Yes 	<ul style="list-style-type: none"> No, for farm-related activities conducted on produce RACs. Yes, for farm-related activities conducted on non-produce RACs.
<ul style="list-style-type: none"> Facilities that would qualify as farms if they did not color RACs 	<ul style="list-style-type: none"> Yes 	<ul style="list-style-type: none"> No, for coloring produce RACs. Yes, for coloring non-produce RACs.
<ul style="list-style-type: none"> Facilities that would qualify as Secondary Activities Farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity such as dried beans 	<ul style="list-style-type: none"> Yes 	<ul style="list-style-type: none"> No, for produce RACs. Yes, for non-produce RACs.

TABLE 2: Summary of Enforcement Policy with Regard to Animal Food

Description of facilities and activities conducted by the facilities	Does enforcement discretion apply for animal food preventive controls requirements?	Does enforcement discretion apply for animal food CGMPs?
<ul style="list-style-type: none"> Facilities that would qualify as Secondary Activities Farms except for the ownership of the facility 	<ul style="list-style-type: none"> Yes 	<ul style="list-style-type: none"> Yes
<ul style="list-style-type: none"> Facilities that would qualify as farms if they did not color RACs 	<ul style="list-style-type: none"> Yes 	<ul style="list-style-type: none"> Yes
<ul style="list-style-type: none"> Facilities that would qualify as Secondary Activities Farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity such as dried beans 	<ul style="list-style-type: none"> Yes 	<ul style="list-style-type: none"> Yes
<ul style="list-style-type: none"> Farm mixed-type facilities making silage food for animals 	<ul style="list-style-type: none"> N/A for small and very small businesses (because they are exempt from animal food preventive controls requirements). Yes, for businesses that are not small or very small. 	<ul style="list-style-type: none"> Yes

A few notes about the charts:

- For those entities covered by the enforcement discretion, the enforcement discretion applies to all their preventive controls requirements, all animal food CGMPs, and all human food CGMPs for non-produce RACs. The enforcement discretion for human food CGMPs does not include activities conducted on produce RACs, many of which have long been subject to human food CGMPs. Further, the human food CGMPs provide an option for establishments to comply with the produce rule for certain activities involving produce RACs.
- The ownership issue pertains to the current requirement that a secondary activities farm be majority-owned by the primary production farm and that the majority of the RACs come from the primary production farm. FDA is considering changes to this requirement.
- A facility that only packs, packages, labels and/or holds RACs that have been dried or dehydrated to create a distinct commodity currently falls outside of the farm definition because the facility is not involved in growing or harvesting the produce so it is not a primary production farm. Further, the facility is not devoted to harvesting, packing and/or holding RACs because these dried/dehydrated commodities are processed foods, so it cannot be a secondary activities farm.

- Coloring RACs is not included within the farm definition. Although it is a type of manufacturing/processing, unlike most manufacturing/processing, it does not convert a RAC into a processed food.
- Silage is food for animals made by storing and fermenting green forage plants, such as corn stalks, bean plants and grass.

■ How will the FDA continue to protect public health while following this enforcement policy?

The FDA will continue to enforce the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce.

2. WRITTEN ASSURANCES IN THE “CUSTOMER PROVISIONS” IN THE PC HUMAN FOOD, PC ANIMAL FOOD, FSVP, AND PRODUCE SAFETY RULES.

Each of the four rules — PC Human Food, PC Animal Food, FSVP, and Produce Safety — includes “customer provisions” intended to provide written assurance to a manufacturer, processor, importer, or farmer that the food will be processed to control for hazards before the food reaches consumers.

For the PC rules, these provisions apply when a manufacturer/processor relies on other entities (commercial customers) in the distribution chain to control certain identified hazards, i.e., when there will be further processing of the food before it reaches consumers.

The FSVP rule includes customer provisions that apply when an importer imports food for which the hazards are controlled after importing.

Additionally, produce is eligible for an exemption from many of the requirements in the Produce Safety rule if it will receive commercial processing that adequately reduces the presence of microorganisms of public health significance, and certain other conditions are met including requirements for disclosure statements and written assurances similar to what’s required by the CGMP & PC rules and FSVP.

In these provisions, “customer” means the commercial customer, not consumers.

■ Why does the FDA intend to exercise enforcement discretion for the written assurance requirements?

The FDA has received feedback that certain product distribution chains would require vastly more written assurances and resources to comply than was anticipated by FDA during the rulemaking process. The agency intends to exercise enforcement discretion for the written assurance requirements, while it considers rulemaking that takes into consideration the complexity of supply chain relationships and the resources required to meet the current requirements of these provisions.

■ How does the FDA intend to protect public health while following this enforcement policy?

During this enforcement policy period, manufacturers, processors, importers, and farmers are still required to disclose to their customer that the relevant hazards have not been controlled. Subsequently, those customers (or other customers thereafter) will still be required to comply with all other applicable requirements in federal and/or state and local laws, including the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce.

3. IMPORTATION OF FOOD CONTACT SUBSTANCES UNDER FSVP

A food contact substance is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. The FSVP regulation applies to the importation of “food” as that term is defined in the Federal Food, Drug and Cosmetic Act, which includes food contact substances.

■ Why does the FDA intend to exercise enforcement discretion for food contact substances under FSVP?

After considering the issue, including comments and information provided by stakeholders, the FDA has determined that because of certain characteristics related to the nature of food contact substances, FDA’s premarket review and oversight of food contact substances, and the regulatory framework for these substances, it is appropriate to exercise enforcement discretion with regards to the FSVP regulation. In other words, FDA does not intend to require importers of food contact substances to comply with the requirements of FSVP.

■ How does the FDA intend to protect public health while following this enforcement policy?

Food contact substances undergo extensive premarket review under the agency’s Food Contact Notification (FCN) and food additive petition processes, which require petitioners to demonstrate that the intended use of the food contact substance is safe. Furthermore, if a food contact substance has not been authorized by the FDA through the FCN or food additive petition processes, the agency would consider the food product adulterated. The FDA will continue to enforce the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce.

4. CERTAIN MANUFACTURING/PROCESSING ACTIVITIES FOR HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD

Human food facilities that are subject to and in compliance with the human food CGMPs and FDA’s other food safety requirements, and that **do not** further manufacture/process their human food by-products once the by-products have been separated for use as animal food are **only** subject to a limited holding and distribution CGMP for their by-products.

Human food facilities that are subject to the PC Human Food rule that **do** further manufacture/process their human food by-products after they separate them for use as animal food are subject to **all** of the requirements in the PC Animal Food rule, unless an exemption applies. However, these facilities have the choice of complying with the PC and CGMP requirements in either the PC Human Food or Animal Food rules.

■ Why does the FDA intend to exercise enforcement discretion in this situation?

In 2016, the FDA published Draft Guidance for Industry #239, “Human Food By-Products For Use As Animal Food,” in which the agency identified some activities it does not consider to be further manufacturing/processing for the purpose of determining whether the human food facility is subject to just the limited holding and distribution CGMPs, or the full range of PC and CGMP requirements.

Since issuing that guidance, the FDA has become aware of concerns about how the preventive controls requirements apply to certain activities performed on human food by-products for use as animal food before they are stored or transported and which do not affect their safety profile.

The agency intends to exercise enforcement discretion for the following activities:

- Drying/dehydrating, evaporating, pressing, chopping and similar activities to reduce weight, bulk, or volume and/or
- Mixing, centrifuging, and similar activities to combine ingredients or separate components (e.g., water and solids).

This enforcement discretion does not apply when these activities are performed to prevent or significantly minimize animal food hazards, or when these activities introduce animal food hazards.

■ How does the FDA intend to protect public health while following this enforcement policy?

The enforcement discretion does not apply to the specified activities when they are performed to prevent or significantly minimize animal food hazards, or when the activities introduce animal food hazards. Additionally, the FDA will continue to enforce the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce.

FDA FACT SHEET

Produce Safety Rule (21 CFR 112)

BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN

What are Biological Soil Amendments of Animal Origin (BSAAO)?

- *Biological soil amendment[s] of animal origin* are biological soil amendments which consist, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term “biological soil amendment of animal origin” does not include any form of human waste¹.
- *Biological soil amendments* are any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.
- *Biological soil amendments of animal origin* include untreated: cattle manure; poultry litter; swine slurry; or horse manure.

Does the Produce Safety Rule prohibit the use of biological soil amendments of animal origin?

No. The Produce Safety Rule **does not prohibit** farms from using a BSAAO, including manure produced as part of a sustainability or co-management program, nor does it prohibit farms from producing or storing compost on site. Covered farms must conduct relevant activities in accordance with the provisions of the Produce Safety Rule, such as handling, conveying, and storing untreated BSAAO such that they do not contaminate treated BSAAO and do not become a potential source of contamination to covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, agricultural water distribution systems, or treated soil amendments.

Where in the Produce Safety Rule can I find the requirements on biological soil amendments of animal origin?

Requirements for biological soil amendments of animal origin can be found in Subpart F (§§ 112.50-60), in the Produce Safety Rule.

What is the difference between treated and untreated biological soil amendments of animal origin?

- A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54.
- A biological soil amendment of animal origin is untreated if it:
 - Has not been processed to completion in accordance with the requirements of § 112.54;
 - Has become contaminated after treatment;
 - Has been recombined with an untreated biological soil amendment of animal origin; or

¹ 21CFR §112.53 states that the use of human waste is prohibited for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

- Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness.

Does the Produce Safety Rule require testing for treated biological soil amendments of animal origin?

No. FDA does not require microbial testing of any biological soil amendments of animal origin. Instead, we have provided the microbial standards to which treatment processes described in §112.54 must be validated. **Farms can use any treatment process or processes that have been validated to meet the relevant microbial standard in § 112.55 without the need to test the end products.** For static and turned composting processes, we have codified in §§112.54(b)(1) and (b)(2), respectively, two scientifically validated BSAAO treatment processes that have already been validated to meet the microbial standards in §112.55(b). If your operation follows one of these two examples of a biological treatment process (i.e., turned or static composting), then you would not have to do any process validation.

When can I harvest my crop after I apply untreated biological soil amendments of animal origin to my field?

We are deferring action on an application interval until we have pursued certain steps. We are conducting a risk assessment and supporting research to supplement science on understanding what effectiveness the integration of an appropriate interval or intervals may have on protecting public health. Following the completion of the risk assessment and research, we expect to:

- (1) Provide stakeholders with data and information gathered from scientific investigations and risk assessment;
- (2) consider such new data and information to develop policy decisions from the science-based conclusions;
- (3) provide an opportunity for public comment on our tentative decisions; and
- (4) consider public input to finalize the provision(s) establishing an appropriate minimum application interval(s).

What documents do I need if I use treated biological soil amendments of animal origin on covered produce?

If you receive treated biological soil amendments of animal origin from a third party, § 112.60(b)(1)(i) requires covered farms to:

- Receive and maintain documentation, at least annually, demonstrating that the process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring.
- Receive and maintain documentation, at least annually, that the biological soil amendment of animal origin has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin.

If your farm produces its own treated biological soil amendment of animal origin, § 112.60(b)(2) requires your farm to have documentation that process controls for the validated treatment process you were achieved during treatment, such as time, temperature, and turnings. Any form of documentation is acceptable, provided that it includes the information required in § 112.60(b)(1) and also follows the general record keeping requirements in § 112.161 (Subpart O).

Should FDA establish application intervals greater than zero days for any uses of biological soil amendments of animal origin at a later date, we will also establish appropriate recordkeeping requirements related to those intervals.

When will FDA update the Produce Safety Rule with new information about untreated biological soil amendments of animal origin?

FDA, in consultation with the U.S. Department of Agriculture, is conducting a risk assessment to evaluate the risk of human illness associated with the consumption of produce grown in growing areas amended with untreated BSAAO that are potentially contaminated with enteric pathogens such as *E. coli* O157:H7 or *Salmonella*. The risk assessment will evaluate the impact of different agricultural and ecological conditions and certain interventions, such as use of a time interval or intervals between application of untreated BSAAO and crop harvest, on the predicted risk. We anticipate that these efforts will take 5 to 10 years to complete from the date of publication of the rule.

For more information:

- **FSMA Final Rule on Produce Safety.**
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- **Produce Safety Network:**
ProduceSafetyNetwork@fda.hhs.gov

Have you seen our Blog? [FDA Voice](#)



The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

FDA FACT SHEET

Produce Safety Rule (21 CFR 112)

EQUIVALENT TESTING METHODOLOGY FOR AGRICULTURAL WATER

FDA has determined that the following quantification methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC)” (December 2009), in accuracy, precision, and sensitivity in quantifying generic *Escherichia coli* in agricultural water when used in connection with the criteria described in § 112.44(a) or § 112.44(b).

1. Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC) (September 2014). U.S. Environmental Protection Agency. EPA-821-R-14-010.
2. Method 1103.1: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using membrane-Thermotolerant *Escherichia coli* Agar (mTEC) (March 2010). U.S. Environmental Protection Agency. EPA-821-R-10-002.
3. Method 1604: Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002). U.S. Environmental Protection Agency. EPA-821-R-02-024.
4. 9213 D – Natural Bathing Beaches (2007). In: Standard Methods for the Examination of Water and Wastewater, 22nd Edition (Rice E.W., et al., Ed.), 9-46 – 9-48. Washington, DC: American Public Health Association. (2012).
5. 9222 B – Standard Total Coliform Membrane Filter Procedure (1997), followed by 9222 G – MF Partition Procedures (1997) using NA-MUG media. In: Standard Methods for the Examination of Water and Wastewater, 21st Edition (Eaton A.D., et al., Ed.), 9-60 – 9-65, and 9-70 – 9-71, respectively. Washington, DC: American Public Health Association. (2005).
6. D 5392-93 – Standard Test Method for Isolation and Enumeration of *Escherichia coli* in Water by the Two-Step Membrane Filter Procedure. In: Annual Book of ASTM Standards, Volume 11.02. ASTM International. (1996, 1999, 2000).
7. Hach Method 10029 for Coliforms – Total and *E. coli*, using m-ColiBlue24 Broth PourRite Ampules.
8. IDEXX Colilert Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.
9. IDEXX Colilert-18 Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.

With regard to criteria described only in § 112.44(a), FDA has determined that the following presence/absence methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC)” (December 2009), in accuracy, precision, and sensitivity in detecting generic *Escherichia coli* in agricultural water.

1. TECTA™ EC/TC medium and the TECTA™ Instrument: A Presence/Absence Method for the Simultaneous Detection of Total Coliforms and *Escherichia coli* (*E. coli*) in Drinking Water. (2014).
2. Modified Colitag™ Test Method for the Simultaneous Detection of *E. coli* and other Total Coliforms in Water. ATP D05-0035. (2009).
3. IDEXX Colilert Test Kit
4. IDEXX Colilert-18 Test Kit
5. IDEXX Colisure Test Kit
6. E*Colite Bag or Vial Test for Total Coliforms and *E. coli* in Potable Water. Charm Sciences, Inc.
7. 101298 ReadyCult Coliforms 100. EMD Millipore (division of Merck KGaA, Darmstadt, Germany).

For more information:

- **FSMA Final Rule on Produce Safety.**
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

Have you seen our Blog? [FDA Voice](#)



The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.



GOOD AGRICULTURAL PRACTICES - GROUPGAP

The USDA Agricultural Marketing Service's Specialty Crops Inspection (SCI) Division provides quality assurance reviews, inspections, food safety audits, and develops national standards for fresh and processed fruits and vegetables and related products that facilitate the marketing of America's specialty crops.

GROUPGAP WILL REMAIN A PILOT PROGRAM UNTIL FURTHER NOTICE

GROUPGAP

The USDA GroupGAP is a farm food safety audit program that allows a group of producers to attain GAP certification as a group.

To take part in the GroupGAP program, a group must:

- Operate under a shared Quality Management System (QMS) that incorporates the requirements of a food safety standard,
- Agree to be audited by USDA as one body,
- Perform internal audits of the member farms to ensure compliance with the chosen food safety standard, and
- Undergo annual USDA unannounced audits on a percentage of farms within the group.

THE POWER OF GROUPGAP

- Provides local and national market access by meeting buyers' increasing requirements for GAP certified suppliers.
- Verifies members' food safety compliance.
- Strengthens economies of small farmers and rural communities.

THE GROUPGAP ADVANTAGE

- Improves group members' accountability and performance by fully leveraging shared resources.
- Decreases documentation and maintenance requirements of group members who operate under a single QMS.
- Maintains members' compliance through internal audits.
- Saves group members money through cost and resource sharing.

FOR MORE INFORMATION

USDA Specialty Crops Inspection Division
1400 Independence Avenue, SW
Room 1536-S, Stop 0240
Washington, DC 20250-0240

Email: SCI@ams.usda.gov

Phone: 202-720-5870

www.ams.usda.gov

The U.S. Department of Agriculture (USDA) prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.) If you wish to file an employment complaint, you must contact your Agency's EEO Counselor (Click the hyperlink for a listing of EEO Counselors), within 45 days of the date of the alleged discriminatory act, event, or in the case of a personnel action. Additional filing information can be found online at http://www.ascr.usda.gov/complaint_filing_file.html. If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form, found online at http://www.ascr.usda.gov/complaint_filing_cust.html, or at any USDA office, or call (866) 632-9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter by mail to the U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue, S.W., Washington, D.C. 20250-9410, by fax (202) 690-7442 or email at program.intake@usda.gov. Individuals who are deaf, hard of hearing or have speech disabilities and wish to file either an EEO or program complaint please contact USDA through the Federal Relay Service at (800) 877-8339 or (800) 845-6136 (in Spanish). Persons with disabilities, who wish to file a program complaint, please see information above on how to contact the Department by mail directly or by email. If you require alternative means of communication for program information (e.g., Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Last updated May 2014



GOOD AGRICULTURAL PRACTICES - HARMONIZED GAPs

WHAT IS HARMONIZED GAPs

Developed under the leadership of the United Fresh Food Safety & Technology Council to drive harmonization of several GAP standards, and to reduce audit fatigue by suppliers, and allow operations to focus their food safety resources on achieving food safety.

- The Produce GAPs Harmonization Initiative, was an all-industry effort including growers, shippers, produce buyers, government agencies, audit organizations and other stakeholders.
- The result is Good Agricultural Practices standards and audit checklists for pre and post-harvest operations, applicable to all fresh produce commodities, and all sizes of on-farm operations and all regions in the U.S.

THE BENEFITS OF HARMONIZED GAPs

- Brings together many audit schemes
- Developed and recognized by major institutional buyers and sellers and minimizes “audit creep”
- Are risk-based, science based, attainable, auditable and verifiable
- Takes into account regional food safety needs
- Not commodity specific - - allowing for adaptability to generally all commodity groups
- Harmonized audits reduce the number of multiple audits for the same operations.
- Evaluates and measures a Grower Risk Assessment
- Includes an evaluation and assessment of worker health and hygiene
- USDA acceptance criteria includes a section for “Global Markets Program” - - an added step to meet international requirements. Including:
 - * Farm supplies are traced and reviewed
 - * Chemical storage and chemical origination
 - * Food Defense

The U.S. Department of Agriculture (USDA) prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.) If you wish to file an employment complaint, you must contact your Agency's EEO Counselor (Click the hyperlink for a listing of EEO Counselors), within 45 days of the date of the alleged discriminatory act, event, or in the case of a personnel action. Additional filing information can be found online at http://www.ascr.usda.gov/complaint_filing_file.html. If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form, found online at http://www.ascr.usda.gov/complaint_filing_cust.html, or at any USDA office, or call (866) 632-9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter by mail to the U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue, S.W., Washington, D.C. 20250-9410, by fax (202) 690-7442 or email at program.intake@usda.gov. Individuals who are deaf, hard of hearing or have speech disabilities and wish to file either an EEO or program complaint please contact USDA through the Federal Relay Service at (800) 877-8339 or (800) 845-6136 (in Spanish). Persons with disabilities, who wish to file a program complaint, please see information above on how to contact the Department by mail directly or by email. If you require alternative means of communication for program information (e.g., Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).



Agricultural Marketing Service

Frequently Asked Questions

USDA Aligns Harmonized GAP Program with FDA Food Safety Rule

AMS/Specialty Crops Program
June 5, 2018

What action did USDA take?

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

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

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

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

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

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

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



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

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

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

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

How does this alignment help me as a producer?

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

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



How does this alignment help me as a buyer?

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

What is a USDA Harmonized GAP audit?

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

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

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

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

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

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

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



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

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

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

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

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

What is the Produce Safety Rule?

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

What is the Food Safety Modernization Act?

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

USDA is an equal opportunity provider, employer and lender.

USDA Harmonized GAP Plus+ Audit Service
A GFSI-Technically Equivalent Food Safety Verification Program

Questions and Answers

1. Why did USDA develop the USDA Harmonized GAP Plus+ audit?

Buyers are increasingly requiring their suppliers to undergo Global Food Safety Initiative (GFSI) audits. USDA introduced this new service that is recognized as being GFSI technically equivalent so that all in the specialty crops supply chain can use a single H-GAP Plus+ audit to meet this and other marketing and regulatory requirements. With this technical equivalence, the USDA Harmonized GAP Plus+ audit program now has greater acceptance within the retail, foodservice and manufacturing buying community. One audit that meets both standards saves sellers time and money.

2. What is the Global Food Safety Initiative (GFSI)?

[Global Food Safety Initiative](#) is an international industry network which is part of [The Consumer Goods Forum](#). GFSI was created in 2000 to find collaborative solutions to reduce food safety risks, reduce audit duplication and costs while building trust within the entire supply chain. GFSI recognizes food safety certification programs to defined requirements outlined in its [Benchmarking Requirements](#). GFSI is composed of food safety experts from retail, manufacturing and food service companies, as well as international organizations, governments, academia and service providers to the global food industry.

3. How is the Harmonized GAP Plus+ audit different from other USDA GAP audits?

The new USDA Harmonized GAP Plus+ audit is the only USDA GAP audit recognized as being Global Food Safety Initiative (GFSI) technically equivalent. To create this service, USDA augmented the USDA Harmonized GAP audit to meet GFSI equivalence standards.

4. Why would I want to use the Harmonized GAP Plus+ service?

USDA's Harmonized GAP Plus+ is the audit service to use if you are required to undergo a GFSI-benchmarked audit for market access. Many retail, food service, and institutional buyers require their suppliers to undergo a food safety audit conducted against one of the GFSI [recognized certification programs](#). With this technical equivalence, the USDA Harmonized GAP Plus+ audit program now has greater acceptability within the retail, foodservice and manufacturing buying community.

5. How do I know if I need a Harmonized GAP Plus+ audit?

Buyers determine what standards they require of producers/sellers, so be sure to verify the specific buyer requirements before scheduling and undergoing an audit. Not all buyers have the same requirements. Most large national and international buyers are increasingly requiring a food safety audit against one of the recognized certification programs benchmarked by GFSI.

6. How does the USDA Harmonized GAP Plus+ service relate to other USDA GAP programs?

USDA offers several types of GAP audit services. USDA GAP audits are our basic service. These audits are aligned with industry best practices and Food and Drug Administration (FDA) recommendations. USDA Harmonized GAP audits meet industry best practices, FDA best practices AND are aligned with the Produce GAP Harmonization Initiative and the Food Safety Modernization Act’s (FSMA) Produce Safety Rule. The new USDA Harmonized GAP Plus+ audits include all USDA GAP and Harmonized GAP alignments AND are recognized by GFSI.

USDA GAP Service Tiers

For market access, I need:	Global Food Safety Technical Equivalence	FDA FSMA Produce Safety Rule Alignment	Produce GAP Harmonization Initiative Alignment	Adherence to Industry and FDA Best Practices
USDA Harmonized GAP Plus+	X	X	X	X
USDA Harmonized GAP		X	X	X
USDA GAP & GHP				X

7. Who conducts Harmonized GAP Plus+ audits?

USDA audits are conducted by trained and licensed federal and federal-state department of agriculture employees who have years of experience and understand the production and marketing of specialty crops.

8. How much does a USDA Harmonized GAP Plus+ audit cost?

By law, USDA must fully recover the cost of these services. Producers are charged for actual hours USDA invests to complete the audit process -- direct time to review, approve, certify and post audit results at the prevailing USDA audit rate published annually in the Federal Register. The new Harmonized GAP Plus+ service also requires payment of an annual \$250 fee to maintain the certification.

9. Why are you charging a \$250 certification fee for USDA Harmonized GAP Plus+ Audits?

The annual \$250 certification fee covers GFSI charges for the benchmarking process.

10. I’m not sure I can afford the Harmonized GAP Plus+ service? Can you help me?

There are several ways you can save money on a GAP audit. USDA offers a [GroupGAP](#) audit program that allows grower groups operating under a single food safety management system to leverage resources and collaborate on food safety issues which lead to reduced costs for GAP certification. Other options are to apply for service as an individual or to coordinate the scheduling of audits with other producers in your area to reduce the travel costs.

11. Why did USDA undertake GFSI Technical Equivalency?

This is an extension of USDA's work to help grow marketing opportunities for specialty crops producers, increase purchasing options for buyers and provide consumers with access to more and diverse fresh, local produce.

Many retail, food service, and institutional buyers require their suppliers to undergo a food safety audit conducted against one of the GFSI [recognized certification programs](#). Without GFSI technical equivalency, the more than 4,000 growers, packers and handlers who utilize the USDA GAP Program could not use the USDA audit to also meet the requirements of those buyers.

Representatives from many specialty crops sectors, including grower groups, commodity boards and trade associations, formally requested USDA consider aligning the USDA GAP Program with GFSI to reduce audit fatigue and overall costs of multiple food safety audits.

12. What is USDA's involvement with GFSI?

In addition to undergoing technical equivalency, USDA has participated in several GFSI technical working groups, most recently the Global Markets for Primary Production working group. USDA was able to provide technical expertise on the primary production practices for fruits, vegetables and other specialty crops.

#



Certified
ORGANIC
Washington State Dept. of Agriculture

Organic and Good Agricultural Practices (GAP)

ORGANIC CERTIFICATION FACT SHEET

Washington State Dept. of Agriculture (WSDA) Organic Program is authorized by USDA to certify operations according to the USDA National Organic Standards. WSDA Fruit and Vegetable Program offers a GAP auditing service to allow you to demonstrate to customers that you are following USDA's Good Agricultural Practices (GAP) for on-farm food safety. A Good Handling Practices (GHP) audit is also available to confirm that handling and processing are done in accordance with USDA GHP standards.

Organic certification is required in order to sell, label, or represent a crop as "organic." Operations are certified based on the type of business and the products that they want to market with an organic claim (crops, livestock, handling or processing). GAP audits are voluntary, but may be required to gain access to certain markets. An operation may choose to be certified for any or all of the scopes that apply to the operation; the GAP auditor will evaluate only those sections of your operation that you have specifically requested to have audited.

As with organic certification's system plan, GAP is structured around implementation of standard operating procedures and requires thorough recordkeeping. While organic standards require operations to prevent contamination of organic crops from prohibited input materials and prevent commingling of organic and nonorganic products, GAP certification ensures that the operation is following practices to minimize the risk of microbial contamination of crops. Both regulations cover practices from planting through harvest, packing, storage and transportation.

If you run a certified organic farm and are looking to expand your marketing options with GAP certification, consider that you are probably already implementing a system that could easily be adapted to meet GAP requirements. You may even be keeping some of the records required by GAP. A basic comparison of Organic and GAP requirements is outlined in this factsheet. This list is not an all-inclusive list of requirements, but instead a useful starting point in evaluating if GAP certification is right for you.



	Organic	USDA Organic Regulation	GAP	USDA GAP/GHP Audit Checklist
Traceability	Begins with seeds, ends with product distribution. Records must be maintained regarding all activities and transactions.	§205.103	Begins in planting field and ends with buyer “one step forward, one step back”.	General Question G-1
Mock Recall	Not required	None	The operator must conduct mock recall 12 months or less prior to GAP audit, or during the audit itself.	General Question G-2
Water Analysis	Analysis not specifically required. However, producer must ensure no prohibited material contamination of crops via irrigation water and must ensure organic practices do not contribute to contamination of water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.	§205.202 §205.203	The operation must have a water risk assessment in place.	General Question G-3; Part 1 Farm Review 1-3 and 1-4
Land Use Risk Assessment	Not required, but land must be free of prohibited materials for three years prior to the harvest of the first organic crop.	§205.202	The operation must document a previous land use risk assessment.	Part 1 Farm Review 1-23
Raw Manure Management	Raw manure must be composted unless it is applied to land used for a crop not intended for human consumption or is incorporated into the soil not less than 90 or 120 days prior to harvest (depending on crop).	§205.203(1)	Raw manure must be incorporated at least two weeks prior to planting and at least 120 days prior to harvest. Cannot be applied to crops harvested within 120 days of planting.	Part 1 Farm Review 1-14 through 1-21
Biosolids	Prohibited	§205.105 §205.203(e)(2)	Biosolids are allowed with proper management.	Part 1 Farm Review 1-18 through 1-21
Lot Numbers	Lot numbers recommended.	205.307(b)	Lot numbers recommended.	General Question G-1, Part I Farm Review 1-26, Part 2 Field Harvest & Packing 2-21

	Organic	USDA Organic Regulation	GAP	USDA GAP/GHP Audit Checklist
Packing Shed Pest Control	Records must be maintained to verify preventative practices are in place prior to use of an input. Records must verify prohibited materials have not contaminated organic products.	§205.103 §205.271	An animal and pest exclusion plan must be maintained, and records and inspection reports must be available for review.	Part 3 House Packing Facility 3-30 - 3-32; Part 4 Storage and Transportation 4-14 & 4-15
Financial Records	Records regarding all activities and transactions related to organic products must be maintained.	§205.103	Financial records are not required.	None
Storage Records	Records regarding all activities and transactions related to organic products must be maintained, and must verify organic products are not contaminated or commingled during storage.	§205.103	Routine sanitation records are required.	Part 4 Storage & Transportation 4-19 through 4-22
Transport	Records must be maintained to verify organic products are not contaminated or commingled during transportation, this includes transportation by 3 rd party.	§205.103 §205.272	Routine sanitation records, along with a plan for transport temperature control, odor control, and cleanliness are required.	Part 4 Storage & Transportation 4-24 through 4-27
Does my certificate expire?	Certification does not expire unless the operation surrenders their certificate or it is suspended or revoked by a certifier. Annual recertification is required.	§205.404 §205.406	Certificates are granted annually after a successful audit. An immediate food safety risk identified at time of audit or through an unannounced visit can result in revocation of certification.	None

For organic certification questions or application forms:

Washington State Department of Agriculture
Organic Program
PO Box 42560; 1111 Washington Street SE
Olympia, WA 98504-2560
(360) 902-1805 | organic@agr.wa.gov
<http://agr.wa.gov/foodanimal/organic>

For GAP questions or to request an audit:

Washington State Department of Agriculture
Fruit and Vegetable Inspection Program
PO Box 42560; 1111 Washington Street SE
Olympia, WA 98504-2560
Yakima District Office: (509) 249-6900
Wenatchee District Office: (509) 662-6161
<http://agr.wa.gov/Inspection/FVInspection/GAPGHP.aspx>

Additional Resources:

USDA National Organic Program (USDA NOP) and links to the USDA organic regulations

<http://www.ams.usda.gov/AMSv1.0/nop>

WSDA Bridging the GAPs

Education and Outreach about USDA GAP/GHP Audit Program in Washington State
GAPedu@agr.wa.gov
<http://agr.wa.gov/Inspection/GAPGHP/>



WSDA Organic Program
PO Box 42560 | Olympia WA 98504-2560
(360) 902-1805 | organic@agr.wa.gov
<http://agr.wa.gov/foodanimal/organic>

RECALL PLAN CHECKLIST

1. Create a Customer/Buyer Contact list. Be sure to update names, phone numbers, and emails annually or as needed.
 - Restaurants or buying club distributors: Two contacts in purchasing/shipping department
 - Your own CSA: All members by email or website
 - Farmer's Market/Roadside stand: Website for customers to look for information, email sign up sheet, signs posted at the market or roadside stand
2. Create a Recall Contact list. This list should include names and phone numbers of media representatives, proper authorities (FDA, NCDA&CS, etc.), your insurance company and your legal counsel.
3. Identify the problem (chemical, physical or microbial risks) and assess the health risks.
4. Determine the products and lot numbers involved. (Only strawberries, or one day's worth of all vegetables, etc.)
5. Determine quantities involved. (cases, boxes, etc.)
6. Determine current inventory on the premises.
7. Determine the amount of product in the marketplace.
8. Identify the customers/buyers who have received the product.
9. Collect pertinent documentation regarding the affected product.
 - Inputs and outputs of affected field associated with the lot number such as notes on flooding, wildlife activity, an ill employee, manure application, etc.
10. You will need to determine:
 - the total amount of suspect product shipped/delivered
 - the total amount of suspect product still in the buyer's possession
 - the total amount of suspect product the buyer has shipped
 - any product discarded
11. Upon completion of the mock recall, outline any issues in the recall plan and how you should change the recall plan to make it better. For example, taking longer than 2 hours and not being able to account for 100% of the product.

To conduct a mock recall, identify one of your products delivered to a customer on a specific date. Call the customer, with a lot number and shipping information and enquire where the product went. Also have the customer create or send you a copy of any written documentation to verify their distribution. This document should be in your food safety manual alongside mock recall log (where the date and this activity is recorded).

In the General Section, the auditor will look in your food safety manual for your traceability program and a record of a completed mock recall and award up to 25 points in questions G-1 and G-2. In Part One and Two, the auditor will look for a record showing how production fields and produce moving out of fields are identified and award up to 10 points for each question (1-26 and 2-21).

Audit Tip #6 Get marketing mileage out of your traceability plan.

A majority of the farms in our study sold directly to the consumer through CSA programs, roadside stands and farmers' markets. In the event of a recall, contacting these types of customers can be difficult to unrealistic. Some of the ways small-farm operators can contact these types of patrons are through email sign up sheets, website notifications, and signs at the farmstand/farmers' markets. The system created by preparing for a recall has marketing benefits as well, as having customer email lists and proactively communicating with direct market clients can help build your brand.

Food Safety for Flooded Farms

Summary

In the aftermath of flooding, fruit and vegetable crops may pose a food safety risk. These catastrophic events can have a lingering and potentially hazardous impact on public health. Crops and other food commodities exposed to flood waters can be considered adulterated and not suitable for human consumption or animal feed. The U.S. Food and Drug Administration (FDA), as well as Universities and Extension Programs across the country, have provided guidance on how to manage flood crops, keeping food safety in mind.

Assessing the Risk

Before cleaning up or destroying crops in flooded fields, check with your crop insurance and/or local Farm Services Agency (FSA) representatives regarding exact documentation to certify losses, procedures for initiating claims, and possible financial assistance.

Several questions should be answered in order to assess the safety of flood covered or damaged crops. The first assessments should involve determining the extent of flooding, what type of contaminants could be in the flood water, and what types of crops are being affected.

Types of Flooding

There are two types of flooding. The first is more typical and occurs after a heavy downpour when fields become saturated and water pools on the soil surface. This type of flooding can reduce yields and even kill plants, but usually will not result in contamination of produce with human pathogens.

The second type of flooding is more severe and occurs when water or runoff from surface waters such as rivers, lakes, or streams overflow and run into fields. Flood waters, as described in the second definition, are likely to contain chemical and biological contaminants that may be harmful to the health of humans and animals.



Keith McCall—Photo Courtesy of the National Resource Conservation Service

Sources of Contamination

There are two primary types of contamination that are of concern for food crops. Not only are these contaminants a concern for human health, they can also be harmful if fed to livestock.

1. Microbial Contamination

- Pathogens may include bacteria, parasites, and viruses.
- Sources of microbial contamination might come from upstream farms, rural septic systems, overflow from industrial sewage systems, and raw manure or feces.

2. Chemical Contamination

- Chemical contaminants may include heavy metals, petroleum products, pesticides, or other agricultural chemicals.
- Potential sources of chemical contamination vary greatly depending on the severity of flood, proximity to operations using chemicals, or runoff from roadways.

Determining Whether Your Crop Is 'Safe'

- **If the edible portion of the crop has been exposed:**

Unfortunately, if the edible portion of a crop has been exposed to flood waters, it is considered adulterated by the U.S. Food and Drug Administration and should not enter human food channels. There is no practical method to recondition the edible portion of a crop to provide reasonable assurance of safety for use as food.

- **If the crop comes in proximity to or is exposed to a lesser degree:**

Crops near flooded areas, or those that were flooded without the edible part of the plant coming in contact with the flood water (such as sweet corn or staked tomatoes), need to be evaluated on a case-by-case basis. These crops as well as those in which the edible portion develops after flood waters recede are not automatically considered adulterated.

1. Is the edible part of the plant developing and if so, how far above the flood water was it?
2. Is there any evidence that flood water splashed up onto edible portion of the crop? Flood water almost certainly contains pathogens and/or harmful chemicals.
3. If feeding the crop to livestock, was it exposed to prolonged periods of moisture and stress that could promote fungal growth or molds that can produce mycotoxins?

Additional Concerns and Considerations

- Place markers at the high-water line so you can identify the areas where crops were in contact with flood waters.
- Leave a 30 foot buffer between flooded areas of fields and adjacent areas to be harvested for human consumption; this is to accommodate a generous turn-around distance for equipment to prevent contact with flooded soil and avoid cross-contamination of non-flooded ground.
- Workers should wear protective clothing such as rubber boots and rubber gloves when working in fields that were flooded. Protective clothing should be discarded or thoroughly cleaned after working in flooded areas.
- If your well head was submerged, re-test your well water to make sure that only safe (drinking-quality) water comes into direct contact with produce.
- Allow at least 60 days between flooding and planting of the next human food crop. In absence of known or suspected biological or chemical contaminants in flood waters (such as sewage discharge or run-off from industrial sites) you can replant after 60 days.
- Organic growers should contact their certifier to discuss damage to the crop. Flood waters might contain residues of prohibited substances.

Recommended Web Resources

- [FDA Notice for Safety of Food Affected by Hurricanes, Flooding, and Power Outages](#)
- [FDA Definition of Adulterated Food](#)
- [California LGMA Flooding and Food Safety](#)
- [Impact of Flooding on Organic Food and Fields](#)



Cleaning and Sanitizing Tools and Harvest Containers

This fact sheet is part of a series about food safety on the farm for fruit and vegetable growers. Developed for the Minnesota Fruit and Vegetable Growers Association by Michele Schermann and Annalisa Hultberg. Reviewed by Dr. Cindy Tong.

Using clean containers and tools can help decrease postharvest losses on sensitive products like summer squash, tomatoes and berries, as well as reduce the chance of spreading foodborne illness-causing pathogens.

All reusable harvest containers and tools should be kept as clean as possible and regularly disinfected. At least weekly, or as often as needed, reusable produce bins, buckets, totes and other containers, should be cleaned of excess soil, vegetable matter and other debris. Tools should be cleaned daily or as needed to keep them clean.

Sanitize tools and totes several times throughout the growing season, and at the end and beginning of each season. A sanitizing solution, such as a weak (50 - 150 ppm) bleach solution, should be applied to harvest tools and containers after cleaning and as needed to kill pathogens.

Cleaning Procedure

Clean harvest containers, tools and food contact surfaces before sanitizing. Sanitizers are more effective if the surfaces are clean and free of soil and other debris.



Wash harvest totes and tools as often as needed to keep them free of excess debris and soil.

- Rinse surface of container to remove soil and debris.
- Wash surface of container with detergent and water. For harvest containers, use a high-pressure sprayer hose.
- Rinse with clean potable water.

Any detergent can be used for the wash step on hard surfaces. Only detergents/

For more information on Cleaning and Sanitizing

- Cleaning and Sanitizing Guide, Iowa State University Extension.
- Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, FDA.
- GAP: A Self-Audit for Growers and Handlers, UC Davis

soaps that come in contact with food need to be labeled as safe for food. Read the label and make sure you follow the instructions on the label.

Sanitizing harvest containers, tools and food contact surfaces

- Apply a fine mist of sanitizer solution to surfaces using a sprayer. (See below for sanitizing products)
- Let containers, tools and surfaces air dry. Do not dry with towels.

Sanitizing Products

Sanitizing can be done with a number of products. Many companies, such as EcoLab, have hydrogen peroxide-based products that are formulated specifically for sanitizing hard surfaces.

Bleach solution (50 ppm is about 1.5 tablespoons of household chlorine bleach per five gallons of water) is an inexpensive and commonly used sanitizing solution.

Vinegar is not an acceptable sanitizer, as it does not adequately sanitize surfaces.

If you are certified organic, there are many allowable solutions to use, but make sure you check with your certifying agency first.

Whatever sanitizer you use, you will need to monitor the concentration to make sure that it is the correct strength. In the case of chlorine bleach, use test strips¹ to make sure the solution is at the needed strength.

Other sanitizers will have different recommended concentrations. Follow all

label directions carefully, and wear protective gear (e.g. gloves, goggles) when pouring all sanitizers; they are dangerous when undiluted.

Many companies have formulations that are specific to hard surfaces.

Sanitizers for Use on Hard Surfaces²

Chlorine bleach (*hypochlorite*):

Assuming a 5.25% hypochlorite in household bleach, use 1 cup per 50 gallons or 1.5 tablespoons per 5 gallons and check with chlorine tester strips for ~50ppm.

EcoLab: numerous hard surface formulations: <http://www.ecolab.com>

Sanidate 5.0: <http://www.johnnyseeds.com/p-8467-sanidate-5-0-liquid-sanitizer-og-2-12-gal-.aspx>

StorOx 2.0 hydrogen peroxide- based sanitizer (Biosafe Systems): <http://www.biosafesystems.com/Product-Ag-StorOx.asp>

Some detergents and sanitizers are dangerous to use, so protecting workers and farmers is important; read the labels.

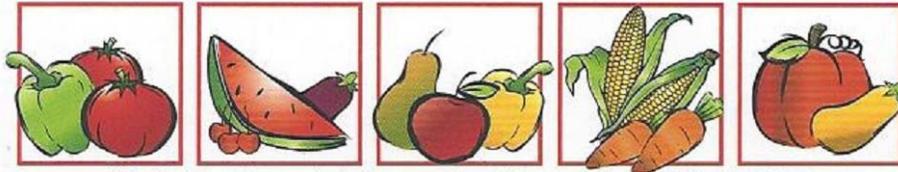
¹Test strips for chlorine are available at restaurant supply stores, and online. Test strips for other products are available from the product supplier.

²These are commonly used sanitizers. This list is for information and should not be viewed as an endorsement of a product by the University of Minnesota, the Minnesota Fruit and Vegetable Growers Association, Minnesota Department of Agriculture, or the USDA.



Photos: M. Schermann. Support for this project was provided to the Minnesota Fruit and Vegetable Growers Association through the Specialty Crop Block Grant Program – Farm Bill, through the Minnesota Department of Agriculture and the USDA – AMS. These institutions are equal opportunity providers. (2012)

IMPERIAL'S GARDEN

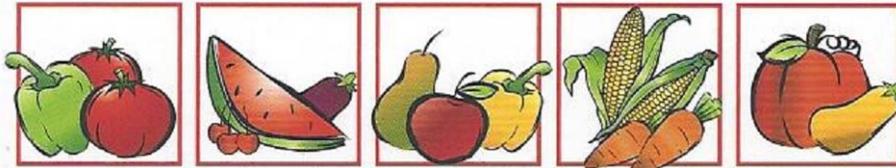


3.12.2 Field Policies

- Hands are to be washed and sanitized before commencing work and break, also after break and when work is completed.
- No children or infants are allowed in the fields
- No animals are allowed.
- No food within 20 feet of the product field.
- No drugs, alcohol or tobacco use:
 - I. **Use of any of these substances in the product field will be terminated immediately.**
- No jewelry or clothing with little rocks is to be worn during harvest or general field work.
- Harvesters are not permitted to use cell phones unless:
 - I. Emergency
 - II. Call foremen or managers of possible food safety
- When items are dropped on the floor they are to be discarded.
- Do not pick decayED vegetables
- Employees will stay at their designated area of operations.
- Produce boxes, lugs and bins are only used for produce
 - No cross contamination
 - Mark "X" on unused cases
 - Non-solid plastic bins are used only for produce
 - Boxes and lugs must be on a pallet at all times
- When evidence of animal intrusion is discovered by an employee it must immediately be reported to management so the proper actions can be taken.
 - I. Corrective Actions for Animal presence in order:
 1. Contact foremen
 2. Foremen will veer the animal outside the product field and ensure it does not come back to the product field.
 3. If the animal seems dangerous to veer away foremen will contact Animal Control (509)-575-6038 and notify managers and owners.
 - II. Corrective Actions for fecal matter, deceased animals, or any other in order:
 1. Contact foremen

2. Foremen will mark the area with markings. (5 feet radius away from the matter)
3. Remove the matter with proper protective gear so that no further contamination will be on the field and product.
4. He/she will notify Food Safety Manager or Owner.
5. Owner, Management and foremen will evaluate the area.

IMPERIAL'S GARDEN



Packing House Policies

Good Manufacturing and Hygiene Practices

The following good manufacturing and personnel hygiene practices have been established and communicated to all employees as a mandatory rule:

- Wash hands thoroughly with soap and warm water, and sanitize, before starting work, after each absence from the work station, after using the restroom, after breaks and at any other time when the hands may have become exposed to soil or contaminated.
- Maintain adequate personal cleanliness. Keep hair tied or short, trimmed and clean fingernails, and, if gloves are not used, free of nail polish.
- Smoking, eating or drinking is not allowed in work areas.
- Personal items are not allowed in work areas (bags, purses, jewelry, watches, musical dev., etc)
- The use of cell phones is not allowed or any electronic devices while working.
- Wear outer garments and remove all items from top outside pockets.
- Remove all protective and outer garments and store them in a designated area when on break and before using the restrooms.
- All minor cuts and wounds must be covered with waterproof detectable blue bandages with metal strip.
- Report any cuts and/or any illnesses that might be a contamination risk to the fresh product.
- Any person showing boils, sores, open wounds or exhibiting signs of food-borne illness must be excluded from operations involving direct and indirect food contact.
- No animals allowed

- No children or infants allowed
- Employees will stay at their designated area of operations.
- Produce boxes, lugs and bins are only used for produce
 - No cross contamination
 - Mark “X” on unused cases
 - Non-solid plastic bins are used only for produce
 - Boxes and lugs must be on a pallet at all times

When in direct contact to food:

- Wear gloves. (If gloves are taken home, employees need to discard it. Only use latex free gloves)
- Wear hats or hairnets.
- No jewelry is allowed, except a plain wedding band.

Corrective Actions

All employees must follow the GM&HP as mandatory rules. If any employee is not in compliance and breaking the food safety rules the following corrective actions must be taken by the immediate supervisor:

- Remind the employee of the rule being broken
- Employee must correct behavior and leave the facility if not able to fulfill the food safety rules (i.e. if he has not reported he is sick)
- Verbal warning for non-complying to the food safety rules
- If reoccurrence, a first written warning will be issued
- If second reoccurrence, a second written warning will be issued and employee will be suspended
- If third reoccurrence, employee will be terminated
- In case of a non-compliance visitor or contractor, the person will receive a verbal warning and will be requested to take a corrective action according to the situation; if the person does not follow the instructions given by the Supervisor or area Manager, the person will be requested to leave the facility.
- If animals is found around the Packing House corrective action will be in accordance with **3.12.2 Field Policies**

Sickness Reports / Return to work policy

When an employee has reported sick/illness, the Supervisor or area Manager must fill a sick/illness report, and the employee will be authorized to return to work if:

- Employee meets the GM&HP stated above and no signs of illness are detected, and/or

- Employee presents a doctor's note stating that he/she can safely return to work. The return to work policy has been communicated to all employees as part of the GMP training program.

General Rules for Glass

- All lights with the production, storage and maintenance areas are protected in some manner. Where Teflon coated bulbs have been used, copies of invoices have been retained.
- No glass items are stored in the storage, production or maintenance areas.
- Glass items are allowed in the break room only – these do enter the production, storage or maintenance areas.
- Staff is not permitted to bring glass into the storage, production or maintenance areas.
- Glass thermometers are not allowed inside the storage and production areas.
- Windows inside the production, storage and maintenance areas are either made of plastic or have been laminated.
- There are no glass skylights in the facility.

Reference: Produce Safety Rule

Reference Documents for the FSMA Produce Safety Rule

This section contains:

- ✦ Text of the FSMA Produce Safety Rule
- ✦ PSA Regulatory Reference Table for the FSMA Produce Safety Rule



FEDERAL REGISTER

Vol. 80 Friday,
No. 228 November 27, 2015

Book 2 of 2 Books
Pages 74353–74672

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11, 16, and 112
Standards for the Growing, Harvesting, Packing, and Holding of Produce
for Human Consumption; Final Rule

Note: This document contains Section 112 of the FSMA Produce Safety Rule, which includes the information most relevant to growers, including the full set of requirements and standards of the Produce Safety Rule. This document does not contain Sections 11 or 16, which primarily contain background information clarifying or supporting Section 112, such as definitions, FDA commentary, and bibliographic references. To access the full text of the FSMA Produce Safety Rule, including Sections 11 and 16, go to www.federalregister.gov/d/2015-28159.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 112

Foods, Fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 11, 16, and 112 are amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 1. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. In § 11.1, add paragraph (k) to read as follows:

§ 11.1 Scope.

* * * * *

(k) This part does not apply to records required to be established or maintained by part 112 of this chapter. Records that satisfy the requirements of part 112 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 4. Amend § 16.1 by:

■ a. In paragraph (b)(1), adding an entry in numerical order.

■ b. In paragraph (b)(2), adding an entry in numerical order.

The additions read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 (see part 112, subpart P of this chapter).

* * * * *

(2) * * *

§§ 112.201 through 112.213, (see part 112, subpart R of this chapter), relating to withdrawal of a qualified exemption.

* * * * *

■ 5. Add part 112 to read as follows:

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION**Subpart A—General Provisions**

Sec.

112.1 What food is covered by this part?

112.2 What produce is not covered by this part?

112.3 What definitions apply to this part?

112.4 Which farms are subject to the requirements of this part?

112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

Subpart B—General Requirements

112.11 What general requirements apply to persons who are subject to this part?

112.12 Are there any alternatives to the requirements established in this part?

Subpart C—Personnel Qualifications and Training

112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

112.22 What minimum requirements apply for training personnel who conduct a covered activity?

112.23 What requirements apply regarding supervisors?

112.30 Under this subpart, what requirements apply regarding records?

Subpart D—Health and Hygiene

112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

112.32 What hygienic practices must personnel use?

112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

Subpart E—Agricultural Water

112.41 What requirements apply to the quality of agricultural water?

112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

112.43 What requirements apply to treating agricultural water?

112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

112.47 Who must perform the tests required under § 112.46 and what methods must be used?

112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

112.50 Under this subpart, what requirements apply regarding records?

Subpart F—Biological Soil Amendments of Animal Origin and Human Waste

112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

112.52 How must I handle, convey, and store biological soil amendments of animal origin?

112.53 What prohibitions apply regarding use of human waste?

112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

112.55 What microbial standards apply to the treatment processes in § 112.54?

112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

112.60 Under this subpart, what requirements apply regarding records?

Subpart G—H—[Reserved]**Subpart I—Domesticated and Wild Animals**

112.81 How do the requirements of this subpart apply to areas where covered activities take place?

112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

Subpart J—[Reserved]**Subpart K—Growing, Harvesting, Packing, and Holding Activities**

112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

112.112 What measures must I take immediately prior to and during harvest activities?

112.113 How must I handle harvested covered produce during covered activities?

112.114 What requirements apply to dropped covered produce?

112.115 What measures must I take when packaging covered produce?

112.116 What measures must I take when using food-packing (including food packaging) material?

Subpart L—Equipment, Tools, Buildings, and Sanitation

- 112.121 What equipment and tools are subject to the requirements of this subpart?
- 112.122 What buildings are subject to the requirements of this subpart?
- 112.123 What requirements apply regarding equipment and tools subject to this subpart?
- 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?
- 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?
- 112.126 What requirements apply to my buildings?
- 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?
- 112.128 What requirements apply regarding pest control in buildings?
- 112.129 What requirements apply to toilet facilities?
- 112.130 What requirements apply for hand-washing facilities?
- 112.131 What must I do to control and dispose of sewage?
- 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?
- 112.133 What requirements apply to plumbing?
- 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?
- 112.140 Under this subpart, what requirements apply regarding records?

Subpart M—Sprouts

- 112.141 What commodities are subject to this subpart?
- 112.142 What requirements apply to seeds or beans used to grow sprouts?
- 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?
- 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?
- 112.145 What requirements apply to testing the environment for *Listeria* species or *L. monocytogenes*?
- 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*?
- 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?
- 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?
- 112.150 Under this subpart, what requirements apply regarding records?

Subpart N—Analytical Methods

- 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?
- 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

- 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

Subpart O—Records

- 112.161 What general requirements apply to records required under this part?
- 112.162 Where must I store records?
- 112.163 May I use existing records to satisfy the requirements of this part?
- 112.164 How long must I keep records?
- 112.165 What formats are acceptable for the records I keep?
- 112.166 What requirements apply for making records available and accessible to FDA?
- 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Subpart P—Variances

- 112.171 Who may request a variance from the requirements of this part?
- 112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?
- 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?
- 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?
- 112.175 Who responds to a petition requesting a variance?
- 112.176 What process applies to a petition requesting a variance?
- 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?
- 112.178 Under what circumstances may FDA deny a petition requesting a variance?
- 112.179 When does a variance approved by FDA become effective?
- 112.180 Under what circumstances may FDA modify or revoke an approved variance?
- 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?
- 112.182 What are the permissible types of variances that may be granted?

Subpart Q—Compliance and Enforcement

- 112.192 What is the applicability and status of this part?
- 112.193 What are the provisions for coordination of education and enforcement?

Subpart R—Withdrawal of Qualified Exemption

- 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?
- 112.202 What procedure will FDA use to withdraw an exemption?
- 112.203 What information must FDA include in an order to withdraw a qualified exemption?
- 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

- 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?
- 112.206 What is the procedure for submitting an appeal?
- 112.207 What is the procedure for requesting an informal hearing?
- 112.208 What requirements are applicable to an informal hearing?
- 112.209 Who is the presiding officer for an appeal and for an informal hearing?
- 112.210 What is the timeframe for issuing a decision on an appeal?
- 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?
- 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions**§ 112.1 What food is covered by this part?**

(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell

and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and

(3) Produce that is not a raw agricultural commodity.

(b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:

(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and

(2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of

microorganisms of public health significance;” and

(3) You must either:

(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(B) Will only sell to another entity that agrees, in writing, it will either:

(1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(4) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:

(i) Documents containing disclosures required under paragraph (b)(2) of this section; and

(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and

(5) The requirements of this subpart and subpart Q of this part apply to such produce; and

(6) An entity that provides a written assurance under § 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 112.3 What definitions apply to this part?

(a) The definitions and interpretations of terms in section 201 of the Federal

Food, Drug, and Cosmetic Act apply to such terms when used in this part.

(b) For the purpose of this part, the following definitions of very small business and small business also apply:

(1) *Very small business.* For the purpose of this part, your farm is a very small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$250,000.

(2) *Small business.* For the purpose of this part, your farm is a small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) For the purpose of this part, the following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Agricultural tea means a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of this rule.

Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Animal excreta means solid or liquid animal waste.

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Biological soil amendment means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term "biological soil amendment of animal origin" does not include any form of human waste.

Composting means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

Curing means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may

or may not involve insulation, depending on environmental conditions.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

Farm means:

(i) *Primary Production Farm.* A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

(A) Pack or hold raw agricultural commodities;

(B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (i)(C)(2)(i) of this definition; and

(C) Manufacture/process food, provided that:

(1) All food used in such activities is consumed on that farm or another farm under the same management; or

(2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(ii) *Secondary Activities Farm.* A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary

Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in paragraphs (i)(B) and (C) of this definition.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food contact surfaces" includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Ground water means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.

Growth media means material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as stabilized compost, manure, non-fecal animal byproducts or table waste).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting 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. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw

agricultural commodities grown on a farm.

Hazard means any biological agent that has the potential to cause illness or injury in the absence of its control.

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.

Known or reasonably foreseeable hazard means a biological hazard that is known to be, or has the potential to be, associated with the farm or the food.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Manure means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health

significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

Non-fecal animal byproduct means solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective 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, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest means any objectionable animals or insects, including birds, rodents, flies, and larvae.

Pre-consumer vegetative waste means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or

corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

(i) In the same State or the same Indian reservation as the farm that produced the food; or

(ii) Not more than 275 miles from such farm.

Raw agricultural commodity (RAC) means "raw agricultural commodity" as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Sanitize means to adequately treat cleaned surfaces by a process that is

effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of "sewage sludge" in 40 CFR 503.9(w).

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Stabilized compost means a stabilized (*i.e.*, finished) biological soil amendment produced through a controlled composting process.

Static composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

Surface water means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.

Table waste means any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

Turned composting means a process to produce stabilized compost in which

air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

Visitor means any person (other than personnel) who enters your covered farm with your permission.

Water distribution system means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

We means the U.S. Food and Drug Administration (FDA).

Yard trimmings means purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

You, for purposes of this part, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of this part.

§ 112.4 Which farms are subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a "covered farm" subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

(b) A farm is not a covered farm if it satisfies the requirements in § 112.5 and we have not withdrawn the farm's exemption in accordance with the requirements of subpart R of this part.

§ 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

(a) A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) the farm sold directly to qualified end-users

(as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

§ 112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

(a) If your farm is eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:

- (1) This subpart (General Provisions);
- (2) Subpart O of this part (Records);
- (3) Subpart Q of this part (Compliance and Enforcement); and
- (4) Subpart R of this part (Withdrawal of Qualified Exemption).

(b) In addition, you are subject to the following modified requirements:

(1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

(3) The complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

§ 112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

If your farm is eligible for a qualified exemption in accordance with § 112.5:

(a) You must establish and keep records required under this provision in accordance with the requirements of subpart O of this part, except that the requirement in § 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts must be dated as required under § 112.161(a)(4).

(b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption that are described in § 112.5, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.

Subpart B—General Requirements

§ 112.11 What general requirements apply to persons who are subject to this part?

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.

(b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.

(c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a)

of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.

Subpart C—Personnel Qualifications and Training

§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.

(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.

(c) Training must be conducted in a manner that is easily understood by personnel being trained.

(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:

(1) Principles of food hygiene and food safety;

(2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is

reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance; and

(3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.

(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:

(1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;

(2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and

(3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.

(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

§ 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.

§ 112.30 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.

Subpart D—Health and Hygiene

§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

(a) You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an

applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

(b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:

- (1) Excluding any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and
- (2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

§ 112.32 What hygienic practices must personnel use?

(a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.

(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:

(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;

(2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;

(3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:

- (i) Before starting work;
- (ii) Before putting on gloves;
- (iii) After using the toilet;
- (iv) Upon return to the work station after any break or other absence from the work station;

(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and

(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;

(4) If you choose to use gloves in handling covered produce or food contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;

(5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and

(6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).

§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

(a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.

(b) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E—Agricultural Water

§ 112.41 What requirements apply to the quality of agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.

§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

(a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

- (1) The nature of each agricultural water source (for example, ground water or surface water);

(2) The extent of your control over each agricultural water source;

(3) The degree of protection of each agricultural water source;

(4) Use of adjacent and nearby land; and

(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

(b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.

(c) You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(d) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

§ 112.43 What requirements apply to treating agricultural water?

(a) When agricultural water is treated in accordance with § 112.45:

- (1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet

the relevant microbial quality criteria in § 112.44, as applicable.

(2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

(b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:

- (1) Used as sprout irrigation water;
- (2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;
- (3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and
- (4) Used for washing hands during and after harvest activities.

(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):

- (1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and
- (2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

(a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:

- (1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or
- (2) Treat the water in accordance with the requirements of § 112.43.

(b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:

- (1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:
 - (i) Applying a time interval between last irrigation and harvest using either:
 - (A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or
 - (B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or
 - (ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate

supporting scientific data and information;

(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or

(3) Treat the water in accordance with the requirements of § 112.43.

§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:

(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

(b) Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):

(1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source.

(i) The initial survey must be conducted:

(A) For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that you establish and use, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years.

(B) For an untreated ground water source, by taking a minimum total of four samples of agricultural water during the growing season or over a period of 1 year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic *Escherichia coli* (*E. coli*) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).

(iii) You must update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.

(2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.

(i) After the initial survey described in paragraph (b)(1)(i) of this section, you must test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze:

(A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).

(B) For an untreated ground water source, a minimum of one sample per year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.

(iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).

(3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which

you believe your microbial water quality profile changed.

(i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(ii) You must modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).

(c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).

§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?

(a) You may meet the requirements related to agricultural water testing required under § 112.46 using:

(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or

(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.

(b) Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.

§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

(a) You must manage the water as necessary, including by establishing and following water-change schedules for recirculated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and

food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).

(b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).

(c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:

(a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);

(b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);

(c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and

(d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A).

§ 112.50 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);

(2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;

(3) Scientific data or information you rely on to support the adequacy of a

method used to satisfy the requirements of § 112.43(a)(1) and (2);

(4) Documentation of the results of water treatment monitoring under § 112.43(b);

(5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *Escherichia coli* (*E. coli*), in accordance with § 112.45(b)(1)(ii);

(6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing);

(7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (2), if applicable;

(8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and

(9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).

Subpart F—Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable

generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.

(b) A biological soil amendment of animal origin is untreated if it:

(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic *E. coli* in 100 mL of water;

(2) Has become contaminated after treatment;

(3) Has been recombined with an untreated biological soil amendment of animal origin;

(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or

(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.

(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

(c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in

accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

(a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7; or

(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:

(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and

(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

(a) For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7, the relevant standards in the table in this paragraph (a); or

For the microorganism—	The microbial standard is—
(1) <i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.

For the microorganism—	The microbial standard is—
(2) <i>Salmonella</i> species	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
(3) <i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

(b) *Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) You must apply the biological soil amendments of animal origin specified in the first column of the table in this

paragraph (a) in accordance with the application requirements specified in the second column of the table in this paragraph (a) and the minimum application intervals specified in the third column of the table in this paragraph (a).

If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be applied—	And then the minimum application interval is—
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.	[Reserved].
(ii) Untreated	In a manner that does not contact covered produce during or after application.	0 days.
(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application.	0 days.
(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).	In any manner (<i>i.e.</i> , no restrictions)	0 days.

(b) [Reserved]

§ 112.60 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and

(ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and

(2) For a treated biological soil amendment of animal origin you

produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.

Subpart G–H [Reserved]

Subpart I—Domesticated and Wild Animals

§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place?

(a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially-enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

(b) The requirements of this subpart do not apply:

- (1) When a covered activity takes place in a fully-enclosed building; or
- (2) To fish used in aquaculture operations.

§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

(a) You must take the steps set forth in paragraph (b) of this section if under

the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.

(b) You must:

(1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and

(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

§ 112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (*i.e.*, to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Subpart J—[Reserved]

Subpart K—Growing, Harvesting, Packing, and Holding Activities

§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

If you grow, harvest, pack or hold produce that is not covered in this part (*i.e.*, excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:

(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and

(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.

§ 112.112 What measures must I take immediately prior to and during harvest activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the

growing area and all covered produce to be harvested, regardless of the harvest method used.

§ 112.113 How must I handle harvested covered produce during covered activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards—for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

§ 112.114 What requirements apply to dropped covered produce?

You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).

§ 112.115 What measures must I take when packaging covered produce?

You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

§ 112.116 What measures must I take when using food-packing (including food packaging) material?

(a) You must use food-packing material that is adequate for its intended use, which includes being:

(1) Cleanable or designed for single use; and

(2) Unlikely to support growth or transfer of bacteria.

(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Subpart L—Equipment, Tools, Buildings, and Sanitation

§ 112.121 What equipment and tools are subject to the requirements of this subpart?

Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment,

palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

§ 112.122 What buildings are subject to the requirements of this subpart?

Buildings subject to the requirements of this subpart include:

(a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and

(b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).

§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?

All of the following requirements apply regarding equipment and tools subject to this subpart:

(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and

(b) Equipment and tools must be:

(1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and

(2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

(c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

(d)(1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.

(e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must

do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.

§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:

- (a) Accurate and precise as necessary and appropriate in keeping with their purpose;
- (b) Adequately maintained; and
- (c) Adequate in number for their designated uses.

§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

Equipment that is subject to this subpart that you use to transport covered produce must be:

- (a) Adequately clean before use in transporting covered produce; and
- (b) Adequate for use in transporting covered produce.

§ 112.126 What requirements apply to my buildings?

(a) All of the following requirements apply regarding buildings:

(1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must:

- (i) Provide sufficient space for placement of equipment and storage of materials;
- (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and

(2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.

(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in

your buildings, as appropriate, considering the potential for such contamination through:

- (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and
- (2) Drip or condensate.

§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

(a) You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:

- (1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or
- (2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.

(b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.

§ 112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.

(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.

(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.

(b) Your toilet facilities must be designed, located, and maintained to:

- (1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;
- (2) Be directly accessible for servicing, be serviced and cleaned at a frequency

sufficient to ensure suitability of use, and be kept supplied with toilet paper; and

(3) Provide for the sanitary disposal of waste and toilet paper.

(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.

§ 112.130 What requirements apply for hand-washing facilities?

All of the following requirements apply to hand-washing facilities:

(a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities.

(b) Your hand-washing facilities must be furnished with:

- (1) Soap (or other effective surfactant);
- (2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and
- (3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).

(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.

§ 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.

(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of

covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

(d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

(a) You must convey, store, and dispose of trash, litter and waste to:

(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and

(2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

§ 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design and be adequately installed and maintained to:

(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities;

(b) Properly convey sewage and liquid disposable waste;

(c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and

(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

(a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:

(1) Adequately control their excreta and litter; and

(2) Maintain a system for control of animal excreta and litter.

(b) [Reserved]

§ 112.140 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:

(1) Growing operations for sprouts; and

(2) Covered harvesting, packing, or holding activities.

Subpart M—Sprouts

§ 112.141 What commodities are subject to this subpart?

The requirements of this subpart apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.

§ 112.142 What requirements apply to seeds or beans used to grow sprouts?

In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.

(a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.

(b) Except as provided in paragraph (c) of this section, if you know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen (either because it has been associated with foodborne illness; or based on microbial test results, including a positive finding of a pathogen in tests required under § 112.144(b)), you must:

(1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter commerce; and

(2) Report the information (association with illness and/or findings of microbial testing) to the seed grower,

distributor, supplier, or other entity from whom you received the seeds or beans.

(c) If your reason to believe that a lot of seeds or beans may be contaminated was based only on microbial test results:

(1) You are not required to take the steps set forth in paragraph (b)(1) of this section if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans; or

(2) You are not required to take the steps set forth in paragraphs (b)(1) and (2) of this section if you later reasonably determine, through appropriate followup actions, that the lot of seeds or beans is not the source of contamination (e.g., the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).

(d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.

(e) You must either:

(1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or

(2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that:

(i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and

(ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

§ 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?

You must take all of the following measures for growing, harvesting, packing, and holding sprouts:

(a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.

(b) Any food contact surfaces you use to grow, harvest, pack, or hold sprouts must be cleaned and sanitized before

contact with sprouts or seeds or beans used to grow sprouts.

(c) You must conduct testing during growing, harvesting, packing, and holding sprouts, as specified in § 112.144.

(d) You must establish and implement a written environmental monitoring plan as specified in § 112.145.

(e) You must take certain actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment, as specified in § 112.146.

(f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in § 112.147.

(g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in § 112.148.

§ 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?

All of the following testing must be done during growing, harvesting, packing, and holding sprouts:

(a) You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of § 112.145.

(b) You must either:

(1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147; or

(2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in-process stage (*i.e.*, while sprouts are still growing) for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147.

(c) In addition to *E. coli* O157:H7 and *Salmonella* species, you must conduct tests as provided in paragraph (b) of this section for additional pathogens when the following conditions are met:

(1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and

(2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts).

§ 112.145 What requirements apply to testing the environment for *Listeria* species or *L. monocytogenes*?

All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes*.

(a) You must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment.

(b) Your written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes*.

(c) Your written environmental monitoring plan must include a sampling plan that specifies:

(1) What you will test collected samples for (*i.e.*, *Listeria* species or *L. monocytogenes*);

(2) How often you will collect environmental samples, which must be no less than monthly, and at what point during production you will collect the samples; and

(3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.

(d) You must aseptically collect environmental samples and test them for *Listeria* species or *L. monocytogenes* using a method as set forth in § 112.152.

(e) Your written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*.

§ 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*?

You must, at a minimum, take the following actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment:

(a) Conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche;

(b) Clean and sanitize the affected surfaces and surrounding areas;

(c) Conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated;

(d) Conduct finished product testing when appropriate;

(e) Perform any other actions necessary to prevent recurrence of the contamination; and

(f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce.

§ 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in § 112.144(b):

(a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.

(b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using a method as set forth in § 112.153. You must not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* species, and, if applicable, a pathogen meeting the criteria in § 112.144(c).

(c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c).

§ 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?

You must, at a minimum, take the following actions if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c):

(a) Take appropriate action to prevent any food that is adulterated under

section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce;

(b) Take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c));

(c) Clean and sanitize the affected surfaces and surrounding areas; and

(d) Perform any other actions necessary to prevent reoccurrence of the contamination.

§ 112.150 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e);

(2) Your written environmental monitoring plan in accordance with the requirements of § 112.145;

(3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.147(a) and (c);

(4) Documentation of the results of all analytical tests conducted for purposes of compliance with this subpart;

(5) Any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153; and

(6) Documentation of actions you take in accordance with §§ 112.142(b) and (c), 112.146, and 112.148.

Subpart N—Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?

You must test the quality of water using:

(a) The method of analysis published by the U.S. Environmental Protection Agency (EPA), “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-09-007,” December, 2009. The Director of the Federal Register approves this incorporation by reference

in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue NW., Washington, DC 20460. You may inspect a copy at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html; or

(b)(1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or

(2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.

§ 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* using:

(a) The method of analysis described in “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples,” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(b) A scientifically valid method that is at least equivalent to the method of analysis in § 112.152(a) in accuracy, precision, and sensitivity.

§ 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:

(a) For *E. coli* O157:H7, *Salmonella* species:

(1) The method of analysis described in “Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(2) A scientifically valid method that is at least equivalent to the method of analysis in § 112.153(a)(1) in accuracy, precision, and sensitivity; and

(b) For any other pathogen(s) meeting the criteria in § 112.144(c), a scientifically valid method.

Subpart O—Records

§ 112.161 What general requirements apply to records required under this part?

(a) Except as otherwise specified, all records required under this part must:

(1) Include, as applicable:

(i) The name and location of your farm;

(ii) Actual values and observations obtained during monitoring;

(iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;

(iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

(v) The date and time of the activity documented;

(2) Be created at the time an activity is performed or observed;

(3) Be accurate, legible, and indelible; and

(4) Be dated, and signed or initialed by the person who performed the activity documented.

(b) Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162 Where must I store records?

(a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.

(b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

§ 112.163 May I use existing records to satisfy the requirements of this part?

(a) Existing records (*e.g.*, records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 112.164 How long must I keep records?

(a)(1) You must keep records required by this part for at least 2 years past the date the record was created.

(2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

§ 112.165 What formats are acceptable for the records I keep?

You must keep records as:

(a) Original records;

(b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or

(c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 112.166 What requirements apply for making records available and accessible to FDA?

(a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.

(b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.

(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

§ 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart P—Variances

§ 112.171 Who may request a variance from the requirements of this part?

A State, Federally-recognized tribe (or "tribe"), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where the State, tribe, or foreign country determines that:

(a) The variance is necessary in light of local growing conditions; and

(b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure

that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?

To request a variance from one or more requirements of this part, the competent authority (*i.e.*, the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under § 10.30 of this chapter.

§ 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:

(a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part;

(b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply;

(c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?

We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request.

§ 112.175 Who responds to a petition requesting a variance?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance.

§ 112.176 What process applies to a petition requesting a variance?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a variance.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register**, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (*e.g.*, because their farm is covered by the petition or as a person similarly situated to persons covered by the petition).

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing and will also make public a notice on FDA's Web site announcing our decision to either grant or deny the petition.

(1) If we grant the petition, either in whole or in part, we will specify the persons to whom the variance applies and the provision(s) of this part to which the variance applies.

(2) If we deny the petition (including partial denials), our written response to the petitioner and our public notice announcing our decision to deny the petition will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied).

§ 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?

(a) A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30 of this chapter. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and 112.173.

(b) If we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition.

(c) If we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location.

§ 112.178 Under what circumstances may FDA deny a petition requesting a variance?

We may deny a variance request if it does not provide the information required under § 112.173 (including the requirements of § 10.30 of this chapter), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.179 When does a variance approved by FDA become effective?

A variance approved by FDA becomes effective on the date of our written decision on the petition.

§ 112.180 Under what circumstances may FDA modify or revoke an approved variance?

We may modify or revoke a variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter.

(2) We will publish a notice of our determination that a variance should be modified or revoked in the **Federal Register**. This notice will establish a

public docket so that interested parties may submit written comments on our determination.

(3) When applicable, we will:

(i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked;

(ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and

(iii) Include in the **Federal Register** notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located.

(b) We will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows:

(1) We will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter.

(i) If FDA grants a hearing, we will provide the State, tribe, or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of the hearing.

(ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing).

(2) We will consider written submissions submitted to the public docket from interested parties.

(c) We will provide notice of our final decision as follows:

(1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter.

(2) We will publish a notice of our decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

§ 112.182 What are the permissible types of variances that may be granted?

A variance(s) may be requested for one or more requirements in subparts A through O of this part. Examples of permissible types of variances include:

(a) Variance from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b);

(b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and

(c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b).

Subpart Q—Compliance and Enforcement

§ 112.192 What is the applicability and status of this part?

(a) The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria and definitions in this part apply in determining whether a food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

or

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.193 What are the provisions for coordination of education and enforcement?

Under section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act, FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches.

Subpart R—Withdrawal of Qualified Exemption

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

(a) We may withdraw your qualified exemption under § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

(b) Before FDA issues an order to withdraw your qualified exemption, FDA:

(1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

(a) The date of the order;

(b) The name, address and location of the farm;

(c) A brief, general statement of the reasons for the order, including

information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or

(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.

(d) A statement that the farm must either:

(1) Comply with subparts B through O of this part on the date that is 120 calendar days from the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

(e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 112.213;

(f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.208;

(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(i) The name and the title of the FDA representative who approved the order.

§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

(a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a

timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

(a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order:

(1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 120 calendar days from the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in §§ 112.6 and 112.7.

§ 112.206 What is the procedure for submitting an appeal?

(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

§ 112.207 What is the procedure for requesting an informal hearing?

(a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

If the owner, operator, or agent in charge of the farm requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of the opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented

at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (2), (3), and (5) of this chapter and 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.210 What is the timeframe for issuing a decision on an appeal?

(a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the

presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order

within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

(d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption.

(b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office

of Compliance in the Center for Food Safety and Applied Nutrition); and

(2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-28159 Filed 11-13-15; 8:45 am]

BILLING CODE 4164-01-P

Produce Safety

ALLIANCE

FSMA Produce Safety Rule Regulatory Reference Table

Disclaimer

This educational tool was designed to provide produce growers and packers with an easy-to-use reference table that outlines the Food Safety Modernization Act (FSMA) Produce Safety Rule provisions. The regulatory requirements are summarized by subpart within this document, but this document does not represent the regulation in full. Using this tool does not guarantee compliance with the regulation but is meant to help navigate the regulation to quickly identify requirements. The complete *Title 21 of the Code of Federal Regulations, Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (a.k.a., the Produce Safety Rule)* can be found at the FDA's website at: <http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>. The codified section is included in the FSMA section of this manual.

Tool Design and Use

The first table shown in this tool, the **Summary Table**, provides a broad overview of what is included in each of the regulation's subparts, including their titles and section numbers.

After the Summary Table is a collection of **Subpart Tables** where subparts in the FSMA Produce Safety Rule are outlined with a general description of what they cover. While much of the language in these tables is verbatim from the FSMA Produce Safety Rule, there are instances where some sentences have been shortened for ease of use.

There are four primary columns in each **Subpart Table**.

- The first column denotes the subpart section in which the provision is located.
- The second column identifies the subpart number.
- The third column summarizes the language of the FSMA Produce Safety Rule provision.
- The last column denotes the PSA module where the information can be found. Subparts M, P, Q, and R do not contain references to the PSA modules. These subparts focus on regulatory areas beyond the scope of this curriculum. Subpart O also does not contain references to curriculum modules since this information (Records) applies to all curriculum modules.

Summary Table

Subpart	Numbers	Section Description
A – General Provisions	112.1- 112.7	Produce covered and not covered by regulation, definitions, who is subject to requirements, eligibility for qualified exemptions, modified requirements for exemptions, records kept for exemptions
B – General Requirements	112.11- 112.12	General requirements, alternatives to requirements
C – Personnel Qualifications and Training	112.21- 112.30	Training requirements for those who handle produce or food contact surfaces, supervisor requirements, training record requirements
D – Health and Hygiene	112.31- 112.33	Measures to prevent contamination from ill or injured workers, hygienic practices, prevention of contamination from visitors
E – Agricultural Water	112.41- 112.50	General water quality requirements, and criteria for certain intended uses, water source and water distribution system inspection, testing frequency, sampling and analysis requirements, corrective actions including treatment of agricultural water, measures to take during harvest, packing, and holding activities, permissible alternatives, recordkeeping requirements
F – Biological Soil Amendments of Animal Origin and Human Waste	112.51- 112.60	Determining the status of a biological soil amendment of animal origin, handling, conveying, and storage of soil amendments, prohibitions for use of human waste, acceptable treatment processes, microbial standards, application requirements and intervals, recordkeeping requirements
G – Reserved		
H – Reserved		
I – Domesticated and Wild Animals	112.81- 112.84	Requirements for working and domesticated animals, animal grazing in fields, threatened or endangered species protection, management of animal intrusion events
J – Reserved		
K – Growing, Harvesting, Packing, and Holding Activities	112.111- 112.116	Measures to take if growing both covered and excluded produce, handling harvested produce, exclusion of dropped produce for fresh market, packaging activities and packing material requirements

L – Equipment, Tools, Buildings, and Sanitation	112.121-112.140	Requirements for maintenance of equipment, tools, and buildings, requirements for calibration of instruments (e.g. thermometers), transportation of covered produce, pest control, toilet and handwashing facilities, sewage disposal, litter management, plumbing, domesticated animal excreta and litter
M – Sprouts	112.141-112.150	Requirements for growing, harvesting, and handling sprouts, testing requirements, management of sprout irrigation water, records required
N – Analytical Methods	112.151-112.153	Acceptable analytical methods for testing agricultural water quality for produce other than sprouts, for the sprout growing, harvesting, packing, and holding environments, and spent sprout irrigation water
O – Records	112.161-112.167	Record keeping requirements, storage, duration, accessibility, acceptable formats, disclosure of records outside FDA
P – Variances	112.171-112.182	Who may request variances, state, tribe and foreign country requests, data and information to submit, processing, approval, denial, modification, revocation of variance requests
Q – Compliance and Enforcement	112.192-112.193	Criteria and definitions as applicable to FD&C Act, failure to comply, coordination or education and enforcement
R – Withdrawal of Qualified Exemptions	112.201-112.213	FDA procedures and reasons for withdrawal of qualified exemptions, procedure for submitting appeals, requirements for requesting an informal hearing, timeframe for appeals, circumstances to reinstate a qualified exemption

Subpart A – General Provisions

	Number	Requirement Description	Module #
A	112.1(a)	Outline of foods covered by the regulation, which in general covers produce (raw agricultural commodities) unless excluded by 112.2	1
A	112.1(b)	<p>Covered produce includes the following:</p> <p>1) almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops) citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guava, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapple, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, sourop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons and yams; and</p> <p>2) Mixes of intact fruits and vegetables (such as fruit baskets)</p>	1
A	112.2(a)	<p>Produce that is not covered by this part:</p> <p>1) 'Rarely consumed raw' produce: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas, cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.</p> <p>2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and</p> <p>3) Produce that is not a raw agricultural commodity</p>	1

A	112.2(b)	<p>Produce is eligible for exemption under these conditions (except as noted in 112.2(b)(1), (2), and (3)):</p> <ol style="list-style-type: none"> 1) The produce receives commercial processing (including refining and distilling) that adequately reduces the presence of microorganisms of public health significance (e.g., processing of tomato paste or shelf stable tomatoes, processing produce into products such as sugar, oil, spirits, wines, and beer) 2) You must disclose in documents accompanying the produce, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and 3) You must either: <ol style="list-style-type: none"> i) Annually obtain written assurance, subject to the requirements of 112.2(b)(6), from the customer that performs the commercial processing described in 112.2(b)(1) that the customer has established and is following procedures that adequately reduce the presence of microorganisms of public health significance; or ii) Annually obtain written assurance, subject to the requirements of 112.2(b)(6), from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in 112.2(b)(1) and that the customer: <ol style="list-style-type: none"> A) Will disclose in documents accompanying the food that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and B) Will only sell to another entity that agrees, in writing, it will either: <ol style="list-style-type: none"> 1) Follow procedures that adequately reduce the presence of microorganisms of public health significance; or 2) Obtain similar written assurance from its customer that the produce will receive commercial processing described in 112.2(b)(1) and that there will be disclosure in documents accompanying the food, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and 4) You must establish and maintain documentation of your compliance with requirements in 112.2(b)(2) and (3) in accordance with the requirements of subpart O (Records), including: <ol style="list-style-type: none"> i) Documents containing disclosures required under 112.2(b)(2); and ii) Annual written assurances obtained from customers required under 112.2(b)(3); and 5) The requirements of subpart A (General Provisions) and subpart Q (Compliance and Enforcement) apply to such produce; and 6) An entity provides a written assurance under 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance 	1
A	112.3(a)	<p>Definitions and interpretations of terms in section 201 of the FD&C Act (21 U.S.C. 321) apply to terms used in subpart A</p>	

6—FSMA Regulatory Reference Table

A	112.3(b)	Definitions of very small and small businesses: 1) <u>Very small business</u> – if subject to subpart A and on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000 2) <u>Small business</u> – if subject to this subpart A and on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$500,000, and your farm is not a very small business as described above	1
A	112.3(c)	Definitions which apply to the FSMA Produce Safety Rule – see curriculum glossary or 112.3(c) for full list of FSMA Produce Safety Rule definitions	Glossary
A	112.4(a-b)	Outlines who is subject to the regulation – a) A “covered farm” is any farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of more than \$25,000 (on a rolling basis), use 2011 as the baseline year for calculating the adjustment for inflation b) A farm is not a covered farm if it satisfies the requirements in 112.5 and has not had exemptions withdrawn according to subpart R (Withdrawal of Qualified Exemptions)	1
A	112.5(a)	Qualified exemptions and modified requirements in a calendar year: 1) During the previous 3-year period, the average annual monetary value of food sold directly to qualified end users exceeded the average annual monetary value of food the farm sold to all other buyers (See definitions in 112.3(c)) AND 2) The average monetary value of all food the farm sold in the 3-year period was less than \$500,000, adjusted for inflation	1
A	112.5(b)	To determine whether the average monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, use 2011 as the baseline year for calculating the adjustment for inflation	1
A	112.6(a)	If your farm is eligible for a qualified exemption according to 112.5, you are subject to: 1) This subpart A (General Provisions); 2) Subpart O (Records); 3) Subpart Q (Compliance and Enforcement); and 4) Subpart R (Withdrawal of Qualified Exemptions)	1

A	112.6(b)	<p>In addition to 112.6(a), you are subject to the following modified requirements:</p> <p>1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown</p> <p>2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice</p> <p>3) The complete business address must include the street address or PO box, city, state, and zip code for domestic farms, and a comparable full address for foreign farms</p>	1, 7
A	112.7(a-b)	<p>If your farm is eligible for a qualified exemption in 112.5:</p> <p>a) You must establish and keep records, according to subpart O (Records), except for in 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Receipts must be dated as required in 112.161(a)(4)</p> <p>b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies criteria for a qualified exemption in 112.5, including a written record reflecting that you have performed an annual review and verification of your farm’s continued eligibility for exemption</p>	1

Subpart B – General Requirements

	Number	Requirement Description	Module #
B	112.11	You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act	1
B	112.12(a)	You may establish alternatives to certain specific requirements of subpart E (Agricultural Water), as specified in 112.49, provided you satisfy the requirements of 112.12(b) and (c)	5
B	112.12(b)	You may establish alternatives to the requirements in 112.12(a) provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection and not increase the likelihood that your covered produce would be adulterated under section 402 of the FD&C Act	5
B	112.12(c)	Scientific data and information used to support an alternative may come from available scientific literature, developed by you, or available from a third party. You must maintain documentation in accordance with subpart O (Records). You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.	5

Subpart C – Standards Directed to Personnel Qualifications and Training

	Number	Requirement Description	Module #
C	112.21(a)	All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are supervisors of said personnel, must receive adequate training per person's duties, upon hiring and periodically thereafter, at least once annually	2
C	112.21(b)	All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are supervisors of said personnel, must have a combination of education, training, and experience necessary to perform the person's duties	2
C	112.21(c)	Training must be conducted in a manner that is easily understood by personnel being trained.	2
C	112.21(d)	Training must be repeated, as necessary and appropriate in light of observations or information indicating personnel are not meeting standards in subparts C – O	2

C	112.22(a)	Minimum training requirements for personnel who handle covered produce during covered activities or supervise the conduct of such activities must include: 1) The principles of food safety and hygiene 2) The importance of health and personal hygiene for visitors and all personnel, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance 3) The standards in subparts C through O that apply to the employee’s job responsibilities	2, 6
C	112.22(b)	Persons who conduct harvest activities must be trained on the following: 1) Recognizing when covered produce must not be harvested because of contamination risks 2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean and maintained so as not to become a source of contamination 3) Correcting and reporting any problems with harvest containers or equipment	2, 4, 6
C	112.22(c)	At least one supervisor from your farm must complete food safety training at least equivalent to the standardized curriculum recognized as adequate by the FDA	2, 7
C	112.23	You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance	2, 7
C	112.30(a)	You must keep records under this Subpart C (Personnel Qualifications and Training) in accordance with requirements in Subpart O (Records)	2
C	112.30(b)	You must keep records of training that document required training of personnel including: date of training, topics covered, person(s) trained	2, 4, 7

Subpart D – Standards Directed to Health and Hygiene

	Number	Requirement Description	Module #
D	112.31(a)	Measures must be taken to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea)	2, 6
D	112.31(b)	The following measures must be taken to satisfy 112.31(a): 1) Exclude any person from working in any operations that may result in contamination of covered produce or food contact surfaces if they are shown to have or appear to have an applicable health condition 2) Instruct personnel to notify supervisors if they are ill or have an applicable health condition	2
D	112.32(a)	Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination	2, 6
D	112.32(b)	The following hygienic practices must be used to satisfy 112.32(a): 1) Maintain personal cleanliness to protect against contamination of covered produce and food contact surfaces 2) Avoid contact with animals other than working animals, and take action to minimize likelihood of contamination of covered produce 3) Wash hands thoroughly using soap (or other effective surfactant) and water (must satisfy requirements in 112.44(a)), dry hands thoroughly using single-service towels, sanitary towel service, electric hand dryers or other hand drying devices: i) Before starting work ii) Before putting on gloves iii) After using the toilet iv) Upon return to the work station after breaks v) As soon as practical after touching animals or animal waste vi) At any other time workers hands may become contaminated 4) If using gloves, maintain in an intact and sanitary manner and replace when necessary 5) Remove or cover hand jewelry that cannot be cleaned and sanitized when covered produce is manipulated by hand; and 6) Do not eat, chew gum, or use tobacco products in the area used for a covered activity (drinking beverages are permitted)	2, 4, 6
D	112.33(a)	Visitors must be made aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and steps must be taken to ensure visitors comply with such policies and procedures	2
D	112.33(b)	Toilet and handwashing facilities must be accessible to visitors	2

Subpart E – Standards Directed to Agricultural Water

	Number	Requirement Description	Module #
E	112.41	All agricultural water must be safe and of adequate sanitary quality for its intended use	5
E	112.42(a)	At the beginning of the growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent that they under your control, to identify food safety hazards including consideration of the following: 1) The nature of each agricultural water source (e.g., ground water or surface water) 2) The extent of your control over each agricultural water source 3) The degree of protection of each agricultural water source 4) Use of adjacent and nearby land; and 5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm	5
E	112.42(b)	All agricultural water distribution systems must be maintained, to the extent that they are under your control, as necessary to prevent the system from being a source of contamination, including regularly inspecting and adequately storing all equipment used in the system	5
E	112.42(c)	All agricultural water sources, to the extent that they are under your control, must be maintained by regularly inspecting each source, correcting any deficiencies, and keeping the source free of debris, trash, domesticated animals, and other sources of contamination to the extent practicable and appropriate	5
E	112.42(d)	As necessary and appropriate, measures must be implemented to reduce the potential for contamination of covered produce as a result of contact with pooled water (such as, using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method)	5
E	112.43(a)	When agricultural water is treated according to 112.45: 1) Any method used to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in 112.44, as applicable 2) Treatment of agricultural water must be delivered in a manner that ensures the treated water is consistently safe and of sanitary quality for its intended use and/or meets microbial quality criteria in 112.44, as applicable	5

12—FSMA Regulatory Reference Table

E	112.43(b)	Any treatment of agricultural water must be monitored at a frequency adequate to ensure the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets microbial quality criteria in 112.44, as applicable	5
E	112.44(a)	<p>You must ensure there is no detectable generic <i>Escherichia coli</i> (<i>E. coli</i>) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:</p> <ol style="list-style-type: none"> 1) Used as sprout irrigation water 2) Applied in any manner that directly contacts covered produce during or after harvest activities, including when used to make ice that contacts covered produce 3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces, and 4) Used for washing hands during and after harvest activities 	2, 5, 6
E	112.44(b)	<p>When agricultural water is used during growing activities for covered produce using direct water application method, the criteria in 112.44(b) (1) and (2) apply unless you use alternative criteria in accordance with 112.49</p> <ol style="list-style-type: none"> 1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic <i>E. coli</i> per 100 mL of water; and 2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic <i>E. coli</i> per 100 mL of water 	5
E	112.45(a)	<p>If you have determined or have reason to believe that your agricultural water does not meet the requirements of 112.41 or 112.44(a) you must immediately discontinue that use(s), and before you resume use of the water source and/or distribution system, you must either:</p> <ol style="list-style-type: none"> 1) Re-inspect the entire affected agricultural water system, to the extent that it is under your control, identify conditions that introduce foreseeable hazards to covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine effectiveness to ensure the criterion in 112.44(a) are met, as applicable; or 2) Treat the water in accordance with 112.43 	5

E	112.45(b)	<p>If it is determined that your agricultural water does not meet the microbial quality criteria required under 112.44(b) (or any alternative criteria, if applicable), you must discontinue use as soon as practicable and no later than the following year unless:</p> <p>1) A time interval (in days) and/or a calculated log reduction is applied by:</p> <ul style="list-style-type: none"> i) Applying a time interval between last irrigation and harvest using either: <ul style="list-style-type: none"> A) A microbial die-off rate of 0.5 log per day to achieve a calculated log reduction of the GM and STV to meet the microbial quality criteria in 112.44(b), for no more than 4 consecutive days; or B) An alternative microbial die-off rate and any accompanying maximum time interval according to 112.49; and/or ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data <p>2) Re-inspect the entire affected agricultural water system under your control, identify conditions that introduce known or reasonably foreseeable hazards, make necessary changes, and take adequate measures to determine effectiveness to ensure criteria in 112.44(b) (or any alternative microbial criteria, if applicable) are met; or</p> <p>3) Treat the water in accordance with 112.43</p>	5
E	112.46(a)	<p>There is no requirement to test any agricultural water that is subject to the requirements of 112.44 when:</p> <p>1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA), that meets the microbial requirements under those regulations or those of a State approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;</p> <p>2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in 112.44(a), and you have public water system results or certificates of compliance; or</p> <p>3) You treat water in accordance with the requirements of 112.43</p>	5, 6
E	112.46(b)	<p>Except for agricultural water as provided in 112.46(a), you must take the following steps for each source of water that is subject to the requirements of 112.44(b) (those that relate to application during growing activities):</p>	5, 6

14—FSMA Regulatory Reference Table

E	112.46(b)(1)	<p>Conduct an initial survey to develop a microbial water quality profile of the agricultural water source</p> <p>i) The initial survey must be conducted:</p> <p style="padding-left: 20px;">A) For an untreated surface water source, by taking a minimum of 20 samples over a minimum period of 2 years, but not greater than 4 years</p> <p style="padding-left: 20px;">B) For an untreated ground water source, by taking a minimum of 4 samples during the growing season or over a period of 1 year</p> <p>ii) The samples must be representative of your use and must be collected as close in time as practical to, but prior to, harvest. The microbial water quality profile (consisting of a GM and an STV) of generic <i>E. coli</i> per 100 mL is calculated using this data set. You must determine the appropriate way the water may be used based on your microbial water quality profile in accordance with 112.45(b)</p> <p>iii) You must update the microbial water quality profile annually as required by 112.46(b)(2) and (3)</p>	5
E	112.46(b)(2)	<p>Conduct an annual survey to update the microbial water quality profile of your agricultural water</p> <p>i) After the initial survey (described in 112.46(b)(1)(i)), you must test the water annually to update your existing microbial water quality profile to confirm the appropriate use of the water. You must analyze:</p> <p style="padding-left: 20px;">A) For an untreated surface water source, a minimum of 5 samples per year</p> <p style="padding-left: 20px;">B) For an untreated ground water source, a minimum of 1 sample per year</p> <p>ii) The samples of agricultural water must be representative of your use and must be collected as close in time as practicable to, but prior to, harvest</p> <p>iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual water survey data from within the previous 4 years, to make up a rolling data set of:</p> <p style="padding-left: 20px;">A) At least 20 samples for untreated surface water sources; and</p> <p style="padding-left: 20px;">B) At least 4 samples for untreated ground water sources</p> <p>iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with 112.45(b)</p>	5

E	112.46(b)(3)	<p>If you know or have reason to believe your microbial water quality profile no longer represents the quality of your water, you must develop a new microbial water quality profile reflective of the time period at which you believe the water quality profile changed (e.g. significant changes occur to adjacent land use likely to impact the quality of the water source).</p> <p>i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current water survey (if taken after the time of change), combined with new data, to make up a data set of:</p> <ul style="list-style-type: none"> A) At least 20 samples for untreated surface water sources; and B) At least 4 samples for untreated ground water sources <p>ii) You must modify your water use based on the revised GM and STV values in your updated microbial water quality profile in accordance with 112.45(b)</p>	5
E	112.46(c)	<p>If you use untreated ground water for purposes that are subject to the requirements in 112.44(a), you must initially test the microbial quality of each water source at least 4 times per growing season or over a period of one year, collected to be representative of the intended use. Based on these results, you must determine whether the water can be used for that purpose, in accordance with 112.45(a). If the samples tested meet the microbial quality criterion of 112.44(a) (no detectable generic <i>E.coli</i> per 100 mL), you may test once annually thereafter, collecting one sample that is representative of your use. You must resume testing at least 4 times per growing season or year if any annual test fails to meet the applicable microbial quality criterion in 112.44(a).</p>	5
E	112.47(a)	<p>You may meet the requirements related to agricultural water testing in 112.46 using:</p> <ul style="list-style-type: none"> 1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or 2) Data collected by a third party or parties, provided the water source(s) sampled adequately represent your agricultural water source(s) and all other applicable requirements of subpart E are met 	5
E	112.47(b)	<p>Agricultural water samples must be aseptically collected and tested using a method as set forth in 112.151</p>	5
E	112.48(a)	<p>You must manage water used for harvesting, packing, and holding activities as necessary, including by establishing and following water-change schedules for re-circulated water to maintain safety and adequate sanitary quality (for example, from hazards that may be introduced into the water from soil adhering to the covered produce)</p>	5, 6
E	112.48(b)	<p>You must visually monitor the quality of water that you use during harvesting, packing, and holding activities (e.g. water used for washing or hydrocooling covered produce) for build-up of organic material (such as soil or plant debris)</p>	5, 6

16—FSMA Regulatory Reference Table

E	112.48(c)	You must monitor the temperature of water and maintain at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) to minimize the potential for contamination through infiltration of microorganisms into the produce	5, 6
E	112.49(a-d)	You may establish and use one or more of the following alternatives, provided you satisfy the requirements in 112.12: a) An alternative microbial quality criterion using an appropriate indicator of fecal contamination instead of the microbial quality criteria in 112.44(b) b) An alternative microbial die-off rate and an accompanying maximum time interval instead of those in 112.45(b)(1)(i) c) An alternative minimum number of samples used in the initial survey for an untreated surface water source instead of the minimum required in 112.46(b)(1)(i)(A) d) An alternative minimum number of samples used in the annual survey for an untreated surface water source instead of the minimum required in 112.46(b)(2)(i)(A)	5
E	112.50(a)	You must establish and keep records required under subpart E (Agricultural Water) in accordance with the requirements of subpart O (Records)	5
E	112.50(b)	You must establish and keep the following records: 1) The findings of your agricultural water system inspection as required by 112.42(a) 2) Documentation of the results of all analytical tests conducted on agricultural water for compliance with Subpart E (Agricultural Water) 3) Scientific data or information you rely on to support the adequacy of the methods used to satisfy 112.43(a)(1) and (2) 4) Documentation of the results of water treatment monitoring as required by 112.43(b) 5) Scientific data or information you rely on to support microbial die-off or removal rates that are used to determine the time interval (in days) between harvest and end of storage, including other activities, such as commercial washing, as applicable, used to achieve the calculated log reduction of generic <i>E.coli</i> in order to satisfy 112.45(b)(1)(ii) 6) Documentation of actions you take in accordance with 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with 112.45(b)(1)(i) and/or (ii), documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities (such as, dates of last irrigation and harvest, the dates of harvest and end of storage, and/or dates of activities such as commercial washing) 7) Annual documentation of the results or certificates of compliance from a public water system as outlined in 112.46(a)(1) or (a)(2), if applicable 8) Scientific data or information you rely on to support any alternative that you establish and use according to 112.49 9) Any analytical methods you use instead of the method that is referenced in 112.151(a)	5, 6, 7

Subpart F – Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

	Number	Requirement Description	Module #
F	112.51(a)	A biological soil amendment of animal origin is treated if it has been processed to completion to reduce microorganisms of public health significance in accordance with 112.54, or in the case of agricultural tea, the biological materials of animal origin have been processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic <i>E.coli</i> in 100 mL of water	3
F	112.51(b)	A biological soil amendment of animal origin is untreated if it: 1) Has not been processed to completion in accordance with 112.54, or in the case of agricultural tea, the biological materials of animal origin have not been processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic <i>E.coli</i> in 100 mL of water 2) Has become contaminated after treatment 3) Has been recombined with an untreated biological soil amendment of animal origin 4) Is or contains a component of untreated waste that you have reason to believe is contaminated or has been associated with foodborne illness 5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive	3
F	112.52(a)	You must handle, convey, and store any biological soil amendment of animal origin in a manner and location so that it does not become a potential source of contamination to covered produce, food contact surfaces, areas where produce packing or handling occur, water sources, water distribution systems, and other soil amendments	3, 4
F	112.52(b)	You must handle, convey, and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin	3, 4
F	112.52(c)	You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated	3
F	112.53	You may not use human waste for growing covered produce, except sewage sludge biosolids in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements	3
F	112.54	112.54(a)-(b) provide treatment processes acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce	3

18—FSMA Regulatory Reference Table

F	112.54(a)	A scientifically valid controlled physical process (e.g. thermal), chemical process (e.g. high alkaline pH), biological process (e.g. composting), or a combination of scientifically valid controlled physical, chemical, and/or biological processes that has been validated to satisfy the microbial standard in 112.55(a) for <i>Listeria monocytogenes</i> , <i>Salmonella</i> species, and <i>E. coli</i> O157:H7; or	3
F	112.54(b)	A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in 112.55(b) for <i>Salmonella</i> and fecal coliforms. Scientifically valid controlled biological processes (e.g. composting) include: 1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55 °C) for 3 consecutive days and is followed by adequate curing; and 2) Turned composting that maintains aerobic conditions at a minimum of 131°F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing	3
F	112.55(a)	The following microbial standards apply to the treatment processes in 112.54. For <i>L. monocytogenes</i> , <i>Salmonella</i> species, and <i>E. coli</i> O157:H7, the relevant microbial standards are: 1) <i>L. monocytogenes</i> : Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or mL) analytical portion 2) <i>Salmonella</i> species: Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or mL) of total solids (dry weight basis) 3) <i>E. coli</i> O157:H7: Not detected using a method that can detect 0.3 MPN per 1 gram (or mL) analytical portion; or	3
F	112.55(b)	<i>Salmonella</i> species are not detected using a method that can detect three MPN <i>Salmonella</i> species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis)	3

F	112.56(a-b)	<p>a) Requirements and minimum application intervals of biological soil amendments of animal origin that must be met:</p> <ol style="list-style-type: none"> 1) i) Untreated, applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application: [application interval is Reserved] ii) Untreated, applied in a manner that does not contact covered produce during or after application: 0 day application interval 2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of 112.54(b) to meet the microbial standard in 112.55(b), applied in any manner that minimizes the potential for contact with covered produce during and after application: 0 day application interval 3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of 112.54(a) to meet the microbial standard in 112.55(a), applied any manner (no restrictions): 0 day application interval <p>b) [Reserved]</p>	3
F	112.60(a)	You must establish and keep records required under subpart F (Biological Soil Amendments and Human Waste) in accordance with the requirements of subpart O (Records)	3
F	112.60(b)	<p>For any biological soil amendment of animal origin you use, you must establish and keep records for:</p> <ol style="list-style-type: none"> 1) A treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that: <ol style="list-style-type: none"> i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and 2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature and turnings) were achieved 	3, 7

Subpart I – Standards Directed to Domesticated and Wild Animals

	Number	Requirement Description	Module #
I	112.81(a)	The requirements of subpart I (Domesticated and Wild Animals) apply when covered activities take place in an outdoor area or a partially-enclosed building and when there is a reasonable probability that animals will contaminate covered produce	4
I	112.81(b)	The requirements of subpart I do not apply: 1) When a covered activity takes place in a fully-enclosed building; or 2) To fish used in aquaculture operations	4
I	112.83(a)	You must take steps listed in 112.83(b) if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce	4
I	112.83(b)	You must: 1) Assess relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and 2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta, or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of 112.112 and take reasonable measures during growing to assist you during harvest when you must identify, and not harvest, covered produce that is likely to be contaminated with a known or reasonably foreseeable hazard	4
I	112.84	This regulation does not authorize the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages	4

Subpart K – Standards Directed to Growing, Harvesting, Packing, and Holding Activities

	Number	Requirement Description	Module #
K	112.111(a-b)	If you grow, harvest, pack or hold produce that is not covered in subpart K (i.e., excluded produce in accordance with 112.2) and also conduct activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with subpart K, you must take measures during these covered activities to: a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce	6
K	112.112	You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta	2, 4, 6
K	112.113	You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards (e.g., by avoiding contact of cut surfaces of harvested produce with soil)	2, 6
K	112.114	You must not distribute covered produce that drops to the ground before or during harvest (dropped covered produce). Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds)	2, 6
K	112.115	You must package covered produce in a manner that prevents the formation of <i>Clostridium botulinum</i> toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms)	6
K	112.116(a-b)	a) You must use food-packing material that is adequate for its intended use, which includes being: 1) Cleanable or designed for single use; and 2) Unlikely to support growth or transfer of bacteria b) If you reuse food-packing material, you must take steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or by using a clean liner	6

Subpart L – Standards Directed to Equipment, Tools, Buildings, and Sanitation

	Number	Requirement Description	Module #
L	112.121	Equipment and tools that are subject to the requirements of Subpart L (Equipment, Tools, Buildings and Sanitation) are those that are intended to, or likely to, contact covered produce and any instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance	6
L	112.122(a-b)	Buildings subject to the requirements of subpart L include: a) Fully and partially enclosed buildings used for covered activities, including those that have a roof but no walls b) Storage sheds, buildings, and other structures used to store food contact surfaces (such as harvest containers and food-packing materials)	6
L	112.123(a)	You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and	6
L	112.123(b)	Tools and equipment must be: 1) Installed and maintained to facilitate cleaning of equipment and of all adjacent spaces; and 2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests	3, 6
L	112.123(c)	Seams on food contact surfaces of equipment and tools must be smoothly bonded or maintained to minimize the accumulation of dirt, filth, food particles, and organic material, therefore minimizing the opportunity for the harboring or growth of microorganisms	6
L	112.123(d)	1) You must inspect, maintain, clean, and sanitize when necessary and appropriate, all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce 2) You must maintain and clean all non-food contact surfaces of equipment and tools used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce	3, 6
L	112.123(e)	Pallets, forklifts, tractors, and other vehicles that are intended to or likely to contact covered produce must be used in a manner that minimizes the potential for contamination of covered produce or food contact surfaces	3, 6
L	112.124(a-c)	Instruments used to measure, regulate, or record temperatures, pH, sanitizer efficacy, or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be: a) Accurate and precise; b) Adequately maintained; and c) Adequate in number for their designated uses	6

L	112.125(a-b)	Equipment used to transport covered produce must: a) Be adequately cleaned prior to transporting covered produce b) Adequate for use in transporting covered produce	6
L	112.126(a)	All of the following requirements apply regarding buildings: 1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination. Buildings must: i) Provide sufficient space for equipment and storage of materials ii) Permit proper precautions to be taken to reduce the potential for contamination through separation of operations by location, time, partition, enclosed systems, or other effective means; and 2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building	6
L	112.126(b)	You must implement measures to prevent contamination of covered produce and food contact surfaces in your buildings from: 1) Floors, walls, ceilings, fixtures, ducts, or pipes; and 2) Drip or condensate	6
L	112.127(a)	Reasonable precautions must be taken to prevent contamination by: 1) Excluding domesticated animals from fully-enclosed buildings where covered produce is stored, food contact surfaces or food-packing materials are exposed; or 2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted by location, time or partition	4, 6
L	112.127(b)	Guard or guide dogs may be allowed in some areas of fully enclosed buildings as long as they are not likely to contaminate produce, food contact surfaces, or food-packing materials	4
L	112.128(a-c)	Requirements regarding pest control in buildings: a) Measures must be taken as reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established (such as by use of screens) or by monitoring for the presence of pests and removing them when present	4, 6
L	112.129(a)	Adequate, readily accessible toilet facilities, must be provided to personnel, including toilet facilities readily accessible to growing areas during harvesting activities	2

24—FSMA Regulatory Reference Table

L	112.129(b)	Toilet facilities must be designed, located, and maintained to: 1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distributions systems with human waste 2) Be directly accessible for servicing and be cleaned and stocked on a sufficient schedule to ensure suitability of use 3) Provide for the sanitary disposal of waste and toilet paper	2, 6
L	112.129(c)	During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a handwashing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands	2
L	112.130(a)	Handwashing facilities must be provided to personnel during growing activities that take place in a full-enclosed building and during covered harvest, packing, or holding activities	2
L	112.130(b)	Handwashing facilities must have: 1) Soap or other effective surfactant 2) Running water that satisfies 112.44(a) 3) Drying devices, such as, single use towels, sanitary towel service, or electric hand dryers	2
L	112.130(c)	You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a handwashing facility and take appropriate measures to prevent waste water from a handwashing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards	2
L	112.130(d)	Antiseptic hand rubs may not be used as a replacement for washing hands with soap and water	2
L	112.131(a)	Sewage must be disposed of into an adequate sewage or septic system or through other adequate means	4, 6
L	112.131(b)	You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards	4, 6
L	112.131(c)	You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems	2, 4, 6

L	112.131(d)	After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems	2, 5
L	112.132(a-b)	Requirements for the control and disposal of trash, litter, and waste: a) You must convey, store, and dispose of trash, liter and waste to: 1) Minimize attracting or harboring pests 2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and water distribution systems b) You must adequately operate systems for waste management and disposal so they are not a potential source of contamination	5, 6
L	112.133(a-d)	Plumbing must be of adequate size and design, and be adequately installed and maintained to: a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or handwashing and toilet facilities b) Properly convey sewage and liquid disposable waste c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources d) Not allow backflow from or cross-connections between piping systems that discharge waste water or carry water for a covered activity, for sanitary operations, or for use in handwashing facilities	5, 6
L	112.134(a-b)	a) Animal excreta and litter from domesticated animals must: 1) Be adequately controlled to prevent contamination 2) Have a system to maintain control of litter and excreta b) [Reserved]	3, 4, 5
L	112.140(a-b)	Records for Subpart L (Equipment, Tools, Buildings, and Sanitation) must: a) Be established and kept in accordance with Subpart O (Records) b) Be established and kept to document the date and method of cleaning and sanitizing equipment subject to subpart L used in: 1) Growing operations for sprouts; and 2) Covered harvesting, packing, or holding activities	2, 6

Subpart M – Standards Directed to Sprouts

	Number	Requirement Description
M	112.141	The requirements of subpart M apply to growing, harvesting, packing, and holding of all sprouts, except soil or substrate-grown sprouts harvested without their roots
M	112.142(a-e)	<p>In addition to requirements in subpart M, all the following requirements apply to seeds or beans used to grow sprouts:</p> <p>a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.</p> <p>b) If you know or have reason to believe that a lot of seeds or beans may have been contaminated with a pathogen (either because it has been associated with foodborne illness or based on microbial test results, including positive results from tests required in 112.144(b), you must:</p> <ol style="list-style-type: none"> 1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter the market; and 2) Report the information associated with illness and/or findings of microbial testing to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans <p>c) If contamination of seeds or beans is based only on microbial test results:</p> <ol style="list-style-type: none"> 1) You are not required to discontinue use of all seeds or beans (112.142(b)(1)) if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance; or 2) You are not required to discontinue use of all seeds or beans (112.142(b)(1)) or report the information (112.142(b)(2)) if you later reasonably determine, through followup actions, that the lot of seeds or beans is not the source of contamination (e.g. the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts) <p>d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards</p> <p>e) You must either:</p> <ol style="list-style-type: none"> 1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or 2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of seeds or beans, provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that: <ol style="list-style-type: none"> i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination

M	112.143(a-g)	<p>You must take all of the following measures for growing, harvesting, packing, and holding sprouts:</p> <ul style="list-style-type: none"> a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building b) Any food contact surfaces you use to grow, harvest, pack, and hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts c) You must test the growing, harvesting, packing, and holding environment as specified in 112.144 d) You must establish and implement a written environmental monitoring plan as specified in 112.145 e) You must take certain actions if you detect <i>Listeria</i> species or <i>L. monocytogenes</i> in the growing, harvesting, packing, and holding environment as specified in 112.146 f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in 112.147 g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in 112.148
M	112.144(a-c)	<p>All of the following testing must be done during growing, harvesting, packing, and holding sprouts:</p> <ul style="list-style-type: none"> a) You must test the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i> in accordance with the requirements of 112.145 b) You must either: <ul style="list-style-type: none"> 1) Test spent sprout irrigation water from each production batch of sprouts for <i>E. coli</i> O157:H7, <i>Salmonella</i> species and any pathogens meeting the criteria in 112.144(c) in accordance with the requirements of 112.147; or 2) If testing spent sprout irrigation water is not practicable (for example, for soil-grown sprouts or hydroponically grown sprouts), test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for <i>E. coli</i> O157:H7, <i>Salmonella</i> species and any pathogens meeting the criteria in 112.144(c) in accordance with the requirements of 112.147 c) In addition to <i>E. coli</i> O157:H7 and <i>Salmonella</i> species, you must conduct tests provided in 112.144(b) for additional pathogens when the following conditions are met: <ul style="list-style-type: none"> 1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and 2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts)

M	112.145(a-e)	<p>All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i></p> <p>a) You must establish and implement a written environmental monitoring plan that is designed to identify <i>L. monocytogenes</i> if it is present in the growing, harvesting, packing, or holding environment</p> <p>b) Your written environmental monitoring plan must be directed to sampling and testing for either <i>Listeria</i> species or <i>L. monocytogenes</i></p> <p>c) Your written environmental monitoring plan must include a sampling plan that specifies:</p> <ol style="list-style-type: none"> 1) What you will test collected samples for (i.e., <i>Listeria</i> species or <i>L. monocytogenes</i>); 2) How often you will collect environmental samples, which must be no less than monthly and at what point during production you will collect the samples; and 3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment <p>d) You must aseptically collect environmental samples and test them for <i>Listeria</i> species or <i>L. monocytogenes</i> according to the method in 112.152</p> <p>e) Your written environmental monitoring plan must include a corrective action plan that at a minimum, requires you to take the actions in 112.146 and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for <i>Listeria</i> species or <i>L. monocytogenes</i></p>
M	112.146(a-f)	<p>You must take the following actions if you detect <i>Listeria</i> species or <i>L. monocytogenes</i> in the growing, harvesting, packing, or holding environment:</p> <p>a) Conduct additional testing of surfaces and areas surrounding the area where <i>Listeria</i> species or <i>L. monocytogenes</i> was detected to evaluate the extent of the problem, including the potential for <i>Listeria</i> species or <i>L. monocytogenes</i> to have become established in a niche;</p> <p>b) Clean and sanitize the affected surfaces and surrounding areas;</p> <p>c) Conduct additional sampling and testing to determine whether the <i>Listeria</i> species or <i>L. monocytogenes</i> has been eliminated;</p> <p>d) Conduct finished product testing when appropriate;</p> <p>e) Perform any other actions necessary to prevent reoccurrence of the contamination; and</p> <p>f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into the market</p>

M	112.147(a-c)	<p>All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in 112.144(b):</p> <p>a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.</p> <p>b) In accordance with the written sampling plan required in 112.147(a), you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using the method in 112.153. You must not allow the production batch of sprouts to enter into the market unless the results of the testing of spent sprout irrigation water or sprouts are negative for <i>E. coli</i> O157:H7, <i>Salmonella</i> species or a pathogen meeting the criteria in 112.144(c)</p> <p>c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in 112.148 and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for <i>E. coli</i> O157:H7, <i>Salmonella</i> species or a pathogen meeting the criteria in 112.144(c)</p>
M	112.148(a-d)	<p>You must take the following actions if samples of spent sprout irrigation water or sprouts test positive for <i>E. coli</i> O157:H7, <i>Salmonella</i> species or a pathogen meeting the criteria in 112.144(c):</p> <p>a) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into the market;</p> <p>b) Take steps required in 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under 112.142(c);</p> <p>c) Clean and sanitize the affected surfaces and surrounding areas; and</p> <p>d) Perform any other actions necessary to prevent reoccurrence of the contamination</p>

M	112.150(a-b)	<p>a) You must establish and keep records required under subpart M (Sprouts) in accordance with the requirements of subpart O (Records)</p> <p>b) You must establish and keep the following records:</p> <ol style="list-style-type: none"> 1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment according to the requirements in 112.142(e); 2) Your written environmental monitoring plan in accordance with the requirements of 112.145; 3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of 112.147(a) and (c); 4) Documentation of the results of all analytical testing conducted for the purposes of compliance with subpart M (Sprouts) 5) Any analytical methods you use instead of the methods that are referenced in 112.152 and 112.153; and 6) Documentation of actions you take in accordance with 112.142(b) and (c), 112.146, and 112.148
---	--------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Subpart N – Analytical Methods

Number	Requirement Description	Module #
N 112.151(a-b)	<p>You must test the quality of water using a method of analysis:</p> <p>a) As published by the EPA “Method 1603: <i>Escherichia coli</i> (<i>E. coli</i>) in Water by Membrane Filtration Using Modified membrane-Thermotolerant <i>Escherichia coli</i> Agar (Modified mTEC), EPA-821-R-09-007,” December, 2009, which is available from U.S. EPA or at http://www.epa.gov/cwa-methods/approved-cwa-microbiological-test-methods; or</p> <p>b) 1) A scientifically valid method that is at least equivalent to the method of analysis in 112.151(a) in accuracy, precision, and sensitivity; or</p> <p>2) For any other indicator of fecal contamination you may test for pursuant to 112.49(a), a scientifically valid method</p>	5
N 112.152(a-b)	<p>You must test the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i> using:</p> <p>a) The method of analysis described in “Testing Methodology for <i>Listeria</i> species or <i>L. monocytogenes</i> in Environmental Samples,” Version 1, October 2015, U.S. Food and Drug Administration; or</p> <p>b) A scientifically valid method that is at least equivalent to the method of analysis in 112.152(a) in accuracy, precision, and sensitivity</p>	Refer to Sprout Safety Alliance

N	112.153(a-b)	<p>You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:</p> <p>a) For <i>E. coli</i> O157:H7, <i>Salmonella</i> species:</p> <ol style="list-style-type: none"> 1) The method of analysis described in "Testing Methodologies for <i>E. coli</i> O157:H7 and <i>Salmonella</i> species in Spent Sprout Irrigation Water (or Sprouts)," Version 1, October 2015, U.S. Food and Drug Administration; or 2) A scientifically valid method that is at least equivalent to the method of analysis in 112.153(a)(1) in accuracy, precision, and sensitivity; and <p>b) For any other pathogen(s) meeting the criteria in 112.144(c), a scientifically valid method</p>	Refer to Sprout Safety Alliance
---	--------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------

Subpart O – Requirements Applying to Records That You Must Establish and Keep

	Number	Requirement Description
○	112.161(a)	<p>1) All records required under subpart O (Records) must include, as applicable:</p> <ol style="list-style-type: none"> i) Name and location of your farm; ii) Actual values and observations obtained during monitoring; iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record; iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and v) The date and time of the activity documented; <p>2) Be created at the time an activity is performed or observed;</p> <p>3) Be accurate, legible, and indelible; and</p> <p>4) Be dated, and signed or initialed by the person who performed the activity documented</p>
○	112.161(b)	Records required under 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party
○	112.162(a-b)	<p>Record Storage:</p> <ol style="list-style-type: none"> a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm
○	112.163(a-b)	<ol style="list-style-type: none"> a) Existing records kept for compliance with other regulations do not need to be duplicated if they contain all the information required by subpart O b) The information required by subpart O does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by subpart O, may be kept separately or combined with the existing records

32—FSMA Regulatory Reference Table

○	112.164(a-b)	<p>Record Storage Duration:</p> <p>a) 1) You must keep records required by subpart ○ for at least 2 years past the date the record was created</p> <p>2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with 112.5 and 112.7, must be retained as long as necessary to support the farm’s status during the applicable calendar year</p> <p>b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued</p>
○	112.165(a-c)	<p>You must keep records as:</p> <p>a) Original records;</p> <p>b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or</p> <p>c) Electronic records, in compliance with part 11 of this chapter</p>
○	112.166(a-c)	<p>a) You must have all records required under subpart ○ (Records) readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying</p> <p>b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible</p> <p>c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request</p>
○	112.167	<p>Records required by subpart ○ are subject to the disclosure requirements under part 20 of this chapter</p>

Subpart P – Variances

	Number	Requirement Description
P	112.171(a-b)	<p>A State, Federally-recognized tribe (or “tribe”), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of subpart P (Variances), where the State, tribe, or foreign country determines that:</p> <ul style="list-style-type: none"> a) The variance is necessary in light of local growing conditions; and b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P
P	112.172	<p>To request a variance from one or more requirements of subpart P, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under 10.30 of this chapter</p>
P	112.173(a-c)	<p>In addition to the requirements set forth in 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:</p> <ul style="list-style-type: none"> a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P; b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of subpart P to which the variance would apply; c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P
P	112.174	<p>FDA will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request</p>
P	112.175	<p>The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance</p>

P	112.176(a-d)	<p>Process applicable to a petition requesting variance:</p> <p>a) In general, the procedures set forth in 10.30 of this chapter govern FDA's response to a petition requesting a variance</p> <p>b) Under 10.30(h)(3) of this chapter, FDA will publish a notice in the Federal Register, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (e.g., either because their farm is covered by the petition or as a person similarly situated to persons covered by the petition)</p> <p>c) Under 10.30(e)(3) of this chapter, FDA will respond to the petitioner in writing and will also make public a notice on FDA's website announcing their decision to either grant or deny the petition</p> <p>1) If FDA grants the petition, either in whole or in part, FDA will specify the persons to whom the variance applies and the provision(s) of subpart P to which the variance applies</p> <p>2) If FDA denies the petition (including partial denials), their written response to the petitioner and their public notice announcing their decision to deny the petition will explain the reason(s) for the denial</p> <p>d) FDA will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied)</p>
P	112.177(a-c)	<p>a) A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with 10.30 of this chapter. These comments must include the information required in 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with 112.172 and 112.173</p> <p>b) If FDA grants a petition requesting a variance, in whole or in part, FDA may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition</p> <p>c) If FDA specifies that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, FDA will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of their decision in writing and will publish a notice on their website announcing their decision to apply the variance to similarly situated persons in that particular location</p>
P	112.178	<p>FDA may deny a variance request if it does not provide the information required under 112.173 (including the requirements of 10.30 of this chapter), or if FDA determines that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P</p>

P	112.179	A variance approved by FDA becomes effective the date of their written decision on the petition
P	112.180	FDA may modify or revoke a variance if they determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P
P	112.181(a)	<p>a) FDA will provide the following notifications:</p> <ol style="list-style-type: none"> 1) FDA will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if they determine that a variance granted in response to its petition should be modified or revoked. FDA's direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter 2) FDA will publish a notice of their determination that a variance should be modified or revoked in the Federal Register. This notice will establish a public docket so that interested parties may submit written comments on FDA's determination 3) When applicable, FDA will: <ol style="list-style-type: none"> i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of their determination that the variance should be modified or revoked; ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and iii) Include in the Federal Register notice, as described in 112.181(a)(2), public notification of their decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located
P	112.181(b)	<p>FDA will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows:</p> <ol style="list-style-type: none"> 1) FDA will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter <ol style="list-style-type: none"> i) If FDA grants a hearing, they will provide the State, tribes, or foreign country with an opportunity to make an oral submission. FDA will provide notice on their website of the hearing, including the time, date, and place of the hearing ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about their determination that a particular variance should be modified or revoked, FDA may consolidate such requests (for example, into a single hearing) 2) FDA will consider written submissions submitted to the public docket from interested parties
P	112.181(c)	<p>FDA will provide notice of their final decision as follows:</p> <ol style="list-style-type: none"> 1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter 2) FDA will publish a notice of their decision in the Federal Register. The effective date of the decision will be the date of publication of the notice

P	112.182(a-c)	<p>Examples of permissible types of variances include:</p> <p>a) Variance from the microbial quality criteria, established in 112.44(b), when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method;</p> <p>b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in 112.45(b)(1)(i); and</p> <p>c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of 112.44(b), established in 112.46(b)</p>
---	--------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Subpart Q – Compliance and Enforcement

	Number	Requirement Description
Q	112.192(a-b)	<p>a) The failure to comply with the requirements of subpart Q (Compliance and Enforcement), issued under section 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h), is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(vv))</p> <p>b) The criteria and definitions in subpart Q apply in determining whether a food is:</p> <ol style="list-style-type: none"> 1) Adulterated within the meaning of: <ol style="list-style-type: none"> i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or 2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264)
Q	112.193	Under Section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h(b)(2)(A)), FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches

Subpart R – Withdrawal of Qualified Exemption

	Number	Requirement Description
R	112.201(a)	<p>FDA may withdraw your qualified exemption under 112.5:</p> <ol style="list-style-type: none"> 1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or 2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm
R	112.201(b)	<p>Before FDA issues an order to withdraw your qualified exemption, FDA:</p> <ol style="list-style-type: none"> 1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction; 2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and 3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption
R	112.202(a-d)	<ol style="list-style-type: none"> a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with 112.202(a) c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order

R	112.203(a-i)	<p>An order to withdraw a qualified exemption applicable to a farm under 112.5 must include the following information:</p> <ul style="list-style-type: none"> a) The date of the order; b) The name, address and location of the farm; c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order: <ul style="list-style-type: none"> 1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or 2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm d) A statement that the farm must either: <ul style="list-style-type: none"> 1) Comply with subparts B through O of subpart R on the date that is 120 calendar days from the date of receipt of the order; or 2) Appeal the order within 15 calendar days of the receipt of the order in accordance with the requirements of 112.206 e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in 112.213; f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(f)) and of subpart R; g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in 112.208; h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and i) The name and the title of the FDA representative who approved the order
R	112.204(a-b)	<p>The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under 112.5 must either:</p> <ul style="list-style-type: none"> a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of 112.206

R	112.205(a-b)	<p>a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.</p> <p>b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order:</p> <ol style="list-style-type: none"> 1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of subpart R within 120 calendar days of the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and 2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in 112.6 and 112.7
R	112.206(a-b)	<p>a) To appeal an order to withdraw a qualified exemption applicable to a farm under 112.5, the owner, operator, or agent in charge of the farm must:</p> <ol style="list-style-type: none"> 1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, e-mail address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and 2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies <p>b) In a written appeal of the order withdrawing an exemption provided under 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in 112.207</p>
R	112.207(a-b)	<p>a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:</p> <ol style="list-style-type: none"> 1) May request an informal hearing; and 2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with 112.206 within 15 calendar days of the date of receipt of the order <p>b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial</p>

40—FSMA Regulatory Reference Table

R	112.208(a-b)	<p>If the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request:</p> <p>a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA</p> <p>b) The presiding officer may require that a hearing conducted under subpart R be completed within 1 calendar day, as appropriate</p>
R	112.208(c)	<p>FDA must conduct the hearing in accordance with part 16 of this chapter. <i>* 112.208(c)(1-7) are not included on this table for brevity, please see page Please see page 74567 in the codified section.</i></p>
R	112.209	<p>The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director</p>
R	112.210(a-b)	<p>a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed</p> <p>b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:</p> <ol style="list-style-type: none"> 1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or 2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed
R	112.211(a-d)	<p>An order to withdraw a qualified exemption applicable to a farm under 112.5 is revoked if:</p> <p>a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or</p> <p>b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or</p> <p>c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time</p> <p>d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702</p>

R	112.213(a)	If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption
R	112.213(b)	You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of subpart R as follows: 1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and 2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak
R	112.213(c)	If your qualified exemption was withdrawn under 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under 112.5, and FDA will notify you in writing that your exempt status has been reinstated.
R	112.213(d)	If your qualified exemption was withdrawn under 112.201(a)(1) and (a)(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under 112.5, in accordance with the requirements of 112.213(b)

Reference: GAP/GHP Audit

Reference Documents for the USDA GAP/GHP Audit

This section contains:

- ✦ USDA Audit Request Form
- ✦ USDA Audit Agreement to Participate Form
- ✦ USDA GAP/GHP Audit Checklist

**AGRICULTURAL MARKETING SERVICE, SPECIALTY CROPS PROGRAM
REQUEST FOR AUDIT SERVICES**

(This is the only acceptable form for fax or electronic submission to USDA for audit requests)

NOTE: Fill in all appropriate blocks. Requested services may be delayed because of incomplete information. Type of service requested must be selected below. Services will be declined if the request is beyond our scope of certification. Once a request has been received, a USDA representative will make contact within 48 hours of receipt to schedule the audit.

DATE OF REQUEST:	ANTICIPATED DATE OF AUDIT:
-------------------------	-----------------------------------

AUDITEE INFORMATION		FARM / FACILITY INFORMATION	
Company Name:		Location:	
Street Address:			
City, State & Zip:			
Phone Number:		Total Acres / Total Sq Feet to be audited:	
Contact Person:			

APPLICANT INFORMATION		COMMODITIES TO BE COVERED BY AUDIT (Please List)	
Company Name			
Phone Number:			
Fax Number:			
E-mail:			
Contact Person:			

TYPE OF AUDIT SERVICES REQUESTED (Please choose at least one)

<input type="checkbox"/> Produce GAPs Harmonized Audit - <i>Field Operations & Harvesting</i>
<input type="checkbox"/> Produce GAPs Harmonized Audit - <i>Field Operations & Harvesting w/ Global Markets Primary Production Addendum</i>
<input type="checkbox"/> Produce GAPs Harmonized Audit - <i>Post Harvest</i>
<input type="checkbox"/> Produce GAPs Harmonized Audit - <i>Post Harvest w/ Global Markets Primary Production Addendum</i>
<input type="checkbox"/> Mushroom Specific GAP Audit (M-GAP)
<input type="checkbox"/> Tomato Audit Protocol - <i>Open Field Production, Harvest & Field Packing</i>
<input type="checkbox"/> Tomato Audit Protocol - <i>Packinghouse</i>
<input type="checkbox"/> Tomato Audit Protocol - <i>Greenhouse</i>
<input type="checkbox"/> Tomato Audit Protocol - <i>Repacking and Distribution</i>
<input type="checkbox"/> Plant Systems Audit (PSA)

<input type="checkbox"/> USDA Good Agricultural Practices and Good Handling Practices (GAP&GHP) Audit (choose scopes below)
<input type="checkbox"/> Part 1 – Farm Review
<input type="checkbox"/> Part 2 – Field Harvest & Field Packing Activities
<input type="checkbox"/> Part 3 – House Packing Facility
<input type="checkbox"/> Part 4 – Storage & Transportation
<input type="checkbox"/> Part 6 – Wholesale Distribution Center / Terminal Warehouse
<input type="checkbox"/> Part 7 – Preventative Food Defense Procedures
<input type="checkbox"/> Food Defense
<input type="checkbox"/> Other:

ADDITIONAL REMARKS	
---------------------------	--

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0125. The time required to complete this information collection is estimated average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Non-Discrimination Policy: In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at How to File a Program Discrimination Complaint and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.



UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL MARKETING SERVICE, FRUIT AND VEGETABLE PROGRAM
AGREEMENT FOR PARTICIPATION IN AUDIT VERIFICATION PROGRAMS
Good Agricultural Practices & Good Handling Practices Audit Program (GAP&GHP)
Identity Preservation Program (IP)
Partners in Quality Audit Program (PIQ)

Company Information

I _____ a duly authorized representative of

 (Insert Name)

 (Name of Company)

 (Street Address, City, State, and Zip Code)

hereinafter referred to as the applicant, do hereby agree to be audited under a voluntary USDA, AMS, Specialty Crops Inspection Division audit program. The audit shall include verification of the company's farm(s), packing facilities, storage facilities, wholesale distribution centers or other locations as applicable to the audit scope(s).

1. The applicant agrees that with respect to:

- a. Laws, Regulation, Statutes** - To conform with all applicable Federal, State, and local government laws, regulations, or statutes, including, but not limited to: Regulations Governing Inspection and Certification of Fruits and Vegetables and Related Products (7 CFR, Part 51), any other pertinent regulations, and any such instructions covering inspection and certification of the products and verification of the processes as may be issued by AMS.
- b. Audit Request** - To contact and schedule the audit with the appropriate federal or federal-state inspection office (using the FV-237A form). The request for the initial audit will be made no later than two (2) weeks prior to the end of the growing/harvesting/packing season.
- c. Records** - To maintain all records required by the specific audit program including, but not limited to, quality manual, food safety manual, water test results, employee training records, manure use records, laboratory testing results and other records as required by the quality manual, food safety manual or specific audit program requirements. The applicant shall make these records available to USDA federal and/or federal-state auditors.
- d. Access to Facilities** - To grant permission for AMS authorized personnel to enter any and all farms and/or facilities covered by the specific audit program for the purposes of conducting the audit. This includes the initial audit and any unannounced audits as may be required by the program.
- e. Payment** - To pay by credit card, check, draft, or money order drawn to the order of the appropriate federal or federal-state agency for the services covered herein on or before the due date specified on the billing statement. Charges for GAP&GHP audits include, but are not limited to, the audit fee as listed in the fee schedule or Federal Register and travel expenses for the initial audit and any unannounced audits as may be required by the program. Failure to pay for services will result in decertification.

2. AMS agrees that with respect to:

- a. Perform Audit** – To provide objective third-party verification of the applicant's specific audit program using internationally recognized audit principles.
- b. Opening & Exit Interviews** - To discuss the audit prior to and report the results and observations with the applicant after each audit and provide a timeframe in which a copy of the completed audit report or checklist will be provided.
- c. Reports** - To issue to the applicant reports of all audits and evaluations of the applicant's specific audit program and provide written notification of any deficiencies found, if any.
- d. Confidentiality** - To consider and treat any trade secrets or confidential information as proprietary and confidential. To consider any records and related information provided to AMS as information that is voluntarily submitted to AMS because of their participation in the specific audit program.
- e. Issuance of Certificate, Posting and Sharing Audit Results** - To issue a certificate to the applicant and to post audit results to the USDA website, only when the applicant meets the USDA acceptance criteria for each scope being audited. NOTE: If an applicant does *not* want their company to be posted on the USDA website they must put their request in writing. To provide the specific applicant checklist and results of individual questions to other parties or web-based systems only at the written request of the applicant (See the *Optional* section on page 2 of this form). NOTE: Reports containing a compilation of audit information can be shared with the Food and Drug Administration. In addition, AMS will notify FDA in the event of an imminent food safety risk.

3. It is mutually agreed that with respect to:

- a. Length of Service** - That the audit results for GAP&GHP audits are valid for one year from the date of the initial audit, provided that the USDA acceptance criteria is met on both the initial audit and any unannounced audits that may be required by the program. For all other audit programs, the length of service is outlined in the specific audit program policy guide. This agreement shall remain in effect for the length of time the auditee remains a participant in the specific audit program.
- b. Maintaining Certification** - That a company's information will only remain on the USDA website if any and all unannounced audits show satisfactory adherence to the program. If the minimum passing score is not achieved, the company's information will be removed from the website until a follow-up audit is conducted by AMS verifying that effective corrective actions have been taken and the company attains the minimum score on all appropriate scopes of the audit.

Approved By:

Name of Applicant (Print): _____ Title: _____

Signature: _____ Date: _____

USDA Agricultural Marketing Service, Fruit & Vegetable Program/ Federal or Federal-State Inspection Program Supervisor

Name of Representative (Print): _____ Title: _____

Signature: _____ Date: _____

(OPTIONAL) The applicant request AMS to release audit results to:

a. Web-based Systems- The auditee designates the audit report is loaded into the following database (check all that apply):

icix Azzule Systems FoodLogiQ

b. Other Parties- The auditee designates the specific applicant checklist and results of individual questions be sent to:

 (Name of Company/Representative) (Email Address) (Phone)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0125. The time required to complete this information collection is estimated to average 2 minutes/hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD). To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, S.W., Washington, D.C. 20250-9410, or call (800) 795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer.

**USDA Good Agricultural Practices Good Handling Practices
Audit Verification Checklist**



This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," and generally recognized good agricultural practices.

Firm Name: _____

Contact Person: _____

Audit Site Address: _____

City: _____ **State:** _____ **Zip:** _____

Mailing Address: _____

City: _____ **State:** _____ **Zip:** _____

Telephone No: _____ **Fax:** _____

E-mail: _____

Auditor(s) (list all auditors with the lead listed first):

USDA or Fed-State Office performing audit: _____

Arrival Date: _____ **Time:** _____

Departure Date: _____ **Time:** _____

Travel Time (hours) _____

**Person(s)
Interviewed:**

Did the auditee participate in GAP & GHP training?

Yes No

Is there a map that accurately represents the farm operations?

Yes No N/A

Legal Description/GPS/Lat.&Long. of Location: _____

Are all crop production areas located on this audit site?

Yes No N/A

Total acres farmed (Owned, leased/rented, contracted, consigned): _____

Does the company have more than one packing facility?

Yes No N/A

Is there a floor plan of the packing house facility(s) indicating flow of product, storage areas, cull areas, employee break rooms, restrooms, offices?

Yes No N/A

Is any product commingled prior to packing?

Yes No

Audit Scope: (Please check all scopes audited)

General Questions (All audits must begin with and pass this portion)

Part 1 – Farm Review.....

Part 2 - Field Harvest and Field Packing Activities.....

Part 3 - House Packing Facility.....

Part 4 – Storage and Transportation.....

Part 5 – (Not Used)

Part 6 – Wholesale Distribution Center/Terminal Warehouse.....

Part 7 – Preventive Food Defense Procedures.....

Commodities:

Conditions Under Which an Automatic "Unsatisfactory" Will be Assessed

- An immediate food safety risk is present when produce is grown, processed, packed or held under conditions that promote or cause the produce to become contaminated.
- The presence or evidence of rodents, an excessive amount of insects or other pests in the produce during packing, processing or storage.
- Observation of employee practices (personal or hygienic) that have jeopardized or may jeopardize the safety of the produce.
- Falsification of records.
- Answering of Questions P1 or P2 as "NO".

Auditor Completion Instructions

- For clarification and guidance in answering these questions, please refer to the Good Agricultural Practices & Good Handling Practices Audit Verification Program Policy and Instruction Guide.
- Place the point value for each question in the proper column (Yes, No, or N/A).
- Gray boxes in the "N/A" column indicate that question cannot be answered "N/A".
- Any "N/A" or "No" designation must be explained in the comments section.
- The "Doc" column:
 - A "D" indicates that a document(s) is required to show conformance to the question. A document may be a combination of standard operating procedures outlining company policy as well as a record indicating that a particular action was taken.
 - A "R" indicates that a record is required to be kept showing an action was taken.
 - A "P" indicates that a policy/standard operating procedure (SOP) must be documented in the food safety plan in order to show conformance to the question.

General Questions

Implementation of a Food Safety Program

Questions		Points	Yes	NO	N/A	Doc
P-1	A documented food safety program that incorporates GAP and/or GHP has been implemented.					D
P-2	The operation has designated someone to implement and oversee an established food safety program. Name _____					D

Traceability

Questions		Points	Yes	NO	N/A	Doc
G-1	A documented traceability program has been established.	15				D
G-2	The operation has performed a "mock recall" that was proven to be effective.	10				R

Worker Health & Hygiene

Questions		Points	Yes	NO	N/A	Doc
G-3	Potable water is available to all workers.	10				R
G-4	All employees and all visitors to the location are required to follow proper sanitation and hygiene practices.	10				P
G-5	Training on proper sanitation and hygiene practices is provided to all staff.	15				D
G-6	Employees and visitors are following good hygiene/sanitation practices.	15				
G-7	Employees who handle or package produce are washing their hands before beginning or returning to work.	15				
G-8	Readily understandable signs are posted to instruct employees to wash their hands before beginning or returning to work.	10				
G-9	All toilet/restroom/field sanitation facilities are clean. They are properly supplied with single use towels, toilet paper, hand soap or anti-bacterial soap, and potable water for hand washing.	15				
G-10	All toilet/restroom/field sanitation facilities are serviced and cleaned on a scheduled basis.	10				R

Total Points earned for General Questions =

Total Possible = 180 *The total number of points possible for this section.*

Subtract "N/A" = _____ *Enter the additive number of N/A points (+points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score*

Passing Score = _____

Pass **Fail** **(please mark one)**

This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," and generally recognized good agricultural practices.

For further information regarding the USDA GAP & GHP Audit Program, please contact:

USDA Fruit and Vegetable Program, Specialty Crops Inspection Division, Audit Services Branch at 202-720-5021, or FVAudits@ams.usda.gov



Part 1 - Farm Review

Water Usage

(1-1) What is the source of irrigation water? (Pond, Stream, Well, Municipal, Other)
 Please specify:

(1-2) How are crops irrigated? (Flood, Drip, Sprinkler, Other) Please specify:

Questions		Points	Yes	NO	N/A	Doc
1-3	A water quality assessment has been performed to determine the quality of water used for irrigation purpose on the crop(s) being applied.	15				D
1-4	A water quality assessment has been performed to determine the quality of water use for chemical application or fertigation method.	15				D
1-5	If necessary, steps are taken to protect irrigation water from potential direct and non-point source contamination.	15				

Sewage Treatment

Questions		Points	Yes	NO	N/A	Doc
1-6	The farm sewage treatment system/septic system is functioning properly and there is no evidence of leaking or runoff.	15				
1-7	There is no municipal/commercial sewage treatment facility or waste material landfill adjacent to the farm.	10				

Animals/Wildlife/Livestock

Questions		Points	Yes	NO	N/A	Doc
1-8	Crop production areas are not located near or adjacent to dairy, livestock, or fowl production facilities unless adequate barriers exist.	15				
1-9	Manure lagoons located near or adjacent to crop production areas are maintained to prevent leaking/overflowing, or measures have been taken to stop runoff from contaminating the crop production areas.	10				

Questions		Points	Yes	NO	N/A	Doc
1-10	Manure stored near or adjacent to crop production areas is contained to prevent contamination of crops.	10				
1-11	Measures are taken to restrict access of livestock to the source or delivery system of crop irrigation water.	10				
1-12	Crop production areas are monitored for the presence or signs of wild or domestic animals the entering the land.	5				R
1-13	Measures are taken to reduce the opportunity for wild and/or domestic animals from entering crop production areas.	5				R

Manure and Municipal Biosolids

Please choose one of the following options as it relates to the farm operations:

_____ Option A. Raw manure or a combination of raw and composed manure is used as a soil amendment.

_____ Option B. Only composted manure/treated municipal biosolids are used as soil amendments.

_____ Option C. No manure or municipal biosolids of any kind are used as soil amendments.

Only answer the following manure questions (questions 1-14 to 1-22) that are assigned to the Option chosen above. DO NOT answer the questions from the other two options. The points from the manure and municipal biosolids are worth 35 of a total 190 points, and answering questions from the other two options will cause the points to calculate incorrectly.

Option A: Raw Manure		Points	Yes	NO	N/A	Doc
1-14	When raw manure is applied, it is incorporated at least 2 weeks prior to planting or a minimum of 120 days prior to harvest.	10				R
1-15	Raw manure is not used on commodities that are harvested within 120 days of planting.	10				R
1-16	If both raw and treated manure are used, the treated manure is properly treated, composted or exposed to reduce the expected levels of pathogens.	10				R
1-17	Manure is properly stored prior to use.	5				

Option B: Composted Manure		Points	Yes	NO	N/A	Doc
1-18	Only composted manure and/or treated biosolids are used as a soil amendment.	10				R
1-19	Composted manure and/or treated biosolids are properly treated, composted, or exposed to environmental conditions that would lower the expected level of pathogens.	10				D
1-20	Composted manure and/or treated biosolids are properly stored and are protected to minimize recontamination.	10				
1-21	Analysis reports are available for composted manure/treated biosolids.	5				R
Option C: No Manure/Biosolids Used		Points	Yes	NO	N/A	Doc
1-22	No animal manure or municipal biosolids are used.	35				P

Soils

Questions		Points	Yes	NO	N/A	Doc
1-23	A previous land use risk assessment has been performed.	5				R
1-24	When previous land use history indicates a possibility of contamination, preventative measures have been taken to mitigate the known risks and soils have been tested for contaminants and the land use is commensurate with test results.	10				R
1-25	Crop production areas that have been subjected to flooding are tested for potential microbial hazards.	5				R

Traceability

Questions		Points	Yes	NO	N/A	Doc
1-26	Each production area is identified or coded to enable traceability in the event of a recall.	10				R

COMMENTS:						

USDA Good Agricultural Practices and Good Handling Practices
 Audit Verification Checklist

Total Points earned for Farm Review = _____

Total Possible = 190 *The total number of points possible for this section.*

Subtract "N/A" = _____ *Enter the additive number of N/A points (+points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score*

Passing Score = _____

Pass **Fail** **(please mark one)**

This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," and generally recognized good agricultural practices.

Part 2 - Field Harvest and Field Packing Activities

Field Sanitation and Hygiene

Questions		Points	Yes	NO	N/A	Doc
2-1	A documented pre-harvest assessment is made on the crop production areas. Risks and possible sources of crop contamination are noted and assessed.	15				D
2-2	The number, condition, and placement of field sanitation units comply with applicable state and/or federal regulations.	10				
2-3	When question 2-2 is answered "N/A" (sanitation units are not required), a toilet facility is readily available for all workers.	10				
2-4	Field sanitation units are located in a location that minimizes the potential risk for product contamination and are directly accessible for servicing.	10				
2-5	A response plan is in place for the event of a major spill or leak of field sanitation units or toilet facilities.	10				P

Field Harvesting and Transportation

Questions		Points	Yes	NO	N/A	Doc
2-6	All harvesting containers and bulk hauling vehicles that come in direct contact with product are cleaned and/or sanitized on a scheduled basis and kept as clean as practicable.	10				D
2-7	All hand harvesting equipment and implements (knives, pruners machetes, etc.) are kept as clean as practical and are disinfected on a scheduled basis.	10				D
2-8	Damaged containers are properly repaired or disposed of.	5				
2-9	Harvesting equipment and/or machinery which comes into contact with product is in good repair.	10				
2-10	Light bulbs and glass on harvesting equipment are protected so as not to contaminate produce or fields in the case of breakage.	10				

USDA Good Agricultural Practices and Good Handling Practices
Audit Verification Checklist

Questions		Points	Yes	NO	N/A	Doc
2-11	There is a standard operating procedure or instructions on what measures should be taken in the case of glass/plastic breakage and possible contamination during harvesting operations.	5				P
2-12	There is a standard operating procedure or instructions on what measures should be taken in the case of product contamination by chemicals, petroleum, pesticides or other contaminating factors.	5				P
2-13	For mechanically harvested product, measures are taken during harvest to inspect for and remove foreign objects such as glass, metal, rocks, or other dangerous/toxic items.	5				
2-14	Harvesting containers, totes, etc. are not used for carrying or storing non- produce items during the harvest season, and farm workers are instructed in this policy.	5				P
2-15	Water applied to harvested product is microbially safe.	15				R
2-16	Efforts have been made to remove excessive dirt and mud from product and/or containers during harvest.	5				
2-17	Transportation equipment used to move product from field to storage areas or storage areas to processing plant which comes into contact with product is clean and in good repair.	10				
2-18	There is a policy in place and has been implemented that harvested product being moved from field to storage areas or processing plants are covered during transportation.	5				P
2-19	In ranch or field pack operations, only new or sanitized containers are used for packing the product.	10				D
2-20	Packing materials used in ranch or field pack operations are properly stored and protected from contamination.	10				
2-21	Product moving out of the field is uniquely identified to enable traceability in the event of a recall.	10				D

COMMENTS:

Total Points earned for Field Harvesting & Field Packaging = _____

Total Possible = 185 *The total number of points possible for this section.*

Subtract "N/A" = _____ *Enter the additive number of N/A points (+points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score*

Passing Score = _____

Pass **Fail** **(please mark one)**

This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," and generally recognized good agricultural practices.

Part 3 - HOUSE PACKING FACILITY

Receiving

Questions		Points	Yes	NO	N/A	Doc
3-1	Product delivered from the field which is held in a staging area prior to packing or processing is protected from possible contamination.	5				
3-2	Prior to packing, product is properly stored and/or handled in order to reduce possible contamination.	5				

Washing/Packing Line

Questions		Points	Yes	NO	N/A	Doc
3-3	Source water used in the packing operation is potable.	15				R
3-4	If applicable, the temperature of processing water used in dump tanks, flumes, etc., is monitored and is kept at temperatures appropriate for the commodity.	10				D
3-5	Processing water is sufficiently treated to reduce microbial contamination.	10				D
3-6	Water-contact surfaces, such as dump tanks, flumes, wash tanks and hydro coolers, are cleaned and/or sanitized on a scheduled basis.	10				D
3-7	Water treatment (strength levels and pH) and exposure time is monitored and the facility has demonstrated it is appropriate for the product.	10				D
3-8	Food contact surfaces are in good condition; cleaned and/or sanitized prior to use and cleaning logs are maintained.	15				D
3-9	Product flow zones are protected from sources of contamination.	10				
3-10	The water used for cooling and/or making ice is potable.	15				R
3-11	Any ice used for cooling produce is manufactured, transported and stored under sanitary conditions.	10				R

Packing House Worker Health & Hygiene

Questions		Points	Yes	NO	N/A	Doc
3-12	Employee facilities (locker rooms, lunch and break areas, etc.) are clean and located away from packing area.	10				
3-13	When there is a written policy regarding the use of hair nets/beard nets in the production area, it is being followed by all employees and visitors.	5				P
3-14	When there is a written policy regarding the wearing of jewelry in the production area, it is being followed by all employees and visitors.	5				P

Packing House General Housekeeping

Questions		Points	Yes	NO	N/A	Doc
3-15	Only food grade approved and labeled lubricants are used in the packing equipment/machinery.	10				R
3-16	Chemicals not approved for use on product are stored and segregated away from packing area.	10				
3-17	The plant grounds are reasonably free of litter and debris.	5				
3-18	The plant grounds are reasonably free of standing water.	5				
3-19	Outside garbage receptacles/dumpsters are closed or are located away from packing facility entrances and the area around such sites is reasonably clean.	5				
3-20	Packing facilities are enclosed.	5				
3-21	The packing facility interior is clean and maintained in an orderly manner.	5				
3-22	Floor drains appear to be free of obstructions.	5				
3-23	Pipes, ducts, fans and ceilings which are over food handling operations, are clean.	5				
3-24	Glass materials above product flow zones are contained in case of breakage.	10				
3-25	Possible wastewater spillage is prevented from contaminating any food handling area by barriers, drains, or a sufficient distance.	10				
3-26	There is a policy describing procedures which specify handling/disposition of finished product that is opened, spilled, or comes into contact with the floor.	15				P

Questions		Points	Yes	NO	N/A	Doc
3-27	Only new or sanitized containers are used for packing the product.	10				D
3-28	Pallets and containers are clean and in good condition.	5				
3-29	Packing containers are properly stored and protected from contamination (birds, rodents, and other pests).	10				

Pest Control

Questions		Points	Yes	NO	N/A	Doc
3-30	Measures are taken to exclude animals or pests from packing and storage facilities.	10				D
3-31	There is an established pest control program for the facility.	10				D
3-32	Service reports for the pest control program are available for review.	5				R
3-33	Interior walls, floors and ceilings are well maintained and are free of major cracks and crevices.	5				

Traceability

Questions		Points	Yes	NO	N/A	Doc
3-34	Records are kept recording the source of incoming product and the destination of outgoing product which is uniquely identified to enable traceability.	10				D

COMMENTS:

USDA Good Agricultural Practices Good Handling Practices
 Audit Verification Checklist

Total Points earned for House Packing Facility = _____

Total Possible = 290 *The total number of points possible for this section.*

Subtract "N/A" = _____ *Enter the additive number of N/A points (+points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score*

Passing Score = _____

Pass **Fail** **(please mark one)**

This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," and generally recognized good agricultural practices.

Part 4 - STORAGE AND TRANSPORTATION

Product, Containers & Pallets

Questions		Points	Yes	NO	N/A	Doc
4-1	The storage facility is cleaned and maintained in an orderly manner.	5				
4-2	Bulk storage facilities are inspected for foreign material prior to use and records are maintained.	5				R
4-3	Storage rooms, buildings, and/or facilities are maintained and sufficiently sealed or isolated and are protected from external contamination.	10				
4-4	Storage grounds are reasonably free of litter and debris.	5				
4-5	Floors in storage areas are reasonably free of standing water.	5				
4-6	Possible wastewater spillage is prevented from contaminating any food handling area by barriers, drains, or sufficient distance.	10				
4-7	There is a policy describing procedures which specify handling/disposition of finished product which is opened, spilled, or comes into contact with the floor.	15				P
4-8	Packing containers are properly stored and sufficiently sealed, to be protected from contamination (birds, rodents, pests, and other contaminants).	10				
4-9	Pallets, pallet boxes, tote bags, and portable bins, etc. are clean, in good condition and do not contribute foreign material to the product.	5				
4-10	Product stored outside in totes, trucks, bins, other containers or on the ground in bulk is covered and protected from contamination.	10				
4-11	Non-food grade substances such as paints, lubricants, pesticides, etc., are not stored in close proximity to the product.	10				
4-12	Mechanical equipment used during the storage process is clean and maintained to prevent contamination of the product.	5				D

Pest Control

Questions		Points	Yes	NO	N/A	Doc
4-13	Measures are taken to exclude animals or pests from storage facilities.	10				D
4-14	There is an established pest control program for the facility.	10				D
4-15	Service reports for the pest control program are available for review.	5				R
4-16	Interior walls, floors, and ceilings are well-maintained and are free of major cracks and crevices.	5				

Ice & Refrigeration

Questions		Points	Yes	NO	N/A	Doc
4-17	The water used for cooling and/or making ice is potable.	15				R
4-18	Manufacturing, storage, and transportation facilities used in making and delivering ice used for cooling the product have been sanitized.	10				R
4-19	Climate-controlled rooms are monitored for temperature and logs are maintained.	5				D
4-20	Thermometer(s) are checked for accuracy and records are available for review.	5				D
4-21	Refrigeration system condensation does not come in contact with produce.	10				
4-22	Refrigeration equipment (condensers, fans, etc.) is cleaned on a scheduled basis.	10				D
4-23	Iced product does not drip on pallets of produce stored below.	10				

Transportation

Questions		Points	Yes	NO	N/A	Doc
4-24	Prior to the loading process, conveyances are required to be clean, in good physical condition, free from disagreeable odors, and from obvious dirt/debris.	10				P
4-25	Produce items are not loaded with potentially contaminating products.	10				P
4-26	Company has a written policy for transporters and conveyances to maintain a specified temperature(s) during transit.	10				P
4-27	Conveyances are loaded to minimize damage to product.	5				P

Total Points earned for Storage & Transportation = _____

Total Possible = 255 *The total number of points possible for this section.*

Subtract "N/A" = _____ *Enter the additive number of N/A points (+points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score*

Passing Score = _____

Pass **Fail** **(please mark one)**

This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," and generally recognized good agricultural practices.

Part 6-Wholesale Distribution Center/Terminal Warehouses

Receiving

Questions		Points	Yes	NO	N/A	Doc
6-1	All companies that supply fresh produce are required to have passed a third party audit verification of GAP and/or GHP.	15				D
6-2	Upon receiving, conveyances are required to be clean, in good physical condition and free from obvious objectionable odors, dirt and/or debris at time of unloading.	10				P
6-3	Company does not accept produce items that are loaded with or are not protected from potentially contaminating products.	10				P
6-4	Refrigerated commodities are monitored for temperatures at the time of receiving.	5				R
6-5	The company has a written policy regarding the disposition of product when temperatures are not within the company's guidelines at the time of receiving.	5				P

Storage Facility/Temperature Control

Questions		Points	Yes	NO	N/A	Doc
6-6	The facility is clean and maintained in an orderly manner.	5				
6-7	Refrigerated rooms are monitored for temperature and logs are maintained.	5				D
6-8	Thermometer(s) are checked for accuracy and records are available for review.	5				D
6-9	Refrigeration system condensation does not come into contact with produce.	10				
6-10	Refrigeration equipment (condensers, fans, etc.) is cleaned on a scheduled basis.	10				D
6-11	Iced product does not drip on pallets of produce stored below.	10				
6-12	The water used for cooling/ice is potable.	10				R
6-13	Manufacturing, storage, and transportation facilities used in making and delivering ice used for cooling the product are sanitized on a scheduled basis.	10				D
6-14	There is a policy describing procedures which specify handling/disposition of finished product which is opened, spilled, or comes into contact with the floor.	15				P

Questions		Points	Yes	NO	N/A	Doc
6-15	Product flow zones are protected from sources of contamination.	10				
6-16	Glass materials above product flow zones are contained in case of breakage.	10				
6-17	The grounds are reasonably free of litter and debris.	5				
6-18	The grounds are reasonably free of standing water.	5				
6-19	Outside garbage receptacles/dumpsters are closed or are located away from facility entrances and the area around such sites is reasonably clean.	5				
6-20	The facility is enclosed.	5				
6-21	Floor drains appear to be free of obstructions.	5				
6-22	Pipes, ducts, fans, and ceilings in the facility are reasonably clean.	5				
6-23	Possible wastewater spillage is prevented from contaminating any food storage or handling area by barriers, drains, or a sufficient distance.	10				
6-24	Non-food grade substances such as paints, lubricants, pesticides, etc., are not stored in close proximity to the product.	10				

Pest Control

Questions		Points	Yes	NO	N/A	Doc
6-25	Measures are taken to exclude animals or pests from the facility.	10				D
6-26	There is an established pest control program for the facility.	10				D
6-27	Service reports for the pest control program are available for review.	5				R
6-28	Interior walls, floors and ceilings are well-maintained and free of major cracks and crevices.	5				

Repacking/Reconditioning

(6-29) Does the facility repack and/or recondition product?

YES NO (please mark one)

If the answer to question 6-29 is YES, answer questions 6-30 through 6-41. If the answer for question 6-29 is NO, then questions 6-30 through 6-41 are answered N/A.

Questions		Points	Yes	NO	N/A	Doc
6-30	Repacking/reconditioning processes are confined to an established location in the facility.	5				P
6-31	Food contact surfaces are in good condition; cleaned and/or sanitized prior to use and cleaning logs are maintained.	15				D
6-32	Source water used in the repacking operation is potable.	15				R
6-33	Processing water is sufficiently treated to reduce microbial contamination.	10				D
6-34	Water treatment (strength levels and pH) and exposure time is monitored and is appropriate for product.	10				D
6-35	If applicable, the temperature of processing water used in dump tanks, flumes, etc., is monitored and is kept at temperatures appropriate for the commodity.	10				D
6-36	Any ice used for cooling produce is manufactured, transported and stored under sanitary conditions.	10				R
6-37	Water used for chilling and/or to make ice is potable.	15				R
6-38	Only food grade approved and labeled lubricants are used in the repacking equipment/machinery.	10				D
6-39	Only new or sanitized containers are used for product repacking.	10				P
6-40	Pallets and other containers are clean and in good condition.	5				
6-41	Packing containers are properly stored and protected from contamination (birds, rodents, and other pests, etc.).	10				

Worker Health and Personal Hygiene

Questions		Points	Yes	NO	N/A	Doc
6-42	Employee facilities (locker rooms, lunch and break areas, etc.) are clean and located away from repack and storage area.	10				
6-43	When there is a written policy regarding the use of hair nets/beard nets in the facility, it is being followed by all affected employees and visitors.	5				P

Questions		Points	Yes	NO	N/A	Doc
6-44	When there is a written policy restricting the wearing of jewelry in the facility, it is being followed by all affected employees and visitors.	5				P

Shipping/Transportation

Questions		Points	Yes	NO	N/A	Doc
6-45	Prior to the loading process, conveyances are required to be clean, in good physical condition, free from disagreeable odors and from obvious dirt/debris.	10				P
6-46	Produce items are not loaded with potentially contaminating products.	10				P
6-47	Company has a written policy for transporters and conveyances to maintain a specified temperature(s) range during transit.	10				P

Traceability

Questions		Points	Yes	NO	N/A	Doc
6-48	Records are kept recording the source of incoming product and the destination of outgoing product which is uniquely identified to enable traceability.	10				D

COMMENTS:						

USDA Good Agricultural Practices and Good Handling Practices
 Audit Verification Checklist

**Total Points earned for Wholesale Distribution
 Center/Terminal Warehouse =** _____

Total Possible = 410 *The total number of points possible for this section.*

Subtract "N/A" = _____ *Enter the additive number of N/A points (+points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the
 Passing Score*

Passing Score = _____

Pass **Fail** **(please mark one)**

This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," and generally recognized good agricultural practices.

Part 7 - Preventive Food Defense Procedures

Based on the U.S. Food and Drug Administration's Food Producers, Processors, and Transporters:
 Food Security Preventive Measure Guidance for Industry.

Secure Employee/Visitor Procedures

Questions		Points	Yes	NO	N/A	Doc
7-1	The company has a documented food defense plan and a person has been designated to oversee it. Name: _____	5				D
7-2	Food defense training has been provided to all employees.	5				D
7-3	Employees are aware of whom in management they should contact about potential security problems/issues. Name of management representative: _____	5				
7-4	Visitors are required to check in (showing proof of identity) and out, when entering/leaving the facility.	5				D
7-5	The purpose of visitation to site is verified before admittance to the facility.	5				D
7-6	Visitors are prohibited from the packing/storage areas unless accompanied by an employee.	5				D
7-7	Incoming and outgoing employee and visitor vehicles to and from the site are subject to inspection.	5				D
7-8	Parked vehicles belonging to employees and visitors display a decal or placard issued by the facility.	5				
7-9	Staff is prohibited from bringing personal items into the handling or storage areas.	5				D
7-10	Staff access in the facility is limited to the area of their job function and unrestricted areas.	5				D
7-11	Management is aware of which employee should be on the premises, and the area they are assigned to.	5				D
7-12	A system of positive identification of employees has been established and is enforced.	5				

Secure Facility Procedures

Questions		Points	Yes	NO	N/A	Doc
7-13	Uniforms, name tags, or identification badges are collected from employees prior to the termination of employment.	5				D
7-14	The mailroom is located away from the packing/storage facilities.	5				
7-15	Computer access is restricted to specific personnel.	5				D
7-16	A system of traceability of computer transactions has been established.	5				
7-17	A minimum level of background checks has been established for all employees.	5				D
7-18	Routine security checks of the premises are performed for signs of tampering, criminal or terrorist activity.	5				D
7-19	Perimeter of facility is secured by fencing or other deterrent.	5				
7-20	Checklists are used to verify the security of doors, windows, and other points of entry.	5				D
7-21	All keys to the establishment are accounted for.	5				D
7-22	The facility has an emergency lighting system.	5				
7-23	The facility is enclosed.	5				
7-24	Storage or vehicles/containers/trailers/railcars that are not being used are kept locked.	5				
7-25	Delivery schedules have been established.	5				
7-26	The off-loading of incoming materials is supervised.	5				
7-27	The organization has an established policy for rejecting deliveries.	5				D
7-28	Unauthorized deliveries are not accepted.	5				D
7-29	The company does not accept returned (empty) containers for packing of product unless they are sanitized containers intended for reuse.	5				D
7-30	The facility has a program in place to inspect product returned to the facility for tampering.	5				D
7-31	The company has identified the individual(s), with at least one backup, who are responsible for recalling the product.	5				D
7-32	The company has performed a successful mock recall of product to the facility.	5				D

**Total Points earned for Preventative Food Defense
Procedures =** _____

Total Possible = 180 *The total number of points possible for this section.*

Subtract "N/A" = _____ *Enter the additive number of N/A points (+points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the
Passing Score*

Passing Score = _____

Pass **Fail** **(please mark one)**

**Good Agricultural Practices & Good Handling Practices
 Audit Verification Program Scoresheet**

www.ams.usda.gov/gapghp



Facility Name (Print) as it should appear on Certificate:

Street Address (Print):		City (Print):		State (Print):		Zip (Print):	
e-mail Address (Print):		fax number:		Date Audit Requested:		Date of Previous Audit :	
Date Audit Began:	Date Audit Completed:	Date Audit Completed:		USDA Commodity Procurement Audit?		Check One Yes <input type="checkbox"/> No <input type="checkbox"/>	
Time Audit Began:	Time Audit Completed:						

EVALUATION ELEMENTS

Scopes Requested	Element	Possible Points	Less N/A Points	Adjusted Points	Passing Score*	Facility Score	Pass Fail	Date Passed	General Questions	Reviewing Official	Unannounced
X	General Questions	180									
	Part 1 – Farm Review	190									
	Part 2 – Field Harvesting & Field Packing Activities	185									
	Part 3 – House Packing Facility	290									
	Part 4 – Storage and Transportation	255									
	Part 6 – Wholesale Distribution Center/ Warehouses	410									
	Part 7 – Preventative Food Defense Procedures	180									

*A Passing Score is 80% of the Possible Points, or the Adjusted Points if adjustments are necessary, with no "automatic unsatisfactory" conditions.

Commodities:	
Send completed GAP&GHP Certificate to: (choose one)	Inspection office: (list office) _____ Directly to auditee above: _____

Lead Auditor Name (Print): _____ **Signature & Date:** _____

Duty Station: _____ **All Scores Completed:** _____

For USDA HQ use:

Reviewing Official Name (Print): _____

Signature & Date: _____

To verify a company's continued good standing in the USDA GAP&GHP Program please visit <http://www.ams.usda.gov/gapghp>

USDA Good Agricultural Practices and Good Handling Practices USDA Checklist

USDA, AMS, Fruit and Vegetable Program Good Agricultural Practice & Good Handling Practices CORRECTIVE ACTION REPORT	Report #: <div style="text-align: center;">_____ of _____</div>
Company Name/Farm:	Date:
Lead Auditor:	
Crops(s):	
Description of Non Conformity:	
Notified company staff at time of finding non-conformity (Yes or No):	
Checklist question number and/or section of auditee food safety plan associated with non-conformity:	
Corrective Action Proposed and Time Frame for Implementation: <i>(Attach separate sheet if necessary)</i>	
Company Representative Signature: <i>Signature affirms statements concerning Non-Conformity, Corrective Action, and Implementation are correct.</i>	
Auditor signature for acceptance of proposed corrective action and timetable for implementation:	

Top portion for AUDITOR USE ONLY; bottom portion for Company and Auditor use.



Washington
State Department of
Agriculture

For more information, visit WSDA's Bridging the GAPs
website at agr.wa.gov/inspection/GAPGHP