



University of Idaho
Extension

“WHY DO I HAVE TO DO FSMA IF I DO GAP?”

**Understanding the differences and importance of
produce safety programs in Idaho**

Lu Hauger, Associate Extension Educator, Commercial
Produce Safety, FSMA, Boise

Made in collaboration with the Idaho
State Department of Agriculture 3rd
Party Verification and Produce Safety
Programs.



HOUSEKEEPING



Close all other programs running on your computer



Check your sound – problems with clarity, speed, etc. switch to the phone

Call-in number provided in the welcome email

Mute computer sound when using phone



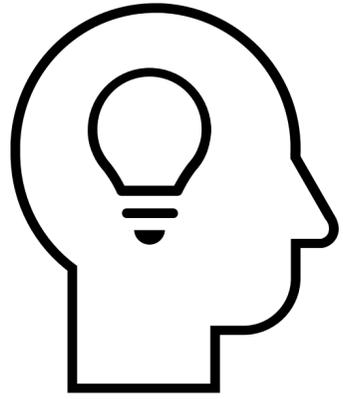
Type in questions for speakers (or for help with viewing & sound) into question box



Handouts are available to download on your computer



This webinar and Q&A will not discuss COVID-19-related produce safety questions



OBJECTIVES



After this webinar, you should have a better understanding of:

- The origins of both the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) and Good Agricultural Practices (GAPs) programs
- The difference between an **audit** and an **inspection**
- What types of GAP **audits** are available and what to expect from an audit
- How PSR **inspections** operate and Idaho and what to expect from a regulatory inspection

AN AUDIT IS NOT AN INSPECTION.



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These terms are often interchanged in produce safety, but they mean very different things:

- An **audit** refers to a voluntary 3rd party verification – such as Good Agricultural Practices (GAPs) certification
- An **inspection** refers to a mandatory, regulatory PSR visit conducted by the FDA or state investigators.
- A GAP **audit** cannot be done in place of a FSMA **inspection**.
- A PSR inspection may be enough to determine baseline food safety by law, but if a buyer requires GAP certification to purchase, a PSR inspection will not replace a GAP certification.

WHY IS THIS IMPORTANT?



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WHY IS THIS IMPORTANT?



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Audits and inspections are conducted by different departments of government in unique ways

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**WHAT CAN
YOU EXPECT
FROM AN
INSPECTION
VERSUS AN
AUDIT?**



Sherri Horrocks

3rd Party Audit Verification
Program Manager
Idaho State Department of
Agriculture



Casey Monn

Produce Safety Division
Program Manager
Idaho State Department of
Agriculture

FOOD SAFETY MODERNIZATION ACT



HISTORY

- Food Safety Modernization Act (FSMA) was signed into law on January 4th, 2011
- This represents the nation's largest overhaul of the federal food safety laws since 1938
- The goal of FSMA is to prevent foodborne outbreaks before they occur by taking proactive measures and shifting from a reactionary approach to a proactive approach
- In total, FSMA is made up of seven federal rules that address produce, human food, animal food, transportation, and imported food

PRODUCE SAFETY RULE

BACKGROUND

- Idaho adopted the Produce Safety Rule (Title 21 CFR Part 112 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption) in 2018
- Idaho State Department of Agriculture Produce Safety Division operates under a grant provided by the Food and Drug Administration (FDA)
- The Produce Safety Rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.
- The Produce Safety Rule includes six key requirements: (1) Agricultural Water; (2) Biological Soil Amendments; (3) Sprouts; (4) Domesticated and Wild Animals; (5) Worker Training and Health and Hygiene; and (6) Equipment, Tools and Buildings



PRODUCE SAFETY RULE

BACKGROUND

- Section 22-5404, Idaho Code – Idaho Produce Safety
- Produce Safety Inspections are mandatory, and not optional
- All covered farms will receive or have received an initial inspection based upon compliance date:
 - Inspections began with Large Covered Farms (\$500,000+ average annual produce sales) in the summer of 2019
 - Inspections continued with Small Covered Farms (\$250,000-\$500,000 average annual produce sales) throughout 2020
 - Inspections will continue with Very Small Covered Farms (\$25,000-\$250,000 average annual produce sales) throughout 2021

PRODUCE SAFETY INSPECTIONS



2019 IDAHO INSPECTION DATA

- In 2019 Idaho State Department of Agriculture Produce Safety Division (ISDA) Inspected **46 covered farms**
- **13 farms** recorded observations during an inspection
- **7 farms** were able to correct observations on site
- **63 inspections** were conducted total in 2019

Subpart E - Agricultural Water is currently under review and is not currently being enforced

PRODUCE SAFETY INSPECTIONS



2020 IDAHO INSPECTION DATA

- In 2020 Idaho State Department of Agriculture Produce Safety Division (ISDA) Inspected **38 covered farms**
- **8 farms** recorded observations during an inspection
- **5 farms** were able to correct observations on site
- **43 inspections** were conducted total in 2020

Subpart E - Agricultural Water is currently under review and is not currently being enforced

PRODUCE SAFETY INSPECTIONS



OVERALL IDAHO INSPECTION DATA

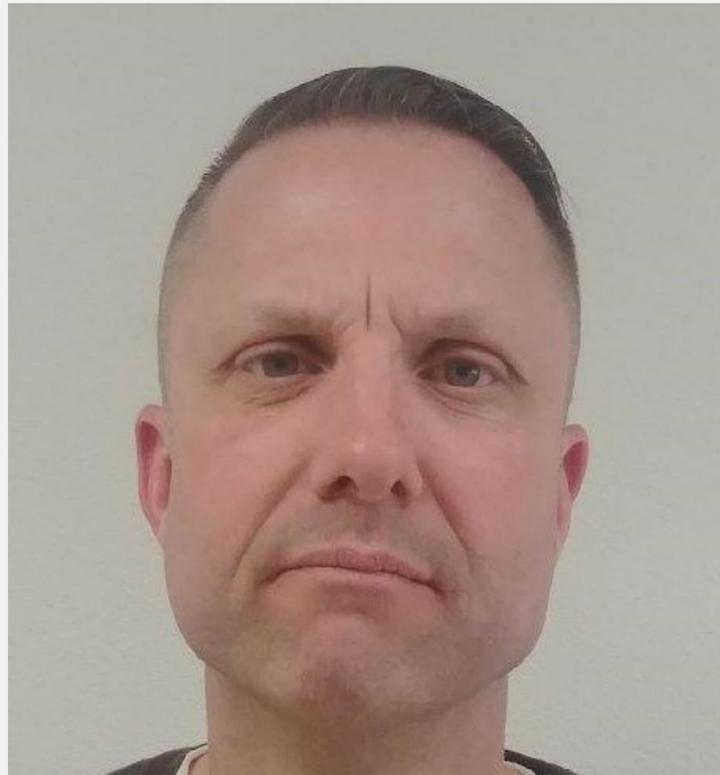
- In total, Idaho State Department of Agriculture Produce Safety Division (ISDA) inspected **84 covered farms**
- Average inspection time per farm is around **5.5 hours in total**
- **21 farms total recorded observations** during an inspection
- **12 farms total** were able to correct observations on site
- **106 inspections** have been conducted to date by ISDA

Subpart E - Agricultural Water is currently under review and is not currently being enforced



ISDA INVESTIGATORS

ISDA Produce Safety Investigators conduct Produce Safety Inspections



Greg Blahato
Agriculture Investigator Sr.,
Greg.Blahato@isda.Idaho.gov
Office: (208) 332-8603



Lacy Phelps
Agriculture Investigator Sr.,
Lacy.Phelps@isda.Idaho.gov
Office: (208) 332-8679

WHAT TO EXPECT:

PRE-INSPECTION



- ISDA may conduct an inspection on your farm for a variety of reasons such as an initial, routine, follow-up, or for-cause inspection
- An ISDA Ag. Investigator Sr. will call the person in charge or the point of contact established within your farm to schedule an inspection
- During the pre-inspection call the investigator will ask questions to confirm the Produce Safety Rule (PSR) applies to your operation and to update your farms information with ISDA
- During the pre-inspection call the investigator will discuss covered produce as it relates to your farm, the covered activities your farm conducts, the size of the operation, and an inspection date

WHAT TO EXPECT:

PRE-INSPECTION

- ISDA Investigators will schedule an inspection date that works for both ISDA and the person in charge/point of contact
- ISDA Investigators will ask about the farm's biosecurity practices, hazards, safety protocols, personal protective equipment, and other requirements the Investigators need to be aware of and adhere to before the visit
- Lastly, ISDA Investigators will agree on a meeting place with the person in charge/point of contact

WHAT TO EXPECT:

UNANNOUNCED



- Most inspections will be announced, but there are circumstances in which unannounced inspections may be conducted
- If a farm is unresponsive or unwilling to negotiate a set date for inspection
- If the farm has had Produce Safety issues in the past and the issues have not been corrected
- During a follow-up inspection if warranted to observe necessary changes being made
- In response to a complaint, recall, or foodborne outbreak investigation

WHAT TO EXPECT:

DAY-OF INSPECTION

- An ISDA Investigator will arrive on the farm and meet with person in charge or point of contact
- The ISDA Investigator will provide you with a brief description of the reason for and scope of the inspection and activities to be conducted during the inspection
- The amount of time the inspection takes depends on the type of inspection, farm activities, size of the farm, and observations made during the inspection.
- The ISDA Investigator will ask questions specific to the farm's activities and commodities throughout the inspection



WHAT TO EXPECT:

DAY-OF INSPECTION



- ISDA Investigators will observe your farm operating during its normal conditions
- ISDA Investigators may take notes throughout the entirety of the inspection, conduct educational discussions, and write up investigative reports in the event an out of compliance observation is made
- ISDA Investigators may explain what they are looking at and why, if there are regulatory concerns the investigator will discuss and explain reasons for each regulatory concern and the public health significance

WHAT TO EXPECT:



ENDING INSPECTION

- At the conclusion of the inspection, the ISDA Investigator will go over the inspection form with the person in charge or point of contact
- If an out of compliance was observed, investigators will review the investigative report with the person in charge or point of contact
- If needed, the ISDA Investigator will notify the farm of the follow-up inspection date
- At the conclusion of the exit interview the ISDA Investigator will request a signature from the person in charge or point of contact validating the inspection occurred.
- The ISDA Investigator will then sign and email a copy of the inspection to the person in charge or point of contact

WHAT TO EXPECT:



CONCLUSION

- ISDA's goal is to help farms in Idaho achieve compliance with regards to the Produce Safety Rule, and prevent future foodborne outbreaks
- ISDA in collaboration with University of Idaho Extension offers an On-Farm Readiness Review. This is a free, voluntary, non-regulatory, confidential “readiness” service to help farms align their practices with the requirements of the Produce Safety Rule. It consists of a preparedness work sheet and a walk around your farm with ISDA personnel and University of Idaho Educators
- ISDA in collaboration with University of Idaho Extension have developed Produce Safety Education videos to help enhance knowledge with the Produce Safety Rule

<https://agri.idaho.gov/main/inspections/fsma-main/produce-safety-rule-training-videos/>

Sherrri Horrocks

Third Party audit Verification Program Manager
Idaho State Department of Agriculture-FF & V



USDA GAP/GHP Auditing Program

Audits Performed in 2020 by ISDA...

- 347 – USDA GAP Farm/Grower Audits
(Farm Review-Harvest/Storage & Transportation)
- 147 – Harmonized GAP, Harmonized GAP Plus+ Audits
(Farm-Harvest/Storage & Transportation)
- 16 – USDA GHP Packinghouse Audits
- 9 – *Harmonized GAP, Harmonized GAP Plus + Post-Harvest Audits*
- 9 – *Unannounced Verification Audits*

Total of 528 Audits performed for the 2020 season.



ISDA has a Cooperative Agreement with USDA

• Audits that ISDA Performs...Non-regulated

-
- **USDA GAP/GHP Audits**
(Is a basic audit – does not align with the Produce Safety Rule)
 - **Harmonized GAP Audits**
(Aligns with Produce Safety Rule-Does not take the place of the regulatory Audit)
 - **Harmonized GAP Plus+ Audits** (GFSI Technical Equivalence) (Aligns with Produce Safety Rule-Does not take the place of the regulatory Audit)
 - **PSI Audits**

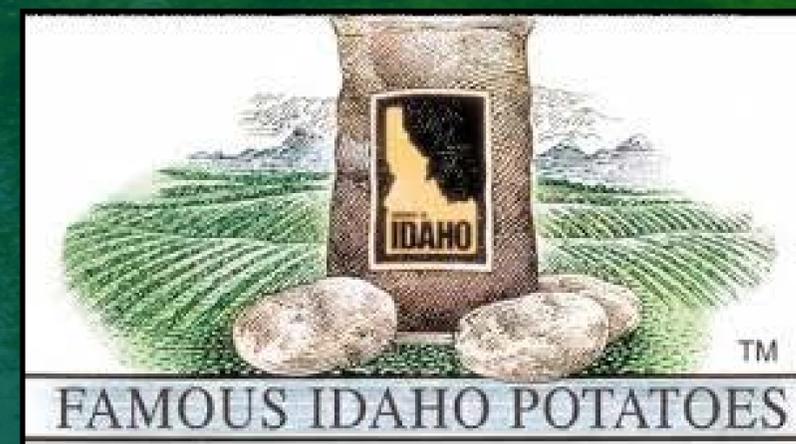




USDA GAP Audit History



- Established in 2001 at industry request
- Created in response to growing concern that fresh produce is safe to eat
- Developed in conjunction with FDA, AFVISA and state partners, industry groups, and academia
- Based on federal (FDA) guidelines and industry best practices
- Over time have incorporated buyer requirements, industry-specific requirements, and now federal regulation





Harmonization Initiative Government Technical Equivalency



Sonia Jimenez
Deputy Administrator, Specialty Crops Program

We are proud to be your partner and we've had an exciting summer, culminating in the [announcement](#) August 13 that the Harmonized Good Agricultural Practices (GAP) Plus+ Audit Program for Specialty Crops is now accepted as technically equivalent by the Global Food Safety Initiative (GFSI). The achievement of technical equivalency is the result of a multi-year effort of numerous divisions within SCP working with the specialty crops industry, the Food and Drug Administration's [Food Safety Modernization Act \(FSMA\)](#) team, and GFSI to give America's specialty crops sector a new tool for delivering safe products to consumers and growing markets for their products. Since the program began in 2012, USDA has certified more than 5,300 producers to the Harmonized GAP Standard. GFSI recognition means these producers now have a new tool demonstrating they meet the standards required by many of the largest food distributors. This will help the specialty crops industry selling in international markets, including distributors in the European Union and Japan where GFSI certification is often required.



USDA GAP/GHP- Harmonized GAP Audit ?





Commodity Based Audit...





**Good Agricultural Practices for Food Safety
in Blueberry Production:
Basic Principles**

Prepared by

Anamaria Gómez Rodas, Les Bourquin, Carlos García Salazar,
Anamaria Varela-Gómez and John C. Wise

Department of Entomology, Trevor Nichols Research Complex; Department of Food
Science and Human Nutrition; MSU Extension Central Region - Ottawa County

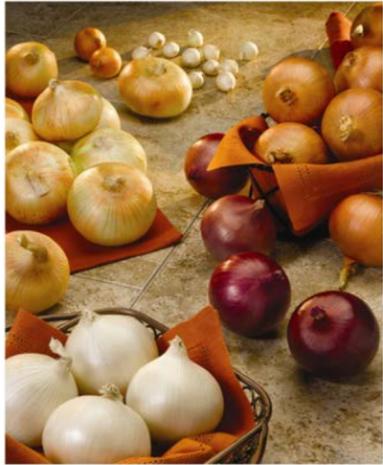



COMMODITY-SPECIFIC FOOD
SAFETY GUIDELINES FOR
THE PRODUCTION,
HARVEST, STORAGE, AND
PACKING OF
POTATOES



June 17, 2013

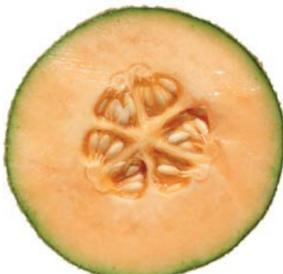
Commodity Specific
Food Safety Guidelines
for the
Dry Bulb Onion Supply Chain



1st Edition
December 2010

NATIONAL

Commodity-Specific Food Safety Guidelines for
Cantaloupes and Netted Melons



March 29, 2013
Version 1.1

Commodity Specific Food
Safety Guidelines for the
Fresh Tomato Supply Chain

2ND EDITION

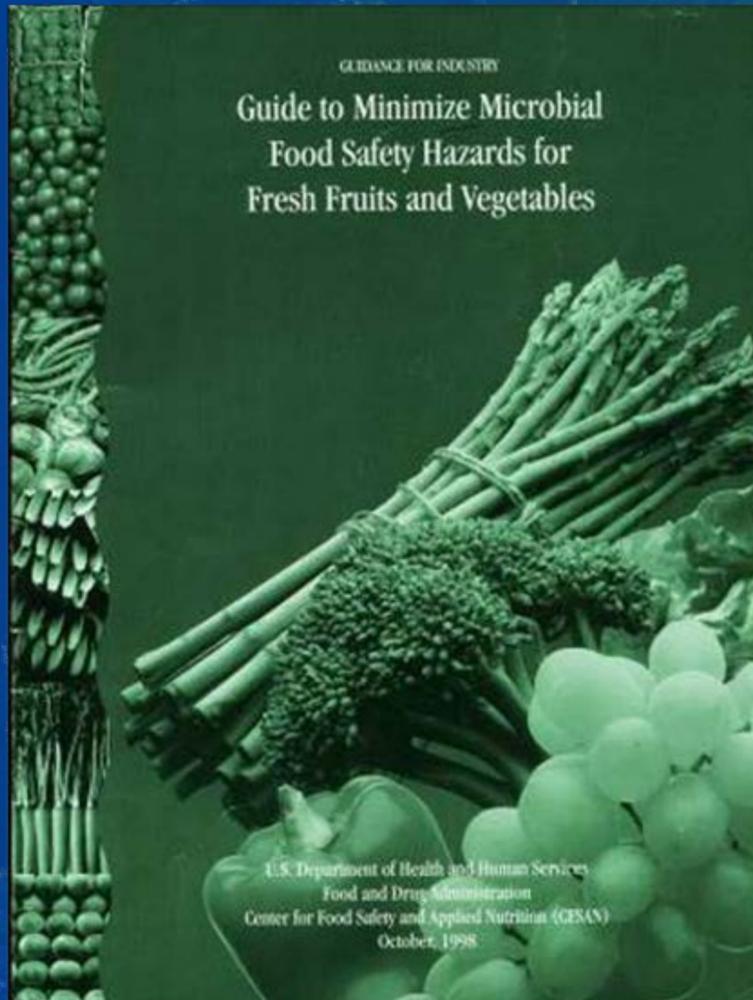






Guidance Documents...

FDA FOOD SAFETY
MODERNIZATION ACT





USDA GAP/GHP - Harmonized Standards



United States Department of Agriculture

Agricultural Marketing Service

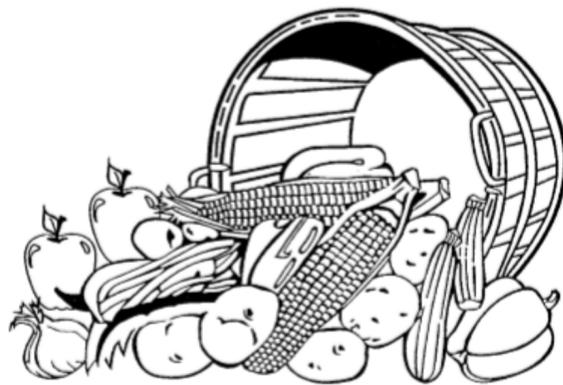
Fruit and Vegetable Programs

Fresh Products Branch

November 2009

Good Agricultural Practices and Good Handling Practices Audit Verification Program

Policy and Instructions



United States Department of Agriculture

Marketing and Regulatory Programs

Agricultural Marketing Service

Specialty Crops Program

Specialty Crops Inspection Division

Produce GAPs Harmonized Food Safety Standard

February 8, 2021



United States Department of Agriculture

Marketing and Regulatory Programs

Agricultural Marketing Service

Specialty Crops Program

Specialty Crops Inspection Division

Harmonized GAP Plus+ Standard

A global market-access solution for the specialty crops industry

February 8, 2021





USDA GAP Scopes-Parts of Audit



Part 1 Farm Review

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: Potatoes 620, Onions 300



Part 4 Storage/Transportations



Part 2 Harvest



Scopes of Harmonized GAP Plus Audit...

- Five scopes

1. General Questions (G)
2. Field Operations and Harvesting (F)
3. Post-Harvest (P)
4. Logo Use (L) – *only for auditees who apply for and are using the USDA GAP& GHP Logo*
5. Tomato Audit Protocol (New)

- General Questions must be answered for all audits

- Other scopes as applicable





Harmonized GAP + Standard

GENERAL QUESTIONS (G)

G-1: Management Responsibility

Req. #	Requirement	DOC	MAN	Procedure	Verification	Corrective Action
G-1.1	A food safety policy shall be in place.	WP	<ul style="list-style-type: none">•	A written policy shall outline a commitment to food safety, in general terms, how it is implemented and how it is communicated to employees, and be signed by Senior Management.	The auditor observes the food safety policy, observes that it is signed by Senior Management, and observes that it has been communicated to all employees in a manner that can be understood.	The Operation creates or revises the policy, or its communication to employees, to be in compliance.

Requirement Number





Harmonized GAP + Standard

Requirement = Specifications
the auditee must meet

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Harmonized GAP + Standard

DOC = Records, Policies, Documents etc. Requirement in detail

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Harmonized GAP + Standard

Mandatory = Questions must be compliant to meet acceptance criteria

GENERAL QUESTIONS (G)

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Harmonized GAP + Standard

Procedure = Explains the requirement in greater detail



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Harmonized GAP + Standard

Verification = How the Auditor validates the requirement.

GENERAL QUESTIONS (G)

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Harmonized GAP + Standard

Corrective Action = Actions leading to correction of the non-conformity

GENERAL QUESTIONS (G)

G-1: Management Responsibility

Req. #	Requirement	DOC	MAN	Procedure	Verification	Corrective Action
G-1.1	A food safety policy shall be in place.	WP	•	A written policy shall outline a commitment to food safety, in general terms, how it is implemented and how it is communicated to employees, and be signed by Senior Management.	The auditor observes the food safety policy, observes that it is signed by Senior Management, and observes that it has been communicated to all employees in a manner that can be understood.	The Operation creates or revises the policy, or its communication to employees, to be in compliance.



FDA Notification



- Failure to protect ready-to-eat foods
- Obvious signs of pest damage to food
- Obvious and significant pest infestation
- Improper handling or labeling of food allergens
- Indication of contamination by gases
- Improper cooling of potentially hazardous foods
- Exposure of food to human blood



Review



- Harmonized GAP Plus+ achieved “Government Technical Equivalence” towards GFSI Certification
- Harmonized GAP Plus+ Audit is a commodity-based audit adherence to current industry practices, regulatory requirements and prevailing regulations. (FDA, PSA, FSMA, etc.)
- Built on the concepts of risk identification, control and mitigation risks. Monitoring, verification & documentation included. HACCP.
- Five scopes of Audits (General, Field Operations/Harvesting, Post-Harvest, Logo use, and Tomato Protocol)
- Three separate standards with three separate checklists (USDA GAP/GHP, Harmonized GAP Plus+ Standard, Harmonized Food Safety Standard)
- FDA Notification of serious offenses



USDA Harmonized GAP Audit

What One USDA Audit Can Do For You

USDA

USDA Harmonized GAP

- Global Food Safety Initiative (GFSI) option via USDA H-GAP Plus+ audit
- Compliance with Produce Harmonized GAP Standard
- Aligns with Produce Safety Rule technical requirements
- Voluntary, fee-for-service
- Annual
- USDA-licensed auditor
- USDA certification of meeting audit standard and acceptance criteria
- Result on USDA website

Market Access
AUDIT

Regulatory
INSPECTION

USDA GAP /
FDA PSR Alignment

One Audit – Multiple Uses

FDA

Produce Safety Rule

- Confirms compliance with Produce Safety Rule
- Mandatory
- Intermittent
- No cost
- FDA or State regulatory inspector
- Documentation provided to farmer
- Significant deficiencies recorded for correction

USDA's alignment of the requirements of USDA Harmonized GAP audit to the minimum regulatory requirements of the FDA's Produce Safety Rule means your USDA GAP audit will:

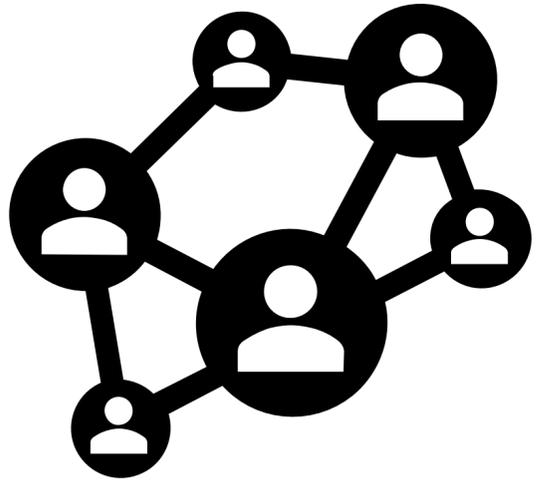
- ✓ Confirm you are in compliance with the Produce Harmonized GAP Standard AND implementing the relevant technical components of the Produce Safety Rule
- ✓ Provide you metrics that help you meet the Produce Safety Rule's ultimate goals of increasing food safety

SUMMARY

GAP AND FSMA PSR PROGRAMS

- GAP and FSMA are both key parts of the produce safety landscape in Idaho.
- Both programs have different application, coverage and use for growers.
- ISDA implements GAP and PSR in Idaho, but different departments govern each.
- Growers that are looking to expand their market may benefit from pursuing GAP certification, depending on buyer needs, but it is not required by law.
- Compliance with PSR is required by law for many growers.
- If you need guidance on how to get started with the GAP certification process or are unsure how the Produce Safety Rule affects you, we have people that are happy to assist.

ADDITIONAL RESOURCES



ON-FARM READINESS REVIEW

- Assist farmers with understanding how the PSR applies to their operation.
- Are voluntary, non-regulatory reviews to prepare farmers for regulatory inspections if they are covered by the PSR.
- Provide specific educational tools to individual operations on how to comply with the PSR.

UI EXTENSION PRODUCE SAFETY WEBSITE

<https://www.uidaho.edu/extension/food-safety-for-produce-growers>

- Training videos
- Spanish resources
- Templates for documentation
- Free on-farm resource online ordering
- Produce Safety Newsletter
- Webinars

To set up and OFRR / for any other questions contact
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University of Idaho
Extension



Live Q&A Panel

Topic: GAP and FSMA Programs



Ariel Agenbroad
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Third Party Audit Verification Program
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Commercial Produce Safety



Casey Monn
FSMA Program Manager
Idaho State Department of
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Thank you for all that you do.

FSMA PRODUCE SAFETY WEBINAR SERIES

Tuesdays in April @ 10 am PST | 11 am MDT

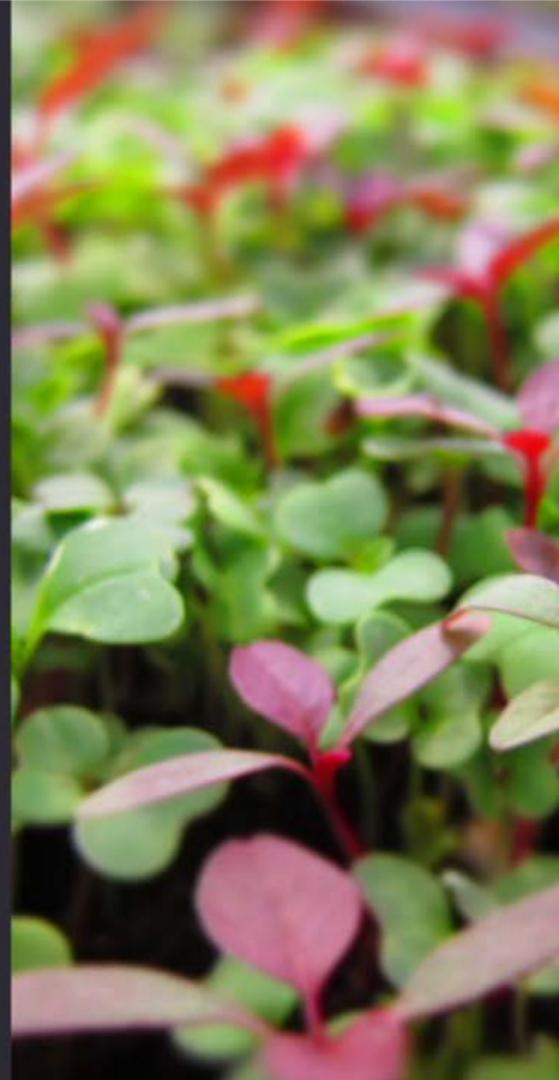
April 6 *Be a Bad Neighbor: Making your building less attractive to mice and birds*

Guest Speaker: Stephen M. Vantassel, CWCP, ACE
Vertebrate Pest Specialist, Montana Department of Agriculture

April 20 *Why do I have to do FSMA if I do GAP?*

ISDA Guest Speakers: Sherri Horrocks Third Party Audit Verification Program Manager; Casey Monn, FSMA Food Safety Program Manager

April 27 *Approaches to Composting Safely*



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