

## Comparing Apples and Pears: FSMA's Produce Safety Rule & USDA's GAP Audits



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MAINE DEPARTMENT OF AGRICULTURE, CONSERVATION & FORESTRY  
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## What is FSMA?

### Food Safety Modernization Act:

- **Mandatory** food safety law with 7 different parts.
- **Produce Safety Rule** applies to **produce farms**.
- Falls under **FDA regulatory authority**.
- Issues and non-compliances **must** be resolved.
- Non-compliances can lead to **enforcement actions**.
- Compliance dates are staggered based on farm size.
- **Fed/State Inspection Service** does **outreach, education, technical assistance** as well as the **compliance inspections under FDA authority**.



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## What is GAP?

### Good Agricultural Practices Audits:

- **Voluntary** audit of good agricultural practices for produce.
- Fee-for-service **USDA Marketing Services program**.
- Audits are **scored on a points basis**.
- There is a **checklist** that is scored by the auditor.
- Some issues are **automatic fails**.
- Happens annually.
- Issues **certificate** for commodities included in audit.
- **Fed/State Inspection Service** does all **GAP/GHP audits in the State of Maine** and submits them to the USDA.



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## What Are the Underlying Ideas?

Both are based on:

- **Controlling risks** to consumer health.
- Having **systems of preventive actions** in place.

Both based on consumer health fundamentals:

- Microbial pathogens can make people sick.
- Pathogens are commonly found in animal and human feces.
- Pathogens most commonly contaminate food via:
  - People
  - Water
  - Equipment and food contact surfaces.
  - Biological soil amendments



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## The Million Dollar Question: How Much Do They Overlap?

ANSWER: A LOT.

***GAP audits will get you ~80% of the way there to FSMA Produce Safety Rule compliance.***

GAP audits go beyond the microbiological focus of FSMA, but all produce farms should think about possible physical and chemical contamination. The FD&C Act requires preventing adulteration from those sources as well as from pathogens.

*The GAP standard won't include everything required by FSMA, but it will help you set up routine food safety measures.*



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## What Does a GAP Audit Cost?

- Average FSIS charges for GAP Audits: **\$793.**
- Average USDA charges for GAP Audits: **\$345.**

FSIS CHARGES	AVERAGE TIME ESTIMATE	HOURLY RATE	AVERAGE BILLING ESTIMATE
Admin Fee	1 HOUR	\$115/hr	\$115
Preparation Time	~0-0.5 HOURS	\$115/hr	\$0-\$57.50
Travel Time	~0.5-6 HOURS	\$115/hr	\$57.50-\$690
Audit Time	~1-2.5 HOURS	\$115/hr	\$115-\$287.50
<b>TOTAL ESTIMATE:</b>	<b>~2.5-10 HOURS</b>	<b>\$115/hr</b>	<b>\$287.50-\$1,500</b>

<b>USDA CHARGES</b>	<b>2-5 HOURS</b>	<b>\$115/hr</b>	<b>\$230-\$575</b>
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Hourly rates are set by USDA and cannot be changed.



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## Good News for 1<sup>st</sup> Time GAP Auditees!

- In 2019, the Department of Agriculture, Conservation & Forestry made funds available to promote food safety on Maine's farms by providing partial reimbursement for 1<sup>st</sup> time GAP audit costs.

**New GAP applicants will be reimbursed for 50% of their audit costs, up to \$500 for their first audit.**

- These reimbursements are only for first-time audits.
- You don't need to fill out any paperwork to get this reimbursement—the DACF processes it in-house.



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## What Are the Major Differences?

### FSMA:

- Is **mandatory** and has **no inspection costs**.
- Focuses primarily on **microbiological hazards**.
- Has specific requirements for *how* records are done.
- Does not require exhaustive records or documentation.
- **Regulations determines** which activities and crops are covered.

### GAP Audits:

- Are **voluntary** and **fee-for-service**.
- Focuses on **microbiological, chemical, and physical hazards**.
- Requires a **written food safety plan**.
- Requires extensive records or documentation.

**Farmer decides** which crops and scopes to include.



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## How Do FSMA Inspections Work?

**PREPARATION**

- Connect with DACF.
- Attend a training.
- Ask for On-Farm Readiness Review.
- Work on any problem areas.

**INSPECTION**

- DACF schedules with you.
- Opening interview.
- Field & facility visit.
- Discuss any issues.
- Inspection forms issued during inspection.

**FOLLOW THROUGH**

- Inspection reports written & mailed to you.
- Make plan to address issues.
- May be follow up inspections.

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## How Do GAP Audits Work?

**1. YOU:**

- Choose your scopes.
- Choose your crops.
- Call or email FSIS to request an audit.
- Set up your vendor account with the USDA.

**2. FSIS:**

- Schedules your audit.
- Assigns an auditor.

**3. TOGETHER WE:**

- Meet at your farm.
- Have our opening meeting.
- Review your documents and food safety plan.
- Go over the audit questions for your chosen scopes.
- Visit your fields and facilities.
- Observe your operations.
- Talk with your staff.
- Go over your results in our closing meeting.

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## What Happens After the GAP Audit?

**YOU:** Pay your FSIS bill before we leave your farm.

**FSIS:** Completes your audit report when we return to the office and submit it to the USDA.

**USDA:** Reviews your file and asks us for any additional info or clarification.  
Determines if you pass or fail the audit.  
Issues and posts your certificate if you pass.  
Bills you directly for their portion of the audit.

**YOU:** Send your GAP certificate to any customers who require or want documentation.  
Pay your USDA bill directly to the USDA.

**TOGETHER:** Depending on the length of your active farm season, you may get a follow-up, unannounced audit to verify your audited food safety system is still functioning properly.



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## What Are The Most Common FSMA Issues?

1. BUILDINGS & CLEANABILITY
2. EQUIPMENT & TOOLS
3. RECORD KEEPING
4. WORKER TRAINING
5. CONTACT WITH THE GROUND

**\*\*NOTE: FSMA's entire Water Subpart is currently under review, and compliance is delayed.\*\***



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## What Are The Most Common GAP Challenges?

1. WATER ISSUES
2. TRACEABILITY HOLES
3. MISSING SOPs OR LOGS
4. PRE-HARVEST RISK ASSESSMENTS
5. REFRIGERATION EQUIPMENT CLEANING



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## What Are The Most Common Overlap Holes?

1. MISSING WORKER HYGIENE & TRAINING TOPICS (missing FSMA requirements):
  - Keeping gloves clean and intact, and replacing when not.
  - Not chewing gum in food areas.
  - Avoiding contact with animals.
  - Washing hands before wearing gloves, after contact with animals or when returning from break.
  - Removing or covering hand jewelry that can't be cleaned.
2. RECORDS MISSING INFORMATION (missing FSMA requirements):
  - Topics training covered on training logs.
  - Methods of cleaning on cleaning logs.
  - Review, signature, and date by a supervisor for training and cleaning logs.



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3. VISITORS (missing FSMA requirements):
  - Making them aware of health and hygiene policies and food safety practices that will protect public health.
  - Making toilets and hand-washing facilities available.
  
4. PHYSICAL & CHEMICAL HAZARDS (missing GAP requirements):
  - Controlling risks of foreign materials by having glass guards or eliminating broken pallets, etc.
  - Separate, designated chemical storage.
  - Controlling risks of chemical contamination.



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5. EMPLOYEE BREAKS & BELONGINGS(missing GAP requirements):
  - Designated area for employee breaks and meals.
  - No personal belongings in containers that will be used for foods.
  
6. TRACEABILITY PROGRAM (missing GAP requirements):
  - Fields or production areas labelled to enable traceability.
  - Product is uniquely identifiable to the field and date it was harvested.
  - Lot identification travels physically with product from harvest through shipping.



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## IN SUMMARY:

### FSMA: Produce Safety Rule:

- Mandatory regulation.
- There are some exemptions for farms.
- Compliance dates have begun.
- Does not give many specific prescriptions.
- Inspections assess your **compliance with the regulations.**

### USDA GAP Audits:

- Voluntary audit.
- You choose which scopes and crops you want certified.
- Has many specific requirements, and many documentation requirements.
- Audits assess your **adherence to your food safety plan**, and your **fulfillment of the requirements.**



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THANK YOU!



CONTACT US WITH QUESTIONS ANY TIME!

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