

## Harmonized GAP Audit Highlights & Updates



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MAINE DEPARTMENT OF AGRICULTURE, CONSERVATION & FORESTRY  
*Quality Assurance & Regulations*

1

## The Purpose of 3<sup>rd</sup> Party Food Safety Audits

**3rd party food safety audits are independent assessments of a business' overall food safety system and practices. They:**

- Evaluate the farm or business' food safety protocols & systems for management of **biological, physical, & chemical hazards**.
- Use published objective standards of minimum practices to benchmark against.
- Determine whether preventive measures are in place to **prevent** food safety hazards from impacting consumers.
- Offer growers and buyers a way to get an independent evaluation of whether their food safety practices are **complete, functioning, and current**.




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2

## USDA GAP Audits

**USDA offers 3 levels of food safety audits for farms and produce companies:**

- **Basic GAP/GHP Audits:**
  - Requires basic food safety practices on farms or in produce handling businesses.
  - Designed to be accessible to an entry level applicant.
- **Harmonized GAP Audits:**
  - Applies food safety management systems to farm businesses.
  - Designed to align with FSMA's Produce Safety Rule.
- **Harmonized GAP Plus+ Audits:**
  - Incorporates additional levels of hazard management required for global businesses.
  - Designed and accepted as equivalent to GFSI (Global Food Safety Initiative) audit schemes.



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3


## USDA GAP Audits

**Each USDA GAP audit has:**

- A **published checklist** that auditors use.
- **Scoring criteria** used to determine whether audits pass or fail.
- **Conditions** that would cause an audit to **fail automatically**.
- **General Questions** that must be assessed for every audit.
- A **choice of audit scopes** the applicant can choose from.
- A **choice of which crops or locations** to include in the audit.
- An **80% minimum passing score**.

**In addition, the Harmonized and Harmonized Plus+ audits each have:**

- A **published Standard** that explains each requirement and what the auditor has to evaluate.



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4

## Harmonized & Harmonized Plus+ Audits

**Compliant (C)** - The operation meets the requirements of the USDA Harmonized GAP Plus+ Standard.

**Corrective Action Needed (CAN)** - The operation does not meet the requirement(s) of the USDA Harmonized GAP Plus+ Standard, however the non-conformance is not considered to be an immediate food safety risk.

**Immediate Action Required (IAR)** - The operation does not meet the requirement(s) of the USDA Harmonized GAP Plus+ Standard and the non-conformance is considered an imminent food safety risk. An imminent food safety risk is present when produce is grown, processed, packed or held under conditions that promote or cause the produce to become contaminated. Observation of employee practices (personal or hygienic) that jeopardize, or may jeopardize, the safety of the produce are considered an "IAR". The presence or evidence of rodents and an excessive amount of insects or pests are also considered an "IAR".

**Not Applicable (N/A)** - The question is not applicable to the operation.



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5

## Harmonized & Harmonized Plus+ Audits

### USDA Acceptance Criteria for the Harmonized GAP Plus+ Audit

1	No questions are assessed as an "IAR", Immediate Action Required.
2	Falsification of records is considered an "IAR".
3	Any question marked with a ● in the MAN column must be assessed as "compliant".
4	Operation must have performed all risk assessments, designated with an "A" in the DOC column, in the USDA Harmonized GAP Plus+ Standard.
5	Produce GAPs Harmonized Food Safety Standard previously, the auditee must have addressed all associated CANs or IARs, following their established corrective action procedure.
6	In each major section (G, F, and P) of the audit, at least 80% of the questions not answered as "N/A" must be answered as compliant.




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6

### Harmonized Plus+ Checklist

Name of Auditee:								
Date of Audit:								
Req. #	Requirement	DOC	MAN	C	CAN	IAR	NA	Auditor Comments
G-6	Traceability							
G-6.1	A documented traceability program shall be established.	WP, R	•					
G-6.1.a	Packaging must include product identification.							
G-6.1.b	If product is intended for export, product meets labeling regulations of the country(ies) the product is being exported to.							
G-6.2	A trace back and trace forward exercise shall be performed at least annually.	R						
G-7	Recall Program							
G-7.1	A documented recall program, including written procedures, shall be established.	WP, R	•					




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7

### Harmonized Plus+ Standard

Req. #	Requirement	DOC	MAN	Procedure	Verification	Corrective Action
<b>G-6: Traceability</b>						
G-6.1	A documented traceability program shall be established.	WP, R	•	Records that enable reconciliation of product delivered to recipients (one step forward) shall be maintained except for direct to consumer sales. Records shall be maintained that link product with source of the produce or production inputs, e.g., soil amendments, fertilizers, seeds/transplants, agricultural chemicals, homemade preparations (one step backward). Records shall include the date of harvest, quantities, farm identification (field or block), transporter and non-transporter. Additional information may be included. Contents and retention of records shall be consistent with applicable regulations.	Auditor reviews traceability program and verifies Operation's ability to trace product accurately one step forward and one step back.	Operation establishes an effective traceability program.
G-6.1.a	Packaging must include product identification.			Operation must include product identification on all packaging. The product identification must include: 1) the origin of the producer; 2) the name and address of the producer; 3) the country of origin; and 4) the date of production or packaging.	Auditor reviews the product identification on all packaging.	Operation establishes product identification on all packaging.



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8

## Key Concepts for H-GAP Success

- **Mandatory Risk Assessments**
- **Written Risk Management Plans**
- **Trace Back + Trace Forward Exercise**
- **Mock Recall**
- **Water Tests**
- **Water System Descriptions**



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9

## Risk Assessments

Harmonized & Harmonized GAP Plus+ audits require many risk assessments. **All are mandatory.**

### General Questions:

- Food Defense (Plus+)
- Food Fraud (Plus+)

### Field Operations & Harvesting:

- Land History & Adjacent Land Use
- Each Production Area (Plus+)
- Water System
- Animal Activity
- Soil Amendments
- Preharvest

### Post-Harvest Operations:

- Packinghouse (Plus+)
- Allergen Program, if applicable
- Produce Washing Process




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10

## Risk Assessments

Risk assessments follow a general format:

- **Get specific** about your land, layout of plumbing or equipment, animal activity/pressure, methods of application for chemicals, water, or soil amendments, and other on-farm processes.
- **Identify potential biological, chemical, & physical hazards** in each area.
- **Evaluate the risk level posed by each potential hazard.** Risk evaluations are based on:
  - The severity of consequences if not controlled.
  - The estimated likelihood of occurrence.
  - Known data about risk factors of application methods, type of crop, or outbreak histories.




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11

## Risk Assessments

Potential Risk	Type of Hazard	Severity of Consequences	Likely to Happen?	Overall Risk
Chickens getting loose	Biological	Could be high.	No; good fence.	Low
Wildlife passing through field (deer, turkey, moose)	Biological	Medium.	Yes, especially in lettuce.	<b>Med – High</b>
Animals nibbling produce	Biological	Medium.	Yes, deer in lettuce.	<b>High</b>
Farm dogs marking in growing areas	Biological	Low.	Maybe, if we're not watching.	Low
Birds roosting over harvest containers	Biological	High.	Yes, under overhang. No in shed.	<b>High</b>
Customers letting their dogs out	Biological	Medium.	Occasional, but not often.	<b>Med</b>




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12

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Animals nibbling produce	Biological	Medium.	Yes, deer in lettuce.	<b>High</b>
Birds roosting over harvest containers	Biological	High.	Yes, under overhang. No in shed.	<b>High</b>
Customers letting their dogs out	Biological	Medium.	Occasional, but not often.	<b>Med</b>

For each hazard identified in our risk assessment, we then need to make a risk management plan to try to control the risks to our customers.



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13

## Written Risk Management Plans

Potential Risk	Type of Hazard	Severity of Consequences	Likely to Happen?	Overall Risk
Birds roosting over harvest containers	Biological	High.	Yes, under overhang. No in shed.	<b>High</b>

A risk management plan needs to establish preventive actions to minimize the potential hazard. In this case, our written risk management plan might address the hazard by:

- Installing netting above harvest container storage area, monitoring for roosting activity, and recording monitoring on a log.
- Moving the harvest containers to a different storage, establishing written policy about where to store them, training workers in storage protocols, documenting training.
- Written SOP to inspect and sanitize harvest containers prior to use, documenting worker training in SOP.



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14

## Written Risk Management Plans

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Wildlife passing through field (deer, turkey, moose)	Biological	Medium.	Yes, especially in lettuce.	Med – High
Animals nibbling produce	Biological	Medium.	Yes, deer in lettuce.	High

Our written risk management plan might address these hazards by:


- Creating SOPs to inspect the harvest area for signs of animal contamination prior to harvest, and identify areas not to be harvested.
- Training workers in a written SOP to leave a set back area not to be harvested and documenting training.
- Creating a written procedure of applying coyote urine to field perimeters, reapplying based on activity, and documenting application.




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15

## Known Produce Risk Factors



<p><b>Produce That's Usually Cooked</b> Potatoes, winter squash, beets</p> <p><b>Subsoil Water Application</b> Drip tape, furrow irrigation</p> <p><b>Chemical or Treated Soil Amendments</b> Verified composts, treated manures</p> <p><b>Municipal Water</b> Town/City water</p>	<p><b>High Risk Crops</b> Lettuce, tomatoes, melons, cucumbers, peppers</p> <p><b>Direct Contact Water</b> Overhead sprinklers, boom sprayers, center pivots</p> <p><b>Untreated Soil Amendments</b> Manures, untreated compost</p> <p><b>Ground Water</b> Drilled wells</p> <p><b>Surface Water</b> Streams, rivers, ponds, dug wells</p>
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16



## Trace Back / Trace Forward Exercise

Both Harmonized & Harmonized GAP Plus+ audits require an **annual trace back / trace forward exercise** to be done. It:

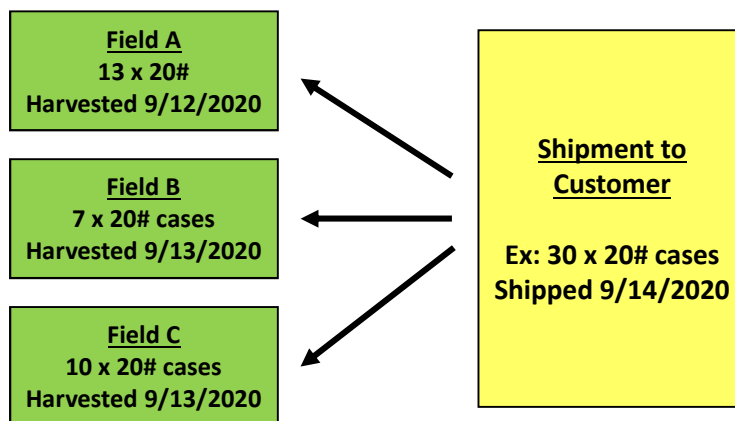
- Must be completed within 4 hours.
- Must achieve 100% reconciliation of product.
- Must trace product 1 step forward to customers.
- Must trace product 1 step backward to the production location and production inputs.
- Is required as part of the Mock Recall, which is mandatory.



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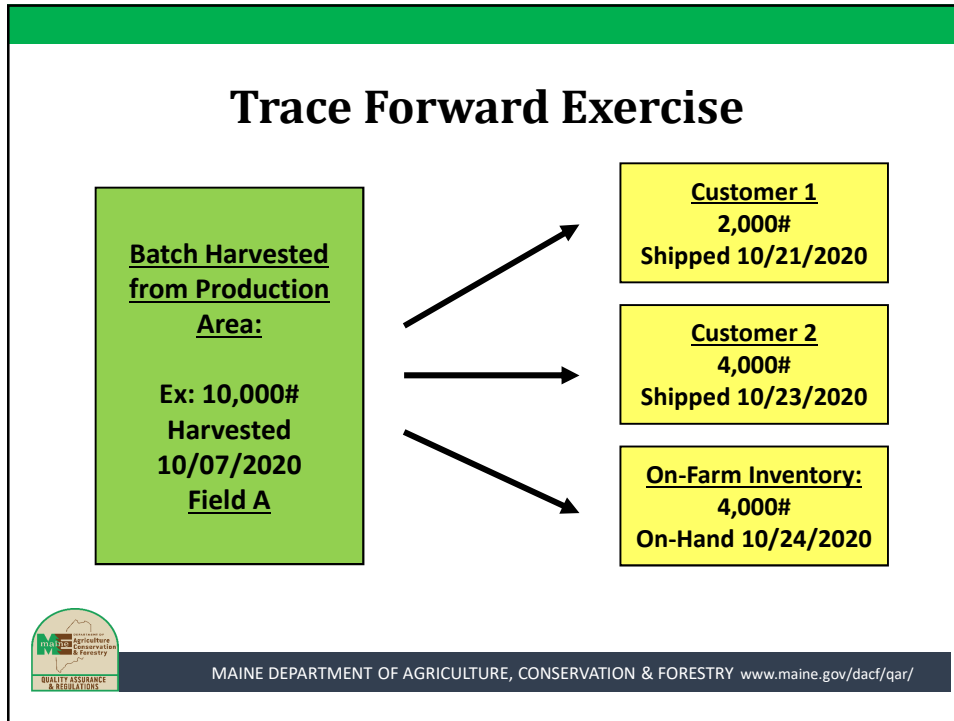
17

## Trace Back Exercise



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18



19

### Trace Back / Trace Forward Exercise


For a **trace back** exercise to work, your records have to:

- Link the product shipped to when and where it was harvested.
- Record the date and quantities harvested from each production area.
- Show what production inputs were applied when to each area.

For a **trace forward** exercise to work, your records have to:

- Show the date and quantities harvested from the production area.
- Link the harvest records to the customer shipment record.
- Document how much product was shipped, disposed of, or is still on-hand.

Your **trace back/trace forward exercise** needs to show your **start & finish time**, and account for **all the volume of product** in your lot.

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20

## Mock Recall

Both Harmonized & Harmonized GAP Plus+ audits require an **annual mock recall** to be done. Do this you must:

- Have a designated mock recall team.
- Identify all affected product.
- Verify contact information for all affected customers and relevant public health authorities.
- Include a successful trace back/trace forward exercise.
- Documented the mock recall with records.

**Note:** Your chosen reason for a mock recall can be hypothetical, but you must use real product data to perform the mock recall.



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21

## Mock Recall

<b>Lot Selected:</b>	<b>Harvest Date:</b>	<b>Harvest Amount:</b>	<b>Harvest Location:</b>

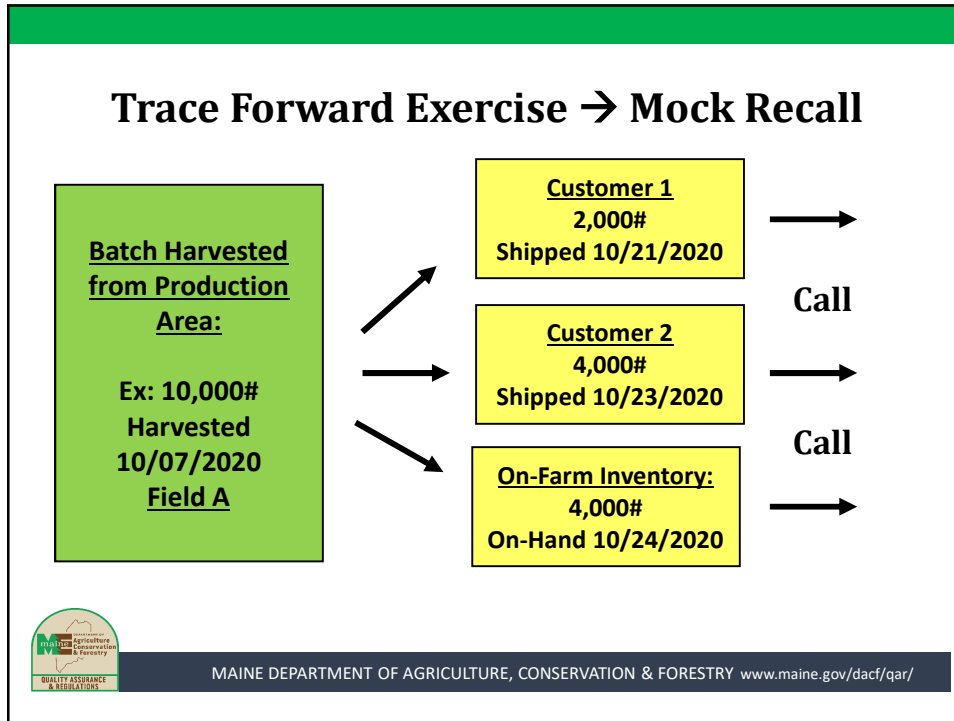
  

Product Recipient:	Amount Shipped per Farm Records:	Amount Customer Reports:	Verified (Time & Date)
Customer 1	Amt: Ship date: Doc #:	Sold: Disposed of: Still on Hand:	
Customer 2	Amt: Ship date: Doc #:	Sold: Disposed of: Still on Hand:	
On-Farm Inventory		Still On Hand:	
<b>TOTAL AMT IN LOT:</b>			
<b>TOTAL PRODUCT ACCOUNTED FOR:</b>			



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22



23

## Mock Recall

Key points for **mock recalls**:

- You do need to have a designated recall team and have written recall SOPs.
- You do not have to tell your customers you're doing a mock recall.
- You do have to contact your customers to at least confirm that their contact information is current.
- You do need to contact your public health authority to confirm that their contact information is current.
- If you've done your trace back/trace forward exercise, most of your mock recall will be done.
- You must document/record your mock recall.

**Mock recalls are MANDATORY to pass the audit.**

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24

## Water Tests

Annual farm water test frequency:

- **Municipal water:** 1 annual report or test result certificate.
- **Ground/well water:** 1 annual water test per well.
- **Surface water:** 3 annual tests staggered across growing season **per source**.

Surface water tests must be spaced out over the growing season:

- 1<sup>st</sup> at planting.
- 2<sup>nd</sup> at peak use.
- 3<sup>rd</sup> at or near harvest.

Workers must have potable water available to them.

**\*\*LACK OF POTABLE WATER ON-SITE IS AN AUTOMATIC FAIL!\*\***



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25

## Water Tests

For Harmonized & Harmonized GAP Plus+ audits there are a few special considerations for **water tests**:

- You set the microbial criteria for water you use in the field in your food safety plan.
- Water used for hand-washing, or post-harvest uses must have **0 detectable generic *E. coli***.
- You must use a GLP lab for your water tests. (This usually means an accredited lab.)
- You must have your water tests done before your audit.
- You must have water tests before using a water source for spraying or irrigation.
- If you think you might need to apply a water source to produce, get your tests done.



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26

## Water System Descriptions

Water system descriptions are required for both the Field Operations & the Post-Harvest Operations scopes. **They are a mandatory.**

**Water system descriptions must include:**

- Water sources
- Permanent fixtures (including wells, gates, reservoirs, valves, returns and other above ground features that make up a complete irrigation system).
- The flow of the water system (including holding systems, reservoirs, or water captured for re-use).

**They can be in one or more of the following formats:**

- Maps
- Photographs
- Drawings
- Written text

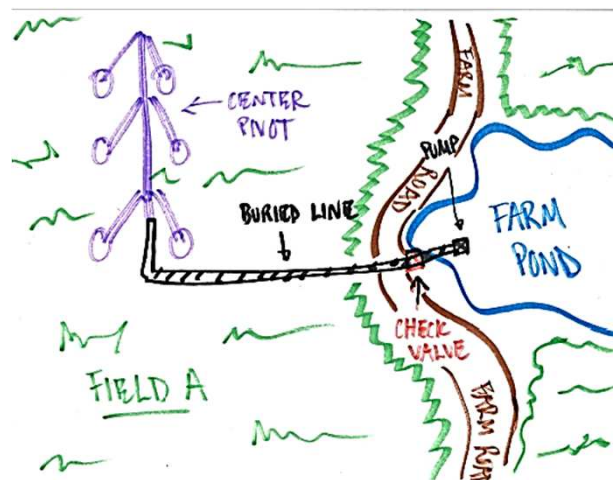
**The auditor should be able to locate anything in the field by using it.**



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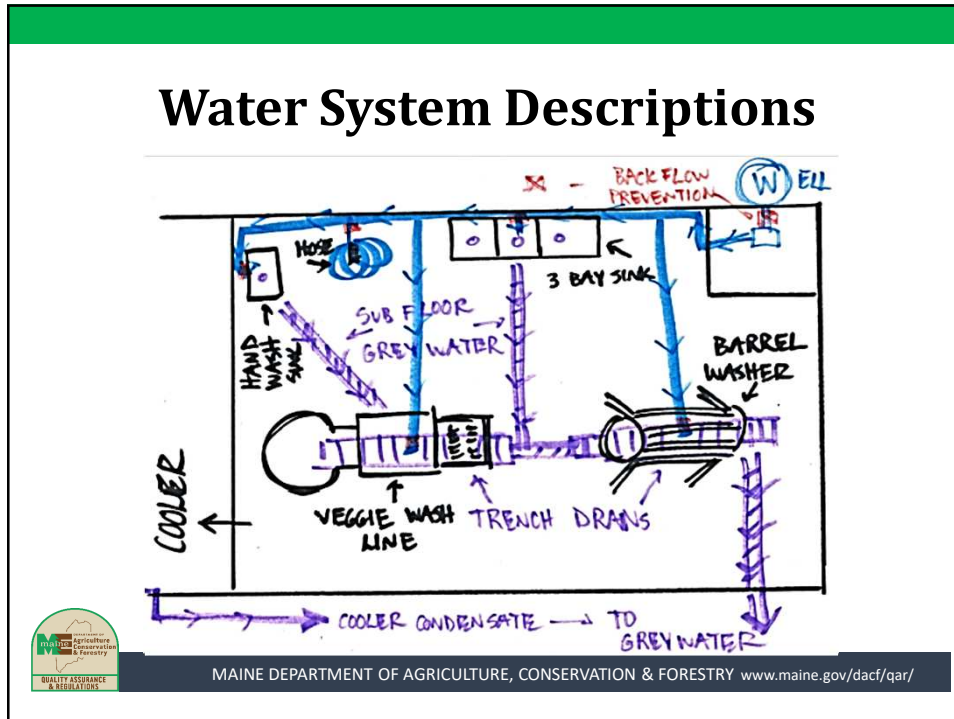
27

## Water System Descriptions



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28



29

## That's A Lot To Digest

Sure is. If you want to learn more, there are lots of resources to get you started:

- Our **DACF webpages** explain more about each GAP audit and link to useful templates:  
<https://www.maine.gov/dacf/qar/gapaudits/index.shtml>
- Our team **reviews food safety plans** for free when we have time in the winter/spring months.

Call 207-764-2100 or email us: [leah.cook@maine.gov](mailto:leah.cook@maine.gov),  
[jeff.gagnon@maine.gov](mailto:jeff.gagnon@maine.gov)

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30

## Templates and Manuals

- The **Carolina Farm Stewardship Association** has templates, a manual, and they're offering an **in-depth webinar** in February:

<https://www.carolinafarmstewards.org/usda-harmonized-gap-handbook-and-recordkeeping-templates/>

- Penn State Extension also has templates and primers on writing food safety plans:

<https://extension.psu.edu/tools-for-writing-a-farm-food-safety-plan>



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31

## News & Updates

- Funding from the Risk Management Agency (RMA) has made Harmonized and Harmonized GAP Plus+ audits **FREE** in 16 states, including Maine.
- This funding will last until it is gone, and is anticipated to fully fund H-GAP costs in Maine through 2021.
- The USDA is **finalizing major revisions** of the Harmonized/Plus+ Standard.
- There will be new questions, reworded questions, and clearer and more structured requirements.

**We will be sharing updates on this as soon as it is finalized.**



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32



## In Summary:

- **Mandatory Risk Assessments** – come first, lead into:  
➡ **Written Risk Management Plans**
- **Traceback + Trace forward Exercise** – come first, lead into:  
➡ **Mock Recall**
- **Water Tests** – get ‘em done on time, in season.
- **Water System Descriptions** – use whatever format works so we can find the features and follow the flow.



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33

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34