Preparing and Writing USDA Harmonized GAP Audit Risk Assessments

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Portions of this presentation are based on the USDA Harmonized GAP and Harmonized+ standards, instructions to USDA licensed GAP auditors and the USDA Harmonized and Harmonized+ audit checklists.

MDA notifies growers that are currently USDA Harmonized or Harmonized + certified of changes to the standards and audit checklists.

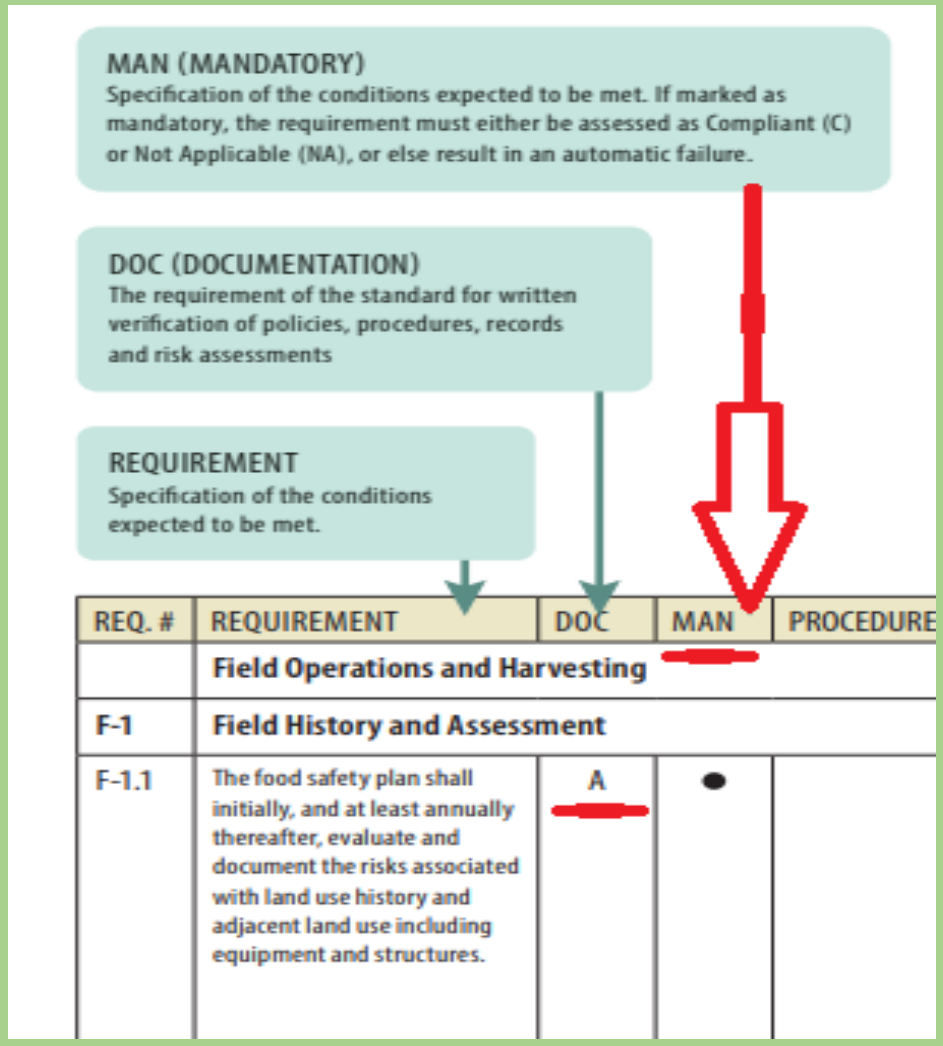
Current Harmonized standards, audit checklists and resources can be found at https://www.ams.usda.gov/services/auditing/gap-ghp

What Are The Types Of **Written Elements** I Need to Construct for an HGAP Audit?

Written Policy	**Record**	**Risk Assessment**
In Food Safety Plan, displayed on property, given as a handout during training	Can include a log, checklist, lab tests, or billing forms	Usually a log, some could be a checklist

Name of Auditee:				0				
Date of Audit:				1/0/1900				
Req. #	**Requirement**	**DOC**	**MAN**	**C**	**CAN**	**IAR**	**NA**	**Auditor Comments**
F-6.2	The Operation routinely monitors for animal activity in and around the growing area during the growing season.	R	•					
F-6.3	Based on the risk assessment, there shall be measures to prevent or minimize the potential for contamination from animals, including domesticated animals used in farming operations.	WP, R	•					
F-7	**Soil Amendments**							
F-7.1	The food safety plan shall address soil amendment risk, preparation, use, and storage.	A, R	•					
F-7.2	If a soil amendment containing raw or incompletely treated manure is used, it shall be used in a manner so as not to serve as a source of contamination of produce.	R	•					

Risk Assessments for Harmonized GAP Audits



Common Grower Questions on Risk Assessments

- What questions do I need to assess about my operation or with my team to meet the standard?
- How often do these need to be performed?
- How do I record it?

What Is A Risk Assessment?

Risk Assessment (A)

A risk assessment provides verification that efforts have been made to evaluate potential food safety risks within your operation.

Conducting a Risk Assessment

Risk assessments are the most important elements of a food safety program and involve reviewing all aspects of the farm and its operational practices.

The most common pathogen contamination hazards come from four sources: water, workers, waste, and wildlife.




https://www.carolinafarmstewards.org/wp-content/uploads/2019/06/HGAPmanual_v09-web-printable.pdf

Basics of a Risk Assessment

1 What is the hazard?

2. What is the likelihood of the hazard taking place?

3. If it takes place, what is the likelihood that crop will be affected?

4. What can I put in place now to prevent this hazard from occurring?

5. If something occurs, what can I do to remedy the issue and prevent it from happening again?

Risk Reduction

What are the Required Risk Assessments for an HGAP Audit?

Scope	Section Number	Required Risk Assessments
General Questions		None
Field Operations And Handling	F 1.1	Land Use History and Adjacent Land Use
	F 4.1	Water System
	F 6.1	Animal Control
	F 7.1	Soil Amendment
	F 9.1	Pre-harvest
Postharvest Operations	P 3.6	Allergen
	P 7.4	Produce Washing
Logo Use		None

Land Use Risk Assessment – Field Scope

Field Operations and Harvesting (F)

Req. #	Requirement	DOC	MAN	Procedure
F-1: Field History and Assessment				When land use history or adjacent land use indicates a possibility of physical, chemical or biological contamination, preventive controls shall be performed and documented to mitigate food safety risk. The assessment is re-performed, and documented, at least annually for environmental conditions or risk awareness that has changed since the last assessment. The assessment shall include indoor growing facilities and structures such as green houses and hydroponics.
F-1.1	The food safety plan shall, initially and at least annually thereafter, evaluate and document the risks associated with land use history and adjacent land use including equipment and structures.	A	•	

Land Use Risk Assessment -- Meeting the Requirement

What you will do:

1) Take into consideration **physical, chemical,** and **microbial** hazards associated with land, including:

- ❑ Current or past land use of your property
- ❑ State of your septic system
- ❑ Potential for runoff / flooding to enter crop areas
- ❑ State of water distribution system and any changes this year
- ❑ New construction on your or your neighbor's property
- ❑ Chemical applications / holding structures on / near crop areas
- ❑ For indoor growing: building integrity

2) Identify likelihood of hazard affecting your production area, record what you are doing to reduce those risks.

How the auditor will assess:

Your record will be reviewed to verify that risks associated with field history, adjacent land use, and indoor growing facilities have been evaluated for the year and controls are implemented.

How Will a Risk Assessment Be Assessed?

Immediate Action Required

You do not meet the requirement *and* there is an imminent food safety risk

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What Could a Land Use Risk Assessment Look Like?

Sample Land Use Risk Assessment Log

Name and address of farm: _____

This evaluation should be completed yearly or as changes are made to the farm or production practices.

Task	Yes or No	Observations	Corrective Actions	Date	Initials
Are there any current or previous land uses that may represent a risk of contamination to fruit and vegetable production?	No	Was woods before farming started 8 years ago		2/20/21	AMF
Have there been any significant changes to land use this year (e.g. addition of grazing animals, field location changes)?	Yes	Added a petting zoo on property	Sited animal housing in NE corner of farm, away from water source. Trained workers on new hygiene practices	2/20/21	AMF
Have neighboring properties changed or added activities that might affect fields and water sources (e.g. animals, manure or compost storage)?					
Has there been any runoff from compost and manure storage areas, animal pens, or grazing areas?					
Were there any flooding events this year or last year?					
Have you inspected your well head to make sure it is in good condition and not in need of any repair?					

On-Farm Decision Tree Project: Land Use—v5 07/02/2014
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

https://gaps.cornell.edu/educational-materials/decision-trees/

Land Use Risk Assessment, Field Scope

What Do You Think?

Scenario 3: The annual assessment of risk states "no change" from the previous year's assessment. The prior assessment is available and compliant. Both the initial assessment and the "no change" assessment are dated to demonstrate that the assessment has been conducted annually.

Assessment:

Reason:

Scenario 4: A grower conducted a risk assessment. Upon visiting the farm site, the auditor sees that an adjacent hobby farm with two milk cows is not addressed in the risk assessment. Appropriate buffer distances and double fencing are in place.

Assessment:

Reason:

Water System Risk Assessment – Field Scope

F-4: Water System Risk Assessment				
F-4.1	An initial risk assessment shall be performed and documented that takes into consideration the historical testing results of the water source, the characteristics of the crop, the stage of the crop, and the method of application.	A	•	A review or new assessment shall be conducted seasonally and any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. The risk assessment shall address potential physical, chemical, and biological hazards and hazard control procedures for the water distribution system.

Categorizing Risks Associated with Water Use

Lower Risk	Higher Risk
Municipal Water Sources	Surface Water Sources
Crops not eaten raw	Crops eaten raw
Drip irrigation	Overhead irrigation
Sewing the seed	Before harvest

Items to Include in your Water Risk Assessment

All water sources:

- ❑ Use/crop/method of application?
- ❑ How well do you know the microbial quality of the source?
- ❑ Condition and maintenance of distribution systems?
- ❑ Sanitary conditions of water storage tanks?

Municipal Water

- ❑ Record of test results from municipality on file?
- ❑ Ever had a boil water ordinance?

Ground Water

- ❑ Integrity of well head and casing?
- ❑ Backflow preventers?
- ❑ Wildlife access and runoff risks ?

Surface Water

- ❑ Degree of animal access?
- ❑ Runoff potential?
- ❑ Overhead application?

What Could a Water Risk Assessment Look Like?

APPENDIX: Risk Assessments
Carolina Farms, LLC
Title: Water System Risk Assessment

Effective Date: 01.01.19
Document #: F-4.1-A
Revision #: R 1.0
Revision Date: TBD

Water System Risk Assessment (Conduct Seasonally and any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system) (F-4.1)

If your answer to a question indicates a risk of a food safety hazard, then further understanding, conducting a risk assessment and/or Preventive or Corrective Action(s) are needed to minimize possible contamination.

Area of Potential Risk with Water System and Use	Yes	No	NA	What is the potential risk identified?	Likelihood (Circle One)	What Preventive/Corrective Action(s) will you use to minimize the risk?	Date/Initials
Is the source of water used for irrigation clearly identified?					Low Medium High		
Is the potable water source clearly identified with laboratory testing to support no detectable levels of generic *E.coli*?					Low Medium High		
Are water distribution systems monitored and maintained and currently in working order?					Low Medium High		
Is the method of water used in irrigation and fertigation identified?					Low Medium High		
Is the quality of water used in the application of plant protection products (PPPs) considered?					Low Medium High		

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

Animal and Wildlife Risk Assessment

F-6: Animal Control				Procedure
F-6.1	The Operation has a written risk assessment on animal activity in and around the production area.	A	•	There shall be a written assessment of the growing fields and adjacent land, prior to each growing season, focusing on domestic and wild animal activity including grazing and feeding operations, noting crop characteristics, type and approximate number of animals, proximity to the growing field, water sources, and other relevant factors.

Animal and Wildlife Risk Assessment

Soil Amendments Risk Assessment – Field Scope

F-7: Soil Amendments				Procedure
F-7.1	The food safety plan shall address soil amendment risk, preparation, use, and storage.	A, R	•	If animal-based soil amendments or biosolids are used, records of composition, dates of treatment, methods utilized and application dates must be documented. Evidence of processing adequate to eliminate pathogens of human concern, such as letter of guarantee, certificate of analysis (COA) or any test results or verification data (e.g., time and temperature) demonstrating compliance with process or microbial standards, shall be documented. Such soil amendments must be produced, stored and applied in accordance with applicable federal, state, or local regulations.

If no soil amendments are used by the auditee, this requirement may be assessed as N/A.

Which of These Are Animal Based Soil Amendments?

A

B

C

D

E

F

Soil Amendments Risk Assessment – Field Scope

What is in this amendment?

Are you composting? How are you managing that process?

How do you manage application on the field?

How close is this to the field or water source?

Preharvest Risk Assessment – Field Scope

Harvesting				
F-9: Preharvest Assessment				
F-9.1	A preharvest risk assessment shall be performed.	**A**	•	The Operation shall have a preharvest assessment procedure, which describes when the assessment is performed and that it includes an evaluation of conditions that may be reasonably likely to result in physical, chemical, or biological contamination of the produce, and demonstrates that the Operation is in compliance with the food safety plan. Results of the evaluation shall be documented.

Preharvest Risk Assessment – Field Scope

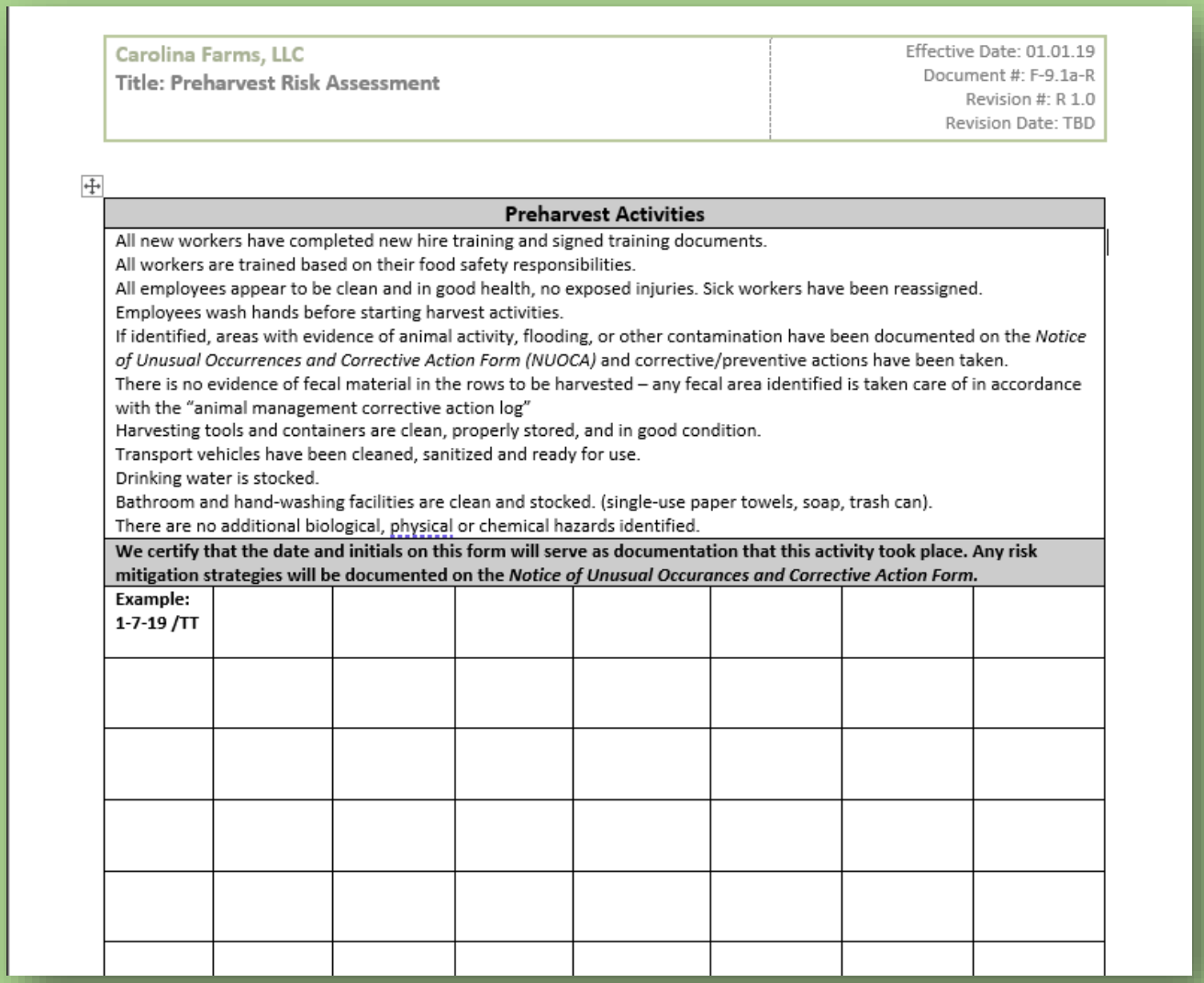
Verification	Corrective Action
Auditor reviews most recent preharvest assessment for completeness and consistency with the food safety plan.	Operation develops and implements a preharvest assessment procedure.

Also consider, did it address the following areas:

- Intrusion by animals
- Flooding
- Potential contamination materials
- Condition of water source and distribution system
- Unexpected adjacent land activity that will pose a risk to food safety
- Worker hygiene and sanitary facilities

The date of the assessment and the projected date of harvest along with a signature or initials, must be included. The assessment may be documented in various forms such as a self-completed audit checklist or a separate pre-harvest checklist. This question cannot be answered N/A. The comment should include the date of the pre-harvest risk assessment.

What Could A Preharvest Assessment Log Look Like?



Carolina Farms, LLC
Title: Preharvest Risk Assessment

Effective Date: 01.01.19
Document #: F-9.1a-R
Revision #: R 1.0
Revision Date: TBD

Preharvest Activities							
All new workers have completed new hire training and signed training documents. All workers are trained based on their food safety responsibilities. All employees appear to be clean and in good health, no exposed injuries. Sick workers have been reassigned. Employees wash hands before starting harvest activities. If identified, areas with evidence of animal activity, flooding, or other contamination have been documented on the *Notice of Unusual Occurrences and Corrective Action Form (NUOCA)* and corrective/preventive actions have been taken. There is no evidence of fecal material in the rows to be harvested – any fecal area identified is taken care of in accordance with the "animal management corrective action log" Harvesting tools and containers are clean, properly stored, and in good condition. Transport vehicles have been cleaned, sanitized and ready for use. Drinking water is stocked. Bathroom and hand-washing facilities are clean and stocked. (single-use paper towels, soap, trash can). There are no additional biological, physical or chemical hazards identified.							
We certify that the date and initials on this form will serve as documentation that this activity took place. Any risk mitigation strategies will be documented on the *Notice of Unusual Occurances and Corrective Action Form.*							
Example: **1-7-19 /TT**							

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

Allergen Risk Assessment – Post Harvest Scope

Requirement	P-3.6. If applicable, Operation has a written Allergen Control Program.
Procedure	The Allergen Control Program lists the allergens in use or storage at the Operation specific to country regulations. If applicable, procedures address identification and segregation of allergens during storage and handling as based on a risk assessment conducted by the Operation.
Verification	Auditor reviews Allergen Control Program and inspects Operation for evidence of allergen use and storage.
Corrective Action	Operation develops and implements an Allergen Control Program or eliminates allergens from the Operation.
Documents Required	Risk Assessment, Written Policy.
Mandatory	•

Example Scenarios

Scenario 1: The operation has no allergen control program and there is no evidence that they handle allergens.

Assessment:

Reason:

Produce Washing Risk Assessment – Postharvest Scope

Req. #	Requirement	DOC	Procedure
P-7.4	Operation's Food Safety Plan includes produce washing process, if used.	A, WP	If produce is washed, an initial risk assessment of the washing process shall be performed that takes into consideration the commodity, type of wash system, type of sanitizer, and water quality.

Lower Risk **Higher Risk**

Single Pass Water

(e.g. Hose)

Recirculated Water

(e.g. Dunk Tanks)

Produce Washing Risk Assessment – Postharvest Scope

Requirement	P-7.4. Operation Food Safety Plan includes produce washing process, if used.
Procedure	If produce is washed, an initial risk assessment of the washing process shall be performed that takes into consideration the commodity, type of wash system, type of sanitizer, and water quality.
Verification	Auditor reviews Food Safety Plan and operational procedures to determine if washing process has been considered.
Corrective Action	Operation revises Food Safety Plan to include produce washing process.
Documents Required	Risk Assessment, Written Policy.
Mandatory	•

Scenario 2: An overhead spray bar is used to wash incoming product. The water source was tested by a lab and the results state it is of drinking water quality. The water is re-circulated and treated with sodium hypochlorite appropriately and is recorded in a timely manner. The date on the box of sodium hypochlorite test strips used to test the water indicates the test strips are two months beyond the expiration date.

Assessment

Reason:

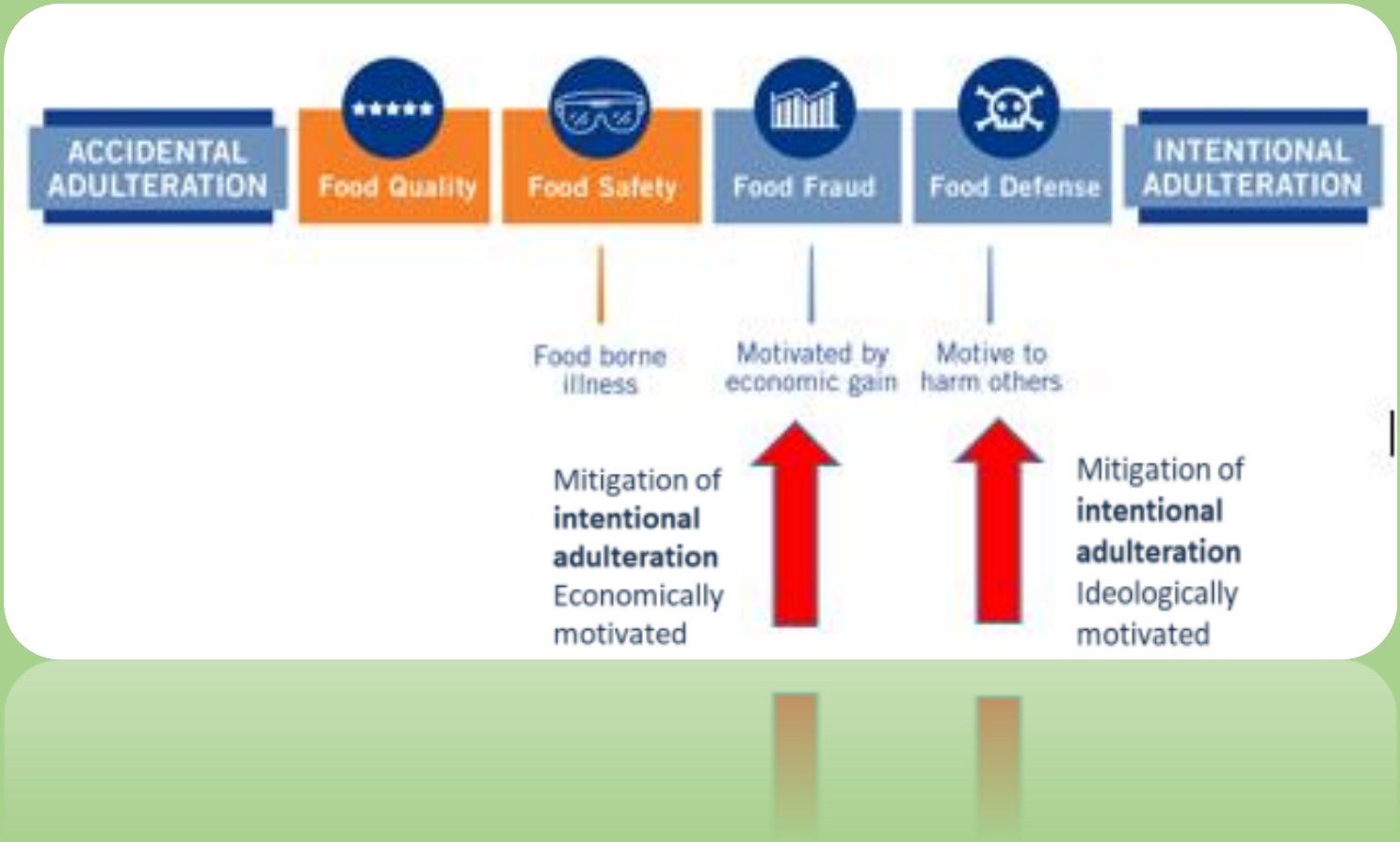
USDA HARMONIZED GAP + Audit

Specific Risk Assessments

Scope	Section Number	Required Risk Assessments
General Questions	G 12.1(a)	Food Defense
	G 13.1(a)	Food Fraud
Field Operations And Handling	F 1.1(a)	Risk assessment of production area prior to harvest
Postharvest Operations	P 3.1(a)	Risk Assessment of the Packinghouse
Logo Use		None

USDA HARMONIZED GAP + Audit

Food Defense and Food Fraud



https://www.eurofinsus.com/food-testing/resources/why-you-need-a-food-defense-plan/

HGAP+ Audit
Risk Assessments
FIELD

F-1: Field History and Assessment				
F-1.1	The food safety plan shall, initially and at least annually thereafter, evaluate and document the risks associated with land use history and adjacent land use including equipment and structures.	**A**	•	When land use history or adjacent land use indicates a possibility of physical, chemical or biological contamination, preventive controls shall be performed and documented to mitigate food safety risk. The assessment is re-performed, and documented, at least annually and upon significant events, for environmental conditions or risk awareness that has changed since the last assessment. The assessment shall address flooding and shall include indoor growing facilities and structures such as green houses and hydroponics.
F-1.1.a	Operation has performed and documented a risk assessment of each production area prior to the harvest of that location.	**A**	•	A system shall be established to maintain the record of agricultural activities undertaken at each production unit and records shall be available to demonstrate that sites (on farm and adjacent sites) have been evaluated with regards to potential food safety hazards.

Summary

- Work with your team to consider hazards specific to your operation; focus on water, wildlife, sources of feces, runoff, historic information, and other information to appropriately assess hazards and your extent of control to reduce risk.

- There is some flexibility in recording, but remember *any time* something changes in your operation, you should re-visit your risk assessments.

Don’t forget to register for our next seminar!

Research Spotlight: *Salmonella* in Mid-Atlantic Irrigation Water Sources

February 23rd, 2021 @ 7:00 a.m.

Register today at
mdadvancedgap2021.eventbrite.com

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