Assessing Risk of Pre-Harvest Agricultural Water

Background and Introduction

The Produce GAP Harmonized Standard initiative began in 2009 as an all-industry effort including growers, shippers, produce buyers, government agencies, audit organizations and other stakeholders to reduce audit fatigue through the development of a standard that achieves the goal of "One audit by any credible third party, acceptable to all buyers". United Fresh Produce Association facilitated this process and remains the Secretariat for the Harmonized Standard, coordinating the efforts of both the Harmonized Technical Working Group and Calibration Committee.

Within the Combined Harmonized Food Safety Standard V.1.1 (2016), requirement 2.2.2.1. states that, with regard to water used in growing activities:

"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."

The compliance procedure further states:

"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.

The full requirement as it appears in the Harmonized Standard may be found in **Table 1**.

United Fresh's Food Safety & Technology Council and Harmonized Calibration Committee agreed that the industry would benefit from a document that a grower can use to guide their thought process through the assessment of their agricultural water risk. The following materials are a compilation of existing resources and approaches developed by the volunteer workgroup.

Objective

The purpose of this document is to provide growers with guidance on the minimum factors that should be considered when assessing the risk of their pre-harvest agricultural water systems. Following the identification of potential hazards that may increase the risk associated with a pre-harvest agricultural water sources or systems, examples of mitigation strategies are also given. Templates for documentation of the assessment may be found on the the website.

Audience

The primary audience for this document is producers who are audited against the produce GAPs Harmonized Standard, which applies to growers of both 'covered' and 'uncovered' produce as defined in the FDA Produce Safety Rule. However, regardless of which GAP certification standard a grower follows, this guidance may be useful to all producers of fresh produce. This guidance is not specific to one commodity or group of commodities.

Note to Users

Pre-harvest agricultural water risk assessments for fresh produce are context dependent, particularly with regard to commodity type, water source, water application system, timing of application, and more. As such, while the principles behind the assessment of agricultural water risk may be similar, readers using this guidance should evaluate their own growing operations individually and should also consider guidance developed specifically for their commodity, if applicable.

Table 1: Combined Harmonized Standard (v 1.1, 2016) requirement for pre-harvest agricultural water risk assessment

2.2.2	Water System Risk A	ssessment		
	Requirement	Procedure	Verification	Corrective Action
2.2.2.1	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 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.	Auditor reviews the risk assessment for completeness of consideration of potential hazards.	Operation develops or updates the risk assessment.

Conducting the Assessment

The flow chart on page 5 provides a general step-by-step process that a grower may use to categorize the potential biological risk to their crop resulting from their ag water system. Each step of the flow chart considers certain characteristics of water systems and broadly classifies various combinations of these characteristics by inherent risk (low, medium, or high) based on historical knowledge of produce growing and ag water systems. The defining characteristics considered in the assessment are:

- Crop use,
- Water source,
- Water delivery system, and
- Application method

While there are many potential biological hazards associated with ag water systems that must be considered, these four categories greatly impact the degree of risk posed by the identified hazards. For example, geese activity can have a greater negative impact on ag water quality when near an open pond used for irrigation when compared to geese activity near a closed water system utilizing groundwater. It is up to the individual grower to understand the hazards associated with the surrounding environment, their own growing practices, and the overall impact on risk to pre-harvest ag water.

Crop Use, the first step in the process, refers to whether the product it is generally consumed raw or "rarely consumed raw (RCR)", as defined in the FDA Produce Safety Rule (FDA; 21 CFR part 112). If the product will be consumed raw (whether covered by the Produce Safety Rule or not), biological hazards from ag water or any other source may persist. If it will be thoroughly cooked, biological hazards will be addressed by heating, thus reducing the ultimate risk to consumers.

It should be noted that although this risk assessment focuses on biological risks, the Harmonized Standard (and other produce GAP standards) requires that chemical risks within a water system also be assessed and adequately controlled. This can include, but is not limited to, proper storage and use of chemicals and equipment, as well as chemical analysis of water quality following contamination events (including floods) or to build historical knowledge of chemical water quality. Therefore, while producers of RCR crops may

shift some of their focus away from biological hazards, chemical and physical hazards must still be considered.

Water Source is the next component of the decision tree, broken into three main categories: a public water system ("municipal"), ground, or surface. The following definitions for each water source are given in the Produce Safety Rule (FDA; 21 CFR part 112):

Public water system/ municipal water: defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141,as "a system for the provision to the public of water for human consumption through pipes or, after August 5, 1998, other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year. Such term includes: any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system; and any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system. Such term does not include any "special irrigation district." A public water system is either a "community water system" or a "noncommunity water system". Within the context of the definition, the public water system furnishes water that meets the microbial requirements under the SDWA regulations or under the regulations of a State (as defined in 40 CFR 141.2)

Ground water: 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.

Surface water: Water either stored or conveyed on the surface and open to the environment. (e.g. rivers, lakes, streams, reservoirs, etc.)

Municipal water is generally of high quality, (i.e. tested and regulated to contain no indicators of fecal contamination) as certified by a third-party supplier, unless the delivery system used to convey the water is improperly maintained, or is open to the environment.

Similarly, natural physical, chemical, and biological processes result in appropriate microbiological quality of ground water. However, depth of the well may also impact quality, with deeper wells generally of higher quality than shallow. Delivery systems should be monitored and well maintained so as not to serve as sources of contamination or increased risk.

Because it is open to the environment and sources of contamination, surface water poses the highest risk and should be limited to applications that avoid the edible portion of the plant as much as possible, unless the water is adequately treated and monitored, or other science-based mitigation measures are available. Growers should be especially familiar with environmental and animal hazards that may impact the microbiological safety of the surface water and ensure that any subsequent mitigation adequately controls the hazards most likely to occur in that region and environment. Growers should also take caution when using surface water for "other" methods of water application, such as for chemigation or other plant protection purposes, if the water contacts the edible portion of the crop. Additionally, note that the Combined Harmonized Standard requirement 3.2.2 states that water used for cleaning and sanitation of food contact harvest equipment and tools must meet the microbial standards for drinking water (as defined by prevailing regulations), or be treated to achieve these standards.

Water delivery systems are also important components to an agricultural water system that can negatively impact otherwise high quality water if not properly managed or maintained. Water systems consist of closed, open, or mixed delivery systems (both open and closed). The California Leafy Greens Marketing Agreement defines the systems as follows:

Closed delivery system: A water storage or conveyance system which is fully enclosed and protected such that water is not exposed to the environment from the water source to the point of use.

Open delivery system: A water storage or conveyance system which is partially or fully open and unprotected such that water is exposed to the environment at any point from the water source to the point of use.

Examples of open delivery systems include ponds, reservoirs, canals, and uncovered water tanks. Although mixed delivery systems may include components which are closed, they should be considered as essentially open delivery systems in the context of a risk assessment.

Finally, **Application Method** considers how the water is applied, whether foliar or nonfoliar. In other words, during foliar application water is intended to, or is reasonably likely to, contact the edible portion of the crop. If water of poor microbiological quality is used in foliar applications, contamination may be spread to the crop. Non-foliar irrigation methods greatly reduce this risk. Examples of application methods that often result in contact with the edible portion of the crop include sprinkler, overhead, spray (irrigation, fertigation, cooling, etc.), or flood.

Examples of water applications that are *not* intended to contact the edible portion of the crop can include drip (microirrigation), furrow/flood (dependent on commodity), microjet, or seepage (sub irrigation or water table control).

After having considered these key points, the risk of contamination of produce via agricultural water may be broadly classified as high risk, medium risk, or low risk. *Take note* that these designations are intentionally simplistic and focus mainly on biological hazards. True risk follows a spectrum, and broad risk categorization may not capture all variables of a grower's ag water system. However, growers should be aware of the characteristics of their water system that led to that risk classification and subsequently consider mitigation steps and other factors that may be taken to reduce the risk of the associated hazards. **Table 2** shows the full requirement for a water management plan as it is written in the Combined Harmonized Standard, while **Table 3** includes a detailed description of various production components, their produce safety significance, potential sources, and recommended management strategies.

Table 2: Combined Harmonized Standard (v 1.1, 2016) requirement for water management plan

2.2.3.	Water Management			
	Requirement	Procedure	Verification	Corrective Action
2.2.3.1.	There shall be a water management plan to mitigate risks associated with the water system on an ongoing basis.	The water management plan shall include the following: preventive controls, monitoring and verification procedures, corrective actions, and documentation. The plan shall be reviewed following any changes made to the water system risk assessment and adjusted accordingly to incorporate such changes. Training and/or retraining of personnel having oversight or performance duties shall be documented.	Auditor reviews the water management plan for accuracy and completeness relative to the risk assessment.	Operation develops or updates the water management plan.

Figure 1: Assessing potential biological risk associated with pre-harvest agricultural water

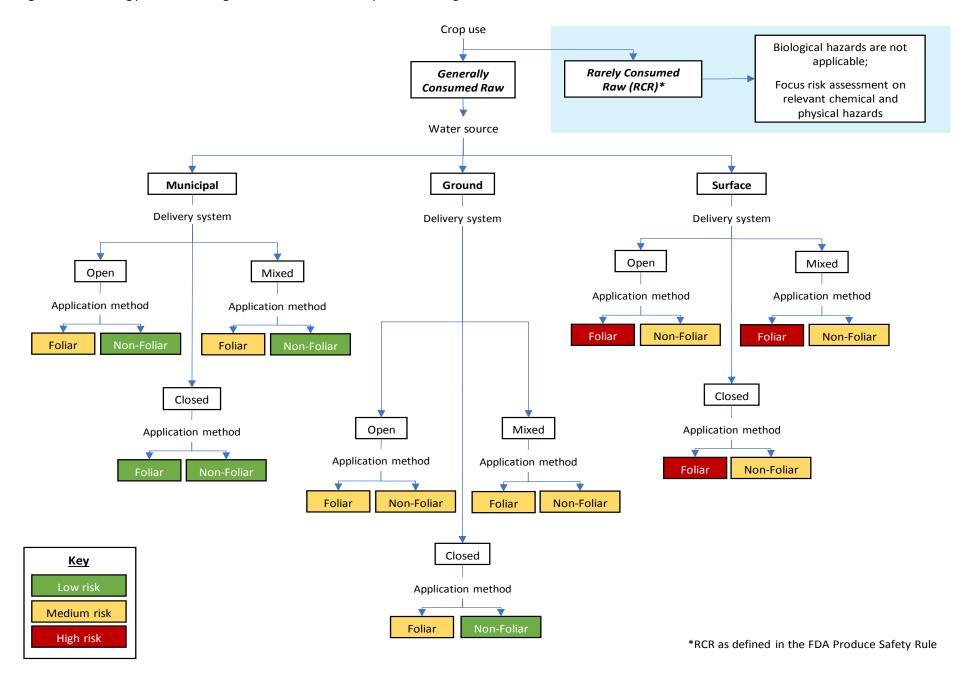


Table 3. Risk Mitigation and Management Strategies for various production components of fresh produce operations

Production Component	Significance	Key Risk Factors	Risk Mitigation and Management Strategies
Crop consumption	If product is consumed raw, biological hazards from ag water or any other source will persist. If product will be cooked, biological hazards will be addressed by heating.	Product is generally not heated prior to consumption (i.e. is not rarely consumed raw)	 Applicable Produce Safety Rule regulations are followed, and assessment of agriculture water is completed as needed. Use of lowest risk water is recommended, as much as practical. Consider the use of treated water in higher risk situations, as determined by the risk assessment.
Water Application	Highest risk occurs when surface water directly contacts the edible portion of the crop (if consumed raw) close to harvest. If water is directly applied earlier in the growth cycle there is the potential for microbial die-off because of UV light, though penetration and efficacy is dependent on crop type, density, and growing/environmental conditions. The more water contacts the crop, the greater the chance that contaminated water will contaminate produce. Water that only incidentally contacts the edible portion presents a lower, yet still presentrisk.	Water contacts harvestable portion of the plant or tree Timing of application	 Avoid using irrigation water that directly contacts the harvestable part of the crop. Avoid using irrigation water directly for application of plant protection products or fertilizers where the harvestable parts are in contact with water. For irrigation of crops where the harvestable parts are in contact with water, consider use of treated water with disinfectant (or other physical, energetic, or chemical agent) as allowed by local regulations. Establish a minimum interval between application and harvest with consideration to microbial die-off rates, if supported by available research applicable to the commodity and region of growth. Avoid foliar application of surface water or water of unknown quality on crops close to harvest, particularly those that will not be cooked prior to eating. Treat surface water if using foliar application on crops close to harvest Establish a science-based minimum interval between application and harvest to define "close to harvest" for the above statements

Water Source/ Distribution System	Water source can greatly impact microbial risk, with surface water posing highest risk compared to ground or municipal water. Regardless of source, improperly maintained or unprotected water distribution systems will increase the potential for hazards to enter the water system. Wells generally maintain appropriate microbial quality naturally and thus have higher standard, but they must be maintained and monitored to prevent outside contamination.	Improper construction, maintenance, and management of: -Wells -Pumps -Delivery systems -Storage tanks -Irrigation water hoses -etc.	 Develop an SOP for the maintenance of ancillary equipment and water storage and conveyance components of each ag water system used in your operations. Periodically review water distribution systems to ensure proper construction and maintenance. Address deficiencies (e.g. cracks, corrosion, or other damage) as needed. Area surrounding well should be sloped to drain surface runoff away. No water should be gathering near the opening of the well. Wells should be closed and covered with a tightly fitting, vermin-proof well cap or sanitary seal to prevent entry into the well. Pipes and pumps must be closed and maintained clean. Ensure backflow prevention device is properly functioning. If gas engine is used to pump water, a drip pan should be used to prevent irrigation water contamination. Ensure there are no cross-connections with human or animal waste systems.
		-Irrigation ponds -Reservoirs Water treatment equipment	 Monitor and maintain structural elements of the water source (e.g. lining, piping, etc.). Address deficiencies as needed. Limit use of open water sources to applications that avoid the edible portion of the plant as much as possible, unless the water is adequately treated and monitored, or other science-based mitigation measures are available See below for additional mitigation strategies as they relate to open water sources Periodically review water treatment equipment and system to ensure proper construction
Animals and	Animals may harbor pathogenic	and system Presence of wild animals:	and maintenance. Address deficiencies as needed. Monitor and record the presence of animals [observed animals, fecal material, carcasses,
Animal Manure	bacteria, which can then be transmitted into water sources. Surface water is at the highest risk of this, though animal presence should be monitored and controlled regardless of source.	rodents, deer, birds, etc.	 tracks, burrows, etc.] Employ procedures to control unwanted pest access to the storage and conveyance systems (e.g.: avian deterrents, fencing, rodent monitoring), keeping in mind prevailing environmental regulations. Use fencing and other methods of pest control, where necessary, to prevent entrance of animals. Remove heavy vegetation near water sources that may attract or harbor animals.
		Feedlots, dairy operations and/or grazing animals	 Avoid animals grazing upstream of a river abstraction point or other water source Implement practices to minimize potential rain water or other run-off from animal operations.

		Domestic animals: horses, dogs, etc.	Control access to water sources and supplies used on food crops.
		Manure storage and/or application	 Store manure away or downhill from water sources and supplies. Protect and maintain storage to avoid leachates towards water sources. Limit and control manure applications near water sources and supplies.
Domestic Waste/Sewage	Hazardous contaminants can be carried or leached into water sources as a result of poorly maintained and managed waste and sewage systems.	Septic lines or tanks, leach or lateral fields, cesspools, pit toilets/privies, etc.	 Inspect and ensure that human waste water systems are separate from irrigation water systems. Monitor and maintain condition of septic lines and tanks, leach or lateral fields, cesspools, pit toilets, etc. located near water sources and supplies; address deficiencies as needed. Consider increased monitoring if septic system is in close proximity to water source.
		Portable sanitation facilities	 Inspect water channels to ensure their separation from sanitary facility waste channels. Monitor and maintain sanitation facilities in good condition. Locate and service/ empty facilities as far as possible and practical from water sources and supplies.
		Wastewater treatment facilities	Consider the risk of sewage treatment plant overloading by storm water into the water source.
		Biosolid/sludge storage or application	Human biosolids are not to be used in food crop production.
		Water systems conveying human waste	 Inspect and ensure that human waste water systems are separate from irrigation water systems.
Solid / Hazardous Materials	Hazardous contaminants can be carried or leached into water sources as a result of improper storage and use of chemicals and machinery.	Chemical storage/application	 Limit and control pesticide and fertilizer storage and applications near water sources and supplies; Avoid mixing of chemicals near the water source. Employ spill containment units near waterways, ponds, rivers, etc. Use check valves and backflow prevention devices for chemical or fertilizer applications through the water delivery system. Implement practices such as grass/sod waterways, diversion berms, runoff control structures, and buffer areas to minimize possible run-off, leaching, spillage, and/or drift from potential hazards. Ensure compliance with all local, state and federal laws, regulations and guidelines in the mixing, application and disposal of all agricultural chemicals.
		Machinery storage / maintenance areas	Do not use water channels or conduction systems for washing equipment, harvest tools, etc.
Environmental Factors	Environmental events may lead to contamination of ag water that might not otherwise occur in regular use.	Surface run-off during times of heavy rain or melting snow, or potential for other upstream contamination of water source	 Implement practices such as grass/sod waterways, diversion berms, runoff control structures, and buffer areas to minimize possible run-off, leaching, spillage, and/or drift from potential hazards. Utilize berms, slopes and diversion ditches for prevention of rain or irrigation run-off into water storage and conveyance systems.
		History of environmental events (flooding, earthquake, etc.)	Develop a contingency plan in the occurrence of environmental events, including a reanalysis of water sources, to evaluate if damage to distribution systems or contamination has occurred.

History of Water Source	The water quality history (both chemical and microbiological) of a water source can provide valuable insight as to the relative risk of various hazards, and should be considered when making risk assessment judgements and determining applicable, effective mitigation strategies.	quality test results	 Heightened inspection of water system components that were the root cause of historical deviations Apply water in accordance with apprpriate die-off rates, if supported by available research applicable to the commodity and region of growth. Consider treatment of ag water as necessary, in accordance with applicable regulations 	
	For municipal water sources, growing operations should request the most recent water test results and maintain them on file.			

References

CA LGMA. 2019. Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens (v16). https://lgma.ca.gov/wp-content/uploads/2019/05/190419-CA-LGMA-Metrics-with-Decision-Trees-1.pdf

United Fresh Produce Association. 2016. Combined Harmonized Standards (v. 1.1).

US FDA. 2015. Food That Is Covered and That Is Not Covered (§§ 112.1 and 112.2, and Definition of "Produce" in § 112.3(c)). 80 FR 74384 – 74391. https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf

Additional Resources

FSMA Final Rule on Produce Safety -

https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm .

Produce Safety Alliance - https://producesafetyalliance.cornell.edu/resources/general-resource-listing/

CA LGMA "Sanitary Surveys and Remediation Guidelines for Water Resources" https://lgma.ca.gov/wp-content/uploads/2014/09/appendix_a_water_sanitary_survey.pdf

Western Growers "Ag Water System Assessments and Remediation Guidelines" https://www.wga.com/sites/default/files/resource/files/ appendix a ag water system assessment.pdf

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