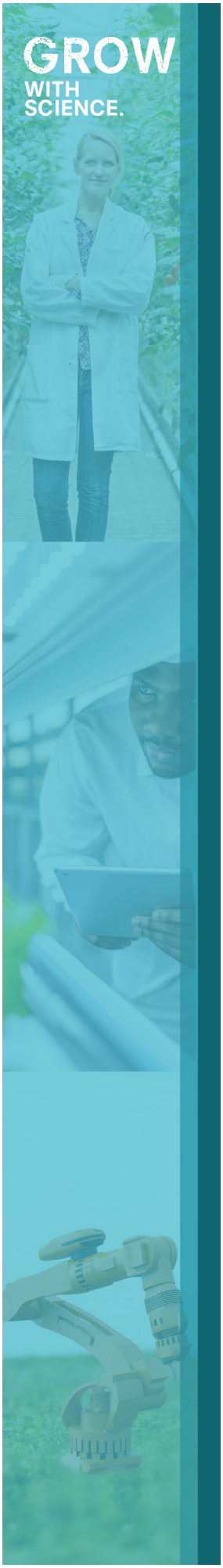

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Appendix R

Root Cause Analysis for Water Resources

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Disclaimer:

Root Cause Analysis is strongly encouraged to address a variety of food safety incidents or failures. The Root Cause Analysis principles included in this document can be applied to different food safety issues and are intended to cover key considerations to conduct Root Cause Analysis in relation to water resources. The authors, contributors and reviewers make not claims or warranties about any specific actions contained herein. The providers of this document do not certify compliance with local, state and federal laws, rules and regulations.

Executive Summary

This document outlines general information about Root Cause Analysis to be used as guidance when implementing requirements of the *Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens* (hereby referred to as *the Leafy Green Guidelines*). For purposes of this document a Root Cause Analysis is conducted to determine why:

- Generic *E. coli* levels in irrigation water are above the acceptance criterion.
- In the case of treated irrigation water, why total coliform bacteria exceed the acceptance criterion.

A Root Cause Analysis:

- Helps to identify the initiating cause of elevated generic *E. coli* above the acceptance criterion or, in the case of treated water, also elevated total coliform bacteria exceeding the acceptance criterion.
- Provides solutions to reduce the risk of reoccurrence.
- Fosters continuous improvement in your processes.
- Supports interventions at the source of the issue/deficiency thus maximizing their risk reduction.

Root Cause Analysis

Root cause analysis (RCA) is a systematic method of evaluating possible explanations for a failure until the underlying cause is identified. This is achieved by following a protocol to determine how and why a failure occurred. There are many different methods of conducting RCA (see the *Resources* section below), but the process involves going back through events to determine what happened and working to determine why it happened.

How to conduct a root cause analysis

Step 1 – Initiate the process:

Define the problem by describing what happened—it may seem simple, but make sure you have a complete description of the failure event and select personnel accordingly to conduct the analysis. Depending upon how serious the potential food safety risk involved preemptive actions such as putting field on hold, buffering etc. may be indicated until RCA is completed.

Example:

What happened? For example, at the most recent sampling event, your water sample taken at the last sprinkler head of your ranch's irrigation system has a generic *E. coli* level of 1,850 MPN/100 mL. Your water source is an irrigation district canal.

What to do? Designate a RCA team, which can include you and/or a designated food safety professional and the field operations manager. The RCA team should work with personnel involved in taking water samples, conducting environmental assessments of the growing environment, and setting up and maintaining the irrigation system.

Step 2 – Collect evidence in the form of data and information

Begin as soon as possible after an event occurs to prevent loss or change in conditions as a result of the occurrence/event. Effective RCAs consider four types of factors:

- Physical – structures, systems
- Operational – performance, decision-making, communication
- Organizational – policies, structures, culture
- External – environmental factors, weather, upstream activities, regulations

Evidence may take the form of:

- Samples – This goes beyond microbial water quality data and includes other types of data that are related to water quality test results and performance of the water treatment system.
- People – Personnel that were involved in the event and/or have knowledge about what happened.
- Paper and electronic record review – Ensure worker accounts match what was documented.

Example:

When data collection begins, your RCA team should do the following:

Check the schedule during the week before the water samples were collected to see what events occurred on that particular ranch and checks with neighboring ranches upstream along the irrigation canal regarding their irrigation water tests and field operations.

- Work with personnel who set up and maintain your irrigation system to check the integrity of the water lines/pipes.

- Work with personnel who conduct environmental assessments to check their records for notable, relevant observations prior to the water samples being taken.
- Work with personnel who took the water samples to retake samples at the source and the last sprinkler for follow-up testing.
- Check all relevant records and documentation applicable to the ranch.
- Interview personnel asking questions about the information and data they gathered and about their methods for completing relevant tasks.
- Observe those collecting water samples to ensure they are following the sampling protocol and using sanitary practices.
- Check the weather-related data for the week before the samples were taken.

Step 3 – Event reconstruction

Describe *what* happened

- Outline what happened (step by step – if possible)
- Exactly what was the deviation from SOP, expected result or Protocol?
- Create a timeline (sequence of events that took place)
- Use maps, diagrams to describe the events / what happened

Example:

The RCA team meets and brings all its information together and discusses the details of what happened prior to and during the water sampling event.

- Upstream from your ranch soil amendments were spread on fields adjacent to the irrigation canal. The soil amendment contained animal manure from a stack located uphill from the canal, and it is unknown whether it was adequately processed to eliminate human pathogens.
- The day sampling occurred there were higher than normal wind speeds causing high turbidity of irrigation canal water.
- Field assessment records for the week prior to sampling show there was evidence (e.g., scat) of feral pig activity near the irrigation canal upstream of the ranch.
- The field manager reported that the neighboring ranch upstream also had above threshold levels of generic *E. coli* in their irrigation water samples.
- Contrary to the sampling protocol, personnel taking water samples were observed placing the sample container's lid on the ground while collecting the water.
- Personnel collecting water samples report that the most recent samples contained generic *E. coli* levels under the acceptance threshold.

The designated food safety professional writes an event report including a timeline of weather events, ranch activities, and observations made during the environmental assessments conducted the week before the implicated water samples were taken.

Step 4 – develop a hypothesis of why the event/failure happened

Identify all issues and events that contributed to the problem

- Causal factor – A condition or event that results in or contributes to an event; describes ***what*** happened.
  - Primary cause

  - Complicating factors
  - Why did the issue happen
- Contributing cause – A cause that added to an event but, by itself, would not have caused the event; partially describes *why* something happened, but is not sufficient in and of itself to cause the failure.
- Root cause – The cause that directly resulted in the event/occurrence; describes ***why*** the failure happened.

Example:

The RCA team meets to discuss their findings regarding potential causes and contributing factors for the elevated generic *E. coli* levels. Based on a preponderance of evidence, the group determines the root cause of the transient high generic *E. coli* levels in the irrigation water was the manure stack located uphill from the canal and spread on alfalfa fields adjacent to the canal. High wind on the sampling day was a contributing cause in that it stirred up the water prior to and during irrigation water sampling.

Step 5 – Describe steps for solution(s), corrective Action(s), and prevention

Describe what actions have been taken. Measure success of any changes resulting from the analysis by implementing a follow-up corrective action plan and timeline that includes:

- Target completion dates
- Monitoring and verification

Identify any actions/practices that, had they happened/occurred, would have *prevented* this occurrence/ event.

- Investigate why these things did not occur or were not permitted to exist.
- Design and implement changes to eliminate them using solutions that address the problem and prevent it from happening again or reduce the probability of it happening again.

Example:

The food safety personnel responsible for environmental assessments do not have regular communication with the ranch growing alfalfa upstream from your operation. The RCA team implemented a procedure to increase communication and arranges meetings with the field operations manager of the upstream ranch to share environmental assessment observations with neighboring ranches when they are deemed pertinent to food safety for the growing community in the area.

The RCA team discussed ways to prevent runoff from manure stacks and field applications from accessing irrigations canals. They explored various barrier options and arranged a stakeholder meeting that included irrigation district personnel and local ranchers to discuss their options. At the meeting, all stakeholders agreed that monitoring and controlling manure storing, processing, and field application was in everyone's best interest. The irrigation district instructed its personnel to be on the lookout for manure contamination sources on their routine patrols of the irrigation canals. They established an email listserv to notify the growing community of potential contamination issues.

Resources

Federal Energy Regulatory Commission. Overall approach to root cause analysis https://www.ferc.gov/ industries/hydropower/safety/projects/taum-sauk/consult-rpt/sec-5-overall.pdf

Association of Public Health Laboratories. The Pew Charitable Trusts presentation: Root Cause Analysis and Environmental Assessments https://www.aphl.org/conferences/proceedings/Documents/2017/ InFORM/43-Hoelzer.pdf

HACCP Mentor. Root Cause Analysis and the Food Industry https://haccpmentor.com/haccp/root-cause- analysis-and-the-food-industry/

Appels K, Kooijmans R. 2017. The most powerful way to perform Root Cause Analysis. Food Safety Experts. https://www.foodsafety-experts.com/food-safety/powerful-root-cause-analysis/

Strong B. 2015. CAPA and Root Cause Analysis for the Food Industry. Food Safety Technology. https://foodsafetytech.com/feature_article/capa-and-root-cause-analysis-for-the-food-industry/

Collaborative Food Safety Forum. 2016. https://www.resolve.ngo/docs/root-cause-analysis-summary-6-14- 17-final.pdf

American Society for Quality. Root Cause Analysis. https://asq.org/quality-resources/root-cause-analysis#conducting