

When To Do Root Cause Analysis

A Decision-Making Guide for the Produce Industry

Contributors to this Guide

















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THE RCA PROCESS – BACKGROUND

Root cause analysis (RCA) is a process for systematic investigation where incident-specific information is assembled, and problem-solving techniques are used to analyze and evaluate why an incident or event happened. The RCA process provides structure and guidance for an "analysis" by breaking down or dividing a potentially complex set of circumstances into smaller parts. Incidents may occur due to a single lynchpin breakdown of a control point or a cascade of multiple elements. Catastrophic failures are clearly possible, and while these have a root cause, they may not require RCA to resolve what happened and why.

RCA ensures an analysis goes beyond an obvious solution or superficial fix for the immediate circumstances, such as discing down a field after a pre-harvest test is positive for a foodborne pathogen. The RCA process seeks to resolve what led to the failure such as an unanticipated causal factor or previously unrecognized risk. RCA problem-solving techniques can be effectively applied in helping to resolve any number of hazards, conditions, or process controls in many situations including food safety, quality, pesticide tolerance exceedances, on the job injuries, etc.

This document provides guidance on when to do root cause analysis for products generally consumed raw during situations that may be encountered in growing and handling operations and taking into consideration company-specific resources and risks. Despite many commonalities in root causes, RCA is generally not a cookie-cutter process where the steps followed and outcome achieved can be copied or reproduced from one seemingly similar situation to another. While there are often similar origins of a failure, the point of failure or source of risk is often unique. In addition, experience has shown that not all common RCA approaches are applicable to open-environment production systems.

Why should we do RCA?

Unless you determine the root cause of an issue or failure, you cannot make changes to remove a hazard or reduce the risk of it reoccurring. RCA is a tool to help you understand the sequence of events which lead to *why* something happened. In getting to *why* something happened, you explore *what* happened and investigate *how* it happened.

The **objectives** of RCA are:

- 1. To determine the underlying reason or reasons that caused the unexpected event or incident.
- 2. To identify the actions needed to eliminate the problem, and to determine if there were multiple co-dependent factors or interrelated issues.
- 3. To prevent it from happening again.

Without understanding *why* an incident occurred, you may apply a corrective action and think the problem is solved only to have it reoccur in the future. Without RCA, corrective actions often address "symptoms" of an issue, but they do not alleviate or solve the basic (root) causes of the underlying issue(s) causing the exceedance, failure, or defect. For instance, a crop protection spray intended for foliar applications tests positive for a foodborne pathogen. The corrective action is to dispose of the crop treatment in a manner that does not pose a risk to crops. In this situation, the underlying cause is how the crop protection spray became contaminated in the first place. Without determining how the contamination occurred means the next batch could also be contaminated. RCA is the means to finding the "cause" of the contamination so that preventive controls can be implemented to prevent future issues. With RCA, corrective action, after being incorporated into revised processes, addresses the underlying fundamental issue and leaves you better equipped to prevent similar situations from reoccurring.

Who should do the RCA?

The RCA process may be conducted as an individual investigation but most commonly involves and benefits from a team of individuals throughout the vertical and horizontal layers of an organization or across organizations. In assembling a team, the goal is to ensure all production and process elements are accounted for as you are determining the specifics of what happened. It is vital that the team includes members of management who are decision-makers and have the authority to define the scope, provide the resources needed, and implement any necessary operational and policy changes. You may also include someone from outside your organization who has experience in conducting RCA. An outsider, though they may not know your particular operations, may bring added value by listening and asking insightful and probing questions when facts would not appear to align. The external party can often be instrumental in viewing the situation and evolving analysis from a different perspective.

For each event that you determine requires RCA, your core team can be rounded out with those who are familiar with the relevant products, processes, equipment, etc. But keep in mind you can also involve appropriate personnel by interviewing them and not necessarily adding them to the team. Just as important as gathering critical information is keeping your team manageable in number. There are no set formulas for who to include on your team and how to manage engaging those who understand the problem or who "hold" the relevant facts and data.

When Should We Conduct RCA?

Not every incident or event that results in a product being defective or out of compliance, poses a potential food safety risk requiring a detailed RCA. Whether simple or complex, application of the right tool may greatly accelerate finding the necessary solutions and is almost always a vital learning and building block for your food safety culture. Some problems are minor, isolated, and do not directly impact product safety and, more importantly, you know why they happened (a "known factor" in Figure 1). In some cases, a simple correction or revision of company procedures or polices may be all that is needed to address the issue (illustrated in Figure 1 and Figure 2 on the following pages).

Figure 1. Making the Decision - When should we do RCA?

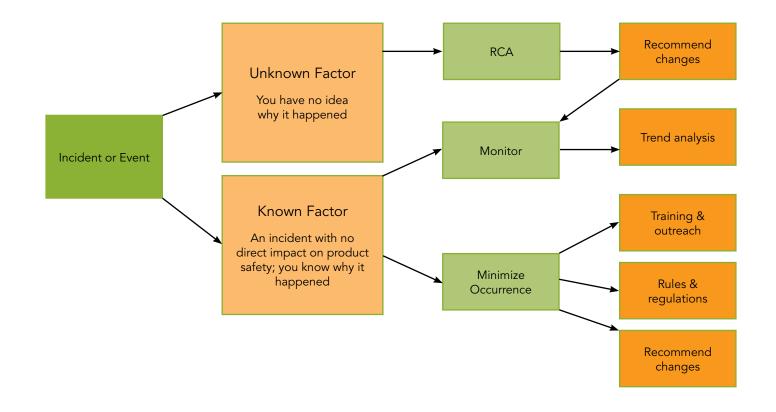
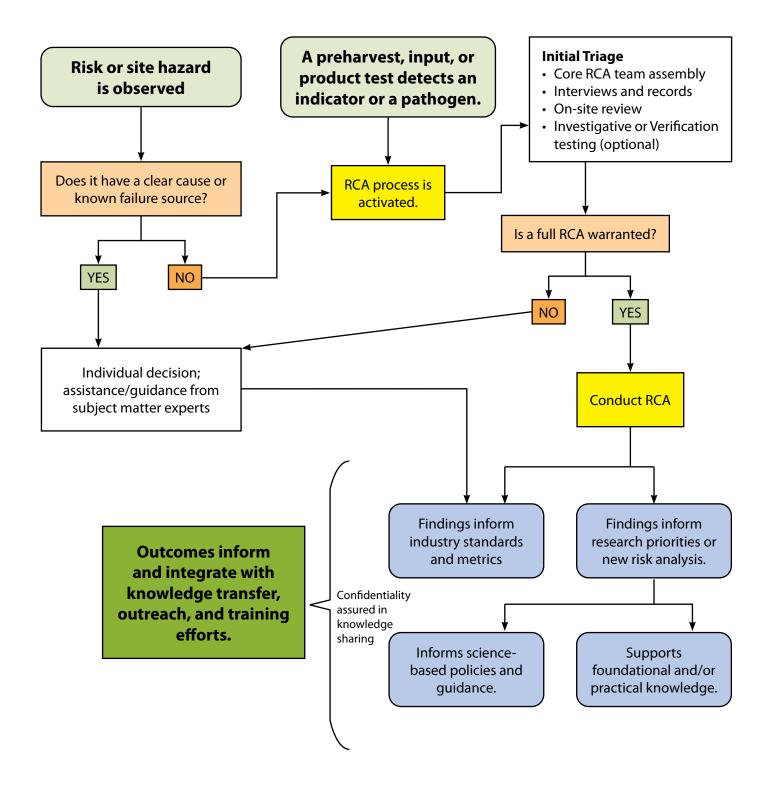


Figure 2. Decision and Outcome Transfer Flow Diagram



Decision Matrix

In addition, it is important in conducting RCA to be realistic and pragmatic in setting the scope and goals to prevent consumer health risks keeping in mind resources at your disposal. Below are criteria to consider when deciding whether to do RCA and a template to rate the risk using the RUN decision matrix:

- **R**epetition or frequency: Same issue/situation repeatedly happening (e.g., workers have been repeatedly bringing food and drink into the field over the past 2 weeks or higher than average turbidity in irrigation canal or lateral in the past 3 days)
- **U**rgency: Involves the severity of consequences does it directly impact product safety; how widespread would the effect be if contamination occurs? (e.g., widespread visible crop damage throughout the field or water treatment issues requiring immediate adjustments)
- **N**umber or volume: There is a high number of food safety hazards observed (e.g., unusual food waste and debris in the field or water treatment issues with several ranches)

The RUN decision matrix can help you identify issues with higher repetition, urgency, and number or volume. Regardless of the decision matrix or process you use, once you determine RCA is necessary, there are some steps you should take into consideration during the RCA process to determine why an incident or event occurred.

Example of a Decision Matrix – can be used to evaluate situations of noncompliance, circumstances that present food safety hazards, potential and actual contamination events, etc. Note that this is a tool to help you make decisions and not a prescriptive method that works for every event/incident.

Incident/Event	R	U	N	R + U + N

Example of how you could assign scores:

Repetition/Frequency

- 1 = This is the first time it has happened.
- 2 = It has happened before within the past year.
- 3 = It has happened several times within the past year.
- 4 = It has happened several times within the past 3 months.
- 5 = It has happened several times within the past 4 weeks.

Urgency

- 1 = It is not urgent, nor does it cause immediate damage or pose an immediate risk, and we understand how and why it occurred.
- 2 = It is only slightly urgent now, but it may become more urgent over time; there is potential to cause harm and our understanding of how and why it happened is incomplete.

- 3 = It is urgent and / or will potentially worsen in the short term; it can cause harm/pose a risk; our understanding of how and why it happened is incomplete.
- 4 = It is very urgent and / or will worsen in the short term; it poses a significant risk and/or has potential to cause significant harm; we have minimal understanding of how and why it happened.
- 5 = It is extremely urgent, presents an immediate food safety risk / may have already caused harm, and needs to be addressed immediately; we have minimal to no understanding of how and why it happened.

Number/volume

- 1 =It does not directly affect any product.
- 2 = It affects very little product and can be easily isolated.
- 3 = It affects or has potential to affect a fair amount of product but could still be easily isolated.
- 4 = It affects or has potential to affect a large amount of product, which could be isolated with some effort.
- 5 = It affects an extremely large volume of product and cannot be isolated.

Potential actions to be taken based on your combined (summed) score:

Total score	Action
3 – 4	Implement corrective actions; monitor and document the situation; may not require RCA.
5 - 8	Implement corrective actions; monitor and document the situation, and schedule RCA to be completed within the next week.
9 – 11	Implement corrective actions immediately; document the situation; retrain/notify workers if revised practices are needed; notify the RCA team and begin the RCA process as soon as possible.
12 – 15	Do whatever is necessary to stabilize the situation, if possible; alert the appropriate people, contact the RCA team, and begin the RCA process immediately.

Resources

A Guide for Conducting a Food Safety Root Cause Analysis | The Pew Charitable Trusts (pewtrusts.org)

LGMA Appendix R - Root Cause Analysis for Water Resources (Igmatech.com)

Process maps and flowcharts: <u>Process Flowchart - Draw Process Flow Diagrams by Starting with Business</u> <u>Process Mapping Software | Process Flowchart Symbols | Process flow diagram | workflow diagram</u> (conceptdraw.com)

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Designed by Western Growers.