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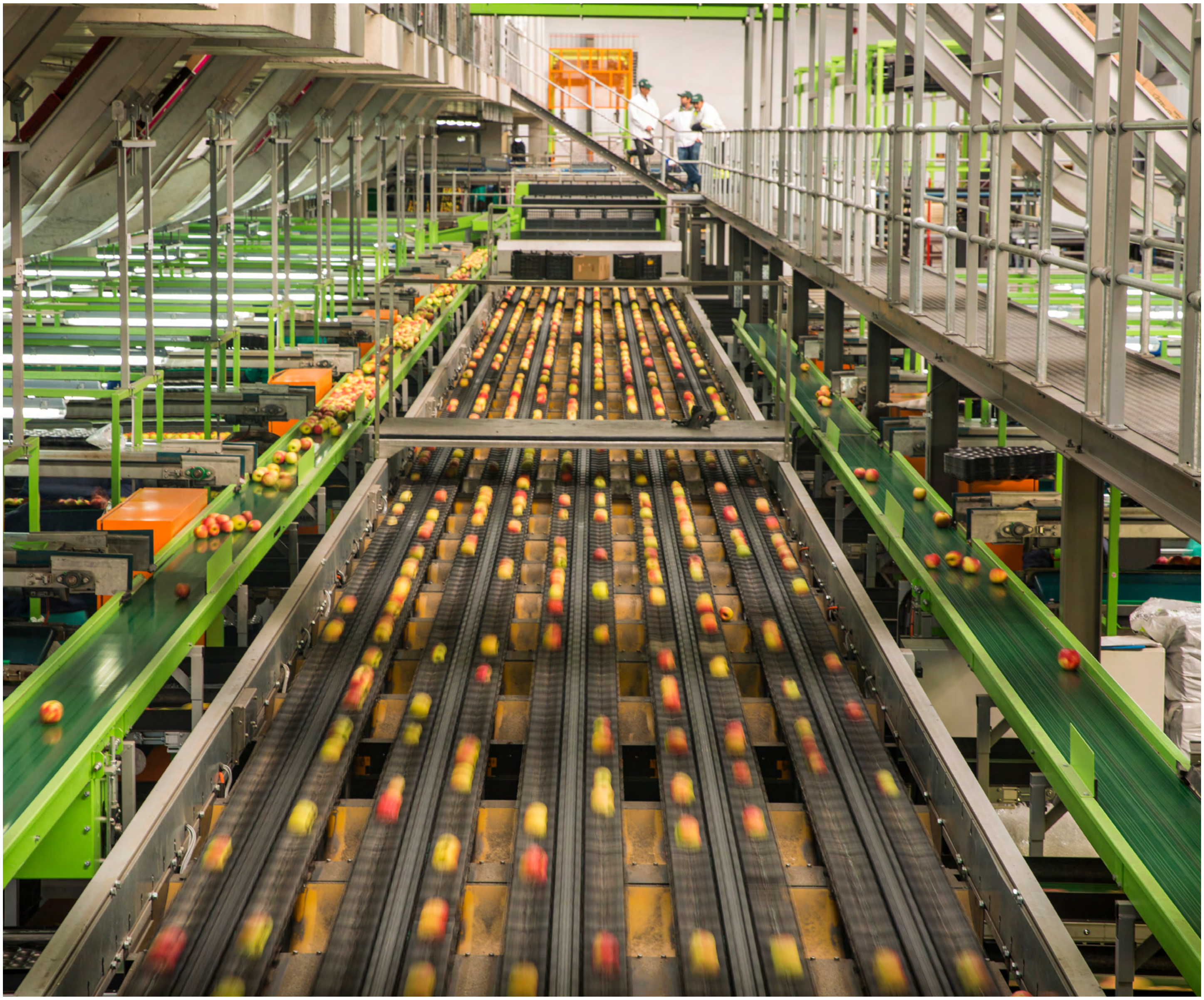

A Guide for Conducting a Food Safety Root Cause Analysis

Approaches for investigating contamination incidents and preventing recurrence

Contents

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Comments from federal agencies

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I. Introduction

A. The purpose of this guide

Learning from food contamination events and foodborne illness outbreaks helps uncover weaknesses in food safety systems and is a foundational property of a truly prevention-based system. Foodborne illness investigation methods continue to evolve to keep pace with changing hazards, technologies, and food production, processing, and distribution systems in an increasingly globalized food supply. However, investigation methods for identifying the root causes of food contamination have not yet been harmonized across food industries, regulatory agencies, academic institutions, and other key stakeholder groups.

Elements of root cause analysis (RCA)—commonly used to investigate air traffic accidents, patient safety issues, and other problems in various industries—have been included in many investigations of foodborne illness, where the technique can identify opportunities for improvement in the food safety system and strategies to solve them. Effective execution and communication of RCA can foster collaboration, trust, and knowledge-sharing among food producers, regulatory and nonregulatory agencies, and consumers. RCA also makes good business sense, because smoothly running operations have less downtime, fewer quality and safety holds, and improved employee morale.

The purpose of this guide is to improve food safety by encouraging the use of RCA in food operations and by safety regulators, and the sharing of information and lessons learned from these investigations. Food operations may include manufacturing and production facilities, farms, restaurants, caterers, or any other business that grows, handles, processes, distributes, prepares, or serves food. Food safety regulators include national, state, and local health agencies engaged in public health protection, inspections, and investigation of foodborne illness.

This guide is based on research on RCA in other industries as well as in-depth discussions among key stakeholders involved in food safety, including those that produce and sell food, those that have regulatory oversight over food, and those involved in the identification and resolution of foodborne illness outbreaks. The guide describes practices for effective RCA that, if used routinely, would help identify lessons learned from food safety failures and ultimately prevent foodborne illnesses. The guide provides approaches and rationales for how stakeholders can prepare for and conduct an RCA, report findings and conclusions, and apply lessons learned to prevent recurrence.

Investigators and management are encouraged to use this guide to plan RCAs, ensure the process includes steps essential to finding root causes, and design corrective actions that will prevent recurrence. To help decision-makers determine whether dedicating resources to RCA is worthwhile, the impacts of RCA in different industries are discussed. Users may also consider the following overarching questions to gauge progress and assess the strengths and weaknesses of the investigation:

- Do we have the right investigation team?
- Does our investigation have the characteristics of an effective RCA?
- Did we identify root causes and if not, do we know why?
- Did we communicate our findings to others, so the food industry may collectively improve food safety?

What Is Root Cause Analysis?

This systematic method of problem-solving can be used to determine the underlying reasons for how and why an event (such as product contamination or foodborne illness outbreak) occurred. It also helps clarify what steps are needed to correct the cause of the problem so that it will not recur.[1]

Specifically, had the root causes not occurred, the event would have been prevented or had less of an impact. A series of contributing factors may have played a part in the event, but root causes are its most fundamental underlying reasons.[2]

B. How to use this guide

This guide is intended for anyone who may conduct or manage an RCA or may be responsible for the allocation of resources to support such analysis at any point along the food production chain. This could include individuals employed by the food industry; federal, state, or local agencies with regulatory oversight over food; public health or agricultural agencies; trade or professional associations; academia; private consulting companies; or other entities with a vested interest in food safety. This group necessarily includes people with varying backgrounds and degrees of experience in an array of settings. Likewise, the factors included in this guide are for consideration in a variety of investigation settings, from assessments in individual farms or food production facilities to analyses of nationwide outbreaks.

RCA is an inherently scalable technique. The type and size of the organization, the significance of the event being investigated, the level of difficulty of the investigation, and resources available usually determine its scope. This document is intended to serve as a general guide for investigators and may also serve as a template for organizations seeking to develop internal standard procedures for conducting an RCA. In cases where not every step and recommendation will be applicable or appropriate, the document can still serve as a reference as stakeholders develop tailor-made practices and procedures. More detailed resources with further information on conducting RCAs are provided in the endnotes and Appendix A.

C. Root cause analysis has a long history in other industries

RCA was initially developed to improve manufacturing productivity in the car industry and is now used in various settings.

The technique was initially developed in the 1950s by Taiichi Ohno, former executive vice president of the Toyota Motor Corp. and developer of the Toyota Production System, as part of an operations management concept that would allow Toyota to catch up with American productivity after World War II. Ohno adapted the observational technique of Sakichi Toyoda, the founder of Toyota Industries, called the technique "five whys," and integrated it into the Toyota Production System.[3] The idea of asking "why?" five times is to explore problems until the root causes are found, so that the quality of products and manufacturing processes can be improved. Due in part to its reliance on RCA, Toyota Motor Corp. is now the largest auto company in the world.[4]

Inspired by this success, various industries around the world have adopted RCA principles to improve operations by conducting investigations of major or catastrophic incidents to prevent their recurrence. In the United States, this includes governmental and quasi-governmental agencies such as the National Aeronautics and Space Administration (NASA), National Transportation Safety Board (NTSB), the Chemical Safety Board, and the Nuclear Regulatory Commission. This approach has led to significantly better safety records in these industries. The case studies from other industries described below provide tangible implementation examples and valuable lessons learned that can inform improvements in the food industry as well.

Routine use of RCA helped rectify deficiencies in space flight's safety culture.

NASA uses RCA as a critical component of operations. This has included, for instance, analyzing the fatal accidents of space shuttles Columbia and Challenger. In these cases, RCA uncovered persistent organizational and cultural problems that were discovered in the Challenger accident but remained unaddressed and contributed to the Columbia disaster. Similar challenges to organizational change can be found in any food-producing or regulatory organization, and studying how they were ultimately solved provides valuable lessons for the food industry. The Columbia Accident Investigation Board concluded that physical mechanisms and organizational causes contributed to the loss of the Columbia and its crew in 2003.[5] The same root causes had contributed to the Challenger accident 17 years earlier, demonstrating that complex organizational cultures are difficult to change even if root causes have been identified.

The physical cause of the Columbia accident was a breach in the thermal protection system initiated by a damaged piece of insulating foam. But the Columbia Accident Investigation Board found deeper organizational root causes stemming from the space shuttle program's history and culture, cuts in NASA's budget starting in the early 1970s, and schedule pressures. Under these conditions, organizational practices and cultural traits that were detrimental to safety developed and created barriers to communication of critical safety information.[6] Now, in an effort to maintain an organizational culture of safety and prevent future accidents, the NASA Johnson Space Center's Flight Safety Office maintains a Significant Incidents and Close Calls in Human Spaceflight chart to disseminate lessons learned from the incidents and encourage continued vigilance in the space flight community.[7] NASA's Office of Safety and Mission Assurance also oversees Mishap Investigation, a program that allows NASA to understand the root causes of accidents and to prevent recurrences.[8] This example demonstrates the challenges in changing organizational safety culture, but future operations can become safer with the continued implementation of the lessons learned from root cause investigations.

Transparency through RCA has helped reduce fatal accidents in civil transportation.

Since 1975, the civil aviation industry has used RCA to help prevent avoidable accidents through a voluntary and confidential incident reporting system that allows the aviation community to report unsafe occurrences and hazardous situations. Created by NASA and the Federal Aviation Administration (FAA), the Aviation Safety Reporting System (ASRS) is mandated and funded by the FAA and is administered by NASA—a division of labor and protection against conflicts of interest.[9] The ASRS identifies potential safety hazards through analysis of voluntary aviation safety incident reports and issues safety alerts back to the aviation stakeholders so that potentially hazardous conditions can be corrected. This reporting model has been copied by aviation safety systems worldwide, and has been replicated in other industries including patient safety. (See text box "The Impact of Root Cause Analysis on Patient Safety.")[10]

The NTSB also conducts RCAs. Established in 1967 as an independent agency (part of the executive branch but independent of presidential control), the NTSB has the authority to investigate the causes of accidents in aviation, highway, marine, pipeline, railroad, and hazardous waste transportation[11] and make safety recommendations so that similar accidents do not recur. As of 2017, the NTSB had made more than 14,500 safety recommendations; more than 80 percent of these recommendations have been implemented, which has undoubtedly contributed to the prevention of fatal accidents.[12] As of 2019, there have been no fatal airline crashes in the United States in 10 years.[13] These successes have led to RCA being mandated by aviation legislation around the world. For instance, in 2013, the European Commission published regulations requiring the European Aviation Safety Agency to perform RCA.[14]

RCA has led the engineering industry to develop improved safety systems.

Following the Exxon Valdez oil spill in 1989, the NTSB found faults in Exxon's personnel policies and management's decision-making in the root cause investigation of the accident.[15] Exxon responded by building a rigorous safety system that today is used throughout the company, and is credited with preventing another potentially disastrous accident in a deep-water exploration well called Blackbeard, located in the Gulf of Mexico. In 2007, the Blackbeard drilling team voiced major concerns about a potential blowout due to the extreme temperature and pressures of drilling at a depth of more than 30,000 feet. Exxon's then-chairman, Rex Tillerson, sided with the drillers and abandoned the well.[16]

The considerable value of this decision came into focus in 2011 when a competitor, BP, suffered an explosion on the Deepwater Horizon well, killing 11 workers and dumping roughly 4.9 million barrels of oil into the Gulf of Mexico. Root causes of this accident identified by the National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling were management decisions that increased risk, poor communication between BP and its key contractor, Halliburton, and failure to communicate lessons learned about an earlier near-miss incident involving another contractor called Transocean.[17] As these incidents demonstrate, the implementation of effective safety systems that are built from RCA findings can prevent disasters.

Sharing RCA findings led to evidence-based recommendations to prevent adverse events in patient safety.

Routine use of RCA, and regular reporting and sharing of findings, has improved recommendations to protect patient safety. Since 1996, the Joint Commission (a nonprofit organization that accredits hospitals and other medical services) has required accredited health care organizations to conduct an RCA for all sentinel events—patient safety events, unrelated to the natural course of the patient's illness, that lead to death, permanent harm, or severe temporary harm. Accredited health care organizations are also encouraged to report sentinel events so that they may be added to the commission's Sentinel Event Database. Sentinel event statistics are reported yearly, but because fewer than 2 percent of all sentinel events are reported, no conclusions can be drawn about frequency or trends.[18] However, reported information is analyzed by the commission, and recommendations are disseminated to reduce the risk of future sentinel events. For example, a study on objects unintentionally left in patients' bodies after surgery—the most frequently reported sentinel event—resulted in recommendations to improve surgical safety that address the most commonly identified contributing factors.[19]

The Impact of Root Cause Analysis on Patient Safety

A 2013 study on the relationship between use of RCA and patient safety at 139 U.S. Department of Veterans Affairs (VA) medical centers found that rates of postoperative complications were higher at centers that performed fewer RCAs.[20]

This study was made possible through standardization of RCA for patient safety and creation of a framework to share results and corrective actions. The VA National Center for Patient Safety (NCPS) developed and mandated an RCA process for all VA hospitals, and maintains a confidential reporting system, the Patient Safety Information System, for patient safety incidents and RCAs.[21] The VA NCPS maintains the information system to drive continuous improvement in this sector. This work demonstrates the potential value in standardization of food safety RCA procedures and in creating a platform to share findings so that industry-wide analyses can be performed that provide similar assessments.

Routine RCA use allowed the recreational diving community to identify and mitigate common risk factors.

The Divers Alert Network (DAN) was created to provide real-time emergency assistance as well as access to relevant information and education to the recreational diving community.[22] Dive incidents—such as equipment failures, human errors, or entrapment underwater—are routinely reported to DAN, analyzed, and the root causes shared in incident reports posted on the network's website. This provides valuable and actionable information to the recreational diver community.[23]

For instance, in 2012, DAN researchers conducted an RCA of approximately 1,000 diving accidents to understand what events led to diver fatalities.[24] They found cardiac incidents caused at least one-quarter of all dive fatalities. Risk factors for cardiac fatalities were age (greater than 40 years old) and existing cardiovascular disease.[25] No other triggers (such as equipment problems) were associated with these fatalities. In response, DAN focused considerable outreach and education efforts on the risks of experiencing cardiac incidents during diving as well as available mitigation options.

D. History of modern food safety and opportunities for further integration of RCA

A new era of food safety oversight began with the development of hazard analysis and critical control points (known as HACCP), a systems analysis approach to food safety developed in the 1960s by the Pillsbury Co. when it began providing food for space expeditions. A HACCP system analyzes a food product's processing steps, identifies points where hazards (such as biological, physical, or chemical contamination) are reasonably likely to occur, and designs procedures to prevent or control these risks. The U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) put in place HACCP requirements for meat and poultry operations in the mid-1990s, and the FDA Food Safety Modernization Act requires a similar approach for FDA-regulated food-processing plants.

Prevention is an integral concept in HACCP, and existing federal agency directives and regulations instruct food establishments and government investigators to identify the causes of incidents and to establish actions to prevent recurrence.[26] RCA can be used in these cases as the approach that supports development of preventive actions, to strengthen HACCP plans, and as a tool to fulfill agency directives. Although there are differences between HACCP and RCA, both are systematic analyses that originated in engineering disciplines that try to detect and eliminate risks, and are fundamental to food safety. HACCP is prospective in predicting risks and developing control strategies for those risks, whereas RCA is retrospectively initiated in response to an incident and attempts to prevent a recurrence by investigating why a control strategy failed or why a risk was not identified.[27] For example, a hypothetical RCA conducted after a contamination incident found that an equipment breakdown caused a control step (e.g., heat treatment) to be bypassed. An employee failed to monitor the equipment per the HACCP plan and identify that the control step was not met. Root causes of the incident were inadequate training due to language barriers and company policies that failed to address language differences in employee trainings.

Since 1961, the Centers for Disease Control and Prevention (CDC) has been reporting foodborne disease outbreaks and routinely analyzing data to identify outbreak sources. Early outbreak investigation reports were based on inspector observations at retail establishments, and focused more heavily on detecting formal code violations than factors that contributed to the outbreak. Because not all contributing factors or root causes to an outbreak were formal violations, and not all violations that caused unsanitary conditions led to the outbreak, true root causes were rarely recorded. Recognizing limitations in outbreak reporting, CDC began to focus efforts on identifying causative factors rather than violations and to integrate systems theory into investigations by way of HACCP principles.[28] Outbreak-related information was initially grouped into five broad categories of contributing factors:[29]

1. Improper holding temperatures of food.
2. Improper cooking temperatures of food.
3. Using contaminated utensils and equipment.
4. Poor health and hygiene of food handlers.
5. Obtaining food from unsafe sources.

CDC incorporated this list into its outbreak reporting forms in the 1990s and continues to use an updated version that groups contributing factors into three broad categories: contamination (the pathogen or hazard gets into food), proliferation (the pathogen grows), and survival (the pathogen survives a processing step designed to reduce it).[30] Contributing factors are not root causes; root causes are the reasons why the contributing factors occur.[31] Nevertheless, this move by CDC was an important step forward in identifying potential causes of outbreaks and strategies to prevent recurrence.

To further improve outbreak investigations, CDC's National Center for Environmental Health (NCEH) began incorporating root cause concepts (also referred to as environmental antecedents) into its environmental assessment process in the early 2000s.[32] Environmental assessments determine how and why foodborne illness outbreaks occurred and are used here synonymously with RCA. FDA and FSIS incorporated principles of CDC's environmental assessment guidance into their foodborne disease outbreak investigations in the late 2000s. Results from these investigations show that they are subject to four important challenges, which are to some extent unique to food: complexity and interconnectivity of food supply chains, requiring high levels of critical thinking skills; time lag between food preparation and recognition of a foodborne illness outbreak, resulting in difficulties reconstructing events and determining food consumption histories; distinctions between regulatory infractions and contributing factors or root causes; and seasonality in the growing of food, where production operations may have ceased by the time an investigation is launched.[33]

Product, pathogen, and consumer-specific factors including unexpected consumer behaviors can further complicate the analysis of foodborne illness outbreaks. Cross-contamination is another potential challenge for RCAs that is unique to food. For example, in an outbreak of Shiga toxin-producing *E. coli*, wheat likely became contaminated in the field, then was shipped to flour processing facilities and mixed in large silos with flour from other suppliers.[34] Investigators traced the outbreak back to one flour company, but assessing the root causes at the farm level was not feasible given the mixing of multiple sources of flour and lack of traceability back to the field of origin. As another example, in several *Listeria* outbreaks, cross-contamination in retail delis has posed similar challenges in identifying the root causes.[35] Deli slicers and knives that have not been properly cleaned and sanitized may spread *Listeria* from a single contaminated meat or cheese product to many other items sold in the deli. Because *Listeria* primarily sickens high-risk population groups—such as pregnant women, the elderly, and immunocompromised individuals—contaminated food will likely only cause an outbreak if consumed by these people. By chance, the contaminated food items that initially brought the bacteria into the deli may have only been consumed by healthy individuals and not caused any illness, while the food items consumed by susceptible individuals and associated with the *Listeria* outbreak may have been cross-contaminated at the deli, thus limiting the ability to identify root causes for the outbreak.

Fresh food products with short shelf lives pose another particular challenge for conducting effective RCAs.[36] Fresh produce is sold and consumed in a brief time frame and is usually gone from store shelves and homes by the time an outbreak is identified. Investigations of contamination from an open farm setting may have too many uncontrolled factors (such as weather or wild animal invasion) that may be difficult to reconstruct with cause-and-effect relationships that are too complex to fully understand, even through a similar systematic RCA approach. Corrective actions for produce may involve a wide spectrum of interventions from the farm to the consumer; correcting only one potential cause may not be sufficient to mitigate the contamination risk.[37]

All of these challenges require creative solutions, which are discussed further in Section IV, subsection F, "What factors should be included in the design of a robust corrective or preventive action plan?"

Root Cause Investigations Spur Policy Changes in Food Industry

Findings from foodborne illness outbreak investigations have led to policy changes to improve food safety, as these four examples show. Investigation of a 2006 outbreak of *E. coli* O157:H7 illnesses in fresh spinach identified the potential importance of wildlife intrusion into fresh produce fields as a likely source of contamination and established a basis for improved good agricultural practices that emphasize wildlife barriers to control animal populations in the field.[39] A 1994 outbreak of *Salmonella* illnesses associated with commercially produced ice cream revealed cross-contamination during transportation of ice cream pre-mix and contributed to the passage of the 2005 Sanitary Food Transportation Act requiring FDA to regulate food transportation practices.[40] A 1989 outbreak of *Salmonella* illnesses associated with mozzarella cheese revealed a breakdown in sanitary procedures as the mozzarella manufacturer approached bankruptcy as the root cause for a multistate outbreak.[41] In restaurant settings, investigation of numerous outbreaks of norovirus associated with ill food workers have identified multiple reasons why food workers work while ill, leading to broader policy changes—from maintaining employee illness logs to mandating provision of employee sick leave.[42]

E. Methodology

The recommendations included in this guide were informed by the opinions and suggestions of food safety experts, review of the available literature, working groups, and discussions with RCA experts from other industries. In three separate day-long, in-person meetings, The Pew Charitable Trusts convened key food safety experts and stakeholders from federal, state, and local health agencies, the food industry and relevant trade associations, academia, and consumer protection and public health organizations to discuss the advantages of—and barriers to—conducting food safety RCAs; steps for conducting a successful root cause investigation; and strategies to communicate findings. In addition to these meetings, Pew convened smaller working groups remotely to address key issues identified during the in-person meetings.

This guide is organized by four major questions based on themes that arose from the discussion:

1. What is an RCA?
2. What should be considered before conducting an RCA?
3. How should an RCA be conducted?
4. How should findings from an RCA be communicated?

II. What is an RCA?

For this document, an RCA, or environmental assessment, is defined as a retrospective investigation method used to identify why an incident occurred.[38] An incident can be an outbreak, an event that could have caused microbial, chemical, or physical contamination, a processing failure, or a food safety system failure. The goal of this type of investigation is to determine the factor(s) underlying the problem and identify actions that can be taken to eliminate the problem, prevent its recurrence, and ultimately reduce the risk of foodborne illness. To accomplish these goals, the investigation team should take the necessary steps to identify the actual root causes, or environmental antecedents, of the problem and not just the contributing factors.

Key Definitions

Root cause analysis (also called environmental assessment): a retrospective investigative tool used to determine the underlying reason(s) that caused an incident and what actions can be done to eliminate the problem, prevent recurrence, and reduce risk. Investigation is used synonymously with root cause analysis in this document.

Root cause (also called environmental antecedent): the underlying reasons that resulted in a system breakdown. If the root cause had not occurred, the event would not have occurred or would have been of significantly lower impact.

Contributing factor: the physical, biological, behavioral, or attitudinal factors that directly or indirectly resulted in an outbreak or other incident.

A. What is the difference between a contributing factor and a root cause?

Distinguishing between root causes and contributing factors is crucial to ensuring that the investigation has been sufficiently thorough to arrive at the root causes.[43] A contributing factor is *what* went wrong, whereas a root cause is *why* it went wrong. Oftentimes, contributing factors are also violations of food safety regulations (such as improper holding temperature). Inspections or incident investigations should continue after food safety violations are identified to determine why the violation occurred.[44] Root cause findings may or may not be clear regulatory violations; however, ending investigations at violations or contributing factors will diminish the prevention power of the RCA approach.

Control of contributing factors without addressing the underlying reason why they were present can result in a repetitive cycle of short-term correction followed by gradual loss of food safety controls and recurring problems. Making this distinction encourages prevention of the problem rather than just mitigation of the effects of an incident.

To illustrate how to distinguish contributing factors from root causes, here are two hypothetical examples of contamination in different food settings:

Example 1: A processed food is recontaminated after pasteurization and enters the market.

- **Contributing factors:** A valve in the plant was bypassed, leading to recontamination of product after pasteurization; product was not monitored for post-processing recontamination.
- **Root causes:** A lack of defined maintenance standard operating procedures allowed plant staff to develop their own ad hoc fixes to address issues; the company was economically stressed and therefore not able to hire people with the adequate food safety expertise, leading to an insufficient HACCP plan that did not consider post-pasteurization recontamination or examination of food post-pasteurization to verify that the pathogens had been adequately reduced.

Example 2: *Salmonella*-contaminated tree nuts cause an outbreak.

- **Contributing factors:** A weather event led to increased contamination at harvest; pathogen reduction interventions were insufficient to control *Salmonella* contamination levels on the highly contaminated nuts.
- **Root causes:** A lack of adequate scientific knowledge among food safety experts, food industry personnel, and regulatory officials (regarding, for instance, risk factors to predict *Salmonella* contamination on incoming product or *Salmonella* survival in low moisture foods); a company culture that did not adequately understand product risks and, therefore, failed to factor in sufficient control measures in its HACCP plan.

Why Accidents Happen Despite Safety Barriers

James Reason's Swiss cheese model is a frequently used illustration of the difficulties in understanding incidents and fixing root causes in complex systems.[45] Many layers of defense—or slices of Swiss cheese—may be erected as barriers to prevent problems, but each of these slices has holes due to unintended weaknesses. Sometimes these holes align across each barrier to allow a hazard to slip through and cause an accident. Corrective action plans can be adapted to address root causes; however, cementing these changes in complex food systems is not an easy task. An organizational culture that supports constant vigilance and provides tools to help staff validate corrective actions is essential for strengthening food safety practices.

B. In what situations can an RCA be performed?

Because of its broad origins in a variety of industries, RCAs can be used to investigate a wide range of adverse events affecting safety or quality—from singular, unusual events to patterns of recurrences—in a variety of food industry settings. An RCA can be helpful any time a food company or regulatory agency needs to know why a foodborne illness outbreak or other incident occurred and how to prevent it from recurring. There is no event too big or too small for which an RCA cannot be performed; however, it is important that the investigation techniques and approaches be appropriately tailored to match the scope and significance of the event. To be most effective in preventing food safety failures, RCAs should be integrated within a self-evaluating organizational culture and linked with existing continuous process improvement initiatives.

The following examples illustrate who may conduct an RCA in response to an incident in a few common situations:

- **A large, multistate outbreak.** The RCA tends to be conducted by the food company with help from federal and, possibly, state and local regulatory and public health agencies.
- **Regional, multistate outbreak.** This situation is similar to large, multistate outbreaks in many respects, including the potential involvement of experts from the food company as well as governmental agencies.

However, the investigation team is often made up of state and local regulatory and public health agencies from the affected states. If the company involved is a federally regulated facility, state and local regulatory and public health agencies would play a large role in the outbreak investigation but a limited role in the RCA. Federal agencies would play a major role in RCAs at federally regulated facilities. Federal and state public health officials may be integrated into an Incident Command System (ICS), allowing personnel from multiple agencies to collaborate rapidly under a common management structure.[46]

- **A small, geographically limited outbreak associated with a restaurant** (or retail space such as a grocery store deli or cafeteria). Local and state officials tend to conduct the investigation until the contributing factor or regulatory control point is found, but may continue work to complete an RCA with input from the business owner and employees. Preventive actions would need to be implemented by the establishment staff.
- **Process-control issue, or "near miss."** This is an unplanned event or chain of events caused by a deviation from a safety plan that could have caused illness or injury but did not. (See Appendix B: Glossary of terms.) In this instance, the company likely conducts its own internal RCA.

C. What are the advantages of performing an RCA? What are the challenges?

Advantages

The findings from RCAs are critically important for understanding what went wrong in a food safety operation so that corrective actions can be implemented. Findings from RCAs should also indicate what went right, such as where safety measures and other aspects of the production system were operating as intended and prevented or mitigated the impact of an event.

Companies may also benefit from incorporating RCA in their food safety systems in the following ways:

- Preventing future product recalls and foodborne outbreaks, protecting the health of customers, and minimizing loss of consumer confidence.
- Gaining potentially positive public perception and brand recognition, and improved customer trust, which could lead to greater profits.
- Demonstrating food safety commitment to supply-chain partners and consumers.
- Encouraging employee engagement in improving company food safety systems.
- Fostering employee pride and engagement.
- Strengthening self-evaluation, continuous process improvement, and quality assurance capacities within the company or organization's culture.

By adopting a systems-based approach, companies can equip their employees to better evaluate interdependent factors that can affect food safety (such as environment, facility, supply chain, equipment, or employee behaviors), actively consider and anticipate risk, and foster a food safety culture that prevents contamination rather than responds after it occurs.[47] In addition to adopting a standardized RCA practice, companies may also develop a consistent framework for sharing investigation results and lessons learned, both within their organization as well as broadly to other industry partners and regulatory agencies. This practice encourages positive working relationships between food companies, regulators, and public health investigators, in which industry engages in self-reporting and the agencies work with the industry to examine the data and provide guidance on analysis.

There are economic advantages to conducting an RCA. Strict liability laws mean that responsibilities for foodborne outbreaks fall most heavily on the food industry. Single cases of severe illnesses like hemolytic uremic syndrome associated with *E. coli* O157:H7 can easily result in liability costs exceeding several million dollars per case.[48] As demonstrated in the energy sector, RCAs can help prevent these financial losses. An operator of more than 17,000 miles of crude oil and natural gas pipeline in North America analyzed internal RCAs and found them to be a cost-effective process for the company. One RCA generated an estimated $16 million in savings.[49] RCA can also help identify inefficiencies that affect production costs and quality issues. Optimizing a company's food safety system is beneficial in a highly competitive economic environment.

RCA also has value if it is not immediately clear why an incident occurred or how recurrences can be prevented. In certain cases, an RCA may reveal additional vulnerabilities in systems used to implement corrective actions even if the factors that led to the event are known.

The Economic Impact of Foodborne Illness Outbreaks and Recalls

Outbreaks and product recalls can cost companies millions of dollars and damage brand reputations.[50] For example, the 2010 outbreak associated with shell eggs cost the industry more than $100 million that September alone due to price drops from negative media attention.[51] In addition, the recall costs of a multistate outbreak in 2007 linked to *Salmonella*-contaminated peanut butter were $78 million, with an estimated cost to the entire peanut industry of $1 billion.[52] In retail, with lost sales, legal fees, lawsuits, and fines, the costs of a large foodborne illness outbreak may exceed a restaurant's annual revenue.[53]

Challenges and potential solutions

RCAs tend to be time- and resource-intensive. Because not all RCAs provide an equal amount of insight and value, organizations need to develop a risk-based framework to systematically and consistently prioritize incidents for RCA. Factors used to prioritize RCAs in other industries include the actual or potential impact of the event and the likelihood of recurrence.[54] Events due to known contributing factors, in particular those that are outside of the organization's control, may receive a lower priority compared to those due to novel contributing factors. This framework should also emphasize the opportunity to target key causes in circumstances in which previous RCAs had multiple potential root causes, particularly where similar events occurred repeatedly.

There are numerous barriers to successfully performing RCAs, including staff's unwillingness to participate, interprofessional differences, and a lack of time.[55] Additional factors that may hinder investigations include lack of:[56]

- Access to farms or food-manufacturing facilities, records, and interviewees.
- RCA resources, including appropriately trained staff, specialized expertise, and support throughout the investigation.
- Leadership commitment.
- Necessary skills and ability to investigate beyond initial hypothesis to identify root causes.

Small and midsize operations often lack the resources large operations can summon to conduct investigations, and they may not be able to conduct full RCAs, particularly for smaller incidents or near misses. These companies could benefit from the sharing of findings from RCAs conducted by large companies in response to outbreaks and near misses.[57] In addition, access to specialized external expertise could be valuable. The University of Minnesota's "Team Diarrhea" could be one interesting model for extending resources while simultaneously providing valuable learning opportunities for student investigators.[58] Team Diarrhea is composed of students from the University of Minnesota's School of Public Health who are extensively trained by the Minnesota Health Department to conduct interviews after foodborne illness cases identified through surveillance. Using a student team approach such as this and expanding the scope of responsibilities from interviewing to RCA investigations or creating separate RCA teams for collaboration with food producers could enhance the efficiency of state health departments and provide much-needed resources to smaller operations.[59]

Communicating the results of RCAs may present a challenge for companies concerned about enforcement actions, liability, confidentiality, and brand protection. Companies may withhold or delay the release of RCA results over concerns about confidential or private data or uncertainty of the backlash of disclosing that information.[60] Regarding liability, there are concerns that public disclosure of RCA results could expose companies to consumer litigation. But companies may be able to explore ways to prevent the disclosure of confidential commercial information, such as by adapting existing expert forums and roundtables or potential sources of tools such as the Global Food Safety Initiative, trade associations, USDA Agricultural Research Service, or as part of a university extension. Platforms to share anonymous results may be able to help communication of results between regulators and industry, between large and small operations, and across industry segments. Potential unintended legal consequences of sharing RCA findings and strategies for mitigating these risks, albeit beyond the scope of this guide, are clearly important considerations and deserve further investigation.

Analysis of Repeat Patterns Across Multiple Incidents Helps Identify Root Causes

The NTSB has a long history of assessing similarities across accidents to determine failure patterns and identify root causes. For instance, NTSB pieced together critical information from the investigations into the crashes of United flight 585 in 1991 and USAir flight 427 in 1994, and a nonfatal incident in 1996 involving Eastwind Airlines flight 517 to uncover key evidence that ultimately allowed investigators to identify a mechanical malfunction critical to all three aircraft.[61]

Two recent accidents involving new Boeing 737 Max airplanes occurred within five months of each other in Indonesia and Ethiopia, and both planes exhibited similar flight patterns. The similarities led authorities around the world to take immediate action, grounding the aircraft type until the likely root causes can be resolved. In the U.S. the accidents have spurred congressional inquiries into FAA's certification program for the new Boeing 737 Max airplane and other potential weaknesses in the aviation safety system.[62]

III. What should be considered before conducting an RCA?

A. How should the scale of an RCA be determined?

Stakeholders should develop a shared understanding of when to conduct an in-depth, resource-intensive RCA. Developing robust and evidence-based criteria for scoping an RCA before an incident occurs is important for transparent decision-making regarding whether a food safety system failure requires a large-scale RCA or a more abbreviated analysis. Criteria can include triggers to help staff recognize more serious or complex incidents with high public health significance that require additional resources and expertise to investigate and control.

While there is broad consensus among food safety stakeholders regarding the importance of prevention, several factors can limit the feasibility and cost-effectiveness of a full-scale RCA. Examples include:

- Lack of sufficiently accurate and specific information about location, time, and product to pinpoint the contamination source.
- Too much time has lapsed since the incident and the investigation trail has grown cold.
- Competing priorities of perceived higher operational importance.
- Limitations in technical or financial resources available to conduct the investigation.
- Opportunity costs for the investigation team, and any other potential lost profits if the facility is forced to shut down to accommodate the investigation.

When an RCA is deemed necessary, investigators will need to adjust the intensity and scale of the analysis to meet the needs of the incident to conserve and appropriately deploy resources. Factors that should be considered when deciding how to scale the investigation include:[63]

- Strength of hypothesis.
- Magnitude of contamination.
- Severity of illnesses.
- Number of cases (local, statewide, or nationwide outbreak).
- Propensity of the outbreak to spread.
- Type of contamination (e.g., existence of a known, localized contamination source).
- Novelty of incident.
- Similar past incidents from the same food operation.
- Illnesses have/are occurring at high-risk establishments such as child care centers, nursing homes, prisons, schools, hospitals.
- Available resources (such as public health staff and laboratory capabilities).
- Availability of records, witnesses, and other evidence.
- Timeliness of investigation (time passed since the incident and amount of information lost).
- Level of public concern.
- Efforts made to manage event locally before escalation.
- Potential legal implications.
- Whether investigation will generate new knowledge and shareable information to improve food safety.
- Whether investigators will gain valuable experience.

Tools such as checklists can be useful for determining the appropriate scale of the investigation and can help avoid haphazard decision-making (consult resources from patient safety and occupational health[64]). For example, the International Association for Food Protection published key factors to consider in the investigation of outbreaks of foodborne diseases. These are organized in tables and can be used by investigation teams to identify and prioritize elements that likely led to contamination so that resources can be used wisely.[65] For instance, if a salmonellosis outbreak is initially linked to a cooked meat product, data from previous outbreaks suggest that a principal cause to investigate would be post-processing contamination from a worker in the facility.[66]

Factors Used by NTSB to Scale an Investigation

Following notification of a major aviation accident, the Office of Aviation Safety, in consultation with the safety board, makes the decision to dispatch a core investigation team, called the "go team." The composition of the go team is then determined, based on the potential scope of the investigation, the magnitude of the tasks, and other factors, including:

- Number of injuries or fatalities.
- Previous accidents of the same type.
- Location of the accident.
- Public interest.
- Specialist workloads.

Evaluation of initial evidence from the accident is also used to determine whether certain specialists are needed. A full investigation team may be composed of numerous specialists in different areas; for instance, air traffic control, operations, meteorology, human performance, power plants, or metallurgy. Other groups may be formed to interview witnesses or examine the response of aircraft rescue and firefighting personnel.[67]

B. Does your organization have sufficient capacity to perform an RCA or have plans and procedures in place for capacity development?

Ideally, the individuals who make up a root cause investigation team will have the opportunity to participate in appropriate training before the need to conduct an RCA arises. (See Appendix A for additional training resources.) Before initiating an investigation, assess the current capacity to conduct RCA for different types of food safety incidents and determine:[68]

- How many adequately trained and experienced staff are currently available to conduct basic, midlevel, and advanced RCAs.
- What RCA capacity should be developed given the business model, regulatory requirements, and stakeholder expectations.
- If resources can be dedicated to training staff to perform RCA or if outside consultants will be hired to perform the analysis.

Capacity to perform RCA can be built internally before any incidents by reviewing available staff and resources, identifying and training a multidisciplinary team that can be mobilized when needed, and identifying a team leader who has specialized training and experience (see Appendix A for training resources). Stakeholders can train front-line investigators in foundational principles, how to recognize indicators of when investigation scale-up is warranted, and how to make appropriate notifications to initiate the expansion when needed. Main steps in capacity development are to:[69]

- Develop plans and procedures.
- Identify the staff, equipment, and other resources necessary to perform RCA.
- Provide training to ensure designated staff have expertise and familiarity to function effectively as a team.

- Conduct exercises to evaluate capacities and build experience by partnering experienced staff with less experienced staff during investigations.
- Evaluate, identify, and track corrective actions. (See Section IV, subsection F, "What factors should be included in the design of a robust corrective or preventive action plan?" for further discussion.)

Figure 1
Core Steps of Capacity Development for RCA

Source: U.S. Department of Homeland Security, "Target Capabilities List: A Companion to the National Preparedness Guidelines" (2007), https://www.fema.gov/pdf/government/training/tcl.pdf.

Because multiple disciplines and entities may play roles in an RCA, clearly identifying the relative priority of various objectives and establishing targets for completion are important for creating a shared understanding of what is in and out of the scope of the investigation, and what expertise may be required. Core team members for a major investigation may include:

- Investigation lead.
- Communications lead.
- Liaison lead for coordination with key stakeholders.
- Trained regulatory investigator.
- Team manager/facilitator.
- Technical experts (multidisciplinary expertise—such as epidemiologists, toxicologists, microbiologists, water and sanitation experts, food scientists, or veterinarians).
- Process representative (company-specific production knowledge, quality assurance/quality control managers/technicians, maintenance technicians, or ingredient procurement).
- Others as needed (consumer/customer representative, additional stakeholders).

For a smaller-scale RCA, a facilitator along with a trained investigator or professionals in environmental health and epidemiology may suffice. Companies that do not have ready access to necessary technical experts should consider developing, as part of their scaling criteria, a set of procedures (see Section III, subsection A, "How should the scale of an RCA be determined?") so that access to relevant expertise can be obtained.

Basic Capacities for an RCA Investigator

The composition of team members along with their roles and responsibilities will differ across RCA teams in different contexts. However, investigators should have the following basic competencies:[70]

- **Evaluate and analyze data:** Ability to focus on multiple streams of evidence.
- **Critical thinking and problem-solving:** Ability to identify human factors, equipment issues, or problems in underlying systems that contributed to an incident.
- **Collaborate and build relationships:** Ability to gather evidence from individuals involved in the incident without placing blame.
- **Communicate effectively:** Ability to write and speak clearly to communicate complex causal relationships.
- **Be flexible:** Ability to adapt investigations for near misses or serious accidents to derive benefits gained from investigating a wider range of incidents.

RCA is data-driven, and core team members should be data-oriented with strong problem-solving skills. Some organizations may find new training programs necessary to develop relationship-building and interpersonal communication skills for productive RCAs. In the regulatory context, shifting focus from issuing citations for food safety incidents to building cooperative relationships between companies and public health officials was a successful strategy.[71]

Other multidisciplinary team members may be selected when appropriate. The NTSB (see "Factors Used by NTSB to Scale an Investigation," above) decides on the composition of the investigation team after notification of an accident. Additional experts may be selected based on the investigation scope and the magnitude of the tasks.

C. How long should the RCA take?

Expected length of the RCA depends on many factors, including priority and level of resources that will be dedicated. Initial assessment of the project timeline and periodic re-evaluation as the investigation progresses may be necessary to determine if projections are realistic. By setting expectations and objectives early, the investigation team can plan according to the amount of time allotted to conduct the analysis, based on available resources and schedules. However, enough time should be allowed to complete the investigation even if unexpected delays occur. Unavoidable delays should not stop the investigation team from releasing findings that may prevent incidents even before the root causes are identified.

RCAs should begin with the end in mind; identifying the root causes of the incident should always be an explicit investigation objective, even if an analysis cannot be completed because of lack of evidence, support, time, or competing priorities. Ideally, though, the investigation should be allowed to continue for as long as necessary to identify root causes and to share those findings.

NTSB Shares Findings During Investigations

In 1996, four years before the final investigation report on TWA Flight 800 was released, the NTSB distributed urgent safety recommendations once it determined that an explosion in the center wing fuel tank was the probable cause of the accident (a root cause identified later was a certification process that failed to identify the faults in a design concept that placed heat sources below the fuel tank). The early release of urgent safety information likely prevented accidents in other aircraft.[72]

IV. How is an RCA conducted?

A. What steps should be taken before performing an RCA?

Data gathering for RCA should begin as early as possible following the incident when critical evidence can be secured. The following steps are not part of the RCA but are important data-gathering steps that affect the quality of the analysis and are included here for awareness.[73]

1. **Remove contaminated product from the marketplace.[74]**

   When a foodborne outbreak or incident is initially detected, key information is often lacking regarding the food vehicle, source of contamination, contributing factors, and root causes. General control measures are typically used during the early phases of investigations to address the most apparent contributing factors that caused an incident. Actions may involve industry issuing recall notices or government announcements advising the public to destroy any contaminated product in the home after the pathogen or other contaminant is identified (note that this is different from understanding *how* and *why* the agent contaminated the food). Specific control measures can be implemented as investigators learn more about the sources, contributing factors, and root causes of the outbreak.

2. **Form the investigation team.[75]**

   It is often helpful to identify objective criteria that staff can use to determine what level of RCA is likely most appropriate—standard operating procedures or expanded investigations warranting notifications and approvals. After an initial evaluation of evidence to determine *what* happened, an investigation team with the appropriate expertise should evaluate the incident, identify the events leading up to the incident and the contributing factors, and ask *why* they happened. The team will determine the investigation approach and will devise a plan to carry out the RCA. In addition to conducting the actual investigation, the team should also assess whether the investigation requires any additional expertise[76] and build in time to report any findings.

Characteristics of Effective Root Cause Analyses

- Initiation of the investigation in a timely manner.
- Availability of appropriate technical expertise.
- Frequent communication with stakeholders.
- Comprehensive understanding of the incident and systematic evaluation of all possible causes.
- Evidence-based conclusions and recommendations.
- Unbiased and transparent analysis.
- Clear and concise reporting.

B. What are the steps for conducting an RCA?

Specific steps and procedures for conducting an RCA may vary depending on the organization; different methods may be chosen to identify root causes. General steps are provided below as an overview for those new to the issue, to help with planning and resource allocation, and to ensure a consistent approach.[77]

1. **Collect data and define the problem.**

   Describe the incident and collect as much information as possible about the incident and the events leading up to it to create an accurate picture. This step may also involve identification of persons at risk, the size and scope of the incident and its consequences, the mode of transmission and vehicle, the source of contamination using epidemiologic and laboratory data, and other data sources.[78]

2. **Assess information and develop a hypothesis.**

   Develop an initial hypothesis of what factor or factors ultimately led to the incident, with an understanding that this hypothesis may evolve over time. Then, identify the contributing factors to the incident. It is important to note that this is a preliminary hypothesis to guide the RCA. Even with it, the investigation should be able to proceed organically and be driven by the available data or evidence. Further control measures that help prevent additional illnesses may be implemented as needed at this phase of the investigation as stakeholders determine the potential for ongoing transmission.

3. **Categorize evidence.**

   Gather all available data and evidence and categorize them based on source, credibility, likelihood, or other relevant classifications. Categorize the contributing factors and determine which basic systems may have broken down and potentially caused the incident. This step may involve further data collection.

4. **Identify the root cause(s).**

   Identify the fundamental reason for the incident, carefully differentiating contributing factors from root causes, which, if corrected, should prevent recurrence of the incident. (See the following section for common tools used to organize and analyze data and evidence to determine root causes.)

5. **Define preventive/corrective control strategies.**

   These actions may include, for instance, updating operating procedures, enhancing monitoring systems, instituting a training program, or ensuring that regular safety checks are in place and regularly reviewed.

6. **Implement and validate a control plan.**

   Research the incident to find out if this type of food incident has occurred before within the current setting. Root cause analyses cannot proceed in a vacuum and must be informed by history to ensure that prior lessons learned are considered. If the problem recurs, it is necessary to return to step 1, redefine the problem, and collect more data.

7. **Review the process and develop a communication plan.**

   Identify lessons learned. Determine how such knowledge can be shared internally and, if appropriate, externally. Review the RCA process and evaluate whether it has the capacity to continuously improve the analysis process.

C. What tools are commonly used for conducting RCA?

Table 1

Summary of Select RCA Methods and Their Strengths and Limitations

Root cause analysis method	Objectives and when to use	Description	Strengths	Limitations
Brainstorming[79]	To gather ideas, potential contributing factors, and root causes. Use at the start of the investigation.	Think through all possible ideas or questions related to the incident to define the scope of the investigation. Can be structured or unstructured. Team members record their ideas on flip charts, index cards, or Post-it Notes that can be organized in a logical format later. Idea gathering should be unranked and inclusive.	Good for identifying potential causes and contributing factors and for team building.	May include biased or incorrect information. Not a data-gathering technique. Need to differentiate between opinions and observations.
Five Whys[80]	Simple, fast problem-solving method. Use in tandem with fishbone diagram or other causal diagramming techniques.	Ask "why" five times or as many times as necessary until the nature of the incident becomes clear. Construct a "why" tree.	Simple, straightforward tool, and an easy method to begin with.	Investigators may prematurely stop process at contributing factors.[81] This may happen because investigators cannot go beyond current knowledge or are using this initial phase as a stand-alone tool without conducting the necessary preliminary hypothesis phase. If several root causes exist, there may be a tendency to focus on one root cause. No validation for any answers to the "why" questions.

Continued on next page

Root cause analysis method	Objectives and when to use	Description	Strengths	Limitations
Fishbone or Ishikawa diagram[82]	To sort many possible causes into categories in a nonlinear fashion. Use throughout the investigation to organize data and evidence.	Fishbone diagrams, a type of cause-and-effect diagram, visually represent the various categories of factors or events that could have resulted in or contributed to the incident. Basic categories (and examples) of causes that should be considered: • Methods • Materials • Food • Measurement • Policies • Environment • Machines/Equipment • Processes • People • Management • Economics	Can be used to track and organize evidence for complex RCAs.	May be difficult to communicate the relationships between multiple factors in the diagram. Other types of cause-and-effect diagrams may be used to help elucidate more complex relationships.
KNOT chart[83]	Use to classify evidence and data items throughout the investigation.	A KNOT chart allows the investigation team to record all evidence and data collected during brainstorming, interviews, sampling, site visits, etc., and then categorize by: • **K**now: Available and credible data • **N**eed to know: Required data, but unavailable • **O**pinion: Possibly credible, but need more information to support opinion • **T**hink we know: Possibly credible, but need to verify data A column is included in the chart to record required action items to verify claims or certain data sources (e.g., with interviews).	Useful for driving decision-making during the investigation.	Attempting to verify all data may be daunting or time-consuming, but this should not deter investigators from gathering enough information to verify or exclude potential causes.
Fault tree analysis[84]	Allows investigators to follow events leading to the incident. Typically performed as part of hazard analysis (before an incident) to identify risks and probabilities of occurrence.	A deductive procedure that begins with the conclusion and builds potential causes using a fault tree (a type of cause-and-effect diagram). Events are categorized as the Incident (at top of the tree), Intermediate, Basic, and Undeveloped events. Events are connected with AND or OR "gates." AND/OR gates indicate if multiple events simultaneously are causes or if at least one of the events may be a cause.	Aids in logical understanding of events leading to the incident.	Requires a detailed knowledge of production process.

D. How do you know when you have identified the root cause or causes?

When conducting an RCA, it is important to acknowledge that there typically is no single cause. Often, a combination of several root causes resulted in the event. In these cases, it may be difficult to identify all root causes and to be sure when all have been identified. However, a systematic, data-driven investigative approach may increase the likelihood that all root causes are recognized.

To determine whether the root causes have been successfully identified, take the following steps:

- Validate if any of the identified factors had an impact on the incident being investigated using facts and data (hypothesis testing/further data analysis).
- Review what is known about incidents involving the agent and foods involved in previous incidents.
    - Create a short summary of the typical food vehicles, contributing factors, and categories of root causes.
    - Consider the range and relative likelihood of various root causes identified in the past using existing tools and documents, remembering that understanding of foodborne illness is continually growing.
    - Create a checklist, which can help ensure that all relevant factors are being considered.
- Systematically evaluate each possible root cause (see fishbone diagram description in Table 1). Once the investigation has gone back as far as possible and all hypotheses have been exhausted, there can be some confidence that the relevant root causes have been found.
    - A logic model approach (see fault tree analysis in Table 1) can help to ensure that all potential root causes have been identified.
    - This evaluation should include identifying any "people issues" (such as behavior, training, supervision).

People-related issues are frequently found to be root causes when a full RCA is conducted. The investigation team should be cautious, however, in biasing investigations toward staff nonconformities over process issues as this may discourage staff from participating in the RCA. Nonetheless, investigations may be incomplete until people-related issues have been at least considered or identified.

It is also important to have a firm understanding of whether the incident was the result of a previously identified root cause or the result of a novel one. This understanding will allow appropriate planning for changes to the food safety system to prevent recurrences. Consider and plan for changes in the short, medium, and long terms. (In other words, how will this affect operations in 48 hours, one month, and six months?)

Divers Alert Network Uses Multiple Evidence Sources to Find Root Causes

To determine the root causes of recreational diving accidents, investigators draw upon all available information to determine in a data-driven way what went wrong and why. As one example, eyewitness accounts, equipment performance data, medical records, and other relevant information (e.g., training and experience of those involved, and diving conditions at the time of the accident) allowed investigators to determine the root causes of a fatal night dive.[85] The diver had become entangled in kelp and ultimately drowned. His air tank was full and functional although the diver was recovered with the regulator (i.e., the mouthpiece of the breathing apparatus) out of his mouth. Interviews with other divers present during the incident established that the deceased lacked adequate training and experience, became separated from other divers, was entrapped in kelp, and lacked a knife to cut himself free. Ultimately, investigators concluded that the combination of these conditions caused the decedent diver to panic, make an irrational decision, and drown. The root causes were a lack of appropriate training and certification, and related lack of knowledge of basic diver safety techniques including the buddy system to avoid separation from other divers.

E. When has the investigation gone far enough? What if root cause(s) cannot be identified?

When should an investigation be concluded?

A transparent process for determining and documenting when and why to stop an RCA should be established by every organization engaging in an RCA. Clarifying a stopping point at the outset of an investigation can secure buy-in from leadership as well as from other stakeholders, and can help preserve time and resources. This can be done by developing a checklist or toolkit in advance that, for example, lists the information that needs to be collected through the investigation.

If the information or evidence important to the investigation cannot be collected, stakeholders may see this as an endpoint to the RCA. However, this could result in concluding an investigation before factors that are key to preventing incident recurrence have been identified. The investigation should be continued if there is a sense that valuable information can still be learned. Determining the most appropriate time to end an investigation may depend on:

- The likelihood of success.
- The opportunity costs (in other words, resource diversion from other issues to conduct the RCA).
- If relevant information remains to be gathered.
- The ability to cooperate with partners (such as suppliers) and to generate or collect information.
- If data have been collected that support the hypothesis but are not sufficient to reach a conclusion.
- Availability of sufficient time and resources to ensure findings are communicated to key stakeholders.

Is there value in conducting an RCA if no root cause is identified?

RCAs are often not fully successful. Some reasons why root causes may not be found include:

- Looking in the wrong location or time period.
- Too much time elapsed since the problem has occurred.
- Lacking resources to conduct a proper investigation.
- Inadequate preparation for the investigation.
- Investigation team lacks appropriate training or expertise.
- Limited lab support.
- Ending the RCA prematurely.
- Fear of embarrassment, legal concerns, or other issues that may be caused by releasing the findings.
- Too many possible root causes or the uncertainty is so high that it is nearly impossible to determine causality.
- Lack of management support or employee engagement in the process.
- Fear of blame.

These challenges do not mean that an investigation should not have been conducted. Thorough investigations invariably identify points along the system that can be improved; therefore, every investigation should ultimately be viewed as a valuable learning opportunity, even those that fail to identify the root cause. An RCA can reveal where food safety systems failed and where corrective actions should be taken. To this end, manage expectations and recognize that a root cause may never be identified—but an RCA may find food safety risks that could have contributed to the event under investigation, as well as risks that may not be directly related to the event. These efforts can ultimately improve the food safety system.

If the RCA fails to find the root cause, an evaluation of the investigation techniques might be warranted. This exercise is useful for identifying learning opportunities and how the investigation process can be improved moving forward. Questions to ask when evaluating the investigatory method include:

- Why was a root cause not identified?
- Have all the investigated root causes been eliminated based on the data? Or, do you have sufficient data to rule out any hypotheses?
- Did timing (such as the length of time between the event and the start of the investigation) play a role? Is there value in developing approaches to reduce the delay between the event and the start of the investigation?
- Are there recurring patterns or themes? Are these documented in the reporting?
- Do investigators have an incentive to properly conduct the RCA?

F. What factors should be included in the design of a robust corrective or preventive action plan?

It is helpful to think of corrective actions as a nested series of measures with different time horizons:

- Short-term—immediate controls for current outbreak.
- Medium-term—changing or institutionalizing controls in highest-risk facilities.
- Long-term—changing industry practices to reduce risks.

A comprehensive corrective action plan will not only address the specific root causes of the incident but should also include corrective actions drawn from lessons learned from other outbreaks and incidents in other facilities.[86] Corrective measures can and should be anchored within an organization's existing continuous quality improvement program (examples include Six Sigma, International Organization for Standardization, Program Standards).[87]

The design of appropriate action plans may be complicated by the food product type, contamination source, impact of cross-contamination, and consumer behavior. For instance, corrective actions for scenarios in which consumer handling contributed to the outbreak may include creating separate processing streams: one for product intended for home use (where consumers are more likely to eat it raw or cross-contaminate surfaces and other foods) and another for use in commercial operations where further processing will convert it into a cooked product.[88]

In situations where no specific brand can be identified and the root cause is therefore not clear, messaging to retailers and consumers can still play an important role in mitigating risk. For example, in a *Listeria* outbreak linked to retail deli products, advice to retailers may include instructions on how to properly clean deli slicers and reduce the risk of cross-contamination on other surfaces as these have been identified as important contributing factors in other outbreaks. Consumer messaging may include advice to thoroughly cook the implicated food items to 165 degrees Fahrenheit.

To address the unique challenges associated with fresh produce and other food items with a short shelf life, companies may need to implement systems to continuously assess farm-level preventive measures, evaluate food safety control measures in all production stages, and change labeling on food packaging to emphasize safe food handling practices.

Corrective action plans for food safety RCAs in which specific root causes have not been identified (whether the complicating factor is cross-contamination in a retail environment, short shelf life, or other reasons) may need to be broad in scope and draw upon learnings from previous outbreaks but can still be in the best interest of the business to prevent future losses.[89]

After a corrective action plan has been implemented, it is essential to verify and validate that corrective actions remain in place and are effective.[90] This can be done by developing a monitoring system to include, for instance, periodic sampling and active managerial controls. If a food manufacturer does not have a HACCP plan, it may be necessary to develop and implement one.[91] However, if a HACCP or other type of preventive control plan is already in place, it may need updates to include steps that allow monitoring of the food safety system to pinpoint when and where a breakdown has occurred. If RCAs repeatedly point to the same causes and contributing factors, then no monitoring has taken place, or the monitoring program is not capturing a significant part of the system, and nothing is being corrected.

An opportunity for improved prevention is identifying cost-effective control measures that can feasibly be implemented across the food industry. The following options can be considered to strengthen an organization's food safety practices:

- Assess how the incident reflects the organizational culture that allowed it to occur.[92]
- Clarify and improve guidance for relevant food processes.
- Revise standardized training, supervision, mentoring, and feedback.
- Share lessons learned more broadly within the organization in a visually engaging manner to capture the attention of a diverse audience.

V. How should findings from an RCA be communicated?

Organizations should plan to release a report that outlines three to four key findings that can be disseminated not only internally, but also to outside stakeholders. Similar to FDA's strategy of posting environmental assessments of foodborne illness outbreaks,[93] a dedicated RCA webpage can be created that lists the results of all or a selected number of RCAs that have been performed. Notifications may also be set up through a subscription service when changes are made or more information is added to the webpage. Industry partners, government, consumers, and other stakeholders can subscribe to this page and circulate the page to other interested parties. RCA findings may also be released in academic and trade journals, through industry and advocacy groups, and by using social media to share lessons learned.

A. How can RCA findings be used to help others outside your organization?

RCA findings can be used in multiple ways to share lessons learned. The following options are adapted from the Council to Improve Foodborne Outbreak Response Guidelines, which provide recommended control measures to be taken after a foodborne outbreak:[94]

- Need for further research. RCA findings might indicate the need for future research and can be shared with academic institutions or industry associations.
- Publication or other report sharing. RCA reports from unusual outbreaks or incidents (for instance, unusual exposure, presence of a pathogen in a food where it had not previously been reported, or magnitude of the outbreak) should be considered for publication or sharing through industry, academic, or government networks.
- Education and training. An RCA can identify the need for broad education of the public, food industry employees, food safety regulators, or health care providers.
- Policy action. Information gained through an RCA is used to identify the need for new public health or regulatory policy at the local, state, or federal level.

Information from RCAs can also be shared and integrated within existing practices through:

- After-action reviews, which are used to improve investigative information and data-gathering processes, by identifying strengths to propagate successful practices and to address weaknesses to avoid missed opportunities.[95]
- Outbreak reports or summaries, which document and share key factual details about the incident, including the food vehicle, agent, source, contributing factors, and root causes.

Sharing the root causes of outbreaks, food contamination events, and system failures allows a broad range of food safety stakeholders—agencies, food industries, academic institutions, and consumers—to coordinate work within their respective spheres of influence to strengthen food safety systems worldwide.

VI. Conclusions and next steps

Routine application of RCA principles and sharing of lessons learned can help improve food safety and prevent foodborne illnesses. This guide provides an overview of steps, approaches, and rationales for planning and conducting RCAs to encourage and harmonize their use in food operations and by food safety regulators. Using this guide as a template or reference, stakeholders can develop mission-relevant plans and procedures for conducting RCAs. For organizations that do not have plans and procedures in place for RCAs, dedicated funds should be made available now, to the extent possible, to cover expected expenses including potential consulting fees. In addition, funding should be provided for activities to prepare for future investigations, including staff training and IT infrastructure development, as well as investments in other processes and tools.

Communication is a critical next step for further development and implementation of food safety RCAs. Different food safety stakeholders and investigators need more tailored tools, training materials, and mechanisms and platforms to share relevant lessons learned. To this end, development of a confidential, nonpunitive reporting system, similar to the Aviation Safety Reporting System or the VA Patient Safety Information System, is an important next step. Additional steps can be designed by monitoring the use of this guide and gathering experiences among users to develop more targeted RCA tools. Likewise, additional research into the cost-effectiveness of RCAs in the food space could help justify the expenditure of time and resources along with the associated opportunity costs of conducting an RCA.

Food safety culture is created and maintained more readily in organizations that adopt RCA approaches and provide RCA tools to their staff. This guide has highlighted where organizational culture contributes to incidents and to the success or failure of the investigation. A root cause culture emphasizes inquiry and insights over enforcement and punishment, and encourages collaboration across stakeholders so that investigations do not stop at violations. This ensures organizations and individuals have sufficient support in conducting RCAs, and lessons learned are used to improve operations and shared with relevant stakeholders. When aggregated, root causes identified across multiple investigations can provide valuable insights into strengths and weaknesses of the food safety system. Such analyses can also provide a data-driven prioritization of improvements and may serve as a powerful justification for needed but potentially difficult to implement changes.

Appendix A: Additional resources

Click on any resource's name below to access it online.

Training and other resources for food safety professionals

- **CDC e-Learning Environmental Assessment Training Series (EATS)**
- **Food Standards Agency Root Cause Analysis Course**
- **FDA Environmental Assessments**
- **Association of Public Health Laboratories Root Cause Analysis Quick Learning Module**
- **HACCP Mentor Training** includes courses on developing preventive controls.
- **ASQ Root Cause Analysis** offers a three-day, 20-hour, in-person training course. Held throughout the country or can be brought to an organization with some customization. Cost: up to $1,599 per person.
- **Colorado Integrated Food Safety Center of Excellence Training**
- **Minnesota Department of Health Root Cause Analysis Toolkit**

Training resources available from other industries

- The **OSHA Training Institute** provides training for federal and state compliance officers, as well as state consultants, other federal agency personnel, and the private sector (e.g., Safety and Health for Grain Handling Operations, Machinery and Machine Guarding Standards).
- The **NTSB Training Center** is the primary training facility for NTSB staff. Courses are offered that are applicable to other fields and may be useful for food safety professionals (e.g., Investigating Human Fatigue Factors, Accident Site Photography).
- The **International Air Transport Association** offers a five-day, 40-hour, in-person training course that includes material on aviation-specific RCA requirements and is open to any professional with operational safety management experience. The association also provides training programs customized for and delivered at individual businesses.

Guidance from various sources for reference

- U.S. Food and Drug Administration Rapid Response Teams (RRT), **The RRT Best Practices Manual: Key Components of Effective Rapid Response for Food and Feed Emergencies**
- U.S Department of Energy, **Root Cause Analysis Guidance Document**
- Human Services Research Institute for the Centers for Medicare & Medicaid Services, **Root Cause Analysis: A Summary of Root Cause Analysis and Its Use in State Developmental Disabilities Agencies**
- International Association for Food Protection, **Procedures to Investigate Foodborne Illness, Procedure Keys**
- U.S. Department of Homeland Security, **Target Capabilities List: A Companion to the National Preparedness Guidelines**
- U.S. Food and Drug Administration, **Guide to Produce Farm Investigations**
- Council to Improve Foodborne Outbreak Response, **Guidelines for Foodborne Disease Outbreak Response**
- National Transportation Safety Board, **Aviation Investigation Manual: Major Team Investigations**

- World Health Organization, **Foodborne Disease Outbreaks: Guidelines for Investigation and Control**
- U.S. Space Program Mission Assurance Improvement Workshop, **Root Cause Investigation Best Practices Guide**
- Centers for Medicare & Medicaid Services, **Quality Assurance & Performance Improvement, How to Use the Fishbone Tool for Root Cause Analysis**
- National Patient Safety Foundation, **RCA2: Improving Root Cause Analyses and Actions to Prevent Harm**

Appendix B: Glossary of terms

Contributing factors: The physical, biological, behavioral, or attitudinal factors that directly or indirectly resulted in an outbreak or food-contamination event, or other incident.[96]

Environmental antecedents: See definition of root causes.

Environmental assessment: An in-depth, retrospective, multidisciplinary, systems-based approach to determining how contamination may have occurred and proliferated so it can be prevented in the future.[97] See also definition for root cause analysis.

Failures: Any breakdowns in the food safety system that prevent the interventions designed to control known or anticipated foodborne illness risks from functioning properly.

Incident: Any deviation from the normal processes in a food system that result in food contamination, unacceptable food-quality issues, or a foodborne illness outbreak.

Food safety culture: How and what the employees in a company or organization think about food safety, and the food safety behaviors that they routinely practice and demonstrate.[98]

Food safety system: The policies, practices, and standard operating procedures that a company uses to produce safe and high-quality food to prevent quality issues, food contamination, and foodborne illness outbreaks.

Near miss: See definition for process-control event.

Process-control event: An unplanned event or chain of events that is the consequence of a deviation from a safety plan, that could have potentially, but did not, result in illness or injury.[99] Also called a near miss.

Root causes: The underlying reasons—related to the people, equipment, food process, food type, economics, and such—that resulted in the system breakdown. A root cause is causally related to the event; if the root cause had not occurred, the event would not have occurred or would have been of significantly lower impact. Also called environmental antecedents.[100]

Root cause analysis: A retrospective investigative tool used to identify who, what, where, when, why, and how a problem or noncompliance occurred, in order to determine the underlying reason or reasons that caused the problem and what actions can be done to eliminate the problem, prevent recurrence, and reduce risk.[101] Also called an environmental assessment.

Stakeholders: Any entity with a vested interest in food safety. Includes food industry; federal, state, or local agencies with regulatory oversight over food; public health agencies; trade or professional associations; academia; or private consulting companies. Food industry may include food manufacturing facilities, farms, restaurants, caterers, or any other business that grows, handles, processes, distributes, prepares, or serves food.

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