Supplementing Hazard Analysis and Critical Control Point with Root Cause Analysis

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SUMMARY

Root cause analysis (RCA) pertains to causal inference science. Simplified methods aid in uncovering root causes and solving issues. This review was conducted to explore core RCA methods, identify components beneficial to hazard analysis and critical control point (HACCP) systems, and assess publications proposing supplementing HACCP with failure mode and effects analysis (FMEA). RCA methods differ in their approaches to defining factors and uncovering causal chains. A general RCA model was used to illustrate commonalities. An understanding of causal mechanisms aids in identifying root causes. Root causes also can be found at failures in detection and system performance. Ishikawa categories of causes were used to organize information, potentially aiding in managing prerequisite programs and corrective actions. Criticality analysis, a key FMEA element, enhances hazard analysis. Ishikawa categories such as work elements can help identify causes and establish more effective controls. Aligning contributing factors from environmental assessment with work elements further enhances HACCP, simplifying epidemiological data integration. Utilizing principles of FMEA and special causes of variation can potentially improve the management of critical control points.

INTRODUCTION

Scientifically, cause and effect analysis is based on the analysis of causal relationships, which serve as the foundation for determining causal inference *(30, 33, 50)*. These relationships are established during the investigation of events and causal factors *(39)* and the study of causal loop systems *(29)*. Causal thinking and the logical structures that result from it can be refined using well-known rules, such as those of Boolean logic utilized in fault trees *(17)*, the categories of legitimate reservation used in the theory of constraints *(38)*, or sets of causation criteria used in epidemiology or the social sciences *(20, 32)*.

Causal thinking can be complemented with other types of thinking. Systems thinking facilitates the analysis of system complexity, identification of intervention points, and evaluation of systems *(40)*. Structured thinking aids in problem breakdown and analysis *(53, 74)*, and statistical thinking assists in identifying sources of variation and enhancing the predictability of process outcomes *(23)*. Principles of systems thinking have been valuable for conducting environmental assessments (EAs) because they aid in understanding the factors influencing the system, the set points or outputs, and the system's complexity and stability *(31, 59)*.

Root cause analysis (RCA) is a problem-solving technique applied to determine the causes of a problem. In food safety management, RCA is used to address compliance issues, manage processes, and investigate outbreaks *(21, 43, 57, 66)*. RCA can be applied reactively to identify the causes of past problems or proactively to address issues during planning *(17)*.

The hazard analysis and critical control points (HACCP) system forms the basis of most food safety management systems, serving as a framework for managing food safety knowledge *(10, 69)*. However, difficulties have been noted with certain components of this system, particularly hazard analysis (HA) *(36, 54, 73)*. Observed deficiencies include the accurate assessment of risk, limited food safety knowledge among users, and errors in analysis execution *(36, 73)*. Some authors have proposed supplementing HACCP with failure mode and effects analysis (FMEA) *(43, 54, 71)*.

The objective of this literature review was to explore the fundamentals of existing RCA methods to determine universal principles and identify components that can enhance the HACCP method. Published studies in which RCA methods were applied to improve HACCP were analyzed to identify appropriate applications of RCA tools with HACCP.

MATERIALS AND METHODS

Most types of publications (books, theses, scientific articles, and periodicals) were researched to identify the most advanced methods for conducting RCA. RCA methods were considered advanced when they offered a unique approach to uncovering root causes.

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TABLE 1. RCA methods and its components

RCA method	Name for effects	Category of causes included	Name for factors	Name for root causes	Reference(s)
Ishikawa	Problem, characteristic (one)	Determined by user (six for processes)	Causes	Not necessary	*47*
Apollo	Effect	Opposed to categorization	Conditions and actions (at least one of each)	Do not exist; defined as the cause where the most effective solution can be applied	*46*
Current reality	Undesirable effects (conditions), core problem	No	Preconditions, effects; intermediate effects, constraints	Root causes	*3, 6*
Fault trees	Fault (undesired event)	No	Failures (intermediate events)	Basic events	*5, 49*
Events and causal (contributing) factors	Accident	No	Causal (contributing) factors (events, conditions, actions)	Root causes	*2, 48, 52*
FMEA	Loss of function	Yes	Failure modes	Causes	*5, 44*

Ten scientific articles were selected to determine the use of RCA as a complement to HACCP *(1–4, 6, 7, 47, 48, 58, 70)*. Articles related to food by-products were not considered *(64)*. The selected articles were compared based on their approach to supplementing HA and facilitating the management of critical control points (CCPs).

RESULTS AND DISCUSSION

RCA basics

RCA can be conducted using a variety of methods and techniques, but only a few of them have clearly defined features that make them different. Comparison of these methods was facilitated by identifying how each component of the method was used.

RCA types

The types of RCA can be divided into two major groups: those that use matrices (lists) and those that use graphics (trees) *(Table 1)*. Matrix types include the "is/is not," "five-whys," "cause effect matrices," and FMEAs *(24, 35, 43, 46)*. Graphic RCA methods include Ishikawa, Apollo, fault, current reality, and events and causal factors analysis *(21, 35, 46, 55, 56)*.

The matrix-type RCAs can be expanded to consider additional factors such as "Is not?" "Why not?" and "How?" *(24)*. FMEA may be the most well-developed RCA method in the tables category because it includes elements of a causal chain *(9)*. Graphics help visualize causal relationships between conditions and actions. Some graphic-type RCAs follow a defined type of logic. For example, Boolean logic (true or false) is used in fault trees *(17)*, and necessity logic (in order to we must) is used in current reality trees *(39)*.

The most notable difference noticed among the RCA methods was that the Ishikawa method utilizes categorical thinking, whereas the Apollo method opposes it, arguing that it limits the thinking to a predefined structure *(27, 74)*. The proposer of the Apollo method does not agree with the existence of a root cause *(27)*. Another difference is that the fault tree is built on events rather than on actions and conditions. Some FMEAs are created considering the mechanisms of failure, which complements the idea of a causal chain.

Specialized forms of RCA were also found. The most applicable to food safety management is called EA. EAs are used to investigate foodborne outbreaks *(18)*, and they are also called environmental investigations or environmental

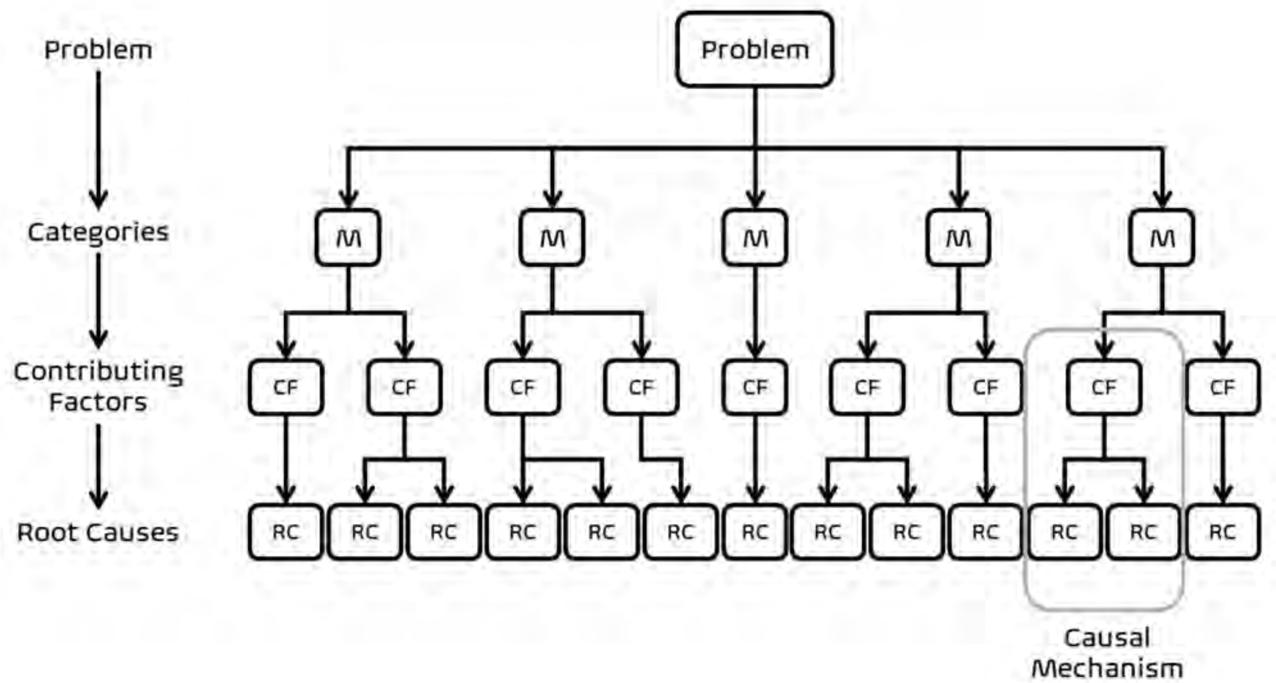

FIGURE 1. General root cause analysis diagram.

(and food) investigations *(77)*. These methods are similar to events and causal factors analysis *(15, 16)*. Some differences from other methods are that root causes are called environmental antecedents, and the analysis is conducted from an epidemiological perspective. The EA method has served as a base to create matrices that facilitate relating foods and pathogens to the most likely factors of microbial and chemical hazards *(62)*.

RCA components

Most RCA methods analyzed are built on the concept of the causal chain. Components of most RCA methods include the problem (or effect), causes (or factors) at different levels, and root causes *(Fig. 1)*. Almost all methods agree that a clear definition of the problem is key to completing an RCA *(21, 56)*. The definition of the problem can also determine the extent of the RCA. The root cause of a problem detected at the operations level may be more easily identified than a problem detected at the consumer level.

Categories

Categorical thinking is used in the Ishikawa approach to conduct RCA *(34)*. The number and type of categories of causes depend on the analyst. Kaoru Ishikawa initially proposed four categories and later expanded the number to six *(74)*. Some Ishikawa categories are also utilized in process FMEA analysis in the form of work elements and noise factors *(9, 17)*. Categories of causes or variables are also utilized to identify sources of variation. Process variation can be attributed to categories such as materials, machines, humans, environment, methods, and measurements *(23)*.

Some categories used in Ishikawa diagrams can be related to the internal system variables utilized in EA when they are considered sources of variation *(19, 59)*. EAs typically consider five categories of variables: food, equipment, people, processes, and economics *(31, 59)*. These categories can be practically useful when analyzing closed systems. However, most systems are not closed *(11)*, and the environment can induce changes even in the sturdiest construction materials.

The definition of work elements was derived from Ishikawa categories *(9, 37)*. Work elements encompass materials, machines, humans, and the environment *(Fig. 2)*. Work elements are the most fundamental categories of causes and do not include the methods and measurement categories. The four basic categories can be correlated with five of the six categories listed in the RCA model proposed by the Food Standards Agency and Food Standards Scotland *(26)*. Their model includes three categories: equipment (pieces and devices), plant (vessels and ovens), and environment (lighting and natural disasters) *(26)*. The four work elements can be used interchangeably to identify the location (where) and cause (why) of the problem *(Fig. 2)*.

These four Ishikawa categories considered in the work elements also may be more fundamental than the methods and measurements categories because these two categories could be related to some form of human intervention.

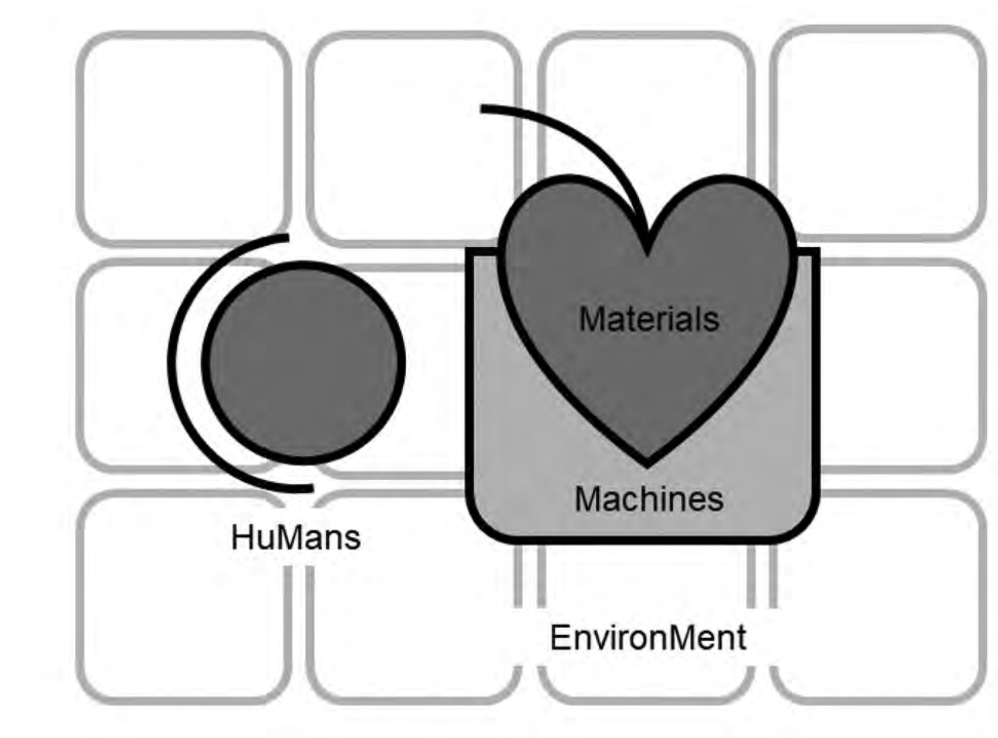

FIGURE 2. Ishikawa work elements.

Because humans make measurements or create, implement, or verify methods *(42)*, most of the errors could be attributed to humans. Human errors can be classified as failures of intention or execution *(42)*.

Factors

The linear continuum of causes has been referred to as the causal chain in certain RCA methods *(27)*. In the context of FMEA, this chain is a failure chain, established from the relationship between the effect, failure mode, failure mechanism, and cause *(9, 17)*.

Most RCAs utilize top-down discovery elements such as the why questions, the pairing of passive (conditions) and active (actions) causes, and the relationship between undesirable effects (symptoms) and preconditions and actions *(27, 35, 78)*. These discovery elements can be used interchangeably in larger RCAs *(78)*.

Causes are termed variables, and causes that are not root causes are termed factors. The term causative factor (or contributory or contributing factor) describes intermediary causes *(21)*. Contributing factors to food safety events have been examined to generate more comprehensive reports of outbreaks and integrate the results into prevention strategies *(12–14, 28, 60, 63, 75, 77)*. Reports of foodborne outbreak investigations typically include an enumeration of the factors contributing to the events *(67)*.

Root causes

Most authors agree that controlling or eliminating the root cause is the goal of conducting an RCA. The definitions of root cause vary depending on the context of its application and use. Philosophically, any chain of causation can be extended to infinity, but for practical purposes the analysis should cease when a leverage point (something of low cost and high return) is identified within the span of control *(35)*. Some authors have suggested that the root cause should be the cause for which an effective solution can be implemented *(27)*. Others have proposed that a root cause should be linked to the absence of a best practice or failure to implement knowledge *(49)*. At least two authors defined root cause as either a condition (latent failure) or an action (active failure) *(27, 42)*.

In FMEA, the root cause is the manufacturing deficiency or source of variation that results in the failure mode *(17)*. Root causes in process in the context of FMEA are defined in terms of process characteristics (variables and parameters) and should consider the mechanisms under which the failure occurs *(17)*. Failure mechanisms are useful for explaining the failure mode and require an understanding of events and root causes *(17)*.

Root causes are not necessarily found by drilling down to technical details. Automotive problem-solving guidelines include three types of root causes: occurrence (technical cause or why did the problem occur), escape (detection cause or why did the problem reach the next operation),

TABLE 2. Prerequisite programs organized into categories (work elements)

Category	Codex Program
Materials	13. Control of operation (materials, packaging, products)
	14. Product information and consumer awareness
Machines	9. Establishment (equipment)
	11. Establishment (cleaning)
Humans	10. Training and competence
	12. Personal hygiene
Environment	8. Primary production
	9. Establishment: design of facilities and equipment
	11. Establishment maintenance, cleaning and disinfection, pest control
	15. Transportation
Methods and measurements	11. Establishment maintenance (monitoring effectiveness)
	13. Control of operation (verification, controls, records)
	14. Product information and consumer awareness (education)

and systemic (why did the plan fail to identify the cause and detect the failure) *(8)*. This type of scrutiny agrees with the idea of using the "Swiss cheese" concept to identify failures when controls have already been implemented. Failures could occur even when three layers of control have been implemented: prerequisite programs (PRPs), HACCP, and verification *(42)*. Some experts have suggested that up to 80% of serious events are related to human performance, with a significant portion of these errors due to the organizational system *(46)*.

Root causes are challenging to identify in large outbreak investigations. Reviews of foodborne outbreak data have revealed that most investigations have not uncovered the root causes *(41, 60)*. Identification of the contributing factors or causal mechanisms can also be useful in cases where a root cause cannot be identified *(Fig. 1)*.

HACCP PRPs and RCA

Food safety management systems based on HACCP require the implementation of good manufacturing practices (GMP) or good hygienic practices (GHP) before establishing an HACCP system *(10, 25, 44)*. GHPs aim to provide "conditions and activities that support producing safe food at all stages" *(25)*. GMPs and GHPs are also referred to as PRPs in European Union guidelines *(22)*. PRPs can be found in most HACCP guidelines and standards. They have evolved from simple operational requirements to specialized programs such as allergen control and consumer awareness programs *(10, 25, 44)*.

Practices or programs answer the question of "how" and are intended to prevent causes or "why." Based on this idea, the principle of categorization used in RCA could be applied to improve PRPs. Categorization could be applied to programs or individual practices. *Table 2* illustrates the idea of categorizing the GHPs listed in the most recent Codex guidelines *(25)*. The logic used to organize programs differs from the logic used to analyze work elements. A categorical perspective helps reveal that current practices do not differentiate between equipment and the environment and pay little attention to food materials. Use of the categorization principle can also help small operations reduce the number of programs to a reasonable few.

HACCP HA and RCA

HA is the first principle and the heart of the HACCP method. Conducting an HA requires specialized knowledge and science to assess hazards and prioritize the use of controls *(36)*. HA includes two stages: identification and evaluation of hazards *(10, 44)*. According to most guidelines, each significant hazard should be evaluated based on its severity and likelihood of occurrence in the evaluation stage, and a control measure should be applied to the most important hazards in a subsequent stage *(10, 44)*. The identification of two risk factors (severity and occurrence) has led to the use of qualitative ranking tools to prioritize the control of food safety hazards *(10)*.

HA and FMEA

Several researchers have noted that HA is the most important element of HACCP and the most misunderstood *(36, 54, 73)*. Manyf authors have chosen to apply the criticality element of FMEA to facilitate risk prioritization

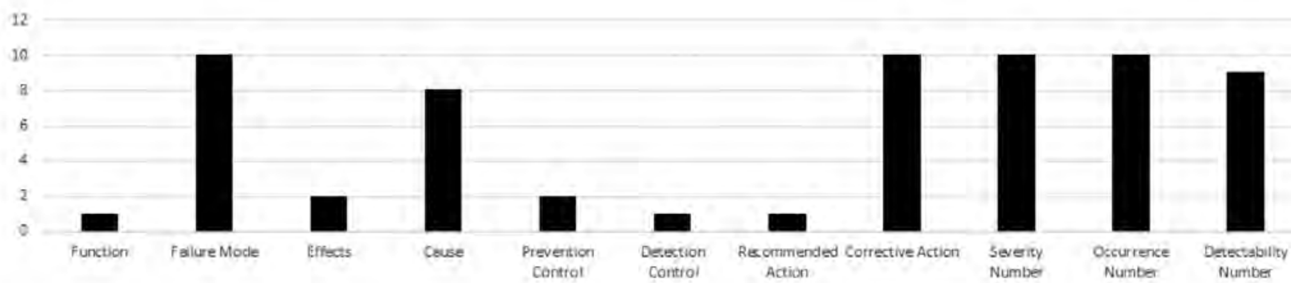

FIGURE 3. Elements of failure mode and effects analysis considered complements of hazard analysis.

(1–4, 47, 48, 70). FMEA is considered superior to traditional HA tables because it provides structure, facilitates risk assessment, and considers the probabilities of detection *(54)*.

However, some adjustments have been made to the FMEA procedure to use it in HA. In all of the articles analyzed here, the authors considered the failure mode as the occurrence of food safety hazards, and a significant number listed the cause of food safety hazards in the analysis *(Fig. 3)*. Fewer articles included the function, effects, controls, or recommended actions *(Fig. 3)*. However, almost all authors listed the corrective actions and risk priority numbers in their analysis *(Fig. 3)*. Thus, direct statement of the causes of food safety hazards has been considered important by most authors, and RCA principles could be used for the improvement of HACCP. In all the articles analyzed, the focus on FMEA elements has been on criticality analysis. Criticality helps prioritize the management of hazards based on risk assessment, but it should not be used it to determine CCPs because they are selected based on a different criterion *(25, 44, 61)*.

HA and work elements

The activity of pairing steps with hazards during the HA can also be improved by considering the work elements or Ishikawa categories *(Fig. 4)*, which requires previously identifying the work elements during the preparation of the flow chart. Identification of the work element of the step where the food safety hazard occurs can provide more precision for the analysis and facilitate the selection of more effective controls.

HA and contributing factors

The idea of utilizing data generated from outbreak reports to improve HACCP was envisioned in the early years of studying contributing factors *(75)*. At that time, grouping of epidemiological data by contributing factors was thought to be useful in HA. Initial work on the study of contributing factors to microbial and chemical outbreaks aimed to improve the risk assessment element of HACCP *(75)*. Recent updates of the EA procedures include a set of matrices called the International Association for Food Protection keys *(62)*. These tables list 44 contributing factors associated with three stages of production and are available for six groups of food materials *(62)*.

Classification of contributing factors based on the Ishikawa categories can also facilitate this task. An attempt to classify these factors them was made for this review, which revealed that no contributory factors were associated with machines and only a few times were these factors related to humans *(Table 3)*. Most of the contributory factors could be placed in the environment and methods categories at first sight *(Table 3)*. However, a deeper analysis of the problem of following inadequate procedures may relate the issue to some type of human factor.

HA and PRPs

Several food researchers have also considered following the ISO 22000 standard approach to HA instead of HACCP guidelines because the standard approach can provide a better HA *(4, 5, 7, 70–72)*. ISO 22000 calls for the creation of three types of controls that can be used in HACCP plans: PRPs, operational PRPs (OPRPs), and CCPs *(71)*. The concepts of OPRP and PRP are now listed in European guidelines *(22)*. OPRPs are required to have measurable or observable criteria and recorded corrections when control is lost *(22)*. The level of control of OPRPs is lower than that of CCPs, which are required to have measurable critical limits, preset corrections on the product, and possible corrective actions on the process *(22)*. The control of CCPs is required to be more effective than the control of OPRPs, and the control of PRPs is the least effective *(Fig. 5)*. The ability to compare control measures based on effectiveness can also contribute to a better HA because enhanced controls can be applied to the most severe and frequently occurring hazards *(Fig. 5)*.

HACCP CCPs and RCA

The most important controls of a HACCP system are the CCPs. These control points are deemed critical because they represent the final step in the production flow, where controls

TABLE 3. Environmental assessments, contributing factors, and work elements

Factors	Materials	Machines	Humans	Environment	Method
Farm or field					
Colonized, infected, toxigenic animals	■				
Feed	■				
Water	■				
Worker			■		
Animal feces, manure				■	
Soil, grass, mud				■	
Sewage				■	
Sewage, animal access				■	
Storage				■	
Storage conditions				■	
Environment, climate				■	
Cooling, inadequate					■
Storage, prolonged					■
Processing					
Starter culture failure	■				
Use of contaminated water	■				
Packaging, improper or defective	■				
Worker			■		
Environment				■	
Cross-contamination				■	
Cooling (cross-contamination)				■	
Cleaning of equipment, improper					■
Manipulation, spread					■
Holding temp (room, outdoor)					■
Storage, prolonged					■
Refrigeration, inadequate					■
Heat process failure					■
Organism, toxin survives process					■
Hot holding, improper					■
Cooling, improper					■
Reheating, inadequate					■
pH adjustment, improper					■
Water activity, improper					■

Table continued on the next page.

TABLE 3. Environmental assessments, contributing factors, and work elements (cont.)

Factors	Materials	Machines	Humans	Environment	Method
Retail, service, home					
Worker, person			■		
Cross-contamination				■	
Reconstitution, cross-contamination				■	
Cleaning of equipment, improper					■
Hot holding, improper					■
Refrigeration, inadequate					■
Storage, prolonged					■
Holding temp (room, outdoor)					■
Heat process, failure					■
Cooling, improper					■
Reheating, inadequate					■
Organism, toxin survives process					■

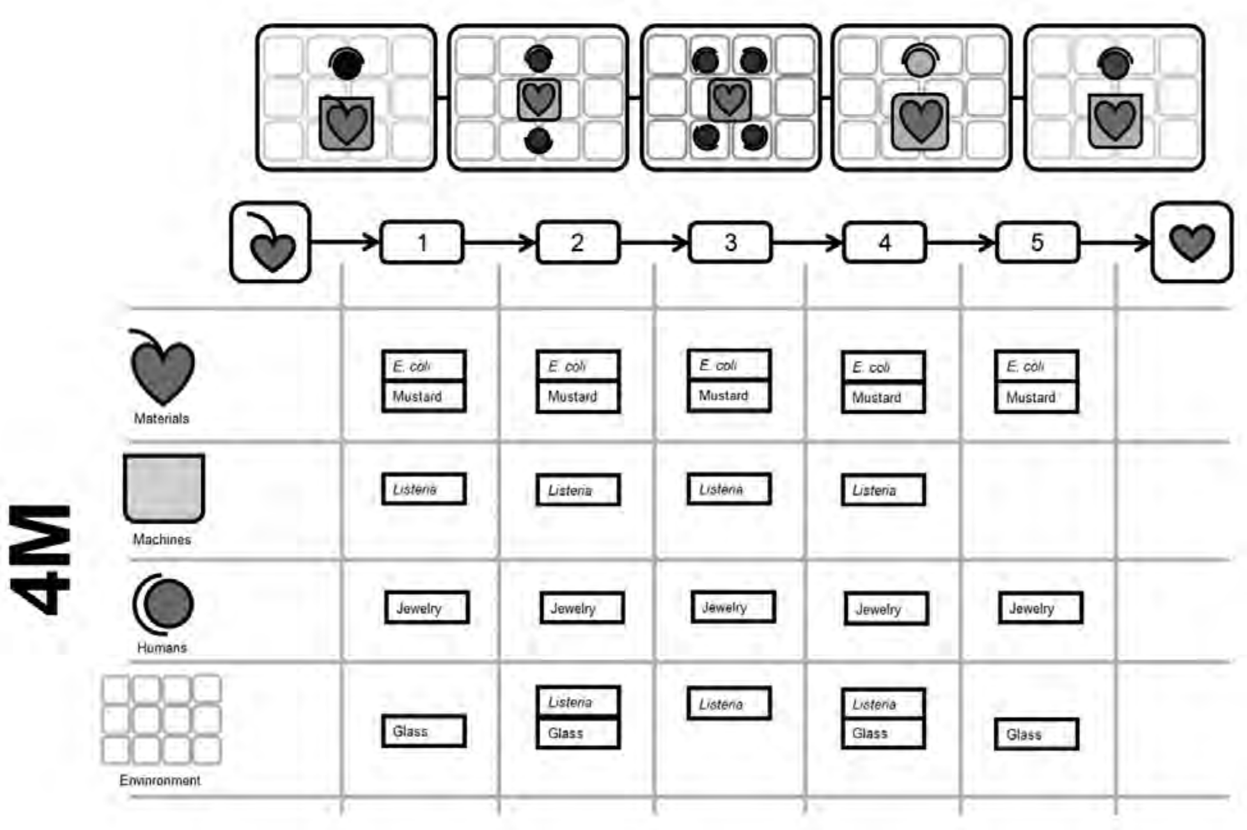

FIGURE 4. Example of flow chart and hazard analysis considering work elements at the hazard identification stage.

N	Recall Type	Frequency of Hazard at Cause	Control	Detection Method
10	Class I	Daily	Behavioral	Not Detectable
7	Class II	Weekly	Good Practice (PRP – No Criteria)	Human Inspected
4	Class III	Monthly	Preventive Control (OPRP – Criteria)	Machine Inspected
1	No recall	Annually	Process Control (CCP – CL)	Error-proofed
	Severity (S)		*Occurrence (O)*	*Detectability (D)*

Step	Work Element	Hazard	Cause	Control	Control Type	S	O	RPN
1	Materials	*E. coli*	Supplier Contamination	Insulate	OPRP	10	7	70
2	Materials	*E. coli*	Supplier Contamination	Insulate	OPRP	10	7	70
3	Materials	*E. coli*	Supplier Contamination	Insulate	**CCP**	10	7	70
4	Materials	*E. coli*	Supplier Contamination	Insulate	OPRP	10	7	70
1	Machines	*Listeria*	Inadequate Cleaning	Sanitize	OPRP	10	7	70
2	Machines	*Listeria*	Inadequate Cleaning	Sanitize	OPRP	10	7	70
3	Machines	*Listeria*	Inadequate Cleaning	Sanitize	OPRP	10	7	70
4	Machines	*Listeria*	Inadequate Cleaning	Sanitize	OPRP	10	7	70
2	Environment	*Listeria*	Permeability in Building	Permeabilization	PRP	10	7	70
3	Environment	*Listeria*	Permeability in Building	Permeabilization	PRP	10	7	70
4	Environment	*Listeria*	Permeability in Building	Permeabilization	PRP	10	7	70
1	Environment	Glass	Accidents	Shatter-proofing	PRP	7	4	28
2	Environment	Glass	Accidents	Shatter-proofing	PRP	7	4	28
4	Environment	Glass	Accidents	Shatter-proofing	PRP	7	4	28
1	Humans	Jewelry	Disobedience	Personnel responsibilities	PRP	7	4	28
2	Humans	Jewelry	Disobedience	Personnel responsibilities	PRP	7	4	28
3	Humans	Jewelry	Disobedience	Personnel responsibilities	PRP	7	4	28
4	Humans	Jewelry	Disobedience	Personnel responsibilities	PRP	7	4	28
1	Materials	Mustard	Permeability of packaging	Separation of materials, activities	PRP	7	4	28
2	Materials	Mustard	Permeability of packaging	Separation of materials, activities	PRP	7	4	28
3	Materials	Mustard	Permeability of packaging	Separation of materials, activities	PRP	7	4	28
4	Materials	Mustard	Permeability of packaging	Separation of materials, activities	PRP	7	4	28

FIGURE 5. Example of an improved hazard analysis.

TABLE 4. Failure mode and effects analysis of a critical control point

Process item (step)	Function	Failure mode	Effect	Cause	Action on process operation	Action on food material
Homogenization	Standardizes fat content					
Pasteurization	Reduces microbial pathogens	Lower critical limit not achieved (undercooked)	Performance criterion (microbial reduction) cannot be guaranteed	Thermometer failed at coldest location	Replace thermometer	Repasteurize
				Thermometer out of calibration	Calibrate thermometer	Repasteurize
		Process interrupted before completion (partially cooked)	Performance criterion (microbial reduction) cannot be guaranteed	Power outage	Contact electric authority	Repasteurize
				Emergency stop	Solve safety issue before continuing	Repasteurize
		Upper critical limit exceeded (overcooked)	Safety and functionality of material cannot be guaranteed	Error in setup of thermometers	Set up thermometers properly	Discard food material
				Thermometer out of calibration	Calibrate thermometers	Discard food material
Cooling	Preserves material (prevents spoilage)					

can be applied to eliminate the most significant hazards or reduce them to acceptable levels *(10, 25, 44)*. Because of this significance, the level of control of CCPs is expected to be higher than that of other types of controls (OPRPs and PRPs), and predetermined corrective actions should be in place for "out of control" situations. These corrective actions can be derived from an RCA. Earlier reviews of the HACCP guidelines required only identification of the causes of deviation from CCP critical limits to implement effective corrective actions *(10, 44)*. The most recent reviews of the HACCP guidelines now mandate the completion of an RCA when a deviation from the critical limit occurs *(25)*.

CCPs and FMEA

Food researchers have illustrated the application of RCA tools at CCPs. Seven of the 10 articles analyzed included a fishbone diagram associated with each CCP. The preferred tool was the 4M&1E approach: man, material, machine, and method plus environment. These 10 studies demonstrated the practical use of visualizing all possible causes of problem variables at the CCP *(2, 3, 17)*. An additional improvement could be listing the measurement category of causes because monitoring of critical limits typically requires measurements. However, a fishbone diagram may not be the most appropriate RCA method to meet the HACCP guidelines because it does not include the corrective actions required to adjust a process when it is out of control.

A more detailed analysis of the factors that affect the CCP could be presented in a subsystem FMEA because it will include actions to take in case of deviations. Several elements of FMEA are ideal for managing out-of-control events at CCPs *(Table 4)*. The first element of an FMEA (function) can be the best to describe the idea of selecting a CCP: reducing food safety hazards. Failure modes can be defined for variations above or below critical limits and the causes of corrective actions. Regular FMEAs include controls and recommended actions, but these may not be necessary for this type of application.

CCPs and special causes of variation

Ann understanding of the concept of process control and the special causes of variation becomes useful in this component of the HACCP analysis. Control can be exercised via norms and graphs; ideally, the norms should be linked to the causes and have established actions to solve the problem and prevent their recurrence *(34)*. Early quality specialists established that a process is controlled when all variation is predictable *(51)*. They also observed that there are always some unknown causes of variation, referred to as common or chance causes, whereas other causes that can be easily identified are called assignable or special causes *(51)*. identification and management of special causes of variation are essential because these variations can have more severe consequences than smaller variations due to common causes *(23)*.

Statistical process control aims to minimize variation by eliminating causes that can be easily identified. A series of tests and rules were developed to detect special causes of variation in manual charts, known as Nelson or Western Electric rules *(45, 76)*. The association of these rules with causes depends on the process being analyzed, but generic causes were identified and associated with various forms of variation in the early years *(76)*. Variables also may not occur separately, and there will be interactions that are not understood, but when their combined effect is stable and can be predicted statistically, the process can be considered under control *(23)*.

The HACCP guidelines suggest that identification and reduction of the special causes of variation and bringing the process under control are parts of the second, third, and fourth principles of the HACCP method *(25)*. Most special causes of variation should have been identified during the identification and validation of the CCP. Establishment of these causes through use of an RCA method can facilitate troubleshooting when deviations occur. As technology advances, implementation of statistical process control and management of special causes of variation will become easier *(52)*.

CAs and RCA

The requirements for identifying corrective actions differ with the type of problem and control (CCP, OPRP, or PRP). Corrective actions for the process are also required for OPRPs and PRPs, but corrective actions for the product must be evaluated on a case-by-case basis *(22, 25)*. Thus, completion of an RCA for corrective actions in OPRPs and PRPs may not have been suggested yet. RCAs for one significant or various minor corrective actions are considered necessary *(37)*.

Corrective actions can be predetermined for OPRPs and PRPs, in a manner similar to that for CCPs. This can be facilitated by using a structured management system and RCA, which also makes problem solving easier. The user must realize that predetermined corrective actions are also problems that must be eliminated if their recurrence becomes too frequent.

Typically, the corrective actions identified in an RCA require a modification of the management system. The new practices or root causes to control, identified via RCA, can be more easily determined when the RCA and management system follow the same structure. Use of a structured approach such as that of Ishikawa to organize PRPs that prevent root causes can facilitate the integration of solutions for root causes.

CONCLUSIONS

At least six types of well-developed RCA methods were found in the articles reviewed. These methods were fundamentally different in their approach to uncovering root causes. Some of the differences were the categorization of causes, how the contributing factors are identified, the logic utilized to link the causal chain, and the existence of root causes. Any of these methods could be used to solve food safety problems reactively or as a complement to EAs in a food safety investigation.

Most RCA methods have same general structure: define the problem, then identify causal factors, and finally uncover root causes. This general structure emphasizes the fact that there may be fundamental causal mechanisms that are related to contributing factors and root causes and can be identified and studied to properly uncover the root causes. Causal mechanisms can be related to failure mechanisms, which explain the failure mode. Problems of higher magnitude may not always be solved with technical solutions implemented at the root cause. Recent recommendations include identification of the root causes of why the detections and the systems failed.

Some components of the various RCA methods can be useful for improving HACCP systems. These components can be applied to the entire management system at the PRPs and corrective actions or specific elements of HACCP such as the HA and the CCPs. The Ishikawa categories can be used to organize PRPs based on a structured approach, which in turn can make it easier to implement corrective actions. Four of these categories of causes (materials, machines, humans, and environment) have been called work elements to ease their identification on the processing floor. Identification of the work element at which the food safety hazard occurs can increase the effectiveness of HA and its controls. Several authors stated that the most important elements of FMEA that can be used in HA are identification of the cause and implementation of a criticality analysis. The HA can also be strengthened by integrating the principle of EA contributing factors. These factors have been derived from epidemiological data and could be further improved as information technology advances. The management of CCPs can be improved based on the principles of FMEA and by applying the concepts of special causes of variation in statistical process control. These tools may be more appropriate for CCPs than for Ishikawa diagrams. FMEAs are specifically intended to address failures of critical functions such as CCPs. The science of relating process variation to causes is continually evolving.

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