Conducting Root Cause Analysis

A "How-To" Guide for the Produce Industry

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Contributors to this Guide

Acknowledgments

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INTRODUCTION — HOW TO DO RCA

The **objectives** of root cause analysis (RCA) are:

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

RCA is a systematic approach to problem-solving, but it is not a rigid, inflexible process. Although it follows an investigative process, it may not always occur in a stepwise or linear sequence, as suggested below. For instance, it is common that you may initially have very little information and struggle to describe what happened. You may be compelled to start by assembling a team (step #2), laying out what seems to be known, and planning a strategy for gathering information before you can coherently describe what happened and define the problem. After you assemble a team and start the investigation process, the information they gather will result in a more well-rounded description.

For each step in the RCA process described below, two examples are provided to illustrate the actions taken.

1. Identify and define the problem

Before you can determine why something happened, you must first understand what happened. Describe what happened in as much factual detail as possible. Some details to include in your description include:

- Exactly what was the specific incident, such as a positive pathogen detection, recall or outbreak, deviation from SOP / GAP, expected result, or protocol?
- Where did it happen?
- Establish a timeline: What is the timing? What is the sequence of events that led to the incident?
- What is the scope of the problem – i.e., what elements of your operation are involved? Who was involved and should be interviewed?
- What factors may have contributed to the problem? What was different this time compared to past instances when this did not occur?
- What are the consequences?

At this first step in the RCA process, it may be helpful to use RCA resources to organize information related to the incident (see section II where these resources are described).

<u>Example 1</u>: At the most recent sampling event, the water sample taken at the last sprinkler head of your ranch's irrigation system has a generic *E. coli* level of 1,850 MPN/100 ml. The water source is an irrigation district canal.

<u>Example 2</u>: A knife was found in a product carton by a customer.

2. Assemble RCA team

Before you meet with your team, it is a good idea to have a description of the incident/event written down. Come into the meeting with information regarding the incident that can help the team to frame the information set needed and launch the investigative work. The team should consider the following in the investigation planning process:

- Brainstorm: Discuss the possibilities that may explain the potential cause(s) (Note: It is important that this does not result in selecting only the information that fits the ideas presented. Keep an open mind and revisit ideas as new information becomes available).

- Develop a work plan: Outline the work that needs to be done (e.g., identify all parts of your organization that are involved in the situation, prioritized interviews, additional inspections and samplings, etc.).

It is a good idea to include an estimated cost to accept or reject each idea so you can plan accordingly how far it may be possible to pursue each node and branch in an investigation. Often times assembling data and putting "boots on the ground" is adequate, and expensive investigative testing or research, while possibly advantageous, is not essential.

Example 1: You call a meeting with the RCA team, which includes you and/or a designated food safety professional, the field operations manager, and other relevant employees. You describe what you know about the sampling event, confirm the roles of each team member, and outline the next steps including who to interview and research to find relevant data and information.

3. Investigate – do the work / research and gather relevant information and data

This is the "discovery" part of RCA – gathering the missing information to help complete the picture. This process generally looks for factors that contributed to the incident. Remember to look at things that may have changed recently – what is new or different as well as deviations or noncompliance issues. You may also uncover new information that may lead you in a different direction and prompt you to ask more questions, so do not just focus on evidence that "proves" your idea of what happened is correct or you may miss consequential, valid evidence.

- Factors that contributed to the event/incident may include:
  - Physical – structures, equipment, and recent changes or failures in these over time
  - Operational – performance, decision-making, communication, failure to observe, failure to report an observation, etc.
  - External – weather, surveillance testing, changing policies or specifications, regulations, complaint calls, etc.
  - Organizational – policies, culture, structures, etc.
- Data and information may come from several different sources:

- Samples – collect samples that are relevant to and representative of the circumstances.
- People – it is important to question the right people and ask the right questions. This is very hard to describe as it is generally situation- and operation-specific.
- Paper and electronic record review – Ensure workers' verbal recounts match what is documented. Look for evidence of what did or could not have happened and not assume what was meant to happen, did happen.

Remember that it is common for people to forget and, at times, to fail to recall failures or to coverup failures to notice or act. The "soft skills" of creating trust and confidence in those being questioned is generally hard to teach. Sincerely seeking the cause and the right corrective actions, rather than blame, generally sets a productive tone for those being questioned, which allows the team to more effectively work through this part of RCA discovery.

Remember to pursue all leads: Don't assume anything and keep a mindset of looking "behind the curtain".

Example 1: The RCA team will interview personnel involved in taking water samples (operational factors), conducting environmental assessments of the growing environment (external factors), and setting up and maintaining the irrigation system (physical factors). Team members will gather relevant contemporary weather data (historical data may be helpful as well) for the preceding and concurrent days the samples were collected.

Example 2: The RCA team will first interview personnel in charge of the harvesting crew the day of harvest (operational factors) and then interview harvest workers according to the information gathered from the harvest supervisors. Another team member will review equipment inventory records logged for the day of harvest (physical factors).

4. Root cause determination

After the RCA team has collected data and information, the team can revisit the incident and use RCA resources (see Appendix A) to evaluate what they have gathered. It is important to document this information and the assessment of it.

- Compile and analyze the data.
- Use maps, diagrams to describe the events / what happened.
- Look for connections – Failures are rarely caused by one factor or a singular circumstance.
- Team discussions may help to narrow the list of possible causes.

Example 1: The RCA team meets and brings all its information together and discusses the details of what happened prior to and during the water sampling event. The designated food safety professional writes an event report including a timeline of weather events, ranch activities, and observations made during the environmental assessments conducted the week before the implicated water samples were taken.

Example 2: The RCA team meets and brings all its information together and discusses the details of what happened prior to, during, and after harvest on the day the product was harvested. The designated food safety professional writes an event report including a timeline of relevant activities and observations made during the harvest that day.

5. **Root cause resolution**

This step is where the team builds on its findings to establish a resolution including corrective action(s) for any existing contributing factors that still pose a food safety risk (e.g., a point source such as a manure pile or non-point source such as workers' systematic poor hygiene behavior).

- Explain how the incident/event happened; determine and implement corrective actions.
- Do the facts presented fit the event/incident/situation? Do they explain the problem?
- Develop and implement corrective action(s) to correct the problem if it still exists; if there are multiple contributing factors, there may also be multiple corrective actions. Some correction actions and lasting preventive controls may involve or require an external party.

It's important to note that, in some cases, a root cause is not determined for various reasons. This does not mean the RCA is not successful, and there should be no expectation to name a cause if evidence does not support it. Even in cases where a resolution cannot be determined, the RCA process provides opportunity to learn more about procedures and processes, reinforces the necessity of preventive practices already in place, and may expose non-causative, unanticipated issues that need to be addressed.

Example 1: The RCA team discusses their findings regarding potential causes and contributing factors for the elevated generic *E. coli* levels. Based on a preponderance of evidence, the team determines the root cause of the transient high generic *E. coli* levels in the irrigation water was a manure stack located upslope from the canal several weeks prior to sampling and subsequently spread on alfalfa fields adjacent to the canal. Weather data showed substantial rainfall on numerous occasions while the manure stack was present. For this example, since the high *E. coli* levels were transient and the manure stack was no longer present, corrective actions may include building better communications with neighboring farms and re-training of farm labor to improve notification of observations to foreman/supervisors.

Example 2: The RCA team discusses their findings regarding potential causes and contributing factors for the misplaced harvesting tool. Based on a preponderance of evidence, the team determined there were dual root causes:

1. A newly hired harvest worker who was not properly trained in harvest tools SOPs due to time constraints. She failed to follow SOP for equipment storage during toilet usage (i.e., put it in the designated bucket/holding receptacle). Near the end of harvest, the worker went to the toilet and left her knife in the harvested product carton she had just finished harvesting (another SOP violation).
2. Inaccurately conducted equipment inventory – While the new worker was using the toilet, a coworker put her carton on the finished product stack without noticing the knife. When she immerged from the toilet, she joined the others getting into the bus forgetting about her missing knife. In the meantime, the field operations manager took an inventory of the harvest equipment and failed to notice the missing knife.

6. **Verify and evolve**

So, you have completed the RCA, but your work is not yet complete. In fact, the most critical part remains – doing what you can to prevent the incident or event from happening again. Now is the time for the team to develop and implement preventive actions.

- Ask yourself – "now what's next?" Are there any follow-up tasks after RCA is complete?

- Develop *preventive* action(s) to ensure the incident/event does not happen again.
- Periodically verify and assess the effectiveness of the preventive action(s).
- Consider sharing your findings to benefit the broader industry.

Example 1: The food safety personnel responsible for environmental assessments do not have regular communication with the ranch growing alfalfa upstream from your operation. The RCA team implemented a procedure to increase communication and arranges meetings with the field operations manager of the upstream ranch to share environmental assessment observations with neighboring ranches when they are deemed pertinent to food safety for the growing community in the area.

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

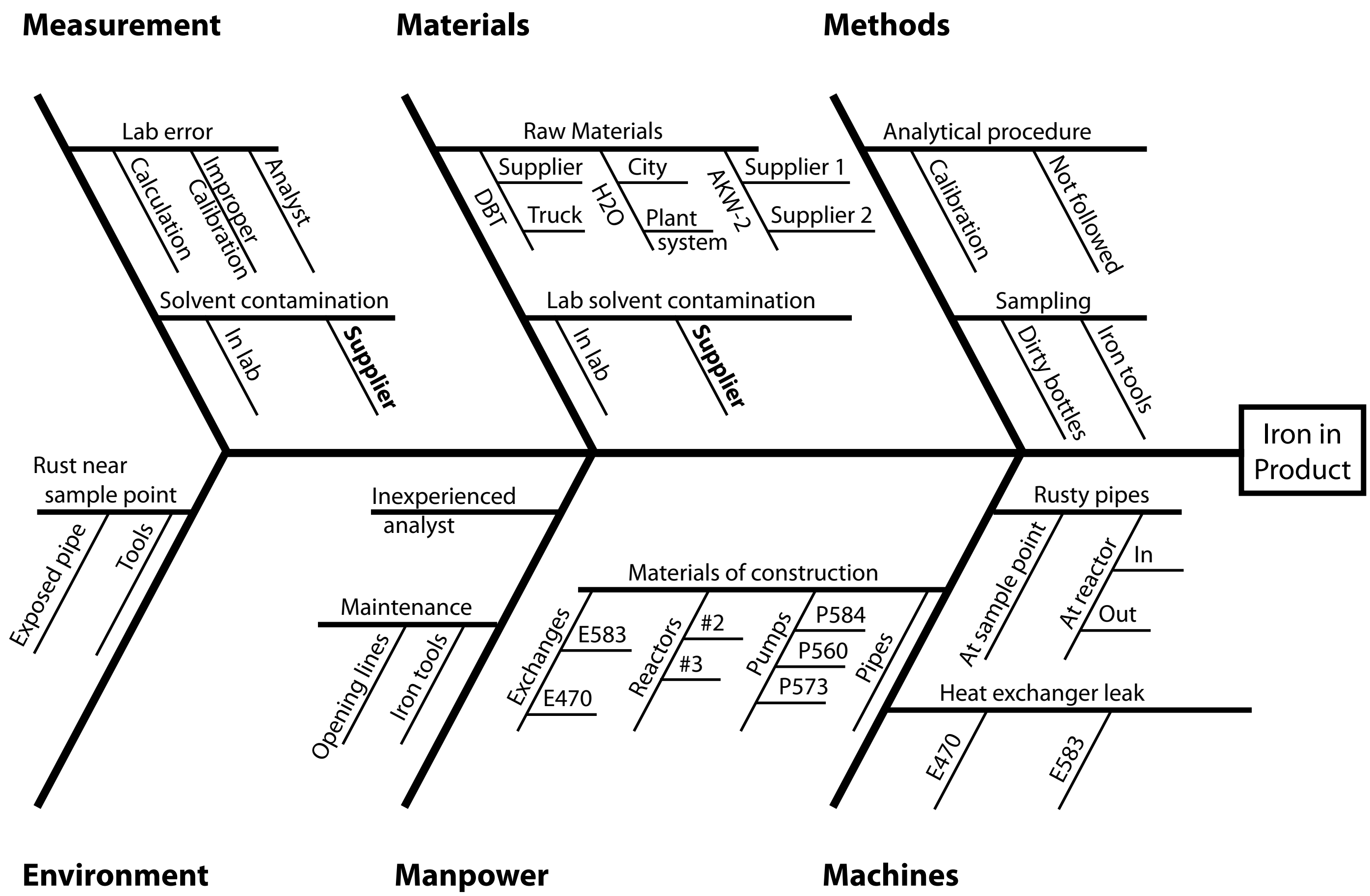
Example 2: The food safety director implemented a new inventory system in which all harvesting knives were numbered and which knife each worker used was recorded prior to beginning harvest. Workers were required to sign in and out of the toilet and place their knives in a designated receptacle while they were using the toilet. A training explaining the new rules was given at the beginning of the next scheduled harvest. The harvest supervisors were reminded that a thorough training for workers new to the harvest crew was absolutely essential prior to beginning work in the field.

Appendix A – Methods & Tools

Table A1. Common tools / methods used in conducting RCA (See illustrated examples of these resources following the table.)

RCA Tool/ Method	Description	Potential Uses	Limitations
Fishbone Diagram (also called Cause & Effect or Ishikawa)	A graphic tool created to explore factors contributing to an "effect" such as an unexpected and often undesirable incident or event.	Identifying potential contributing factors.	Does not lend itself well to depicting complex interrelationships among multiple contributing factors
5-WHYs	Asks "why" 5 times or as many as necessary to get a clear explanation for why an incident occurred	Simple linear technique for simple, uncomplicated incidents	Not conducive for solving or gaining a better understanding of complex issues such as positive pathogen test results for pre-harvest crops
Fault tree	A systemic description depicting potential pathways between cause and effect.	Analyzing failures in a packing or processing system. Often used for equipment failures	Can be too binary (e.g., Yes or No) for nuanced circumstances; relies on symbolic shapes that may be difficult to remember for those not trained in its use.
Process maps, flowcharts	A technique to represent a process by organizing information in a graphical manner or sequential diagram.	Helpful for understanding what went wrong in a system or process e.g., packing or processing incident	Requires detailed knowledge of a process
Check sheets/ tables, KNOT chart	Organizes potential contributing factors or data element in a table with the categories: **K**now, **N**eed to know, **O**pinion, and **T**hink we know (requires an action to obtain objective evidence prior to changing to a K).	Helps to organize information and evidence.	Does not emphasize or provide room for analyzing relationships between or among factors.

Fishbone Diagram

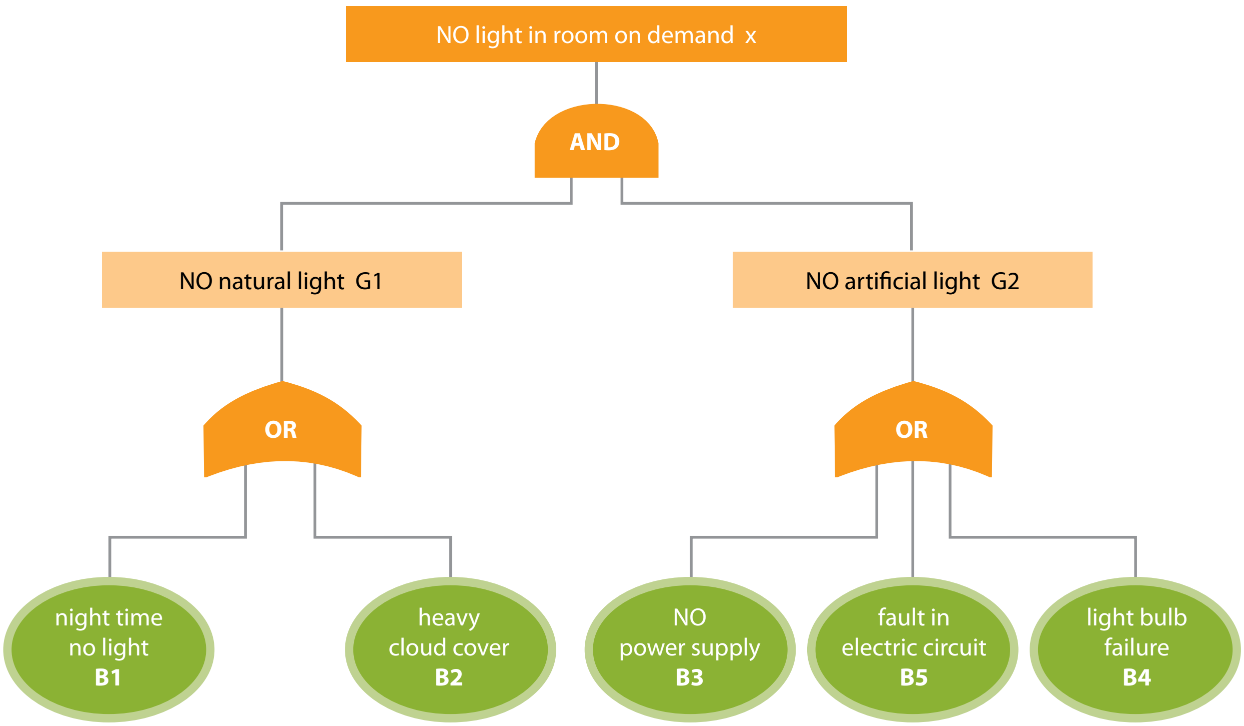


5-WHYs Analysis Template

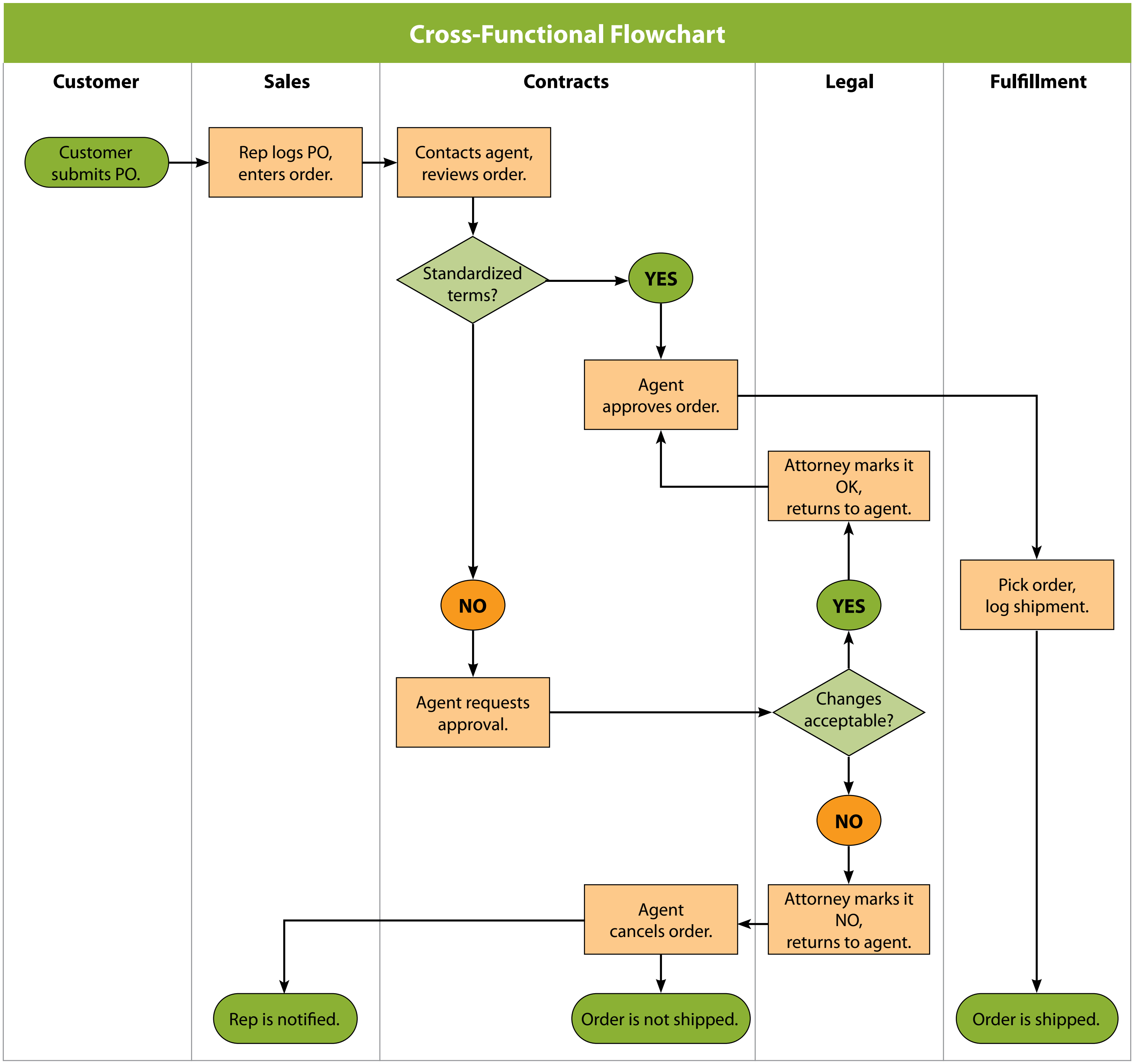
Problem / Defect

	Answer what caused the specific situation	*Answer why the problem wasn't detected*	*Answer why the problem wasn't detected*
1st WHY?			
2nd WHY?			
3rd WHY?			
4th WHY?			
5th WHY?	Should be at the root cause near 5th question		

Fault Tree


NO light in room on demand x
AND
NO natural light G1
NO artificial light G2
OR
OR
night time
no light
B1
heavy
cloud cover
B2
NO
power supply
B3
fault in
electric circuit
B5
light bulb
failure
B4

Process maps, flowcharts



Appendix B – Case Example #3: Consecutive Pre-Harvest STEC Detection

Problem Definition – Preharvest pathogen detection on tender greens expands from single to multiple fields in short succession.

1. A preharvest sample (25 g) 7 days before harvest tests positive for *Salmonella*.
    - 32 hours later, secondary samples from 1 of 5 one-acre blocks test positive for Salmonella and STEC.
    - Initial response was discing positive one-acre field block.
2. Contiguous five-acre block tests positive for STEC preharvest overlapping with STEC, *Salmonella* and STEC + *Salmonella* positives on finished product from the initial harvested four-acre block.
3. Non-contiguous five-acre block more than 0.25 mile from the initial positive block, tests positive preharvest for both STEC and *Salmonella*. Testing overlapped with harvest/re-sampling decision-making around second block results.
    - Re-sampling second and third scheduled harvest blocks results in 3 of 10 STEC and Salmonella positives.
    - Raw product from both harvest blocks were tested with a diversity of positive results observed in 4 of 10 samples.
    - All product was destroyed.
4. Twelve days after the initial positive test results, a fourth field preharvest sampled in 5 one-acre units (125 g) is negative for STEC and *Salmonella*. This field was approximately 1.5 mi from the initial field.
    - However, finished product testing in larger mass units (175 g) revealed a mix of STEC, *Salmonella*, and STEC + *Salmonella* positives. Samples representing 6 of 24 pallets had positive outcomes.
    - All product was destroyed.

Initial Review for Contributing Factors – Field Operations Team and Food Safety Manager Assemble

- Initial review of field, raw harvest, and finished product outcomes and spatial distribution was confusing with no discernable connections between fields, equipment, or inputs.
- All fields were managed by conventional practices with overhead irrigation and last irrigation was 10 days before the scheduled harvest.
- All water is sourced from irrigation district canals directly or from a series of secondary laterals except for one field which used more remote well water during a heavy demand period.
- After three rounds of internal review with field operations and review of audit checklists, no unifying risk-based or contributing factors emerged.
- Positive tests were experienced within the same large ranch but with different crop types over the following weeks.

Root Cause 1° Hypothesis Generation Exercise

- Owners and senior management gathered a broader internal team and brought in the contracted crop management consultant firm and harvest contractors.

- Monthly water tests did not reveal any non-compliant results for generic *E. coli*.
- Compost (dairy manure and chicken litter sources were included in the feedstock) was applied to some but not all ranch blocks the preceding early summer more than 60 days before pre-irrigation and seeding. The noncontiguous ranch blocks, in rotation to receive this compost, did have one large lot field-side deposited, approximately 15 tons (~3 tons/ac), at each location for spreading and incorporation, and remaining in dump piles for up to three weeks. One COA was supplied for all the delivered commercial compost.
- Most fields of the same commodity shared common seed lots.
- No pre-plant fertilizers were of animal or biological origin.
- Adjacent land features and use activities were largely agricultural and no clear presumptive risks or new use aspects were apparent.
- No single harvest contractor or harvest equipment could account for all field lots testing positive.
- All crop management foliar sprays were specified, by company SOP, to be filled with municipal water sourced at the company equipment yard or from a nurse water tank truck also filled with this municipal water source.
- Monitoring records included observations of birds and bird droppings, coyote prints and scat, and dog prints, but judged as low numbers and limited intrusion; nothing at all unusual.
- No other input, activity, or weather event was considered notable.
- No fields were impacted to any notable level by insect pressure or plant disease.
- Cross-contamination from internal closed-loop collapsible harvest totes was discussed, but no clear inter-field use pattern emerged.
- More records were reviewed, and details were discussed and debated but the group did not arrive at a consensus hypothesis or plausible root cause.
- An expanded and inclusive interview plan was the agreed action.

Root Cause 2° Hypothesis Generation Exercise

- Management approved testing residual sump pump water and conducting swabs of the irrigation mainline, pipes and emitters associated with positive lots.
- Interviews were conducted with the labor contractor engaged to conduct field sanitation.
- Swabs of harvest machines and harvest totes was considered but deferred as no cross-connections of use could explain the spatial and temporal distribution of positives and negatives.
- Jumping a few steps and several meetings ahead… field observations at the two earliest contiguous blocks with positive lots revealed clear evidence of irrigation lateral canal clearance which, though observed by field operations during the events and in initial RCA field inspections following the positives, was not mentioned in the initial hypothesis generation exercise.
- Positive results, mostly for *Salmonella* but some STEC, were obtained from the PTO sump, mainline, and sprinkler sections… once a presumptive root-cause was agreed on by the team and advisor, it was decided not to culture or sub-type the molecular positives as it was too costly.

Best Assessment – Root Cause Determination

Further interviews in the process revealed that the field sanitation contractor needed more hours to retain the crew availability in advanced of the first harvests.

- A decision was made to use this crew to rake the extensive macroalgae from the lateral canals and areas of the PTO sump.
- This maintenance effort was conducted during irrigation events at both blocks which released algae fragments, subsequently found to harbor *Salmonella* and STEC, disturbed sediments likely to harbor both pathogens into the water flow, and this water passed from these sumps after each irrigation set to lateral connections conveying water to other ranch blocks.
- It was further determined that algal extract formulations with growth boosting microbes and supporting nutrients were included in the fertigation program. These were added to the program by the crop consultant but not communicated to the management level in a way that provoked recall during hypothesis generation exercises. However, it was not likely to have raised a question within RCA until noted by an external advisor.
- It was further determined during pointed interviews that some foliar application tanks were periodically filled at the PTO sump equipment when the water tanker was not immediately available. These tractor-mounted sprayers were moved widely around the ranch operations, but records were incomplete, and recall was questionable in relation to positive and negative ranch lots.
- Though the RCA was terminated at this point, a consensus view was that algae removal and sediment agitation resulted in contamination of the crop during irrigation and established these pathogens at higher-than-normal levels in a persistent manner in the irrigation sumps and pipes.
- The addition of the injected biostimulant formulation was not determined to be a confirmed root cause contributor but recommended follow-on research confirmed that both *Salmonella* and *E. coli* O157:H7 would grow in algal extracts and fish emulsion in canal water at the environmental temperatures and was especially likely in the spray lines and irrigation pipes.

Final Assessments

Though not possible to unequivocally prove cause and effect, it was reasonable to determine via the RCA process that canal disturbance during active irrigation was the key contributing factor in the widely dispersed contamination. This likely contributed to the complex and inconsistent lot-to-lot positives and was compounded when this same surface water was used in some foliar spray equipment potentially contaminating it.

- The patterns of positives were never fully resolved but management felt they had carried out the RCA far enough to implement several programmatic changes in training, communication, record-keeping, and revised SOPs with frequent spot verification.
- Clear instructions for notification and detailed communication of any repair or management issues were implemented to include the food safety manager.
- Numerous uncertainties surrounded the possible contribution of the compost to *Salmonella* introduction into the water distribution system as the material in the initial field was place immediately across from the lateral. However, based on the COA, and no additional testing, it was impossible to rule-in or definitively rule-out.

Secondarily, the observations of variable pathogen test outcomes particularly between pre-harvest testing and finished product tests raised questions regarding the need to modify the sampling plans and detection platforms.

Resources

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

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

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

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