Root Cause Analysis: A guide for investigating food safety issues

This guide offers a structured, practical approach to investigating food safety issues. It is designed to help uncover the underlying or root cause of an issue or incident, and can be adapted to suit your specific site, systems or operations. Templates are included to assist with documenting findings during the investigation process.

Introduction

What is a food safety issue or incident?

An issue or incident is an event that occurs during the manufacture of dairy food that results in:

- **Non-compliance w**ith the Victorian *Food Act 1984*, *Dairy Act 2000*, or the *Australia New Zealand Food Standards Code*
- **Deviation** from your Food Safety Program
- **Failure** of critical controls or other key manufacturing specifications
- **Unexpected events** that could impact food safety

Why investigate?

The goal of any investigation is to:

- Identify the root cause
- Take effective corrective action
- Prevent recurrence

If the root cause of an issue isn't identified, corrective actions may be ineffective leading to recurring problems and wasted time and money. Food businesses of all sizes should investigate issues thoroughly, document their findings, and keep records of any corrective actions taken.

How to conduct an investigation

A thorough root cause investigation includes three key steps:

1) **Identify** the real cause of the issue or incident
2) **Implement** appropriate corrective actions to resolve the issue and prevent it from recurring
3) **Verify** the effectiveness of corrective actions for sustained outcomes

Step 1: Identify the real cause of an issue or incident

a) Identify the issue and define the problem (Use Template 1)

Start by clearly identifying and describing the issue. This helps ensure that everyone involved has a shared understanding.

Information sources may include microbiological test results, customer complaints, non-conformances, staff observations, Corrective Action Requests (CARs) issued at audit, process failures or quality control data.

Ask:

- ***What** is the issue?*
  Describe the problem clearly
- ***How** was it identified?*
  Outline how the problem was identified for example, test results, complaints, observations
- ***How** big is the problem?*
  Identify how many products or systems are affected
- ***Where** did it occur?*
  Identify which line, team or factory area was involved

- ***Who** was involved?*
  Identify which staff have key information or may have raised or identified the issue
- ***When** did it happen?*
  Determine date, shift or time as appropriate

b) Form an investigation team

Assemble a cross functional team. Including people from different departments brings diverse perspectives and improves the chances of finding the true cause.

- Staff who witnessed or identified the issue
- Operators familiar with the process
- Supervisors and managers
- Staff from other departments with process or factory knowledge (e.g. Quality, Maintenance, Cleaning); and
- Any other staff members with relevant expertise

Start with a brainstorming session to identify possible causes. Document ideas and gather supporting data.

c) Collect data, records and information (Use Template 2)

Collect all relevant documentation before, during, and after the incident. Examples include:

- Records from the incident, including photographs, witness statements and any other relevant information
- Daily production records such as pre-operative checks and cleaning records
- Critical Control Point (CCP) and Quality Control Point (QCP) verification results
- Incoming goods records such as certificates of analysis and results from in-house testing of ingredients
- Maintenance and repair logs
- Verification testing records such as product and environmental testing
- Results of subsequent testing (product, ingredients, environment)
- Standard operating procedures (SOPs), work instructions and training records.
- Investigation records from past similar incidents

Other records, data or relevant information may need to be reviewed for a complete investigation.

d) Conduct a walk through and further investigations (Use Template 3)

A visual inspection during production can reveal potential causes that may not be apparent in records. Walk through processing areas during production to observe staff behaviours, equipment condition, and overall cleanliness. These observations can help to help identify the cause of an issue. During the walkthrough, keep these points in mind.

Inspect the factory environment and equipment (whole line) for any damage that could pose potential contamination risks. This may include stripping down and pulling the equipment apart.

- Concentrate on areas where past incidents or near-misses have occurred, looking for patterns or recurring issues
- Consider any recent changes to processes, raw materials, or packaging
- Consider maintenance or breakdowns that have occurred recently
- Observe cleaning and sanitation practices looking for any potential issues with practices that may have contributed to the incident
- Spend time observing staff behaviours and practices particularly how staff carry out their tasks and their adherence to SOPs and Good Manufacturing Practices (GMP) / Good Hygienic Practices (GHP)

Seek insights from operators about potential causes of issues, as they often have a deeper understanding of the risks and underlying factors.

Investigative sampling may also be considered and can include in-process samples and environmental swabs.

e) Consider external expert input

External experts such as equipment manufacturers or chemical suppliers can provide insights into cleaning protocols, chemical usage, or machinery faults that might otherwise be missed. They often have experience solving complex issues or can provide guidance about areas to review, for example chemical strengths and applications or equipment maintenance.

f) Identify the root cause (s) (Use Template 3)

After gathering all the relevant information, completing the walk-through, making observations, collecting samples, and speaking with staff, the next step is to identify the root cause of the issue. If you're working with an investigation team, review the information together. Look for anything unusual or any deviations from normal practices or behaviours that may have contributed to the issue.

- Review records and data carefully for any irregularities such as out-of-spec results, missing information, or any inconsistencies. It is also helpful to check records from before and after the dates of concern to look for patterns or contributing factors
- Compare staff behaviours and practices with SOPs to identify any differences between what is written and what is being done
- Talk with staff to understand why procedures may not have been followed. Look for knowledge gaps or other factors that may have contributed to the issue
- Identify potential contamination risks from equipment due to maintenance or cleaning failures

Any deviations between the SOP's and performance of tasks could indicate potential safety or quality issues that could contribute to incidents.

Avoid making assumptions that may rule out potential causes. Instead, consider all possibilities and eliminate them systematically. Multiple causes may contribute to a singular issue or incident.

g) Record all findings

Maintain clear, detailed records of:

- Investigation steps
- Observations
- Decisions made
- Justifications for each decision and conclusion

This provides a thorough record for audits and captures key learnings for future investigations.

Step 2: Prevent recurrence

The investigation team should develop a plan and agree on actions to address and control each of the causes identified during the investigation. Resolving the problem may involve using multiple strategies, rather than relying on a single corrective action to address the issue.

When looking to correct a problem, it is important to identify and address the real or underlying cause and not the symptoms.

- A symptom is usually what we see
- Symptoms can mask the real cause/s
- Solutions for symptoms fail to correct the real cause/s

Develop and implement corrective actions (Use Template 4)

For each potential root cause identified, define one or more corrective actions to prevent or minimize the likelihood of the issue recurring. These may include:

- Updating SOPs
- Training staff
- Adjusting cleaning or maintenance schedules
- Changing suppliers or equipment

Corrective actions can be short-term or long-term, especially if changes to equipment or facilities are needed. When implementing corrective actions, it is important to:

- Clearly document the corrective actions, including who is responsible for completing and verifying each action, and set realistic deadlines
- Prioritise tasks based on urgency and risk and ensure that they will not cause other issues after implementation
- Allocate the necessary resources, such as people, time, and equipment, to complete each action properly
- Communicate the changes to all relevant staff and stakeholders. Involve them in the process where appropriate
- Update any relevant records or procedures to reflect the changes, ensuring accurate documentation for future reference
- Monitor progress to ensure corrective actions are being carried out as planned. Know what success looks like and aim for that standard
- Verify that the corrective actions have been fully implemented and that they address the root causes of the issue

Step 3: Check that corrective actions are working

Verify implementation and effectiveness of corrective actions (Use Template 4)

Once corrective actions are in place, monitoring and review activities should be conducted to confirm that the issue is effectively resolved. Without this verification, there is no evidence that the problem has been fixed or that it won't happen again. Verification helps ensure the issue is fully addressed and should not recur.

- Understand what needs to be verified and how to measure success.
- Ensure that the corrective actions are clearly defined, with specific, measurable, achievable, relevant, and time-bound goals
- Track progress to confirm corrective actions are implemented as planned. This can include observing work processes or reviewing reports
- Conduct post implementation checks and inspections. Inspect the affected to ensure corrective actions are in place and working as intended
- Continue verification over time to make sure corrective actions remain effective
- Keep records updated to reflect changes and support ongoing monitoring (if needed)
- Use data and performance metrics to evaluate success. This may include key performance indicators (KPIs), customer feedback, production data, or defect rates

Verifying corrective actions provides documentation for future reference, audits or when similar issues may occur. It provides evidence that the issue was addressed and resolved effectively.

Templates

Template 1: Identify the issue and define the problem

Define	
What is the problem? *What is the problem or symptom?*	
How big is the problem? *(Identify how much and which products, processes or systems are affected.)*	
How was it identified? *(e.g. test results, complaint, FSP deviation)*	
Where did it happen? *Line, team, factory area?*	
Who was involved? *(Identify operators with key information)* *(Is the issue related to skills?)*	
When did it happen? *(e.g. the time of day, shift change, after breaks etc)*	
Assumptions?	

Template 2: Data to consider

This is the basic information to begin collecting when investigating incidents or issues. Other data that is more specific to the process or site should also be considered.

Data/measures/checks	
Incoming goods	
• Certificates of Analysis	
• In-house screening/testing	
Daily production records	
• CCP checks	
• Temperature checks	
• Processing records	
• Pack off records	
• Pre-op checks	
• Cleaning records	
• Maintenance records	
• Pest control	
• Calibration records	
• Training records including competency checks	
Verification checks	
• Environmental monitoring results	
• Finished product testing results	
Any other data being collected e.g:	
Risks highlighted from incoming goods checks?	
Gaps in records or missing checks?	
Deviations from FSP?	
Indicators of contamination?	
Pathogen detections - environment or product?	
Other potential contamination risks?	

Template 3: Investigation prompts

These prompts provide a starting point for consideration when investigating incidents or issues. Other information or data that is specific to the process or site should also be considered.

Area	Record relevant information/anomalies
Materials *(risks related to incoming goods, storage and movement throughout the process)*	
What materials are involved?	
Raw materials? – C of A/testing or other incoming goods assurance	
Are there any risks from the packaging?	
Any potential contamination risks from materials?	
Equipment & Environment *(risks related to the maintenance/condition, cleanliness of factory environment and equipment)*	
Where did the incident occur?	
Where is there product contact? e.g. pipework, vats, tables, hoses etc.)	
Relevant equipment condition? e.g. evidence of damage, potential issue	
Is there a preventative maintenance (PM) program in place?	
Who does the PM and what skills/training do they have?	
Has the PM program been conducted as scheduled? Is there evidence?	
Has there been any equipment and area inspection since the incident? And if so, what did it identify?	
Were any maintenance issues identified?	
Were there any issues identified with the cleanliness of the equipment/factory?	
Has the cleaning been observed? Any issues identified?	
Is cleaning robust and being done as expected?	
Who is doing the cleaning & what training have they had?	
Has external expertise been sought on cleaning practices/chemical strengths and usage?	
Any potential contamination risks?	
Systems and People *(risks related to poor understanding and implementation of required expectations)*	
What procedures are being used in the incident area/line?	
Are procedures up to date?	
Are procedures being used?	
Collect observations of operators performing tasks	
Cross check all practices with procedures – via observations	
Do the practices align with procedures?	
Are there any risks from staff flow and equipment movement?	
Talk to operators to gauge their understanding of tasks and expectations	
Is PPE in place and adequate to prevent contamination?	
Are GMP/GHP practices consistent and in line with expectations?	
Were there any insights provided from operators?	
Any deviations in operators performing the tasks?	
Any risky practices identified?	
Any gaps in operator knowledge or understanding?	
Any potential contamination risks?	

Template 4: Outcomes and corrective actions

Issue identified	Implementation activities				Verification activities		
	Action	**Due Date**	**Person Responsible**	**Date completed**	**Date verified**	**How was this verified?**	**Person responsible**
Measurement *(actions to address risks identified due to data anomalies)*							
Materials *(actions to address risks related to incoming goods, storage and movement throughout the process)*							
Equipment & Environment *(actions to address risks related to the maintenance/condition, cleanliness of factory environment and equipment)*							
Systems and People *(actions to address risks related to poor understanding and implementation of required expectations)*							

Glossary

This guidance uses the following terms and acronyms:

Term/Acronym	*Description*
Issue or incident	An issue or incident refers to any event or situation that poses a risk to food safety, quality, or compliance with regulations and can include product contamination, deviations from CCPs, labelling errors, maintenance issues, product recall and non-compliance with regulatory standards.
RCA	Root cause analysis (RCA) is a problem-solving method that is aims to identify the root (underlying/real) causes of problems or events.
Corrective action	Actions put in place to prevent the recurrence of a problem or non-conformance.
Preventive action	Actions put in place to eliminate potential problems before they happen.
CAR	Corrective Action Request
PM	Preventative Maintenance
GMP	Good Manufacturing Practices
PPE	Personal Protective Equipment
SOP	Standard Operating Procedures
C of A	Certificate of Analysis
CCPs	Critical Control Points
QCPs	Quality Control Points

Other resources

Culture: Growing dairy exports is a course the Department of Agriculture, Fisheries and Forestry (DAFF) for dairy manufacturers. It aims to build skills and knowledge of exporters by promoting whole-of-system thinking to support stronger self-regulation within Australia's export dairy sector. Module 3 (of 5) focuses on root cause analysis. It covers understanding root cause analysis, systems thinking and continuous improvement practices to enhance problem solving and quality control. More information can be found here.

Further information

Further food safety technical information is available at www.dairysafe.vic.gov.au or by contacting Dairy Food Safety Victoria at info@dairysafe.vic.gov.au

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