SQF INSTITUTE

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# 3rd Party Audits and Regulatory Inspections

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a division of FMI THE FOOD INDUSTRY ASSOCIATION

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Over 30 years of foodservice experience specializing in supply chain food safety and quality assurance.

Currently the Vice President of Technical Affairs for the Safe Quality Food (SQF) Institute responsible for the technical elements of the SQF program including the development, maintenance and technical support of the SQF Code and supporting materials.

Held leadership positions in many food supplier sites in addition to overseeing the ServSafe food safety program at the National Restaurant Association as the Director of Science and Regulatory Relations.

Holds a B.S. in Food Science from Iowa State University and is active with many organizations including GFSI, AFDO and the International Association for Food Protection.

# Objectives

1. Apply more risk-based approaches to conduct quality inspections.
2. Learn how to leverage evidence to support the writing of accurate, valid inspection reports.
3. Understand how to identify special processes and review food safety plans.
4. Identify the signs of an effective pest control system (or not).
5. Improve operator interviewing skills to drive productive conversations and listen effectively.
6. Identify the difference between aggression versus violence, and how to de-escalate potential conflicts to create a calmer environment.
7. Modify body language to offset cultural differences and respect diversity.

# Definitions

**Food Inspection**. Examination of foods to assure wholesome and clean products free from unsafe microbes or chemical contamination, natural or added deleterious substances, and decomposition during production, processing, packaging, etc.

**Audit.** A systematic and independent examination of a site's food safety and/or quality System by a food safety auditor to determine whether food safety, quality systems, hygiene and management activities are undertaken in accordance with that system documentation and comply with the requirements of the relevant food safety code, as appropriate, and to verify whether these arrangements are implemented effectively.

# What do Auditors look for?

- Management responsibility & accountability
- Food Safety fact decisions rather than business decisions
- Employee engagement and knowledge
- Employee actions
- Employee empowerment
- Evidence of continuous improvement

# What do Regulators look for?

Chat it in!

# Top Non-Conformance Comparison

## SQFI- Top 3

Pest Prevention (Critical and majors)

Food Safety Plan (Critical and majors)

Cleaning & Sanitation (Majors and minors)

## Retailers

Food Safety Plan

Food Safety Plan

Food Safety Plan

## FDA Inspections

Develop FSVP- 789

Sanitary Operations- 191

Evaluation- performance, risk (foreign supplier)- 188

Pest Control- 173

Personnel (practices)- 152

Controls- (micro, allergen, contamination)- 146

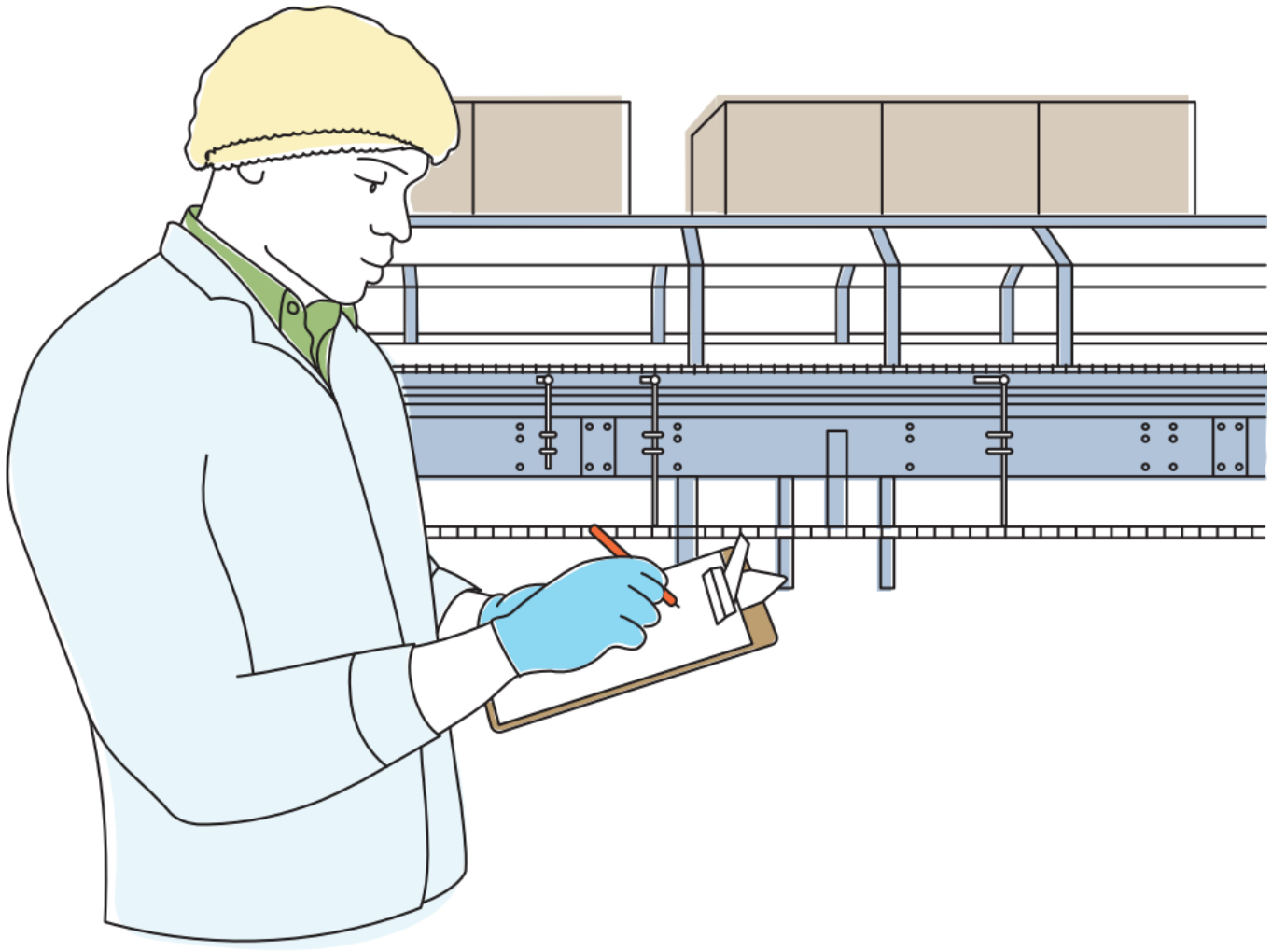
Equipment & utensils- 139

Verification activity before import- 121

Sanitation monitoring- 120

Hazard analysis- 120

# Programs Contributing to Recalls



- Corrective actions
  - Internal non-conformances
  - Customer complaints
- Environmental monitoring
  - Hazards
  - Testing locations
- Change management
  - Supplier specifications
  - Construction controls
  - Contractor monitoring
  - Glass and brittle plastic programs
- Changeovers
  - Label control
  - Mobile equipment placement
- Crisis event reaction
  - Flooding

# Food Safety Plan Issues

- Inadequate hazard analysis and identification of controls.
- Improper identification of the risk.
- Process flow does not reflect the HACCCP plan.
- Lack of monitoring records.
- Not following the HACCP plan.

*Codex definition of Significant hazard: A hazard identified by a hazard analysis as reasonably likely to occur at an unacceptable level in the absence of control, and from which control essential given the intended use of the food.*

# Conduct a Proper Hazard Analysis

- Consider what makes the food safe.
- List the specific hazard.
- Evaluate the severity of the food safety hazard.
- Thoroughly vet the likelihood of occurrence.
- What is the likelihood in the absence of control?
- Be specific about how the hazard manifests itself.
- Two step approach:
  - Hazard analysis for ingredients
  - Hazard analysis for process step

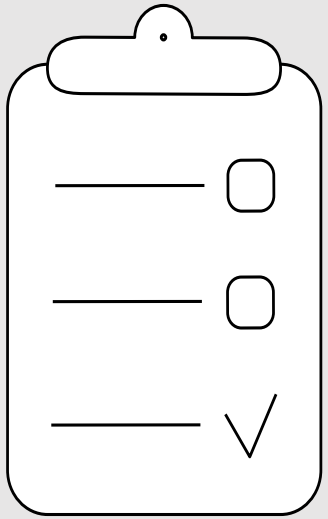
| Risk score | Risk level category |
|---|---|
| 1 to 4 | Low |
| 5 to 10 | Moderate |
| 11 to 18 | High |
| 19 to 25 | Critical |

| Severity | Likelihood: Rare (1) | Unlikely (2) | Possible (3) | Likely (4) | Almost certain (5) |
|---|---|---|---|---|---|
| Catstrophic (5) | Moderate | Moderate | High | Critical | Critical |
| Major (4) | Low | Moderate | High | High | Critical |
| Moderate (3) | Low | Moderate | Moderate | High | High |
| Minor (2) | Low | Low | Moderate | Moderate | Moderate |
| Insignificant (1) | Low | Low | Low | Low | Moderate |

| | | | |
|---|---|---|---|
| Severe | Medium Risk | High Risk | High Risk |
| Moderate | Low Risk | Medium Risk | High Risk |
| Mild | Low Risk | Low Risk | Medium Risk |
| | Unlikely | Possible | Likely |

# Internal Audit- By the Numbers

## EDITION 9- TOTAL NONCONFORMANCES



MINORS
2247
MAJORS
90

## AVERAGE AUDIT SCORES

**AVERAGE OF ALL SITES** 94.76

**SITES WITH A MINOR NON-CONFORMANCE IN INTERNAL AUDIT** 90.83

**SITES WITH A MAJOR NON-CONFORMANCE IN INTERNAL AUDIT** 79.23

# Internal Audit Program

- Do…
  - Use a checklist
  - Report evidence for compliance
  - Corrective actions for non-conformances
- Don’t…
  - Have one person do the audit.
  - Just do a GMP inspection
  - Ignore front line employees

# Types of Actions

## Correction

- Action taken to eliminate a detected non-conformity
- Usually immediate
- Reactive response to something already occurring

## Corrective Action

- Action taken to eliminate the cause of a detected non-conformity
- After the RCA is completed
- Reactive response to something already occurring

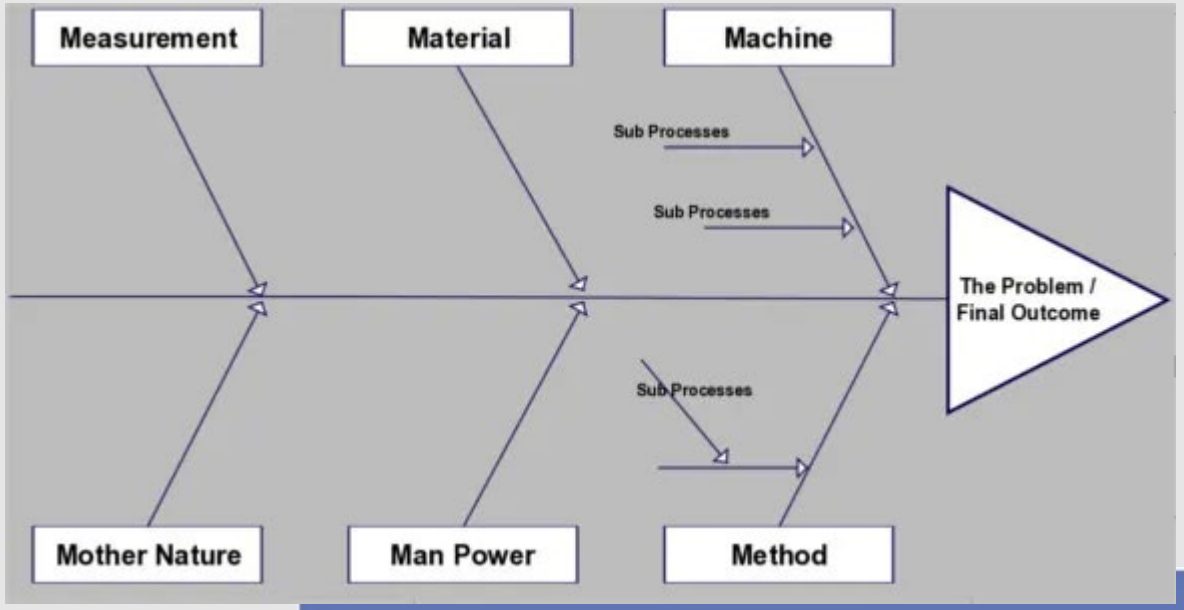
## Preventative Action

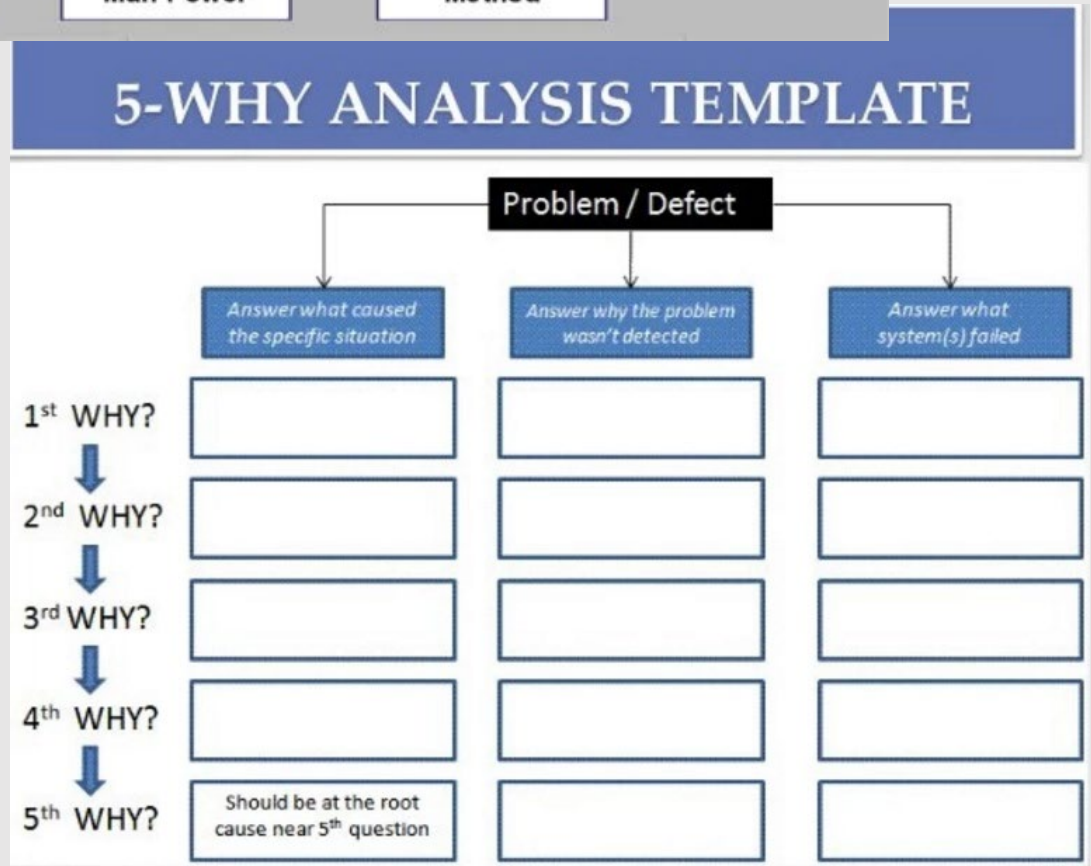
- Action taken to prevent recurrence on similar products and processes
- After the corrective action is identified
- Proactive response to something that has the potential to occur
- Can be used as a part of continuous improvement

# Root Cause Analysis

A method of problem solving to identify and resolve the core issue(s) that cause a non-conformity, deviation, or other adverse food safety or quality event.





# 5-Why Template (3 ways)

**Use of unapproved pesticide (Raid) in the boiler room.**

| Why did it occur? | Why wasn't it detected? | Why did the system allow it to happen? |
|---|---|---|
| There were wasps in the boiler room | The exit door is only used in the event of an emergency. | This boiler room is not part of the monthly GMP inspection |
| There was a gap in the exit door. | Because it is an alarmed door used only when necessary. | The boiler room has limited access. |
| The door seal was worn. | | For food defense purposes, only maintenance has a key to this room. |
| It was old and degraded over time. | | |
| | | |

# Roles and Responsibilities

Same Goal;
Mutually
Complimentary

**How would you rate the relationship between Regulatory and Industry?**

1. Not good- Very adversarial
2. Okay
3. Neutral
4. Good
5. Great- Good partnership.