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CONNECTING THE DOTS FROM HAZARD ANALYSIS TO RISK ASSESSMENT

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AGENDA

01 **Learning Objectives**

02 **Hazard Analysis**

03 **Hazard vs Risk**

04 **Basics of Risk Assessment**

05 **Implementation within SQF Program**

06 **Risk Assessment Example**

LEARNING OBJECTIVES

- Understand hazards
- Review the methodology of risk assessment
- Understand the difference between a risk and a hazard
- Apply the methodology of risk assessment to the implementation of the SQF Code
- Perform a risk assessment



HAZARD ANALYSIS - THE BEGINNING

Conducting a Hazard Analysis, you:

1. Identify and evaluate all the **hazards** that present a **risk** to the food product you are producing, AND
2. Determine how you control these hazards

Hazards are to be identified in:

- Product ingredients / Incoming materials
- Processing steps
- Plant layout

WHAT IS A HAZARD? HOW DO WE ASSESS IT?

Hazard: Any factor that leads to a negative food safety or quality outcome.

Types of Hazards: Biological (pathogen), chemical, physical or a condition resulting from a process, practice or equipment at a facility.

Potential Impact: Effect on consumers and ultimately food industry, suppliers and producers.

HAZARD VS RISK - CONNECTING THE DOTS

Hazard – A factor that may lead to undesirable effects. A substance present in food that has the ability or potential to cause an adverse health effect to the consumer.

Risk – Refers to the probability that these hazards will occur. Consideration of the likelihood of consumption and the nature of severity posed by the hazard.

RISK ASSESSMENT

- Is the process of determining the level of action needed to prevent or eliminate an adverse food safety (quality) event.
- Structured way for you to understand the risks associated with your process.
- Does not have to be overly complicated or time consuming.
- Keep it simple!
 - I. Define Scope
 - II. Identify/Assess Hazards
 - III. Categorize Risks
 - IV. Control Risks

TIP:

The simpler you make it the more effective it usually is.

"IDENTIFY / ASSESS / CONTROL"



Risk Assessment – What does this mean for SQF?

- A risk assessment is a specific requirement in the food safety codes where the SQF practitioner or delegated resources perform a structured approach to identifying, evaluating, and estimating levels of risk to hazards that might be present or reasonably likely to occur in the process.

Risk assessments are the backbone to any functioning food safety system.

Where do we see Risk Assessment in the SQF Code?

Allergen Management – 2.8.1.5

Jewelry – 11.3.3.8

Ice Supply – 11.5.4.2

Detection of Foreign Objects – 11.7.4.2

Approved Suppliers

BASICS OF RISK ASSESSMENT

A structured way to identify, rank and take appropriate steps to address food safety and quality hazards.

A process that determines:



SEVERITY VS LIKELIHOOD

- Severity - How bad is the outcome likely to be?
- Likelihood - what are the chances of the outcome happening?

Risk score	Risk level category	Likelihood				
1 to 4	Low					
5 to 10	Moderate					
11 to 18	High					
19 to 25	Critical					
Severity	Catstrophic (5)	Rare (1)	Unlikely (2)	Possible (3)	Likely (4)	Almost certain (5)
	Major (4)	Moderate	Moderate	High	Critical	Critical
	Moderate (3)	Low	Moderate	High	High	Critical
	Minor (2)	Low	Moderate	Moderate	High	High
	Insignificant (1)	Low	Low	Moderate	Moderate	Moderate

LIKELIHOOD

Likelihood	Highly likely	MEDIUM RISK	HIGH RISK	CRITICAL
	Possible	LOW RISK	MEDIUM RISK	HIGH RISK
	Remote	LOW RISK	LOW RISK	MEDIUM RISK
		Mild	Moderate	Severe
SEVERITY				

THE RISK MATRIX

Clearly define the Risk Matrix for your facility.

Severity Criteria

1. Failure of "XX" is unlikely to pose an immediate risk to the consumer
2. Failure of "XX" is unlikely to pose an immediate risk to the consumer but repeated failure may be a potential risk
3. Failure of "XX" is likely to lead to an immediate health impact, recall

Likelihood Criteria

1. Failure is unlikely to happen or rare
2. Failure can happen but not too frequently
3. Failure is likely to happen, often frequent

THE RISK MATRIX

Clearly define the **Outcome and Decisions** –
Examples:

1. Cleaning frequencies
 - **LOW** – Cleaning frequency monthly
 - **MEDIUM** – Cleaning frequency weekly
 - **HIGH** – Cleaning frequency daily
2. Audit frequencies
 - **LOW** – Audit frequency set to 12 months
 - **MEDIUM** – Audit frequency set to 6 months
 - **HIGH** – Audit frequency set to 3 months



HOW DO I START A RISK ASSESSMENT

Questions:

- What is the potential for product contamination?
- How is the product protected?
- How likely are we to ship contaminated product?
- Is there a visible measure to identify contaminated product?
- How effective are these controls?
- What is the reason for changing/reducing procedure/policy?
- Is there a chance for food safety to be compromised?
- Will exclusion affect any other areas of food safety program?

HOW TO START ON SEVERITY

- What would happen if contaminated food product is ingested?
- Have all vulnerable groups been considered? I.e., allergies, small children
- Is it likely to cause serious harm? Death?

HOW TO START ON LIKELIHOOD

- How likely is this to occur?
- What is the ease at which this can happen intentionally?
- Have there been any Recalls causing adverse effects?
- History in the facility?
- History with Supplier?

RISK ASSESSMENT EXAMPLES

SQF



“Do we need to do an Allergen Changeover between Products”

Scope: Do we need to do a wet clean between allergen runs?

Risks: i) Cross contamination, ii) Potential Recall – illnesses, iii) Product build up (spills)

Records Reviewed: GMP Audits, MSS, Internal Audit, Complaints, Recalls

Identify Risk Level: Likelihood: HIGH Severity: HIGH

Outcome: An allergen wet clean is required between runs of different allergens.

“Do we need to do an Allergen Changeover between Products”

Outcome and Decisions

LOW RISK – No allergen clean needed.

MEDIUM RISK – Visual check of line / remove excess product build up

HIGH / CRITICAL RISK – Complete allergen wet clean

"Do we need to do an Allergen Changeover between Products"

Identify Risk Level: Likelihood: **LIKELY** Severity: **SEVERE**

THE RISK MATRIX

Likelihood	Likely			High Risk
	Possible		Medium Risk	
	Unlikely	Low Risk		
		Mild	Moderate	Severe

Severity

Outcome: HIGH RISK - Allergen clean required between allergen runs. .

“DOES PALLET RACKING NEED TO BE 18” FROM THE OUTSIDE WALL”

Scope: Can we move the pallets closer to the wall to have more storage space in the warehouse?

Risks: i.) Not able to clean behind pallets, ii.) Potential pest infestation in pallets stored by wall, iii.) Product build up (spills)

Records Reviewed: GMP Audits, MSS, Internal Audit, Complaints, Pest Control

Identify Risk Level: Likelihood: HIGH Severity: LOW

Outcome: Pallets cannot be moved against the outside wall but can be moved to within 9” of the outside wall. This will allow for inspection, cleaning, and pest control inspections.

“DOES PALLET RACKING NEED TO BE 18” FROM THE OUTSIDE WALL”

Outcome and Decisions

- LOW RISK – Move the pallets directly against the wall
- MEDIUM RISK – Allow for pallet to move closer but not directly up against
- HIGH/CRITICAL RISK – Pallets cannot move and must stay 18” from wall

“DOES PALLET RACKING NEED TO BE 18” FROM THE OUTSIDE WALL”

Identify Risk Level: Likelihood: **LIKELY** Severity: **MILD**

THE RISK MATRIX

Likelihood	Likely			High Risk
	Possible		Medium Risk	
	Unlikely	Low Risk		
		Mild	Moderate	Severe

Outcome: MEDIUM RISK Pallets cannot be moved against the outside wall but can be moved to within 9” of the outside wall. This will allow for inspection, cleaning, and pest control inspections.

Q&A



THANK YOU!

DOWNLOAD THE RISK
ASSESSMENT GUIDE

<https://www.nsf.org/knowledge-library/gfsi-compliance-risk-assessment>

