Guidance for GMP Risk Assessments

Packinghouse, Storage & Distribution, Cooling & Cold Storage, Processing

Risk assessment: An evaluation of specific characteristics of an operation to determine whether sufficient measures exist to control hazards or whether additional measures are necessary to control the identified hazards.

Hazard: Any biological, chemical (including allergens) or physical agent that has the potential to cause harm, injury or illness. Food safety hazards may occur naturally, be unintentionally introduced or intentionally introduced.

Severity: The magnitude of a hazard or the degree of consequences that can result when a hazard exists.

Likelihood: The probability of a food safety hazard or serious failure in the food safety system occurring i.e., frequency.

Risk: A function of the probability of a hazard occurring, frequency or likelihood and the severity or consequence (s) of that hazard. Risk is a combination of likelihood/probability and severity/consequence related to an identified hazard.

Significance: Similar in meaning to Risk. Significance is a function of or combination of likelihood/probability and severity/consequence.

Risk assessments are required to evaluate food safety measures and support a functioning food safety management system. In PrimusGFS, they are a required part of the audit scheme.

A risk assessment helps an operation focus on the risks that have the potential to cause real and serious harm. While there are different methods of conducting a risk assessment, this document describes the principles for conducting any risk assessment.

This is only a guideline and there are other risk assessment methods that are more detailed for more complex risks and/or situations. Use of this document does not guarantee compliance and/or corrective action acceptance.

One approach to completing and documenting a risk assessment:

1) Identification of hazards at any process step or location. The operation should consider any biological, chemical (including allergens) or physical hazards that could occur and what can cause them. Consider all hazards that are likely to occur in the absence of controls. For conducting a risk assessment of a process or activity, start with listing each of the steps. For a site, area or location, list the potential hazards or environmental factors that could have an impact on the site, area or location.

2) Evaluate the potential for any type (biological, chemical, physical) of hazard to occur at a step (such as associated with a process) or associated with an environmental factor (such as associated with activities around the site of an operation). It is important to consider the potential for a hazard or hazards to occur **IN THE ABSENCE** of any control. It is incorrect to fail

to identify a hazard due to a control that you may have in place. A control may be in place, but it is implemented because there is a perceived hazard. When conducting a risk assessment, it is important to identify the hazards irrespective of any controls because the ultimate objective of the risk assessment is to develop the appropriate control(s) in line with the level of risk associated with a hazard.

3) Evaluate the **probability** or **likelihood** for each of the identified hazards to occur – again, **IN THE ABSENCE** of a control. Utilization of a risk assessment matrix or similar tool (such as shown below) is helpful. Consider available scientific as well as industry experience when determining the probability/likelihood.

4) Evaluate the **consequence** or **severity** for each of the identified hazards if they actually should occur – again, **IN THE ABSENCE** of a control. Utilization of a risk assessment matrix or similar tool (such as shown below) is helpful. Consider available scientific as well as industry experience when determining the result of this evaluation.

5) Estimate the overall risk level of the hazard(s) identified using a likelihood vs severity risk assessment matrix or similar tool such as the examples shown below.

6) Identify and implement controls or mitigation measures to address those hazards where the risk level indicates the need for a control to protect the safety of the product(s) or site/location. The control(s) identified must be capable of controlling the hazard(s) identified and there should be a system in place to monitor these controls to both ensure they are being implemented as well as actually working as intended.

7) Document how the risk assessment was developed and implement the controls/actions taken. Results of implementing controls should show that the identified risks have been dealt with and controlled to an acceptable level.

8) Review and update the risk assessment at least annually to identify any factors that warrant update(s) and/or when any significant change(s) occur.

Risk Matrix – Example 1

The multiplication of the **Probability** by the **Severity** to give an estimate of **Risk** and whether it is a significant concern.

Likelihood of Occurrence

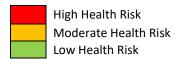|		Low	Medium	High
Severity	High	H/L	H/M	H/H
	Medium	M/L	M/M	M/H
	Low	L/L	L/M	L/H

Severity in this instance it is categorized as **High** (the presence of the hazard will result in unsafe food, death or major injury may occur), **Medium** (the presence of the hazard may result in unsafe food, will not cause long-term effects) and **Low** (the presence of the hazard is unlikely to result in unsafe food).

Likelihood in this instance it is categorized as **High** (high probability of occurring), **Medium** (average probability of occurring) and **Low** (unlikely probability of occurring).

After rating each point, the multiplication of the severity and probability rating determines whether a point is high, medium or low with regard to significance/risk level.

Key:

🟥	High Health Risk
🟧	Moderate Health Risk
🟩	Low Health Risk

The information gathered from the hazard analysis is used to determine:

- The severity of the hazard
- Risks associated with hazards identified at various stages of the operation.
- The points, steps or procedures at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level, i.e., critical control points (CCPs).

Risk Matrix – Example 2

		Consequence				
		Negligible 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
Likelihood	Almost certain 5	Moderate 5	High 10	Extreme 15	Extreme 20	Extreme 25
	Likely 4	Moderate 4	High 8	High 12	Extreme 16	Extreme 20
	Possible 3	Low 3	Moderate 6	High 9	High 12	Extreme 15
	Unlikely 2	Low 2	Moderate 4	Moderate 6	High 8	High 10
	Rare 1	Low 1	Low 2	Low 3	Moderate 4	Moderate 5

Example

Process Step	Potential Hazards	Likelihood of Hazard to occur	Severity of Hazard	Risk of Hazard	Hazard a Significant Risk?	Reason/Justification for the Risk Level & Significance Determination	Control measures applied to reduce, prevent or eliminate Hazard	CCP?
Flume Wash with Anti-microbial Treatment	Biological: Pathogens (*L. monocytogenes, Salmonella*, Shiga-toxin producing *E. coli, Shigella*, hepatitis A virus, norovirus, and *Cyclospora cayetanensis*)	Medium	High	High	Yes	Previously contaminated product cross contaminates product in wash water system.	Automated PAA addition with manual monitoring every 30 minutes. Worker Training	**YES CCP 1**
	Chemical: No significant							No
	Physical: Foreign material	Low	Low	Low	No	Foreign material from field or equipment.	Supplier Program Pre-operational Inspection Preventive Maintenance Program Worker Training Metal detection at subsequent step	No