

<p>Enter Company Logo Here</p> <p>Enter Company Address Here</p>	Risk Assessment Template	
	Document #:	Effective Date:
	Author: Kellerman Consulting	Supersedes: N/A
	Approved By:	Revision #: Original

Risk Assessment Purpose:

The purpose of this worksheet is to show risk assessment and the rationale associated with the facility choosing to review specific potential hazards and impacts on product safety and quality. The product safety and quality risk analysis are completed based on Severity and Probability of a potential problem and is rated on a scale **(1-4) and NULL** if it does not apply.

Hazards to be considered, where relevant:		
M	Microbiological	Substances produced by organisms that pose a threat to human health.
P	Physical	Foreign object found in, on or around the product
C	Chemical	Chemical compounds or allergens that are unintentionally or incidentally present
R	Recycled materials	Concerns about product made from recycled matter
L	Legality	Act, agreement, or contract that is not consistent with the law
Q	Quality	Certain standards that fail to achieve uniformity of a product
CS	Defects critical to consumer safety	Defects deemed to be hazardous or unsafe
FI	Functional integrity	Performance likely to create failure for its intended purpose
UM	Unintended migration of substances	Transfer of substances, residues of processing chemicals, impurities into food contact material
MI	Malicious intervention	The intent, without just cause or reason, to commit a wrongful act that will result in harm to another

Product Safety	
Severity Definitions	Probability / Frequency Definitions
Minor – Insignificant	Unlikely - Rare chance of occurrence, some possibility exists
Serious – Could result in a customer complaint or packaging safety non-compliance	Possible - Moderate chance of occurring
Major – Product Recall or Agency Action	Probable - Could occur or may have occurred in the past
Critical – Fatality/Serious Illness	Very Likely - Common occurrence

Product Quality	
Severity Definitions	Probability / Frequency Definitions
FYI – Informational	Unlikely - Rare chance of occurrence, some possibility exists
Complaint #1 - Product quality customer grievance w/ non-credit	Possible - Moderate chance of occurring
Complaint #2 - Product quality customer rejection w/ credit	Probable - Could occur or may have occurred in the past
Loss of Business – Commerce forfeiture	Very Likely - Common occurrence

		Probability / Frequency			
		Unlikely	Possible	Probable	Very Likely
Severity	Minor	1	1	1	2
	Serious	1	2	3	3
	Major	2	3	3	4
	Critical	3	4	4	4

		Probability / Frequency			
		Unlikely	Possible	Probable	Very Likely
Severity	FYI	1	1	1	2
	Complaint #1	1	2	3	3
	Complaint #2	2	3	3	4
	Loss of Business	3	4	4	4

Risk Level 1	Risk Level 2	Risk Level 3	Risk Level 4
<p>These hazards will not create a significant risk for product safety or quality. Therefore, additional actions are not required for this risk level.</p>	<p>The Food Safety or Quality Team may need discussion of risk and evaluation of fundamental programs to maintain the hazard at a Level 2. This risk level is low, and no further actions may be required.</p>	<p>At this risk level an additional evaluation is required. The Food Safety Team must discuss risk and perform further hazard analysis to determine if a Critical Control Point exists. Hazard Evaluation must be completed for this risk level.</p> <p>This risk level is at the high end of the spectrum. The Product Quality Team should have a discussion of potential risk and evaluate the fundamental programs which mitigate a Critical Quality Point.</p>	<p>At this risk level an additional evaluation is required. The Food Safety or Quality Team must discuss risk and perform further hazard analysis to determine if a Critical Control Point exists. Hazard Evaluation must be completed for this risk level. This will likely be identified as a Critical Control Point (CCP) or a Critical Quality Point (CQP).</p>

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	Process Step	Hazard	Controls/Preventive Measures	Risk Level
Product Safety				
Product Quality				
Product Safety				