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| **Enter Company Logo Here**    **Enter Company Address Here** | **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.

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| **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 |

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| **Product Safety** | |  | **Product Quality** | |
| **Severity Definitions** | **Probability / Frequency Definitions** |  | **Severity Definitions** | **Probability / Frequency Definitions** |
| **Minor** – Insignificant | **Unlikely** - Rare chance of occurrence, some possibility exists |  | **FYI** – Informational | **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 |  | **Complaint #1**- Product quality customer grievance w/ non-credit | **Possible** - Moderate chance of occurring |
| **Major** – Product Recall or Agency Action | **Probable** - Could occur or may have occurred in the past |  | **Complaint #2** - Product quality customer rejection w/ credit | **Probable** - Could occur or may have occurred in the past |
| **Critical** – Fatality/Serious Illness | **Very Likely** - Common occurrence |  | **Loss of Business** – Commerce forfeiture | **Very Likely** - Common occurrence |

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|  |  | **Probability / Frequency** | | | |  |  |  | **Probability / Frequency** | | | | |
|  |  | **Unlikely** | **Possible** | **Probable** | **Very Likely** |  |  |  | **Unlikely** | **Possible** | **Probable** | **Very Likely** |
| **Severity** | **Minor** | **1** | **1** | **1** | **2** |  | **Severity** | **FYI** | **1** | **1** | **1** | **2** |
| **Serious** | **1** | **2** | **3** | **3** |  | **Complaint #1** | **1** | **2** | **3** | **3** |
| **Major** | **2** | **3** | **3** | **4** |  | **Complaint #2** | **2** | **3** | **3** | **4** |
| **Critical** | **3** | **4** | **4** | **4** |  | **Loss of Business** | **3** | **4** | **4** | **4** |

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| **Risk Level 1** | **Risk Level 2** | **Risk Level 3** | **Risk Level 4** |
| These hazards will not create a significant risk for product safety or quality. Therefore, additional actions are not required for this risk level. | 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. | 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.  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. | 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). |

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