

# SUPPLIER ASSURANCE

## FOOD MANUFACTURING AUDIT STANDARD

### PROGRAM REQUIREMENTS MANUAL

JANUARY 1, 2018

<b>Version – Revision:</b>	1.4
<b>Authorized By:</b>	Nicole James
<b>Date:</b>	January 1 2018
<b>Created By:</b>	Nicole James
<b>Scheme/Customer:</b>	SAA Food Safety Expectations and Criteria for Food Processing



## REVISION HISTORY

Version	Date	Author	Description
1.4	January 1, 2018	Nicole James	<ul style="list-style-type: none"> <li>• Updated formatting, layout, sentence structure and grammar</li> <li>• Change in title</li> <li>• Merge of B1 audit type version 1.3 with NSF-GFTC FSQS version 14</li> <li>• Inclusion reference to customer, industry best practices and global regulatory requirements</li> <li>• Updated allergen list and addition of FARRP international allergen list</li> <li>• Inclusion of traceability activity for audit</li> <li>• Inclusion of wood requirement</li> <li>• Inclusion of food fraud references</li> </ul>
1.3	May 3, 2014	NSF International	Food Safety Expectations and Criteria for Food Processing Facilities

# 1 TABLE OF CONTENTS

<b>2 INTRODUCTION .....</b>	<b>6</b>
<b>3 DOCUMENTATION .....</b>	<b>7</b>
<b>4 TERMS AND DEFICIENCY CLASSIFICATIONS.....</b>	<b>9</b>
<b>5 SCORING GUIDELINES .....</b>	<b>12</b>
<b>Corrective Action and Improvement .....</b>	<b>14</b>
<b>Repeat Deficiencies.....</b>	<b>14</b>
<b>6 EXPECTATIONS OF THIS STANDARD .....</b>	<b>15</b>
<b>A: ADMINISTRATION &amp; REGULATORY COMPLIANCE .....</b>	<b>15</b>
A1. Administration, Management and Organization.....	15
A2. Regulatory Compliance .....	16
A3. Product Identification and Traceability .....	16
A4. Recordkeeping and Retention.....	18
A5. Crisis and Natural Disaster Management.....	19
A6. Customer/Consumer Complaint Management .....	19
<b>B: HACCP.....</b>	<b>20</b>
B1. Preliminary Tasks.....	20
B2. Hazard Analysis (HACCP Principle 1) .....	21
B3. Critical Control Points (Principle 2) .....	22
B4. Critical Limits (Principal 3) .....	23
B5. CCP monitoring (HACCP principle 4) .....	23
B6. Corrective Actions (HACCP Principle 5) .....	23
B7. Verification and Validation (HACCP Principle 6).....	24
B8. Documentation and Record Keeping (HACCP Principle 7) .....	24

<b>C. FACILITIES &amp; EQUIPMENT.....</b>	<b>26</b>
C1. Water, Steam and Ice .....	26
C2. Plant Construction, Design and Condition.....	27
C3. Plant Condition (state of repair, cleanability).....	28
C4. Employee facilities.....	28
C5. Hand washing facilities .....	28
C6. Equipment Layout, Design and Condition .....	29
C7. Utensils.....	30
C8. Plant lighting.....	30
C9. Maintenance Standards .....	30
<b>D. CLEANING, SANITATION, HOUSEKEEPING, HYGIENE .....</b>	<b>32</b>
D1. Cleaning and Sanitation .....	32
D2. Personal Hygiene and Good Manufacturing Practice .....	33
D3. Self Inspection .....	34
<b>E. RODENT AND PEST CONTROL MANAGEMENT .....</b>	<b>35</b>
E1. Pest Control .....	35
<b>F. APPROVED SUPPLIERS, RECEIVING, STORAGE, SHIPPING, INVENTORY CONTROL.....</b>	<b>37</b>
F1. Approved Supplier Program .....	37
F2. Vehicle and Materials Inspection.....	38
F3. Storage, Temperature and Inventory Control .....	39
F4. Product Release, Retained Product and Returns.....	39
<b>G. PROCESS &amp; PRODUCT EVALUATION .....</b>	<b>41</b>
G1. Specification and Formulation Control .....	41

G2. Verification of Operational Equipment and Measuring Devices.....	42
G3. Allergen Management Program.....	42
<b>H. Foreign Material Control .....</b>	<b>44</b>
H1. Foreign Material Control.....	44
<b>I. Chemical Control.....</b>	<b>47</b>
I1. Chemical Control .....	47
<b>J. PACKAGING &amp; LABELING.....</b>	<b>48</b>
J1. Packaging and Labeling .....	48
<b>K. TRAINING REQUIREMENTS.....</b>	<b>49</b>
K1. Training.....	49
<b>L. LABORATORY SUPPORT.....</b>	<b>51</b>
L1. Laboratory Support.....	51
<b>M. FOOD DEFENSE .....</b>	<b>52</b>
M1. Food Defense .....	52
<b>N. READY-TO-EAT (RTE), HIGH RISK/HIGH CARE FOOD PROCESSING REQUIREMENTS .....</b>	<b>54</b>
N1. Ready-To-Eat Food Processing.....	54
<b>7 DEFINITIONS.....</b>	<b>56</b>
<b>8 APPENDIX.....</b>	<b>61</b>
<b>Product Zone Decision Tree .....</b>	<b>61</b>

## 2 INTRODUCTION

NSF International's Supplier Assurance audit for food manufacturing facilities focusses on the development, implementation and control of systems that impact Food Safety, Food Quality and Food Defense. The expectations outline the management programs and performance criteria expected for a modern food processing facility to meet the basic food safety, quality, and defense requirements of the public, regulatory agencies and customers.

The expectations are considered essential to producing safe, wholesome and quality products on a consistent basis. Demonstrating consistent conformance with these expectations is the expectation of our clients.

The audit evaluates the adequacy of documentation, compliance to documented procedures, and effectiveness of procedures to control the process within defined limits and the ability to implement corrective and preventive action plans.

This manual provides criteria and expectations that the facility will be audited against and is generic for all types of food processing establishments. Some specific criteria may not be applicable. It is the responsibility of the manufacturer to justify that a specific criterion is not applicable. Likewise, additional criteria may be applied based on changing regulatory requirements, specific client needs or the ever-changing food safety and food defense environment. Food defense is the terminology used to describe the actions that need to be implemented to prevent the intentional tampering with product to cause harm to the consuming public.

Manufacturing plants located outside the U.S.A. and exporting to the U.S.A. shall meet customer expectations and FDA/USDA regulatory requirements. Where these expectations are applied in other jurisdictions for food not intended for export to the U.S.A., the regulations and customer expectations in those jurisdictions shall apply.

The following expectations and supporting documentation are based on customer specifications, industry best practices and regulatory Acts, Amendments and Regulations, including, but not limited to, those enforced by agencies globally.

## 3 DOCUMENTATION

### DOCUMENTS REVIEWED DURING THE AUDIT

This list is to provide guidance to the type of documents and procedures the auditor may ask to review during the audit. There may be additional documents, policies and procedures requested that are not included in this list. Some of these documents may not apply to every type of facility. When policies are stored electronically or held at a corporate location, it is the facility's responsibility to demonstrate to the auditor that they are aware of where and how to access documents related to the facility's operations, policies and procedures.

#### ADMINISTRATION AND REGULATORY COMPLIANCE

- Plant management organization chart and QA responsibilities
- Food Safety and Quality Policies and Procedures Manual
- Product list or proposed product list for client
- Product specifications for client or plant product specifications
- Policy and documentation of management and employee training
- Detailed Product Recall Manual, including records of mock recalls
- Regulatory compliance policies and documents of regulatory visits or comments
- Document management and record keeping policies and procedures
- Change management policies to address changes in management, process or product specifications
- Emergency or catastrophic event product management program
- Policy compliance and effectiveness review program
- Consumer complaint policy & procedures and records

#### HACCP MANAGEMENT

- Current, signed HACCP Plan with team members designated
- HACCP Team member credentials
- Documented records of HACCP team program oversight
- Plans are available for auditor review
- Flow Chart of process
- Hazard analysis and documentation
- Critical Control Point (CCP) validation, including application of relevant process capability evaluations
- Monitoring and Corrective Action policies and documentation
- Rework policies and procedures in HACCP plan and Flow Chart
- Records Management & Security policies
- Verification and Validation procedures and documentation
- Prerequisite program documentation and performance records

**NOTE:** HACCP Plan shall include the following:

- Identification of HACCP team
- Description of the food and its distribution
- Description of customer and intended use
- Documented detailed hazard analysis for all ingredients, process steps and products
- Detailed process flow charts, showing all inputs, outputs, and product rework/recycle pathways
- Annual review (at minimum) by HACCP team and signed by the most senior on-site executive responsible for the facility and its operation

**NOTE:** If a specific client allows a facility's deviation from an expectation or specification of this document, the facility shall obtain written approval from the client for the variance/deviation prior to the audit process. This approval shall be made available to the auditor during the audit process. Variances are in effect for one calendar year from the date of issuance or as specified by the client.

## 4 TERMS AND DEFICIENCY CLASSIFICATIONS

Within the expectations of this Standard, the following terms have these meanings:

- **Shall** – An absolute requirement.
- **Should** – A strong suggestion for a component of a Food Safety/Quality System.
- **Annually** - a 12 month period.

The audit report will not contain recommendations or suggestions for enhancement for improvement, nor will non conformances be cited for situations where best practices are not implemented in a facility (provided that the expectations of this Standard are being met). Conversely, no additional points are awarded in this audit as a result of best practices. The audit is intended as an objective assessment of the food safety management programs in a food facility.

The auditor will evaluate documented policies and procedures, past and present monitoring records and facility conditions and practices as they exist at the time of the visit. Ratings and scoring will be based on these observations. Corrective actions taken during the audit will not remove any non-conformance observations nor change the scoring, but the auditor will document those immediate corrective actions in the audit report. Any documentation provided to the auditor after the conclusion of the exit meeting will not change scoring.

**“Acceptable”** ratings are awarded when the element being audited meets or exceeds the applicable expectation.

**“Non-conformance”** is the assessment made when:

- a. The element being audited does not fully meet expectations of an element.
- b. Improvements are required to meet the expectation.

**“Major Non-conformance”** is the assessment made when:

- a. Deficiencies of an element present a high probability of food safety or regulatory failure.
- b. Significant improvement is needed to meet the expectations.
- c. HACCP requirements have not been fully documented or implemented
- d. An element of the standard has not been documented (if required) or implemented
- e. A situation is observed where, based on objective evidence, there is significant doubt as to the conformity of product being supplied.
- f. There are numerous findings of non-conformance that indicate a lack or failure in a required section and a potential risk to product safety, quality or regulatory non-compliance exists.

**“Critical Non-conformance”** is the assessment made when:

- a. There is clear objective evidence of or direct observation that product is unsafe, could potentially cause serious illness or death or is a risk to health and is subject to a Class I or Class II recall.

- b. There is a complete failure to meet an **ESSENTIAL** element of the expectations as listed in the **ESSENTIAL** Elements Chart in this section.

**Any Critical Non-conformance will result in a failure of the audit.**

Some expectations of this Standard are identified as **ESSENTIAL**. A complete failure to meet the intent of these expectations shall be assessed as a critical non-conformance and cause audit failure.

The following are **ESSENTIAL** elements in the Supplier Assurance Expectations:

A3.5 Traceability.	The lack of any system to trace ingredients and finished product as per regulatory requirements and customer expectations shall be assessed as a Critical Non-conformance
A 4.2 Records.	Evidence of intentional record falsification shall be assessed as a Critical Non-conformance.
B 6.1 Specific correction actions to deal with deviations shall be in place for each CCP.	Failure to take corrective action for a critical limit deviation shall be assessed as a Critical Non-conformance.
C 1.1. Potability of water, ice and steam supply.	Use of non-potable water as part of or in contact with food, food contact equipment or other inappropriate use shall be assessed as a Critical Non-conformance.
C2.2 Plant construction and layout is not a source of contamination	Any condition in the facility that, on the basis of objective evidence or observation, results in product or raw material contamination and adulteration shall be assessed as a Critical Non-conformance.
C6.1 Equipment is not a source of contamination.	Finding through observation or on the basis of objective evidence that equipment or food contact materials are unsuitable for use with food or that equipment condition is a cause of product contamination shall be assessed as a Critical Non-conformance
C 9.2 Equipment affecting food safety is effectively calibrated.	Equipment found to be out of calibration leading to potential for illegal or unsafe food shall be assessed as a Critical Non-conformance.
H 1.4 Metal detection systems shall be managed.	
E1.3 Pests are not a source of contamination.	Observation of pests on or in ingredients, packaging, work in process, or finished goods shall be assessed as a Critical Non-conformance.
G3. Allergen Management is effective.	Evidence of cross-contact with allergens that will result in a threat to health and would result in a Class I or Class II recall

	<p>shall be assessed as a Critical Non-conformance.          Mislabeled product contain regulated allergens that are not declared on the label shall be assessed as a Critical Non-conformance.</p>
J1.1 Product is not misrepresented on labels.	Evidence of systematic use of incorrect labels that misrepresent the product shall be a Critical Non-conformance.
J1.2 Product declared quantities meets regulations.	Evidence of failure to meet regulatory standards for quantities on product shipped shall be a Critical Non-conformance

## 5 SCORING GUIDELINES

### EXPLANATION OF SECTION SCORINGS:

Section scorings in the below table are provided as a reference and are calculated on the following formula:

- **Non-Conformance** = deduction of 5% per finding
- **Major Non-Conformance** = deduction of 25% per finding
- **Critical** = deduction of 100%

Section	Non Conformance	Major Non Conformance	Critical	Section Score (%)
ADMINISTRATION AND REGULATORY COMPLIANCE	0	0	0	100
HACCP	0	0	0	100
FACILITIES AND EQUIPMENT	0	0	0	100
SANITATION, HOUSEKEEPING AND HYGIENE	0	0	0	100
RODENT AND PEST CONTROL MANAGEMENT	0	0	0	100
APPROVED SUPPLIERS, RECEIVING, STORAGE, SHIPPING, INVENTORY CONTROL	0	0	0	100
PROCESS AND PRODUCT EVALUATION	0	0	0	100
FOREIGN MATERIAL CONTROL	0	0	0	100

CHEMICAL CONTROL	0	0	0	100
PACKAGING & LABELING	0	0	0	100
TRAINING REQUIREMENTS	0	0	0	100
LABORATORY SUPPORT	0	0	0	100
FOOD DEFENSE	0	0	0	100
READY TO EAT FOODS PROCESSING REQUIREMENTS	0	0	0	100

### EXPLANATION OF OVERALL AUDIT RESULT:

The overall score result is based on the total number and level of non-conformances. The overall audit is allocated 100% and deductions made as follows:

- **Non-Conformance** = 1% deduction per finding off the total score
- **Major Non-conformance** = 10% deduction per finding off the total score
- **Critical Non-conformance** = 25% deduction per finding off the total score

FINAL AUDIT RATING	BASED ON SCORE
Meets Expectations	100-95%
Needs Improvement	94-85%
Significant Improvement Needed	84-76%
Fail	≤ 75%

While a score is provided for this report, NSF strongly recommends putting the emphasis on identification and correction of non-conformances, so as to drive continuous improvements in food safety. NSF also offers an un-scored version of this Supplier Assurance Audit

**Scoring Example 1**

Section A contains 2 nonconformance ratings and Section B contains 1 major non-conformance, giving Section Scores for Section A = 90% and Section B = 75%. If there are no further non-conformances then the overall audit score is 88% (-2% for the 2 non-conformances and -10% for the major nonconformance) and the overall audit rating is "Needs Improvement"

**Scoring Example 2**

The audit identifies one major non- conformance in Section C (75% Section Score) and one major non- conformance in Section D (75% Section Score) and 2 non-conformances in Section N (90% Section Score). If there are no further non-conformances then the overall audit score is 78% (-2% for the 2 non-conformances and -20% for the 2 major non-conformances) and the overall audit rating is "Significant Improvement Needed"

**CORRECTIVE ACTION AND IMPROVEMENT**

Improvements and Corrective actions for any finding noted in this audit should be implemented and documented. The findings noted in the audit should be evaluated and reviewed regardless of the numerical score.

Corrective action is defined as the correction of the immediate problem as well as prevention of reoccurrence of the problem.

**REPEAT DEFICIENCIES**

Repeat assessments of non-conformance, where the facility has not taken corrective action to effectively address previously cited deficiencies in the most recent NSF International Supplier Assurance audit, will be noted by the auditor in the report. Repeat non-conformance ratings may cause an additional downgrade of the audit question's rating, depending on nature of the deficiency and its impact on food safety at the facility. In addition, repeat non-conformances without effective correction actions taken shall be reflected as a non-conformance against management commitment (A1.3)

## 6 EXPECTATIONS OF THIS STANDARD

### A: ADMINISTRATION & REGULATORY COMPLIANCE

#### A1. ADMINISTRATION, MANAGEMENT AND ORGANIZATION

1.1. THERE SHALL BE A PLANT MANAGEMENT ORGANIZATION CHART INDICATING THE REPORTING STRUCTURE OF THE PLANT OPERATING DEPARTMENTS.

- a. There shall be an up to date organizational chart outlining the organizational structure.
- b. There shall be a suitably trained member of the facility's management team available at all times during production hours.

1.2. THERE SHALL BE IMPLEMENTED AND DOCUMENTED POLICIES AND PROCEDURES THAT ADDRESS RELEVANT FOOD SAFETY, QUALITY AND SECURITY REQUIREMENTS FOR THE RECEIVING, HANDLING, MANUFACTURING AND SHIPPING OF PRODUCT.

- a. A quality assurance program shall be fully described and include a food safety, quality and security policy and key quality measurables (such as key performance indicators) that drive continuous improvement at the facility.
- b. The plant shall have documented policies and procedures covering all aspects of ingredient receipt, food manufacture, and storage and shipping. These policies and procedures shall be well organized, available, current, dated and approved by an authorized person.
- c. Policies and procedures shall be reviewed for effectiveness annually with reporting on this review to the facility's senior management.
- d. The plant shall have a documented policy to manage change. The policy shall describe how to effectively communicate changes in personnel and changes in documents (such as specifications, policies, and procedures) and records to all levels of the facility's organization.

1.3. THERE SHALL BE MANAGEMENT COMMITMENT AND ACTIVE SUPPORT OF THE FACILITY'S FOOD SAFETY, QUALITY AND SECURITY SYSTEMS.

- a. Adequate financial and staffing resources shall be provided for food safety, product quality, and security programs, as well as for overall facility and equipment upkeep.
- b. There shall be management participation in the audit process and a commitment to the completion of corrective actions resulting from both outside and internal audits and inspections.
- c. There shall be documented management reviews (internal audits) to assess the level of conformance to operational policies. Management reviews of internal audits shall be conducted at least annually.

---

## **A2. REGULATORY COMPLIANCE**

---

### **2.1. A FILE OF REGULATORY AUDIT VISITS AND REPORTS SHALL BE MAINTAINED.**

- a. The facility shall maintain a file of regulatory actions, visits, reports or other notifications received from any regulatory agency.
- b. Written responses with appropriate corrective actions shall be documented.
- c. The facility shall provide copies of the above reports to the auditor for evaluation of corrective and preventive actions.

---

### **2.2. THE FACILITY SHALL HAVE A DOCUMENTED PROCESS FOR THE IDENTIFICATION OF REGULATIONS THAT ARE APPLICABLE TO THEIR SPECIFIC PROCESS. THIS PROCESS SHALL INCLUDE IDENTIFICATION OF REGULATIONS FOR PRODUCTS IN COUNTRIES IN WHICH THE FACILITY'S PRODUCTS ARE EXPORTED.**

- a. The facility shall have a documented procedure outlining how they ensure that all regulatory requirements are met for all applicable processes. The procedure shall also include how the facility ensures regulatory requirements are met when products are exported to other countries. The facility shall be able to show that they are properly licensed to operate.

---

## **A3. PRODUCT IDENTIFICATION AND TRACEABILITY**

---

### **3.1. THERE SHALL BE A DOCUMENTED, CURRENT AND IMPLEMENTED PLANT SPECIFIC RECALL PLAN.**

- a. The recall manual shall be current and include a detailed process of how complaints, information or crises leading to withdrawal, recalls or potential recalls are processed.
- b. Recall procedures shall include investigation, analysis and corrective and preventive action where appropriate.
- c. Decision making protocol, risk assessment guidelines, documents and individuals responsible for the recall execution shall be clearly stated.

---

### **3.2. RECALL MANAGEMENT RESPONSIBILITY SHALL BE ASSIGNED**

- a. There shall be a designated recall team.
- b. The recall team roster shall include the responsibilities for all team members including alternates.
- c. There shall be back up personnel assigned for each team role.
- d. There shall be a designated team leader or coordinator.
- e. There shall be a contact list of all personnel within the company who would be involved in a recall. The list shall include 24 hour contact numbers. The list shall be up to date and current. Additionally, a contact list shall be present for all customers and regulatory entities who would need to be contacted in the event of a recall.

### 3.3. TRACEABILITY EXERCISES SHALL BE CONDUCTED AT A MINIMUM OF TWICE ANNUALLY.

- a. Trace exercises shall be conducted at a minimum of twice annually, with at least one of these exercises completed outside of normal business hours.
- b. Trace exercises shall be conducted on both finished product and raw materials, including food contact packaging.
- c. Traceability exercises shall demonstrate a 99.5% to 105% accounting within 4 hours, taking into account normal loss, waste or shrinkage.

**NOTE:** An effective raw material trace exercise is one where a received lot of raw material is traced to all the finished product it was used in and a mass balance calculation achieves 99.5-105% recovery taking into account normal yields, loss, waste or shrinkage. An effective finished product traceability exercise is one where a finished product lot is traced to the first level of distribution taking into account normal yields, loss, waste or shrinkage.

### 3.4. A DOCUMENTED MANAGEMENT ASSESSMENT SHALL BE COMPLETED AFTER EACH TRACEABILITY EXERCISE TO EVALUATE THE EXERCISE FOR NEEDED IMPROVEMENTS AND ANY CORRECTIVE ACTIONS TAKEN

- a. Records from the exercise shall include a material (mass) balance sheet taking into account:
  - Total quantity of product made,
  - Finished product shipped and destination,
  - Finished product on hand,
  - Finished product otherwise categorized (e.g., damaged, lost, samples),
  - Finished product unaccounted for,
  - A calculated percent recovery,
  - Start and end times for the exercise.
- b. All corrective actions resulting from trace exercises are documented and implemented prior to a subsequent trace exercise.

### 3.5. **ESSENTIAL** THERE SHALL BE EVIDENCE OF TRACEABILITY FOR ALL INGREDIENTS, REWORK, CARRYOVER, WORK IN PROCESS, AND FOOD CONTACT PACKAGING MATERIALS INTO FINISHED PRODUCT. FINISHED PRODUCT SHIPPING RECORDS SHALL BE AVAILABLE.

- a. Materials shall be traceable including:
  - Ingredients,
  - Rework,
  - Carryover,
  - Work in process,
  - Food contact packaging materials

- Samples (e.g., reference, laboratory, sensory)
- b. Bulk ingredients, when used, shall maintain the same ability to be traced as other ingredients. If absolute traceability is not possible because of commingling, validated procedures shall be documented to ensure that full traceability of bulk ingredients is possible.

**\* ESSENTIAL ELEMENT: THE COMPLETE LACK OF A SYSTEM TO TRACE INGREDIENTS AND FINISHED PRODUCT AS PER REGULATORY REQUIREMENTS AND CUSTOMER EXPECTATIONS SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.**

### 3.6 THE FACILITY SHALL BE ABLE TO SUCCESSFULLY DEMONSTRATE THE TRACEABILITY SYSTEM DURING THE AUDIT.

- a. The facility shall be able to demonstrate that they are able to effectively trace product during the audit. The auditor will select a finished product and the facility shall demonstrate how they are able to locate information on the raw materials for that product and how the product will be tracked to the first customer (one step up and one step back). Successful demonstration will be accounting for 99.5% to 105% within a four hour time frame.

## **A4. RECORDKEEPING AND RETENTION**

### 4.1. THE FACILITY SHALL HAVE A RECORD RETENTION AND STORAGE POLICY.

- a. The facility shall have procedures for the retention and storage of records relevant to the control of the process or evaluation of food safety, food quality and food defense.
- b. The time period for retention of records shall be documented and shall be as per customer requirements or, as a minimum, the product shelf life plus 1 year.

### 4.2. **ESSENTIAL** RECORDS RELEVANT TO THE CONTROL OF THE PROCESS OR EVALUATION OF FOOD SAFETY, FOOD QUALITY AND FOOD DEFENSE SHALL BE PROPERLY COMPLETED.

- a. All records shall be:
  - Genuine and legible.
  - Initialed by operator and independently verified for accuracy.
  - Recorded in ink on a timely basis with accurate date and time.
  - Errors shall be marked with single line-out and initialed.
  - Marked to record or chart out-of-control or out-of-specification conditions.
  - Records shall indicate disposition of product and corrective actions taken.

**\* ESSENTIAL ELEMENT: EVIDENCE OF INTENTIONAL RECORD FALSIFICATION SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.**

---

## **A5. CRISIS AND NATURAL DISASTER MANAGEMENT**

5.1. CRISIS MANAGEMENT POLICIES AND PROCEDURES SHALL BE DEVELOPED TO ADDRESS ANY CRITICAL SITUATIONS THAT MAY OCCUR (E.G., PRODUCT RECALLS AND BUSINESS CONTINUITY INTERRUPTIONS, SUCH AS NATURAL DISASTERS, CATASTROPHIC EVENTS AND OTHER EMERGENCY SITUATIONS INCLUDING, BUT NOT LIMITED TO, POWER OUTAGE, TAMPERING.)

- a. The policy shall assign management responsibility for the following activities in the event of crisis:
  - Determine the status of ingredients, food contact packaging materials, in-process materials, and finished product involved in a crisis event situation.
  - Ensure all ingredients and materials are suitable for use prior to the start of production.
  - Ensure there is a documented evaluation of all product involved in a crisis event.
  - Ensure there is a documented release of any affected product prior to shipping.
- b. Records of the activities are maintained.

5.2. MANAGEMENT RESPONSIBLE FOR CRISIS MANAGEMENT SHALL CONDUCT MOCK CRISIS EXERCISES AT MINIMUM ANNUALLY.

- a. These exercises shall include all of the activities outlined in 5.1.

---

## **A6. CUSTOMER/CONSUMER COMPLAINT MANAGEMENT**

6.1. THE PLANT SHALL MANAGE CUSTOMER AND OR CONSUMER COMPLAINTS.

- a. There shall be a written procedure for handling and documenting customer and/or consumer complaints that addresses responsibilities, response time, root cause investigation and, where appropriate, corrective action.
- b. Records of complaints received and actions taken shall be made available to the auditor.

## B: HACCP

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Codex Alimentarius Commission (CODEX) provide internationally recognized resources for understanding the principles of Hazard Analysis and Critical Control Point (HACCP).

The HACCP system is science based and provides a systematic approach to identify specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess potential hazards and establish control systems that focus on prevention rather than relying on finished product testing.

A HACCP system shall be developed by each food establishment and tailored to its individual products, processes, and distribution conditions. The HACCP plan shall analyze and identify control measures for the potential biological, chemical and physical hazards from procurement, receipt, and storage of raw materials through the production, handling, manufacturing, storage, distribution and consumption of the finished product. It is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan.

Approval of the HACCP plan shall be documented with a written signature from top management. The plan shall be kept current with regular performance reviews by the HACCP management team. Experts who are knowledgeable in the food process shall either participate in or verify the completeness of the hazard analysis and the HACCP plan.

**NOTE:** If the product is subject to a mandatory HACCP plan requirement, then the plan shall be in compliance with the regulatory requirements. If a mandatory HACCP plan is not required, the facility shall still comply with prerequisite programs (found in subsequent Sections of this document) and all HACCP requirements.

### **B1. PRELIMINARY TASKS**

**1.1. A HACCP TEAM SHALL BE ASSEMBLED WITH INDIVIDUALS HAVING THE APPROPRIATE PRODUCT, PROCESS, AND SANITATION SPECIFIC KNOWLEDGE AND EXPERTISE NECESSARY FOR THE DEVELOPMENT OF AN EFFECTIVE HACCP PLAN.**

The HACCP team shall:

- a. Have a team leader who has formal in-classroom HACCP training of at minimum two days duration.
- b. Have the appropriate product, process, and sanitation specific knowledge. Where such expertise is not available on site, expert advice shall be obtained from other sources, but the site shall still retain ownership and understanding of the Plan even if external expertise is used.
- c. Be clearly identified with their responsibilities as part of the HACCP plan.
- d. Be representative of major functions within the organization that have an impact of food safety.

---

**1.2. THERE SHALL BE A WRITTEN HACCP PLAN. THE HACCP TEAM SHALL PARTICIPATE IN HACCP PLAN DEVELOPMENT AND MAINTENANCE.**

The HACCP Team shall:

- a. Be involved in the development, final approval, and subsequent reviews of the plan.
- b. Develop a description of the product (composition, ingredients, physical/chemical properties, processing details, packaging, shelf life and storage) and determine the intended use of the product based on the expected uses of the product by the end user or consumer.
- c. Conduct reviews and approvals of changes and revisions. Hold documented review team meetings at minimum annually to assess HACCP records and issues.
- d. Assess all deviations, documentation errors, corrective actions, and assure that corrective actions are monitored for effectiveness.
- e. Ensure that all products produced at the facility, including processed products, repackaged product or reworked product shall be listed and assigned to a designated HACCP plan.

---

**1.3. THE HACCP TEAM SHALL CONSTRUCT A CLEAR AND EASY TO UNDERSTAND PROCESS FLOW DIAGRAM FOR EACH HACCP PLAN.**

The Process Flow Diagram shall:

- a. Outline each step involved in the process that is directly under the control of the establishment. The same flow diagram may be used for a number of products that are manufactured using similar processing steps.
- b. Indicate the ingredient and material categories used in all preparation steps.
- c. Include all process equipment including packaging equipment and each process steps including blending steps, processing steps.
- d. Include introduction of rework and returned products, and packaging materials.
- e. Include the steps preceding and following the process.

---

**1.4. THE PROCESS FLOW SHALL INCLUDE CCPs, SHALL BE CURRENT AND SHALL BE VERIFIED.**

- a. The HACCP team shall perform and document an on-site review of the operation to verify the accuracy and completeness of the process flow diagram during all stages and hours of operation. Modifications shall be documented on the flow diagram, as necessary.
- b. The process flow diagram shall remain current.
- c. Once CCPs have been determined, they shall be clearly identified on the flow diagram and numbered to correspond with the Hazard Analysis and CCP records and documentation.

---

**B2. HAZARD ANALYSIS (HACCP PRINCIPLE 1)**

2.1. THE HACCP TEAM SHALL PREPARE A LIST OF ALL OF THE HAZARDS (CHEMICAL, PHYSICAL, BIOLOGICAL, RADIOLOGICAL OR OTHER) THAT MAY BE REASONABLY EXPECTED TO OCCUR AT EACH STEP, FROM RAW MATERIAL RECEIPT, PROCESSING, MANUFACTURE, STORAGE, AND DISTRIBUTION UNTIL THE POINT OF CONSUMPTION. EVALUATION SHALL INCLUDE ALL INGREDIENTS, EQUIPMENT, PROCESSING STEPS, AND PACKAGING MATERIALS.

- a. The HACCP team shall conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. Consideration should be given to what identified, prerequisite control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specific control measure
- b. The hazard analysis shall include:
  - The likelihood of hazards and the severity of their adverse health effects.
  - The qualitative and/or quantitative evaluation of the presence of hazards.
  - Survival or multiplication of microorganisms of concern.
  - Production or persistence in foods of hazardous toxins, chemicals or physical agents.
  - Conditions leading to the above.
  - All raw materials and process steps.
- c. A preventive control measure shall be identified for all significant hazards listed

### **B3. CRITICAL CONTROL POINTS (PRINCIPLE 2)**

3.1. THE HACCP TEAM SHALL DETERMINE THE CRITICAL CONTROL POINTS.

- a. Critical Control Points shall be determined using a logical, reasoned, documented approach, such as a decision tree and/or defined regulatory requirements (for example, thermal processing defined by a Process Authority). If a formal hazard analysis is not used to determine the need for CCPs, there shall be a documented risk assessment for that purpose.
- b. Documentation for determining whether a step or process is a CCP shall be clear and thoroughly explained, defining the hazard and the specific controls that eliminate or reduce the hazard.

**NOTE:** If it has been determined that there are no hazards OR no CCPs, no further plan development is necessary. However, the HACCP Team shall continue to conduct regular meetings to review any changes in the process or procedures that could affect the hazard or CCP determination.

**NOTE:** Regardless of whether there are no hazards or no CCP's, the requirements of sub-sections "Verification and Validation" (HACCP Principle 6) and "Documentation and Record Keeping" (HACCP Principle 7) below shall always be satisfied to verify HACCP conclusions and to document all HACCP decisions and conclusions.

## **B4. CRITICAL LIMITS (PRINCIPAL 3)**

### **4.1. CRITICAL LIMITS SHALL BE SPECIFIED AND VALIDATED FOR EACH CCP.**

- a. Critical limits shall be measurable. Variable or attribute measures are acceptable.
- b. There shall be a scientific or regulatory basis, with appropriate documentation or regulatory references, for both the hazard and the control required. Proprietary data may be acceptable, providing there are sufficient data approved by an appropriate, qualified process authority.
- c. Documented process capability studies or CCP monitoring records shall be available to demonstrate that established CCP limits are compatible with the plant process and capable of being met.

**\*FAILURE TO DEMONSTRATE THAT CCP CRITICAL LIMITS ARE SCIENTIFICALLY AND/OR TECHNOLOGICALLY SOUND FOR CONTROLLING EACH HAZARD SHALL BE RATED AS A MAJOR NON- CONFORMANCE.**

## **B5. CCP MONITORING (HACCP PRINCIPLE 4)**

### **5.1. CCPS SHALL BE MONITORED.**

- a. Monitoring procedures shall be able to detect loss of control at the CCP.
- b. All CCP's shall have a documented and fully implemented and executed procedure that describes how the CCP is to be monitored, who is responsible for performing it, how often it is completed and where the activity is to be documented. The type and frequency of monitoring shall be sufficient to guarantee the CCP is in control
- c. Monitoring data shall be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

### **5.2. CCP MONITORING RECORDS SHALL BE MAINTAINED.**

- a. Documentation of the measured attribute shall be clearly identified in HACCP records.
- b. Records shall have CCPs identified by name and number, the item to be measured, the frequency of the measurement, the CCP limit, the responsible monitor and the corrective action required in the event that a measurement is not in compliance. All corrective action procedures shall clearly indicate where deviations are recorded and who is responsible for actions taken.
- c. A deviation log shall be maintained and available for review.
- d. All records and documents associated with monitoring CCPs shall be signed by the person(s) doing the monitoring.

## **B6. CORRECTIVE ACTIONS (HACCP PRINCIPLE 5)**

### **6.1. **ESSENTIAL** SPECIFIC CORRECTIVE ACTIONS TO DEAL WITH DEVIATIONS FROM ESTABLISHED CRITICAL LIMITS SHALL BE IN PLACE FOR EACH CCP.**

- a. Corrective actions shall include instructions of necessary actions to take to secure and manage affected product, including who needs to be informed in the event that a critical limit is exceeded.
- b. Corrective actions shall ensure that the CCP has been brought under control and require that an assessment be conducted to prevent a recurrence of the situation.
- c. There shall be documented product disposition procedures in the event that of a CCP deviation.

**\*ESSENTIAL ELEMENT--FAILURE TO TAKE CORRECTIVE ACTION FOR A CRITICAL LIMIT DEVIATION SHALL BE ASSESSED AS A CRITICAL NONCONFORMANCE.**

## **B7. VERIFICATION AND VALIDATION (HACCP PRINCIPLE 6)**

7.1. THERE SHALL BE WRITTEN VERIFICATION ACTIVITIES THAT CONFIRM THAT THE PLAN IS BEING IMPLEMENTED AS INTENDED.

- a. Verification activities shall include where appropriate:
  - Review of the HACCP system and Plan and its records.
  - Review of deviations and product dispositions.
  - Confirmation that CCPs are properly monitored and kept under control.
  - Management sign-off that no deviations took place or that all deviations resulted in the prescribed corrective action.

7.2. THERE SHALL BE DOCUMENTED VALIDATION OF THE EFFECTIVENESS OF THE HACCP PROGRAM.

- a. Validation of the HACCP plan shall be available through documentation or supporting data that confirms:
  - The Plan is scientifically and technically sound.
  - All hazards have been identified.
  - CCPs are effective and valid and that if the HACCP plan is properly implemented, these hazards will be effectively controlled.
- b. The HACCP plan shall be reviewed and validated by the HACCP team at minimum annually, or as needed based on changes to raw materials/processes/product change, and/or corrective and preventive actions. At the time of the HACCP plan review, the HACCP team shall also include a review of the training needs and competency of its members, to ensure that the expertise of the team remains current. This validation of the plan and review of the team shall be documented.

## **B8. DOCUMENTATION AND RECORD KEEPING (HACCP PRINCIPLE 7)**

8.1. THERE SHALL BE DOCUMENTATION AND RECORD KEEPING THAT IS APPROPRIATE TO THE NATURE AND SIZE OF THE OPERATION.

- a. Documentation and record keeping shall be sufficient to assist the business to verify that the HACCP controls are in place and being maintained.
- b. Documentation shall include:
  - Hazard analysis.
  - CCP determination.
  - Risk analysis (likelihood and severity).
  - Critical limit determination.
- c. Records shall include:
  - CCP monitoring activities.
  - Deviations and associated corrective actions.
  - Verification procedures performed.
  - Modifications to the HACCP plan.
  - Effective access control, in the event that the records are electronic.
  - Appropriate signing and initialing to verify compliance and completeness
- d. Deviations from the HACCP plan shall be thoroughly documented with detailed corrective actions and product dispositions.
- e. The documents and their data shall be self-explanatory and complete. The records shall be in ink (not pencil) and signed by the operator. There shall be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation shall be provided.
- f. All records and documents associated with HACCP plan monitoring shall be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company. Signatures of the operator, supervisor and designated record reviewer are required in some regulated situations.
- g. Records shall be easily retrievable and secured in a safe storage area.

## C. FACILITIES & EQUIPMENT

The following guidelines are provided as minimum requirements for food processing facilities. They are general in nature and may not be appropriate for all operations, but the intent of the requirements, as stated, shall be achieved. Some products or processes may require more stringent elements.

### C1. WATER, STEAM AND ICE

1.1. **ESSENTIAL** THE PLANT SHALL DEMONSTRATE THAT THE WATER, ICE AND STEAM SUPPLY IS POTABLE AND THAT POTABILITY IS MAINTAINED AT ALL TIMES. POTABILITY CRITERIA FOR MICROBIOLOGICAL, CHEMICAL AND PHYSICAL PARAMETERS SHALL BE USED.

- a. There must be an adequate supply of water for processing and sanitation. Ice produced in the facility from the facility's own water supply shall follow the potability requirements as per this section (1.1) subparts b-d.
- b. Potability testing of municipal water supplies shall be conducted by a certified laboratory at minimum annually. Potability certificates available from municipal water suppliers are acceptable. If the facility is using water from a private well, there shall be a credible potability test at minimum every 3 months.
- c. Plants operating their own water systems shall be able to demonstrate, through credible testing at minimum every 3 months, that plant water meets applicable regulatory standards for drinking water.
- d. Potability shall meet local regulatory requirements at a minimum.
- e. Steam used for product manufacture and that touches product contact surfaces, including food contact packaging materials, shall be potable. Documentation shall be made available that indicates all boiler water additives are approved for use with food.
- f. Water treatment program shall be documented along with training or qualification of personnel involved in the process.
  - All chemicals used shall have food grade approval and be documented as such.
  - Treatment records shall include testing results, amounts used and when used.
  - Water treatment shall be verified by 3rd party vendors.
- g. Purchased ice (manufactured ice brought into the facility from an outside vendor) shall have annual certificates of potability or documented satisfactory microbiological testing results.
- h. Potable water distribution systems shall be segregated or adequately protected from cross contamination.
  - There shall be no cross connections between potable and non-potable water supplies.
  - All hoses, taps or other similar sources of possible contamination shall be designed with properly maintained back flow preventers.
  - Water filters shall be kept effective as per the manufacturers' recommendations and maintained in a sanitary manner.

- Volume, temperature and pressure of water shall be adequate to meet operational and sanitation needs.
- Water storage, if necessary, shall be in adequately designed, maintained and identified storage facilities.
- Recirculated water shall be treated, monitored and maintained for its intended use. It shall be clearly identified.

**\*ESSENTIAL ELEMENT—THE USE OF NON-POTABLE WATER, STEAM OR ICE AS PART OF OR IN CONTACT WITH FOOD, FOOD CONTACT EQUIPMENT OR OTHER INAPPROPRIATE USE SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.**

## **C2. PLANT CONSTRUCTION, DESIGN AND CONDITION**

2.1. THE EXTERIOR OF THE FACILITY IS CONSTRUCTED AND MAINTAINED TO FACILITATE THE PRODUCTION OF WHOLESOME PRODUCT AND THAT IT AT MINIMUM MEETS THE CUSTOMER AND REGULATORY FOOD SAFETY AND QUALITY REQUIREMENTS.

- a. The facility exterior (yards, grounds, parking lots and roads) is maintained free of debris, refuse and adequately drained.
- b. Building exteriors are designed and maintained to prevent contamination or entry of pests, contaminants (such as, but not limited to, dust and chemicals) or unauthorized personnel.
- c. Procedures and records shall be in place to support building maintenance.

2.2. **ESSENTIAL** PLANT CONSTRUCTION AND LAYOUT SHALL BE SUCH THAT EXPOSED PRODUCT IS ADEQUATELY SEPARATED AND PROTECTED FROM ANY OPERATIONS THAT COULD CAUSE CONTAMINATION.

- a. There shall be no evidence of potential for cross-contamination, including allergen cross-contamination, due to plant layout or construction. For facilities with high risk/high care areas, requirements under Section N shall be assessed.
- b. There shall be no cross connection between sewage and other waste effluent systems and effluent shall not present a hazard due to contact or odor. Sewage must be disposed of using adequate means.
- c. Adequate heating, ventilation or refrigeration shall be provided in all areas to maintain proper environmental and sanitary conditions for ingredients, finished product, equipment, and packaging materials. This maintenance of proper conditions includes, but is not limited to, minimizing risk of allergen cross-contamination and condensate/frost/ice buildup.

**\* ESSENTIAL ELEMENT--ANY CONDITION IN THE FACILITY WHICH, BASED ON OF OBJECTIVE EVIDENCE OR OBSERVATION, RESULTS IN PRODUCT OR RAW MATERIAL CONTAMINATION AND/OR ADULTERATION SHALL BE ASSESSED AS A CRITICAL NONCONFORMANCE.**

---

### **C3. PLANT CONDITION (STATE OF REPAIR, CLEANABILITY)**

3.1. PLANT FACILITIES SHALL BE DESIGNED AND MAINTAINED IN A SUITABLE CONDITION SO AS NOT TO IMPEDE THE ABILITY TO THOROUGHLY CLEAN ALL SURFACES, PROVIDE PEST HARBORAGE, OR PRESENT OPPORTUNITIES FOR FOREIGN MATERIAL CONTAMINATION

- a. Materials used to construct walls, floors, overhead structures and ceilings shall be smooth, non-porous, nonabsorbent and easily cleanable. Joints or cracks in walls, floors and ceilings shall be properly sealed.
- b. Walls, ceilings, overhead structures and floors are maintained in good repair.
- c. Floors are sufficiently sloped, as needed, to provide drainage and to prevent the accumulation of liquid.
- d. Drainage is designed away from higher risk areas and to minimize product contamination.
- e. Wet processing and wash areas shall have floor drains with grates that are easily removed for cleaning and inspection.
- f. Windows in processing areas shall be shatter proof or properly sealed to prevent glass contamination.
- g. No unprotected glass shall be allowed in close proximity to processing or storage areas.
- h. Doors and windows shall be in suitable condition (see Pest Control section for additional requirements regarding doors and windows).
- i. Facilities used to clean equipment (COP), wash bays, sinks and germ baths are constructed of appropriate material, are identified with signage and provided with supplies and potable water at correct temperatures. They are adequately separated from storage, processing and packaging areas. Tiled and coved areas and stainless steel sinks are required.

---

### **C4. EMPLOYEE FACILITIES**

4.1. EMPLOYEE FACILITIES SHALL BE ADEQUATE IN SIZE, READILY ACCESSIBLE, SEPARATE FROM PROCESSING, AND PROPERLY MAINTAINED.

- a. Cafeteria, Locker Rooms and Toilet facilities shall be:
  - Adequate in size for the maximum number of employees,
  - Readily accessible by employees,
  - Physically separated from food production areas
- b. They shall be maintained to set an example of clean and orderly food sanitation and housekeeping requirements.

---

### **C5. HAND WASHING FACILITIES**

**5.1. HAND WASH REQUIREMENT SIGNS, IN APPROPRIATE LANGUAGES AND/OR GRAPHICS, SHALL BE CLEARLY POSTED AT REQUIRED LOCATIONS AND CONTAIN INSTRUCTIONS AS PROVIDED BELOW.**

- a. Signs shall instruct employees to wash their hands prior to returning to work. Signs shall be located at
  - Locker room and toilet facility exits
  - Entrances to food handling and food processing areas
- b. Signs at hand wash stations shall instruct employees on the proper procedure for washing their hands and be in appropriate languages for the facility.

**NOTE:** Washing hands prior to exiting the locker room and toilet facilities does not substitute for washing hands just prior to or immediately upon entrance to food handling and food processing areas

**5.2. HAND WASHING STATIONS SHALL BE ADEQUATE IN LOCATION, SUITABLY DESIGNED, OPERATIONAL AND PROPERLY STOCKED**

- a. Hand wash stations shall be strategically located and have adequate room to accommodate the number of personnel in the area and prevent delays that may discourage proper hand washing procedures
- b. Hand washing stations in or adjacent to processing areas shall be 'hands-free' activated so that hand contact is not required to turn water 'On' or 'Off'.
- c. The hand washing stations shall deliver water at a suitably warm temperature within 30 seconds. There shall be an adequate supply of hand sanitizing soap. Single service towels shall be available and protected with an appropriate dispenser with convenient disposal at each station. Where specific customer requirements or country regulations apply to hand-washing, these shall take precedence.

**C6. EQUIPMENT LAYOUT, DESIGN AND CONDITION**

**6.1. ESSENTIAL ALL FOOD PRODUCTION AND PACKAGING EQUIPMENT SHALL MEET FOOD SANITARY DESIGN REQUIREMENTS AND BE INSTALLED IN SUCH A MANNER AS TO PERMIT PROPER OPERATION AND ACCESS FOR CLEANING AND INSPECTION.**

- a. All equipment is in good repair and does not pose a product contamination issue. No spot welding, flaking paint, excess lubrication, oil drips shall be evident.
- b. Equipment in direct contact with food shall be of smooth, impervious, non-toxic, nonabsorbent and corrosion-resistant material. Seams on food contact surfaces shall be smoothly bonded.

**\*ESSENTIAL ELEMENT--FINDING THROUGH OBSERVATION OR ON THE BASIS OF OBJECTIVE EVIDENCE THAT EQUIPMENT OR FOOD CONTACT MATERIALS ARE UNSUITABLE FOR USE WITH FOOD OR THAT EQUIPMENT CONDITION IS A CAUSE OF PRODUCT CONTAMINATION MAY BE ASSESSED AS A CRITICAL NON-CONFORMANCE**

---

## **C7. UTENSILS**

7.1. UTENSILS, TOOLS AND CONTAINERS USED TO HANDLE EDIBLE MATERIAL ARE NOT USED TO HANDLE INEDIBLE MATERIAL. ALL UTENSILS, TOOLS AND CONTAINERS USED ARE CLEARLY IDENTIFIED AND MAINTAINED IN SUITABLE CONDITION.

- a. Utensils, tools and containers shall be properly identified for their intended use by labels and/or color coding.
- b. Utensils, tools and containers used to handle edible material shall not be used to handle inedible material and are clearly identified and maintained.
- c. Utensils, tools and containers shall be maintained, cleaned and stored in order to prevent cross contamination of products. An example of proper storage includes, but is not limited to, making provision for appropriate drying of utensils, tools and containers, as needed.
- d. Single use containers used for microbiologically sensitive or allergenic products shall not be reused.

7.2. AIR AND OTHER GASSES USED AS AIDS OR PART OF THE PROCESS SHALL BE APPROPRIATELY SOURCED, TREATED AND FILTERS MAINTAINED

- a. Air and other gasses used as a processing technique is appropriately sourced, treated and filters maintained.
- b. Fans shall be on sanitation schedules and compressed air lubricants shall be food grade.

---

## **C8. PLANT LIGHTING**

8.1. PLANT LIGHTING SHALL BE SUITABLE.

- a. Plant lighting shall be adequate and appropriate for sanitation, inspection and processing tasks being performed. Plant light levels shall be tested to confirm adequacy based on local regulatory and industry requirements at least annually or when changes are made.
- b. Light bulbs and fixtures in areas where food products and packaging material are exposed are shielded or protected against breakage.

---

## **C9. MAINTENANCE STANDARDS**

9.1. MAINTENANCE PROGRAM AND STANDARDS SHALL BE IN PLACE.

- a. Plant shall have a documented preventative maintenance program that covers all equipment and facilities.
- b. Nonfood grade materials or otherwise inappropriate materials including, but not restricted to, wire, tape, string, plastic or cardboard shall not be used for temporary repair in processing areas.
- c. Temporary repairs shall have specific time line for permanent repair.
- d. Repair parts and replacement equipment shall be stored in properly maintained storage areas.

- e. There shall be a procedure to ensure that cleaning and sanitation is done following maintenance as needed. This shall include a reconciliation of all tools and spare parts used during the maintenance work to ensure that the work site has been returned to conditions for safe processing.
- f. Records of all maintenance activity shall be maintained.

9.2. **ESSENTIAL** EQUIPMENT OR CONTROL DEVICES THAT IMPACT ON FOOD SAFETY AND/OR PRODUCT COMPLIANCE TO QUALITY AND REGULATORY REQUIREMENTS ARE EFFECTIVELY CALIBRATED

- a. Equipment or control devices requiring calibration could include, but are not limited to, temperature controllers, flow meters, pressure regulators, divert devices, CIP instrumentation, scales, speed controllers.
- b. Control and monitoring devices essential to the control, monitoring or testing of regulatory parameters, food safety critical limits, pre-requisite program parameters and/or quality parameters shall be calibrated by trained personnel according to a pre-determined schedule and as required by the maintenance program.
- c. Appropriate action and investigation shall be taken if devices are found to be out of calibration and shall include a food safety or quality assessment where appropriate.
- d. Measuring devices for food safety and quality are traceable to a national standard.

**NOTE:** Calibration of laboratory equipment specifically is assessed under L1.3

**NOTE:** Calibration of metal detectors specifically is assessed under H1.4

**\*ESSENTIAL ELEMENT--EQUIPMENT FOUND TO BE OUT OF CALIBRATION LEADING TO POTENTIAL FOR ILLEGAL OR UNSAFE FOOD SHALL BE A CRITICAL NON-CONFORMANCE.**

## D. CLEANING, SANITATION, HOUSEKEEPING, HYGIENE

### D1. CLEANING AND SANITATION

#### 1.1. THERE SHALL BE A MASTER CLEANING AND/OR SANITATION SCHEDULE AND MONITORING AND RECORDING OF CLEANING.

- a. This schedule shall include:
  - Operational areas (floors, walls, drains, overheads),
  - Equipment (including portable and temporary equipment)
  - Warehouse,
  - Storage,
  - Maintenance,
  - Employee facilities (locker rooms, cafeteria, break areas and toilet facilities),
  - Other plant areas including the building, grounds and roof areas.
- b. The scheduled tasks shall be monitored for completion and documented with sign off on a consistent basis.

#### 1.2. THERE SHALL BE STANDARDIZED CLEANING PROCEDURES (E.G., STANDARD SANITATION OPERATING PROCEDURES OR SSOPS)

- a. The plant shall have documented cleaning procedures for:
  - Operational areas
  - Individual pieces of food processing equipment
  - Facility areas and structures.

#### 1.3. THERE SHALL BE A DOCUMENTED PRE-OPERATIONAL INSPECTION

- a. A pre-operational inspection, including both visual and document review, shall occur prior to production activities and after the completion of the following activities:
  - Production line clean-ups,
  - Allergen clean-ups or changeovers,
  - Maintenance activities due to breakdowns or preventative maintenance after planned sanitation activities.
- b. Corrective action procedures are established and documented for incomplete or inadequate sanitation practices. Records of corrective actions completed shall be maintained.

#### 1.4. OPERATIONAL HOUSEKEEPING SHALL BE EFFECTIVE.

- a. Accumulation of garbage, trash and waste materials shall be kept at a minimum and removed in a manner that does not create any food safety risks.
- b. All equipment, utensils, containers shall be cleaned as necessary during and post operations and stored off the floor as applicable when not in use. This also includes cleaning and sanitizing equipment, which must be stored properly when not in use (for example, hoses used for cleaning hung up after use so that nozzle ends are not left directly on the floor).
- c. Floors, walls, ceilings and overhead structures shall be cleaned as necessary to provide a hygienic environment.

## **D2. PERSONAL HYGIENE AND GOOD MANUFACTURING PRACTICE**

#### 2.1. THE FACILITY HAS A DOCUMENTED PROGRAM FOR GMP AND PERSONAL HYGIENE PRACTICES TO WHICH COMPLIANCE IS MONITORED AND RECORDED.

- a. Food plant employees shall observe personal hygiene practices as outlined in the relevant regulations.
- b. Personal hygiene practices shall include:
  - A written dress code for all employees (including new and part-time), visitors, vendors and contractors. Employees shall wear clean clothing and shoes appropriate for the working conditions.
  - The use of fine mesh net hair restraints for head and facial hair in production, processing and warehouse areas by all employees.
  - No false fingernails, fingernail polish, jewelry (rings, exposed body piercings, bracelets), or watches.
  - No working in food handling/processing areas for employees that have an infectious or communicable illness, or have open sores on hands, face, arms or other exposed skin areas.
  - Employees shall notify management if they are diagnosed with a communicable disease that may be transmitted through food or are experiencing symptoms of diarrhea, vomiting, fever or jaundice.
  - Production area employees shall wash and sanitize their hands before starting to work, after each absence from the work station and any time their hands may have become contaminated.
  - If gloves are worn, they shall be intact, with no holes, and kept clean. Non disposable gloves shall be washed and sanitized if they become contaminated. Disposable gloves shall be replaced if they become contaminated.
  - If dedicated uniforms, aprons, lab coats, gloves, or smocks are utilized, the plant shall provide these. Employees shall use a means to avoid contamination of their dedicated outer clothing when using the toilet facilities. For example, coat hooks or other means can be made available for employees to store their outer protective garments before entering toilet facilities.
  - Eating, drinking, spitting, chewing or using tobacco products shall only be permitted in designated areas.
  - Pens, combs, pencils, thermometers, tools and similar loose objects shall not be carried above the waist at any time while in food handling/processing areas.
  - Plasters (bandages) shall be available and shall be a contrasting color from the product being produced. In facilities that utilize metal detection, plasters (bandages) shall be metal detectable.
  - Personal hygiene monitoring records shall be maintained.

---

### **D3. SELF INSPECTION**

---

#### **3.1. GMP SELF INSPECTIONS SHALL BE COMPLETED.**

- a. There shall be routine facility inspections (can be completed by a cross functional team or by a designated individual at the facility) performed to assure management that GMP policies have been
  - Effectively implemented
  - Facilities and equipment are maintained to meet sanitary and operational needs.
- b. Inspections shall be documented to show non-conformances identified and corrective actions taken.

## E. RODENT & PEST CONTROL MANAGEMENT

### E1. PEST CONTROL

#### 1.1. THERE SHALL BE A DOCUMENTED AND SPECIFIC PEST CONTROL PROGRAM

- a. There shall be a current Pest Management manual, program or file available for review.
- b. A current Pest Control Operator (PCO) applicator's license and letter of liability insurance shall be on file, along with Safety Data Sheet (SDS) for all chemicals used.
- c. There shall be written procedures to direct the activities conducted by the PCO and trained employees. They shall include:
  - Types of pests being controlled
  - Frequency of monitoring/inspection
  - Method of labeling, inspecting and recording of inspections.
  - The record of service verification tag or bar code label shall be on the inside of the traps, bait stations or other devices
- d. Company employees engaged as PCOs shall have proof of appropriate training and licensing as required by local regulations.
- e. An up-to-date site map of all pest control devices shall be maintained

#### 1.2. OUTSIDE PREMISES MANAGEMENT SHALL MINIMIZE OPPORTUNITY FOR PESTS

- a. Outside premises shall be free of conditions (including, but not limited to, stored equipment, litter, waste, weeds, tall grass) that may provide harborage or attractants for insects, birds, rodents or other pests. There shall be at minimum an 18 inch (46 cm) vegetation free perimeter around exterior of facility.
- b. Outside bait stations shall be placed around the exterior perimeter of the building at intervals as directed by the Pest Control Company (PCO). If the PCO has not provided this direction, the outside bait stations shall be placed at 50 foot (15.25 meter) intervals
- c. Exterior pest control devices shall be tamper resistant, locked, labeled and secured.

#### 1.3 **ESSENTIAL** THERE SHALL BE NO EVIDENCE OF INFESTATION

- a. There shall be no evidence of pest infestation inside the facility.
- b. There shall be no observation of pests on ingredients, packaging, work in process, or finished goods.

**\* OBSERVATION OF A PEST INFESTATION INSIDE THE FACILITY IS A MAJOR NON-CONFORMANCE**

**\*ESSENTIAL ELEMENT--OBSERVATION OF PESTS, PEST EXCRETA OR INFESTATION IN OR ON INGREDIENTS, PACKAGING, WORK IN PROCESS, OR FINISHED GOODS SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE (DIRECT CONTAMINATION)**

---

#### 1.4. PEST CONTROL DEVICES SHALL BE PROPERLY MANAGED.

- a. All devices shall be identified and placed to correspond to the map location.
- b. Devices shall be in proper working order.
- c. Exterior pest control devices shall be inspected and documented at minimum once/month in winter and twice per month in summer months.
- d. Insect light traps shall be suitably located and not located over, adjacent to or within 8 feet (2.44 meters) of product, packaging or processing equipment.
- e. Labelled mechanical rodent traps shall be placed based on recommendations of the Pest Control Service provider and, at a minimum, inside and on either side of doors that exit to the exterior, including all dock doors with wall signage indicating location.
- f. Interior pest devices shall be inspected weekly. If less frequently, a documented risk assessment with supporting current trend data is required. Inspections can be carried out by trained company personnel in addition to scheduled visits by a service provider.
- g. There shall be no bait used inside the facility other than pheromone traps where required.

---

#### 1.5. DOORS AND WINDOWS SHALL BE TIGHT FITTING AND CLOSED WITH OPENINGS SEALED TO PREVENT PEST ENTRY INTO THE BUILDING

- a. Doors, windows and docks (including doors and dock plates) shall be adequately sealed to prevent pest entry.
- b. Doors, windows and dock doors shall remain closed when not in use for product and material transfer or be suitably screened.

---

#### 1.6. PEST CONTROL REPORTS SHALL BE MAINTAINED.

Pest Control records shall:

- a. Record all pest control activities.
- b. Record all pest activity, findings, investigations and corrective actions.
- c. Record observations and findings of conditions that compromise pest management including recommendations and corrective actions.
- d. An adequately trained plant or facility employee shall be responsible to ensure that all corrective actions resulting from pest control inspections are completed and documented. Corrective actions shall be completed as required as a result of the pest control inspections.
- e. Record on a pesticide usage log the usage of chemicals and pest control agents, including name, amount, lot codes, relevant regulatory registration or approval information, location(s) where applied, the date, and purpose for use.

## F. APPROVED SUPPLIERS, RECEIVING, STORAGE & SHIPPING AND INVENTORY CONTROL

The plant is expected to have detailed, written policies describing how suppliers are approved, receiving criteria for carrier and raw material acceptance, and handling and storage criteria for raw materials.

### F1. APPROVED SUPPLIER PROGRAM

#### 1.1. THERE SHALL BE A DOCUMENTED APPROVED SUPPLIER PROGRAM. THE PROGRAM SHALL BE BASED ON RISK ASSESSMENT OF THE SUPPLIERS.

- a. The program shall require written criteria for approving suppliers based on risk assessment.
- b. The program shall indicate how suppliers are evaluated and/or approved for use. This shall include quality, food safety, food security, and food fraud evaluations.
- c. Suppliers shall provide information to the facility that includes:
  - Process capabilities
  - Process descriptions
  - HACCP program information
  - Allergen information
  - Third party audit that includes HACCP.

**NOTE:** If the raw material is supplied by an importer, broker or distributor, the above information must be obtained for the original processor of the material.

#### 1.2. SUPPLIERS SHALL BE REQUIRED TO PROVIDE RELEVANT DOCUMENTATION TO SUPPORT THEIR STATUS AS AN APPROVED SUPPLIER.

- a. Approved suppliers shall resubmit information as per F1.1 (c) annually or if changes in their product occur. The date of expiry for the third party audit shall be taken into consideration, in the event that the third party audit is valid for more than one year as per the expiration date documented on the audit or its associated documentation (certificate or similar). If there is no expiration date on the third party audit, then it shall be considered to have a one year validity.
- b. Certificates of analysis (C of A) or a testing report or an inspection record shall be provided for each batch of raw material or food contact packaging received.
- c. In the absence of Certificates of Compliance, Certificates of Conformity, or Certificates of Analysis there shall be current continuing letters of guarantee required for all ingredients and food contact packaging materials
- d. There shall be specifications for each ingredient and food contact packaging material supplied.
- e. If appropriate, raw material testing protocol, standards and documents shall be in place for all ingredients and materials required.
- f. Corrective actions shall be implemented and documented for ingredients and materials not meeting specifications

## **F2. VEHICLE AND MATERIALS INSPECTION**

### **2.1. THERE SHALL BE A WRITTEN PROCEDURE FOR THE INSPECTION OF DELIVERY VEHICLES. THIS SHALL APPLY TO RECEIVING AND SHIPPING. PROCEDURES SHALL DEFINE WHEN CARRIERS ARE TO BE REJECTED.**

- a. The carrier inspection (including bulk carrier) procedure shall describe acceptable and unacceptable conditions including, but not limited to, clean and intact, free of moisture and offensive odors, pests, chemicals, and glass.
- b. All receiving and shipping equipment (including loading and unloading equipment, hoses and ports, pumps, screens, and filters for bulk deliveries) shall be secure, clean and stored in sanitary manner.
- c. Bulk tankers shall have documented cleaning and sanitizing programs.
- d. Receiving and transfer procedures for bulk ingredients or products shall include:
  - inspection and use of seals,
  - connection ports capped and locked when not in use, and
  - hoses are clean, capped and stored off the ground.
- e. Cleaning procedures shall be in place where required for equipment and carriers.
- f. Finished product requiring temperature control shall be shipped in vehicles capable of ensuring proper temperatures through all phases of transportation.
- g. The temperature setting and operation of all outbound refrigerated trailers shall be verified.
- h. Vehicles shall be pre-cooled prior to loading and shipping of finished product.
- i. Records of carrier inspection and acceptance or rejection shall be maintained.

### **2.2. THERE SHALL BE A WRITTEN PROCEDURE FOR THE INSPECTION AND RECEIPT OF INGREDIENTS, RAW MATERIALS, AND PACKAGING**

- a. The procedures shall:
  - Confirm all receipts are from approved suppliers.
  - Verify that delivery requirements have been met and materials are in good condition, free from contamination and damage.
  - Include the recording of results for any testing required at receipt.
  - Include temperature verification at receipt and confirmation of receipt of Certificates of Analyses or similar documentation as per F1.2 where specified.
- b. Records of carrier inspection and acceptance or rejection shall be maintained.
- c. Receiving areas for ingredients, chemical and supplies shall be adequately separated from processing areas such that product contamination is prevented.

### **2.3. THERE IS A WRITTEN PROCEDURE FOR APPROVAL FOR USE OF RAW MATERIALS, INGREDIENTS AND PACKAGING**

- a. There shall be a defined material release process that shall prevent use of ingredients before approval and ensure that non-conforming materials are not used.

### **F3. STORAGE, TEMPERATURE AND INVENTORY CONTROL**

#### **3.1. RAW MATERIALS, INGREDIENTS, PACKAGING AND FINISHED PRODUCT SHALL BE SECURE AND PROTECTED IN STORAGE.**

- a. Storage areas and material in storage shall be clean, orderly and free from spilled damaged or exposed product.
- b. Racks shall be clean.
- c. Product shall be stored six inches (15 cm) off the floor or on pallets.
- d. An effective inspection perimeter (at minimum 18 inches/46 cm) shall be maintained between walls and ceilings and product.
- e. Chemical storage shall be segregated from food materials and packaging and secured with restricted access.

#### **3.2. STORAGE TEMPERATURES SHALL BE CONTROLLED AND MONITORED.**

- a. Refrigerated, frozen, and other controlled temperature storage rooms shall be monitored at minimum daily, or through continuous recording and alarming devices, to ensure that appropriate temperatures are maintained for their contents (typically less than or equal to 40°F/4°C for refrigerated and equal to or less than 0°F/-18°C for frozen).
- b. Temperature logs shall be maintained.

#### **3.3. INVENTORY CONTROL SHALL BE IN PLACE.**

- a. There shall be an inventory management process that ensures that goods are used in rotation.
- b. There shall be an inventory management process that ensures that finished product is shipped in rotation.
- c. No expired or obsolete materials shall be used.
- d. Electronic inventory systems, if properly executed, may preclude the need for a paper-based system (such as the use of paper hold tags or similar).

### **F4. PRODUCT RELEASE, RETAINED PRODUCT AND RETURNS**

#### **4.1. THERE SHALL BE POLICIES AND PRACTICES FOR THE CONTROL OF RETAINED AND RETURNED PRODUCTS**

Retained and Returned (hold) policy and procedure shall include:

- a. A permanent written log of each product or item placed on hold. The hold log shall list the:
  - Date,
  - Product,
  - Quantity,
  - Reason for the hold,
  - Results of the evaluation,
  - Disposition,

- Authorizing person.
- b. A designated area(s) for Retained and Returned Products.
- c. Clear identification of returned or retained product.

---

#### 4.2. PRODUCT CAN BE SHIPPED ONLY WITH PROPER AUTHORIZATION.

- a. There shall be a documented finished product release procedure.
- b. Product shall not be released until all procedures and records are completed.
- c. Products produced under mandatory regulatory HACCP programs shall have an authorized signed release verifying that all HACCP records are complete, properly signed and that there are no CCP deficiencies prior to shipment.

## G. PROCESS & PRODUCT EVALUATION

The plant shall have written policies and procedures specifying the operational control practices required to assure that the manufacturing process operates in control and compliance to product formulations on a continuing basis. Operating records shall be available to verify conformance to these policies.

Measuring, metering or protective devices (including, but not limited to, thermometers, scales, flow meters, and metal detectors) shall be properly calibrated to assure the accuracy of these activities and the effectiveness of their performance. Accurate measurements are critical for monitoring HACCP CCPs.

### 1.1. SPECIFICATION AND FORMULATION CONTROL

#### 1.1.1. THERE SHALL BE WRITTEN SPECIFICATIONS AND OPERATING PROCEDURES TO MANAGE COMPLIANCE TO FORMULATION AND PROCESS PARAMETERS

- a. There shall be documented finished product specifications that define acceptable product attributes.
- b. Standards for raw materials, work in process and finished products shall be documented.
- c. Standards shall properly identify the products or materials and criteria for evaluation.
- d. The facility shall have a procedure and documentation to ensure specification changes or additions properly implemented for all products.
- e. Finished product testing protocol, standards and documents shall be in place for all products as required based on risk.
- f. There shall be procedures to control conformance to formulation and processing requirements.
- g. Corrective actions shall be implemented and documented for product not meeting specifications.

#### 1.1.2. RECORDS OF COMPLIANCE TO MANUFACTURING AND PRODUCT SPECIFICATIONS SHALL BE AVAILABLE

- a. Records shall be available demonstrating compliance to all manufacturing and finished product specifications including customer specifications, if applicable.
- b. Process records including blending and mixing records, shall show process parameters such as temperatures, pressures, belt speed, mix times, mixer speeds, ingredient quantities and the lot identification of ingredients used.

#### 1.1.3. REWORK SHALL BE CONTROLLED

- a. There shall be defined process and procedure for the management and use of out of specification product, rework and carryover that shall include clean breaks in any carryover or rework cycle and includes a same-into-same policy.

---

## **G2. VERIFICATION OF OPERATIONAL EQUIPMENT & MEASURING DEVICES**

### **2.1. THERE SHALL BE ONGOING VERIFICATION OF OPERATIONAL CONTROLS AND MEASURING DEVICES.**

- a. There shall be a program to verify and record the performance of measuring devices to assure accuracy on a day-to-day basis. This shall include:
  - Thermometers used for product evaluations
  - Scales used for batching production and finished products
  - Mass flow meters and pumps

---

## **G3. ALLERGEN MANAGEMENT PROGRAM**

### **3.1. THERE SHALL BE A DOCUMENTED PROGRAM TO CONTROL ALLERGENS.**

- a. The site has a list of allergens in the facility and a documented allergen control program.
- b. The program shall ensure compliance with allergen regulations of the country where the product is to be sold and consumed.

### **3.2. ALLERGEN INGREDIENTS SHALL BE CONTROLLED.**

- a. Ingredients containing allergens shall be clearly identified as such and properly controlled, segregated in receiving, storage, production or batching areas to prevent cross-contamination.
- b. Use of allergen-containing rework or carryover shall be controlled so only same-into-same is used.
- c. All ingredients in use, work-in-process (WIP) and rework and carryover shall be properly labeled with identification, date, lot number, allergen information so as to prevent accidental substitution, ensure traceability and prevent allergen cross-contact.

### **3.3. CONTROLS SHALL BE USED TO PREVENT ALLERGEN CROSS-CONTACT.**

- a. Production scheduling shall be used to minimize opportunities for allergen cross-contact.
- b. Utensils used for allergens shall be dedicated or be thoroughly cleaned between uses.
- c. Food grade lubricants and chemicals used for sanitation, including, but not limited to, hand soaps, shall be allergen free.

### **3.4. PERSONNEL SHALL NOT BE A SOURCE OF CROSS-CONTACT.**

- a. Personnel, when handling different allergen-containing products, shall take appropriate measures such as changing outer garments (e.g., coats, hair nets, gloves, sleeve guards).

3.5. **ESSENTIAL** ALLERGEN CLEANING SHALL BE PART OF ALLERGEN MANAGEMENT CONTROLS.

- a. Cleaning procedures to remove allergenic residues from equipment and utensils shall be validated as effective. This validation shall be done utilizing (where available) objective and specific allergen-protein test methods.
- b. Verification that allergen cleaning followed the validated process shall be documented.
- c. Allergen spills shall be promptly cleaned.

**\*ESSENTIAL ELEMENT--EVIDENCE OF CROSS-CONTAMINATION WITH ALLERGENS THAT WILL RESULT IN A THREAT TO HEALTH SHALL BE ASSESSED AS CRITICAL NON-CONFORMANCE.**

3.6. **ESSENTIAL** DOCUMENTS AND PRODUCTS SHALL BE PROPERLY LABELED WITH ALLERGEN IDENTIFICATION AND LABELING.

- a. Production documents, batch sheets, and formulas shall clearly identify the presence of allergens.
- b. Labeling for allergen containing products shall meet legal and customer requirements.
- c. Packaging and labeling operations shall have a documented line clearance procedure to ensure labels and products are removed from the line and labeling equipment during product changeovers.

**\*ESSENTIAL ELEMENT--MISLABELED PRODUCT THAT CONTAIN REGULATED ALLERGENS NOT DECLARED ON THE LABEL SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.**

## H. FOREIGN MATERIAL CONTROL

All finished product shall be inspected for potential metal contamination. The highly preferred method is for all finished packaged product to be scanned through an electronic instrument calibrated to identify and separate contaminated product. Typical systems include metal detectors or x-ray units. If electronic devices are not used, other measures designed to prevent physical contamination shall be employed. Examples of such measures would include liquids that pass through a fine mesh screen, free-flowing items that pass over, under, or through rare earth magnets or food items that are secured in the final package with metal fasteners, but pass through metal detection devices in the filling process. These "other measures" shall also be calibrated, monitored and documented. The plant shall have a documented procedure for monitoring their process and finished product for the presence of foreign material.

### H1. FOREIGN MATERIAL CONTROL

#### 1.1. OPEN PRODUCT SHALL BE PROTECTED

- a. All processing vessels, ingredients in use and work-in-process (WIP) shall be adequately covered and or protected to reduce the risk of contamination by foreign material.
- b. Plants packing product in glass containers shall provide shielding to protect product and ingredients in the event of glass breakage during production.

#### 1.2. THERE SHALL BE A PROGRAM TO MANAGE GLASS AND BRITTLE PLASTIC.

- a. There shall be a procedure to segregate and clean areas after glass breakage occurs.
- b. All essential glass or brittle plastic that exists in any area of the plant including, but not limited to, cameras, emergency lighting, dial and gauge covers shall be documented to indicate location and condition.
- c. Monitoring of the condition of glass and brittle plastic shall be documented at minimum monthly.

#### 1.3. SIEVES, FILTERS, SCREENS AND MAGNETS SHALL BE USED WHERE APPROPRIATE AND PROPERLY MANAGED AND MAINTAINED.

- a. Sieves, filters and screens that are designed to or that serve to capture or remove foreign objects from a product stream shall be appropriately sized, monitored, and inspected.
- b. When magnets are used for the detection and removal of potential metal contaminants, their effectiveness shall be verified periodically using the methodology and frequency recommended by the manufacturer.

1.4. **ESSENTIAL** METAL DETECTION SYSTEMS, WHERE THEY HAVE BEEN DETERMINED BY THE FACILITY'S RISK ASSESSMENT TO BE REQUIRED FOR FOOD SAFETY OR QUALITY CONTROL REASONS, SHALL BE MANAGED, AT A MINIMUM, ACCORDING THE METAL DETECTOR OPERATION EXPECTATIONS (SEE H1.4.1). FACILITIES MAY ALSO HAVE ADDITIONAL CUSTOMER REQUIREMENTS REGARDING THE USE AND MANAGEMENT OF METAL DETECTION SYSTEMS. METAL DETECTION SYSTEMS SHALL INCLUDE THE DETECTION HEAD AND A REJECT DEVICE. SIMILAR PROCEDURES SHALL BE EMPLOYED FOR X-RAY DETECTORS IF THESE HAVE BEEN DETERMINED TO BE THE FOREIGN MATERIAL DETECTION DEVICE.

- a. There shall be a written procedure describing the maintenance, set-up and verification tests of detector systems and reject devices.
- b. Metal detection verification shall include ferrous, non-ferrous and stainless steel test pieces.
- c. X-ray verification test piece selection shall be based on risk assessment for the product and process. Test pieces could include glass, hard plastics, wood, stones and metal.
- d. The system shall be verified at minimum at the start of production, at breaks, at the end of production and at any additional frequency determined by the customer or determined by risk assessment.
- e. There shall be a deviation and corrective action procedure for failure of the metal detector or X-ray to detect and reject test pieces.
- f. Rejected product shall be logged and investigated for the presence of foreign material.

**ESSENTIAL ELEMENT—METAL DETECTORS OR X-RAYS FOUND TO BE OUT OF CALIBRATION AND/OR NOT FUNCTIONING PROPERLY WITH THE POTENTIAL RESULT LEADING TO PRODUCTION OF ILLEGAL OR UNSAFE FOOD SHALL BE A CRITICAL NON-CONFORMANCE.**

**NOTE:** Having a metal detector is considered a good industry practice for the detection of foreign metal contaminants. However, metal detection systems (metal detectors and X-ray devices) may not be required or possible, depending on the product and process being evaluated. For certain industries, including, but not limited to, shell eggs, fluid processing, some whole muscle meat processors, the use of a metal detector or X-ray device is not common industry standard. However, all facilities must have assessed the foreign material contamination risk to their products and processes and employed suitable measures to control that contamination. If there is no metal detector or X-ray device utilized, the auditor must assess and document the facility's program that supports the detection of foreign material contamination.

#### 1.4.1 METAL DETECTOR OPERATION EXPECTATIONS.

- a. Detectors shall have calibration and set-up verified by placing the test units or cards containing them along with the first product or package through the detector.
  - Calibration shall include the use of ferrous, non-ferrous and stainless steel test samples.
  - Customer specifications shall be used, if available.

- b. Test units shall be placed along with the product in a sanitary manner so as to avoid product contamination. Special care shall be given to make sure that test units are promptly recovered from the test packages.
- c. Test units shall be placed with product to pass through the geometric center of the Metal Detector aperture.
- d. A successful verification check shall detect and reject three successive challenges for each test unit.
  - For those situations where three successive challenges may be difficult to accomplish, one challenge for each test unit is acceptable during the production run; however, three successive challenges are still required at start up and at finish. An example of this might be a system where detection is conducted just prior to packaging of a bulk ground meat product that is conveyed in line and insertion of the test unit is quite complicated.
  - Product used in the verification checks shall be re-run through the detector after the test units have been removed from the package to ensure that the product itself is free from metal contamination and has not influenced the test.
  - Frequency of verification checks during production and test metal samples used shall be sufficient to assure continued accurate performance. Some customers may require specified verification frequencies and test metal samples used.
  - A verification check of the detector performance shall be made on the last product run during the shift or lot. This will provide documentation that the detector was functioning properly from beginning to the end of production.
- e. Rejected units from the detector shall be retested and pass 3 successive times in different orientation before accepted as a false positive. The detector shall be properly calibrated at the time the rejected product is retested.
- f. Contaminated units shall be examined to determine the source of the problem.
- g. A record of detector rejects and the cause for rejection shall be recorded on the verification/test log.
- h. Verification failure and corrective action. In the event the detector fails a verification check, all product produced since the last documented successful verification shall be held and retested and shall successfully pass through a properly functioning detector device before release.

#### 1.5. BLADES, WHERE USED, SHALL BE CONTROLLED AND INSPECTED

- a. Knives, blades, cutters, dicers, saws, and other devices are controlled, clean, of proper design and routinely inspected for damage and their condition recorded.

#### 1.6 WOOD, WHERE USED, SHALL BE CONTROLLED AND INSPECTED

- a. Wooden pallets and other wooden utensils used in the facility shall be dedicated for that purpose, clean, maintained in good order and inspected as needed based on risk assessment, and their condition documented.

## I. CHEMICAL CONTROL

### 1. CHEMICAL CONTROL

1.1. NON-FOOD CHEMICALS (INCLUDING, BUT NOT LIMITED TO, THOSE USED FOR SANITATION, MAINTENANCE, AND PEST CONTROL) SHALL BE APPROVED FOR USE, SECURELY STORED, CLEARLY IDENTIFIED AND USED ONLY BY TRAINED PERSONS.

- a. Non-food chemicals shall be stored when not in use in areas away from finished products, product packaging materials, processing equipment, and ingredients. The chemical storage area(s) shall be properly vented, provide for adequate spill control and be secured with access restricted to properly authorized personnel.
- b. Safety Data Sheet (SDS), letters of guarantee or similar information shall be readily available for all chemical compounds in the facility.
- c. All personnel handling chemicals shall be trained in chemical control measures and safety.
- d. All chemical containers, whether original or secondary, shall be properly identified with the contents.
- e. If it is necessary to maintain pest management chemicals at the plant, they shall be stored in a secured location with limited access.
- f. Chemicals used for cleaning and sanitizing shall be securely stored when not in use.

1.2. LUBRICANTS SHALL BE PROPERLY STORED AND IDENTIFIED.

- a. Food grade lubricants shall be stored separately from non-food grade lubricants. Nonfood grade lubricants shall be clearly identified as not for use in food contact areas.

## J. PACKAGING & LABELING

### J1. PACKAGING AND LABELING

#### 1.1. **ESSENTIAL** LABELS SHALL BE ACCURATE AND COMPLY WITH ALL REGULATIONS.

- a. The facility shall have a program to assure that labels in use and product being produced are matched and do not lead to mislabeling or product adulteration.
- b. Labels shall satisfy regulatory requirements for the country of manufacture and/or for the country of sale.
- c. Procedures shall be documented and implemented to ensure obsolete labels or labels from a prior production run are removed before running another product on the same line.

**\*ESSENTIAL ELEMENT--EVIDENCE OF SYSTEMATIC USE OF INCORRECT LABELS OR LABELS THAT MISREPRESENT THE PRODUCT SHALL BE A CRITICAL NON-CONFORMANCE.**

#### 1.2. **ESSENTIAL** THE PRODUCT SHALL COMPLY WITH REGULATION OR SPECIFICATIONS FOR NET WEIGHT, NET QUANTITY OR PIECE COUNT.

- a. Net weight, volume, or count control checks shall be performed and documented at an appropriate frequency to assure ongoing label declaration compliance.

**\*ESSENTIAL ELEMENT--EVIDENCE OF FAILURE TO MEET REGULATORY QUANTITIES ON PRODUCT SHIPPED SHALL BE A CRITICAL NONCONFORMANCE.**

#### 1.3. THERE SHALL BE CLEARLY VISIBLE AND LEGIBLE CODES ON INDIVIDUAL AND CASED PRODUCT.

- a. Each individual sell unit shall have a production or lot code. Packages within the sell unit shall have a lot code, except for single use consumer units such as condiments.
- b. Lot codes shall be present, legible, and contain accurate information.
- c. Lot codes and labels shall be verified prior to the production of each lot of product.

#### 1.4. THE PACKAGING INTEGRITY AND FUNCTION SHALL ADEQUATELY PROTECT THE PRODUCT.

- a. Both the sell unit package and the shipping unit shall be designed and assembled to provide the necessary protection for the product from environmental and shipping conditions.

## K. TRAINING REQUIREMENTS

### K1. TRAINING

#### 1.1. NEW EMPLOYEE AND TEMPORARY EMPLOYEES SHALL BE TRAINED IN APPROPRIATE POLICIES AND PROCEDURES.

- a. Training shall be provided to new hires (operating and management personnel) for the topics below, at a minimum:
  - Food safety (including HACCP overview),
  - Food defense,
  - Food fraud,
  - Personal hygiene and GMP's ( before starting work),
  - Basic safe food handling,
  - Allergens,
  - Food Defense.
- b. There shall be specific training for identified critical food safety jobs. This shall include:
- c. HACCP Critical Control Point monitoring, corrective action and verification responsibilities prior to the individual being assigned sole responsibility for such activities.
- d. Sanitation employees (including new sanitation employees, applicable operators, temporary sanitation employees, and contract sanitation employees). Training shall include master Sanitation Schedule, Standard Sanitation Operating Procedures (SSOPs), food handling sanitation, and sanitation chemical safety.

#### 1.2. TRAINING SHALL BE CONDUCTED IN THE APPROPRIATE LANGUAGE(S).

- a. Training shall be provided in the language and presentation format that can be easily and clearly understood by the trainee.

#### 1.3. REFRESHER TRAINING SHALL BE CONDUCTED.

- a. Refresher training on the topics identified in 1.1 shall be provided to all employees and documented at minimum annually, or when changes in the facilities are such that refresher training is required.

#### 1.4. THERE SHALL BE A METHOD OF ASSESSMENT TO DETERMINE PROOF OF LEARNING FOLLOWING TRAINING

- a. There shall be a method to document individual understanding at the conclusion after the training. Methods may include testing or documented performance evaluations by supervision.
- b. Assessments shall be conducted within a reasonably short period of time after training (14 to 30 days).

- c. Assessments shall be an integral part of the training program.

---

**1.5. TRAINING RECORDS SHALL BE MAINTAINED.**

- a. Employee training records shall be maintained and include the information below for all staff levels:
- Employee name,
  - Training date,
  - Employee position/title,
  - Trainer name,
  - Training agenda and/or training content.

## L. LABORATORY SUPPORT

### L1. LABORATORY SUPPORT

#### 1.1. THE LABORATORY FACILITY SHALL NOT CONTRIBUTE TO POTENTIAL CONTAMINATION.

- a. The laboratory shall be isolated from the production area and control procedures shall be implemented to ensure that the laboratory does not contribute to potential contamination (based on risk assessment of the laboratory activities, control procedures include, but are not limited to, restricted access to laboratory area and materials used within, appropriate signage, dedicated sinks for cleaning and handwashing, proper decontamination and disposal of waste, appropriate ventilation and plumbing systems).
- b. Pathogen analyses shall not be performed at a plant laboratory unless there is an effective program to secure pathogen organisms from misuse. The pathogen testing laboratory shall comply with relevant regulatory requirements as well as the Good Laboratory Practices (GLP) requirements. Laboratory Procedures and Documentation shall meet recognized standards. Labs certified to ISO 17025 shall be acceptable.

#### 1.2. LABORATORY PROCEDURES AND DOCUMENTATION SHALL MEET RECOGNIZED STANDARDS.

- a. A documented laboratory control and practices program shall be established and include procedures, calibration control, chemical control, access and appropriate records
- b. Microbiological test procedures shall meet accepted standards (accepted by recognized authority and/or regulatory body—the Bacteriological Analytical Manual (BAM) from the USA FDA regulatory body, as an example).
- c. Chemical test procedures shall meet accepted standards (AOAC or other recognized authority).
- d. The documented laboratory control and practices program shall also apply to externally sourced laboratories. In other words, the facility must ensure that any laboratories that are being used for testing (internal or external) are meeting recognized standards.

#### 1.3. LABORATORY EQUIPMENT SHALL BE CALIBRATED.

- a. Balances and laboratory test equipment shall be calibrated by a competent company or individual at a prescribed frequency as defined by the manufacturer.
- b. Records of calibration shall be maintained.

## M. FOOD DEFENSE

### M1. FOOD DEFENSE

#### 1.1. THERE SHALL BE A WRITTEN PROGRAM WHICH DESCRIBES ASSIGNED RESPONSIBILITY FOR FOOD SECURITY AND HOW IT IS MAINTAINED.

- a. A Food Defense team shall be established that will evaluate the vulnerabilities and risks that exist from ingredient sourcing, storage, processing, shipping of finished goods, and personnel.
- b. This team shall meet to review the food defense plan at a minimum annually, as well as whenever changes are planned or made and after any incident.

#### 1.2. EACH FACILITY SHALL CONDUCT AND DOCUMENT A FOOD DEFENSE RISK EVALUATION TO ELIMINATE OR SIGNIFICANTLY REDUCE THE RISK OF EXTERNAL AND INTERNAL INTENTIONAL ADULTERATION OF FOOD (INCLUDING FOOD FRAUD).

- a. The facility shall have conducted a documented Food Defense Evaluation that takes into account all aspects of the physical facility and the manufacturing process. The potential of food fraud shall also be considered in this evaluation.
- b. Food Security inspections shall be conducted to measure effectiveness of the program and ensure buildings and grounds are secure.

**NOTE:** No details of food defense control measures will be identified in the audit report unless requested by the plant.

#### 1.3. A COMPREHENSIVE FOOD DEFENSE PLAN SHALL BE IMPLEMENTED TO MANAGE THE RISKS IDENTIFIED IN THE EVALUATION.

The implemented Food Defense Plan shall include:

- a. Security assessment of off -site storage,
- b. Protection of air, gas and water supplies,
- c. Protection of process control systems,
- d. Protection of environmental control systems,
- e. Protection of sensitive data systems and the data (e.g., formulations, specifications, business information),
- f. Identification and management of unusual occurrences.

#### 1.4. EMPLOYEES SHALL BE SCREENED, TRAINED IN FOOD DEFENSE AWARENESS AND ACCESS TO THE FACILITY SHALL BE CONTROLLED.

- a. New and existing employees shall be screened to ensure they are appropriate for employment in a food facility.
- b. Employee training programs are established to address food security issues.

- c. This includes:
  - Awareness for possible tampering occurrences in mail, ingredients, in-process materials and finished products.
  - Reporting requirements for unusual occurrences, observed behavior or unrecognized people in the facility.
- d. Visitor and contractor access to the facility shall be controlled.
- e. Employee identification methods shall be used to ensure that only authorized personnel are allowed in the facility or in restricted areas.
- f. Temporary (unscreened) employees shall only work in areas with pre-packed, coded and labeled product and do not have direct access to unprotected product.
- g. Temporary workers shall be adequately supervised at all times when on site.

#### 1.5. INCOMING AND OUTGOING MATERIALS SHALL BE PROTECTED AND INSPECTED.

- a. The site shall assess the vulnerability of incoming shipments and shall take appropriate actions such as:
  - Inspect vehicles and incoming product for evidence of tampering,
  - Require incoming vehicles to be locked or sealed,
  - Match seal numbers to shipping documents at receiving.
- b. The site shall assess the vulnerability of finished product packaging and use tamper evident packaging where possible.
- c. The transportation systems being used to deliver products shall be reviewed to ensure food security is maintained from pick-up to delivery, including locking or sealing outgoing vehicles.

#### 1.6. PLANTS SHALL BE REGISTERED WITH THE APPROPRIATE REGULATORY AUTHORITY.

- a. There shall be proof that the facility is registered with the relevant authorities

**NOTE:** For facilities in the USA, or those exporting to the U.S.A, proof shall be demonstrated that the facility is registered with the FDA under the PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002 or the USDA, as applicable.

**\*FAILURE TO REGISTER OR SHOW PROOF OR "CERTIFICATION" OF REGISTRATION IS A "MAJOR NONCONFORMANCE".**

## N. READY-TO-EAT (RTE), HIGH RISK/HIGH CARE FOOD PROCESSING REQUIREMENTS

This section shall apply to ready-to-eat (RTE) foods that, if contaminated after processing, can support the growth of pathogenic organisms (see Appendix 1—this section applies to foods manufactured in high risk or high care areas as defined by the product zone decision tree).

### N1. READY-TO-EAT FOOD PROCESSING

#### 1.1. AIRBORNE CONTAMINANTS SHALL BE MINIMIZED

- a. Ready to eat processing and high risk area shall be positive air. Sufficient filtered air shall be brought into high risk/high care processing areas where potentially hazardous foods are exposed post lethality to provide a net positive pressure differential in the exposed product area(s) relative to surrounding areas. Positive pressure shall be demonstrable at all openings between higher risk and lower risk areas.
- b. Air used directly on products or ingredients shall be designed such that contamination of the product does not occur.
- c. The creation of aerosols that could potentially disperse harmful organisms into the processing environment shall be strictly controlled when exposed product is present in the processing area and after sanitation has been completed and the area and equipment awaits the start of production.

#### 1.2. PROTECTIVE CLOTHING SHALL BE USED TO MINIMIZE POTENTIAL OF CROSS-CONTACT.

- a. Employees shall don distinctively colored clothing immediately prior to entry into the high risk/high care area. The clothing designated for these areas shall be protected from contamination. Disposable garments shall be changed prior to entering any high risk/high care area.

#### 1.3. ENTRANCE SANITATION CONTROLS

- a. The facility shall have a captive footwear program for high risk/high care areas or there shall be an effective program of cleaning and sanitizing of non-captive footwear.
- b. The wheels of equipment that are brought into high risk/high care areas shall be, at minimum, cleaned and sanitized prior to entry. It is recommended that the equipment used in RTE areas be captive to that area.
- c. Anyone seeking to enter the RTE area for any reason shall appropriately clean and sanitize their hands prior to entry and don the appropriate apparel.

1.4. ENVIRONMENTAL MONITORING FOR A PATHOGEN (OR APPROPRIATE INDICATOR ORGANISM) SHALL BE CONDUCTED AS APPROPRIATE TO THE FACILITY, THE FOOD, AND THE NATURE OF THE PREVENTIVE CONTROLS.

- a. There shall be written procedures for environmental monitoring. These procedures shall:
- Be scientifically valid;
  - Identify the test microorganism(s);
  - Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites shall be adequate to determine whether preventive controls are effective.
  - Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples shall be adequate to determine whether preventive controls are effective;
  - Identify the test(s) conducted, including the analytical method(s) used;
  - Identify the laboratory conducting the testing;
  - Include corrective action procedures.

1.5 PRODUCT TESTING FOR A PATHOGEN (OR APPROPRIATE INDICATOR ORGANISM) OR OTHER HAZARD SHALL BE CONDUCTED AS APPROPRIATE TO THE FACILITY, THE FOOD, AND THE NATURE OF THE PREVENTIVE CONTROL AND ITS ROLE IN THE FACILITY'S FOOD SAFETY SYSTEM.

- a. There shall be written Procedures for product testing. These procedures shall:
- Be scientifically valid;
  - Identify the test microorganism(s) or other analyte(s);
  - Specify the procedures for identifying samples, including their relationship to specific lots of product;
  - Include the procedures for sampling, including the number of samples and the sampling frequency;
  - Identify the test(s) conducted, including the analytical method(s) used;
  - Identify the laboratory conducting the testing; and
  - Include corrective action procedures.

## 7 DEFINITIONS

**ALLERGEN:** Food compounds can cause an allergic or food intolerance response in sensitive individuals. Food allergens elicit serious adverse reactions in some individuals. Allergic individuals can tolerate very little of the offending food.

In the United States, allergens of concern include:

- Milk,
- Egg,
- Fish,
- Crustacean Shellfish,
- Tree Nuts,
- Wheat ,
- Peanuts,
- Soybeans.

The US-FDA Food Allergen Labeling Act that went into effect January 1, 2006 defines allergens as follows:

The term 'major food allergen' means any of the following:

- a. Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
- b. A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:
- c. Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.
- d. A food ingredient that is exempt under paragraph (6) or (7) of section 403(w)."

(The exemptions would include those ingredients that are submitted for exemption and granted by the Secretary, those ingredients where scientific evidence is presented that demonstrates the allergen is not present or those where the allergen does not present an allergenic response that poses a risk to human health)

In Canada, allergens of concern include:

- Peanut or its derivatives, e.g., Peanut - pieces, protein, oil, butter, flour, and Mancelona nuts (an almond flavored peanut product). Peanut may also be known as ground nut.
- Tree Nuts (almonds, Brazil nuts, cashews, hazelnuts (filberts), macadamia nuts, pecans, pine nuts (pinyon, piñon), pistachios and walnuts or their derivatives, e.g., nut butters and oils.
- Sesame or its derivatives, e.g., paste and oil.
- Milk or its derivatives, e.g., milk caseinate, whey and yogurt powder.

- Eggs or its derivatives, e.g., frozen yolk, egg white powder and egg protein isolates.
- Fish or its derivatives, e.g., fish protein and extracts.
- Crustacean shellfish (including crab, crayfish, lobster, prawn and shrimp)
- Mollusks (including snails, clams, mussels, oysters, cockle and scallops) or their derivative, e.g., extracts.
- Soy or its derivatives, e.g., lecithin, oil, tofu and protein isolates.
- Wheat and triticale or its derivatives, e.g., flour, starches and grains.
- Sulphites, e.g., sulphur dioxide and sodium metabisulphites.
- Mustard

Additional international regulatory information regarding allergens can be accessed through the University of Nebraska’s Food Allergy Research and Resource Program. As of September 21 2017, the international regulatory chart for priority allergens is provided below, and can be accessed through the following link...

<https://farrp.unl.edu/IRChart>

International Allergens	USA	Canada	EU	Australia/New Zealand	Hong Kong	China	Japan*	Korea	Argentina	Bolivia	Chile	Colombia	Costa Rica	Cuba	Mexico	Nicaragua	Venezuela
Crustacean Shellfish	X	X	X	X	X	X	X (Crab, Shrimp, Prawn)	X (Crab, Shrimp, Prawn)	X	X	X	X	X	X	X	X	X
Egg	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Fish	X	X	X	X	X	X		X (Mackerel)	X	X	X	X	X	X	X	X	X
Milk	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Peanut	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Soy	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X
Tree nuts	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X
Wheat	X	X	X	X		X	X	X		X		X	X	X		X	X
Cereals with Gluten		X	X	X	X				X	X	X	X	X	X	X	X	X
Buckwheat							X	X									
Celery			X														
Lupin			X														
Molluscan Shellfish		X	X	X													
Mustard		X	X														
Sesame		X	X	X													
Sulfites	≥10 mg/kg	Directly added or ≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg				≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg				
Bee Pollens/Propolis				X													
Royal Jelly				X													
Peach								X									
Pork								X									
Tomato								X									

**CALIBRATION OF INSPECTION, MEASURING AND TEST EQUIPMENT:** Calibration of measuring equipment against an accepted industry standard shall be conducted at a frequency sufficient to confirm accuracy and precision.

**CERTIFICATES OF ANALYSIS:** Written documentation of specific microbiological, chemical or functional analysis based on customer specifications that are required on lots of product or ingredients prior to customer acceptance.

**CERTIFIED LABORATORY:** A laboratory that is able to calibrate its performance standards by performing crosscheck sample analysis with an accredited lab on a quarterly basis.

**LETTER OF GUARANTEE:** Document provided by supplier indicating that product provided by supplier (including, but not limited to food, food contact packaging materials, inks, and coatings) comply with all regulatory requirements.

**CORRECTIVE ACTION:** Action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

**GOOD MANUFACTURING PRACTICES (GMPs):** Manufacturing Guidelines as cited in the Code of Federal Regulation 21, Part 110, (USA FDA) or similar regulatory bodies

## HACCP DEFINITIONS

---

**CCP Decision Tree** – A sequence of questions to assist in determining whether a control point is a critical control point (CCP).

**Control** – Managing conditions of an operation to maintain compliance with established criteria.

**Control Measure** – Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

**Control Point** – Any step in the process at which biological, chemical or physical hazard can be controlled, reduced or eliminated.

**Corrective Action** – Documented procedures followed when a process or product deviation occurs.

**Criterion** – A requirement on which a judgment or decision can be based.

**Critical Control Point** – A step at which control can be applied and is essential to prevent or eliminate a food safety hazard likely to occur or reduce it to an acceptable level.

**Critical Limit** – A maximum and/or minimum value to which a biological, chemical or physical parameter shall be controlled at a CCP to prevent, eliminate or reduce the occurrence of a food safety hazard to an acceptable level.

**Deviation** – Failure to meet a critical limit.

**HACCP** – (Hazard Analysis and Critical Control Point) A systematic approach to the identification, evaluation and control of food safety hazards reasonably likely to occur.

**HACCP Plan** – The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

**HACCP System** – The result of the implementation of the HACCP plan.

**HACCP Team** – The group of people who are responsible for developing, implementing and maintaining the HACCP system.

**Hazard** – A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

**Hazard Analysis** – The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and shall be addressed in the HACCP plan.

**Monitor** – To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

**Prerequisite Programs** – All procedures used in the facility, which address operational conditions providing the foundation for the HACCP system.

**Ready-to-eat food (RTE food)** -- any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

**Severity** – The seriousness of the consequences of exposure to the hazard.

**Step** – A point, procedure, operation or stage in the food system from primary production to final consumption.

**Validation** – Collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, is effectively controlling the hazards that are reasonably likely to occur.

**Verification** – The application of surveillance, methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.

**INTERNAL G.M.P. AUDITS (self-inspections):** Audits conducted of the company by the company or for the company that assess the company's compliance to GMPs (Good Manufacturing Practices).

**SHALL:** A mandatory requirement of the standard.

**POTABLE WATER:** Water that is safe for human consumption.

**PRE-REQUISITE PROGRAMS:** Required programs that shall be implemented by a plant in order to produce a safe and quality product and support a HACCP program. Examples would be Sanitation Programs, Good Manufacturing Programs, Pest Management Programs, etc.

**PREVENTIVE ACTION:** Action taken to eliminate the causes of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence.

**PROCESS CAPABILITY:** The statistical determination of the capability of a process to produce a product within specified limits.

**REPACKAGING:** Activities whereby previously packaged product is opened to the environment and placed in new packages. This activity requires elements such as labels, net or random weight, and coding.

**REPEAT FINDING:** An exact deficiency cited at the most recent NSF International Supplier Assurance audit, which has not been effectively addressed with corrective action.

**RETAINED:** Product that is being held from further distribution pending information necessary to determine the proper disposition of the product.

**RETURNED:** Returned products are products that have left the control of the facility being audited.

**REWORK:** Product which has the physical identity altered and is reincorporated into another product.

**RISK:** This is the likelihood that a food safety hazard will happen.

**SENSITIVE AREAS:** Sensitive areas are those areas that provide a greater likelihood or severity for contamination to occur. In the case of Food Defense, a sensitive area is one that poses a greater likelihood of deliberate contamination if left unattended.

**SENSITIVE INGREDIENTS:** Food intolerances (other than allergens) which affect a limited number of individuals and which do not involve immunologic mechanisms.

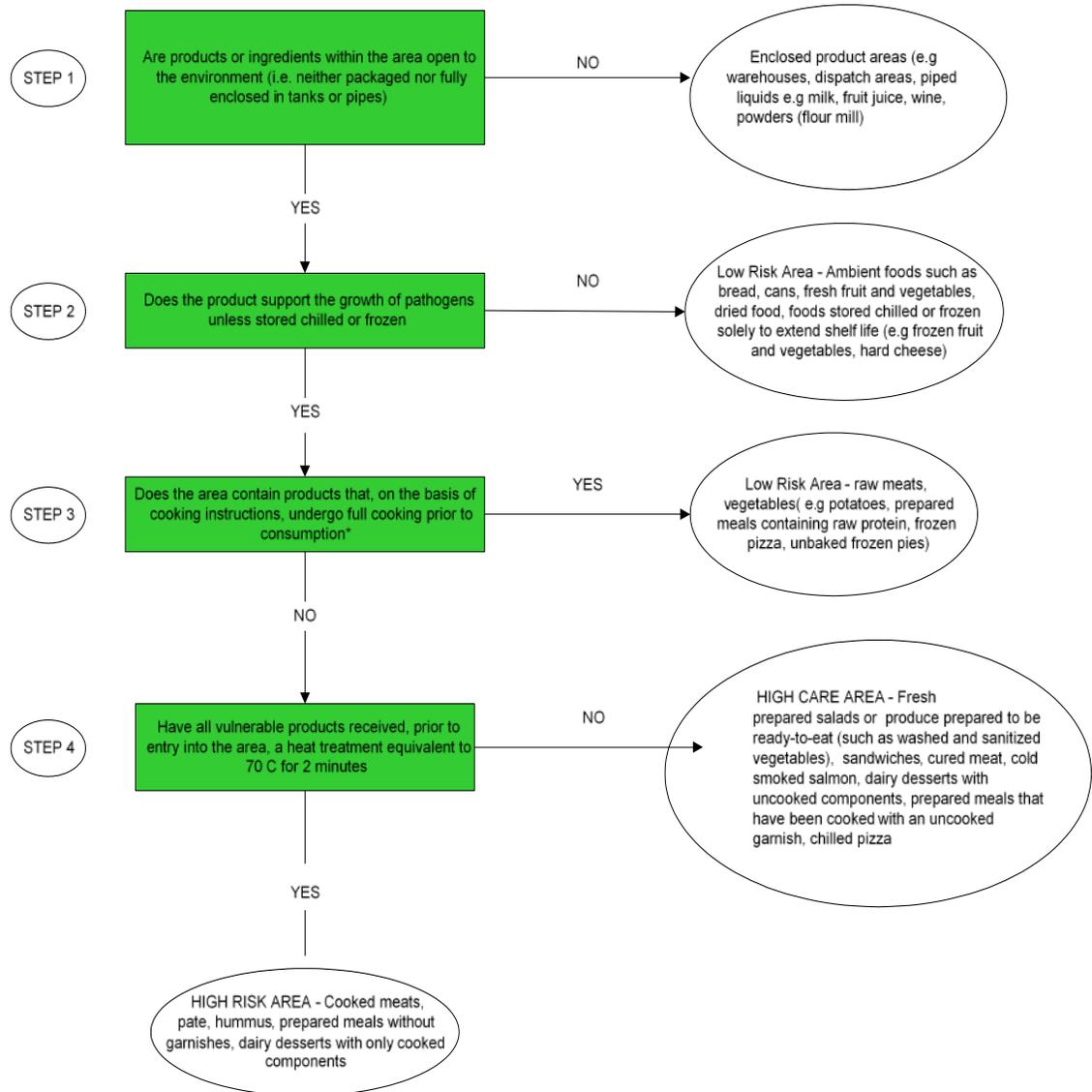
**SHOULD:** Should is used to express what is highly recommended, probable or expected in most situations.

**STATISTICAL CONTROL:** The control of a process to meet a predetermined outcome through the gathering of data related to the process and the mathematical evaluation of the data to predict and set limits for conformance to the predetermined outcome.

# 8 APPENDIX

## PRODUCT ZONE DECISION TREE

The decision tree below can be utilized to determine if Section N is appropriate to your facility.



**This decision tree is a guide only for the designation of production zone for the purposes of audit classification. A detailed risk assessment shall be undertaken to take into account specific product characteristics (e.g. pH, Aw) and identified product risks (such as potential Salmonella contamination in chocolate, peanut butter)**