



## Supplier Assurance

# Food Safety Expectations and Criteria for Food Processing Facilities – May 2014

Prepared by  
**NSF International**  
789 N. Dixboro Road  
Ann Arbor, MI 48105

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Document Title: <b>NSFI Supplier Assurance Audit Checklist for Food Safety Expectations and Criteria for Food Processing Facilities</b>	
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NSF International SUPPLIER ASSURANCE audits focus on the development, implementation and control of systems that impact Food Safety, Food Quality and Food Defense.

The audit evaluates the adequacy of documentation, compliance to documented procedures, 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 U.S.A. (FDA, USDA, Department of Commerce (seafood) 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 are based on customer specifications and:

- Food, Drug and Cosmetic Act (21 CFR) and appropriate amendments
- Food Code, 2013 edition (FDA/USPHS) and appropriate supplements
- Federal Meat Inspection Act (9 CFR) and amendments
- Poultry Products Inspection Act (9 CFR) and amendments
- Egg and Egg Products Inspection Act (EPIA) and amendments

#### **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 your type of facility. When policies are stored electronically or held at a corporate location it is the facilities responsibility to demonstrate to the auditor that they are aware of where and how to access documents related to the facilities 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

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- 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 must 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.

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## DEFICIENCY CLASSIFICATION AND GUIDELINES

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Within the Expectation Manual, the following terms have these meanings:

**Shall or Must** – An absolute requirement of this expectation document.

**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. The audit is intended as an objective assessment of the food safety management programs in a food facility.

### **Audit Question/Statement Answers Options:**

*\*\*Some expectations or elements are identified as Essential. A lack of compliance to these expectations shall cause audit failure. The Essential Elements are listed below.*

**"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"**. An assessment of Major non-conformance may be 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"**. An assessment of Critical Non-conformance may be made when:

- a. There is objective evidence or direct observation that product is unsafe, could potentially cause serious illness, death or is a risk to health and is subject to a Class I or Class II recall.
- b. The product or process does not meet regulatory requirements.
- c. There is failure to meet an Essential element of the expectations as listed in the standard.

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

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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 may 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.
E1.3 Pests are not a source of contamination.	Observation of pests or infestation on 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 shall be assessed as a Critical Non-conformance.  Mislabelled product contain regulated allergens that are not declared on the label shall be assessed as a Critical Non-conformance.
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

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## Scoring.

A non-scored version of the audit report is available. The non-scored format focuses the outcome on identification of items needing improvement and corrective action. The scoring system for a scored audit is detailed below.

### Explanation of Section Scorings

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

<b>Non-Conformance</b>	Deduction of 5% per finding
<b>Major Non-Conformance</b>	Deduction of 25% per finding
<b>Critical</b>	0%

Summary By Section				
	Non-Conformance	Major Non-Conformance	Critical	Section Score (%)
Section A - ADMINISTRATION & REGULATORY COMPLIANCE	0	0	0	100
Section B - HACCP	0	0	0	100
Section C - FACILITIES & EQUIPMENT	0	0	0	100
Section D - SANITATION, HOUSEKEEPING & HYGIENE	0	0	0	100
Section E - RODENT & PEST CONTROL MANAGEMENT	0	0	0	100
Section F - APPROVED SUPPLIERS, RECEIVING, STORAGE & SHIPPING & INVENTORY CONTROL	0	0	0	100
Section G - PROCESS & PRODUCT EVALUATION	0	0	0	100
Section H - FOREIGN MATERIAL CONTROL	0	0	0	100
Section I - CHEMICAL CONTROL	0	0	0	100
Section J - PACKAGING & LABELING	0	0	0	100
Section K - TRAINING REQUIREMENTS	0	0	0	100
Section L - LABORATORY SUPPORT	0	0	0	100
Section M - FOOD DEFENSE	0	0	0	100
Section N - READY TO EAT (RTE) 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:

<b>Non-Conformance</b>	= 1% deduction per finding off the total score
<b>Major Non-conformance</b>	= 10% deduction per finding off the total score
<b>Critical Non-conformance</b>	= 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 moving away from a scoring system and put 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 the Supplier Assurance Audit.

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## Scoring Examples

### Example 1

Section A contains 2 “nonconformance” ratings and Section B contains 1 “major nonconformance” rating, 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 nonconformances and -10% for the major nonconformance) and the overall audit rating is "Needs Improvement"

### 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 nonconformances and -20% for the 2 major nonconformances) and the overall audit rating is "Significant Improvement Needed"

**Corrective Action and improvement.** Improvements and Corrective actions for any finding noted in this audit must 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 re-occurrence of the problem.

### Examples of Critical deficiencies are defined as:

- Direct observation of product contamination and/or adulteration.
- Significant deviation from identified CCP in the HACCP plan.
- Mislabeled or misbranded product.
- Record falsification.
- Facility is not operating in compliance with applicable regulatory requirements.
- Failure to meet an Essential expectation as identified in the standard.

### Repeat Deficiencies

Repeat assessments of less than "Acceptable", 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 a downgrade of the current audit rating depending on the nature of the deficiency.

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## EXPECTATIONS AND CRITERIA FOR FOOD PROCESSING FACILITIES

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The following 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.

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.

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 the observation nor change the scoring but will be documented in the audit report. Existing documentation provided to the auditor after the conclusion of the exit meeting will not change scoring.

Best Practices are not assessed as part of this audit and no additional points are awarded as a result of best practices.

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## A. ADMINISTRATION & REGULATORY COMPLIANCE

### 1. Administration and Organization

- 1.1. There must 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.
- 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. The plant shall have documented policies and procedures covering all aspects of ingredient receipt, food manufacture, storage and transport.
  - b. 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.

### 2. Regulatory Compliance

- 2.1. A file of regulatory 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.

### 3. 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 recalls or potential recalls are processed.
  - b. Recall procedures shall include investigation, analysis and corrective and preventive action where appropriate.
- 3.2. Recall management responsibility shall be assigned
  - a. There shall be a designated recall team.
  - b. The roles of team members shall be defined.
  - c. There shall be back up personnel assigned for each team role.
  - d. There shall be a designated team leader or coordinator.
  - e. 24/7 contact information for team members shall be documented.
- 3.3. Traceability Exercises shall be conducted at least twice annually.
  - a. Trace exercises shall be conducted on both finished product and raw materials, including food contact packaging.
  - b. Traceability exercises shall demonstrate a 99.5% to 105% accounting within 4 hours, taking into account normal 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.

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.

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- 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:
    - i. A material balance sheet taking into account total quantity of product made,
    - ii. Finished product shipped,
    - iii. Finished product on hand,
    - iv. Finished product otherwise documented (damaged, lost, samples, etc.),
    - v. Finished product unaccounted for,
    - vi. A calculated percent recovery, and
    - vii. Start and end times for the exercise.
  - b. All corrective actions resulting from trace exercises are adequately documented and implemented prior to a subsequent trace exercise. It shall include finished product otherwise documented (damaged, lost, samples, etc.), and finished product unaccounted for; a calculated percent recovery; and start and end times for the 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 must be available.
- a. Materials shall be traceable including:
    - i. Ingredients,
    - ii. Rework,
    - iii. Carryover,
    - iv. Work in process, and
    - v. Food contact packaging materials.
  - 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.

\*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.

## 4. 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.
- 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.
- All records shall be:
- a. Genuine and legible.
  - b. Initialed by operator and independently verified for accuracy.
  - c. Recorded in ink on a timely basis with accurate date and time.
  - d. Errors shall be marked with single line-out and initialed.
  - e. Marked to record or chart out-of-control or out-of-specification conditions.
  - f. Records shall indicate disposition of product and corrective actions taken.

\*Evidence of intentional record falsification shall be assessed as a Critical Non-conformance.

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## 5. Crisis and Natural Disaster Management

5.1. Crisis management policies and procedures shall be developed to address any critical situations that may occur, i.e. natural disasters and catastrophic events and other emergency situations (power outage, tampering, etc.)

The policy shall assign management responsibility for the following activities in the event of crisis:

- a. Determine the status of ingredients, food contact packaging materials, in-process materials, and finished product involved in a critical event situation.
- b. Ensure all ingredients and materials are suitable for use prior to the start of production.
- c. Ensure there is a documented evaluation of all product involved in a critical event.
- d. Ensure there is a documented release of any affected product prior to shipping.
- e. Records are made of actual and mock crisis events.

## 6. Customer/Consumer Complaint Management

6.1. The plant shall manage customer and or consumer complaints.

- a. There shall be a consistent process for handling customer and/or consumer complaints.
- b. Records of complaints received and actions taken shall be made available to the auditor.

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## 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.

### 1. 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.
 

Where such expertise is not available on site, expert advice should be obtained from other sources.

The HACCP team shall;

  - a. Have a team leader who has formal HACCP training of at least two days duration.
  - b. Have the appropriate product, process, and sanitation specific knowledge.
  - c. Be clearly identified with their responsibilities as part of the HACCP plan.
- 1.2. The HACCP team shall participate in HACCP program development and maintenance. The HACCP Team Shall:
  - a. Be involved in the development, final approval, and subsequent reviews of the plan
  - b. 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.
  - d. Hold documented review team meetings at least annually to assess HACCP records and issues.
  - e. Assess all deviations, documentation errors, corrective actions, and assure that corrective actions are monitored for effectiveness
- 1.3. The HACCP Team shall construct a clear and easy to understand process flow diagram for each HACCP plan.

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The same flow diagram may be used for a number of products that are manufactured using similar processing steps.

The Process Flow Diagram shall include Critical Control Points (CCPs), shall be current and shall be verified.

- a. The Process Flow Diagram shall:
  - i. Outline each step involved in the process that is directly under the control of the establishment.
  - ii. Indicate the ingredient and material categories used in all preparation steps.
  - iii. Include all process equipment including packaging equipment and each process steps including blending steps, processing steps.
  - iv. Include introduction of rework and returned products, and packaging materials.
  - v. Include the steps preceding and following the process.
- 1.4. The Process Flow shall include CCPs, shall be current and shall be verified.
  - b. 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.
  - c. The process flow diagram shall remain current.
  - d. 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.

## 2. Hazard Analysis (HACCP Principle 1)

- 2.1. The HACCP team shall prepare a list of all of the hazards (chemical, physical, biological 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. The hazard analysis shall include:
    - i. The likelihood of hazards and the severity of their adverse health effects.
    - ii. The qualitative and/or quantitative evaluation of the presence of hazards.
    - iii. Survival or multiplication of microorganisms of concern.
    - iv. Production or persistence in foods of hazardous toxins, chemicals or physical agents.
    - v. Conditions leading to the above.

Note: 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.

## 3. 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. 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 CCPs, no further HACCP 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.

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The requirements of sub-sections "Verification and Validation" (HACCP Principle 6) and "Documentation and Record Keeping" (HACCP Principle 7) below shall also be satisfied to verify HACCP conclusions and to document all HACCP decisions and conclusions.

#### 4. Critical Limits (Principal 3)

4.1. Critical limits shall be specified and validated for each CCP.

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.

- 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. (Validation) 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.

#### 5. 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. 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.
- 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.

#### 6. 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.
- 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.

\*Failure to take corrective action for a critical limit deviation shall be assessed as a Critical Non-conformance.

#### 7. Verification and Validation (HACCP Principle 6)

7.1. There shall be verification documentation that confirms that the plan is being implemented as intended.

- a. Verification activities shall include where appropriate:

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- i. Review of the HACCP system and Plan and its records.
  - ii. Review of deviations and product dispositions.
  - iii. Confirmation that CCPs are properly monitored and kept under control.
  - iv. 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:
    - i. The Plan is scientifically and technically sound.
    - ii. All hazards have been identified.
    - iii. CCPs are effective and valid and that if the HACCP plan is properly implemented, these hazards will be effectively controlled.
  - b. Validation of the Plan shall be performed and documented on an ongoing basis as needed based on changes, corrective and preventive actions and shall be performed at least annually.

## 8. 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. It shall be sufficient to assist the business to verify that the HACCP controls are in place and being maintained
- a. Documentation shall include:
    - i. Hazard analysis.
    - ii. CCP determination.
    - iii. Risk analysis, (likelihood and severity).
    - iv. Critical limit determination.
  - b. Records shall include:
    - i. CCP monitoring activities.
    - ii. Deviations and associated corrective actions.
    - iii. Verification procedures performed.
    - iv. Modifications to the HACCP plan.

Records may be electronic, but if so, access shall be effectively controlled
  - c. Deviations from the HACCP plan shall be thoroughly documented with detailed corrective actions and product dispositions.
  - d. 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.
  - e. 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. Note: Signatures of the operator, supervisor and designated record reviewer are required in some regulated situations.
  - f. Records shall be easily retrievable and secured in a safe storage area.

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## C. FACILITIES & EQUIPMENT (The Manufacturing Environmental Controls Prerequisite System)

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

### 1. 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.
  - a. Potability testing of water supplies shall be conducted by a certified laboratory at least 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 least every 6 months.
  - b. Plants operating their own water systems must be able to demonstrate, through credible testing at least every 6 months, that plant water meets applicable regulatory standards for drinking water.
  - c. Potability shall meet local regulatory requirements at a minimum.
  - d. 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.
  - e. Purchased or manufactured ice shall have annual certificates of potability or documented satisfactory microbiological testing results.
  - f. Potable water distribution systems shall be segregated or adequately protected from cross contamination.

\*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. Potability criteria for microbiological, chemical and physical parameters shall be used.

### 2. Plant Construction and 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 least meets the customer and regulatory food safety and quality requirements.
  - a. Yards, grounds and roads in close proximity to buildings are free of debris, refuse and adequately drained.
  - b. Building exteriors are designed and maintained to prevent contamination or entry of pests, contaminants or unauthorized personnel.
    - i. Design and maintenance standards of the exterior of buildings shall prevent entry of pests or contaminants.
    - ii. Procedures and records shall be in place to support building maintenance.
- 2.2. ESSENTIAL.\*Plant construction and layout must 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 due to plant layout or construction.
  - b. Materials used to construct walls, floors, and ceilings must be smooth, non-porous, non-absorbent and easily cleanable.

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- c. Adequate heating, ventilation or refrigeration must be provided in all areas to maintain proper environmental and sanitary conditions for ingredients, finished product, equipment, and packaging materials.

\* Any condition in the facility which, based on objective evidence or observation, results in product or raw material contamination and/or adulteration shall be assessed as a Critical Non-conformance.

### 3. Plant Condition (state of repair cleanability, etc.)

- 3.1. Plant facilities shall be designed and maintained in an orderly, clean condition so as not to impede the ability to thoroughly clean all surfaces, provide pest harborage, or present opportunities for foreign material contamination
  - a. Walls, ceilings, overhead structures and floors are maintained and constructed of suitable material and where appropriate, joints are sealed and angles coved.
  - b. Floors are sufficiently sloped to provide drainage and to prevent the accumulation of liquid
  - c. Door and windows are close fitting, screened and in good repair.

### 4. Employee facilities

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

### 5. Hand washing facilities

- 5.1. Hand wash requirement signs, in appropriate languages and/or graphics, must 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
    - i. Locker room and toilet facility exits
    - ii. Entrances to food handling and food processing areas
  - b. Signs at hand wash stations shall instruct employees on the proper procedures for washing their hands.

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, suitably designed, operational and properly stocked
  - a. Hand wash stations shall have adequate room to accommodate the number of personnel in the area to 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 tempered water at a temperature and in a timely manner to promote adequate hand-washing. There shall be an adequate supply of hand sanitizing soap and/or sanitizing agent. Single service towels must be available with convenient disposal at each station. Where specific customer requirements or country regulations apply to hand-washing these shall take precedence.

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## 6. Equipment Layout, Design and Condition

- 6.1. **ESSENTIAL\***. All food production and packaging equipment must meet food sanitary design requirements and be installed in such a manner as to permit proper operation and access for cleaning and inspection.
- g. 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
  - h. Equipment in direct contact with food must be of smooth, impervious, non-toxic, non-absorbent and corrosion-resistant material.

\*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

## 7. Utensils

- 7.1. Utensils & containers used to handle edible material are not used to handle inedible material and are clearly identified and maintained.
- 7.2. Air and other gasses used as an aid or part of the process.
- a. Air and other gasses used as a processing technique is appropriately sourced, treated and filters maintained.

## 8. Plant lighting

- 8.1. Plant lighting shall be suitable.
- a. Plant lighting must be adequate and appropriate for sanitation and processing tasks being performed.
  - b. Light bulbs and fixtures in areas where food products and packaging material are exposed are shielded or protected against breakage

## 9. 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. Temporary repairs shall be consistent with GMPs and must not permit the use of inappropriate materials. Permanent repairs shall be made promptly.
  - c. Nonfood grade materials such as wire, tape, string, plastic or cardboard shall not be used for temporary repair in processing areas.
  - d. There shall be a procedure to ensure that cleaning and sanitation is done following maintenance where appropriate. Records shall be maintained.
- 9.2. **ESSENTIAL\***. Equipment or control devices that impact on food safety are effectively calibrated. Equipment or control device that impact on product compliance to quality and regulatory requirements are effectively calibrated  
Calibration could include, but is not limited to, temperature controllers, flow meters, pressure regulators, divert devices, CIP instrumentation, scales, speed controllers, etc.
- \*Equipment found to be out of calibration leading to potential for illegal or unsafe food shall be a Critical Non-conformance.
- a. Control and monitoring devices essential to the control or monitoring of regulatory or food safety critical limits and pre-requisite program parameters shall be calibrated by trained personnel according to a pre-determined schedule and as required by the maintenance program.

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- b. 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.
- c. Control and monitoring devices essential to the control, monitoring or testing for compliance to quality parameters shall be calibrated by properly trained persons, according to a predetermined scheduled and as required
- d. Measuring devices for food safety and quality are traceable to a national standard.

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## D. SANITATION, HOUSEKEEPING & HYGIENE

### 1. Sanitation

- 1.1. There shall be a Master Sanitation Schedule (MSS) and monitoring and recording of cleaning.
  - a. The MSS shall include:
    - i. Operational areas (floors, walls, drains, overheads),
    - ii. Equipment,
    - iii. Warehouse,
    - iv. Storage,
    - v. Maintenance,
    - vi. Employee facilities (locker rooms, cafeteria, break areas and toilet facilities) and,
    - vii. 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 regular basis.
- 1.2. There shall be Standard Sanitation Operating Procedures (SSOPs)
  - a. The plant must have documented SSOPs for:
    - i. Operational areas,
    - ii. Individual pieces of food processing equipment and,
    - iii. Facility areas and structures.
- 1.3. There shall be a documented Pre-operational Inspection
  - a. A documented inspection program shall be in place to assess sanitation effectiveness and line conditions prior to startup.
  - b. Deficiencies shall be documented and corrected.
  - c. There shall be a clear explanation documented of the activities performed to bring the equipment into a sanitary condition.
- 1.4. Operational Housekeeping shall be effective.
  - a. Accumulation of garbage, trash and waste materials shall be kept at a minimum and done in a manner that does not create any food safety risk.
  - b. All containers shall be properly labeled i.e., edible, inedible, trash, etc.
  - c. Equipment and floors shall be cleaned, as necessary, during operations to provide a hygienic environment.

### 2. 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 must observe the strictest of personal hygiene practices as outlined in the relevant regulations. (In USA Code of Federal Regulations, Section 21, Part 110, “Current Good Manufacturing Practices” for food plants).
  - b. These shall include:
    - i. A written dress code for all employees (including new and part-time), visitors, vendors and contractors. Employees must wear clean clothing and shoes appropriate for the working conditions.
    - ii. Fine mesh net hair restraints for head and facial hair in production, processing and warehouse areas by all employees.
    - iii. No false fingernails, fingernail polish, jewelry, rings, exposed body piercings, watches, etc.

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- iv. Not working in food handling/processing areas if employees have an infectious or communicable illness, or have open sores on hands, faces or arms, etc. Employees must 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.
- v. Production area employees must 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
- vi. If gloves are worn, they must be intact, with no holes, and kept clean. They must also be washed and sanitized, or replaced, if they become contaminated.
- vii. If dedicated aprons, lab coats, smocks, etc. are utilized, the plant must provide and the employees must 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.
- viii. Eating, drinking, spitting, chewing or using tobacco products shall not be permitted except in designated areas.
- ix. Pens, combs, pencils, thermometers, etc. must not be carried above the waist at any time while in food handling/processing areas.
- x. Monitoring records are maintained.

### 3. Self Inspection

#### 3.1. GMP Self Inspections shall be completed.

- a. There shall be routine facility inspections performed to assure management that GMP policies have been
  - i. Effectively implemented and
  - ii. Facilities and equipment are maintained to meet sanitary and operational needs.
- d. GMP/Facility Inspections shall be documented to show any non-conformances identified and corrective actions taken.

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## E. RODENT & PEST CONTROL MANAGEMENT

### 1. Pest Control

- 1.1. There shall be a Documented and Specific Pest Control Program
  - a. There shall be a current Pest Management Manual 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 Material Safety Data Sheet (MSDS) for all chemicals used.
  - c. There shall be written procedures to direct the activities conducted by the PCO and trained employees. They shall include:
    - i. Types of pests being controlled
    - ii. Frequency of monitoring
    - iii. 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 state or 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 must be free of conditions that may provide harborage or attractants for insects, birds, rodents or other pests. There shall be at least an 18 inch vegetation clear perimeter around exterior structures.
  - b. Outside bait stations shall be place around the exterior perimeter of the building at intervals recommended by the Pest Control Company (usually at 50 foot intervals)
  - c. The stations shall be identified, locked, secured in place, and inspected at least monthly (weather permitting)
- 1.3. **ESSENTIAL\***. There shall be no evidence of infestation

#### Management Inside Premises

- 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 pest infestation inside the facility is a major non-conformance

\*\*Observation of pests or infestation on ingredients, packaging, work in process, or finished goods shall be assessed as a Critical Non-conformance.

- 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. Insect light traps shall be suitably located and not located over, adjacent to or within 8 feet of product, packaging or processing equipment.
  - d. Mechanical rodent traps shall be placed based on recommendations of the Pest Control Service provider and, at a minimum, inside and on either side doors that exit to the exterior, including all docks doors.
  - e. 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.
  - f. There shall be no bait used inside the facility other than pheromone traps where required.

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- 1.5. Doors shall be tight fitting and closed with openings sealed to prevent pest entry into the building
  - a. Doors and docks shall have adequate seals to prevent pest entry.
  - b. Doors, windows and dock doors shall remain closed 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. Record on a pesticide usage log the usage of chemicals pest control agents, including name, amount lot codes, EPA registration number or equivalent approval, location(s) where applied the date and purpose for use.

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## 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.

### 1. Approved Supplier program

- 1.1. There shall be a documented approved supplier program.
  - a. The program shall require written criteria for approving suppliers
  - b. Suppliers shall complete a pre-qualification questionnaire that includes:
    - i. Process capabilities
    - ii. Process descriptions
    - iii. HACCP program information
    - iv. Allergen information
    - v. Third party audit that includes HACCP.
- 1.2. Suppliers shall be required to provide relevant documentation to support their status as an approved supplier.
  - a. Approved suppliers shall re-submit questionnaire and audit results annually
  - b. Certificates of analysis (C of A) shall be provided for each batch of raw material or food contact packaging. In the absence of Certificates of Compliance, Certificates of Conformity or Certificates of Analysis there shall be current continuing Letters of Pure Food Guarantee for all ingredients and food contact packaging materials
  - c. There shall be specifications for each ingredient and food contact packaging material supplied.

### 2. 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
  - a. The carrier inspection (including bulk carrier) procedure shall describe acceptable and unacceptable conditions, whether clean and intact, free of moisture and offensive odors, pests, chemicals, glass, etc.
  - b. Bulk receiving and shipping equipment (hoses and ports, pumps, screens filters etc.) shall be secure, clean and stored in sanitary manner.
  - c. Cleaning procedures shall be in place where required for equipment and carriers
  - d. The temperature setting and operation of all outbound refrigerated trailers shall be verified.
  - e. Outbound refrigerated trailers shall be pre-cooled before loading.
  - f. 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
    - i. Confirm all receipts are from approved suppliers.
    - ii. Verify that delivery requirements have been met and materials are in good condition, free from contamination and damage.
    - iii. Include temperature verification at receipt and confirmation of receipt of Certificates of Analyses where specified.
  - b. Records shall be maintained

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- 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.

### 3. Storage Conditions and Inventory Control.

- 3.1. Raw materials, ingredients, packaging and finished product shall be secure and protected.
  - 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 off the floor or on pallets.
  - d. An effective inspection perimeter shall be maintained between walls and product.
  - e. Chemicals 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 must be monitored at least daily to ensure that appropriate temperatures are maintained for their contents (typically <40°F or 4°C for refrigerated and < -10°F or -23°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 hold tag system.

### 4. Product release, Retained Product and returns

- 4.1. There shall be policies and practices for the control of Retained and Returned Products
 

A Hold Tag procedure must include:

  - a. A permanent written log of each product or item placed on hold. The hold log shall list the:
    - i. Date,
    - ii. Product,
    - iii. Quantity,
    - iv. Reason for the hold,
    - v. Results of the evaluation,
    - vi. Disposition, and
    - vii. Authorizing person.
  - b. Designated Areas for Retained and Returned Products.
  - c. Returned or retained products must be clearly identified as such.
- 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 must have an authorized signed release verifying that all HACCP records are complete, properly signed and that there are no CCP deficiencies prior to shipment.

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## 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 (such as thermometers, scales, flow meters, metal detectors, etc.) 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. Specification and Formulation Control

- 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. There shall be procedures to control conformance to formulation and processing requirements.
- 1.2. Records of compliance to manufacturing and product specifications shall be available
  - a. Records must be available demonstrating compliance to all manufacturing and finished product specifications including customer specifications, if applicable.
  - b. Process records including blending and mixing records must show process parameters such as temperatures, pressures belt speed, mix times, mixer speeds, ingredient quantities and the lot identification of ingredients used
- 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 cycles and includes a same into same policy

### 2. Verification of Operational Equipment & Measuring Devices

- 2.1. There shall be ongoing verification of operational controls and measuring devices.
  - a. There must also be a program to verify and record the performance of measuring devices to assure accuracy on a day-to-day basis. This shall include
    - i. Thermometers used for product evaluations
    - ii. Scales used for batching production and finished products
    - iii. Mass flow meters and pumps

### 3. ESSENTIAL\*. 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 must be clearly identified as such and properly controlled, segregated in 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.

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- c. All ingredients in use, work-in-process (WIP) and rework and carryover must 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.
- 3.4. Personnel must not be a source of cross-contact.
- a. Personnel, when handling different allergen-containing products, must take appropriate measures such as changing outer garments (Coats, hair nets, gloves, sleeve guards etc.).
- 3.5. Essential.\* Allergen cleaning shall be part of allergen management controls.
- a. Cleaning procedures to remove allergenic residues from equipment 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.
- \*Evidence of cross-contamination with allergens that will result in a threat to health and would result in a Class I or Class II recall shall be assessed as a Critical Non-conformance.
- 3.6. Essential.\* Documents and products shall be properly labeled with allergen identification and labeling.
- a. Production documents, batch sheets, formulas, etc. shall clearly identify the presence of allergens.
  - b. Labeling for allergen containing products must meet legal and customer requirements.
  - c. Packaging and labeling operations must have a documented line clearance procedure to ensure labels and products are removed from the line and labeling equipment during product changeovers.
- \*Mislabeled product that contain regulated allergens not declared on the label shall be assessed as a Critical Non-conformance.

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## 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 must 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” must 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.

### 1. Foreign Material Control

- 1.1. Open product shall be protected
  - a. All processing vessels, ingredients in use and work-in-process (WIP) must 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 etc. shall be documented to indicate location, and condition.
  - c. Monitoring shall be documented at least monthly.
- 1.3. Sieves, Filters, and Screens 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.
- 1.4. Metal detectors shall be managed according the Metal Detector Operation Expectations, below (see H1.4.1). Metal detection systems shall include the detection head and a reject device. Similar procedures shall be employed for X-ray detectors.
  - a. There must 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 pieces should include glass, hard plastics, wood, stones and metal.
  - d. The system shall be verified at the start of production, breaks and at the end of production and at any frequency determined by the customer
  - e. There shall be a deviation and corrective action procedure for failure of the metal detector to detect and reject test pieces
  - f. Rejected product shall be logged and investigated for the presence of foreign material

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- g. 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

#### 1.4.1 Metal Detector Operation Expectations.

- a. **Calibration.** 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.
  - i. Calibration shall include the use of ferrous, non-ferrous and stainless steel test samples.
  - ii. Customer specifications shall be used, if available.
- b. **Frequency.** At the start of the production run, the first product through shall be tested to verify performance and ability to detect and reject the specified test units.
- c. **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.
- d. **Test units** shall be placed with product to pass through the geometric center of the Metal Detector aperture
- e. **Verification method.** A successful verification check shall detect and reject three successive challenges for each test unit.
  - i. 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.
  - ii. 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.
  - iii. 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.
  - iv. 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.
- f. **Rejected material.** 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.
- g. **Contaminated units** shall be examined to determine the source of the problem.
- h. **Records.** A record of detector rejects and the cause for rejection shall be recorded on the verification/test log.
  - i. **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.

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- 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

## I. Chemical Control

### 1. Chemical Control

- 1.1. Non-food chemicals shall be approved for use, securely stored, clearly identified and used by trained persons
  - a. Non-food chemicals used for maintenance, sanitation, or pest control must be stored in areas away from finished products, product packaging materials, processing equipment, and ingredients. The chemical storage area(s) must be secured with access restricted to properly authorized personnel.
  - b. Material Safety Data Sheet (MSDS) information must be readily available for all chemical compounds in the facility.
  - c. All personnel handling chemicals must be trained in chemical control measures and safety.
  - d. All chemical containers, whether original or secondary, must be properly identified with the contents
- 1.2. Lubricants shall be properly stored and identified
  - a. Food grade lubricants must be stored separately from non-food grade lubricants. Non-food grade lubricants must be clearly identified as not for use in food contact areas.
- 1.3. Pest Control Chemicals shall be properly stored
  - a. If it is necessary to maintain pest management chemicals at the plant, they must be stored in a secured location with limited access. (It is preferred that pest control chemicals are stored with the pest contractor and brought to the plant when needed and removed at the time the PCO leaves the plant)
- 1.4. Cleaning Chemicals and Sanitizer shall be securely stored
  - a. Chemicals used for cleaning and sanitizing must be securely stored when not in use

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## J. PACKAGING & LABELING

### 1. 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.
- 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.

\*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.

\* Evidence of failure to meet regulatory quantities on product shipped shall be a Critical Non-conformance.

1.3. Clearly visible and legible Codes on Individual and Cased Product

- a. Each individual sell unit must have a production or lot code. Packages within the sell unit must have a lot code, except for single use consumer units like condiments.
- b. Lot codes must be present, legible, contain accurate information, and be correctly formatted.

1.4. The packaging Integrity and Function shall adequately protect the product.

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

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## K. TRAINING REQUIREMENTS

### 1. Training

- 1.1. New employee and temporary employees shall be trained in appropriate policies and procedures.
  - a. Training shall be provided to new hire operating and management personnel for at least the topics below:
    - i. Food safety (including HACCP overview),
    - ii. Food defense,
    - iii. Personal hygiene and GMP's ( before starting work),
    - iv. Basic safe food handling,
    - v. Allergens, and
    - vi. Food Defense
  - b. There shall be specific training for identified critical food safety jobs. This shall include:
    - i. HACCP Critical Control Point monitoring responsibilities prior to the individual being assigned sole responsibility for such activities,
    - ii. 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 must 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 in the topics identified in 1.1 a. and b. must be provided and documented at least annually.
- 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 must be maintained and include the information below for all staff levels:
    - i. Employee name,
    - ii. Training date,
    - iii. Employee position/title,
    - iv. Trainer name, and
    - v. Training agenda and/or training content.

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## L. LABORATORY SUPPORT

### 1. Laboratory Support

- 1.1. The laboratory facility and staffing shall not contribute to potential contamination.
  - a. The laboratory must be isolated from the production area and control procedures must be implemented to ensure that it does not contribute to potential contamination.
  - b. Pathogen analyses must not be performed at a plant laboratory unless there is an effective program to secure pathogen organisms from misuse. The pathogen testing laboratory must comply with BSL2 requirements as well as the Good Laboratory Practices (GLP) requirements set forth in 21 CFR 58. 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. Microbiological test procedures must meet accepted standards (BAM, USDA or recognized authority).
  - b. Chemical test procedures must meet accepted standards (AOAC or recognized authority).
- 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

### 1. Food Defense

- 1.1. 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.
  - a. There shall be a Food Defense Team.
  - b. The team shall meet to review the food defense plan at a minimum annually and whenever changes are planned or made and,
  - c. After any incident.
- 1.2. Each facility must conduct and document a Food Defense Risk Evaluation to eliminate or significantly reduce the risk of external and internal intentional adulteration of food. NOTE: No details of food defense control measures will be identified in the audit report unless requested by the plant.
  - a. The facility shall have conducted a documented Food Defense Evaluation.
- 1.3. A Comprehensive Food defense Plan shall be implemented to manage the risks identified in the evaluation that 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 (formulations, specifications, business information, etc.),
  - f. Identification and management of unusual occurrences.

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- 1.4. Employees shall be screened, trained in food defense awareness and access to the facility shall be controlled.
  - a. All employees shall be screened prior to employment.
  - b. Visitor and contractor access shall be controlled
  - c. All employees shall receive training in food defense awareness and reporting requirements for unusual occurrences, observed behavior or unrecognized people in the facility.
- 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:
    - i. Inspect vehicles and incoming product for evidence of tampering,
    - ii. Require incoming vehicles to be locked or sealed,
    - iii. 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.
- 1.6. Plants shall be registered with the appropriate regulatory authority.

In the USA or if exporting to the U.S.A. then the plant, warehouse or distribution center must demonstrate proof of having registered their facility 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".

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## N. Ready-To-Eat (RTE) Foods 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)

- 1.1. Airborne contaminants shall be minimized
  - a. Air brought into processing areas where potentially hazardous foods are exposed post lethality shall be filtered.
  - b. Sufficient filtered air shall be brought into 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.
  - 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 RTE area. RTE clothing shall be protected from contamination. Disposable garments shall be changed prior to entering the RTE area
- 1.3. RTE production area Entrance Sanitation Controls
  - a. The facility shall have a captive footwear program for RTE 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 RTE areas shall be 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 Pathogen Monitoring shall be implemented
  - a. Manufacturers of RTE products shall have an environmental pathogen monitoring program

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## 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.

### United States

In the United States, allergens of concern include:

- a. Milk,
- b. Egg
- c. Fish
- d. Crustacean Shellfish
- e. Tree Nuts
- f. Wheat
- g. Peanuts
- h. 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:

- i. 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.
- j. A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:
- k. Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.
- l. 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)

### Canada

Canadian definition of allergens is as follows:

\* Peanut or its derivatives, e.g., Peanut - pieces, protein, oil, butter, flour, and Mancelona nuts (an almond flavored peanut product), etc. 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 etc.

- m. Sesame or its derivatives, e.g., paste and oil etc.
- n. Milk or its derivatives, e.g., milk caseinate, whey and yogurt powder etc.
- o. Eggs or its derivatives, e.g., frozen yolk, egg white powder and egg protein isolates etc.
- p. Fish or its derivatives, e.g., fish protein and extracts etc.
- q. Shellfish (including crab, crayfish, lobster, prawn and shrimp)

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- r. Mollusks (including snails, clams, mussels, oysters, cockle and scallops) or their derivative, e.g., extracts etc.
- s. Soy or its derivatives, e.g., lecithin, oil, tofu and protein isolates etc.
- t. Wheat or its derivatives, e.g., flour, starches and grains etc.
- u. Sulphites, e.g., sulphur dioxide and sodium metabisulphites etc.
- v. Others (as considered necessary)
- w. (See Sensitive Ingredients)

**CALIBRATION OF INSPECTION, MEASURING AND TEST EQUIPMENT:** Calibration of measuring equipment against an accepted industry standard must 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.

**CONTINUING LETTER OF GUARANTEE:** Document provided by supplier indicating that all food, food contact packaging materials, inks, coatings, etc. comply with all provision of the Food, Drug and Cosmetic Act and Amendments.

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

**FOOD CODE:** Reference Guide published by U.S. Dept. of Health and Human Services, Public Health Service and Food and Drug Administration, 2005 and appropriate supplements.

**GOOD MANUFACTURING PRACTICES (GMPs):** Manufacturing Guidelines as cited in the Code of Federal Regulation 21, Part 110.

#### **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 must 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.

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**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 must 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.

**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** – That element of verification focused on 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 methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

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

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

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

**PRE-REQUISITE PROGRAMS:** Required programs that must 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:** A previously cited deficiency, which has not been effectively addressed with corrective action.

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**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.

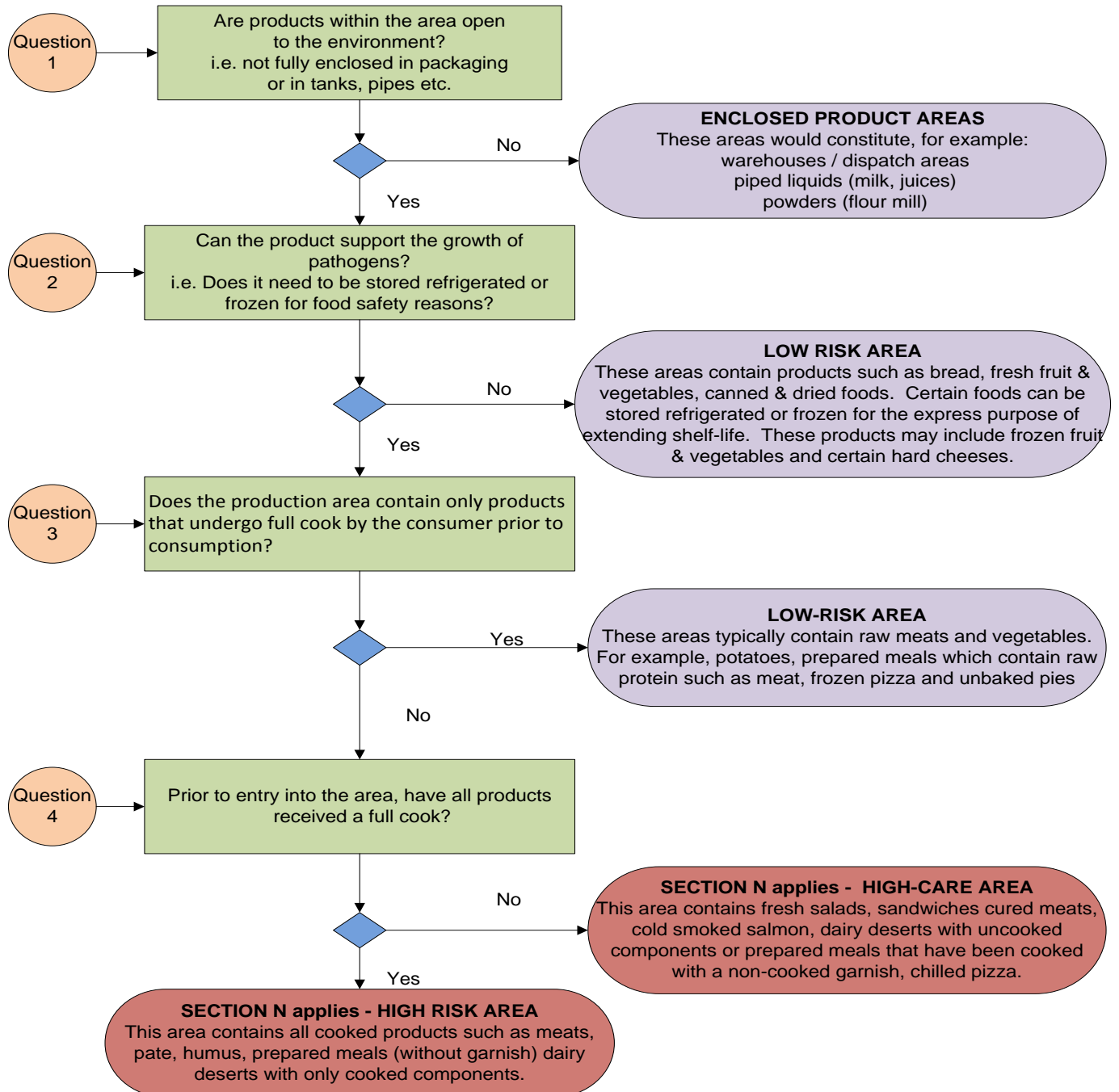
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## Appendix 1

### Production Zone Decision Tree

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



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This decision tree is a guide only for the designation of production zone for the purposes of audit classification. A detailed risk assessment should be undertaken where necessary to take into account specific product characteristics (e.g. pH, aw)

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