NSF International

Supplier Assurance Audit

Product Safety, Quality and Defense Expectations and Criteria for Manufacturing Facilities of - Sanitation and Household Chemicals and Supplies -

December 17th, 2014

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BACKGROUND

NSF International SUPPLIER ASSURANCE audits focus on the development, implementation and control of systems that impact Product Safety, Product Quality and Product 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.

Specifically, this audit evaluates:

- Compliance to Regulatory Standards.
  - In most instances regarding product safety, the Expectations Manual regards regulatory standards as minimum requirements.
- Adherence to policies, procedures, and client specifications.
- The ability to successfully trace product movement and execute a product recall.

This manual provides criteria and expectations that the facility will be audited against and is generic for all types of industrial, consumer, and foodservice chemicals and supplies.

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 product safety and product defense environment.

The stated criteria and expectations are based on:

- Customer specifications and requirements
- 29 CFR (OSHA) and appropriate amendments
- FIFRA
- EPA

Links to these documents and other reference sources are available at our web site:

www.nsf.org

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SCORING GUIDELINES

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:

- **Non-Conformance**: Deduction of 5% per finding
- **Major Non-Conformance**: Deduction of 25% per finding
- **Critical**: 0%

<table>
<thead>
<tr>
<th>Summary By Section</th>
<th>Non-Conformance</th>
<th>Major Non-Conformance</th>
<th>Critical</th>
<th>Section Score (%)</th>
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<tr>
<td>Section A - ADMINISTRATION &amp; REGULATORY COMPLIANCE</td>
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Explanation of Overall Audit Result
The overall score result is based on the total number and level of non-conformances. The overall audit is allocated 100% and deductions made as follows:

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

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<thead>
<tr>
<th>FINAL AUDIT RATING</th>
<th>BASED ON SCORE</th>
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<tr>
<td>Meets Expectations</td>
<td>100-95%</td>
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<td>Needs Improvement</td>
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<td>Significant Improvement Needed</td>
<td>84-76%</td>
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<td>Fail</td>
<td>≤ 75%</td>
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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.
**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 G (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.

**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.

Within the Expectation Manual, the following terms have these meanings:
- **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.

**Alternative Procedures**
At times it may be acceptable to have an alternative procedure or practice to those defined in the criteria. If this occurs, the alternative procedure **Must** accomplish the same degree of control as indicated in the criteria. The sub-section **Should** be considered applicable and rated based on the level of compliance to the intention of the criteria and the alternative procedure **Must** be noted in the comments.
DEFCICENCY CLASSIFICATION AND GUIDELINES

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:**

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

“Non-conformance” is the assessment made when:

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

“Major Non-conformance”. An assessment of Major non-conformance may be made when:

- Deficiencies of an element present a high probability of food safety or regulatory failure.
- Significant improvement is needed to meet the expectations.
- HACCP requirements have not been fully documented or implemented
- An element of the standard has not been documented (if required) or implemented
- A situation is observed where, based on objective evidence, there is significant doubt as to the conformity of product being supplied.
- 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:

- 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.
- The product or process does not meet regulatory requirements.

Note: Any Critical Non-conformance will result in a failure of the audit.
EXPECTATIONS AND CRITERIA FOR MANUFACTURING FACILITIES OF SANITATION AND HOUSEHOLD CHEMICALS AND SUPPLIES

The following requirements outline the management programs and performance criteria expected of a modern manufacturing facility to meet the product safety and quality requirements of the public, regulatory agencies and customers. The marketing and delivery of safe and high quality products requires a dedicated effort of knowledgeable professionals from raw material sources through manufacture, storage, distribution and sale. While product safety programs are the hallmark of modern sanitation and household chemicals and supplies products manufacturers, high quality is an essential ingredient to assure success with the end users. Reliable product manufacturing systems with a disciplined and knowledgeable work force that fully understand both product safety and consistent quality are necessary to compete in today’s market.

The following criteria are considered essential to meeting these goals on a consistent basis. Of course, the intensity of product safety and quality is being increased as leading companies work to improve their level of performance to provide reliably safe and high quality products. Demonstrating consistent conformance with these criteria is the expectation of our clients.

If a client agrees with a facility’s deviation from an expectation or specification, the facility Must obtain written approval for the variance/deviation prior to the audit process. This approval Must be 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 as they exist at the time of the observation. Ratings and scoring will be based on these observations. Corrective actions taken during the audit will not eliminate 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.
A. ADMINISTRATION & REGULATORY COMPLIANCE

1) Organization and Responsibilities

There **must** be a plant management organization chart indicating the reporting structure of the plant operating departments. Consideration **should** be given to responsible parties for product safety and quality. The structure **must** clearly show the reporting relationship of the Quality Manager and the control and release of withheld and retained product **must** be clearly designated as the responsibility of the quality department. The document **must** be current, dated and signed by the appropriate responsible executive. Consideration will be given for smaller plants where individuals have numerous organizational responsibilities.

2) Policies and Procedures Manual

   a) The plant **must** have documented policies and procedures covering all aspects of raw material receipt, manufacturing, storage and transport. The documentation **should** clearly define expectations through detailed product and process specifications, testing procedures, sampling programs and accept/reject criteria.

   b) These policies and procedures **must** be well organized, available, current, dated and signed by management.

   c) Policies and procedures **must** be reviewed for effectiveness annually. Specific policies and procedures will be addressed in detail in later sections.

3) Management Awareness and Commitment

Management commitment and active support is the foundation of an effective Product Safety and Quality Management System. Support can be demonstrated by providing adequate financial and staffing resources for product safety and quality and training programs. It can also be reflected by the general condition of the plant facilities, equipment and employee support facilities.

   a) Management participation in the audit process and an awareness of corrective action programs to outside audits, regulatory inspections and internal audits is expected.

   b) A senior member of management **must** at least be in attendance during the opening and closing meetings during the audit.

4) Product Identification, Traceability and Recall Plans and Procedures

The plant **must** have comprehensive written procedures for product identification, traceability and a recall plan specific to that plant location.

   a) Product identification codes and lot definition **must** be documented. Identification systems **must** include:

      i. Incoming raw materials.

      ii. Rework or returned materials.

      iii. In-process and carryover materials.

      iv. Finished products.

   b) There **must** be evidence of traceability for all raw materials, rework, carryover, and work-in-process into finished product. Finished product shipping records **must** also be available.

   Each plant **must** have procedures specific to that location to effectively trace lots from the
time of receipt to the first level of finished product distribution. Traceability procedures Must include:

i. Documentation of rework or carryover usage Must provide traceability into specific finished product lots. Finished product documentation Must be capable of tracing backwards rework or carryover usage.

ii. Lot numbers of finished products Must be accurately shown on shipping documents and indicate quantities on “split” pallets, if applicable.

iii. Incoming raw materials Must have traceable lot codes upon receipt. Lot codes Must follow the item throughout storage and usage.

iv. An incoming material tracking program Must be in place to trace raw materials from receipt through use into finished product.

v. Bulk raw materials when used Must maintain the same ability to be traced as other ingredients. If absolute traceability is not possible because of commingling, validated procedures Must be documented to ensure that full traceability of bulk raw materials is possible.

c) Traceability Exercises (Mock Recalls) on finished product Must be conducted at least annually to the first level of distribution. In the absence of a recall plan, or if no trace exercises are conducted at all, the rating and score for this item Must be no higher than a “Major Nonconformance”.

i. A management assessment after each traceability exercise is completed Must be conducted and documented to include a material balance sheet of total quantity of identified finished product produced vs. finished product shipped, finished product on hand and finished product otherwise documented (damaged, lost, samples, etc.), finished product unaccounted for, a calculated percent recovery, start and end times for the exercise, and any corrective actions identified.

ii. An effective traceability exercise is one where a finished product exercise (4.c.i) or an exercise where identified lots of raw materials are traced to lots of finished product and to the first level of distribution achieving a 99.5-105% recovery, taking into account normal waste and shrinkage, within four hours. Failure to meet these requirements necessitates a repeat traceability exercise until the criteria are met.

d) The Recall Plan procedures Must be clear and concise and the plan Must be reassessed for effectiveness and signed annually.

i. The recall plan Must include at a minimum the following:

1. Recall Team.
   o Names of members.
   o Responsibilities of team members.
   o A Recall coordinator Must be clearly identified.
   o 24/7 contact information Must be included.
2. Contact numbers for appropriate regulatory contacts Must be included.
3. Contact numbers for clients and customers Must be available.
4. A public relations spokesperson Must be clearly identified.
5. Designation of appropriate records and documents that Must be available for recall actions.

ii. Recall procedures Must include a plan to conduct a traceability exercise at least annually.
iii. The plan **must** include an investigation that is conducted while the recall is underway, to determine the root cause of the problem, initiate corrective actions, and to ensure there are no other lots of product affected.

5) **Regulatory Compliance**

It is essential that plants operate in total compliance to regulatory requirements. Regulatory requirements typically establish a minimum baseline for product safety performance. The NSF International Supplier Assurance Expectations Manual holds the plant accountable to identified Best Industry Practices in addition to minimum regulatory requirements. An evaluation of the plant’s performance in complying with appropriate regulatory agency requirements involves an assessment of documents, “letters” of action, inspection reports and documented responses and corrective actions to issues reported by any regulatory agency. Each written inspection or notice from a regulatory agency **must** have a documented response and corrective action.

**Note:** Refusal by facility to show any requested regulatory report is a “Major Nonconformance” deficiency, since an evaluation of regulatory compliance cannot be completed. Regulatory compliance requirements may be Federal, state, and/or local agencies.

a) The plant **must** maintain a file of all regulatory actions, visits, reports or other notifications received from any regulatory agency.

b) Written responses with appropriate corrective actions **must** be documented for every written inspection, audit or other official notification from any regulatory agency.

c) Written responses **must** be documented for any audit or inspection by customers, third party auditors or internal company auditors. Failure to provide such audit reports is a "Major Nonconformance" since effective corrective action responses cannot be verified.

6) **Document and Record Management**

A policy **must** be available that specifies document control procedures for preparing process documents, identification of areas for control, collecting data, indexing completed forms, controlling distribution of documents, document filing and file storage. The policy **must** identify a specific time limit for holding files and the proper disposition of outdated documents and records. Locations for the storage of documents and records **must** be designated. Documents and records maintained “off site” **must** be retrievable within a reasonable time.

If documents are managed electronically, these criteria apply to electronic and intranet documentation. Applicable authority for change and change dates **must** be a part of the documentation process. Electronic signatures are desirable, however not necessary if the system clearly identifies the individual with the authority to approve changes.

a) A document control policy **must** be available that identifies the current revision status of all documents to avoid use of invalid or obsolete documents.

b) Obsolete documents **must** be clearly identified and retained for historical purposes.

c) All records relevant to the control of the process or evaluation of product safety and quality **must** be:

i. Complete with no missing data or blank blocks without an explanation for lack of data.

ii. Initialed by operator and signed by supervisor to verify accuracy.

iii. Recorded on a timely basis with accurate date and time.
iv. Recorded in ink, not pencil (Error single-lined through and initialed).

v. Marked to record or chart out-of-control or out-of-specification conditions. Records **Must** indicate disposition of product and corrective actions taken. Records **Must** be indexed and easily retrievable.

vi. Evidence of intentional record falsification is a “Major Nonconformance” for this sub-section.

7) **Change Management**

The plant **Must** have a documented policy to manage change. The policy **Must** describe how to effectively communicate changes in personnel and changes in specifications, policies and procedures.

a) There **Must** be a documented procedure to assure that new management and supervisory personnel are aware of all plant policies and procedures impacting product safety and quality.

b) There **Must** be a written procedure for ensuring that all changes to policies, procedures, product formulations, processing equipment, product safety plan monitoring forms or product specifications are adequately communicated to the appropriate management and operational personnel.

8) **Documentation to Track Effectiveness of Policies**

a) There **Must** be documented management reviews or monitoring programs (Internal Audits) to assess the level of conformance to operational policies (See D.8).

b) Management reviews of internal audits **Must** be conducted at least annually.

9) **Crisis and Natural Disaster Management**

A crisis management team **Must** be assembled. The team **Must** include a sufficient number of members representing the necessary departments to handle and resolve any critical situations that may occur, i.e. natural disasters and catastrophic events and other emergency situations (power outage, tampering, etc.).

a) The team **Must** have responsibility for managing all aspects of a crisis situation, including contacting of regulatory officials, law enforcement, or media as necessary.

b) A current list of responsible team members that are available 24 hours a day and 7 days a week, as well as regulatory contacts, corporate contacts, client contacts, outside support (trade associations) contacts, supplier contacts and other key contacts for use by the Crisis Team **Must** be maintained. The list **Must** contain both office and after hours telephone numbers.

c) Team members **Must** receive specific training in the crisis management procedures and responses.

d) The crisis team **Must** meet at least annually to evaluate the status of the program. All meetings and actions **Must** be documented.

e) Detailed plans for handling critical event situations **Must** assure that finished product, in-process product, and raw materials are protected and, in case of prolonged interruptions, that there are plans for alternate product supply to the customer.

f) Policy **Must** designate quality management as responsible for determining the status of raw materials, in-process materials, and finished product that may be involved in a critical event
situation. Quality management **must** make sure that all raw materials are suitable for use prior to the start of production. Finished product involved in a critical event **must** have a documented evaluation and be released by quality management prior to shipping.

10) **Customer/Consumer Complaint Management**

a) The plant **must** have a written program for handling customer and/or consumer complaints. The policy **must** address responsibilities and corrective actions based on an investigation of the complaint.

**Note:** if customer/consumer complaints are handled by a corporate entity, the plant **must** have a copy of the corporate customer/consumer complaint policy/procedure. In addition, the plant **must** have a procedure for how it receives complaint inquiries from corporate, investigates, and determines and implements corrective actions.

b) A complaint log **must** track complaints by product identification, production dates, cause and origin of complaint.
B. FACILITIES & EQUIPMENT (The Manufacturing Environmental Controls Prerequisite System)

The following guidelines are provided as minimum requirements for all Sanitation and Household Chemicals and Supplies Products manufacturing facilities. They are general in nature and may not be appropriate for all operations, but the intent of the requirements, as stated, Must be achieved.

1) Waste Water Management
   a) Waste disposal Must be such that it does not compromise product safety or employee health.

2) Plant Construction and Design
   a) The construction of the facility Must be such that it facilitates the production of safe product and that it at least meets customer and regulatory product safety and quality requirements.
   b) Plant construction and layout Must be such that exposed product is adequately separated and protected from any operations that could cause contamination.
   c) Floors Must be maintained in clean and dry (if possible) condition.
   d) Adequate heating, ventilation or refrigeration Must be provided in all areas to maintain proper environmental conditions required for raw materials, finished product, equipment, and the facility. All systems Must be clean, properly functioning and designed in such a manner to prevent product contamination.

3) Plant Condition (Walls, Ceilings, Floors, etc.)
   a) Plant facilities Must be well maintained in an orderly, clean condition with repairs to floors, walls, ceilings and equipment maintained so as not to provide opportunities for raw material or finished product contamination.

4) Employee Facilities
   a) Cafeteria, locker rooms/areas and toilet facilities Must be maintained to set an example of clean and orderly sanitation and housekeeping requirements.
   b) Adequate storage for employee food items, in easily cleanable areas, Must be available.
   c) Locker rooms/areas Must be clean and orderly. There Must be a policy in place prohibiting food storage anywhere in locker rooms. There Must also be a documented program in place to verify compliance with the policy.
   d) Toilet facilities Must be available and convenient to operational areas.

5) Handwashing Facilities
   a) Handwashing facilities Must be conveniently located. Hand wash stations Must minimally be in toilet facilities.
   b) Signs at toilet facility exits Must instruct employees to wash their hands prior to returning to work.

6) Equipment Layout, Design and Condition
   a) All production and packaging equipment Must meet design requirements and be installed in such a manner as to permit proper operation.
   b) Equipment Must be designed and maintained to provide easy access, disassembly and reassembly for thorough maintenance and cleaning.
   c) Equipment Must be of smooth, impervious, and corrosion-resistant material where it has direct product contact.
   d) Equipment Must be free of cracks and non-continuous or rough welds where product may become embedded and make cleaning difficult.
e) Equipment **Must** be free of oil leaks and excessive grease build-up on bearings and motor housings where they may contaminate product. Bearings and motors near and above product areas **Must** have catch pans to protect product below. The pans **Must** be drained in a sanitary manner.

f) The equipment and process layout **Must** be capable of preventing product cross-contamination.

7) **Plant Lighting and Protection**
   a) Plant lighting **Must** be of such design and construction to provide adequate illumination in production, support, and storage areas.
   b) Plant lighting **Must** be adequate and appropriate for the tasks being performed.

8) **Maintenance Standard**
   a) Engineering and maintenance support **Must** be managed to provide a well-maintained, clean and orderly facility that presents a good image of sanitary processing for employees and visitors. Equipment **Must** be maintained in sound working order as originally designed or with approved modifications. Repairs to facilities and equipment **Must** be addressed in a timely manner and consistent with good manufacturing practices.
   b) Plant **Must** have regularly scheduled internal audits of the facility that identify and correct potential product safety deficiencies.
C. SANITATION, HOUSEKEEPING & HYGIENE (The Sanitation Prerequisite System)
The effective management of sanitation and housekeeping requires the involvement and cooperation of all operating departments and support groups. It requires specific policies covering requirements and expectations, training to communicate those requirements, and management support and follow-up to assure that the requirements are properly met and that all sanitary standards are fully enforced.

1) Master Sanitation Schedule and Monitoring
a) The plant **Must** have a documented cleaning schedule not only for the operational areas and equipment but also for the warehouse, storage, maintenance, employee facilities (locker rooms/areas, cafeteria, break areas and toilet facilities) and other plant areas including the building, grounds and roof areas.
b) The scheduled tasks **Must** be monitored for completion and documented with sign off on a regular basis.

2) Standard Sanitation Operating Procedures (SSOPs) and Monitoring
a) The plant **Must** have documented Standard Sanitation Operating Procedures (SSOP) for individual pieces of processing equipment, as well as facility areas and structures, which specifies and defines:
   i. Standard cleaning methods including the level of disassembly required for cleaning and assigned responsibility for each task.
   ii. Frequency of cleaning.
b) Plant **Must** have detailed SSOP Monitoring Procedures with records of monitoring activity. Records **Must** clearly show facility, structure, and equipment condition and list all deficiencies found. When deficiencies are found there **Must** be a clear explanation of the activities performed to bring the issue into a sanitary condition and a detailed corrective action plan to prevent a recurrence. **Note:** performed activities (fixes) and corrective actions are not the same.
c) Written procedures and schedules for routine cycle cleaning of equipment and facilities **Must** be current and available. A Master Sanitation Schedule **Must** be developed and implemented for non-routine cycle cleaning tasks within all plant, warehouse, and grounds areas.

3) Cleaning Chemical and Sanitizer Control
a) Cleaning and sanitizing chemical control **Must** be a part of an effective sanitation program.
b) Cleaning chemicals **Must** be purchased from approved suppliers and be approved for their intended use.
c) All containers for cleaning chemicals and sanitizers **Must** be properly labeled.
d) All containers for cleaning chemicals and sanitizers **Must** be used for their intended purpose only.
e) Chemicals used for cleaning and sanitizing **Must** be securely stored during periods of non-use.
f) Chemical storage areas **Must** be restricted to authorized personnel and **Must** have applicable signage.
g) Empty containers **Must** be stored in a manner that does not compromise product safety.
h) Plant **Must** have MSDS sheets for all cleaning and sanitizing chemicals readily available.
4) **Pre-Operational Monitoring and Corrective Action**

A pre-operational checklist **Must** be used to verify that the production area and product contact packaging and production equipment are clean prior to a routine cycle start-up.

a) A documented inspection program **Must** be in place to assess sanitation effectiveness and line conditions prior to startup.
b) Deficiencies **Must** be documented.
c) Corrective actions and preventive measures **Must** be documented to prevent recurrence.

5) **Verification of Cleaning Effectiveness**

a) Sanitation effectiveness **Must** be monitored at least visually prior to production start up.

6) **Operational Housekeeping**

a) All areas of the facility **Must** be kept clean, orderly and free from accumulation of debris, unused equipment parts, etc.
b) All containers **Must** be properly labeled.

7) **Personal Hygiene and Good Manufacturing Practices**

a) Eating, drinking, spitting, chewing or using tobacco products **Must** not be permitted anywhere in the facility except in designated areas.

8) **GMP Self-Inspections and Corrective Actions (Internal Audits and Corrective Actions)**

A key management responsibility is to verify that the policies and programs essential in the manufacture of safe products are routinely and effectively implemented. It is necessary that routine internal audits (self assessments) of policies and procedures be conducted to assure management that they are being effectively implemented and that the facilities and equipment are maintained to meet operational needs.

a) Facilities **Must** have documented procedures for planning and implementing internal audits to verify compliance to policies and to evaluate the effectiveness of the policies.
b) The internal audits **Must** assess facility, maintenance, pest control, production, sanitation, and housekeeping conditions for systematic effectiveness and to initiate corrective actions for deficiencies.
c) Internal audits **Must** be scheduled routinely and be performed by responsible, trained individuals. If the internal audits are not conducted by a management person, there **Must** be periodic verification by management. These inspections **Must** be documented along with corrective actions and follow-up.
d) Follow-up inspection activities for deficiencies and repeat items **Must** record the effectiveness of the corrective actions taken. Repeat issues **Must** receive top management priority to effect a timely corrective action.
e) All internal audit reports showing deficiencies **Must** include corrective actions.
D. RODENT & PEST CONTROL MANAGEMENT (The Pest Management Prerequisite System)

All manufacturing, storage and distribution facilities must operate under the authority of a licensed pest control operator (PCO) or contractor. PCOs must have a proper license (or recognition), certification and insurance. They should be expected to provide aggressive support to the plant’s pest control, housekeeping and sanitation programs. Since they are trained experts in recognizing and evaluating conditions that contribute to potential pest activity such as sanitation, housekeeping, properly sealed doors and windows, perimeter accessibility and outside grounds conditions, they must include observation comments on these situations in their service or activity reports with appropriate recommendations. Any comments on the service or activity reports must have a documented response and corrective action, if appropriate.

If pest management is conducted internally without the services of a licensed pest control contractor, the same level of expertise must be provided. Likewise, the same aggressive approach to the above areas of concern must be required with documented activity reports and responses.

The following criteria are in part based on the National Pest Management Association (NPMA) – Pest Management Standards for Product Plants.


1) Documented and Specific Pest Control Program

A written, detailed pest management policy and program must be available. The policy should outline and describe all procedures required to ensure that activities conducted by the Pest Control Operator (PCO) and trained employees are carried out in accordance with prescribed policy. A current Pest Management Manual or file must be available for review. The information contained must include:

a) PCO must submit an activity or service report for each inspection (see sub-section 6).

b) Activity or service reports or a Pesticide Usage Log must document what pesticide chemicals are used, if any, where, why, how much, target pests, method of application, and EPA registration number.

c) Training of company employees can be by the PCO or other qualified experts. Forms used by the PCO and the company personnel should be the same for uniformity.

d) A current PCO applicator’s license and letter of liability insurance must be on file along with appropriate Material Safety Data Sheet (MSDS) forms for all chemicals used. MSDS forms must be retained for a year after the chemical becomes inactive.

e) Company employees engaged as PCOs must have proof of appropriate training and licensing as required by state or local regulations.

f) PCO service must be in compliance with the contract and pest control policy.

g) Per the device service schedule, all traps, bait stations, and vector devices must be opened and inspected. Trained employees or the PCO must conduct effective inspections at the following frequencies.

i. Outside bait stations at least monthly (weather permitting).

ii. Interior rodent glue boards and traps at least weekly.

iii. Vector devices (insect light traps, pheromone traps, and the like) at least weekly.
Note: High pest activity may dictate more frequent servicing and extremely low pest activity may, with a documented risk assessment based on activity trend data, allow for a reduction in frequency.

h) The record of service verification tag or bar code label Must be on the inside of the traps, bait stations or other devices.

i) Site maps for traps, glue boards, bait stations and vector devices Must be reviewed regularly and dated and signed or initialed by the person having responsibility for the program.

2) Outside Premises Management (Grounds, Waste Disposal Areas)

Buildings and grounds Must be well maintained. Bait stations used outside should be placed based on habitat and potential access. They should be positioned to prevent intrusion of casual water and rain and firmly secured to prevent removal from the assigned position or opened by unauthorized personnel. Note: "firmly secured" could be the bait station fixed to a not easily removed concrete block or pad.

a) Outside premises Must be free of discarded equipment or equipment stored on the ground, litter, pallets, weeds and other clutter that may provide harborage or breeding places or attractants for insects, birds, rodents or other pests or that may inhibit evaluation of premises for pest activity.

b) Adequate trash and waste disposal facilities Must be available.

c) There Must be no standing water on the premises that could attract pests.

3) Inside Premises Management

Interior conditions Must reflect orderly and clean conditions throughout the facility, allowing easy access for evaluation along the wall in all areas. Pest control devices should be used inside the facility as a preventive measure in areas where pest activity is likely to occur.

a) Inside walls (perimeter and interior) Must be maintained in a clear and clean manner to allow for full inspection.

b) Only mechanical traps or glue boards Must be used inside the facility. All trapping devices Must be in proper working condition. No rodent bait stations are permitted inside the plant or warehouse.

c) Trap locations should be recommended by the PCO based on potential access, knowledge of pest habits, and device trend data. Exterior opening doorways Must have traps on both sides of the interior side of the doorway.

4) Pest Tight Doors and Entrance Closures

a) All doors, including overhead doors, Must be tight closing with no visible light observed between the floor and doorjams.

b) Exterior holes/cracks in walls, pipe chases, vent openings, windows, etc., Must be filled or screened to prevent entry of pests.

c) Building structure Must be sound with no holes, unscreened exterior openings, broken windows, etc. that may allow pest entry into the facility.
5) Secure Storage and Documentation of Pest Related Chemicals

Pest management chemicals should not be stored in the plant facility. It is preferred that these materials be stored with the PCO contractor and brought to the plant location when needed and removed at the time the PCO leaves the facility. If it is necessary to maintain pest management chemicals at the plant, they must be stored in a secured location with limited access and:

a) A detailed inventory log of chemicals received, quantities used, lot codes, the date used and for what purpose must be maintained. Containers must be destroyed once empty.

b) This inventory must be evaluated regularly to verify that the quantities received, the amount used and the amount currently on hand balance. Any discrepancies must be evaluated and explained.

c) Safety precautions for storage of pest related chemicals must be available, including spill control kits, power ventilation, respirator, fire extinguisher, eyewash and first aid supplies.

6) Detailed Activity Reports Detailed with Corrective Actions

Activity reports by the PCO and/or plant personnel must be available for each inspection and whenever activity is observed. Consideration must be given to pests indigenous to the area.

a) PCO activity or service reports must document the evidence of pests or pest activity such as gnawing, digging, droppings or stains from the outside bait stations, inside traps or glue boards and vector units.

b) PCO activity or service reports must document conditions outside or inside that would compromise the pest management program or make it difficult to evaluate.

c) PCO activity or service reports must document specific sites of activity, type of activity, and recommended corrective action.

d) The PCO activity or service reports or a Pesticide Usage Log must document the specific chemicals used, quantities used, lot codes, EPA registration number, locations where used, the date used and for what purpose.

e) Activity or service reports must be signed by the PCO.

f) Each deficiency noted in the PCO activity or service reports must be addressed by the PCO or management with corrective action documentation. This may be on the activity report itself or attached to the report.
E. APPROVED SUPPLIERS, RECEIVING & INVENTORY CONTROL (The Incoming Materials Prerequisite System)

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

1) Supplier Approval Policies and Procedures

There Must be a documented Supplier Approval Program for suppliers of raw materials that identifies criteria for approving suppliers. The Approved Supplier Program Must contain as a minimum:

a) Specifications for raw materials.

b) Supplier approval criteria and approval process.

c) Allowable circumstances to deviate from an approved supplier.

d) Monitoring of approved suppliers.

2) Incoming Vehicle Inspection and Documentation

There Must be a documented program to ensure that transportation of materials to the plant does not place the safety of the materials received at risk.

a) Plant Must have a written inspection program for all inbound carriers that fully describes acceptable and/or unacceptable conditions.

b) All raw materials Must be received from approved suppliers.

c) Carriers Must be in good repair, with no evidence of pest activity and free of foreign substances such as glass, chemicals or odors.

d) Incoming raw materials Must be inspected for specification compliance and damage. The inspection program Must include:

i. Specific damage evaluation procedures with acceptance criteria.

ii. Sampling plans describing which raw materials are subject to in-plant testing and which raw materials are accepted based on Certificates of Analysis (COA).

iii. Specifications for raw materials and tests to be performed with testing frequencies and accept/reject limits.

e) Documentation of condition of each inbound shipment Must be shown on receiving documents.

f) Records Must be maintained to match supplier codes to the materials received.

3) Release Criteria for Ingredients

All raw materials Must be maintained in a secure fashion and released for use against a defined program.

a) Control procedures Must be in place to prevent use of raw materials before approval and to assure that non-conforming materials are not used.

4) Storage and Handling Policies and Practices

Procedures Must be established to assure that raw materials are not subject to sources of contamination.

a) Receiving docks and areas around and under docks Must be clean and free from litter, spilled material, standing water, etc.
b) Warehouse storage areas **must** be clean and orderly, with no spilled, damaged or exposed raw materials. Opened product containers **must** not be stored in the receiving storage areas.

5) Bulk receiving Systems-Sanitation and Monitoring

   a) Bulk ingredient hoses, piping, and storage tanks **must** be capped and locked when not in use.
   
   b) Bulk storage units **must** be cleaned as evidence dictates.

6) Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds

   a) All restricted or sensitive raw materials and potentially toxic chemicals **must** be maintained under strict control and stored separately to minimize the potential for accidental product contamination.

   b) Material Safety Data Sheet (MSDS) information **must** be readily available for all chemical compounds in the facility.
F. PROCESS & PRODUCT EVALUATION (The Process and Product Control Prerequisite System)

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

1) **Process Control and Documentation Procedures**

   Product **Must** be manufactured under documented control procedures. The procedures **Must** take into consideration all product safety aspects.

   a) Effective application of the Product Safety plan **Must** be clearly evident by the presence of identified monitoring and control points with appropriate and complete documentation.

   b) In-process raw materials, products and packaging materials **Must** be adequately protected and properly labeled with date and lot number.

   c) If the facility utilizes a laboratory in its process controls, the laboratory **Must** operate utilizing documented test methods based on recognized standards, and **Must** utilize appropriate equipment routinely calibrated to maintain accuracy.

2) **Specification and Formulation Control and Accuracy**

   In addition to specification compliance, there **Must** be procedures for assuring control of product formulations.

   a) Documented finished product specifications **Must** be developed by the customer and/or plant that define acceptable product attributes.

   b) Records **Must** be available demonstrating compliance to all manufacturing and finished product specifications including customer specifications, if applicable.

   c) Products with multiple raw materials **Must** have appropriate formulation controls available to the operators with regular verification of accuracy.

   d) Blending and mixing records **Must** show times, quantities and lot identification of ingredients used.

   e) Production records **Must** be maintained for at least twelve months after shipment.

   f) Test protocols and frequencies **Must** be followed as identified in the specification.

   g) Issues, concerns or requests for changes regarding the accuracy, completeness, or frequency of testing **Must** be addressed with the customer, if applicable, with changes only permitted with written authorization.

3) **Routine Calibration of Operational Equipment and Measuring Devices**

   It is essential that all measuring and metering devices (such as thermometers, scales, flow meters, etc.) be properly calibrated to assure the accuracy of these activities and the effectiveness of their performance.

   a) Key process control devices such as thermometers, scales, recording devices, etc., require routine calibration or certification by a credible authority at least annually. There **Must** also be a program to verify the performance of measuring devices to assure accuracy on a day-to-day basis.

   b) Assigned personnel **Must** check scales used for weighing raw materials, production components and finished product preparation daily. Standard weights in the range of the weights being produced **Must** be used for these verification checks. Daily verification checks **Must** be documented.
c) Flow meters, if critical to the food safety plan, **must** be regularly calibrated for accuracy, as recommended by the manufacturer.

d) Calibration procedures **must** describe the frequency of testing, the testing method and the acceptable range of variation.

e) There **must** be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used (thermometer, scale, flow meter, counting device, coder, etc.). All product produced since the last acceptable check **must** be assessed to determine if it **must** be held for further evaluation.

4) **Foreign Material Control**

N/A

5) **Application of Statistical Control**

   a) Process critical limits **must** be attainable on the equipment that is utilized. This can be determined based on a sound process capability study of the equipment or by process monitoring records that demonstrate ongoing achievement of control.

   b) Management of the critical limits **must** be based on individual data points and not on averaged data.

6) **Allergen and Sensitive Ingredient Controls**

N/A

7) **Specification Compliance Documentation**

Quality programs rely on documentation to confirm that the desired quality parameters were achieved. Records **must** be maintained to assure that the appropriate product attributes were evaluated and that the results were consistent over time.

   a) Finished product **must** have documentation verifying that the product meets specifications. Specification compliance documentation **must** be available for review.

   b) A finished product evaluation procedure **must** include frequency of testing, documentation of results and availability of records for 12 months beyond the product ship date.

   c) If the product fails to pass any inspection and/or test, the procedures for control of nonconforming product **must** apply.

8) **Rework and Carryover Products**

The plant **must** have a documented procedure for managing rework. Rework **must** be treated as a raw material and the plant **must** be able to trace rework to its original production lot and to component raw material lots.

   a) The plant **must** be able to trace the usage of all rework products into finished product. Rework is defined as product not meeting initial specifications or retained line accumulation requiring reprocessing or product carry-over from one lot to a subsequent production lot thus commingling lots.

   b) The responsibility for assessment and release of rework product **must** be specified.

   c) Rework **must** be clearly identified with the date of production and original lot number, if appropriate. There **must** be adequate documentation to assure that product tracking records are complete and can easily identify the lots where the product was used.
d) Production dates and original lot numbers **must** be carried forward in production documents when the material is ultimately used.

e) Rework **must** be handled in accordance with documented procedures. Product awaiting disposition **must** be stored in a dedicated place or exhibit an obvious physical indication of its status (i.e. on hold or rework).

f) All rework **must** be kept to a minimum and used promptly at the first opportunity.

g) A documented “same-into-same” policy regarding rework and carryover products **must** be in place.

9) **Analytical Records Management**

An integral part of the product safety function centers on accurate, available product information used for decision making.

a) Quality systems **must** be established to properly store and retrieve analytical information, documents, reports, records, etc.

b) Records and reports of analytical information gathered by organizations (internal and external) **must** be cataloged and maintained in a fashion that provides feedback for operational control.

c) When an outside laboratory is used, documented procedures **must** be available to properly interpret and manage the information provided.
G. PACKAGING & LABELING

1) Label Accuracy and Regulatory Compliance

The facility must have a program to assure that labels in use and product being produced are matched. Plants with variable or optional product specifications must be able to demonstrate that the proper label is always used.

a) Labels must satisfy regulatory requirements and/or customer expectations and must include an accurate product name and a lot identification understood by the customer.

b) There must be some method of matching the proper label with the product or production schedule or formulation, particularly where there are multiple products, customers or formulations that could be used.

2) Net Weight or Count Compliance Policy and Performance

Plants must have a documented policy for net weight, liquid contents or product count to verify compliance to customer requirements and/or specifications.

a) Scales used to determine final product weight must be verified for accuracy by designated individuals. Standard weights in the range of the products being labeled must be used. Verification checks must be documented on the production records. These verification checks must take place at the beginning of the production day to assure all products are properly weighed. More frequent checks are recommended. Scale failure of a verification check must result in an investigation of product produced since the last good check.

b) Net weight, volume, or count control checks must be performed and documented at an appropriate frequency to assure ongoing customer requirement and/or product specification compliance. Hourly intervals are recommended.

c) Product counters must be verified per manufacturer instructions or documented data-based performance studies.

d) Records must be available showing status of conformance and verification checks.

3) Clear Manufacturing Codes on Individual and Cased Product

Clear coding is essential for proper management of production lots and traceability and must meet customer specifications.

a) All product coding and label information must be of such size, color and contrast to afford easy legibility at a reasonable distance.

b) Code may be an open date code or a cryptic code, such as the Julian system, that is clearly understood by both the customer and plant operation.

c) Each individual sell unit must have a production or lot code. If the finished product is contained in shipping cases, the cases must be coded with the same lot code as the sell unit.

4) Package Integrity and Function

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.

a) Plants must have an effective program to assure that the product packages and the shipping cases are properly closed and sealed. Shipping cases must be properly constructed and secure.
b) Finished product cases, if used, **Must** be appropriately sized to provide adequate protection to the internal product.

c) Finished product cases, if used, **Must** be intact and adequately sealed to prevent contamination.

5) **Label Security and Obsolete Label Control**

There **Must** be a written plan describing the security measures for labeling materials to prevent unauthorized or accidental use and to prevent the use of obsolete labels.

a) There **Must** be a documented procedure detailing how labels are controlled so that they are not used out of sequence or co-mingled in storage or at point of use.

b) There **Must** be a procedure for immediate isolation and securing or destroying obsolete labels.
H. STORAGE & SHIPPING

Finished products Must be stored under controlled conditions. Products Must not be released for shipment without assuring that all product safety and quality evaluations have been completed. All product shipped Must be able to be tracked in case of a product recall.

1) Warehouse and Finished Product Management

Warehouse conditions Must be maintained and controlled in a manner to assure product integrity.

a) Only properly packaged product in undamaged containers may be stored in and shipped from the finished warehouse. Product not "cleared" for shipment, or held for any other purpose, Must be clearly identified and not stored in a location in the warehouse where it is likely that it may be shipped in error.

b) Damaged, leaking or unsound product Must be immediately isolated and placed on hold for evaluation by designated personnel. Product disposition should be timely.

c) Partially used or previously opened raw material containers Must not be stored with finished product. Such product may be stored in a designated separate storage area, if it is properly identified and sealed to prevent contamination.

2) Retained and Returned Products

The plant Must establish and maintain documented procedures to ensure that product that does not conform to specified requirements is not shipped. This control Must provide for identification, secured segregation, documentation, evaluation, disposition and reconciliation of product that is placed on hold.


i. The plant Must have a written policy for retained and returned products that describe individuals responsible for evaluating product and making decisions regarding disposition of it. The policy Must be understood by all authorized personnel.

ii. A Hold Tag procedure Must include a permanent written log of each product or item placed on hold.

iii. The plant Must have a policy and procedure for handling returned products.

iv. Returned products Must be identified and placed on hold immediately.

b) Designated Areas for Retained and Returned Products.

i. Products retained or returned to a manufacturing plant Must be handled securely.

ii. There Must be a designated, clearly identified area for returned or retained products or product Must exhibit an obvious physical indication of its status (i.e. on hold or returned). A computer block alone is not acceptable. There Must be some type of records indicating the product is returned or retained.

iii. Returned or retained products Must be clearly identified as such.

c) Verification and Release Documentation.

i. Documents Must be available to show the current location of products not cleared for shipment as well as those that are authorized for shipment.

ii. Disposition or corrective actions Must be commensurate with the seriousness of risk identified. Disposition Must be dated and signed.

iii. All non-conforming products Must be handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.

iv. Product destined for destruction Must be adequately secured and disposed of promptly.
v. Disposition of non-conforming material **must** be tracked to ensure that inventories are adjusted accordingly to facilitate recall.

vi. Damaged, sampled or destroyed finished product **must** be recorded and proper adjustments to the product inventory records **must** be made to accurately account for the inventory loss.

vii. An inventory log **must** be maintained showing current product on hold and list the disposition of all released product with proper authorization.

3) **Storage Facility and Dock Maintenance**

Warehouse storage areas **must** be clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Racks and pallets **must** be used as necessary.

a) Product **must** not be stacked so that it blocks blowers or vents preventing the circulation of air.

b) Wall perimeters **must** be maintained in a clear and clean manner and allow for pest management inspections and sanitation/housekeeping requirements.

c) Pallets, racks and shelving **must** be clean and in good repair.

d) Floors and walls **must** be in good condition and free from holes or damage.

e) Floors under pallets, racks and in aisle-ways **must** be clean and free from dirt, accumulated debris, spilled product or broken pallets.

f) Shipping docks, dock plates, dock levelers and areas around and under the docks **must** be clean and free from accumulated debris, water, etc.

4) **Transport Condition**

Transportation of finished products **must** only be done with acceptable carriers. Procedures **must** be established to minimize concerns that could occur with improper product handling after the finished products leave the facility.

a) Written procedures describing acceptable and/or unacceptable carrier conditions **must** be available to shipping personnel.

b) All outbound trailers **must** be inspected for condition, odors, sanitation, and potential contamination sources. Inspection results **must** be documented on shipping documents.

c) Product **must** not be loaded into unacceptable carriers. Trailers **must** be cleaned, if necessary.

d) Trailers and railcars **must** not be cleaned at the dock, as this creates a warehouse sanitation problem and a potential for pest harborage.

5) **Release Authorization to Ship Product**

Product can be shipped only with proper authorization.

a) Product **must** not be shipped until all the activities specified in the product safety and quality plans have been made available to and approved by management. Records **must** be signed and dated by the person responsible for the release of product.
I. **Training Requirements** (The Employee Training Prerequisite System)

To assure the effective implementation of the facility's product safety and quality programs there must be a documented training program for both management and operational personnel. The facility must have specific training requirements for all personnel relative to their job function and responsibilities. These training requirements should be specific to each job classification. The following are minimum training requirements:

1) **New Hire Training**

   a) Training must be provided to new hire operating and management personnel for at least the topics below. This training must be completed within a predefined, reasonable period of time.
      i. Product safety (including HACCP plan overview, if appropriate).
      ii. Basic safe product handling.
      iii. Plant process and product specific training, as appropriate.

   b) Specific training for HACCP Critical Control Point and other monitoring responsibilities must be provided prior to the individual being assigned sole responsibility for such activities.

   c) Training for new managers, supervisors, and quality technicians must include those product safety and quality policies and procedures for which they will have implementation and oversight responsibilities.

2) **Training Language**

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

3) **Prerequisite Program Training**

   a) The plant must have a documented training policy describing the training program for employees involved in the monitoring of product safety control measures.

4) **Refresher Training**

   a) Refresher training in the topics identified in 1.a, b and 3 above must be provided and documented at least annually.

   b) Documented training covering updates/topical agendas on the above topics must also take place at least quarterly. Regardless of the frequency at which updates/topical training is delivered, it must be documented with at least the training topic, trainer, and attendees identified.

5) **Proof of Knowledge**

   a) A method to document individual understanding, such as testing at the conclusion of the training or documented performance evaluations by supervision, conducted within a reasonably short period of time (14 to 30 days), must be an integral part of the training program.

6) **Training Records**

   a) Employee training records must be maintained and include, at least, the information below for all staff levels:
      i. Employee name.
ii. Training date.
iii. Employee position/title.
iv. Trainer name.
vi. Training agenda and/or training content.
v. Proof of knowledge.

7) Training Program Review

a. The training program **must** be reviewed and updated at least annually and take into consideration new regulatory, media, or customer issues, scientific and technological advances, or new or revised product safety and quality programs.
DEFINITIONS

ALLERGEN: Certain compounds can cause an allergic or intolerance response in sensitive individuals. Allergic individuals can tolerate very little of the offending material.

United States

In the United States, allergens of concern include:

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

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

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

1) 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.
2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:
   a) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.
   b) 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 mandelona 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, pinon), pistachios and walnuts or their derivatives, e.g., nut butters and oils etc.

- Sesame or its derivatives, e.g., paste and oil etc.
- Milk or its derivatives, e.g., milk caseinate, whey and yogurt powder etc.
- Eggs or its derivatives, e.g., frozen yolk, egg white powder and egg protein isolates etc.
- Fish or its derivatives, e.g., fish protein and extracts etc.
- Shellfish (including crab, crayfish, lobster, prawn and shrimp)
- Mollusks (including snails, clams, mussels, oysters, cockle and scallops) or their derivative, e.g., extracts etc.
- Soy or its derivatives, e.g., lecithin, oil, tofu and protein isolates etc.
• Wheat or its derivatives, e.g., flour, starches and grains etc.
• Sulphites, e.g., sulphur dioxide and sodium metabisulphites etc.
• Others (as considered necessary)
• (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.


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 product 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 product safety hazard to an acceptable level.

Deviation – Failure to meet a critical limit.

HACCP – (Hazard Analysis and Critical Control Point) A systematic approach to the identification, evaluation and control of food safety hazards reasonably likely to occur.
HACCP Plan – The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

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

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

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

Hazard Analysis – The process of collecting and evaluating information on hazards associated with the product 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 by the company to 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.

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 product 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 Product 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.