PJRFSI HACCP/GMP Certification Procedure Manual

A Comprehensive Manual on PJRFSI Certification Procedures

Introduction - About PJRFSI

Perry Johnson Registrars Food Safety, Inc. (PJRFSI) is committed to providing value-added food safety certification to clients. Our entire team believes that rigor and consistency during audit activities leads to higher levels of customer and end user satisfaction. PJRFSI is dedicated to uphold the highest standards of professionalism, technical competence and integrity throughout the life cycle of the audit process. We apply the principles of quality management, collaboration and organizational excellence in all our office and field activities and comply with the requirements set forth by the international standards organizations, accreditation bodies and other affected parties. Through this dedication, we have created and maintain a work environment which provides opportunities and a culture of continual improvement, learning and development for clients, auditors, staff and stakeholders within the food chain.

The entire PJRFSI team is committed to the spirit of this quality policy as well as the directives of the Quality Manual and its subordinate documents PJRFSI offers the PJRFSI HACCP/GMP Certification Program to companies seeking independent validation of their HACCP/GMP system. This procedure details from start to finish the life cycle of the HACCP/GMP certification process. Included with this procedure is the PJRFSI HACCP/GMP checklist to assist your organization in preparing for certification.

Note to All Readers - A Legal Statement

This document was created based on industry norms and regulatory mandates. PJRFSI accepts no liability for any misprints or omissions on the information, including any information or opinion contained in this document.
PJRFSI aims to ensure that information in this and other publications are accurate and up to date, but PJRFSI shall not be held liable for any damages or claims in connection with this document or any information contained in it.

Table of Contents

1.0 References

1.1 ISO/IEC 17065: Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services (latest revision)
1.2 Codex Alimentarius General Principals of Food Hygiene (latest standard)
1.3 FS-1 – Food Safety Certification Questionnaire/Client Application
1.4 F-207 – Food Safety Quote Approval and Audit Justification Checklist
1.5 F-3HACCP/GMP – Certification Agreement
1.6 F-3tc – Terms and Conditions
1.7 F-71fs65 – Certification Personnel Statement of Availability Form
1.8 F-163fsi – Audit Scheduling Acknowledgement Form
1.9 F-27fsi – Auditor Assignment Form
1.10 WB-HACCP/GMP(series) – Auditor Workbook
1.11 F-184fs65, F-184fs65-A – Audit Plan Template and Site Plan
1.12 F-67fs65- Audit Package Review Form – Food Safety Programs
1.13 F-67fs65-A, Audit Report Review Form - Food Safety Programs
1.14 F-144fsi Transfer of Certification Body Checklist
1.15 SOP-10 Dispute/Appeal Procedure
1.16 PJView – Perry Johnson Registrars Food Safety Inc.'s client database and project management system

2.0 Definitions

2.1 Operation - The organization seeking HACCP/GMP certification. Until a contract for certification services is signed with PJRFSI, the Operation is initially referred to as an Applicant.

2.2 Scope of Certification – a description of the certification sought by the Operation which will be covered in the audit program and detailed in the certification certificate. The scope includes: the name and address of the site-specific facility(s) covered; the product types and their associated processes and storage/shelf life characteristics. The scope of certification also specifies exclusions, if any, which must be agreed and approved by PJRFSI in advance of the certification audit.

2.3 Site - A single physical address or facility that will be audited and granted a certificate, either individually or as part of a multiple site scheme

2.4 Certificate - A certificate and associated documents affirming that the HACCP/GMP management system operated by the Operation has, as a result of the documented assessment procedure conducted by PJRFSI, been found to be in accordance with the PJRFSI's HACCP/GMP Standard and the scope of certification sought by the Operation.

2.5 Auditor – an employee or contractor of PJRFSI who has been qualified by PJRFSI as a HACCP/GMP Auditor and is therefore qualified to conduct HACCP/GMP certification audits.

2.6 Pre-assessment - An informal and optional onsite evaluation carried out by a PJRFSI auditor to assess the Operation's overall HACCP/GMP food system and to determine the Operation's readiness for a HACCP/GMP certification audit.

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2.7 Certification Audit – an onsite audit of the Operation's overall HACCP/GMP food system and facility conducted by a PJRFSI auditor.

2.8 Recertification Audit – twelve (12) month post-certification conducted by a PJRFSI auditor to assess the continued effectiveness of the Operation's HACCP/GMP system in its entirety and to serve as the basis for re-qualifying the Operation for continued certification.

2.9 Technical Reviewer – the individual(s) who are competent to review audit results and render certification recommendations.

2.10 Designee – a PJRFSI employee who is designated and trained to complete specific procedural functions on behalf of another PJRFSI position. Throughout this SOP-1HACCP/GMP procedure, functions which may be completed by a designee will include the following references: "[position] or designee…" or "[position]/designee…"

3.0 Request for Certification

3.1 The Applicant initiates the application for certification process via a written or verbal request.

3.2 In response, a PJRFSI Project/Sales Manager or the Food Safety Sales Coordinator or designee provides the Applicant with the FS-1 Food Safety Certification Questionnaire/Client Application.

3.3 Duly Authorized representatives of the Applicant must complete and sign the Questionnaire/Application to provide PJRFSI with sufficient information required for providing a quote.

3.4 Upon receipt of the signed application, PJRFSI's Food Safety Sales Coordinator or designee trained in HACCP/GMP quoting procedures conducts an application review to ensure that:

a. Certification requirements are clearly defined, documented, and understood;
b. Any differences in understanding between PJRFSI and the Applicant are resolved; and
c. PJRFSI has the technical resource and competencies to perform the certification services sought by the applicant, and if not, PJRFSIs Food Safety Sales Coordinator or designee in consultation with the Food Safety Program Accreditation Manager will reject the application

The record of this review is the Food Safety Sales Coordinator or designee's signature at the bottom of the FS-1 Food Safety Certification Questionnaire/Client Application and a completed F-207 – Food Safety Quote Approval and Audit Duration Justification Checklist.

3.5 Based on the information furnished by the Applicant and the input from the application review process, the Food Safety Sales Coordinator or designee completes an F-207 which is a record of: the determination of scope including exclusions; the justification for quoted audit days; and the overall quote approval.

3.5.3 Deviations from the audit duration guidance are justified on the F-207. [Due to factors which might only be revealed once the Auditor is onsite, the Auditor may request a deviation in the actual audit time from the quoted audit time. In this case, the Auditor always contacts PJRFSIs Food Safety Program Accreditation Manager or designee for pre-approval.

3.5.4 PJRFSI may conduct HACCP/GMP audits combined with other certification system audits or audit elements, as long as all program rules are met and the integrity of any one component of the combined audit is not compromised. PJRFSI does not, however, conduct any consulting or training in combination with HACCP/GMP audit activity. Details of combined audits are specified on the audit report.

3.6 A pre-assessment is optional but encouraged, particularly those seeking initial certification to the applicable standard

3.7 Transfers are handled in accordance with Section 12 below.

3.8 Based on the information from the application review (FS-1) and quote approval process (F-207), the Food Safety Sales Coordinator or designee completes a quotation in the form of a Certification Agreement (FS-3haccp) to cover the costs of the proposed audit activity
[pre-assessment, certification audit, and/or recertification audit(s) as applicable] and any associated fees.

3.9 A PJRFSI Project/Sales Manager or designee provides the Applicant with a duly authorized copy of the Certification Agreement (FS-3haccp) and the Terms and Conditions (FS-3tc). (In some cases, the Certification Agreement and Terms and Conditions are forwarded directly to the Applicant by PJRFSIs Sales Coordinator or the Food Safety Program Coordinator/designee.) The Applicant then signs and returns a copy
of the Certification Agreement bearing an original signature.

3.10 Signatures by both parties indicate mutual agreement of Certification Agreement including the scope of certification and any exclusions, the certification costs, and the
associated Terms and Conditions. After the Certification Agreement is signed, amendments, agreed upon by both parties, may be made as necessary. However, once the certification audit has begun, the scope of the certification shall not be altered.

3.11 Receipt of the signed Certification Agreement and the first installment payment from the Operation is taken by PJRFSI as an instruction to proceed in accordance with the HACCP/GMP Certification Agreement and the Terms and Conditions. The Food Safety Program Coordinator or designee sends the Applicant, hereafter referred to as the Operation:

a. a summarized version of the Certification Procedure (SOP-01HACCP/GMP);

b. other guidance documents describing the audit process, as appropriate; and
c. a list of documents/information required from the Operation, as necessary, in preparation for the audit.

3.12 The Food Safety Program Coordinator or designee is responsible for monitoring and verifying the progress of the Operation's certification program including but not limited to audit/certification status, and timeline/due date performance for both Operation and Certification Body (PJRFSI) activities.

3.13 If the requirements for certification change at any time and need retroactive implementation, PJRFSIs Food Safety Program Accreditation Manager or designee will ensure that the Operation is notified as soon as possible by the most appropriate means and that the new requirements are followed/implemented at the next onsite audit activity or sooner if necessary.

4.0 Scheduling Audits

4.1 Once the signed Certification Agreement (FS-3haccp) is received, the Food Safety Program Accreditation Manager or designee assigns an auditor to the audit after verifying that:

a. The Auditor is qualified to audit the Operation's scope of certification;
b. The Auditor has had no prior relationship with the Operation which would present a conflict of interest. The Auditor will confirm this by signing a Certification Personnel Statement of Availability (F-71fs65) before completing the audit.

4.2 The Operation is assigned to Food Safety Audit Program Coordinator (Scheduler) who will contact the Operation's Management Representative to schedule dates for the auditing activities. The Scheduler then coordinates the desired dates with the availability of the assigned Auditor pre-selected by the Food Safety Program Accreditation Manager or designee. Often, this process takes several contacts between the Operation and the Auditor before dates for the auditing activities are mutually agreed upon.

4.3 The Scheduler sends the Scheduled Audit Form to the auditor when the dates are confirmed and entered into View.

4.4 The Scheduler then sends the Operation an Audit Scheduling Acknowledgement form (F-163fsi) or equivalent document for the Operation to sign and return by fax which indicates:

a. Operation's acceptance of the proposed audit dates and time;
b. Operation's acceptance of the proposed audit team whose background information is available upon request. The Operation has the right to object in writing to the appointment of any particular auditor or technical expert providing the objection is valid, i.e. employee of a competitor, personal differences, etc.
c. Operation's confirmation that all processes/procedures/activities will be ready by the proposed audit date.

4.5 The Scheduler then creates an Auditor Assignment Form (F-27fsi) and forwards it to the Auditor(s) after approval by relevant Customer Service Personnel.

5.0 The Certification Audit (Initial Certification and Recertification Audits)

5.1 PJRFSI undertakes the Certification Audit to verify the effectiveness of the Operation's HACCP/GMP System in its entirety to establish and ensure:

a. the effective interaction between all elements of the HACCP/GMP System; and
b. that the Operation has demonstrated a commitment to maintaining the effectiveness of the HACCP/GMP System and to meeting regulatory and customer requirements.

5.2 The Auditor is responsible for completing the corresponding Audit Workbook (WB-HACCP/GMP Supplement) and creating an Audit Plan using the F-184fs65 and F-184fs65-A Audit Plan Templates, which will be forwarded to the Operation at least one week in advance of the audit.

5.3 The Operation's senior management personnel, who have the appropriate authority to ensure that corrective actions will be implemented in response to any non-conformities found, are expected to attend the opening and closing meetings for all audit activity. In particular, the most senior operations manager onsite or their nominated deputy shall be available at the audit and attend the opening and closing meetings. All of the Operation's personnel are expected to fully assist the Auditor at all times.

5.4 At the time of the audit, the Operation is expected to have been in operation for at least three (3) months. For planned audits, the Operation shall ensure at the time of the audit that the production program includes all products and processes covered by the scope of the certification. When a significant production process cannot be observed during the audit, PJRFSI may elect to conduct a separate audit at a later time in order to audit that process.

5.5 The onsite audit consists of the following six (6) stages:

1. Opening meeting to confirm the scope and process of the audit. The Auditor will utilize the Opening Meeting Agenda found in the Auditor Workbook (WB-HACCP/GMP series).
2. Document review including a review of the HACCP/GMP food safety management systems.
3. Production facility inspection to review the practical implementation of the systems and which should account for at least 50% of the audit time and include personnel interviews and observations of product changeover procedures.
4. Review of production facility to verify and conduct further documentation checks.
5. Final review of findings by the auditor in preparation for the closing meeting.
6. Closing meeting to review audit findings with the Operation management personnel.

5.6 The Auditor should audit the Operation's processes where they occur. Audit evidence gathered through interviews should be verified by acquiring supporting information from independent sources, such as observations, records, and results of existing measurements. The names, job titles, and working shifts of those interviewed are to be recorded. The Auditor must record copious notes of conformity and nonconformity, including the nature and severity of any nonconformity. These notes serve as the basis for the audit report and will be submitted to PJRFSI with the audit package. Should objective evidence exist to support writing a nonconformity, the following format is used:

a. Citation of the requirement(s) not being met
b. Statement of nonconformity
c. Objective evidence observed that supports the statement of nonconformity

5.7 For multiple day audits, the Auditor must hold a daily wrap-up meeting with the PJRFSI audit team and the Operation's key personnel to discuss a summary of the findings of that day.

5.8 On the last day of the audit, the Auditor will hold a closing meeting using the Closing Meeting Agenda. During this meeting, the Auditor reviews the audit findings, including the non-conformities, with the Operation's senior management personnel. When discussing the findings, the Auditor should never comment on the likely outcome of the certification process.

5.9 At the close of the audit or within one working day of the last day of the audit, the Auditor provides the Operation with a written summary of the non-conformities discussed at the closing meeting.

6.0 Nonconformities and Corrective Actions and Scoring

6.1 PJRFSI defines the following nonconformities and scoring:

NON-CONFORMANCE CLASSIFICATION GUIDE AND SCORING GUIDELINES Rating Criteria	Points
All bold items listed in questions are considered **Critical** if found and would constitute an automatic failure.	All points lost in the question; automatic failure of the audit
Major non-conformance would result in a systemic failure of the question: no program in place, employees unaware of non-compliance, more than 3 observations of the audit violation, or the potential for a food safety incident based on the observation.	All points lost in the question
Minor non-conformance would be an isolated occurrence of the observation (1 or 2 instances), elements missing from records or programs, some inconsistency with document vs. actual practice.	Half of points lost for the question
Compliant would be facility fully meets the established Perry Johnson Registrar Food Safety Inc. criteria, facility is able to demonstrate full implementation of the criteria, employees are aware and in compliance.	0 points deducted per question
Not Applicable (N/A) would be used by the auditor for any question the auditor determines is not applicable for the facility being audited.	Points from question removed from total audit score, no points deducted

6.2 Section summary scores are calculated, and the average is taken to get the overall score. Automatic ratings are linked to a score. Perry Johnson Registrar Food Safety Inc. audit rating system is as follows:

95.0-100 Superior
90.0-94.9 Excellent
85.0-89.9 Compliant
<84.9 Fail

6.3 Once the Auditor has made an observation during the audit, the Operation, if possible, may take corrective action during the audit. However, the Auditor's rating must reflect the condition or status prior to the Operation's corrective actions.

6.4 Regardless of the severity of findings, the Auditor is expected to complete the audit except when extreme circumstances would not allow him/her to do so.

6.5 The findings, as well as the full audit report, are always subjected to a full technical review by PJRFSIs Executive Committee. If the technical review process results in any change in the findings, the Operation will be notified.

6.6 If during the course of the audit, the Auditor identifies a critical finding which would result in non-certification. The auditor will contact PJRFSIs Food Safety Program Accreditation Manager or designee to discuss the findings and verify their severity. If findings are confirmed which would result in non-certification, PJRFSIs Food Safety Program Accreditation Manager or designee immediately suspends certification for a certified Operation.
In this case, the Operation is required to undertake another full audit to allow the auditor to review the HACCP/GMP system and verify all corrections and corrective actions. Where an Operation cannot effectively implement corrective actions and have the Auditor verify their closure by means of an onsite revisit audit within 30 calendar days from the last day of the audit, Food Safety Program Accreditation Manager or designee immediately withdraws certification for a certified Operation.

6.7 In the event of a failure to achieve or maintain certification, Operations, where required by their customers, must notify their customers of the circumstances and the Operation's intended corrective actions.

6.8 For any nonconformity identified, the Operation must:
- **a.** take corrective action to remedy the immediate issue; and
- **b.** undertake a root cause analysis of the nonconformity; and
- **c.** develop a corrective action plan and timeline to address the root cause.

6.9 For all major and minor non-conformities, the Operation should submit satisfactory objective evidence to the Auditor within 28 calendar days of the last day of the audit to allow the Auditor time to close the nonconformities by 30 calendar days of the last day of the audit.

6.10 If satisfactory evidence to close out nonconformities is not provided within the 30 calendars days of the last day of the audit, PJRFSI will not grant certification or will withdraw certification as appropriate and the Operation will require an additional full audit to be considered for certification.

6.11 Any required onsite revisit audit will primarily review the effectiveness of the corrective action taken for nonconformities. However, if new nonconformities are identified during the course of the revisit, these nonconformities must also be satisfactorily resolved before a certificate can be issued.

7.0 Audit Reporting and the Certification Decision

7.1 The Auditor documents the results of the audit using WB-HACCP/GMP series and WB-HACCP/GMP Supplement.

7.2 Within ten (10) calendar days from the last day of the audit, the Auditor submits the preliminary audit report, audit notes, auditor working documents to PJRFSIs Audit Support Assistant or designee to forward to a Technical Reviewer for a preliminary technical and grammatical review.

7.3 PJRFSIs Technical Reviewers are required to sign the F-71fs65 – Certification Personnel Statement of Availability prior to beginning a review of an audit report or package in order to confirm that they are impartial and free from any conflict of interest. Note: the Auditor who carried out the evaluation may not serve as the Technical Reviewer.

7.4 The PJRFSI Technical Reviewer conducts a preliminary technical and grammatical review of the audit package and documents the review on the Audit Report Review Form (F-67fs65-A), or an equivalent format. If needed the report is returned to the Auditor for clarification or revision. A record of reviews is maintained using the Audit Package Review Form (F-67fs65).

7.5 By 30 calendar days from the last day of the audit, the Auditor submits the final audit report and complete audit package, including the Operation's corrective actions to the Food Safety Program Coordinator or designee to forward to a Technical Reviewer for the final technical review and certification decision.

7.6 The Technical Reviewer completes the final technical review and documents it and certification decision on the Audit Report Review Form (F-67fs65-A) or an equivalent format.

7.7 In cases where the Technical Reviewer rejects the package, s/he or the Food Safety Program Audit Support Assistant or designee is responsible for contacting the Auditor or Operation for resolution. As appropriate, the Technical Reviewer or other competent designee is responsible for providing any clarification or any additional training to the Auditor.

7.8 HACCP/GMP Certification is awarded to Operations who have no outstanding non-conformities, meaning all nonconformities have been corrected and verified by PJRFSI by onsite visit or by other appropriate means.

7.9 Certification decision will be taken by PJRFSI's HACCP/GMP technical reviewer. If Certification is granted, PJRFSIs Food Safety Program Coordinator or designee notifies PJRFSIs Food Safety Audit Program Coordinator /PJRFSI Certificate Department.

7.10 The Certificate Department creates a draft certificate conforming to PJRFSI requirements and obtains approval of the certificate from the Operation.

7.11 By 45 calendar days following the first day of the audit, PJRFSIs Food Safety Audit Program Coordinator or designee issues the certificate. Delivery of the Certificate and other documents may be delayed until all outstanding invoices have been paid by the Operation.

7.12 HACCP/GMP Certification by PJRFSI shall provide confidence that the System meets the specified requirements and that the Operation has implemented and is maintaining and operating the HACCP/GMP System effectively and in accordance with the scope specified on the Certificate.

8.0 Ongoing Audit Frequency and Maintenance of Certification

8.1 In order to maintain Certification, an Operation is required to ensure all nonconformities are corrected within specified timeframes.

8.2 Recertification audit due dates are based on the first day of the initial audit. All audits are due within the 45-day window in advance of the due date.

8.3 Audits may be undertaken earlier than the due date in order to reset audit dates to allow combined audits with another program or to include a product produced at a different season. In these cases:

a. The audit report will detail the reasons why an audit has been brought forward.
b. The audit due date and certificate issuance/expiry will be “reset” based on the new audit date.

8.4 When a seasonal Operation’s production schedule is affected by harvest timing, the audit date may vary from the 45-day due date window and the justification for an early or late audit must be detailed in the audit report.

9.0 Conditions for Suspending or Withdrawing Certification

9.1 PJRFSI is responsible for initiating the suspension and withdrawal of the HACCP/GMP Certificate.

9.2 PJRFSI suspends the HACCP/GMP Certificate where:

a. nonconformities as described in Section 6.1 are detected at an audit; or
b. the Operation fails to have a required audit conducted according to their audit frequency except as justifiably allowed.
c. failure of the client to comply with PJRFSI’s terms and conditions (i.e. nonpayment of fees)
d. non-compliance to certification protocol
e. pending complaint investigation
f. major change to the site or its activities that require action
g. a site visit raises doubt to the validity for the current certificate
h. pending appropriate corrective action following an investigation into product recall and/or product withdraw
i. failure to notify PJRFSI of significant changes to the company see Section 10.1

9.3 Where the Operation's HACCP/GMP Certificate is suspended, the Food Safety Program Coordinator or designee will inform the Operation in writing and sent by certified mail, that their certificate has been suspended, the reasons for doing so and action required from the Operation including timescale in order to lift the certification.

9.4 Where PJRFSI has suspended an Operation's HACCP/GMP Certificate, for the duration of the suspension, the Operation:

a. shall not represent itself as holding a HACCP/GMP Certificate of Registration;
b. shall not use any goods, products, packaging, stationery, or other items that contain a PJRFSI Logo that may indicate the Operation holds a HACCP/GMP Certificate;
c. shall notify any customers as required.

9.5 The maximum period for suspension shall be 6 months, after which time the certificate should be either re-instated or withdrawn, if it has not already expired.

9.6 A certificate may be withdrawn by PJRFSI for the following reasons:
a. failure of the client to adequately comply with the Certification Body's request for action following a complaint investigation
b. following investigation or a scheduled audit, where a site is not maintaining the standard
c. the company no longer trades
d. the site no longer undertakes the scope activities e.g. cessation of manufacture due to extensive site damage by fire
e. a suspended site exceeds the 6 months' time period to demonstrate compliance for recertification

9.7 Where the Operation's Certificate is withdrawn, PJRFSIs Food Safety Program Coordinator or designee;
a. informs the Operation that the HACCP/GMP Certificate has been withdrawn, the reason for such action, the date of effect, and in writing sent by certified mail;
b. instructs the Operation to return the Certificate;
c. instructs the Operation to return any electronic copies of the PJRFSI Logo and comply accordingly with the PJRFSI Logo Guidelines;

9.8 PJRFSI's Food Safety Program Accreditation Manager or designee shall require the client to
a. withdraw any claim that imply that the site has been certificated;
b. cease to advertise or use any certification mark issued by PJRFSI;
c. cease using the PJRFSI logo within 48 hours of
certificate withdrawal

9.9 An organization with a withdrawn certificate may reapply to PJRFSI HACCP/GMP Safety Certification Program 6 months from the date the certificate was withdrawn or seek special approval to re-enter the program prior to 6 months.

10.0 Operation Requirement to Notify PJRFSI of Special Situations

10.1 The Operation is required to notify PJRFSI in writing and in a timely manner about any significant change(s), actual or intended, which include but are not limited to:

a. changes in legal or commercial status including changes in name;
b. changes in ownership;
c. changes in key managerial, decision-making or technical staff;
d. changes in the number of employees;
e. changes in location and/or number of sites;
f. damage to the site, e.g., damage by fire or natural disaster such as a flood;
g. changes to the physical building(s) and/or processing operations and equipment;
h. changes to the scope of certification (including expansion or reduction) in terms of products, processes, and/or facilities;
i. changes in the Operation's HACCP/GMP System or factors influencing the Operation's HACCP/GMP
j. System; and
k. a food incident as described in 10.2.

10.2 If at any time based on available information, the Operation becomes aware that concerns about actual or suspected threats to food safety exist which could require intervention to protect consumers' interests, Operation must notify PJRFSI immediately. Upon identification that a food safety event requires public notification (such as a Class I or Class II recall), the Operation shall, within 3 workings days of identifying the event, notify Perry Johnson Registrars Food Safety, Inc's Food Safety Program Accreditation Manager in writing and by phone call:

a. Business hours M-F, 9-5 EST: 248-519-2523
After hours and weekends: 248-648-0216
b. Email: foodsafety@pjrfsi.com;

10.4 When a certified Operation relocates its business premises, the Operation's Certificate is no longer valid until a successful Recertification Audit of the new premises as conducted.

10.5 A certified Operation must notify PJRFSI of any change in ownership with thirty (30) days of the effective change. When a certified Operation's ownership changes but key staff responsible for the HACCP/GMP System have been retained, PJRFSI confirms the continued effectiveness of the HACCP/GMP System within sixty (60) days of the change of ownership by means of a site audit and upon confirmation. This allows the Operation to retain the existing audit frequency status and certification number. If significant changes in key personnel have occurred with the change in ownership, PJRFSI shall complete a full Facility Audit and the Operation's audit frequency status will be based on this new audit activity.

10.6 Reserves the right to conduct special audits during the course of the certification period, and as needed in response to changes/incidents as described above. Where such changes may affect the conformity of the product(s) and/or the Operation's HACCP/GMP System, PJRFSIs Food Safety Program Accreditation Manager or designee as appropriate determines whether the announced changes require further investigation and schedules a special audit as necessary.

10.7 Operation must not promote products, processes, and/or facilities/sites which have not been covered in the scope of certification as audited and approved by PJRFSI. Unauthorized promotion will result in the withdrawal of the Certificate.

10.8 Operation fails to notify PJRFSI of any of the above changes, PJRFSI may accordingly suspend or withdraw, as deemed appropriate, the Certificate and reserves the right to retroactively invalidate the Certificate effective as of the date the change occurred.

11.0 Promotion of HACCP/GMP Certification by Operation

11.1 When providing copies of any certification documents (certificates and audit reports) to interested parties, Operations shall reproduce those documents in their entirety or otherwise seek permission in writing from PJRFSI. The proprietary names and logos of PJRSI and any applicable accreditation bodies, shall not be used by the Operation in any manner which could be misconstrued or defamatory to the respective parties and/or parties' brands. Any misuse of these proprietary names or logos by a certified Operation or an Operation seeking certification shall be reported to the interested parties and responded to with appropriate actions by PJRFSI.

12.0 Conditions for Change of Certification Body (Transfers)

12.1 When providing copies of any certification documents (certificates and audit reports) to interested parties, Operations shall reproduce those documents in their entirety or otherwise seek permission in writing from PJRFSI. The proprietary names and logos of PJRSI and any applicable accreditation bodies, shall not be used by the Operation in any manner which could be misconstrued or defamatory to the respective parties and/or parties' brands. Any misuse of these proprietary names or logos by a certified Operation or an Operation seeking certification shall be reported to the interested parties and responded to with appropriate actions by PJRFSI.

13.0 Disputes and Appeals

13.1 Disputes and appeals are handled in accordance with PJRFSIs Dispute/Appeal Procedure (SOP-10), which is available upon request.

14.0 Confidentiality

14.1 PJRFSI, including all auditors, administrative staff, technical reviewers, Impartiality Committee, and any other employee or contractor, ensures that all records, data, and information received during the execution of any audit activity remain confidential and the property of the Operation. Only with the Operation's authorization will PJRFSI release audit data to any entity except when mandated by law, statute, or the regulations of accreditation bodies. In the event that disclosure of such information is required by law or statute or accreditation body regulations, PJRFSI will disclose the information as required and inform the Operation of such disclosure in writing in a timely fashion.

HACCP/GMP Audit Checklist

On the following pages, we have included a copy of our HACCP/GMP Audit Checklist used during our certification process.

Auditor Name:						
Date of Audit:						
Company Name:						
Announced or Unannounced Audit						
Plant Description:						
Employee Numbers:						
Shift information:						
Exclusions:						
Scoring						
Compliant - full point						
Minor - half points						
Major - no points						
Critical - auto fail						
Management System Elements						
Management Commitment						
Clause #	Requirement		Response	Evidence	Points Awarded	Max Points
1.1.0	Is there an approved product safety/GMP policy signed by senior management? Is the policy reviewed annually by senior management?	Has it described the company's commitment to meeting producing safe food, customer expectations, regulatory requirements and continuous improvement of systems related to food safety?			0	10
1.1.1	Are there food safety objects established to support the product safety/GMP policy? Please list and provide status of each objective.	The objectives shall be documented and include targets or clear measurements; communicated to staff and monitored with results being reported to senior management at relevant frequency.			0	10
1.1.2	How was the policy and food safety objectives communicated to staff?	This can be achieved in meetings, postings or training.			0	10
1.1.3	Is there a Management review of the process to assess the level of conformance to operational policies: include internal / external audits, customer complaints, nonconforming products, effectiveness of corrective actions and preventive actions, and supplier performance and overall effectiveness of the Food Safety Management System at least annually? Are records of review maintained?	A review of the operational policies related to food safety and GMP's shall be conducted at least annually to evaluate the effectiveness of the system. Trends, food safety objectives, CAPA's, Internal/external audit findings, supplier performance, effectiveness of HACCP, resource requirements, regulatory updates, complaints, training competency and opportunities of improvement shall be reviewed and part of the management review record.			0	10
1.1.4	Management commitment must demonstrate adequate financial and staffing resources for implementing and maintaining food safety, product quality, security programs and overall facility and equipment maintenance. Comment on how this is achieved.				0	10
1.1.5	Have roles and responsibilities been defined for personnel responsible for food safety and quality? Organizational chart and job descriptions should be reviewed.	Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements for food safety and GMP's. Employees are informed of their responsibility to report food safety problems to personnel with authority to initiate action.			0	10
1.1.6	The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented to ensure all PRP's and Food Safety programs are current.	Facilities define written procedures to meet legislative requirements as defined by country or export requirements.			0	10
Document Control and Record Keeping					0	40
Clause #	Requirement		Response	Evidence		

1.1.7	Is there an establish document control program in place to include: master list of all control documents to include all Policies, Procedures, SOP's Work Instructions, SSOP's and forms? Comment on the effectiveness of the document control program.	The facility must have a written program outlining how documents will be maintained, updated, and replaced. The facility must maintain a record of all documents and revisions to documents to adequately identify the most current document that is in use. The facility must also identify how all documents will remain secure at all times. Electronic records - server backed up; frequency?			0	10
1.1.8	How are changes to documents or new documents managed and communicated to relevant staff?	Review any recent changes and how it was communicated to staff; training record, posting and meeting records?			0	10
1.1.9	The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented.	All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.			0	10
1.2.0	Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations.	Records must be kept as original records, true copies, or electronic records. Records must be retained for a period defined by the company, taking into consideration the shelf life of the product and any regulatory or customer requirements.			0	10
Customer/Consumer Complaint Management						
Clause #	Requirement		Response	Evidence		
1.2.1	There shall be a written procedure for handling customer and/or consumer complaints that addresses responsibilities, response, root cause investigation and corrective actions where required.	The facility must have written program outlining how customer complaints will be investigated and handled where ever they occur throughout the process.			0	10
1.2.2	Are records maintained for complaints?	The facility must maintain records related to the complaint management program.			0	10
1.2.3	Is there a system to identify trends and opportunities for improvement?	The methods should include trend analysis to ensure continuous improvement.			0	10
Internal Audit System						
Clause #	Requirement		Response	Evidence		
1.2.4	Is there a documented internal audit program and audit schedule based on risk? Are all items audited at minimum of annually?	The facility must have a documented program that outlines the internal audits that are completed at the facility. There must be a system in place that requires the facility to be evaluated on a regular basis to ensure that all programs are properly implemented and are functional.			0	20
1.2.5	Are audits completed by competent auditors that are independent of area being audited?	Internal audits shall be carried out by appropriately trained and competent auditors. Auditors shall not audit their own work where possible.			0	10
1.2.6	Are audit reports documented to include compliance and non-compliance findings?	Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained.			0	10
1.2.7	Are corrective actions/preventive actions assigned and completed per the due date assigned? How are corrective actions/preventive actions verified to be effective? Are records of corrective actions/preventive actions maintained?	Corrective actions/preventive actions shall be assigned and closed out at a acceptable time frame. Effectiveness of preventive actions shall be measure by number of repeat items and trends from internal audit findings.			0	20
Raw Material, Packaging Material, Processing Aids, and Finished Goods Specifications						
Clause #	Requirement		Response	Evidence		

1.2.8	Is there a documented procedure for reviewing and approving specifications for raw materials, packaging materials, processing aids, and Finished Goods?	The methods and responsibility for developing and approving detailed raw material, ingredient, packaging specifications and Finished goods shall be documented. Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, certificate of analysis, or sampling and testing.			0	10
1.2.9	Are specification for raw materials, packaging materials, processing aids, and finished goods on file?	Specifications shall be documented and reviewed.			0	10
1.3.0	Do these specification meet all regulatory requirements and customer requirements if applicable? (i.e. food contact packaging; microbial and etc.)	Specifications and Finished product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel.			0	10
Control of Non-Conforming Materials						
Clause #	Requirement		Response	Evidence		
1.3.1	Is there a documented procedure for managing non-conforming materials to include raw materials, packaging materials, WIP, rework, returned goods and finished goods?	The facility must have outlined procedures for placing product on hold at any point during the process and demonstrate control of materials. **Failure to have a documented procedure to control non-conforming materials will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
1.3.2	Does the procedure include corrective action and root cause investigation based on seriousness of the risk identified? Are records maintained?	The facility should utilize a CAPA process based on seriousness of the non-conforming materials to eliminate repeat holds.			0	10
1.3.3	Are non-conforming materials adequately controlled and identified?	The methods must address product identification, isolation/segregation procedures and areas, current list of product that is on hold (including reason for hold, physical location in the facility, any additional applicable notes).			0	20
1.3.4	Are authorized personnel designated to disposition non-conforming materials adequately qualified?	How has authorized personnel been designated and trained to disposition non-conforming materials?			0	20
1.3.5	Are disposition of nonconforming material traceable for recall or withdrawal?	The facility must be able to track all dispositioned materials to waste, donation or rework in the event of a recall or withdrawal.			0	10
1.3.6	Is there a system in place to identify trends?	Non-conforming materials should be tracked by type of hold, material, cause and etc. in order to identify a trend or system failure.			0	10
1.3.7	Are employees adequately trained on non-conforming procedures?	Auditor should interview employees on process for identifying, communicating and managing non-conforming materials in their roles.			0	10
Approved Supplier and Service Program						
Clause #	Requirement		Response	Evidence		
1.3.8	Is there a documented supplier approval process for materials and services? Are there criteria for selection of suppliers? Describe requirements. Are they adequate to ensure food/product safety?	The facility must detail methods used to select, evaluate, and approve suppliers. The program must also outline the documentation that must be provided by the vendor in order to become an approved supplier. **Failure to have an approved supplier or service program will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
1.3.9	Laboratories used for analyses are independently accredited by a competent body.	Labs should be ISO 17025 Certified			0	10

1.4.0	Suppliers that manufacture or ship products to the USA include foreign supplier verification and import requirements as part of the approval program.	Foreign suppliers must meet all FSMA Foreign Supplier Verification and Import Requirements.			0	10
1.4.1	How is the performance monitoring effected? Is the performance monitoring frequency and criteria based on risk to the facility? Comment on the effectiveness of performance monitoring?	The facility's supplier approval program must include appropriate assessment of the potential vendor's facility (examples: surveys, questionnaires, second party or third party audits, or on-site audits). The type of assessment should be based on risk. The facility's program must also outline the ongoing evaluation of a supplier including on-site audits, sampling and testing of raw materials, and/or review of food safety records including 2nd and 3rd party audits. This evaluation should be conducted at a frequency determined by risk category of the supplier/raw material and take into consideration past supplier performance if applicable.			0	10
1.4.2	Are records kept of supplier selection and performance monitoring?	The facility must ensure that they have access to records of supplier approval. The documentation present must be what is outlined in their written program.			0	10
Crisis Management Program						
Clause #	Requirement		Response	Evidence		
1.4.3	Has the company identified potential threats to its business operations? How are the threats mitigated?	A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis. **Failure to have a documented Crisis Management Plan will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
1.4.4	Have roles and responsibilities been identify for key activities during a crisis?	Key roles and responsibilities shall be identified and communicated to key personnel. How is identified and communicated?			0	10
1.4.5	The responsibility and procedure ensuring food safety and quality integrity has not been impacted by an event to raw materials, packaging material, WIP and finish goods?	Authorized and competent personnel is responsible for ensure the food safety and quality integrity has been defined and procedures outlined.			0	20
1.4.6	The procedure shall be tested annually and records maintained.	A record of annual test of the system shall be maintained.			0	10
1.4.7	Have employees been trained on the crisis management procedures?	Employee awareness training shall be documented annually.			0	10
Regulations Overview						
Clause #	Requirement		Response	Evidence		

1.4.8	How does the company ensure compliance with the applicable regulations? What are the applicable regulations?	The facility must ensure that they are properly registered with all applicable regulators. In the United States this could include the FDA, USDA, and State departments of health. For Canada, this could include the CFIA. The facility must ensure that they are properly registered with destination product regulators, if applicable. The facility must have a documented procedure outlining how they ensure that all regulatory requirements are met for all applicable processes. The procedure should also include how the facility ensures regulatory requirements are met when products are exported to other countries. The facility must be able			0	10
1.4.9	How does the company keep track with changes or new regulations?	The documented procedure and responsibility shall be maintained on process used to stay informed of any changes or new regulations. This can be achieved through professional organizations, publications, regulatory email updates, continuing education, webinars			0	10
1.5.0	Please verify the recent regulatory inspection report. Where there any adverse comment?	Comment on any recent regulatory inspections.			0	10
Corrective Actions						
Clause #	Requirement		Response	Evidence		
1.5.1	Is there a documented procedure for corrective action? Are root cause analyses for the corrective actions implemented in the past appropriate? Please provide evidence.	The program must include identification of the cause for the non-conformance as well as confirmation that the non-conformance has effectively been resolved. All associated records must be documented and maintained.			0	10
1.5.2	Is the system effectively managed? Please provide evidence. Is there any significant trend in the corrective action system?	Effectiveness can be measured by trends and repeat CAPA's.			0	10
Packaging Labeling						
Clause #	Requirement		Response	Evidence		
1.5.3	The facility shall have a program to assure that labels in use and product being produced are matched and do not lead to mislabeling or product adulteration.	Verify a line clearance or label verification process is in place and records are maintained of such activities.			0	20
1.5.4	Labels shall satisfy regulatory requirements for the country of manufacture and/or for the country of sale.	Finished product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel.			0	10
Rework						
Clause #	Requirement		Response	Evidence		
1.5.5	Does the facility have documented controls for the use of re-work, work in progress, and re-packaged product within the process? Is the facility properly adhering to their rework program?	The facility must identify rework and WIP and ensure that product has a clear break from one lot to another. Auditor must verify the identification system of rework and WIP used in the facility and observe it during the audit. The proper tracing of rework would be evaluated in the traceability and recall section of the audit; this question pertains to the proper use and identification of rework. The facility must define the terms if they are in use and determine how much re-work or work in progress (WIP) can be utilized within a "lot" of product. **A facility conducting rework activities and does not have a documented rework program will result in a CRITICAL**			0	20
Product Release						
Clause #	Requirement		Response	Evidence		

1.5.6	Are responsibilities and procedures implemented for product release? Are qualified personnel authorized to release finished product? Please describe requirements.	The procedure shall include: all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.			0	10
Traceability						
Clause #	Requirement		Response	Evidence		
1.5.7	How are products identified and traced in the production system and in the supply chain?	The facility must have a system in place to ensure that all lot codes are being properly documented for raw materials and primary packaging that is used. Rework and work-in-progress must be effectively tracked as well.			0	20
1.5.8	There shall be evidence (trace exercise) of traceability for all ingredients, WIP, rework, food contact packaging into finished product. A trace exercise shall be conducted at a minimum of annually.	The facility must be able to demonstrate that they are able to effectively manage the product recovery system and provide records.			0	10
Recall and Withdrawal Plan						
Clause #	Requirement		Response	Evidence		
1.5.9	Does the documented recall and withdrawal plan contain: • Defined roles and responsibilities • Contact lists for external notification (regulators, customers, public) • Lot identification and verification information • Product disposition procedures Effectiveness check procedures to be used during a recall.	The responsibility and methods used to withdraw or recall product shall be documented and implemented. Identify those responsible for initiating, managing and investigating an incident. Describe the management procedures to be implemented including sources of legal, regulatory and expert advice and essential traceability information. A communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner. Trace process and verification of information shall be documented. Product disposition procedure and records maintained. **Failure to have a documented Recall or withdrawal plan will**			0	20
1.6.0	Does the procedure include corrective actions related to recalls?	Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.			0	10
1.6.1	Has the facility conducted a mock recall at minimum annually? Review effectiveness of mock recall.	The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually.			0	10
1.6.2	Was there any real product recall in the past? If so, review the records and provide evidence the recall management was adequate.	Verify no recall or withdrawal has been initiated in the past year. If recall or withdrawal was initiated verify the effectiveness of process and corrective actions/preventive actions taken.			0	10
Training						
Clause #	Requirement		Response	Evidence		
1.6.3	Is there a documented training program that identifies the required training for employees?	The facility must have a documented training program for all employees and management personnel in the facility. Required training shall be identified for roles and responsibilities of each employee. **Failure to have a documented training program for all employees and management personnel will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
1.6.4	Are employees and management staff adequately trained on GMP, food safety/HACCP, food security, PRP's and allergen management?	Verify employees are receiving annual training for GMP's, food safety/HACCP, food security, PRP's and allergen management. Record shall be on file and interview employees.			0	20

1.6.5	Is there a training matrix or schedule to ensure annual training is completed for all employees and management?	How does the facility ensure all employees are trained as required and at the required frequency?			0	10
1.6.6	How is competency/effectiveness of training measured?	A verification system should be in place (tests, on the job observation, etc.) to show that training was effective. This verification system should be documented. The verification system should have thresholds in place. In the event that thresholds are not met, documentation showing that refresher training is completed should be kept.			0	10
1.6.7	Records of training shall be maintained to include: topic of training; date and signature of trainee.	Training records must be maintained at the facility to show that training is being completed at the frequencies outlined in the facility's training programs. Training records that are maintained must be able to easily show the employee who was trained and what training was provided.			0	10
PRP's						
Allergen Management Program						
Clause #	Requirement		Response	Evidence		
2.1..0	A documented allergen control program shall be implemented to include management of raw ingredients, WIP, processing aids, lubricants, rework and finished goods.	This program must include a risk assessment to identify the allergens of concern and areas where controls must be implemented. The program should also consider allergens permitted in employee break rooms and cafeterias and appropriate controls to prevent cross-contact to production areas. **Failure to have a documented Allergen Control Program will result a CRITICAL non-conformance and an automatic FAILURE. A risk assessment indicating no allergens are present must be in place where facilities have no allergens.**			0	20
2.1.1	Ingredients containing allergens shall be clearly identified as such and properly controlled, segregated in storage, production or batching areas to prevent cross-contamination. All ingredients in use, work-in-process (WIP) and rework and carryover shall be properly labeled with identification, date, lot number, allergen information so as to prevent accidental substitution, ensure traceability and prevent allergen cross-contact.	The facility should have a documented program outlining how allergens are identified from the point of receiving to the packaged finished product. The program should include how the identification system is communicated throughout the organization. Facilities must have systems in place that allow for the easy identification of allergens in storage and in production.			0	20
2.1.2	Controls shall be identified to prevent allergen cross contamination to include: scheduling, utensil/equipment segregation or sanitation requirements between allergen – non allergen runs and etc.	The facility should include methods to prevent potential cross contact when the use of dedicated equipment is not possible and non-allergenic/unlike allergenic product is processed after allergenic product.			0	20
2.1.3	Personnel shall not be a source of allergen cross contamination when handling different allergens: shall take appropriate measures such as changing outer garments (e.g., coats, hair nets, gloves, sleeve guards).	Employees shall be trained to change outer garments when moving from allergen containing products to non-allergen containing products.			0	10

2.1.4	Sanitation controls must be identified as part of the allergen control program to ensure removal of allergen residue is effective and has been validated. Records of validation shall be maintained.	The program should be validated to ensure that it controls the potential chemical hazard along with subsequent verification. The program should also outline how records of validation and verification will be maintained. If the processing of allergenic items is covered by scheduling, there must still be a validation program present for the final sanitation activities that are conducted prior to non-allergenic items being processed. In the event dedicated equipment is used for processing similar allergenic products, this question would be considered not applicable. Auditor Instructions: Validation would require either generic protein swabbing (not ATP) or			0	20
2.1.5	Labeling for allergen containing products shall meet legal and customer requirements. (per country regulations)	The facility must ensure that all labels are accurate and list all allergens that are present in a finished product. A change-over process to ensure accurate labels are being used for allergen containing products must be present.			0	20
2.1.6	Allergen awareness/control training must be completed annually.	All employees with responsibilities in the allergen program must be aware of the controls that are implemented at the facility to ensure that all allergens are properly identified, segregated, and cross contact is avoided.			0	10
Food Defense/Security						
Clause #	Requirement		Response	Evidence		
2.1.7	There shall be a written program which describes assigned responsibility for food security and how it is maintained.	The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained. **Failure to have a documented Food Defense/Security program will result a CRITICAL non-conformance and an automatic FAILURE.**			0	20
2.1.8	Has the company carried out vulnerability assessment to identify threats in respect of intentional contamination? Annual review is required at minimum.	A documented vulnerability site specific assessment shall be documented and reviewed annually for any changes.			0	10
2.1.9	A comprehensive food defense plan shall be implemented to manage the risks identified in the evaluation.	The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing and storage areas through designated access points; the measures taken to ensure the secure receipt and storage of raw materials, packaging, equipment and hazardous chemicals; The measures implemented to ensure raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are held under secure storage and transportation conditions.			0	20
2.2.0	The facility maintains evidence of FDA registration under the Bioterrorism Act and re-registers at the frequency defined by the FDA. (applicable if the facility manufactures, processes, packs, holds and distributes, or exports food for human or animal consumption in the USA.)	Where applicable FDA registration shall be maintained.			0	10
2.2.1	Employees shall be screened, trained in food defense awareness and access to the facility shall be controlled.	Training records shall be maintained for food defense/security.			0	10

Food Fraud						
Clause #	Requirement		Response	Evidence		
2.2.2	Has the company carried out vulnerability assessment to identify any ingredients susceptible to food fraud? Annual review is required at minimum.	The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.			0	20
2.2.3	Has the company identified controls to mitigate any risk to food fraud? Annual review is required.	A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.			0	10
Maintenance Program						
Clause #	Requirement		Response	Evidence		
2.2.4	Plant shall have a documented preventative maintenance program that covers all equipment and facilities. Records shall be on file.	The facility must have a documented maintenance program that outlines the methods in which maintenance activities are to be completed.			0	20
2.2.5	A documented work order program shall be implemented and records maintained for work other than PM's.	The facility is required to maintain records of all maintenance activities that are being conducted on food handling and processing equipment. The records can be hard copy (paper) or soft copy (computer) records. Records must be maintained for the emergency repairs that are being conducted as well.			0	10
2.2.6	There shall be a procedure to ensure that cleaning and sanitation is done following maintenance as needed. This shall include a reconciliation of all tools and spare parts used during the maintenance work to ensure that the work site has been returned to conditions for safe processing.	The facility must document that sanitation activities have been completed once maintenance activities are finished on equipment and in food handling areas. This can be a simple sign off at the bottom of the maintenance work order or a full pre-operational inspection can be conducted. In addition, there must be documentation that all tools and parts used for the maintenance activities are accounted for upon completion of the maintenance tasks. **Failure to have a documented sanitation/line clearance program will result a CRITICAL non-conformance and an automatic FAILURE.**			0	10
2.2.7	Nonfood grade materials or otherwise inappropriate materials including, but not restricted to, wire, tape, string, plastic or cardboard shall not be used for temporary repair in processing areas.	A documented program must be in place which instructs staff that temporary repairs with unauthorized materials (wood, string, cardboard, tape, etc.) that could prevent proper cleaning and pose a threat to product are not permitted. The policy should list the actual materials that are not permitted to be used.			0	10
2.2.8	Any temporary repairs on food contact surfaces are constructed of food-grade material and approved by management; they are dated and replaced with a permanent repair as soon as possible.	The policy must also include clear requirements to make temporary repairs permanent within a reasonable time frame. Employees must be able to demonstrate training by being able to describe who is authorized to make temporary repairs and what materials are restricted. Similarly, they must be able to demonstrate the procedure for ensuring temporary repairs are made permanent (notification, Work Order creation, etc.).			0	10

2.2.9	Only food grade grease shall be used where exposure to food or food contact surfaces is a risk.	The facility must ensure that only food grade lubricants are being used for the greasing and lubricating of food processing equipment. A segregation system must be in place to prevent cross contamination. This segregation system must include the proper storage or lubricants and greases, and the use of dedicated and identifiable grease guns. This program does not have to be documented.			0	10
2.3.0	Catch pans or deflector plates are installed in areas where drive motors and gearboxes are mounted over product zones, and where conveyors cross or run parallel at different levels. No excessive lubrication or grease present.	Controls shall be in place to protect production zones from contamination from over greasing or failure.			0	10
2.3.1	Lubricants are labeled, segregated, and stored in a designated, secure area. Food-grade and non food-grade lubricants are kept separate from each other.	The facility must ensure that only food grade lubricants are being used for the greasing and lubricating of food processing equipment. A segregation system must be in place to prevent cross contamination. This segregation system must include the proper storage or lubricants and greases, and the use of dedicated and identifiable grease guns.			0	10
Calibration Program						
Clause #	Requirement		Response	Evidence		
2.3.2	A calibration program for equipment or control devices that have an impact on food safety and/or product compliance to quality and regulatory requirements is documented.	The program should identify all measuring, test, and inspection equipment used in the facility and the applicable calibration schedule for each piece of equipment. Routine annual calibration (i.e., certification) of equipment by an outside contractor to a recognized standard is required. . Calibration procedures shall describe the frequency of testing, the testing method and the acceptable range of variation.			0	20
2.3.3	Records of calibration activities shall be maintained and traced to a national recognized standard.	Records shall be on file.			0	10
2.3.4	Corrective actions shall be documented for products monitored/controlled with a device found out of calibration.	There shall be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used (e.g., thermometer, scale, flow meter, counting device, metal detector, coder). All products produced since the last acceptable check must be reviewed to determine if they must be held for further evaluation.			0	20
Foreign Material Controls						
Clause #	Requirement		Response	Evidence		
2.3.5	Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food. Describe Foreign Material controls in place.	The responsibility, methods and frequency for monitoring, maintaining, calibrating and using screens, sieves, filters or other technologies to remove or detect foreign matter shall be documented and implemented.			0	20

2.3.6	Is there any evidence of potential or actual contamination of product in the processing areas found during the audit?	**Actual product contamination observed by the auditor during the audit is a CRITICAL non-conformance and FAILURE of the audit.** The auditor must actually observe the contamination. Potential product contamination would be dripping condensate, product stored under open walkway, etc. Any potential contamination that deals with practices and not processing equipment should be recorded here.			0	20
2.3.7	There shall be a program to manage glass and brittle plastic. A glass breakage procedure shall be documented	All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location. Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register.			0	20
2.3.8	Sieves, Filters, Screens and magnets shall be used where appropriate and properly managed and maintained.	PM records and inspection records shall be on file for sieves, filters, screens and magnets.			0	10
2.3.9	Metal detection/X-Ray systems, where they have been determined by the facility's risk assessment to be required for food safety or quality control reasons, shall be managed and calibrated.	Calibration records shall be on file.			0	10
2.4.0	Blade and wood where used, shall be controlled and inspected. Snap-off blades are not used in production, packaging, or raw material storage areas.	Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Knives and cutting instruments used in processing and packaging operations shall be controlled and kept clean and well maintained			0	10
2.4.1	The facility follows Corrective Action and Reporting Procedures to respond to foreign material control device failures. These procedures may address: • Isolating • Quarantining • Re-testing all food produced since the last acceptable test of the device	Corrective actions shall be documented related to foreign material control failures or foreign material findings.			0	10
Chemical Control					0	20
Clause #	Requirement		Response	Evidence		
2.4.2	A written Chemical Control Program that addresses all chemicals used in the facility (e.g., chemicals for Integrated Pest Management, Maintenance, Sanitation, Hygiene, and Laboratories).	A procedure shall be documented to manage the use, storage and handling of all non-production chemicals to prevent chemical contamination.			0	10
2.4.3	The program shall address chemical approval, control and usage, secure storage, labeling, concentrations verification when applicable, inventory control, SDS, spill control and chemical disposition.	The procedure shall include approval, storage, labeling, concentration for sanitation, chemical inventory, disposition requirements and spill controls.			0	10
Personnel GMP's and Facility Conditions						
Personnel Hygiene and GMP's						
Clause #	Requirement		Response	Evidence		

3.1.0	GMP and Personnel Hygiene shall be documented and monitored for compliance for employees, part-time employees, temporary employees, visitors and contractors.	The program must outline all of the practices that must be followed within the facility. The program must address eating and drinking around food products, proper health, cleanliness of employees, washing hands, wearing hair restraints, wearing jewelry, prevention of cross contamination, cuts and wounds, the use of gloves, and use and maintenance of personal equipment, etc. The policy shall outline that all types of employees (seasonal, part time, etc.) visitors and contractors must adhere to GMPs and where these GMPs must be followed. **A systemic observation of employees not following stated GMP's or Personnel Hygiene will result a**			0	20
3.1.1	Personnel hygiene practices must be observed while working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food.	The facility must ensure that all employees follow the GMPs that have been implemented at the facility. Employees must be aware of the GMP program that has been implemented and when they should not be handling food products. Interview employee to determine awareness of GMP's required in their area of work.			0	10
3.1.2	A written dress code for all employees (including new and part-time), visitors, vendors and contractors shall be documented. Employees shall wear clean clothing and shoes appropriate for the working conditions.	Clothing worn by staff engaged in handling food shall be maintained, stored, laundered and worn so as not to present a contamination risk to products.			0	10
3.1.3	<u>High-Risk Clothing Management</u> - Personnel in high-risk operations follow specified procedures for dressing in visually distinctive clean outer garments, headwear, and footwear. Personnel enter high-risk operations through specially designated changing areas. All protective clothing is regularly cleaned on-site or by a contract laundry.	Hygienic zones and outer clothing/shoe control programs shall be in place.			0	20
3.1.4	The use of hair restraints and facial hair, no false fingernails, fingernail polish, jewelry (rings, exposed body piercings, bracelets), or watches.	Hair restraints must be properly worn in all areas where exposed food products are handled. All hair on an employee's head must be properly covered; hair cannot be hanging loose out of the employee's hair restraint. Beard restraints must be worn as appropriate. The facility must ensure that employees are not permitted to wear jewelry in exposed product areas. The facility must also ensure that there are no loose objects carried above the waist in exposed areas to prevent possible product contamination.			0	10
3.1.5	Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.	Employees who enter the exposed food handling areas must wash their hands. Hands must also be properly washed when they become soiled during production. Employees interviewed during the audit must be aware of the hand washing procedures that have been implemented.			0	10
3.1.6	Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.	Employees must properly changing gloves when they become soiled, damaged, or there is any type of contamination. Additionally, employees who handle ready-to-eat food items must wear gloves while handling products.			0	10

3.1.7	Eating, drinking, spitting, chewing or using tobacco products shall only be permitted in designated areas.	Eating, drinking, smoking, and chewing cannot be permitted in the food handling areas.			0	10
3.1.8	Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered(e.g., by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.	The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids from open wounds, coughing, sneezing, spitting, or any other means. Personnel with exposed cuts, sores or lesions shall not engage in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a bandage or an alternative suitable waterproof and colored dressing.			0	10
Plant and Grounds						
Clause #	Requirement		Response	Evidence		
3.1.9	The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food.	The facility must maintain all exterior areas in such a manner that dust, waste, and debris are minimized to prevent possible air-borne contaminants and pest harborage opportunities.			0	10
3.2.0	Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination or pest harborage. This shall include adequate drainage.	Roads, yard and parking lots shall be in good repair and no water pooling.			0	10
3.2.1	Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.	Equipment that is stored on the exterior must be done in such a manner to prevent possible pest attraction and harborage			0	10
Plant Construction and Layout						
Clause #	Requirement		Response	Evidence		
3.2.2	The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes.	The facility must ensure that the structure is maintained in a manner to prevent exterior conditions from posing a threat products that are handled at the facility.			0	10
3.2.3	Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.	Spacing around equipment and storage items shall provide adequate spacing for inspections, maintenance and sanitation activities.			0	10
3.2.4	Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair. No holes or cracks. Floors are sloped to direct the flow of water or effluent toward drains.	The facility must ensure that ceilings, walls, windows, and doors are constructed and maintained in such a manner to prevent possible foreign material hazards.			0	10
3.2.5	Are platforms, mezzanines, ladders, walkways, and walk-overs in good repair? Are those over exposed product lines protected to prevent potential product contamination?	The facility must ensure all platforms and mezzanines are constructed, positioned, and maintained in such a manner to prevent product contamination, potential pest harborage, and ensure appropriate sanitation. All ladders, walkways/walk-overs, platforms and mezzanines positioned above product zones must be rust proof and easy to clean. They must also have solid side plates (ideally 4 inches/100 mm in height) installed to prevent contamination due to falling debris.			0	10

3.2.6	Drains are made of materials that are easily cleaned and kept in good repair. Floor drains with grates are installed, maintained, and operational in all wet processing or wash areas. Equipment and drains should be placed in a way that any processing discharge or overspill goes directly into a drain rather than on the floor.	The facility must ensure that floor drains are constructed so that they adequately remove excess standing waste water, they are easily cleaned and do not pose an additional hazard in the facility. This must be evident due to the lack of standing water throughout the facility. Floor drains must be constructed so that they are easily cleaned and do not pose an additional hazard in the facility.			0	10
3.2.7	Drip or condensate from ceiling, fixtures, ducts and pipes does not contaminate food, food contact surfaces, or food-packaging materials	The facility must ensure that all food handling areas are condensation free. The facility must ensure that all areas are properly ventilated when enclosed food processing areas are in use as this will facilitate the prevention of condensation. Ceilings must be free of vapor leaks that could allow for condensation/ice to accumulate. **Direct observation of drip or condensation onto product zone or product will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	10
3.2.8	Plant lighting shall be adequate and appropriate for sanitation, inspection and processing tasks being performed.	Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively. Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling.			0	10
3.2.9	Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food.	The facility must ensure that all areas are properly ventilated when enclosed food processing areas are in use as this will facilitate the prevention of condensation. Pay close attention to cooking areas or areas where there is a great temperature difference between processing areas]			0	10
3.3.0	Air makeup units are fitted with clean filters and are free of mold and algae. Fans, blowers, filters, cabinets, and plenums are on the Preventive Maintenance Schedule to prevent mold, the development of microbes, insect activity, and foreign material collection.	Records of PM and inspection on air makeup units shall be maintained.			0	10
3.3.1	Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives. Records of filter inspection and replacement are maintained.	Compressed air systems, and systems used to store or dispense other gases used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. Other gases used in product contact are of suitable purity to protect the finished material or are filtered to remove contaminants.			0	10
Sanitary Facilities and Controls						
Clause #	Requirement		Response	Evidence		

3.3.2	Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food packaging materials, or for employee sanitary facilities.	Adequate supply of water at the suitable temperature and pressure must be observed to ensure adequate sanitation activities may be completed.			0	10
3.3.3	Potability testing of municipal water supplies shall be conducted by a certified laboratory at minimum annually. Potability certificates available from municipal water suppliers are acceptable.	Annual testing by 3rd party lab or municipal water supply testing report shall be on file.			0	10
3.3.4	Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.	No cross connections between waste water/sewage lines and potable water lines. Backflow device shall be in place where applicable.			0	10
3.3.5	Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.	Sewage system must meet all local and state requirements and not pose a cross contamination with the potable water supply system.			0	10
3.3.6	Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.	The facility must have adequate number of restroom facilities for male and female employees that are maintained in good repair. The restrooms shall be equipped with self-closing doors, and trash receptacles (sanitary type for women's restroom). Hand sinks must also be properly equipped with soap, warm water (100 °F), paper towels and/or alternative air-drying apparatus. There must be at least one hand wash sign in a conspicuous location and it must be in the languages understood by the employees at the facility.			0	10
3.3.7	Hand-washing facilities: Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food- contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.	The facility must ensure that there is are a sufficient number of hand wash stations located in appropriate areas (personnel entrances from break rooms, restrooms, exterior door ways, trash/compactor rooms, low to high risk product areas, etc.) These hand wash stations must also be properly equipped with soap, warm water (100 °F), paper towels and/or alternative air-drying apparatus, trash receptacle, and a conspicuous hand wash sign that is in languages understood by the employees at the facility. All hand wash stations must be properly supplied and functional during the audit			0	10
Sanitation Program						
Sanitation Program						
Clause #	Requirement		Response	Evidence		
4.1.0	Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food contact surfaces, or food-packaging materials.	Comment of direct observation of the effectiveness of sanitation program.			0	10

4.1..1	Documented standard cleaning procedures shall be implemented to include: what to clean, frequency, chemicals to use, and verification of effectiveness of cleaning. A documented master cleaning program shall be documented to include facility, building and equipment.	The facility must have documented Sanitation Standard Operating Procedures for all sanitation activities that are conducted at the facility. The SSOPs must be present for all pieces of food handling equipment and must cover all processing areas, storage areas, common areas, and the exterior of the facility. The SSOPs must list the method in which the task is to be completed, the chemicals used (along with concentrations or if they are from a pre-mixed dispenser), the equipment used for the task, and the person responsible for the completion of the task. Finally, the facility must have a schedule in place for the completion of all sanitation tasks.			0	20
4.1.2	<u>For CIP systems:</u> Properly maintained and functioning CIP systems are in place to include: Indicating and recording thermometers and pressure sensors are used to monitor the CIP system. Minimum requirements for time/temperature and flow rate are established and documented. Chemical concentration requirements are established and documented.	Records of temperature and pressure are maintained. Required time/temperature and flow rate has been validated and is meet. Chemical concentration are documented and verified for each CIP cycle. Spray balls, pipes, clamps, couplings, and connections are completely disassembled to allow proper cleaning and inspection.			0	20
4.1.3	<u>For CIP systems</u> - CIP records and recording charts are reviewed to determine if defined time/temperature, flow rate, and chemical concentration requirements are applicable to the process and are being met. Review CIP records.	CIP records shall be reviewed and signed off on by trained CIP operator on the proper use of cleaning chemicals and operation of CIP system.			0	20
4.1.4	Cleaning equipment is maintained and stored in a way that does not contaminate foods or production equipment. Separate and distinct utensils are used to clean food contact surfaces (product zones) and structures (product areas). Utensils used to clean restrooms or floor drains are never used for any other cleaning purpose.	All equipment must be properly cleaned on a regular basis and equipment that is in storage must be properly cleaned prior to storage to prevent pest activity and other sanitation issues. Dedicated cleaning utensil should be defined.			0	10
4.1.5	A color-code or other type of classification is in place to identify and separate cleaning utensils based on their intended usage.	All cleaning utensils are cleaned and properly stored after use. Proper storage includes segregation to ensure that cross contamination does not occur. A color-code or other type of classification is in place to identify and separate cleaning utensils based on their intended usage.			0	10
4.1.6	Cleaning chemicals shall be appropriate for use and do not pose a food safety or contamination risk. All cleaning chemicals shall be appropriately labeled. SDS and labels shall be on file.	All cleaning compounds and sanitizers used to clean food contact surfaces have food contact approval documentation. Sanitizer concentrations are tested to make sure they are consistent with the product label.			0	10
4.1.7	A documented verification or pre-operation inspections shall be implemented and records on file.	Records shall be on file and reviewed.			0	20
4.1.8	Corrective action procedures are established and documented for incomplete or inadequate sanitation practices. Records of corrective actions completed shall be maintained.	Documentation of corrective actions and re-inspection prior to production line being released to production shall be documented.			0	10
4.1.9	Sanitizer concentrations are tested to make sure they are consistent with the product label. The facility follows verification procedures and maintains records of chemical concentration testing, retesting, and Corrective Actions.	Sanitizers not rinsed off must be verified to be at acceptable regulatory concentration stated per the label. Records shall be maintained.			0	10
Equipment and Utensils						
Clause #	Requirement		Response	Evidence		

4.2.0	All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross- contact and contamination.	Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.			0	10
4.2.1	Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.	Comment on conditions of food contact surfaces, design of materials/equipment and overall sanitation condition.			0	10
4.2.2	Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.	Seams on food-contact surface shall be smooth bond. No tact welds are allowed.			0	10
4.2.3	Equipment and utensil not in use must be sanitarily stored and maintained to protect against allergen cross- contact and contamination.	All equipment must be properly cleaned on a regular basis and equipment that is in storage must be properly cleaned prior to storage to prevent pest activity and other sanitation issues.			0	10
Microbial Control / Environmental Monitoring						
Clause #	Requirement		Response	Evidence		
4.2.4	A written Microbial Control Program that addresses microbiological analysis for raw materials, finished product, production, and packaging as dictated by a risk assessment completed by the facility.	A risk-based environmental monitoring / microbial control program shall be in place. Roles and responsibilities shall be documented.			0	20
4.2.5	An environmental / microbial sampling and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.	An environmental sampling / microbial and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.			0	20
4.2.6	Environmental / microbial testing results shall be monitored and corrective actions implemented where unsatisfactory trends are observed.	Corrective actions shall be implemented when unsatisfactory trends are seen.			0	10
4.2.7	Records are maintained of laboratory analyses and/or environmental samples that document compliance with the Microbial Control Program.	Records shall be maintained.			0	10
4.2.8	On-site laboratory facilities, if present, do not jeopardize product safety and/or Contract labs maintain appropriate accreditation to carry out the analyses performed	The facility shall ensure that their on-site laboratory is separated from the food processing or handling areas to prevent possible cross contamination. The laboratory must also have signage that indicates that only authorized personnel are permitted to access the laboratory.			0	10
Pest Control						
Clause #	Requirement		Response	Evidence		

4.2.9	A documented Pest Control program shall be maintained and implemented.	The facility must have a documented pest prevention program. The program must detail all of the pest prevention practices that are conducted at the facility. The facility's program must outline how services are to be completed, who is to conduct servicing, and what devices are implemented at the facility. The facility is permitted to use internal personnel for pest control as long as all pesticides, if used, are handled by properly licensed persons. **Failure to have a documented Pest Control program will result will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
4.3.0	<u>Outsourced Monitoring -</u> The program shall include: A current Pest Control Operator (PCO) applicator's license and letter of liability insurance shall be on file, along with Safety Data Sheet (SDS) for all chemicals used. An up-to-date site map of all pest control devices shall be maintained. Frequency of monitoring/inspection. Record of inspections, corrective actions and application of any chemicals applied.	PCO license, Application License, LOLI, SDS, and site map shall be current. Records must be maintained to show that all pest control activities are being conducted at the frequency that is defined in the documented pest control program. The service records must show what pesticides were applied, the target organism, the amount of pesticides used, the concentration of use, and the location of application. In addition to this, the facility must have reports that show if there are any signs of activity and if there are any conditions that could facilitate a pest control issue.			0	10
4.3.1	Pest control devices including: interior, exterior and insect light traps shall be suitably located and not attract pest.	Pest control devices must be placed in a manner that does not allow for any possible contamination of food products. Insect-o-cuter style insect light traps must be placed at least 15 feet away from food products so as to prevent possible contamination. Bait stations are not permitted within the facility.			0	10
4.3.2	No evidence of pest activities or infestation shall be present.	The facility must be free of any evidence that suggests that there are pest issues present (i.e. rodent droppings, insect carcasses, flour beetle trails, etc.). Signs of decomposed rodents in the facility is not permitted as it shows a major deficiency in the pest control program. Stored product pests should be evaluated in this area. Finally, there must be no signs on the exterior of the facility that pests are harboring next to the facility; this means there cannot be burrows or nests on or next to the building. **Direct observation of pest activities, decomposed rodents, or infestation will result will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	10
4.3.3	Pest control awareness training shall be provided annually for employees.	Annual awareness training records shall be maintained.			0	10
4.3.4	Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food contact surfaces, food-packaging materials, water supplies, and ground surfaces.	Waste shall not be a pest attractant.			0	10

4.3.5	Walls, doors and overhead doors shall be adequately pest proof.	There should be no openings to the exterior of the facility at any time so as to prevent possible pest entry into the facility. There should be no gaps greater than 1/4" pedestrian doors which could allow for pest entry.			0	10
Manufacturing Operations, Warehousing, Receiving and Distribution						
Manufacturing Operations						
Clause #	Requirement		Response	Evidence		
5.1.0	Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.	Adequate controls and records of product temperature monitoring shall be documented through out the process of manufacturing, processing packing and storage. **Failure to monitor temperatures and direct observation of temperature abuse will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
5.1.1	Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.	**Failure to measure and control process that are taken to destroy or prevent the growth of undesirable microorganism will result in a CRITICAL non-conformance and an automatic FAILURE**.			0	20
5.1.2	Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary. Describe control measures in place.	**Failure to ensure adequate heat blanching and cooling is implemented and monitored will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
5.1.3	Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level. Describe controls in place.	**Failure to control water activity in products requiring controls in place to prevent the growth of undesirable microorganisms will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
5.1.4	Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below. Describe controls in place.	**Failure to control pH for preventing the growth of undesirable microorganisms will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	20
5.1.5	When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.	Ice must comply with local, national or internationally recognized potable water microbiological and quality standards.			0	10
Warehouse, Receiving and Distribution						
Clause #	Requirement		Response	Evidence		

5.1.6	There shall be a written procedure for the inspection of delivery vehicles. This shall apply to receiving and shipping. Prior to loading, all shipping vehicles are inspected for cleanliness and structural defects that could jeopardize the product. Shipping vehicle inspections are documented. Procedures shall define when carriers are to be rejected.	The receiving program must outline the inspections that are conducted on incoming carriers prior to and during unloading. The inspection program must cover the cleanliness of the trailer, the absence of pests (insects, rodents, etc.) or evidence of pest activity (rodent droppings, spider webs, insect trails), the absence of off odors, the interior physical condition of the trailer and the absence of commingling (raw over ready to eat; chemicals mixed with food products, etc.).			0	20
5.1.7	There shall be a written procedure for the inspection and receipt of ingredients, raw materials, and packaging.	An inspection of incoming goods must be completed to ensure all products are in good condition for use. Inspections must include product condition, shelf life (for perishables), and product temperature.			0	10
5.1.8	Raw materials, ingredients, packaging and finished product shall be secure and protected in storage. Separate or segregated storage areas shall be in place for raw materials, WIP, packaging and finished goods to ensure no cross contamination is a risk.	All products must be properly protected from any form of contamination that could be present. This would include raw commingled with ready to eat items, chemicals commingled with food products, bags or boxes of ingredients that are not properly covered when placed in storage, etc. All ingredients should be kept clean (i.e. free of dust and debris) and properly protected from potential sources of contamination (i.e. roof or condensation leak).			0	10
5.1.9	Raw material inspection or sampling shall be conducted in a manner as to not present a food safety or contamination risk.	Control measures shall be documented on how to sample raw materials without creating a food safety or contamination risk.			0	10
5.2.0	Bulk systems and unloading areas are installed and maintained to prevent adulteration of raw materials and finished product. Outside receiving lines or caps to bulk dry and liquid ingredients are locked, identified, or otherwise secured.	Bulk systems and unloading areas shall be secured when not in use.			0	10
5.2.1	If present, security seals on bulk container hatches or other shipping containers are checked against the seal number on the bill of lading to verify that the numbers match during shipping and receiving.	Security seals for bulk container/tankers shall be inspected for integrity and accuracy against the BOL.			0	10
5.2.2	Tanker Wash Tags or prior load verification are verified and records are maintained.	Tanker wash tags shall be on file when required.			0	10
5.2.3	All bulk dry materials are sifted before use.	Bulk dry material sifter or screened.			0	10
5.2.4	Sifters, sieves, rebolters, and scalpers for finely milled bulk dry materials are inspected for torn screens and other defects at least weekly.	Record of inspection shall be documented.			0	10
5.2.5	The facility shall maintain records of tailing findings for bulk dry ingredients and corrective actions. If foreign material that could damage the sifter, sieve, rebolter, or scalper screens is found in the tailings, those screens are immediately inspected for damage and records maintained.	Procedure and records for tailing checks and corrective actions for foreign materials shall be in place based on risk of FM.			0	10
5.2.6	All bulk liquid materials are filtered with inline receiving strainers. Strainers are cleaned and inspected for integrity after each load. Strainer inspections, findings, and corrective actions are documented and kept on file.	Liquid bulk receiving process shall have a inline strainer or screen. Inspections shall be documented for each load received.			0	10

5.2.7	Storage temperatures shall be controlled and monitored. Raw materials, work-in-process, and finished product capable of supporting the rapid growth of pathogenic microorganisms are properly stored. The facility maintains a record of temperature monitoring activities.	The facility must have a documented program in place that outlines the methods in which temperatures will be monitored in the storage areas including product stored in secured transportation vehicles. The program must outline how temperatures will be monitored and what actions will be taken if elevated temperatures are observed. Temperature monitoring equipment must be placed in the warmest location of the storage area. **Failure to control and monitor temperatures will result in a CRITICAL non-conformance and an automatic FAILURE.**			0	10
5.2.8	Refrigerated and/or Frozen truck temperatures shall be monitor prior to loading and unloading. The refer unit setting, truck temperature and product temperature shall be recorded.	The facility must have a documented program in place that outlines the methods in which temperatures will be monitored in the storage areas including product stored in secured transportation vehicles. The program must outline how temperatures will be monitored and what actions will be taken if elevated temperatures are observed.			0	10
5.2.9	Staging and loading of perishable materials does not pose a food safety risk. Describe how this is managed.	Describe the controls in place to ensure product temperature or integrity is not at risk during staging and loading.			0	10
5.3.0	Security seals or padlocks are provided, and their use is documented as per facility or customer requirements.	Describe controls in place to ensure security of inbound and outbound full loads.			0	10
HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM						
Preliminary Tasks						
Clause #	Requirement		Response	Evidence		
5.3.1	Has the facility developed a documented food safety management plan (HACCP) for each process within the control of the organization?	The facility must have a food safety management plan in place for all products and processes that have been implemented at the facility. This plan will cover all of the control measures that are implemented based on a thoroughly completed hazard analysis. A facility does not have to have identified any CCP. **Failure to complete a risk assessment on the process, ingredients, packaging and finished goods of the facilities process will result in a CRITICAL non-compliance resulting in an automatic FAILURE.**			0	20
5.3.2	A multidiscipline 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.	A documented HACCP team and team leader shall be identified.			0	10
5.3.3	The HACCP team leader formally trained in HACCP? Verify training records and comment on the knowledge of team leaders and team members. Does the HACCP team receive annual refresher training?	Documentation of HACCP team leader training shall be on file. Comment on the experience and knowledge of the additional team members.			0	20

5.3.4	Are product descriptions, distribution and end user documented for each HACCP plan? Do they include the following: a) Ingredients b) Packaging used c) Intended use d) Intended consumers e) Shelf-life f) Labelling instructions g) storage and distribution h) Are consumers in vulnerable groups of the population, e.g. infant and elderly identified and documented?	Does each finish product or category of finished products cover the following: a) Ingredients b) Packaging used c) Intended use d) Intended consumers e) Shelf-life f) Labelling instructions g) storage and distribution h) Are consumers in vulnerable groups of the population, e.g. infant and elderly identified and documented?			0	10
5.3.5	The HACCP team shall develop a process flow chart to include all steps under control of the facility to include packaging materials, ingredients, processes, equipment, rework and product returns.	Verify the flow chart is accurate and been reviewed at least annually.			0	10
5.3.6	The flow chart shall be validated at least annually by the HACCP team and include all identified CCP's. Verify the accuracy of the flow chart during the facility audit.	Document accuracy and last review.			0	10
Conduct Hazard Analysis (Principle 1)						
Clause #	Requirement		Response	Evidence		
5.3.7	A hazard analysis shall be conducted for all hazards (chemical, physical and biological) 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, processing aids, equipment, processing steps and packaging materials.	Comment on all hazards identified and all process steps are included in the analysis.			0	20
5.3.8	The HACCP team shall ensure the hazard analysis has identified which hazards are of such a nature that their elimination or reduction to acceptable levels is required to produce safe food. The hazard analysis shall take into account the likelihood of hazards and severity of their adverse health impact.	The hazard analysis must include an evaluation of the hazards identified to assess the severity of the illness or injury and the probability that the hazard will occur in the absence of controls to determine if a control is necessary. For each hazard that requires control in order to eliminate the hazard or reduce it to acceptable levels, control points must be reviewed to determine those that are critical. Often, the use of a decision tree facilitates this decision.			0	10
5.3.9	Preventive controls shall be identified for all significate hazards identified.	For those controls that are not critical (i.e. those where control is achieved through existing or prerequisite programs), those programs must be stated.			0	20
Critical Control Points (Principle 2)						
Clause #	Requirement		Response	Evidence		
5.4.0	Did the HACCP team determine CCP's using a logical, documented approach? Document CCP's identified.	The determination of critical control point(s) (CCPs) must be documented as part of each process under the HACCP program. Use of a decision tree, indicating a logic reasoning approach should be demonstrated as part of the process.			0	20
5.4.1	Are necessary steps for prevention, elimination or reduction to the tolerable levels of the controllable safety hazards identified as CCP?	Demonstrated evidence must be included that each CCP will properly control food safety.			0	20
Establish Critical Limits (Principle 3)						
Clause #	Requirement		Response	Evidence		

5.4.2	Critical limits shall be documented and validated for each CCP.	Each critical limit must be quantifiable, control each identified hazard and be measurable. Each critical limit must be validated demonstrating that the identified limit adequately controls the identified CCP.			0	20
5.4.3	Documented process capability studies or CCP monitoring records shall be maintained to demonstrate that the CCP limits are compatible with plant process and capable of being met.	A process capability study or CCP records shall be maintained.			0	20
CCP Monitoring (Principle 4)						
Clause #	Requirement		Response	Evidence		
5.4.4	Are monitoring methods documented and implemented for all CCPs to confirm whether the CCPs are effectively controlled? Does the monitoring method specify how the CCP is to be monitored, who is responsible for monitoring, frequency for monitoring and where activity is to be documented?	The facility must have scheduled measurement or observation demonstrating the ability to detect loss of control of each CCP relative to its critical limit(s) must be documented. Procedures must be able to detect loss of control of the CCP. Procedures must also include specifically what and how it is to be monitored, who (by title or role) will perform each monitoring task, the amount or frequency (if not continuous) of the monitoring, as well as all equipment to be used to perform all monitoring tasks.			0	20
5.4.5	CCP monitoring records shall be maintained. Does the monitoring employee date and initial monitoring activities on the CCP monitoring record?	Records for each CCP shall be reviewed for accuracy and compliance to the monitoring frequency defined by the HACCP team.			0	10
5.4.6	Are the CCP monitoring personnel trained as necessary and understand the purpose and significance of the monitoring?	CCP specific monitoring training shall be documented.			0	20
Corrective Actions (Principle 5)						
Clause #	Requirement		Response	Evidence		
5.4.7	Are specific corrective actions developed for each CCP in the HACCP system in order to deal with deviations when they occur?	As a minimum, the HACCP plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken.			0	20
5.4.8	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.	Corrective actions shall ensure the product safety is not jeopardized.			0	20
5.4.9	Corrective actions shall document actions necessary to identify, secure and manage any product effective by the deviation.	Corrective actions shall ensure all inventory produced under deviation is controlled, identified and secured.			0	10
5.5.0	Corrective actions shall include disposition of effective product.	Appropriate disposition shall be identified.			0	10
Established Verification Procedures (Principle 6)						
Clause #	Requirement		Response	Evidence		
5.5.1	Are there verification methods to decide the effectiveness of the HACCP plan to see if the system is working as planned? (Note: Method should be depended on the following rather than inspection of the end product: frequent review of the HACCP plan; verification to confirm if it is in accordance with the HACCP; review of the records of CCP monitoring and corrective actions)	Documented procedures (including a task list) to determine if the HACCP program is working correctly must be present. The frequency of verification should be sufficient to confirm that the HACCP program is working effectively. These tasks should be carried out by someone other than the person(s) responsible for performing monitoring and corrective actions.			0	20
5.5.2	Who is responsible for verification of the plan? At what frequency? (Note: Experts can be either in-house or external)	Roles, responsibilities and frequency shall be defined.			0	10

5.5.3	What method was used to verify HACCP plan? Comment on the appropriateness and effectiveness of the chosen method?	Methods shall be documented in the verification procedure.			0	10
5.5.4	Does the verification include the following? 1) Re-analysis of hazard analysis 2) All elements of the HACCP plan 3) Verification of flow diagram 4) Verification of records pertaining to HACCP plan	Are all elements included?			0	10
Documentation and Record Keeping (Principle 7)						
Clause #	Requirement		Response	Evidence		
5.5.5	Do documents for the HACCP system include the following? 1. Summary of the hazard analysis 2. HACCP Plan: - List of HACCP team and responsibilities of team members. - Product description - Verified flow diagram - Summary list of HACCP plan, which include the following: process steps of CCP; significant hazards; critical limits; monitoring; corrective actions; verification methods / plans; record-keeping methods 3. Supplementary documents such as validation information 4. Records created during HACCP planning.	Ensure the Food Safety Plan (HACCP) includes all elements listed.			0	20

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