Plant Systems Audit (PSA) Program

United States Department of Agriculture

Marketing and Regulatory Programs

Agricultural Marketing Service

Fruit and Vegetable Programs

Processed Products Division

AIM Instructional System

Inspection Series

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Plant Systems Audit (PSA) Program
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INTRODUCTION

This manual is provided to Processed Products Division (PPD) inspection personnel to promote uniform preparation and application of the Plant Systems Audit (PSA) Program. For any situation not covered by the AIM Inspection Series PSA manual, please contact your immediate supervisor as needed.

The information has been compiled or developed from sources available to the public as well as from technical knowledge of personnel in the USDA.

Compliance with the Agricultural Marketing Service (AMS) guidelines does not excuse failure to comply with the Food, Drug, and Cosmetic Act or any other applicable Federal or State laws or regulations. If needed, contact your immediate supervisor for any situation not addressed in this manual.

This manual contains links to various internal and external sources of information. For inspection personnel without internet or intranet access, please contact your immediate supervisor to obtain hard copies of documents as needed.

GUIDE FOR ELECTRONIC USAGE

The Administrative, Inspection, and Management (AIM) System of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address: http://agnis/sites/FV/PPB/default.aspx.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined blue text) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext will link the reader to a different page within the current manual - or even a different manual - with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title within the Table of Contents.

PDF offers a variety of tools depending on the Adobe version the reader has. The newer the version, the more tools available. To learn about the variety of PDF search options available:

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PROGRAM OBJECTIVE

The Plant Systems Audit (PSA) Program is a voluntary, impartial, third-party audit of a food processor's quality assurance system. It assists buyers in evaluating their suppliers for meeting standards or requirements, such as the Food and Drug Administration (FDA) Good Manufacturing Practices, or other specified requirements. The PSA program provides objective information about a supplier. PPD personnel perform Plant Systems Audits to determine if a supplier is conforming to the audit criteria.

A. Quality Policy

The PPD continually strives to understand, meet, and exceed all customer and statutory requirements in the services it provides to promote the efficient marketing of agricultural commodities. PPD accomplishes this by providing value-added services that provide flexibility in a changing market place. These services are continually evaluated for their effectiveness. The results of these evaluations will be used to improve PPD's service processes based on objective practices and procedures. Interested parties can find information regarding the PSA Program at the following PPD Website: http://www.ams.usda.gov/PSA.

It is the policy of PPD's Audit Management Program (AMP) to provide a range of audit services, including the PSA. The AMP was established to meet the Agricultural Marketing Service Industry Services Audit and Accreditation Program requirements. Additional audit policies, procedures and instructions are provided within the AMP 1.0.

B. Program Scope

1. The frequency and scope of the audits provided under the PSA program can be adapted to meet an applicant's needs.

2. In most cases, an audit is performed as a result of a customer requirement; however any food processor may request this audit service to gain an objective assessment of its own operations.

3. PSA audits are required annually and are conducted during actual production.

4. All applicable charges associated with the audits are the responsibility of the applicant (auditee) for service.

5. This voluntary user fee auditing service is available upon request.

6. The Plant Systems Audit includes in-process observations and review of associated documentation and records. During an audit, PPD reviews a processor's Food Safety Controls, Quality Management Systems, Personnel Policies and Practices, Good Manufacturing Practices, Sanitation, Pest Control, Packaging, Labeling, Inventory Practices, Recall/Return, and Food Defense.

7. In each area audited, PPD determines whether or not:

   a. A processor is performing procedures, inspections, and tests identified in their quality assurance program;

   b. The results of inspections and tests are documented;

   c. An auditee's quality assurance system includes corrective actions in the event of a non-conformance or test failure; and

   d. Corrective actions on deficiencies are taken, documented, and verified for effectiveness. Each segment of the audit is assigned a numeric score with the highest possible score of 1,080.

8. The PPD auditor is accompanied by a representative of plant management during the plant tour, and areas of concern are brought to the representative's attention. Frequently corrective actions can be taken immediately, but these are still documented in the report as corrected during the audit. Deficiencies which cannot be corrected immediately are brought to the attention of management for later evaluation.

9. The PPD audit report includes a list of deficiencies observed in each area of the plant. The report describes how well a processor's quality assurance system is working. It will also include information on sanitation deficiencies noted during the audit, including product compliance. Improvements noted after the first audit will be documented in subsequent audit reports.

10. If the result of the audit is a rating of Acceptable (or higher), the PSA Program Manager notifies the applicant and issues a certificate to the auditee indicating their score.

11. If an auditee requests an amendment to the scope of a PSA audit that has already been conducted, the auditee must notify the PSA Program Manager and schedule an audit for the areas/products that are requested for inclusion.

C. Document Control

Applicant-related PSA program documentation is retained by AMS in a secure manner. Only AMS authorized personnel may access the applicant's PSA audit records. An applicant's PSA audit is the property of the applicant and AMS will treat it accordingly.

Audit records are retained by AMS for 3 years from the audit date.

D. Fees

The Agricultural Marketing Act of 1946, as amended, provides AMS general authority for fee-for-service programs. The fee an applicant is charged is based on the time required by AMS personnel to: prepare for the audit, travel to and from the audit site, conduct the Plant Systems Audit, prepare the audit report, and administer the audit program activities. The fee covers associated Agency costs for auditors' training, transportation, and per diem. The current fee is listed on the USDA, AMS, F&V, PPD's internet site at the following internet address: http://www.ams.usda.gov/processedinspection. Click on the "PPD News" link in the "PPD Services" block, next click on the "Current User Fee Information" link in the "PPD Services and Fees" section. Click on the "Audit, Survey, and Verification Programs" link for the current fee. AMS will make any necessary fee rate adjustments to ensure that fees are adequate to cover the costs of providing the service and are not excessive. If audits are requested outside the Continental United States (OCONUS), the actual travel costs will be charged in addition to the hourly fee.

E. Estimated Fees

During the initial communication with a potential applicant, an auditor informs the auditee of the costs associated with the Plant Systems Audit, and the fees that are the responsibility of the auditee, unless otherwise arranged. If the applicant requests the cost estimate for an audit, one will be provided using information provided by the applicant. The estimate may not reflect actual cost. Most audits can be conducted within 4 to 6 hours. Smaller, less complicated facilities may be audited in 3 to 4 hours, while larger, more complicated facilities may take 6 to 8 hours.

F. Cross Utilization

PPD promotes cross utilization with other AMS Programs, agencies, and departments in order to provide the most efficient service at the lowest cost. Once trained, auditors from these programs may be utilized to perform PSA audits to maximize efficiency and to provide technical expertise.

G. Termination, Suspension, or Withdrawal of Service

PSA audits may be performed until suspended, withdrawn, or the agreement is terminated by:

1. Mutual consent;

2. Written notice by AMS if the applicant fails to honor any invoice within 30 days after date of receipt;

3. Bankruptcy of the applicant, business closure, or change in controlling ownership of the firm; or

4. AMS at any time, acting pursuant to the applicable law, rule, or regulation, debarring the applicant from receiving any further benefits of the service.

H. Foreign Audit Inquiries

In order to maintain uniformity in scheduling and cost estimates, and to handle the special Agency approval requirements of foreign travel, inquiries for possible audit work in foreign countries should be directed to the PSA Program Manager.

APPLICATION PROCESS

Interested parties may apply for the audit service using one of the following methods:

A. Audit Service Request

Companies that wish to participate in the PSA Program may apply electronically through email, in writing, or by phone to:

Director, Processed Products Division
Fruit and Vegetable Programs, AMS
U.S. Department of Agriculture
1400 Independence Ave., SW, STOP 0247
Washington D.C. 20250-0247
Email: Randle.Macon@ams.usda.gov
Phone: (202) 720-4693
Fax: (202) 690-1087

B. Food Distributor's Continuous Release Form or Audit Request System

Suppliers to a food distributor may apply for the audit service by completing a food distributor's release form or subscribing to a food distributor's electronic audit request system, e.g., Sodexho's Continuous Release Form, SYSCO's electronic audit request system (iCiX), etc. These requests give the USDA authorization to release PSA audit reports to specified distributor. The food distributor receives these authorizations from their suppliers and provides the information to the PSA Program Manager. The purpose of a continuous release form is to provide authorization to USDA to send the auditee's audit report to the distributor. A continuous release form remains valid until the auditee submits a revised continuous release form with changes and/or corrections to the food distributor.

C. PPD's PSA Release Authorization

The "Plant Systems Audit Program Release Authorization" document may be completed by an applicant to authorize the release of their audit to a third party of their choice. This should be completed at the time the applicant applies for service, and is needed when there is no other release authorization on file.

If an auditee's audit report is sent to another entity, written authorization (e.g., a company's continuous release form, PSA Release Authorization, or other correspondence) must be on file to prevent the release of confidential information to an unauthorized party.

RESPONSIBILITIES

A. PSA Program Manager's Responsibilities

The PSA Program Manager will:

1. Coordinate auditing activities relating to clients, auditees, and auditors;

2. Review the requests for service and enter the information into the PSA Lotus Notes Database;

3. Receive audit reports from auditors and review for accuracy and uniformity;

4. Ensure that each decision on approval is made by a person different from the person who performed the audit;

5. When applicable, distribute the final audit report to food distributors within 10 working days of the date on the audit report;

6. Arrange for the distribution of the certificate and letter stating the results of the audit to the auditees;

7. Update program procedures and "Plant Systems Audit Report" (Attachment 2), as needed;

8. Solicit feedback from auditees;

9. Provide information for updates to the PSA audit program web site;

10. Provide feedback to the Division regarding the audit fee (report total obligations, total revenue, gain/loss to management), upon request;

11. Verify that auditors meet Agency training requirements;

12. Communicate with applicants (outreach) regarding:

    a. Purpose, requirements, expectations, and benefits of the PSA program;

    b. Guidance on how to obtain audit service;

    c. Estimated costs;

    d. Feedback on the PSA program;

    e. Available informational materials;

    f. Program changes (methods, requirements, procedures, updates, etc); and

    g. Auditor qualifications, when requested;

13. Coordinate the 3rd party audit program with food distributors;

14. Communicate with all stakeholders (e.g., PPD auditors; U.S. Department of Commerce, Seafood auditors and management; AMS, Poultry Programs, Shell Egg Program audit coordinator, Fresh Product Division audit coordinator, etc.); and

15. Review an Application for Service or release form and enter the applicant's information into the Lotus Notes database, e.g., scope requested and pertinent contact information.

B. Applicant Responsibilities

The applicant will:

1. Request PSA audit services directly through the Director of the Processed Products Division; indirectly through a distributor's request system, e.g., Sodexho's Continuous Release Form, SYSCO's iCiX system, etc; or through a Processed Products Division office using an FV-356, Application for Inspection and Certificate of Sampling;

2 Meet the applicable requirements, policies, and procedures outlined in this document. Applicants are responsible for keeping up-to-date with PSA program changes by referencing the PSA Program website at: http://www.ams.usda.gov/PSA;

3. Provide a company contact person;

4. Provide the location and access to all facilities/sites (i.e., receiving, production, distribution, etc.) to be audited;

5. Provide the scope of the audit (which products, which locations within the facility, etc.);

6. Specify as to whom they want their audit results provided (specific food distributor, etc.);

7. List the products packed;

8. Make pertinent audit documents, records, and procedures (i.e. consistent with audit questions) available to the auditor for review;

9. Provide interview time with key personnel;

10. Provide an escort for the facility tour;

11. Provide working space for the PSA auditor;

12. Provide appropriate management personnel for the audit and the closing meeting;

13. Pay the applicable audit fee;

14. Comply with the provisions of this document and other relevant documents applicable to receiving audit services;

15. Limit claims regarding approval to only those within the scope for which approval has been granted;

16. Use its program approval in a reputable manner, and only make statements regarding its program approval which are not considered misleading or unauthorized;

17. Discontinue its use of all advertising material that contains any reference to program approval, and return any approval documents upon suspension or cancellation of approval;

18. Use its approval status only to indicate that it and the products produced under its program are in conformance to the PSA requirements;

19. Ensure that no approval or report, or any part thereof including email, is used in a misleading manner;

20. Seek and obtain approval from PPD prior to referencing its PSA approval status within communication media such as brochures and advertising;

21. Take corrective action on deficiencies and continually strive to improve its program; and

22. Agree to follow-up audits by USDA to verify corrective actions for critical and major food safety or food defense deficiencies, as necessary.

C. PSA Auditor Responsibilities

PSA audits are usually conducted by one PSA auditor. It is very important that the PSA auditor dress and act in a professional manner at all times.

The PSA auditor will:

1. Prepare for the audit by:

   a. Arranging for the audit by:

      (1) Notifying the auditee that all PSA audits are unannounced, the projected cost of the audit, and the name(s) of the auditor(s) scheduled to perform the audit;

      (2) Obtaining the current address of the auditee, and the name and phone number for the contact person; and

(3) Checking with the applicant to find out what products are produced, information on seasonal factors and weekly shift plans so that the audit can be conducted during production, and obtain any blackout dates when key personnel are not available.

b. Inform the PSA Program Manager of the audit schedule by entering the proposed date the auditor plans to conduct the audit into the scheduled date in the Lotus Notes Database.

c. Preparing an audit plan to include audit date and times, the resources needed by the auditor, what areas to focus attention on, consideration of deficiencies from previous audit, etc. The auditor may use the Audit Plan format included at the end of this instruction or a similar Audit Plan.

2. Conduct the on-site audit by:

a. Conducting the opening meeting with a professional appearance and demeanor. Upon arrival at the plant, the auditor will:

(1) Introduce himself/herself to plant management,

(2) Explain audit scoring,

(3) Provide a copy of a blank PSA Audit Report and Audit Plan to the auditee,

(4) Explain the scope of the audit,

(5) Request an escort during the audit, and

(6) Arrange for interviewing the pertinent employees necessary to perform the audit.

b. Communicating with the plant representative during the audit to exchange information, inform of deficiencies found, and assess the audit progress.

c. Observing the facility, premises, and processing operation to obtain an overview of the processes, employee activities, and compliance with the auditee's documented programs.

d. Interviewing appropriate employees to verify their knowledge of the auditee's processes and their role in the process. Verify that

they understand the requirements and duties outlined by the company. Interviews are especially useful when inconsistencies are detected in records, and can help determine whether the employee is aware of and understands their responsibilities. If any employee declines an interview, it should be noted in the audit under the proper element.

e. Verifying the applicant's documentation including its written procedures relevant to the audit. An auditee's quality policy and procedures are an important aspect of the audit, as it demonstrates a company's commitment to continued process improvement. Documented policies and instructions that address each phase of processing are required to be maintained by management. Documented records of verification checks completed by plant personnel are required to be completed and available for review. Accurate record keeping provides evidence of proper operation, and serves as a mechanism for indicating potential problems and corrective action.

f. Conferring with other auditors participating in the audit prior to the closing meeting to review the audit findings, if an audit team is assigned.

g. Documenting findings for each appropriate element on the "Plant Systems Audit Report" and determining non-conformance(s).

h. Conducting the exit meeting with the auditee's management representatives to discuss the audit results and findings. In some cases, you may be able to inform them of an estimated audit score, but that the final score will be determined after review by the PSA Program Manager and entry into the database for calculation. The exit meeting with plant representatives should include the Plant Manager, General Manager, and the Quality Assurance/Quality Control Manager. If there are non-conformances that require corrective action, the auditor will discuss a mutually acceptable due date with the auditee for its response to each nonconformance.

i. Recording the name of the meeting attendees for entry into the audit report under "Observations/Improvements."

3. Complete the audit by:

a. Entering the audit information collected during the PSA audit into the PSA Lotus Notes Database, ensuring that the correct address and contact person is included as well as checking grammar and

spelling. All audit reports are to be written using the Lotus Notes form entitled "Plant Systems Audit Report" located in the PSA Database in Lotus Notes. An example is contained at the end of this section.

b. Listing under Products Packed separately listing the products that were observed in production during the audit, and other products also packed by the facility.

c. Notifying and submitting the audit report to the PSA Program Manager for review. The PSA report will be written and submitted (via Lotus Notes Replication) within 5 working days of completing the audit. The PSA Program Manager shall be immediately notified by entering a “Yes” in the databases section on the form that shows the PSA Program Manager that the audit is ready for review. After the PSA Program Manager has reviewed the report, he/she will fill in the “Reviewed” date on the report and contact the auditor to make any editing suggestions.

d. Making any necessary revisions based on the PSA Program Manager’s review. After corrections have been made by the auditor, the auditor will alert the PSA Program Manager that the report is complete. The final audit report is required to be completed within 10 working days of the date of the on-site audit.

e. Distributing the signed audit report along with a cover letter to the auditee after approval by the PSA Program Manager.

f. Verify that the applicant has taken corrective action on critical and major food safety or food defense deficiencies, as necessary.

g. Distributing the official PSA audit records to the Field office where the applicant is located, to file in the applicant’s file. The official PSA audit records required to be provided to the Field office are the following:

- Audit Plan;
- Signed copy of the Plant Systems Audit Report that was sent to the applicant; and
- Any pertinent work papers, as applicable.

h. Entering billing information for each audit into Lotus Notes so that the auditee can be billed. If applicable, the auditor’s Time and

Attendance record and the Travel Voucher corresponding to the audit service should be sent to the Field office where the auditee is located, and where that office's subcenter number was used.

D. Area Office Responsibilities

The Officer-in-Charge will:

1. Determine the auditor who will perform the audits in their field office or coordinate with the PSA Program Manager to request an auditor from outside their area.

2. Ensure there is an official PSA file for each auditee's audit records, labeled with at least the auditee's name, audit program name, and year (for example, AAA Tomato Processor, PSA Audit, 2009). The file shall contain the following:

   - Audit Plan;
   - Signed duplicate copy of the Plant Systems Audit Report sent to the applicant; and
   - Any pertinent work papers, as applicable.

   Document that the applicant requested service. This verification may be through an email, continuous release form from a distributor, email from the PSA Program Manager stating the applicant has requested service through an electronic request service, or any other document indicating the request for service.

3. Ensure that the auditee (applicant) is billed based on the information in Lotus Notes provided by the auditor.

PSA AUDIT SCORING

A. Evaluation Element Categories

The "Plant Systems Audit Report" is comprised of audit questions that fall into one of the following Evaluation Element categories: Food Safety, Quality Management Systems, Personnel, GMPs/Sanitation, Pest Control, Packaging/Labeling/Warehousing, Recall/Return, Food Security, and Contract Review. In order to receive an Acceptable rating, the facility must meet the minimum points or percentage required for each Evaluation Element category. The Food Safety Evaluation Element category is set at a minimum of 90 percent

or 270 out of 300 possible points. All other Evaluation Element categories are set at a minimum of 80 percent.
The audit consists of a basic checklist applicable to all food processing facilities, plus addendum pages that are specific to a particular commodity group. If a particular commodity group is part of the audit scope, then the commodity addendum and corresponding audit questions apply. Commodity addendums are available for Canned, Dried, or Frozen Fruits and Vegetables; Minimally Processed Fresh Fruits and Vegetables; Grain Milling; Dairy; and Seafood.

B. Scoring

The audit is based on a score of 1080 total possible points which is noted as the "Facility Score (total points)." The "Facility Score (percent)" is also listed in the report. Finally, the "Facility Score (percent)" is used to determine the "Facility Ratings." The facility rating categories are as follows:

Category	Percent Range
Superior	98.5 percent to 100 percent
Excellent	95.0 percent to 98.4 percent
Acceptable	87.5 percent to 94.9 percent
Unacceptable	Below 87.5 Percent

Questions listed under the Contract Review Evaluation Element are not scored; however, all other audit questions are either 5 or 10 points. The more critical questions are 10 points each; the others are 5 points. The auditor may assign partial points to a noted deficiency if the audit evidence indicates partial compliance. In this case, a 10 point question would receive 5 points, and a 5 point question would receive 3 points.

The Facility Score is determined by subtracting the total points assigned to the cited deficiencies from the 1080 total possible points. The Facility Score given is for a specific point in time, specifically the day the audit was conducted. This is a spot verification that usually takes place once a year, at the request of the applicant.

C. Unacceptable Rating

PPD requires that any facility found to be deficient with the conditions noted below be considered "Unacceptable." If a facility is rated "Unacceptable," the reason will be stated on the audit report (i.e., Unacceptable on account of a score of less than 90% in the Food Safety Section).

1. A Facility Score below 875 points;

2. A score of less than 270 points (90 percent) in the Food Safety Section or less than 80 percent in any of the other Evaluation Element categories;

3. No sanitation program in place;

4. Storage of food products at improper temperatures;

5. Presence or evidence of rodents, insects, or other pests in food products processing or storage;

6. Any infestation in food product areas;

7. Improper use of pesticides;

8. Use of non-approved sanitizers or cleaning agents;

9. Evidence of product contaminated with foreign material or filth (paint, rust, glass, wood, metal, jewelry, lubricants, chemicals, etc);

10. Observation of unsafe employee practices which could cause product contamination; or

11. Use of procedures that could render a product unsafe or unfit for human consumption.

D. Corrective Action

Any deficiency causing an "Unacceptable" rating because of a Food Safety or Food Defense deficiency requires corrective action by the auditee and may warrant a follow-up audit to ensure the deficiency is corrected.

PSA IN LIEU OF PLANT SURVEY

A Plant Systems Audit may be conducted in lieu of a Plant Survey to meet the USDA, AMS Commodity Procurement Division purchase program requirements. When an auditee requests that a PSA be conducted in lieu of a Plant Survey, the PSA Auditor will:

1. Evaluate the Good Manufacturing Practices and the Food Defense criteria to determine if there are any Major or Critical deficiencies.

2. Record all Major and Critical deficiencies on the PSA form under the section, "GMP Violations and Food Defense Deficiencies that Require Corrective Action."

3. Enter the date that is mutually agreeable to the auditee for the completion of the corrective action(s).

4. Follow the same procedure as is used for the follow-up activity regarding the deficiency for a Plant Survey contained in the AIM Instructional Series, Sanitation and Safety manual.

5. Check the block to indicate that the facility is "Unacceptable" or "Conditional" until the corrective action is completed and verified.

6. Follow-up to verify the auditee's corrective actions, which may require an audit.

7. If corrective action is completed and verified as effective, complete the "Date Corrected" information, and check the block to indicate that the facility is now "Acceptable."

8. Inform the PSA Program Manager that all corrective actions are verified, and the auditee is now rated "Acceptable."

RECONSIDERATIONS AND APPEALS

A. Request for Reconsideration

An applicant has the right to request reconsideration of any adverse audit finding or decision issued regarding its participation in the PSA program. Reconsiderations shall be submitted in writing to the PSA Program Manager or the PPD Director (see the mailing address below) within 30 working days of the date of the official PSA audit report, and shall include the basis for the disagreement with the findings and the requested alternative decision or action.

The PSA Program Manager shall review the request for consideration. A written decision will be sent to the applicant within 30 working days from receipt of the request.

B. Request for Appeal

If the resulting decision by the PSA Program Manager concerning the request for reconsideration is not satisfactory to the applicant, the applicant has the opportunity to appeal the PSA Program Manager's decision. Appeals must be made within 30 working days of the date of the PSA Program Manager's decision and shall include the basis for the appeal and the requested alternative decision or action. Appeals shall be submitted in writing to the PPD Director.

The PPD Director will respond within 30 working days from the date of receipt of the appeal. The applicant shall send the appeal to:

Director, Processed Products Division
Fruit and Vegetable Programs, AMS
U.S. Department of Agriculture
1400 Independence Ave., SW, STOP 0247
Washington D.C. 20250-0247
Email: Randle.Macon@ams.usda.gov
Phone: (202) 720-4693
Fax: (202) 690-1527

The decision made by the Director of PPD is final.

For additional information regarding reconsiderations and appeals refer to the PPD, Quality Management System Manual, Appendix B, QMS B6.0, Complaints, Disputes, and Appeals Procedure.

PSA PROGRAM REQUIREMENTS

A. PSA Criteria

1. Food Safety

The auditee is required to provide reasonable assurance that the facility operates in a manner such that the foods produced, manufactured, processed, packed, or held are safe and in compliance with applicable FDA requirements.

The auditor must have access to the relevant parts of the facility to make this determination.

At a minimum, the product, process, and facility must meet applicable FDA regulatory requirements for foods. These requirements are established by statute and by FDA regulations and will vary depending on the products or processes audited. FDA issues documents that provide guidance and represent FDA's current position on particular topics. This guidance can help auditors evaluate whether the facility is operated in a manner such that the foods it produces, manufactures, processes, packs or holds are safe and in compliance with applicable FDA requirements. FDA's guidance documents can be found at the FDA's internet site at the following internet address: http://www.fda.gov.

An effective, documented program that ensures a safe and secure supply chain for the ingredients or components used in making the foods being

produced, manufactured, processed, packed, or held in the facility is required.

The facility must use effective controls, as appropriate and feasible, to ensure the integrity of their ingredients and suppliers. These controls may include, but are not limited to, such steps as testing incoming materials, periodic inspection of suppliers, purchasing from certified suppliers, and requiring letters of guarantees or certificates of analyses from suppliers.

Process controls are required to be in place for the applicable product(s) processed in the facility as well as foreign material detection systems and allergen controls applicable to the facility.

2. Quality Management Systems

A management system is required to be in place to ensure food safety and compliance with FDA's applicable requirements. Quality system records are required to be kept a minimum of three years. Records are required to be legible, readily retrievable, and protected from deterioration. Company forms are required to include revision dates and form numbers. Company forms may have titles instead of form numbers. The Quality Assurance Department is required to be adequately staffed to perform product evaluations. Establishments are required to have an effective, documented program to verify product safety using scientifically sound methods. A testing program should be used to validate that safety hazards are appropriately identified and controlled. The validation methods will vary depending on the product. The methods used should be subject to periodic testing to ensure that they are still valid and can identify safety problems. Procedures are required to be in place for management to conduct internal reviews of its quality systems.

3. Personnel

An effective, documented program is required to be in place to ensure that employees carrying out activities having an impact on product safety or security are competent and have the appropriate education, training, skill, and experience to do their jobs effectively.

Appropriate safety equipment must be worn by employees. Material safety data sheets (MSDS) must be readily available and properly maintained. Signs must be posted indicating hazardous areas where protective gear is required, and a Lock out/ Tag out program for equipment is required to be in place.

Personnel must adhere to FDA Good Manufacturing Practices (GMPs) with respect to personal hygiene and related requirements.

4. GMPs and Sanitation

An ongoing sanitation program is required to be in place to meet the FDA Good Manufacturing Practices. Receiving areas, processing areas, water supply, and warehouse and storage facilities will be examined closely for potential sources of product contamination. Areas of the plant which provide for the safety and comfort of employees will be evaluated.

5. Pest Control

A pest control program is required to be in place and monitored along with maintenance of pest control records. Any conditions which could contribute to pest problems and plant pest management records will be evaluated.

6. Packaging, Labeling, and Warehousing

Packaging materials are required to be handled in a manner to prevent distribution of unsafe or contaminated food, and to meet applicable FDA requirements. Coding, labeling, and fill weights are required to be correct, and all information on packages must be legible. A shelf-life retention program must be in place. Procedures are to include how miscoded and mislabeled products are discarded or corrected, as appropriate.

7. Recall and Return

An effective, documented system is required to be in place to trace back and forward the movement of raw materials and finished goods at least from their original source through distribution to the entity that purchases the product from the facility.

The facility must have effective, documented recall procedures in place that can be used in the event of a safety problem. The written recall procedure should include:

a. Sharing information about recalls with affected government agencies, including countries where the products are ultimately distributed to consumers;

b. Promptly removing recalled products from the market;

c. Notifying customers and the public about the recalled products;

d. Performing recall audit checks; and

e. Identifying and maintaining records about essential recall information.

8. Food Defense

Preventive controls that include an effective, documented product security program must be in place. Such a program should include a management structure that assigns and maintains responsibility for security measures; employee screening and training; control of visitors in the facility, physical security of the facility, laboratories, and storage facilities; and control of operations that include incoming materials, production, manufacturing, processing, packing, and/or holding.

B. Guidance and References

Guidance and references are shown in the Guidance and References, Plant Systems Audit Program, contained in this section.

1. Evaluation Elements

This column lists the associated questions in the Plant Systems Audit Report.

2. Guidance

Under the Guidance column there may be References, Regulations and/or Requirements.

a. If "Reference" is listed, it is only a reference, not a requirement. It is provided just to give the auditor guidance.

b. If "Regulation" or "Requirement" is listed, the PSA evaluation element requires the facility to meet the regulation or requirement listed.

c. "Evaluation Method" is provided to assist the auditor in determining if an interview, review of documentation or procedures, and/or review of records is appropriate to obtain the best information on which to base findings.

d. "Criteria" are also listed under the Guidance column. This is the basis for determining if the evidence found meets or does not meet the requirements.

Attachment 1

PLANT SYSTEMS AUDIT PROGRAM
Release Authorization

Name Facility to be Audited:			
Street Address:			
City, State and Zip			
Contact Name:		**Title of Contact:**	
Phone:		**Fax Number:**	
Email Address:			

I, _____ provide authorization to USDA to release the results of the PSA audit to the entities indicated below, for the following calendar year: _____. This release form must be completed on an annual basis.

Authorized Company Representative: _____
(Signature)

Date: _____ **Title: _____**

PSA Release Authorization: Please indicate each company to whom you want us to release your PSA audit (use a separate release form for more than one company):

Name of Contact: _____ **Phone: _____**

Company: _____

Street Address: _____

City and State: _____ **Zip: _____**

Email: _____

*****Please fax this application/release to: PSA Program Manager at (202) 690-1527.**

Independent Continuous Release Form: ***Sodexho USA*** *has their own independent continuous release forms for your company to fill out and return back to them. This is not the form for that service.*

Attachment 2

Plant Systems Audit Report

Copy a facility

Date of Audit: August 05, 2010

Facility Name: Example Worksheet
Plant Address:
City:
State: Zip: Country: USA
Telephone:
Fax:

Mailing Address:
Address: Same as Above
City:
State: Zip:

Contact Person for USDA:
Name:
Title:

Audit Category	Audit Report Section	Facility Score	Percentage of Available Point Score	Minimum Points Required 1/	Possible Points
Employee Practices	Section III - Personnel	125	100%	100	125
Food Defense	Section VIII - Food Defense	80	100%	64	80
Food Safety and Processing	Section I - Food Safety Section VII - Recall/Return	370	100%	326	370
Grounds/Equipment and Plant Sanitation	Section IV - GMPs/Sanitation	275	100%	220	275
Pest Control	Section V - Pest Control	50	100%	40	50
Quality	Section II - Quality Management Systems	80	100%	64	80
Receive, Storage, and Shipping	Section VI - Packaging/Labeling/Warehousing	100	100%	80	100

Scoring System	Audit Results Summary
98.5% to 100% = Superior 95.0% to 98.4% = Excellent 87.5% to 94.9% = Acceptable Less than 87.5% = Unacceptable 1/ Facility must meet the minimum points required for each section.	Facility Score (total points): 1080 Facility Score (percent): 100.0% Facility Rating : Superior

Comments/Corrective Action(s) Required: Comments

Lead Auditor: Area Office: Phone:
Lead Trainee: Auditor: Evaluator: Observer:

Auditor's Signature: _____

U.S. Department of Agriculture, AMS, F&V, PPB
STOP 0247, 1400 Independence Ave., SW, Washington, DC 20250
Ph: (202)-720-5021 / Fax: (202)-690-1087 Version 040410

Attachment 2

Supplier: Example Worksheet, ,
Audit Date: 08/05/2010

Products packed:

Summary of Deficiencies:

Observations/Improvements:

Attachment 2

I. Food Safety

A. Internal Quality Audit

1.*	0	Are there procedures in place for management/supervisors to conduct internal reviews of Quality Systems?
2.	0	Are Internal audit findings documented and reported to upper management?
3.*	0	Are Corrective Action Reports followed up and documented to determine effectiveness?

B. Purchasing

4.	0	Is there a system in place to evaluate and approve suppliers?
5.	0	Are suppliers evaluated for good agricultural practices? (i.e. Do they have process controls in place covering pesticide control, harvesting, and transportation practices?)
6.	0	Are purchasing documentation/records, including Certificates of Conformance (COC) and Certificates of Analysis (COA), maintained, current, and applicable?
7.*	0	Are receipt inspections performed and documented on incoming product (Product condition, accuracy of invoice, product identity, etc.)? Is there documentation of the disposition of rejected product?
8.*	0	Are acceptance criteria documented for incoming ingredients? Do these procedures include testing for quality, foreign material, pesticides, and/or microbial contamination?
9.	0	Is domestic origin compliance verified? (i.e., product can be traced to US origins) (where required by contract)

C. Process Control (see attached for appropriate commodity)

10.	0	Is there a system in place for the proper handling, segregation, and storage of raw materials?
11.*	0	Are raw materials washed or cleaned as necessary to remove soil or other contamination?
12.*	0	If water is part of the finished product, is there a drinking water quality analysis available? (chemical analysis)?
13.*	0	Is the processing/ingredient water potability certificate available? Date of certificate:
14.*	0	Is forced air that is used on product or food contact surfaces free from contaminations?
15.1/	0	Microbiological testing includes: 0 Tests required by specification or contract: 0 Routine analysis of food contact surfaces: 0 Environmental testing program (floors, walls, ceilings, etc.): 0 Testing of finished product:
16.	0	Is there a documented empty package integrity testing program? (e.g., can, mylar bags, paper sacks, etc.)
17.*	0	Are procedures in place to prevent shipment/use of non-conforming raw materials or finished product?
18.	0	Are ingredients properly weighed out and pre-blended according to the formula or specification?
19.*	0	Are sensitive ingredients maintained at the correct temperature during staging?

20.	0	Is product handled in manner designed to preclude contamination?
21.	0	Are in-process thermometers, timers, etc. properly calibrated according to a defined schedule and are results documented?

D. Foreign Material Contamination Prevention (Complete 1. and/or 2., as appropriate)

1. Metal Detection

22.*	0	Is calibration performed with ferrous, non-ferrous, and stainless steel standards? Verification?
23.*	0	Is there adequate documentation of metal detector's operation?
24.*	0	Is there an automatic rejection system in place and is it functioning properly?
25.*	0	Is there a written action plan in place for when test or metal detector fails?

2. In-line Magnet Traps, In-line Screen, Line filters, Blower or Rock Traps

26.*	0	Are there an adequate number/location of magnets/screens/filters? Is the frequency of inspection of the magnets/screens/filters adequate? Are the results of every magnet/screen/filter inspection documented?
27.*	0	Does a written action plan exist for when integrity of magnets/screens/filters has been compromised?

3. Extraneous Physical Hazard Prevention Program

28.*	0	Are light bulbs protected?
29.*	0	Is there a glass container accounting system in place?
30.*	0	Are can cleaners (steam, air or water) located on each line for glass, tin or semirigid containers?
31.	0	Is facility free from peeling paint, rust, loose nuts and bolts?

E. Allergen Controls

32.	0	Are there procedures in place for management to identify all allergenic materials (eight major allergens are peanuts, tree nuts, eggs or egg products, milk or dairy products, crustaceans, fin fish, soy and wheat; chemical sensitivities are sulfites and/or food colorings) present in the facility? What are the allergens that have been identified?
33.	0	Are raw material supplies organized in such a way to prevent cross-contamination of products? Are these procedures applied to product being processed and to stored finished product? (Physical segregation/labeling)
34.	0	Are production schedules planned to eliminate possible cross-contamination?
35.	0	Do sanitation procedures address the issue of possible cross-contamination between products? Is allergen cleaning verified? (All allergens cleaned from processing surfaces, etc.)
36.	0	Is allergen control a part of the company's training program with all employees (including new employees and on an annual basis)?
37.	0	Is the presence of an allergen clearly stated on finished product labels in terms understandable by the consumer? Does the firm include warning statements (for example, "May contain peanuts" or "Produced in a facility where peanuts are processed") on product labels when appropriate?
38.	0	Does the company's internal audit system include a review of their allergen control procedures?

Process Control: Canned Fruits and Vegetables — Addendum Sheet

A1.	0	Are processing schedules for thermal processed products on file and available for review?
A2.	0	Are processing parameters posted on cooker panel or in cook room?
A3.*	0	Does the process schedule include (as appropriate): Container dimensions Minimum product initial temperature (IT) Minimum process time and temperature Critical factors (fill weight, maximum pH, etc.) Minimum F-value delivered by the process
A4.	0	Are the critical factors measured and documented during processing?
A5.	0	Are retort records complete and accurate (retort operation/continuous cooker checklist, temperature record chart)?
A6.	0	Is the product cooled in accordance with specifications before packaging?
A7.*	0	If process deviations occur: Is the deviation satisfactorily addressed? Did the proper documentation take place? Is there a process deviation logbook for the last three years, previous to the current year?
A8.*	0	Is double seam tear down performed in accordance with Good Manufacturing Practices (at least every four hours)? Were results documented? Were the can manufacturer's guidelines met?

		Are visual double seam exams completed within current guidelines (1-container/closing machine/closing head/30 minutes)? Were results documented? Does the company recycle water? Are water chlorinating records accurate and complete? How often is the water checked for sanitizer levels?
A9.	0	Does each retort have at least one calibrated mercury-in-glass (MIG) thermometer, one temperature control device, and one temperature recording device? Are the MIG thermometers calibrated annually against a certified thermometer?
A10.	0	Are low acid or acidified products produced? If so, does the supervisor for each shift of operation hold a Better Process Control certification? Does a certified person sign the process records within a 24-hour time frame?
A11.	0	Are low acid products produced? If so, are process records routinely reviewed by any authority (i.e. State or FDA)? Date of last regulatory visit:
A12.	0	Do "hot fill and hold" products meet time and temperature parameters?

Process Control: Frozen Fruits and Vegetables **Addendum Sheet**

A1.*	0	If heat blanching is used, is the product held at the required temperature for an adequate time?
A2.	0	Is there a documented procedure in place for the periodic cleaning of the blancher?
A3.*	0	Do microbiological results show micro levels in control?
A4.*	0	Are the free chlorine levels in the cooling water in control?
A5.*	0	Do non-blanched products go through a sanitizing step?
A6.*	0	Is the finished product maintained at a suitable temperature?

Process Control: Dairy Products **Addendum Sheet**

A1.*	0	Are raw product storage temperatures adequate? Are temperatures recorded?
A2.	0	Are products pasteurized or heat treated and stored as per appropriate Standards of Identity?
A3.	0	Are pasteurization units properly timed and sealed? Documentation of State reports available?
A4.	0	Are pasteurization charts properly identified and marked?
A5.	0	Are finished product temperatures adequate? Are temperatures recorded?
A6.	0	Are raw and finished product processed properly segregated?
A7.	0	Are product streams properly protected?

A8.	0	Do any cross connections exist?

		Process Control: Grain Milling — Addendum Sheet
A1.*	0	Incoming grain inspected for aflatoxin, quality, and infestation?
A2.*	0	Granulation routinely tested to ensure proper milling?
A3.*	0	Proper handling and disposal of grain spills and leaks?
A4.	0	Plant operations conducted in manner designed to minimize potential for explosions, fires, or excessive dust accumulation?
A5.	0	Vitamin and mineral premix added according to specification?
A6.*	0	Process design precludes cross contamination of product streams (especially those designated as animal feed and human consumption).

		Process Control: Dried Fruits & Vegetables — Addendum Sheet
A1.*	0	Is the sulfuring or other preserving process with good commerical practice?
A2.*	0	Do microbiological results show micro levels in control?
A3.*	0	Are the moisture levels or water activity levels evaluated and recorded?
A4.*	0	Do the products go through a sanitizing step?
A5.*	0	Does the process address storage temperature of the finished product? Is it being followed?

		Minimally Processed Fresh Fruits & Vegetables — Addendum Sheet
A1.*	0	Are suppliers required to provide a written guarantee, or other documentation, stating that they have addressed good agricultural practices, such as: a. General condition and history of use of supplier's fields (and fields/areas adjacent to the supplier's fields) appropriate for present use; b. Type of water used for irrigation/pesticide application is appropriate; c. If manure is used as fertilizer, that it has been properly composted and applied; d. Sanitary facilities in field (toilets, handwashing facility), working conditions, and harvesting equipment promote proper handling of produce; e. Handling practices that minimize drift from adjacent fields, manure piles, or storage areas, and that prevent contamination from uncontrolled animal feces. Does the company visit any of the suppliers' fields to verify good agricultural practices?
A2.*	0	Are suppliers required to provide a written guarantee, or other documentation, stating that pesticide application and type of pesticide used is in accordance with all County, State, and Federal Laws and Regulations?
A3.*	0	If the water used in the facility is recirculated or reused, does the water flow counter to the movement of the produce through the facility? Is chlorine, or another antimicrobial agent, added to the wash water?
A4.*	0	During hydro-cooling, do procedures prevent microbial cross contamination between containers due to dripping water/coolant?

A5.*	0	Are bins/containers reused? If so, are there provisions in place to ensure that the food contact surfaces are maintained in clean and sanitary condition?
A6.*	0	Are all animals/birds excluded from the packing, storage, and processing facility?
A7.*	0	Are the storage conditions adequate to maintain product quality and product safety?
A8.*	0	Are the transportation vehicles cleaned and sanitized prior to loading? Are they free from moisture and materials that could contaminate product?
A9.*	0	Does the company have a HACCP/food safety plan in place for this facility? If so, how many critical control points does the plan have?

Attachment 2

II. Quality Management Systems

A. Documentation/Control of Records

39.	0	Are quality systems records kept for required amount of time (minimum of three years)?
40.	0	Are procedures implemented to handle review of records?
41.	0	Are records legible, readily retrievable and protected from deterioration?
42.	0	Do company forms include revision date and form number?

B. Quality Assurance/Control Department

43.*	0	Is the Quality Assurance Department adequately staffed to perform product evaluations?
44.	0	Are finished product inspections performed and documented to ensure that the product conforms to specifications?
45.*	0	Are in-process quality checks performed throughout production?
46.	0	Are laboratory facilities sufficient to perform necessary analysis?
47.*	0	Are all records of product evaluations and analysis complete?
48.	0	Are product evaluation records kept throughout the shelf life of the product plus two years? (or three years, whichever is greater)
49.	0	Are reagents labeled and stored according to manufacturer's requirements and recommendations?
50.	0	Is there complete documentation of calibration on equipment? (schedule, procedures and results?)
51.	0	Is calibration certification of scales performed by a licensed agency? (minimum of annually)

Attachment 2

III. Personnel

52.*	0	Do employees wear clean outer garments, gloves, and aprons that are readily washable as appropriate?
53.*	0	Do employees wear effective hair and beard restraints?
54.*	0	Are employees free from loose jewelry?
55.*	0	Are employees working in direct contact with food free from infected lesions or skin diseases? Do employees inform management if they are sick or have been infected with a food borne illness?
56.*	0	Do employees wash and sanitize hands when entering the processing area? (as applicable)
57.*	0	Do employees remove protective outer garments prior to leaving the processing area where necessary? (e.g., aprons, lab coats, gloves, etc.)
58.*	0	Are personal item storage and food consumption in a separate area away from production?
59.1/	0	Is there regularly scheduled training for new and continuing employees in the following areas? 0 Hygiene Sanitation: 0 Good Manufacturing Practices: 0 Food Safety: 0 Employee Safety: 0 Job/Task Performance: 0 Company Quality Policy and Practices:
60.	0	Are records kept of all training?
61.	0	Are signs posted indicating hazardous areas and where protective gear is required?
62.	0	Is there a Lock out/Tag out program for equipment (including training, instruction, and program implementation)?
63.	0	Is appropriate safety equipment worn by employees (as designated by the company)?
64.	0	Are material safety data sheets (MSDS) readily available and properly maintained?

Attachment 2

IV. Good Manufacturing Practices

A. Facilities, Equipment and Outside Premises

65.	0	Are the outside premises properly surfaced to prevent dust and offensive odors and to promote drainage?
66.	0	Are the outside areas maintained in a manner which will prevent rodent and insect harborage?
67.	0	Are floors, doors, ceilings, walls and overheads in good repair and designed to facilitate proper sanitation and maintenance?
68.	0	Are there back flow prevention devices installed on all water and steam lines?
69.1/	0	Condition (Including proper temperatures) of: 0 Ingredient and raw material storage: 0 Cooler/Freezer: 0 Preparation areas: 0 Processing area: 0 Filling area: 0 Finished Product Storage:
70.	0	Is there a locked storage area for chemicals, cleaning compounds and similar materials separate from product ingredients and container storage? Are chemicals clearly and properly labeled?
71.	0	Is there sufficient lighting to permit efficient operations and cleaning?
72.	0	Are buildings reasonably free from excessive dust, heat, steam, condensation, vapors, smoke or fumes?
73.*	0	Are product contact surfaces of equipment, containers and utensils made of nonabsorbent corrosion resistant material?
74.	0	Is product contact equipment cleanable and in good repair?
75.*	0	Are containers and utensils used in handling the product cleaned, stored and utilized in such a manner as to preclude an unsanitary condition?
76.*	0	Are motors, conveyor belts and drive mechanisms located and protected so that oil or grease will not contaminate the product?
77.*	0	Are catwalks and stiles constructed and located to prevent product contamination?
78.	0	Is equipment constructed and located so that product contact surfaces are accessible for cleaning, maintenance and inspection?
79.*	0	Are production and preparation areas enclosed?
80.*	0	Are doors, windows and other gateways properly protected with screens, air screens or other protective devices?
81.	0	Is there a documented maintenance schedule for equipment and facilities?

B. Plant Sanitation

82.*	0	Is there a formal documented sanitation program?
83.	0	Name and Title of authorized personnel responsible for sanitation and pre-inspections:
84.	0	Is all major equipment disassembled for cleaning or can be cleaned-in-place (CIP)?
85.	0	Are all areas maintained in a clean orderly manner?
86.	0	Does the documented sanitation program include a master cleaning schedule for all production areas, equipment and facilities? Is it available and implemented?
87.*	0	Is sanitation of equipment maintained throughout the day to prevent product contamination?
88.	0	Are routine pre-operation sanitation inspections conducted and documented? Are follow-up procedures documented?
89.1/	0	Rest room facilities: 0 Are they clean, dry and of good general appearance? 0 Do they open directly into production area? 0 Do they have hot and cold water? 0 Do they have sanitizing or antimicrobial soap? 0 Do they have signs posted indicating the importance of hand washing (multilingual if appropriate)? 0 Do they have independent outside ventilation? 0 Do they have clean and accessible waste receptacles? 0 Are the restrooms equipped with self-closing doors? 0 Are they well lighted?
90.	0	Is the capacity of the waste storage sufficient?
91.	0	Is there timely removal of waste?
92.	0	Is idle equipment stored in an orderly fashion?
93.1/	0	Do the hand wash and/or hand dip stations have: 0 Posted signs (bilingual/multilingual)? 0 Sanitizing or antimicrobial soap (Type)? 0 Waste receptacles? 0 Cold and hot water? 0 Controls other than hand operated? 0 Appropriate locations? 0 Acceptable conditions?

GMP Violations: List all violations not previously identified in the report and deduct 5 points for each:

V. Pest Control

94.*	0	Is facility free from pest infestation? (insect, bird, rodent, etc.)?
95.	0	Is pest control station map properly maintained and available?
96.	0	Are pest control devices properly installed and monitored?
97.*	0	Is routine maintenance and inspection of pest control devices documented?
98.	0	Are the number and placement of pest control/deterrent devices adequate to prevent infestation?
99.	0	Are pest control records maintained for at least three years?
100.	0	Are all pest control chemicals properly identified and separated from potentially hazardous cross-contamination?
101.	0	Is the application of restricted use pesticides conducted or supervised by a licensed pest control operator?

Attachment 2

VI. Packaging/Labeling/Warehousing

102.*	0	Are packaging materials clean and stored in dry, clean location?
103.	0	Are visual examinations of packaging completed and documented after closure? (This includes sealing, labeling and coding)
104.	0	Are the packages coded and labeled correctly and legibly? (e.g., does what is in package match the label?)
105.1/	0	Package fill/net weights: 0 Have guidelines been established and is a procedure in place to verify compliance? 0 Are corrective actions taken as needed documented?
106.	0	Are miscoded or mislabeled packages documented and discarded or corrected as appropriate?
107.*	0	Are empty containers protected from contamination?
108.	0	Are there sufficient facilities for handling raw materials and appropriate rotation of materials (first-in, first-out)?
109.*	0	Does raw material storage and handling practices preclude contamination by environmental hazards such as rodents, birds and insects?
110.*	0	Are there temperature-recording devices or a high temperature alarm located in the refrigeration or freezer facilities?
111.	0	Is there a shelf-life sample retention program in place?
112.*	0	Is there appropriate rotation of finished products (first-in, first-out)?
113.	0	Is finished product stored in designated area and separated from raw ingredients?
114.*	0	Is trailer/railcar cleaning and inspection performed and documented prior to loading?

Attachment 2

VII. Recall/Return Program

115	0	Is retained product identified and stored in a clearly designated area?
116.*	0	Is a log of Hold product maintained? Are records kept documenting the disposition of Hold product?
117.	0	Is there a person authorized to release product? (Name/Title)
118.*	0	Is there a recall procedure written and tested according to a defined schedule not less than annually?
119.	0	Are returned goods received in a clearly designated area?
120.*	0	Are raw ingredients traceable throughout the process?
121.	0	Is reworked product documented and traceable?
122.*	0	Is there product tracking capability to the customer?
123.	0	Does product tracking system include container code?
124.	0	Is there a system in place and documented to handle customer complaints?

Attachment 2

VIII. Food Defense

FDA Food Facility Registration Number Verified: **Yes** **Verified Number**

(When a PSA is conducted in lieu of a Plant Survey for USDA Contracts, and if any points are deducted in this section, corrective action is required, and the deficiency shall be listed in Section IX.)

125.*	0	Management - A Food Defense Plan is established, implemented, and reassessed by management to assure it remains relevant to the operation. No
126.*	0	Management - The Food Defense Plan addresses preventative measures relative to product tampering and deliberate contamination at the processing facility and during transport in commerce.
127.	0	Management - Written security practices list management contacts and procedures for notifying appropriate authorities in the case of an emergency or security issue.
128.*	0	Human Element - Staff - Company personnel hiring practices include screening all potential employees. Photo identification or other measures are employed to restrict access to the facility.
129.*	0	Human Element - Staff - Facility employees have received training in Food Defense. The Food Defense training is documented.
130.*	0	Human Element - Public - Supplier delivery personnel, contract workers, and visitors are restricted access to vulnerable product areas of the processing and storage facility when not accompanied by a company representative.
131.*	0	Facility - The outside premises are secure with limited access to vulnerable areas. The grounds and facility are monitored for suspicious activity and unauthorized entry. "No Trespassing" signs are visible along the perimeter of the faciltiy, or other measures are being taken to secure and limit access to vulnerable areas.
132.*	0	Operations - Assurances are provided by suppliers of direct or indirect ingredients, product and equipment cleaning and sanitizing compounds, and packaging materials concerning security practices. This may include the use of tamper evident packaging for raw materials, sealing of trailers, and locking of bulk ingredient receiving ports.
133.	0	Operations - The security of water and utilities within the company's control are addressed in the company's plan and define limited access by designated company representatives.

Attachment 2

IX. Contract Review: (Complete only if plant packs for Government Contracts)

No points assigned. Answer Yes or No with explanation		
134.		Are procedures documented and implemented to ensure contract terms can and will be met?
135.		Are defined procedures documented and implemented for handling amendments?
136.		Are records of contract reviews and amendments kept?
137.		Is this PSA conducted in lieu of the Plant Survey requirement for USDA Contracts? **No** If "YES", and if critical and major GMP deficiencies or Food Defense deficiencies are found, the following corrective action table must be completed. A follow up audit may be required to ensure corrective action has been completed.

GMP Violations and Food Defense Deficiencies that Require Corrective Action	Scheduled Completion Date	Date Corrected

Attachment 2

Question Scoring:

* = 10 point question
1/ = each part of the question is worth 5 points
All other questions are worth 5 points each

In addition to receiving an unacceptable rating for not meeting the minimum percentage required in each section, an unacceptable rating may be given for the following reasons, but not inclusive:
(1) procedures or practices that could render a product unsafe or unfit for human consumption,
(2) unsafe employee practices that could cause product contamination,
(3) evidence of product contaminated with foreign material or filth (paint, rust, glass, wood, metal, jewelry,
lubricants, chemicals, etc.),
(4) use of non-approved sanitizers or cleaning agents,
(5) improper use of pesticides,
(6) infestation by rodents, insects, or other pests in food product processing or storage areas,
(7) products stored at improper temperatures, or
(8) failure to implement a sanitation program.

An unacceptable rating may require corrective action and/or a follow-up audit.

	10 Point Questions	5 Point Questions
Satisfactory = no points deducted	0	0
Need Improvement = points deducted as follows	5	3
Unsatisfactory = all points are deducted	10	5

Attachment 3

Guidance and References

Plant Systems Audit Program

I. Food Safety **A. Internal Quality Audit**		
Question Number	*Evaluation Elements*	*Guidance*
1.	Are there procedures in place for management/supervisors to conduct internal reviews of Quality Systems?	**Reference: ISO 9001-2000, 8.2.2 Internal Audit** **Evaluation Method: Interview management; review documentation presented (procedures; record of reviews).** **Criteria: Evidence of implementation.**
2.	Are Internal audit findings documented and reported to upper management?	**Reference: ISO 9001-2000, 8.2.2 Internal Audit** **Evaluation Method: Interview management; review documentation (record of findings and review by upper management).** **Criteria: Documentation of deficiencies; evidence of report to management.**
3.	Are Corrective Action Reports followed up and documented to determine effectiveness?	**Reference: ISO 9001-2000, 8.2.2 Internal Audit** **Evaluation Method: Interview management; Review documentation (Corrective Action Report).** **Criteria: Evidence of documentation. There should be evidence of monitoring and verification to ensure the effectiveness of corrective actions.**

Attachment 3

I. Food Safety
B. Purchasing

Question Number	*Evaluation Elements*	*Guidance*
4.	Is there a system in place to evaluate and approve suppliers?	**Reference: ISO 9001-2000, 7.4 Purchasing** **Evaluation Method: Interview personnel responsible for purchasing decisions, and/or review of documented procedure and records.** **Criteria: Evidence of system for supplier evaluation.**
5.	Are suppliers evaluated for good agricultural practices? (i.e. Do they have process controls in place covering pesticide control, harvesting, and transportation practices?)	**Regulation: 21 CFR § 110.80 (a)** **Reference: ISO 9001-2000, 7.4.1 Purchasing process** **Evaluation Method: Interview personnel responsible for purchasing decisions, and/or review of documented procedure and records.** **Criteria: Evidence of system for evaluating suppliers for good agricultural practices. This may only be applicable to companies that receive raw, or minimally processed, commodities.**
6.	Are purchasing documentation/records, including Certificates of Conformance (COC) and Certificates of Analysis (COA), maintained, current, and applicable?	**Regulation: 21 CFR § 110.80 (a)** **Reference: ISO 9001-2000, 7.4.1 Purchasing process** **Evaluation Method: Review documentation associated with recent receipt of materials, looking for COCs, COAs, as appropriate.** **Criteria: Evidence of appropriate documentation/records in files.**
7.	Are receipt inspections performed and documented on incoming product (Product condition, accuracy of invoice, product identity, etc.)? Is there documentation of the disposition of rejected product?	**Regulation: 21 CFR § 110.80 (a)** **Reference: ISO 9001-2000, 7.4.3 Verification of purchased product** **Evaluation Method: Review documentation associated with recent receipt of materials. Interview personnel responsible for task(s).** **Criteria: Evidence of appropriate documentation and verification (interview).**

Attachment 3

I. Food Safety
B. Purchasing

Question Number	*Evaluation Elements*	*Guidance*
8.	Are acceptance criteria documented for incoming ingredients? Do these procedures include appropriate testing for quality, foreign material, pesticides, and bacterial contamination?	**Regulation: 21 CFR § 110.80 (a)** **Reference: ISO 9001-2000, 7.4.2 Purchasing information** **Evaluation Method: Review documentation associated with recent receipt of materials (testing results and acceptance criteria).** **Criteria: Evidence of appropriate documentation.**
9.	Is domestic origin compliance verified? (i.e., product can be traced to US origins) (where required by contract)	**Requirement: USDA Commodity Purchase Program contract specification for Product Origin (for USDA contracted facilities); other contracts, as presented by applicant** **Evaluation Method: Review document tracebacks to domestic origin or record of acceptable DOV audit; interview management.** **Criteria: Evidence of appropriate documentation, both in purchase documents and those provided with shipments, such as COC's, etc.**

I. Food Safety **C. Process Control (Includes Commodity Addendums)**		
Question Number	*Evaluation Elements*	*Guidance*
10.	Is there a system in place for the proper handling, segregation, and storage of raw materials?	**Requirement: 21 CFR § 110.80 (a) 1** **Evaluation Method: By interview and observation.** **Criteria: Evidence of implementation.**
11.	Are raw materials washed or cleaned as necessary to remove soil or other contamination?	**Requirement: 21 CFR § 110.80 (a) 1** **Evaluation Method: Observation.** **Criteria: Evidence of appropriate measures.**
12.	If water is part of the finished product, is there a drinking water quality analysis available? (Chemical analysis)?	**Requirement: 21 CFR § 110.80 (a) 1 & 21 CFR § 110.37 (a)** **Evaluation Method: Review documentation.** **Criteria: Evidence of appropriate documentation in files.**
13.	Is the processing/ingredient water potability certificate available? Date of certificate:	**Requirement: 21 CFR § 110.80 (a) 1 & 21 CFR § 110.37 (a)** **Evaluation Method: Review documentation.** **Criteria: Evidence of appropriate documentation in files. Record date of documentation. Confirm that certificate covers actual source in use at the plant.**
14.	Is forced air that is used on product or food contact surfaces free from contaminations?	**Requirement: 21 CFR § 110.40 (a)** **Evaluation Method: Observation.** **Criteria: Evidence of appropriate measures.**

Attachment 3

I. Food Safety **C. Process Control (Includes Commodity Addendums)**		
Question Number	*Evaluation Elements*	*Guidance*
15.	Microbiological testing includes: • Tests required by specification or contract: • Routine analysis of food contact surfaces: • Environmental testing program (floors, walls, ceilings, etc.): • Testing of finished product:	**Requirement: 21 CFR § 110.80** **Evaluation Method: By interview, observation, and document review.** **Criteria: Evidence of appropriate documentation in files.** • Tests required by specification or contract: (As appropriate) • Routine analysis of food contact surfaces: (Required for PSA) • Environmental testing program (floors, walls, ceilings, etc.): (Required for PSA) • Testing of finished product: (As appropriate for the product processed)
16.	Is there a documented empty package integrity testing program? (e.g., can, mylar bags, paper sacks, etc.)	**Requirement: 21 CFR § 110.80 (a) 1** **Evaluation Method: Review documentation.** **Criteria: Evidence of appropriate documentation in files.**
17.	Are procedures in place to prevent shipment/use of non-conforming raw materials or finished product?	**Reference: ISO 9001-2000, 8.3 Control of nonconforming product** **Evaluation Method: By interview, observation, and document review.** **Criteria: Evidence of appropriate measures. Expect to find procedures for handling non-conforming raw materials and/or finished product, and records of disposition of non-conforming raw materials and/or finished product.**
18.	**Are ingredients properly weighed out and pre-blended according to the formula or specification?**	**Reference: ISO 9001-2000, 7.5.1 Control of production and service provision** **Evaluation Method: By interview, observation, and document review. Observe actual formulations.** **Criteria: Evidence of appropriate measures. Expect to find documentation of formulas used and documentation of specifications.**

Attachment 3

I. Food Safety **C. Process Control (Includes Commodity Addendums)**		
Question Number	*Evaluation Elements*	*Guidance*
19.	Are sensitive ingredients maintained at the correct temperature during staging?	**Requirement: 21 CFR § 110.80** **Evaluation Method: By interview, observation, and document review (if appropriate).** **Criteria: Evidence of appropriate documentation in files.**
20.	Is product handled in manner designed to preclude contamination?	**Requirement: 21 CFR § 110.80** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
21.	Are in-process thermometers, timers, etc. properly calibrated according to a defined schedule and are results documented?	**Requirement: 21 CFR § 110.40** **Evaluation Method: Observation and record review.** **Criteria: Evidence of conformance.**

I. Food Safety
D. Foreign Material Contamination

Question Number	*Evaluation Elements*	*Guidance*
22.	Is calibration performed with ferrous, non-ferrous, and stainless steel standards? Verification?	**Requirement: 21 CFR § 110.80 (b) 8** **Evaluation Method: Review documentation and make observations.** **Criteria: Evidence of appropriate documentation in files. Evidence of effective equipment. Do they have standards available?**
23.	Is there adequate documentation of metal detector's operation?	**Reference: ISO 9001-2000, 4.2.4 Control of Records; 7.5.2 Validation of processes for production and service provision** **Evaluation Method: Review documentation.** **Criteria: Records of metal detector's operation**
24.	Is the automatic rejection system functioning properly?	**Requirement: 21 CFR § 110.80 (b) 8** **Evaluation Method: Review documentation and make observations.** **Criteria: Evidence of effective equipment. Evidence that the system is checked periodically, e.g., with "planted" metal, etc. Test during audit.**
25.	Is there a written action plan in place for when test or metal detector fails?	**Reference: ISO 9001-2000, 7.5.1 Control of production and service provision** **Evaluation Method: Review documented procedure for action when the metal detector fails – ask for record of steps taken after latest metal detector failure.** **Criteria: Documentation of appropriate action, back to the last confirmation of system integrity.**
26.	Is there an adequate number/location of magnets/screens/filters? Is the frequency of inspection of the magnets/screens/filters adequate? Are the results of every magnet/screen/filter inspection documented?	**Requirement: 21 CFR § 110.80 (b) 8** **Evaluation Method: Review documentation and make observations.** **Criteria: Evidence of appropriate documentation in files. Evidence of effective equipment.**

Attachment 3

I. Food Safety **D. Foreign Material Contamination**		
Question Number	*Evaluation Elements*	*Guidance*
27.	Does a written action plan exist for when integrity of magnets/screens/filters has been compromised?	**Reference: ISO 9001-2000, 7.5.1 Control of production and service provision** **Evaluation Method: Review documented procedure for action when integrity fails – ask for record of steps taken after latest failure of integrity** **Criteria: Documentation of appropriate action, back to last confirmation of system integrity.**
28.	Are light bulbs protected?	**Requirement: 21 CFR § 110.35** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
29.	Is there a glass container accounting system in place?	**Requirement: 21 CFR § 110.35** **Evaluation Method: Review documentation and make observations.** **Criteria: Evidence of conformance. Evidence of appropriate documentation in files.**
30.	Are can cleaners (steam, air or water) located on each line for glass, tin or semi rigid containers?	**Requirement: 21 CFR § 110.80 (b) (1)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
31.	Is facility free from peeling paint, rust, loose nuts and bolts?	**Requirement: 21 CFR § 110.20** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**

Attachment 3

I. Food Safety
E. Allergen Controls

Question Number	*Evaluation Elements*	*Guidance*
32.	Are there procedures in place for management to identify all allergenic materials (eight major allergens are peanuts, tree nuts, eggs or egg products, milk or dairy products, crustaceans, fin fish, soy and wheat; chemical sensitivities are sulfites and/or food colorings) present in the facility? What are the allergens that have been identified?	**Requirement: Food Allergen Labeling and Consumer Protection Act of 2004** **Evaluation Method: By interview, observation, and document/label review.** **Criteria: Consistent information provided during evaluation, matching your understanding of their product, the ingredients used, and the product labeling.**
33.	Are raw material supplies organized in such a way to prevent cross-contamination of products? Are these procedures applied to product being processed and to stored finished product? (Physical segregation/labeling)	**Requirement: Food Allergen Labeling and Consumer Protection Act of 2004; 21 CFR § 110.80 (a) 1** **Reference: FDA Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients** **Evaluation Method: By interview, observation, and document/label review. Pay special attention to raw material handling, handling during processing, and stored product handling.** **Criteria: Consistent information provided during evaluation, matching your understanding of their product, the ingredients used, and the product labeling.**
34.	Are production schedules planned to eliminate possible cross-contamination?	**Reference: FDA Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients** **Evaluation Method: By interview, observation, and document review. Pay special attention to records of production sequences for handling products identified as allergens.** **Criteria: Consistent information provided during evaluation, matching your understanding of their product, the ingredients used, and the product labeling.**

I. Food Safety
E. Allergen Controls

Question Number	*Evaluation Elements*	*Guidance*
35.	Do sanitation procedures address the issue of possible cross-contamination between products? (All allergens cleaned from processing surfaces, etc.)	**Reference: FDA Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients** **Evaluation Method: By interview, observation, and document review. Are there any special steps taken to address this issue? Any special testing of equipment after sanitation, to verify complete removal of allergens?** **Criteria: Consistent information provided during evaluation, matching your understanding of their product, the ingredients used, and the product labeling.**
36.	Is allergen control a part of the company's training program with all employees including new employees and on an annual basis)?	**Reference: FDA Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients** **Evaluation Method: Interviews and review of training documentation.** **Criteria: Records of annual training provided to all employees for products and processes identified as allergens. The minimum requirement should be the training of those employees working with the identified allergenic products/associated processing lines.**
37.	Is the presence of an allergen clearly stated on finished product labels in terms understandable by the consumer? Does the firm include warning statements (for example, "May contain peanuts" or "Produced in a facility where peanuts are processed") on product labels when appropriate?	**Requirement: Food Allergen Labeling and Consumer Protection Act of 2004** **Reference: FDA Notice to Manufacturers June 10, 1996 - Label Declaration of Allergenic Substances in Foods** **Evaluation Method: By interview, observation, and document/label review.** **Criteria: Review labels of products, looking to see commonly understood terms (Milk, Soy, etc) used to state presence of allergenic ingredients. Do not assume that the "May contain" statement is needed. This should be decided by the company and reflected in their label.**

Attachment 3

I. Food Safety **E. Allergen Controls**		
Question Number	*Evaluation Elements*	*Guidance*
38.	Does the company's internal audit system include a review of their allergen control procedures?	**Reference: ISO 9001-2000, 8.2.2 Internal Audit** **Evaluation Method: Interview management; review documentation presented (procedures; record of reviews).** **Criteria: Evidence of implementation. Allergen control procedures should be part of the company's internal review program.**

Attachment 3

II. Quality Management Systems **A. Documentation/Control of Records and** **B. Quality Assurance/Control Department**		
Question Number	*Evaluation Elements*	*Guidance*
39.	Are quality systems records kept for required amount of time (minimum of three years)?	**Requirement: 21 CFR § 113.100 (low-acid canned); 114:100 (acidified foods)** **Reference: ISO 9001-2000, 4.2.4 Control of records** **Evaluation Method: Review records; interview staff/management.** **Criteria: Evidence of records, at least 3 years old.**
40.	Are procedures implemented to handle review of records?	**Requirement: Company's stated/documented procedure for review (general); 21 CFR § 113.100 (low-acid canned processing records)** **Evaluation Method: Review records; interview staff/management.** **Criteria: Evidence that a review of records was performed.**
41.	Are records legible, readily retrievable and protected from deterioration?	**Reference: ISO 9001-2000, 4.2.4 Control of records** **Evaluation Method: Observation – note as you review records throughout the audit.** **Criteria: Records that should be available, are produced with minimal effort or time required, and that they are legible and in good condition.**
42.	Do company forms include revision date and form number?	**Reference: ISO 9001-2000, 4.2.4 Control of records** **Evaluation Method: Observation – note as you review records throughout the audit.** **Criteria: Forms used by the processor must contain identification numbers and dates of revision. Forms with specific titles (instead of form number) are acceptable.**

II. Quality Management Systems **A. Documentation/Control of Records and** **B. Quality Assurance/Control Department**		
Question Number	*Evaluation Elements*	*Guidance*
43.	Is the Quality Assurance Department adequately staffed to perform product evaluations?	**Reference: ISO 9001-2000, 6.2 Human Resources** **Evaluation Method: Observation and interview of management/staff; review of inspection documentation.** **Criteria: Noting the type of quality assurance program used by the processor, USDA, QAP Program, etc. – evidence of adequate staffing (documentation neat, orderly, readily retrievable; inspection conducted as planned).**
44.	Are finished product inspections performed and documented to ensure that the product conforms to specifications?	**Reference: ISO 9001-2000, Planning of product realization** **Evaluation Method: Observation and interview of management/staff; review of inspection documentation.** **Criteria: Evidence of records of finished product inspections, consistent with stated specification requirements.**
45.	Are in-process quality checks performed throughout production?	**Reference: ISO 9001-2000, Planning of product realization** **Evaluation Method: Observation and interview of management/staff; review of inspection documentation.** **Criteria: Evidence of records of in-process product inspections, consistent with stated specification requirements.**
46.	Are laboratory facilities sufficient to perform necessary analysis?	**Reference: Reference: ISO 9001-2000, 6.3 Infrastructure** **Evaluation Method: Observation and interview of management/staff; review of inspection activities (neat, orderly, inspections conducted as planned).** **Criteria: Evidence of adequate facilities.**

II. Quality Management Systems
A. Documentation/Control of Records and
B. Quality Assurance/Control Department

Question Number	*Evaluation Elements*	*Guidance*
47.	Are all records of product evaluations and analysis complete?	**Reference: ISO 9001-2000, 4.2.4 Control of records** **Evaluation Method: Observation of documentation – note as you review records.** **Criteria: Records of product evaluations and of analyses, compared to specification requirements, are present.**
48.	Are product evaluation records kept throughout the shelf life of the product plus two years? (or three years, whichever is greater)	**Requirement: 21 CFR § 114.100** **Reference: ISO 9001-2000, 4.2.4 Control of records** **Evaluation Method: Review records; interview staff/management.** **Criteria: Evidence of records, at least 3 years old.**
49.	Are reagents labeled and stored according to manufacturer's requirements and recommendations?	**Requirement: 21 CFR § 110.35** **Evaluation Method: Observe reagent storage throughout the facility (mostly in the lab and in areas where in-process evaluations occur).** **Criteria: Stored in accordance with MSDS and CFR; appropriately labeled.**
50.	Is there complete documentation of calibration on equipment? (Schedule, procedures and results?)	**Requirement: 21 CFR § 110.40 (f); Company's stated/documented calibration procedures** **Reference: ISO 9001-2000, 7.6 Control of monitoring and measuring devices** **Evaluation Method: Review records; interview staff/management.** **Criteria: Evidence of records that are consistent with stated procedure/schedule and that match with equipment.**
51.	Is calibration certification of scales performed by a licensed agency? (minimum of annually)	**Evaluation Method: Review documentation and look for stamp/sticker placed on scales by licensed agency.** **Criteria: Evidence of certification by licensed agency.**

III. Personnel		
Question Number	*Evaluation Elements*	*Guidance*
52.	Do employees wear clean outer garments, gloves, and aprons that are readily washable as appropriate?	**Requirement: 21 CFR § 110.10 (b) 1** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
53.	Do employees wear effective hair and beard restraints?	**Requirement: 21 CFR § 110.10 (b) 6** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
54.	Are employees free from loose jewelry?	**Requirement: 21 CFR § 110.10 (b) 4** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
55.	Are employees working in direct contact with food free from infected lesions or skin diseases? Do employees inform management if they are sick or have been infected with a food borne illness?	**Requirement: 21 CFR § 110.10 (a)** **Evaluation Method: Observation and interview.** **Criteria: Evidence of conformance.**
56.	Do employees wash and sanitize hands when entering the processing area? (as applicable)	**Requirement: 21 CFR § 110.10 (b) 3** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
57.	Do employees remove protective outer garments prior to leaving the processing area where necessary? (e.g., aprons, lab coats, gloves, etc.)	**Requirement: 21 CFR § 110.10 (b) 1** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
58.	Are personal item storage and food consumption in a separate area away from production?	**Requirement: 21 CFR § 110.10 (b) 8** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**

III. Personnel		
Question Number	*Evaluation Elements*	*Guidance*
59.	Is there regularly scheduled training for new and continuing employees in the following areas? 0 Hygiene Sanitation: 0 Good Manufacturing Practices: 0 Food Safety: 0 Employee Safety: 0 Job/Task Performance: 0 Company Quality Policy and Practices:	**Requirement: 21 CFR § 110.10 (c)** **Evaluation Method: Interview and document review.** **Criteria: Evidence of appropriate documentation in files.**
60.	Are records kept of all training?	**Reference: ISO 9001-2000, 6.2.2 Competence, awareness and training** **Evaluation Method: Review records.** **Criteria: Evidence of records of training for new employees, and records of regular scheduled training for continuing employees, in each of the areas identified.**
61.	Are signs posted indicating hazardous areas and where protective gear is required?	**Requirement: 29 CFR Part 1910** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
62.	Is there a Lock out/Tag out program for equipment (including training, instruction, and program implementation)?	**Requirement: 29 CFR Part 1910** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
63.	Is appropriate safety equipment worn by employees (as designated by the company)?	**Requirement: 29 CFR Part 1910** **Evaluation Method: Observation. Interview company for additional requirements.** **Criteria: Evidence of conformance.**
64.	Are material safety data sheets (MSDS) readily available and properly maintained?	**Requirement: 29 CFR Part 1910.1200** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**

IV. Good Manufacturing Practices
A. Facilities, Equipment, and Outside Premises

Question Number	*Evaluation Elements*	*Guidance*
65.	Are the outside premises properly surfaced to prevent dust and offensive odors and to promote drainage?	**Requirement: 21 CFR § 110.20 (a) 2 & 3** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
66.	Are the outside areas maintained in a manner which will prevent rodent and insect harborage?	**Requirement: 21 CFR § 110.20 (a) 1** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
67.	Are floors, doors, ceilings, walls and overheads in good repair and designed to facilitate proper sanitation and maintenance?	**Requirement: 21 CFR § 110.20 (b) 4** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
68.	Are there back flow prevention devices installed on all water and steam lines?	**Requirement: 21 CFR § 110.40 (5)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
69.	Condition (Including proper temperatures) of: 0 Ingredient and raw material storage: 0 Cooler/Freezer: 0 Preparation areas: 0 Processing area: 0 Filling area: 0 Finished Product Storage:	**Requirement: 21 CFR § 110.80 (a)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
70.	Is there a locked storage area for chemicals, cleaning compounds and similar materials separate from product ingredients and container storage? Are chemicals clearly and properly labeled?	**Requirement: 21 CFR § 110.35 (2)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
71.	Is there sufficient lighting to permit efficient operations and cleaning?	**Requirement: 21 CFR § 110.20 (b) 5** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**

IV. Good Manufacturing Practices
A. Facilities, Equipment, and Outside Premises

Question Number	*Evaluation Elements*	*Guidance*
72.	Are buildings reasonably free from excessive dust, heat, steam, condensation, vapors, smoke or fumes?	**Requirement: 21 CFR § 110.20 (b) 4 & 6** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
73.	Are product contact surfaces of equipment, containers and utensils made of nonabsorbent corrosion resistant material?	**Requirement: 21 CFR § 110.40 (a)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
74.	Is product contact equipment cleanable and in good repair?	**Requirement: 21 CFR § 110.35 (d)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
75.	Are containers and utensils used in handling the product cleaned, stored and utilized in such a manner as to preclude an unsanitary condition?	**Requirement: 21 CFR § 110.35 (e)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
76.	Are motors, conveyor belts and drive mechanisms located and protected so that oil or grease will not contaminate the product?	**Requirement: 21 CFR § 110.40 (a)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
77.	Are catwalks and stiles constructed and located to prevent product contamination?	**Requirement: 21 CFR § 110.20** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
78.	Is equipment constructed and located so that product contact surfaces are accessible for cleaning, maintenance and inspection?	**Requirement: 21 CFR § 110.40 (a)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
79.	Are production and preparation areas enclosed?	**Requirement: 21 CFR § 110.20 (b)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**

IV. Good Manufacturing Practices
A. Facilities, Equipment, and Outside Premises

Question Number	*Evaluation Elements*	*Guidance*
80.	Are doors, windows and other gateways properly protected with screens, air screens or other protective devices?	**Requirement: 21 CFR § 110.20 (b) 7** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
81.	Is there a documented maintenance schedule for equipment and facilities?	**Requirement: 21 CFR § 110.35** **Evaluation Method: Interview and document review.** **Criteria: Evidence of appropriate documentation in files.**
82.	Is there a formal documented sanitation program?	**Requirement: 21 CFR § 110.35** **Evaluation Method: Interview and document review.** **Criteria: Evidence of appropriate documentation in files.**
83.	Name and Title of authorized personnel responsible for sanitation and pre-inspections:	**Evaluation Method: Obtain name and title from management.** **Criteria: Responsibility for sanitation and pre-inspections assigned to a specific employee(s).**
84.	Is all major equipment disassembled for cleaning or can be cleaned-in-place (CIP)?	**Requirement: 21 CFR § 110.35 (d)** **Evaluation Method: Observation and interviews of management.** **Criteria: Evidence of conformance.**
85.	Are all areas maintained in a clean orderly manner?	**Requirement: 21 CFR § 110.35 (a)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
86.	Does the documented sanitation program include a master cleaning schedule for all production areas, equipment and facilities? Is it available and implemented?	**Requirement: 21 CFR § 110.35** **Evaluation Method: Observation and document review.** **Criteria: Evidence of appropriate documentation in files and evidence of conformance.**

IV. Good Manufacturing Practices **A. Facilities, Equipment, and Outside Premises**		
Question Number	*Evaluation Elements*	***Guidance***
87.	Is sanitation of equipment maintained throughout the day to prevent product contamination?	**Requirement: 21 CFR § 110.35** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
88.	Are routine pre-operation sanitation inspections conducted and documented? Are follow-up procedures documented?	**Requirement: 21 CFR § 110.35** **Evaluation Method: Interview and document review.** **Criteria: Evidence of appropriate documentation in files.**
89.	Rest room facilities: 0 Are they clean, dry and of good general appearance? 0 Do they open directly into production area? 0 Do they have hot and cold water? 0 Do they have sanitizing or antimicrobial soap? 0 Do they have signs posted indicating the importance of Hand washing (multilingual if appropriate)? 0 Do they have independent outside ventilation? 0 Do they have clean and accessible waste receptacles? 0 Are the restrooms equipped with self-closing doors? 0 Are they well lighted?	**Requirement: 21 CFR § 110.37** **Evaluation Method: Observation.** **Criteria:** **Restrooms are separated from processing areas by walls, halls, or airlock vestibules.** **Note name of sanitizer and/or soap used.** **Water temperature should not discourage use.** **Observe signs posted in restrooms.** **Bi-lingual signs are necessary for facilities that have multi-cultural employment base.** **Restrooms are required to be ventilated to the exterior of the building as required by Food and Drug Administration (FDA) regulations.**
90.	Is the capacity of the waste storage sufficient?	**Requirement: 21 CFR § 110.37 (f)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
91.	Is there timely removal of waste?	**Requirement: 21 CFR § 110.37 (f)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**

IV. Good Manufacturing Practices A. Facilities, Equipment, and Outside Premises		
Question Number	*Evaluation Elements*	*Guidance*
92.	Is idle equipment stored in an orderly fashion?	**Requirement: 21 CFR § 110.35 (e)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
93.	Do the hand wash and/or hand dip stations have: 0 Posted signs (bilingual/multilingual)? 0 Sanitizing or antimicrobial soap (Type)? 0 Waste receptacles? 0 Cold and hot water? 0 Appropriate locations? 0 Acceptable conditions?	**Requirement: 21 CFR § 110.37** **Evaluation Method: Observation.** **Criteria:** **Observe signs posted.** **Bi-lingual signs are necessary for facilities that have multi-cultural employment base.** **Note name of sanitizer and or soap used.** **Located near processing operations.**

IV. Good Manufacturing Practices GMP Violations		
Question Number	*Evaluation Elements*	*Guidance*
	GMP Violations: List all violations not previously identified in the report and deduct 5 points for each.	**Requirement: 21 CFR Part 110** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**

V. Pest Control

Question Number	*Evaluation Elements*	*Guidance*
94.	Is facility free from pest infestation? (Insect, bird, rodent, etc.)?	**Requirement: 21 CFR § 110.35 (c)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
95.	Is pest control station map properly maintained and available?	**Evaluation Method: Observation and document review.** **Criteria: Evidence of conformance - schematics of traps; bait boxes are maintained and accurate.**
96.	Are pest control devices properly installed and monitored?	**Requirement: 21 CFR § 110.35 (c)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
97.	Is routine maintenance and inspection of pest control devices documented?	**Evaluation Method: Observation and document review.** **Criteria: Evidence of conformance - records of maintenance by pest control company; trap observations and examinations are documented; note the frequency of review and maintenance activities.**
98.	Are the number and placement of pest control/deterrent devices adequate to prevent infestation?	**Requirement: 21 CFR § 110.35 (c)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
99.	Are pest control records maintained for at least three years?	**Evaluation Method: Observation and document review.** **Criteria: Evidence of conformance - records of pest control for 3 years.**
100.	Are all pest control chemicals properly identified and separated from potentially hazardous cross-contamination?	**Requirement: 21 CFR § 110.35 (b) 2** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**

V. Pest Control		
Question Number	*Evaluation Elements*	*Guidance*
101.	Is the application of restricted use pesticides conducted or supervised by a licensed pest control operator?	**Requirement: 21 CFR § 110.35 (c)** **Evaluation Method: Observation and document review.** **Criteria: Evidence of conformance and proper documentation.**
VI. Packaging/Labeling/Warehousing		
Question Number	*Evaluation Elements*	*Guidance*
102.	Are packaging materials clean and stored in dry, clean location?	**Requirement: 21 CFR § 110.20 (b) 4 & 110.80** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
103.	Are visual examinations of packaging completed and documented after closure? (This includes sealing, labeling and coding)	**Requirement: 21 CFR Part 113.60(a)** **Reference: FDA Guide to Inspections of Low Acid Canned Food Manufacturers** **Evaluation Method: Observation and document review.** **Criteria: Evidence of conformance.**
104.	Are the packages coded and labeled correctly and legibly? (e.g., does what is in package match the label?)	**Requirement: 21CFR 113.60(c)** **Reference: FDA Guide to Inspections of Low Acid Canned Food Manufacturers; ISO 9001: 2000, 7.5.3 Identification and traceability** **Evaluation Method: Observation and document review.** **Criteria: Evidence of conformance.**
105.	Package fill/net weights: 0 Have guidelines been established and is a procedure in place to verify compliance? 0 Are corrective actions taken as needed documented?	**Reference: FDA Guide to Inspections of Low Acid Canned Food Manufacturers -2 pg 8** **Evaluation Method: Observation and document review.** **Criteria: Evidence of conformance.**

VI. Packaging/Labeling/Warehousing

Question Number	*Evaluation Elements*	*Guidance*
106.	Are miscoded or mislabeled packages documented and discarded or corrected as appropriate?	**Reference: ISO 9001: 2000, 8.3 Control of nonconforming product** **Evaluation Method: Observation and document review.** **Criteria: Evidence of conformance - records of disposition of miscoded or mislabeled packages.**
107.	Are empty containers protected from contamination?	**Requirement: 21 CFR § 110.20 (b) 4 & 110.80** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
108.	Are there sufficient facilities for handling raw materials and appropriate rotation of materials (first-in, first-out)?	**Requirement: 21 CFR § 110.80 (a)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
109.	Does raw material storage and handling practices preclude contamination by environmental hazards such as rodents, birds and insects?	**Requirement: 21 CFR § 110.80 (a)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
110.	Are there temperature-recording devices or a high temperature alarm located in the refrigeration or freezer facilities?	**Requirement: 21 CFR § 110.40 (e)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
111.	Is there a shelf-life sample retention program in place?	**Reference: ISO 9001: 2000, 7.5.2 Validation of processes for production and service provision** **Evaluation Method: Interview, observation, and review of documentation.** **Criteria: Evidence of a retention program.**
112.	Is there appropriate rotation of finished products (first-in, first-out)?	**Requirement: 21 CFR § 110.93** **Evaluation Method: Interview and observation - interview shipping and/or warehouse manager on rotation of finished products.** **Criteria: Evidence of conformance.**

VI. Packaging/Labeling/Warehousing

Question Number	*Evaluation Elements*	*Guidance*
113.	Is finished product stored in designated area and separated from raw ingredients?	**Requirement: 21 CFR § 110.93** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
114.	Is trailer/railcar cleaning and inspection performed and documented prior to loading?	**Requirement: 21 CFR § 110.80** **Evaluation Method: Observation and review of documentation.** **Criteria: Evidence of conformance.**

VII. Recall/Return Program		
Question Number	*Evaluation Elements*	*Guidance*
115.	Is retained product identified and stored in a clearly designated area?	**Reference: ISO 9001: 2000, 8.3 Control of nonconforming product** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
116.	Is a log of Hold product maintained? Are records kept documenting the disposition of Hold product?	**Reference: ISO 9001: 2000, 8.3 Control of nonconforming product** **Evaluation Method: Review of documentation.** **Criteria: Evidence of conformance.**
117.	Is there a person authorized to release product? (Name/Title)	**Reference: ISO 9001: 2000, 8.3 Control of nonconforming product** **Evaluation Method: Interview.** **Criteria: Evidence of conformance.**
118.	Is there a recall procedure written and tested according to a defined schedule not less than annually?	**Requirement: FDA Guide to Inspections of Acidified Food Manufacturers** **Reference: ISO 9001: 2000, 8.3 Control of nonconforming product** **Evaluation Method: Interview and review of documentation.** **Criteria: Evidence of documentation and records of annual recall.**
119.	Are returned goods received in a clearly designated area?	**Reference: ISO 9001: 2000, 8.3 Control of nonconforming product** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
120.	Are raw ingredients traceable throughout the process?	**Reference: ISO 9001: 2000, 7.5.3 Identification and traceability** **Evaluation Method: Observation, review of documentation (possible records of trace forward), and interview production manager.** **Criteria: Evidence of conformance.**

VII. Recall/Return Program		
Question Number	*Evaluation Elements*	*Guidance*
121.	Is reworked product documented and traceable?	**Reference: ISO 9001: 2000, 7.5.3 Identification and traceability** **Evaluation Method: Observation, review of documentation (evidence of traceability - for example, if rework includes opening and re-using contents of some containers, verify that ingredient identity is maintained), and interview production manager.** **Criteria: Evidence of conformance.**
122.	Is there product tracking capability to the customer?	**Requirement: FDA Food, Drug, and Cosmetic Act, Section 414 (b)** **Evaluation Method: Interview and review of documentation.** **Criteria: Evidence of documentation (Procedure for tracking product forward to the customer) and records confirming ability.**
123.	Does product tracking system include container code?	**Requirement: 21 CFR § 113.81 (3) c and § 114.80 (b)** **Evaluation Method: Observation.** **Criteria: Evidence of conformance.**
124.	Is there a system in place and documented to handle customer complaints?	**Reference: ISO 9001: 2000, 7.2.3 Customer communication** **Evaluation Method: Observation, review of documentation (procedure for handling customer complaints and records of customer complaints), and interview management.** **Criteria: Evidence of conformance.**

VIII. Food Defense		
Question Number	*Evaluation Elements*	*Guidance*
	FDA Food Facility Registration Number Verified?	**Requirement: Public Health Security and Bioterrorism Preparedness and Response Act of 2002** **Evaluation Method: Observe documentation of FDA Food Facility Registration Number** **Criteria: Record of valid number.**
125.	Management - A Food Security Plan is established, implemented, and reassessed by management to assure it remains relevant to the operation.	**Requirement (if USDA FV Commodity Purchase Contract in place): Notice to the Trade, Fruit and Vegetable Vendor Food Defense Audit, July 14, 2005 (and subsequent contract amendments).** **Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, II. Background; IV. Recommended Actions, A. Management** **Evaluation Method: Observe for implementation; Interview management and staff; Review documentation (if applicable).** **Criteria: Consistent information provided by multiple sources; record of reassessment by management (at least annually).**
126.	Management - The Food Security Plan addresses preventative measures relative to product tampering and deliberate contamination at the processing facility and during transport in commerce.	**Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, IV. Recommended Actions, A. Management** **Evaluation Method: Observe for implementation.** **Criteria: Evidence of implementation.**
127.	Management - Written security practices list management contacts and procedures for notifying appropriate authorities in the case of an emergency or security issue.	**Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, IV. Recommended Actions, A. Management** **Evaluation Method: Review documented contact list and procedure. The information may be contained within the documented recall program.** **Criteria: Documentation, with appropriate availability to management.**

VIII. Food Defense		
Question Number	*Evaluation Elements*	*Guidance*
128.	Human Element, Staff - Company personnel hiring practices include screening all potential employees. Photo identification or other measures are employed to restrict access to the facility.	**Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, IV. Recommended Actions, B. Human Element – Staff** **Evaluation Method: Interview management; Observation of implementation.** **Criteria: Evidence of implementation (identification of employees; restricted access to facility).**
129.	Human Element, Staff - Facility employees have received training in Food Security. The Food Security training is documented.	**Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, IV. Recommended Actions, B. Human Element – Staff** **Evaluation Method: Review documentation.** **Criteria: Record of training for all employees.**
130.	Human Element, Public - Supplier delivery personnel, contract workers, and visitors are restricted access to vulnerable product areas of the processing and storage facility when not accompanied by a company representative.	**Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, IV. Recommended Actions, C. Human Element – Public** **Evaluation Method: Interview management/staff; Observe implementation.** **Criteria: Evidence of implementation.**
131.	Facility - The outside premises are secure with limited access to vulnerable areas. The grounds and facility are monitored for suspicious activity and unauthorized entry. No trespassing signs are visible along the perimeter of the facility or other measures to secure and limit access to vulnerable areas.	**Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, IV. Recommended Actions, D. Facility** **Evaluation Method: Interview management/staff; Observe implementation.** **Criteria: Evidence of implementation.**
132.	Operations - Assurances are provided by suppliers of direct or indirect ingredients, product and equipment cleaning/sanitizing compounds, and packaging materials concerning security practices. This may include the use of tamper evident packaging for raw materials, sealing of trailers, and locking of bulk ingredient receiving ports.	**Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, IV. Recommended Actions, E. Operations, 1. Incoming Materials and Contract Operations** **Evaluation Method: Interview management/staff; Observe implementation, looking for written assurances from suppliers, secure packaging, sealed trailers, locking of receiving ports, etc.** **Criteria: Evidence of implementation.**

Attachment 3

VIII. Food Defense		
Question Number	*Evaluation Elements*	*Guidance*
133.	Operations - The security of water and utilities within the company's control are addressed in the company's plan and define limited access by designated company representatives.	**Reference: FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance, IV. Recommended Actions, E. Operations, 3. Security of Water and Utilities** **Evaluation Method: Interview management/staff; Observe implementation.** **Criteria: Evidence of implementation.**

IX. Contract Review		
Question Number	*Evaluation Elements*	*Guidance*
134.	Are procedures documented and implemented to ensure contract terms can and will be met?	**Reference: ISO 9001: 2000, 7.2.2 Review of requirements related to the product** **Evaluation Method: Verify documentation of procedures; Interview person assigned the responsibility (in the documented procedure) for implementation.** **Criteria: The documentation should reflect a review of the current contract, as well as communication between the company and the contracting office about specific requirements. Verify that contract records reflect compliance with contract requirements. Evaluate purchase requirements provided to suppliers for communication of contract requirements, when applicable. (e.g., U.S. origin, latest season's pack, etc.)**
135.	Are defined procedures documented and implemented for handling amendments?	**Reference: ISO 9001: 2000, 7.2.2** **Evaluation Method: Verify documentation of procedures; Interview person assigned the responsibility (in the documented procedure) for implementing changes.** **Criteria: Verify that contract documentation and procedures reflect contract changes.**
136.	Are records of contract reviews and amendments kept?	**Reference: ISO 9001: 2000, 4.2.4** **Evaluation Method: Review of records of contract reviews and amendments.** **Criteria: Verify that records match latest contract information.**
137.	Is this PSA conducted in lieu the Plant Survey requirement for USDA Contracts? If "YES," and if critical and major GMP deficiencies or Food Defense deficiencies are found, the following corrective action table must be completed. A follow-up audit may be required to ensure corrective action has been completed.	**Requirement: AIM Inspection Series, Sanitation Manual.** **Evaluation Method: By interview.** **Criteria: Follow the Division's normal procedures for documentation and follow-up.**

Attachment 4

Plant Systems Audit (PSA)
AUDIT PLAN

The PSA auditor is responsible for preparing this plan for the activities of the PSA audit. The Audit Plan is discussed with the auditee during the opening meeting. The Auditee is required to sign this Audit Plan and provide it to the Auditor.

Name of Facility (Auditee)	Auditee Street Address (Where the on-site audit is to be conducted.)

Auditee Contact/Representative Name:	Our company agrees to comply with the requirements of the Plant Systems Audit Program. Auditee Contact/Representative Signature:	Date Signed:

Purpose/Products/Scope of Audit:	Auditee Phone Number:
Auditor's Name (Print Name)	**2nd Auditor (Print Name)**

The "REMARKS" area may be used to take notes or record information needed for the audit.

Audit Activities	REMARKS
1. Opening meeting	
2. Walk-through facility to verify operational procedures for the following: Food Safety Quality Management System Personnel GMPs/Sanitation Pest Control Packaging/Labeling/Warehousing Recall/Return Food Defense	
3. Conduct interviews	
4. Verify applicable procedures related to the PSA requirements	
5. Verify applicable records related to the procedures	
6. Prepare summary of deficiencies	
7. Closing meeting	