Part 6 - NOAA Handbook: Fishmeal and Fishery By-products for use as animal feed and industrial treatments, not intended for human consumption.

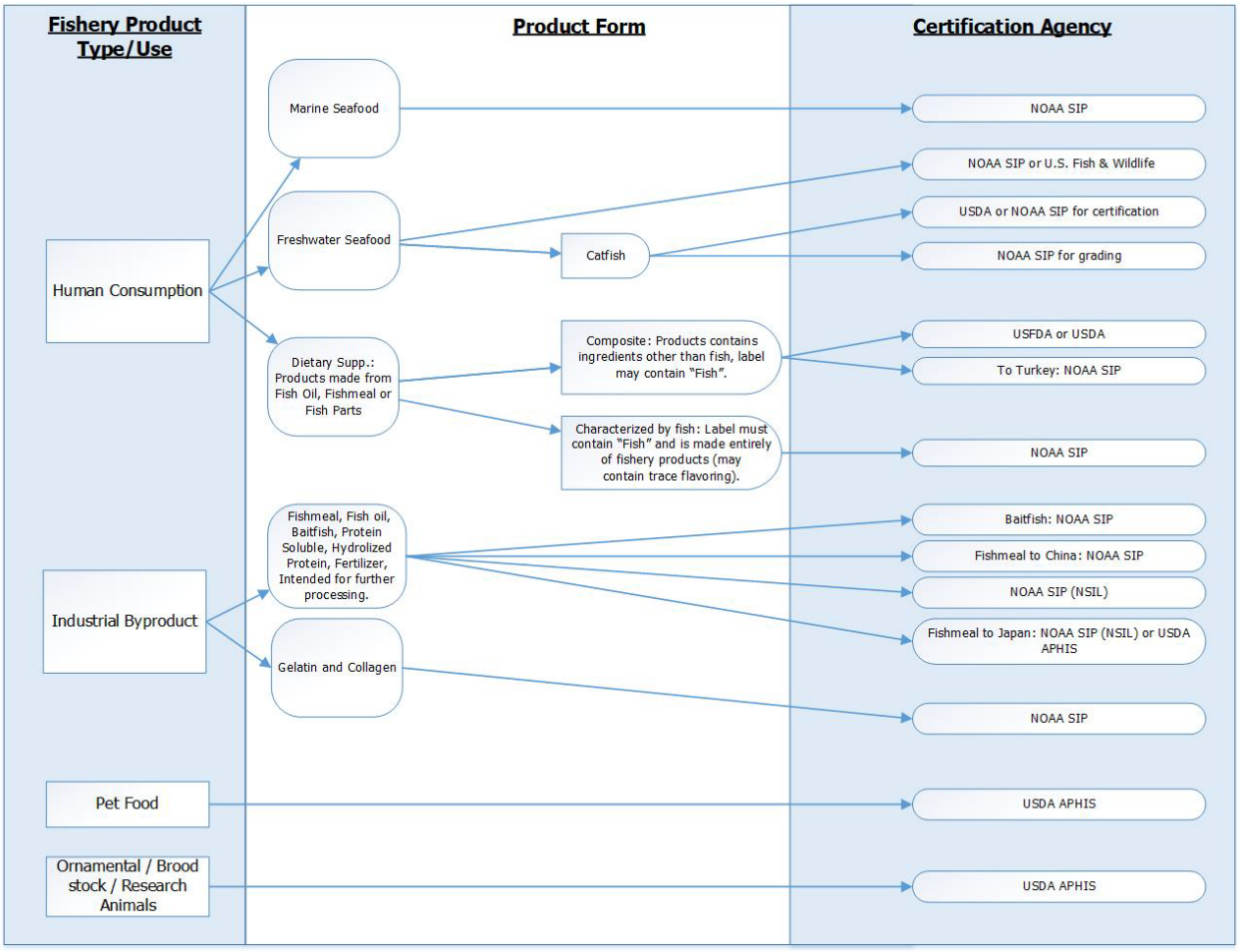
Chapter 1 - Introduction

The National Marine Fisheries Service (NMFS) Seafood Inspection Program (SIP), under the National Oceanic and Atmospheric Administration (NOAA) of the USDC, conducts inspections, audits, and certification of fisheries by-products. The SIP offers several types of inspection and product certification services on a fee-for-service basis for fishery by-products that are not intended for human consumption. Initially SIP performed fishery by-product inspection services to assist the U.S. fishmeal industry in controlling Salmonella. However, due to industry & regulatory changes, the SIP has expanded its services to include assistance in the control of additional hazards associated with products such as fishmeal, krill meal, bone meal, fish oil, frozen fish by-products, hydrolyzed fish proteins and fish solubles.

Additional information regarding U.S. regulatory requirements for animal food and feed can be found at:

https://www.fda.gov/animal-veterinary/products/animal-food-feeds

Below is a tree designed to aid industry in identifying the fishery product certification scope of the various U.S government agencies.



Chapter 2 - Normative References

Fish and Fisheries Product Hazards and Controls Guidance 4th Edition April 2011

21 CFR part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Human Food

21 CFR part 123 Fish and Fishery Products

21 CFR 507 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

21 CFR 509 Unavoidable Contaminants in Animal Food and Food Packaging Material

NOAA Manual 25 Seafood Inspection Program

Chapter 3 - Terms and Definitions

Fishmeal is heat processed, ground, dried fish used as animal feed or fertilizer.

Fish oil is oil derived from the tissues of oily fish.

Fish Solubles is the water soluble by-product pressed from the meal during the production of fish meal.

Bone Meal is a mixture of finely and coarsely ground marine animal bones (other than marine mammals) and processed by - products. It is used as a nutritional supplement for animals.

Krill Meal is a specialty feed ingredient made of small shrimp- like crustacean.

Hydrolyzed fish proteins - products made from fish material by the method of protein hydrolysate (breakage of proteins from which fish tissues are constructed into smaller parts—peptides and finally into amino acids)

Chapter 4 - Program Requirements

Facilities wishing to obtain export health certification for fishmeal, fish oil, and other aquatic animal by-products not intended for human consumption must participate in the SIP Fisheries By-product Approved Establishment program. The minimum requirements to become a SIP Fisheries By-Products Approved Establishment are system audits including the collection of samples conducted two times a year or within an operation season. Facilities wishing to obtain export health certification for fish oil, or other aquatic animal by-products intended for human consumption must follow the Approved Establishment/QMP frequencies for fishery products for human consumption. The facilities management controls and responsibilities; feed safety programs; sanitation and prerequisite programs; and quality systems will be audited according to the following criteria.

System Compliance Rating Criteria for By-product (not human consumption) facilities. (rev. 6/2023)

1.0 Management Controls and Responsibilities

The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of facilities, processes and systems.

1.1.0 Management Responsibilities

1.1.1 Management commitment not properly implemented or communicated.

Top management shall provide evidence of its commitment to the development and implementation of the food safety management system and to continually improving its effectiveness by: a) showing feed safety is supported by the business objectives of the organization, b) communicating to the organization the importance of meeting feed safety standards, statutory and regulatory requirements, as well as customer requirements relating to feed safety, c) establishing a feed safety policy, d) conducting management reviews, and e) ensuring the availability of resources.

Deficiency: Critical

1.1.2 Feed safety policy not prepared or properly implemented.

Top management shall define, document and communicate its feed safety policy. Top management shall ensure that the feed safety policy a) is appropriate to the role of the organization in the feed chain, b) conforms with both statutory and regulatory requirements and with mutually agreed feed safety requirements of customers, c) is communicated, implemented, and maintained at all levels of the organization, d) is reviewed for continued suitability, e) adequately addresses communication, and f) is supported by measurable objectives.

Deficiency: Serious

1.1.3 Feed safety management system planning not properly performed.

Top management shall ensure that a) planning of the feed safety management system is properly carried out to meet all applicable requirements, and b) the integrity of the feed safety management system is maintained when changes to the feed safety management system are planned and implemented.

Deficiency: Serious

1.1.4 Responsibility and authority not properly defined or communicated.

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the feed safety management system. All personnel shall have responsibility to report problems with the feed safety management system to identified person(s). Designated personnel shall have defined responsibility and authority to initiate and record actions.

Deficiency: Serious

1.2.0 Feed Safety Team

1.2.1 Feed safety team leader not appointed.

Top management shall appoint a feed safety team leader who, irrespective of other duties, shall have the responsibility and authority to: a) manage a feed safety team and organize its work, b) ensure relative training and education of the team members, and c) ensure that the feed safety management system is established, implemented, maintained and updated.

Deficiency: Serious

1.2.2 Feed safety team leader does not report to top management.

The feed safety team leader must report to the organization's top management and will inform them on the effectiveness and suitability of the feed safety management system.

Deficiency: Major

1.2.3 Feed safety team is not interdisciplinary as applicable.

The feed safety team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the feed safety management system. This includes, but need not be limited to, the organization's products, processes, equipment and feed safety hazards within the scope of the feed safety management system. Records shall be maintained that demonstrate that the feed safety team has the required knowledge and experience.

Deficiency: Major

1.3.0 Communication

1.3.1 Effective external communication not established, implemented, or maintained.

To ensure that sufficient information on issues concerning feed safety is available throughout the feed chain, the organization shall establish, implement, and maintain effective arrangements for communicating with: a) suppliers and contractors, b) customers or consumers, in particular in relation to product information (including instructions regarding intended use, specific storage requirements, and as appropriate, shelf life), enquiries, contracts or order handling including amendments, and customer feedback including customer complaints, c) statutory and regulatory authorities, and d) other organizations that have an impact on or will be affected by the effectiveness or updating of the feed safety system.

The communication shall provide information on feed safety aspects of the organization's products that may be relevant to other organizations in the feed chain. This applies especially to known feed safety hazards that need to be controlled by other organizations in the feed chain. Records of communications shall be maintained. Feed safety requirements from statutory and regulatory authorities and customers shall be available. Designated personnel shall have defined responsibility and authority to communicate information concerning feed safety externally. Information obtained through external communication shall be included as input to all system updating and management reviews.

Deficiency: Serious

1.3.2 Effective internal communication not established, implemented, or maintained.

The organization shall establish, implement, and maintain effective arrangements for communicating with personnel on issues having an impact on food safety. In order to maintain the effectiveness of the feed safety management system, the organization shall ensure that the feed safety team is informed in a timely manner of changes, including but not limited to the following: a) products or new products, b) raw materials, ingredients and services, c) production systems and equipment, d) production premises,

location of equipment, surrounding environment, e) cleaning and sanitation programs, f) packaging, storage, and distribution systems, g) personnel qualification level and/or allocation of responsibilities and authorizations, h) statutory and regulatory requirements, i) knowledge regarding feed safety hazards and control measures, j) customer, sector, and other requirements which the organization observes, k) relevant enquiries from external interested parties, l) complaints indicating feed safety hazards associated with the product, and m) other conditions which have an impact on feed safety.

The feed safety team shall ensure that this information is included in the updating of the feed safety management system. Top management shall ensure that relevant information is included as input to management review.

Deficiency: Serious

1.4.0 Emergency Preparedness and Response

1.4.1 Emergency response procedures not established, implemented or maintained.

Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact feed safety relevant to the role of the organization in the food chain.

Deficiency: Critical

1.5.0 Management Review

1.5.1 Management review not properly performed or documented.

Top management shall review the organization's feed safety management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for change to the system, including the feed safety and quality policy. Records from management reviews shall be maintained.

The input to management review shall include, but is not limited to information on: a) follow-up actions from previous management reviews, b) analysis of results of verification activities, c) changing circumstances that can affect feed safety or quality, d) emergency situations, accidents, and withdrawals, e) reviewing results of system updating activities, f) review of communication activities including customer feed-back, and g) external audits or inspections. The data shall be presented in a manner that enables top management to relate the information to stated objectives of the feed safety system.

The output from the management review shall include decisions and actions related to: a) assurance of feed safety, b) improvement of the effectiveness of the feed safety management system, c) resource needs, and d) revisions of the organization's feed safety policy and objectives.

Deficiency: Serious

1.6.0 Resource Management

The organization shall provide adequate resources for the establishment, implementation, maintenance and updating of the feed safety management system.

1.6.1 Necessary human resource competencies not identified.

The feed safety team and the other personnel carrying out activities having an impact on feed safety shall be competent and shall have appropriate education, training skills and experience. Where the assistance of external experts is required for the development, implementation, operation, or assessment of the feed safety management system, records of agreement or contracts defining the responsibility and authority of external experts shall be available.

Deficiency: Serious

1.6.2 Personnel have not received documented training necessary for the proper function of the feed system.

The organization shall: a) identify the necessary competencies for personnel whose activities have an impact on feed safety, b) provide training or take other action to ensure personnel have the necessary competencies, c) ensure that personnel responsible for monitoring, corrections, and corrective actions of the management system are trained, d) evaluate the implementation and the effectiveness of a), b), and c), e) ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to feed safety, f) ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on feed safety, and g) maintain appropriate records of training and action as described above.

Training must include the areas of HACCP, good manufacturing practices, and allergens to appropriate personnel. Each firm must have available a person who has met the training requirement by NOAA for this program. The training requirement 1) fulfills the 21 CFR part 123.10 training requirement and, 2) personnel must pass the NOAA HACCP Exam with an 80% or better. In addition, copies of all trained personnel's certificates must on file with the firm. Per 21 CFR part 123, these duties are assigned only to properly trained personnel. However, failure of this element will not likely cause an immediate hazard or defect. Therefore it is rated as a Serious deficiency. Per 21 CFR part 123, these duties are assigned to only properly trained personnel. Failure of this element could lead to an immediate hazard or defect.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

> Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);
>
> Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and
>
> Performing the record review required by Sec. 123.8(a) (3). The trained individual need not be an employee of the processor.

Deficiency: Serious/Critical

1.6.3 Insufficient infrastructure to implement and maintain the feed safety system.

The organization shall provide the resources for the establishment and maintenance of the infrastructure needed to implement a proper feed safety system.

Deficiency: Serious

1.6.4 Work environment is not properly established, managed, or maintained relative to feed safety.

The organization shall provide the resources for the establishment, management, and maintenance of the work environment needed to implement a proper feed safety management system.

Deficiency: Serious

1.7.0 Continual Improvement

1.7.1 Continuous improvement activities not performed.

Top management shall ensure that the organization continually improves the effectiveness of the feed safety management system through the use of communication, management review, internal audit, evaluation of individual verification results, analysis of results of verification activities, validation of control measure combinations, and corrective actions.

Deficiency: Serious

b. 2.0 Feed Safety

The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of facilities, processes and systems.

The organization shall plan and develop the processes needed for the realization of safe products. The organization shall implement, operate, and ensure the effectiveness of the planned activities and any changes to those activities. This includes pre-requisite programs as well as the HACCP plan.

2.1.0 Operational Prerequisite Programs

2.1.1 Operational prerequisite programs not present or not effective.

Each processor shall have and implement a written operational prerequisite procedures or similar document that is specific to each location where fish and fishery products are produced. The operational prerequisite programs shall be documented and shall include the following information for each program: a) feed safety hazard(s) to be controlled by the program, b) control measure(s), c) monitoring procedures that demonstrate that the prerequisite programs are implemented; d) corrections and corrective actions to be taken if monitoring shows that the operational prerequisite programs are not in control; e) responsibilities and authorities; f) record(s) of monitoring.

Deficiency: Serious

2.1.2 Operational prerequisite procedures not followed.

This deficiency will be assessed if it is determined that the firm did not follow their written procedures, whether or not specific s deficiencies were observed.

Deficiency: Serious

2.2.0 Hazard Analysis

2.2.1 Description of products, processes or control measures not properly performed.

All relevant information needed to conduct the hazard analysis shall be collected, maintained, updated and documented. Records shall be maintained.

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis, including the following, as appropriate: a) biological, chemical, and physical characteristics; b) composition of formulated ingredients, including additives and processing aids; c) origin; d) method of production; e) packaging and delivery methods; f) storage conditions and shelf life; g) preparation and/or handling before use or processing; h) feed safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses. The organization shall identify statutory and regulatory feed safety requirements related to the above.

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis, including information on the following, as appropriate: a) product name or similar identification; b) composition; c) biological, chemical and physical characteristics relevant for feed safety; d) intended shelf life and storage conditions; e) packaging; f) labeling relating to feed safety and/or instructions for handling, preparation and usage; g) method(s) of distribution. The organization shall identify statutory and regulatory feed safety requirements related to the above.

The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the hazard analysis. Groups of users and, where appropriate, groups of consumers shall be identified for each product, and consumer groups known to be especially vulnerable to specific feed safety hazards shall be considered.

Flow diagrams shall be prepared for the products or process categories covered by the feed safety management system. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of feed safety hazards. Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include the following: a) the sequence and interaction of all steps in the operation; b) any outsourced processes and subcontracted work; c) where raw materials, ingredients and intermediate products enter the flow; d) where reworking and recycling take place; e) where end products, intermediate products, by-products and waste are released or removed. The feed safety team shall verify the accuracy of the flow diagrams by on-site checking. Verified flow diagrams shall be maintained as records.

All information described above shall be updated as necessary.

Deficiency: Major

2.2.2 Hazard analysis not properly performed.

The feed safety team shall conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure feed safety, and which combination of control measures is required. A feed safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

All feed safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities shall be identified and recorded. Such hazard analysis must also consider any products, including ingredients or additives that may contain allergens as a significant hazard. Allergen assessment must also consider unintentional inclusion of an allergenic ingredient or additive. (21CFR123.6a)

The identification shall be based on a) the preliminary information and data collected according to the previous section, b) experience, c) external information including, to the extent possible, epidemiological and other historical data, and d) information from the feed chain on feed safety hazards that may be of relevance for the safety of the end products, intermediate products and the feed at end use. The step(s) (from raw materials, processing and distribution) at which each feed safety hazard may be introduced shall be indicated.

When identifying the hazards, consideration shall be given to a) the steps preceding and following the specified operation, b) the process equipment, utilities/services and surroundings, and c) the preceding and following links in the feed chain.

For each of the feed safety hazards identified, the acceptable level of the feed safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer feed safety requirements, the intended use by the customer and other relevant data. The justification for, and the result of, the determination shall be recorded.

A hazard assessment shall be conducted to determine, for each feed safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe feed, and whether its control is needed to enable the defined acceptable levels to be met. Each feed safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described, and the results of the feed safety hazard assessment shall be recorded.

Based on the hazard assessment, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these feed safety hazards to defined acceptable levels. In this selection, each of the control measures as determined shall be reviewed with respect to its effectiveness against the identified feed safety hazards. The control measures selected shall be categorized as to whether they need to be managed through operational prerequisite programs or by the HACCP plan.

The existing control measures, process parameters and/or the rigorousness with which they are applied, or procedures that may influence feed safety, shall be described to the extent needed to conduct the hazard analysis. External requirements (e.g., from regulatory authorities or customers) that may impact the choice and the rigorousness of the control measures shall also be described.

The selection and categorization shall be carried out using a logical approach that includes assessments with regard to the following: a) its effect on identified feed safety hazards relative to the strictness applied; b) its feasibility for monitoring (e.g., ability to be monitored in a timely manner to enable immediate corrections); c) its place within the system relative to other control measures; d) the likelihood of failure in the functioning of a control measure or significant processing variability; e) the severity of the consequence(s) in the case of failure in its functioning; f) whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s); g) synergistic effects (i.e., interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects).

Control measure categorized as belonging to the HACCP plan shall be implemented as such. The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.

Deficiency: Serious/Critical

2.2.3 Hazard analysis not available.

The hazard and defect analysis is the foundation of the HACCP plan. If the analysis is not performed, the entire plan and its efficacy is suspect. Firms must provide this analysis to the requesting Consumer Safety Officer in writing. If it is not provided and evidence suggests that it was performed but a written document is not available, a Serious deficiency will be assessed. Otherwise, a Critical deficiency will be assessed.

Deficiency: Serious/Critical

2.3.0 HACCP Plan

2.3.1 No written HACCP plan when one is required.

Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more feed safety hazards that are reasonably likely to occur. (21CFR123.6b)Firms must provide this plan to the requesting Consumer Safety Officer.

Deficiency: Serious

2.3.2 Plan is not location and/or fish species specific.

A HACCP plan shall be specific to:

1. Each location where fish and fishery products are processed by that processor; and
2. Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the feed safety hazards, critical control points, critical limits, and procedures required to be identified and performed are identical for all fish and fishery products so grouped or for all production methods so grouped.

Deficiency: Major

2.3.3 Hazard(s) is not listed in the plan.

The HACCP plan shall, at a minimum list the feed safety hazards that are reasonably likely to occur and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

1. Natural toxins;
2. Microbiological contamination;
3. Chemical contamination;
4. Pesticides;
5. Drug residues;
6. Decomposition in scombroid toxin-forming species or in any other species where a feed safety hazard has been associated with decomposition;
7. Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
8. Unapproved use of direct or indirect feed or color additives or allergens; and
9. Physical hazards

In the event that one or more hazards are not identified, a deficiency will be assessed.

Deficiency: Serious

2.3.4 Hazard(s) is not controlled.

Firms may not have met the requirements of performing the hazard analysis or writing a required HACCP plan. However, controls may still be in place for the hazards identified by the Consumer Safety Officer. If it is determined that the controls are not in place, a Critical deficiency will be assessed.

Deficiency: Critical

2.3.5 CCPs are not properly identified in the plan.

The HACCP plan shall, at a minimum list the critical control points for each of the identified food safety hazards, including as appropriate:

1. Critical control points designed to control feed safety hazards that could be introduced in the processing plant environment; and
2. Critical control points designed to control feed safety hazards introduced outside the processing plant environment, including feed safety hazards that occur before, during, and after harvest. (21CFR123.6c.2)

Deficiency: Serious

2.3.6 Appropriate critical limit(s) is not listed in the plan.

Critical limits shall be determined for the monitoring established for each critical control point. Critical limits shall be established to ensure that the identified acceptable level of the feed safety hazard in the end product is not exceeded. Critical limits shall be measurable. The rationale for the chosen critical limits shall be documented. Critical limits that are evaluated by observation (e.g., visually or by sensory evaluation) shall be supported by instructions or specifications and/or education and training. If evidence is present that the critical limits were improperly identified but those identified were followed, the deficiency will be assessed here. (21CFR123.6c.3)

Deficiency: Serious

2.3.7 Critical limits not followed.

Self-explanatory.

Deficiency: Critical

2.3.8 Monitoring procedure stated in the plan is inadequate.

Monitoring procedures shall be established for each critical limit. (21CFR123.6c.4) The results of monitoring will indicate whether the CCP is in or out of control. The system shall include all scheduled measurements or observations relative to the critical limit(s). The monitoring system shall consist of relevant procedures, instructions and records that cover the following: a) measurements or observations that provide results within an adequate time frame; b) monitoring devices used; c) applicable calibration methods; d) monitoring frequency; e) responsibility and authority related to monitoring and evaluation of monitoring results; f) record requirements and methods. The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed. Where allergen controls are not sufficient or proper or identified allergens are not declared on product labels where appropriate, a critical deficiency will be assessed.

Deficiency: Serious/Critical

2.3.9 Monitoring procedures not followed:

Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed the firm is not in compliance with this item

Deficiency: Serious

2.3.10 Corrective action listed in plan is not appropriate or adequate.

Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the HACCP plan. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented. Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated and the cause of the deviation is corrected (e.g., not injurious to health or adulterated).

A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

1. No product enters commerce that is either injurious to health, is otherwise adulterated as a result of the deviation, or does not meet Program requirements; and
2. The cause of the deviation is corrected. (21CFR123.7)

Deficiency: Serious

2.3.11 Corrective action not taken

Whenever a deviation from a critical limit, sanitation, monitoring or verification procedures occurs, a processor shall take corrective action. Processors shall develop written corrective action plans, which become part of their plans by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit.

A firm is provided room for error in their plan through a system of corrective actions. If an error or problem arises in the conduct of the feed safety management plan, the firm must file a corrective action report. All other deficiencies may possibly be averted in this checklist if corrective action reports are filed for each problem or situation. Failure to file a corrective action report will be considered a failure to take a corrective action and the firm will then not be in compliance with this item.

When a deviation from the plan occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

1. Segregate and hold the affected product.
2. Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review.
3. Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation or does not meet other program requirements;
4. Take corrective action, when necessary, to correct the cause of the deviation;
5. Perform or obtain timely reassessment of the system by an individual or individuals who have been properly trained to do so, to determine whether the plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the plan as necessary.

In addition, the organization shall assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is nonconforming, the organization shall take action appropriate for the equipment and any product affected. Records of such assessment and resulting action shall be maintained.

Deficiency: Critical

2.3.12 Verification procedure stated in plan is inadequate.

The HACCP plan shall list the verification procedures, and frequency thereof, that the processor will use. Every processor shall verify that the HACCP plan is adequate to control feed safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented.

Verification shall include, at a minimum:

1. Reassessment of the feed safety management system. A reassessment of the adequacy of the plan whenever any changes occur that could affect the hazard analysis or alter the plan in any way or at least annually. (21CFR123.8a.1) Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10 of 21 CFR Part 123.

The system shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements.

2. Ongoing verification activities. Ongoing verification activities including:
    a. A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
    b. The calibration of process-monitoring instruments; and,
    c. At the option of the processor, the performing of periodic end-product or in-process testing. (Note: Some end item testing is required as part of the HACCP QMP system. See Program requirements.) (21CFR123.8a.2)
3. Records review. (21CFR123.8a.3) A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:
    a. The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
    b. The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and
    c. The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within 1 week of the day that the records are made.

4. Processors shall immediately follow corrective action procedures whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action. (21CFR123.8b)(See Corrective Action sections listed above.)
5. Reassessment of the hazard analysis. (21CFR123.8c) Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no feed safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a feed safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been properly trained in accordance with 21 CFR 123.10. (See 1.6.2)
6. Recordkeeping. (21CFR123.8d) All verification activities, including the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing, shall be documented and recorded and is subject to the recordkeeping requirements listed below. The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures. Where necessary to ensure valid results, the measuring equipment and methods used a) shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards, where no such standards exist, the basis used for calibration or verification shall be recorded, b) shall be adjusted or re-adjusted as necessary, c) shall be identified to enable the calibration status to be determined, d) shall be safeguarded from adjustments that would invalidate the measurements results, and e) shall be protected from damage and deterioration. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and shall be reconfirmed as necessary.

The output of this activity shall be in a form suitable for the organization's method of operations. Verification results shall be recorded and shall be communicated to the feed safety team. Verification results shall be provided to enable the analysis of the results of the verification activities. If system verification is based on testing of end product samples, and where such test samples show nonconformity with the acceptable level of the feed safety hazard, the affected lots of product shall be handled as potentially unsafe.

The organization shall conduct internal audits at planned intervals to determine whether the feed safety management system a) conforms to the planned arrangements, to the feed safety management system requirements established by the organization, and b) is effectively implemented and updated. An audit program shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any actions resulting from previous audits. The audit criteria, scope, frequency and methods shall be defined and documented. Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate nonconformities and their causes.

The feed safety team shall systematically evaluate the individual results of planned verification. If verification does not demonstrate conformity with the planned arrangements, the organization shall take action to achieve the required conformity. The feed safety team shall analyze the results of verification activities, including the results of the internal and external audits. The results of the analyses and the resulting activities shall be recorded and shall be reported, in an appropriate manner, to top management as input to the management review.

The monitoring system shall consist of relevant procedures, instructions and records that cover the following: a) measurements or observations that provide results within an adequate time frame; b) monitoring devices used; c) applicable calibration methods; d) monitoring frequency; e) responsibility and authority related to monitoring and evaluation of monitoring results; f) record requirements and methods.

Deficiency: Serious

2.3.13 Verification procedures not followed.

Verification procedures are those that provide for management to determine the overall effectiveness of the plan. Not following these procedures could ultimately cause the plan to fail or misidentify a hazard, defect, or control procedure. Since failure of these procedures will likely not immediately cause the plan to fail, it is rated at a Serious level. This item should be checked on a trend basis, not based on isolated incidences unless they are of such severity to warrant action. Firms must reassess their hazard analyses when information or other evidence indicates the need and at least yearly. The plan must be signed and dated by a management official responsible for the operation of the facility. The plan must be signed upon implementation and at least once each year.

Deficiency: Serious

2.4.0 Control of Nonconformity

2.4.1 Traceability system inadequate.

The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records. The traceability system shall be able to identify incoming material from the immediate suppliers and the initial distribution route of the end product. Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements (including those for firm registration and traceability relative to the Bioterrorism Act) and customer requirements and may, for example, be based on the end product lot identification.

Deficiency: Serious

2.4.2 Improper handling of potentially unsafe products

The organization shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the feed chain unless it is possible to ensure that a) the feed safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels, b) the feed safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering the feed chain, or c) the product still meets the defined acceptable level(s) of the feed safety hazard(s) of concern despite the nonconformity.

All lots of product that may have been affected by a nonconforming situation shall be held under control of the organization until they have been evaluated. If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal or recall. The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.

Each lot of product affected by the nonconformity shall only be released as safe when any of the following conditions apply: a) evidence other than the monitoring system demonstrates that the control measure have been effective; b) evidence shows that the combined effect of the control measures for that particular product complies with the performance intended; c) the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the feed safety hazard(s) concerned.

Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities: a) reprocessing or further processing within or outside the organization to ensure that the feed safety hazard is eliminated or reduced to acceptable levels; b) destruction and/or disposal as waste.

Deficiency: Serious

2.4.3 Withdrawals and recalls not designed or implemented properly.

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe a) top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal, and b) the organization shall establish and maintain a documented procedure for

1. notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
2. handling of withdrawn products as well as affected lots of the products still in stock, and
3. the sequence of actions to be taken.

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe. The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review. The organization shall verify and record the effectiveness of the withdrawal program through the use of appropriate techniques (e.g. mock or practice withdrawal).

Deficiency: Serious

2.5.0 Validation

2.5.1 Validation activities improperly performed

The feed safety team shall plan and implement the processes needed to validate control measures and/or control measure combinations. Prior to implementation of control measures to be included in operational prerequisite programs and the HACCP plan and after any change therein, the organization shall validate that a) the selected control measures are capable of achieving the intended control of the feed safety hazard(s) for which they are designated, and b) the control measures are effective and capable of, in combination, ensuring control of the identified feed safety hazard(s) to obtain end products that meet the defined acceptable levels.

If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed. Modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end-product characteristics, methods of distribution and/or intended use of the end product.

Deficiency: Serious

2.6.0 Records

2.6.1 Inadequate information on records (Facility name and location, etc.)

Based on the required information stated in 21 CFR Part 123.9a.

All records required by this part shall include:

1. The name and location of the processor or importer;
2. The date and time of the activity that the record reflects;
3. The signature or initials of the person performing the operation; and
4. Where appropriate, the identity of the product and the production code, if any.

Deficiency: Major

2.6.2 Record data is missing.

All records must be kept up-to-date. Entries must be made as they are measured. The records shall contain the actual values and observations obtained during monitoring or measurement. All time schedules outlined in the QMP plan must be maintained. Examples of non-compliance include: measurement observed to be taken but not entered on record; partial entry of information from monitoring procedures; initials for QA verification not recorded in a timely manner; etc. If record data is missing, a Major deficiency will be assessed.

All labels must be up-to-date. All labels must be kept on file by the firm. If labels are not up-to-date, a Serious deficiency will be assessed.

The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

Deficiency: Major (Serious for Labels)

2.6.3 Records are inaccurate.

All entries must be accurate or the record is meaningless. If calculations, time test measured, etc., are not correct, the box for this deficiency should be checked. Further, as the use of correction fluid and obliterating a record entry are not proper in the keeping of records, their routine use should be considered an inaccurate reading and the serious deficiency assigned. This deficiency will also be used for the compliance of product leaving the firm.

Deficiency: Serious/Critical

2.6.4 Records are not available for inspection.

If the firm is unable to supply the requested record(s) in a reasonable amount of time for inspector review, they are not in compliance with this item. If portions of a record are not available, the firm is not in compliance with this item. All required records shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

Deficiency: Critical

2.6.5 Documents or records are falsified.

This item is self-explanatory. However, intent on the part of the firm or its representatives must be shown. For example, if an item on a record was shown to be corrected with correction fluid or other means of obliteration, the inspector must show that someone with, full knowledge, changed the entry to reflect a value that was not the value measured or observed. Otherwise, this will be considered an inaccurate entry.

Deficiency: Critical

3.0 Sanitation and Prerequisite Programs

The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of facilities, processes and systems.

References: 21 CFR Part 507; 21 CFR Part 123.11(b); 50 CFR Parts 260.96-260.104

3.1.0 Sanitation Standard Operating Procedures and Prerequisite Programs

3.1.1 Sanitation standard operating procedures or prerequisite programs not present or not effective.

Each processor shall have and implement a written sanitation standard operating procedure (SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP shall specify how the processor would meet those sanitation conditions and practices that are to be monitored.

Deficiency: Serious

3.1.2 Sanitation standard operating procedures not followed.

This deficiency will be assessed if it is determined that the firm did not follow their written SSOPs, whether or not specific sanitation deficiencies were observed.

Deficiency: Serious

3.1.3 Sanitation not monitored.

Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in 21 CFR Part 570 and 123 that are both appropriate to the plant and the feed being processed and relate to the following:

1. Safety of the water that comes into contact with feed or feed contact surfaces, or is used in the manufacture of ice;
2. Condition and cleanliness of feed contact surfaces, including utensils, gloves, and outer garments;
3. Prevention of cross-contamination from unsanitary objects to feed, feed packaging material, and other feed contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
5. Protection of feed, feed packaging material, and feed contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions that could result in the microbiological contamination of feed, feed packaging materials, and feed contact surfaces; and
8. Exclusion of pests from the feed plant.

The firm shall define the applicable frequencies of monitoring in their sanitation standard operating procedures and must adhere to these frequencies.

Deficiency: Serious

3.2.0 Safety of Process Water

Process water must be of suitable quality as it directly interfaces or becomes part of the product being manufactured. Therefore, no filth, deleterious chemicals, bacteria, or other contaminants may be present in solution as it will directly affect the safety or wholesomeness of the product. Available water must pass potability standards established by federal, state, and local authorities. Water that is supplied to the plant must meet certain minimum standards. However, processing water must also be reasonably protected in the facility. Conditions that allow contamination to occur cannot be allowed. These may include cross-connection of plumbing, back-siphonage, or back flow from a contaminated source to the supply system or open vessels of water.

3.2.1 Unsafe or unsanitary water supply.

The water supply, including seawater, will be in compliance when by certification or direct testing the supply is found to meet the federal standards set forth by the Environmental Protection Agency or the World Health Organization as applicable. Water used for washing, rinsing, or conveying feed shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying feed if it does not increase the level of contamination of the feed.

Deficiency: Serious/Critical

3.2.2 Water potability certificate not current

Private supplies shall have testing performed at a minimum of every six (6) months. Certification of municipal or community systems should be secured at a minimum of once per year. Where used, seawater must meet processing use requirements and potability must be tested at a frequency sufficient to ensure the acceptability of the water source from that geographic area.

Deficiency: Serious

3.2.3 Self water treatment performed improperly.

Where water supply is treated (such as chlorinated, ozone, UV) on premises, equipment must be properly maintained and/or residual must be within acceptable limits based upon statutory, regulatory, and requirements of the end-user.

Deficiency: Serious

3.2.4 No protection against backflow, back-siphonage, or other sources of contamination.

A facility will be in compliance when all cross-connections are eliminated, backflow prevention devices are installed wherever backflow or siphonage may occur, or where other possible forms of contamination may be present. A diagram or chart of all such devices will be on file for review.

Deficiency: Serious

3.2.5 Inadequate supply of water and hot water.

The water supply shall be sufficient for the operation intended. Plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant. Water shall be sufficient to properly convey sewage and liquid disposable waste from the plant. Running water at a suitable temperature and under pressure as needed, shall be provided in all areas where required for processing of feed, for the cleaning of equipment, utensils and food packaging, or for employee sanitary facilities.

Hot water is necessary for many cleaning techniques. In addition, a hot water supply is necessary to provide a comfortable means for employees to wash their hands. If the tap is on and a luke-warm supply of water is present in sufficient quantities for the tasks it will perform in the facility, the plant is in compliance. The supply must also be easily accessible for its proper use.

Deficiency: Minor (Lack of hot water)/Major (Lack of sufficient water supply)

3.2.6 Ice not manufactured, handled, or used in a sanitary manner.

A facility will be in compliance when potable water is used for manufacturing ice, when the manufacturing equipment is clean, and the ice only contacts impervious surfaces; the ice holding containers are clean and made of appropriate impervious material; handling equipment is clean and appropriate for feed contact; and ice is properly used. For facilities receiving ice from an outside supply, a certificate of conformance will be necessary to ensure that the ice being received meets the standards set forth in this document. In addition, potability checks must be made at a minimum of every six (6) months on ice received.

Deficiency: Major/Critical

3.2.7 Other areas covered by the CGMPs.

Deficiency: Minor

3.3.0 Feed Contact Surfaces

3.3.1 Equipment and utensils' design, construction, location, or materials cannot be readily cleaned or sanitized; does not preclude product adulteration or contamination.

Any equipment used in the manufacturing or handling of the feed product must be designed or constructed so that it can be properly cleaned and inspected. Failure to do so will cause the facility to be out of compliance. In addition, if the materials used are not of a material suitable for its intended purpose or there is reuse of single-service items, then the facility is also out of compliance.

Seams on product-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of feed particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Product-contact surfaces shall be corrosion-resistant when in contact with feed. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of feed and, if applicable, cleaning compounds and sanitizing agents. Feed containers and feed-packaging materials that are safe and suitable are to be used. Product-contact surfaces shall be maintained to protect feed from being contaminated by any source, including unlawful indirect feed additives.

Deficiency: Serious/Critical

3.3.2 Equipment and utensils not maintained in proper repair or removed when necessary. (Feed contact surfaces)

All feed contact surfaces must be kept in good repair. If the contact surface cannot be repaired, then the piece of equipment or utensil should be removed so as not to allow for its use. Failure to provide these conditions will result in non-compliance. Assessment of this deficiency will be made relative to the risk of the product at that stage of production. For example, if the equipment under consideration is being used for handling product after a kill step in the process, this product is higher risk and therefore the deviation is more significant.

Deficiency: Major (Serious for products at a high risk stage of processing)

3.3.3 Feed contact surfaces not cleaned or sanitized before use, after interruptions, or as necessary.

Feed contact surfaces and feed containers must be adequately cleaned using proper techniques to remove dirt and debris and must be adequately sanitized. Sanitizers must be used before product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered non-compliance. Risk should be considered when assessing this deficiency. Product leaving a cooker to be packaged and frozen will have a higher level of risk than a raw fish at receiving.

Deficiency: Serious/Critical

3.3.4 Concentrations of cleaners and sanitizers are not effective, safe, or routinely checked.

All sanitizing agents (e.g., hand sanitizers, equipment sanitizers, etc) must be used in the proper concentration and in the manner prescribed in the usage instructions to be effective.

Deficiency: Major

3.3.5 Other areas covered by the CGMPs.

Deficiency: Minor

3.4.0 Prevention of Cross Contamination

3.4.1 Grounds condition can permit contaminants to enter the facility.

There shall be no conditions on the grounds such as dusty roads or parking lots, standing or ponding water, chemical spills, etc., that can cause contamination to be carried into the plant through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc.

Deficiency: Minor/Major

3.4.2 Facility

3.4.2.1 Design, layout of materials used cannot be readily cleaned and sanitized; does not preclude product contamination. Insufficient lighting for the applicable operation.

Design of the facility structure should be such that access is easily obtained to all areas. This is necessary for proper cleaning and sanitizing of floors, walls and ceilings, as well as for visual inspections. If the rooms (including restrooms and employee break rooms) in the facility are laid out or designed in such a way that they cannot be readily cleaned or sanitized, then the facility is not in compliance. This would include insufficient lighting, improper materials for walls, ceilings, etc., as well as hard-to-reach rooms or corners even when the equipment is removed from the room.

Deficiency: Major

3.4.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.

There must be sufficient separation between different activities in the processing, packaging and handling of feed products such as 1) separation between activities, 2) layout of facility (employee traffic) 3) product sequencing and 4) product display. This includes the complete separation of living/sleeping quarters or heavy maintenance areas from feed-handling areas. The feed product should flow easily from one stage to another and not be allowed to come into contact with non-feed contact surfaces if exposed. In addition, the layout of the facility should not be such that product contamination/adulteration is likely due to issues such as heavy employee traffic through work areas. Production is not organized and scheduled in a manner which precludes cross-contamination or cross-contact of product by allergens. Adequate separation can be by physical barrier, time, space, etc. Sanitary handling procedures and processing methods during operations are to be in place to protect feed against contamination to include physical protection from airborne contamination.

Feed manufacturing areas and equipment used for manufacturing feed should not be used to manufacture food products unless there is no reasonable possibility for the contamination of human food.

Deficiency: Serious/Critical

3.4.3 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.

3.4.3.1 Areas directly affecting product or packaging material.

For those areas that will directly affect product or primary packaging materials, (packaging immediately surrounding product), the roof, ceiling, walls, floors, the storage of ingredients or materials that permits cross-contamination or cross-contact by allergens or ingredients, and lighting fixtures must be maintained as designed and lights must be protected. Failure to do so causes the facility to be out of compliance.

Deficiency: Serious

3.4.3.2 Other.

For areas in the facility other than in 3.4.3.1 above, the roof, ceilings, walls, floors, or lighting fixtures must also be maintained as designed. This does not include those areas designated as offices and in which feed products or primary packaging materials in any stage of production will not be handled or stored.

Deficiency: Major

3.4.4 Cleaning methods permit adulteration or contamination.

Employees must take care to use methods that will not adulterate or contaminate the product. Any cleaning or sanitizing procedures or techniques that may cause the product to become adulterated or contaminated will cause the facility to be in non-compliance. Examples of non-compliance include but are not limited to inadvertent touching of product or product surfaces with wash water, detergent, sanitizers, etc., during production.

Deficiency: Serious (Critical for products at a high risk stage of production)

3.4.5 Finished product/primary packaging material not properly covered or protected.

Finished product must be packaged, covered or protected so as to not permit contamination or adulteration prior to shipment and during transportation. Primary packaging materials should be adequately covered when stored or not in use. Failure to provide these conditions will result in non-compliance.

Deficiency: Major/Serious

3.4.6 Equipment and utensils not maintained in proper repair or removed when necessary. (Non-feed contact surfaces)

All non-feed contact surfaces should also be maintained in good repair. The facility is in non-compliance when the maintenance of all additional equipment or areas of equipment and utensils not referred to in item 3.4.3.1 above is insufficient and may allow indirect product contamination.

Deficiency: Minor (Major for products at a high risk stage of production)

3.4.7 Non-feed contact surfaces, equipment, or areas not cleaned before use.

Non-feed contact areas must also be cleaned prior to use. Areas such as walls, ceilings, floors, as well as equipment must also be cleaned prior to use. However, sanitizing is not required.

Deficiency: Major

3.4.8 Processing or feed handling personnel do not maintain a high degree of personal cleanliness.

All persons, while in feed preparation or handling areas, shall wear clean outer garments and conform to hygienic practices while on duty to the extent necessary to prevent contamination or adulteration of feed. This includes occasional workers or visitors to the area.

Deficiency: Major/Serious

3.4.9 Processing or feed handling personnel do not take necessary precautions to prevent adulteration or contamination of feed.

All persons, while in a feed preparation or handling area, shall:

1. Wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. After washing, the hands must be sanitized.

2. Remove all insecure jewelry, and when feed is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized or properly covered.
3. If gloves are used in feed handling, maintain them in an intact, clean, and sanitary condition. Such gloves shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved. If gloves are used they will be washed and sanitized at the same frequency as employees' hands as described in number one of this list.
4. Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidentally enter the processing areas shall comply with this requirement.
5. Not expectorate; nor store clothing or other personal belongings; not eat food or drink beverages; nor use tobacco in any form in areas where feed or feed ingredients are exposed, or in areas used for feed processing, storage of feed ingredients and/or packaging materials, washing of equipment and utensils, or in production areas.
6. Take other necessary precautions to prevent contamination of feeds with microorganisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.
7. Using sanitary handling procedures during operations to protect feed against contamination, e.g., picking up dropped feed from the floor.

Deficiency: Serious/Critical

3.4.10 Other areas covered by the CGMPs.

Deficiency: Minor

3.5.0 Handwashing, Hand Sanitizing, and Toilet Facilities

3.5.1 Hand washing and hand sanitizing stations not present or conveniently located.

Hand washing and hand sanitizing stations must be present and located properly and in sufficient numbers to provide employees ease of their use. Devices or fixtures, such as water control valves, shall be so designed and constructed to protect against recontamination of clean, sanitized hands.

Deficiency: Serious (Critical for products at a high risk stage of production)

3.5.2 Improper disposal of toilet waste or sewage.

A facility is in compliance when sewage systems drain properly, are vented to the outside, and are connected to an approved private septic system or a public septic and/or sewage system.

Deficiency: Critical

3.5.3 Inadequate supplies/signs for employees.

The restrooms and hand-washing stations must provide supplies such as toilet paper, soap, waste containers, running water (see 3.2.5), sanitary towel service or suitable drying devices, etc., sufficient to meet employees' needs. Readily understandable signs directing employees handling unprotected feed, feed packaging materials, or feed contact surfaces to wash and sanitize their hands at the proper frequency. Refuse receptacles shall be constructed and maintained in a manner that protects against contamination of feed.

Deficiency: Major/Serious

3.5.4 Insufficient number of functional toilets.

The facility must have one operable, clean, in good repair, conveniently accessible toilet per fifteen (15) employees, per gender. For men, urinals may be substituted for toilet bowls, but only to the extent of one-third (1/3) of the total number of bowls required. Facilities shall be maintained in a sanitary condition with self-closing doors that do not open directly into areas where feed is exposed to airborne contamination, except where alternate means of protection have been implemented.

Deficiency: Major/Serious

3.5.5 Other areas covered by the CGMPs.

Deficiency: Minor

3.6.0 Protection from Adulteration

3.6.1 Condensation or other deleterious sources present.

Adequate physical protection of feed from adulterants that may drip, drain, or be drawn into the feed must be in place. Provide adequate physical protection or separation of feed during processing (filling, packaging, assembling, etc.) to protect from contamination. If any condensation, overhead leaks, water splash or other conditions occur that may result in the adulteration of product or primary packaging material, the facility is in non-compliance for this item.

Deficiency: Critical

3.6.2 Adequate air exchange does not exist.

A facility is in compliance when adequate air exchange exists to preclude the development of foul odors or contamination of product.

Deficiency: Minor (Only for products at a high risk stage of production)

3.6.3 Other areas covered by the CGMPs.

Deficiency : Minor

3.7.0 Proper Labeling, Use, and Storage of Toxic Compounds

Plant chemicals are cleaners, sanitizers, rodenticides, insecticides, feed grade machine lubricants, etc. They must be used according to manufacturer's instructions, have proper labeling, and be stored in a safe manner or they may pose a risk of contaminating the feed product that the establishment is handling or manufacturing.

A facility will be in compliance when the chemicals are used according to manufacturer's instructions and recommendations and stored in an area of limited access away from feed handling or manufacturing. All chemicals must be labeled to show the name of the manufacturer, instructions for use, and the appropriate EPA approval.

Only the following toxic materials may be used or stored in a plant where feed is processed or exposed: a) those required to maintain clean and sanitary equipment and surfaces, b) those necessary for use in laboratory testing procedures, c) those necessary for plant and equipment maintenance and operation, and d) those necessary for use in the plant's operations.

3.7.1 Chemical(s) improperly used or handled.

Deficiency: Critical

3.7.2 Chemical(s) improperly stored.

Deficiency: Serious

3.7.3 Chemical(s) improperly labeled.

Deficiency: Major

3.7.4 Material Safety Data Sheets (MSDS) not available for all chemicals in use at the facility.

Deficiency: Serious

3.7.5 Other areas covered by the CGMPs.

Deficiency: Minor

3.8.0 Control of Employee Health Conditions

3.8.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.

No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a feed plant in any capacity in which there is a reasonable possibility of feed or feed ingredients becoming contaminated by such person. Plant management shall require employees to report illness or injury to supervisors.

Deficiency: Serious

3.8.2 Other areas covered by the CGMPs.

Deficiency: Minor

3.9.0 Exclusion of Pests

The presence of rodents, insects, and other animals in the facility must not be allowed because they are sources for the contamination of feed with foreign material, filth, and bacteria, etc.

3.9.1 Harborage and attractant areas present.

The facility and grounds are free of harborage areas. These include but are not limited to: uncut weeds, brush or tall grass; improper storage of unused equipment or materials; presence of litter, waste and refuse; or standing or stagnant water. All garbage and refuse containers are rodent/insect-resistant and outside storage areas are to be properly constructed. If the plant grounds are bordered by grounds not under the operator's control and these grounds are not maintained in a proper manner with regard to this element, care shall be exercised in the facility to exclude pests that may be a source of contamination by the means outlined in the other areas of this element.

Deficiency: Major

3.9.2 Pest control measures not effective.

3.9.2.1 Exclusion

Openings to the outside of or within the facility may allow vermin or other pests to enter. Openings and cracks should be screened or otherwise sealed. Screens must be of a mesh not larger than 1/16th of an inch in order to exclude insects. Cracks or holes should be sealed and doors and windows should close tightly (no opening larger than 1/4 ") to exclude rodents or other animals. Air curtains and strip curtains must be effective. Air curtains shall comply with National Sanitation Standard Number 37 for Air Curtains for entranceways in feed establishments. Strip curtains must run the entire opening with sufficient overlap between flaps (1/2 inch). In addition, every effort should be made to keep birds from areas of the plant where feed is transferred or processed.

Deficiency: Major

3.9.2.2 Extermination

Birds--Nesting areas must be eliminated.

Insects – There should not be a significant number of insects present in the facility. Insect electrocution devices, when used, must be located near the entranceway. Approved insecticides should be used whenever insect populations become noticeable.

Rodents – There should not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal droppings present; urine stains on bags or walls; slide marks along rodent runways; or feeding areas around stored dry goods bags that may be excessive. The facility should have appropriate rodent control measures in place. If not, the facility is not in compliance.

Deficiency: Major/Serious

3.9.3 Improper disposal of processing waste.

A facility is in compliance with regard to processing wastes when they are placed in proper containers, placed at appropriate locations throughout the plant, and removed frequently.

Deficiency: Serious

3.9.4 Inadequate housekeeping.

Any excess clutter in production areas, employee areas, or other areas of the facility will cause the facility to be in non-compliance. This does not include those areas designated as office areas.

Deficiency: Minor

3.9.5 No written pest control program.

Self-explanatory. Diagrams of bait station locations at the facility shall be maintained and kept available for review.

Deficiency: Serious

3.9.6 Pesticides not applied by a licensed individual.

Self-explanatory. However, in some locations, particularly outside the United States, licensing is not performed. In such instances the application shall be performed by a trained individual.

Deficiency: Serious

3.9.7 Other areas covered by the CGMPs.

Deficiency: Minor

Systems Criteria Rating

Seafood Inspection Program
United States Department of Commerce
Systems Compliance Rating
(REV: March 2021)

Name and Address of Facility Audited	Region
	Facility Number
	Phone Number
	CFN Number
Products Concerned	FAX Number
Auditors	E-Mail
Name and Title(s) of Accompanying Individual(s)	Dates of Audit and Report Delivery

Minor(m) Deficiency: A failure on the part of the system relative to facility sanitation which is not likely to reduce materially the facility's ability to meet acceptable sanitation requirements.
Major(M) Deficiency: A significant deviation from plan requirements, such that maintenance of safety, wholesomeness, or economic integrity is inhibited.
Serious(S) Deficiency: A severe deviation from plan requirements such that maintenance of safety, wholesomeness, or economic integrity is prevented; and, if the situation is allowed to continue, may result in unsafe, unwholesome, or misbranded product.
Critical(C) Deficiency: A hazardous deviation from plan requirements such that maintenance of safety, wholesomeness, or economic integrity is absent; will result in unsafe, unwholesome, or misbranded product.

	EXECUTIVE SUMMARY	m	M	S	C	P
1.0	MANAGEMENT CONTROLS AND RESPONSIBILITIES					-
2.0	FEED SAFETY					-
3.0	SANITATION AND PREREQUISITE PROGRAMS					-
						-
						-
	TOTAL					-
1.0	MANAGEMENT CONTROLS AND RESPONSIBILITIES					
1.1.0	Management Responsibilities	m	M	S	C	P
1.1.1	Management commitment not properly implemented or communicated.					
1.1.2	Feed safety policy not prepared or properly implemented.					
1.1.3	Feed safety management system planning not properly performed.					
1.1.4	Responsibility or authority not properly defined or communicated.					
1.2.0	Feed Safety Team	m	M	S	C	P
1.2.1	Feed safety team leader not appointed.					
1.2.2	Feed safety team leader does not report to top management.					
1.2.3	Feed safety team is not interdisciplinary as applicable.					
1.3.0	Communication	m	M	S	C	P
1.3.1	Effective external communication not established, implemented, or maintained.					
1.3.2	Effective internal communication not established, implemented, or maintained.					
1.4.0	Emergency Preparedness and Response	m	M	S	C	P
1.4.1	Emergency response procedures not established, implemented, or maintained.					
1.5.0	Management Review	m	M	S	C	P
1.5.1	Management review not properly performed or documented.					
1.6.0	Resource Management	m	M	S	C	P
1.6.1	Necessary human resource competencies not identified.					
1.6.2	Personnel have not received documented training necessary for the proper function of the feed system.					
1.6.3	Insufficient infrastructure to implement and maintain the feed safety system.					
1.6.4	Work environment is not properly established, managed, or maintained relative to feed safety.					
1.7.0	Continual Improvement	m	M	S	C	P
1.7.1	Continuous improvement activities not performed.					
2.0	FEED SAFETY					
2.1.0	Operational Prerequisite Programs	m	M	S	C	P
2.1.1	Operational prerequisite programs not present or effective.					
2.1.2	Operational prerequisite programs not followed.					
2.2.0	Hazard Analysis	m	M	S	C	P
2.2.1	Description of products, processes, or control measures not properly performed.					
2.2.2	Hazard analysis not properly performed.					
2.2.3	Hazard analysis not available.					
2.3.0	HACCP Plan	m	M	S	C	P
2.3.1	No written HACCP plan when one is required.					
2.3.2	Plan is not location and/or fish species specific.					
2.3.3	Hazard is not listed in the plan.					
2.3.4	Hazard is not controlled.					

2.3.5	CCPs are not properly identified in the plan.					
2.3.6	Appropriate critical limit is not listed in the plan.					
2.3.7	Critical limits not followed.					
2.3.8	Monitoring procedure stated in plan is inadequate.					
2.3.9	Monitoring procedures not followed.					
2.3.10	Corrective action listed in plan is not appropriate or adequate.					
2.3.11	Corrective action not taken.					
2.3.12	Verification procedure stated in plan is inadequate.					
2.3.13	Verification procedures not followed.					
2.4.0	Control of Nonconformity	m	M	S	C	P
2.4.1	Traceability system inadequate.					
2.4.2	Improper handling of potentially unsafe products.					
2.4.3	Withdrawals or recalls not designed or implemented properly.					
2.5.0	Validation	m	M	S	C	P
2.5.1	Validation activities improperly performed.					
2.6.0	Records	m	M	S	C	P
2.6.1	Inadequate information on records. (Facility name and location, etc.)					
2.6.2	Record data is missing.					
2.6.3	Records are inaccurate.					
2.6.4	Records are not available for inspection.					
2.6.5	Documents or records are falsified.					
3.0	SANITATION AND PREREQUISITE PROGRAMS					
3.1.0	Sanitation Standard Operating Procedures and Prerequisite Programs	m	M	S	C	P
3.1.1	Sanitation Standard Operating procedures or prerequisite programs not present or effective.					
3.1.2	Sanitation standard operating procedures not followed.					
3.1.3	Sanitation not monitored.					
3.2.0	Safety of Process Water	m	M	S	C	P
3.2.1	Unsafe or unsanitary water supply.					
3.2.2	Water potability certificate not current.					
3.2.3	Self water treatment performed improperly.					
3.2.4	No protection against backflow, back-siphonage, or other sources of contamination.					
3.2.5	Inadequate supply of water and hot water.					
3.2.6	Ice not manufactured, handled, or used in a sanitary manner.					
3.2.7	Other areas covered by the Current Good Manufacturing Practices.					
3.3.0	Feed Contact Surfaces	m	M	S	C	P
3.3.1	Equipment and utensils' design, construction, location, or materials cannot be readily cleaned or sanitized; does not preclude product adulteration or contamination.					
3.3.2	Equipment and utensils not maintained in proper repair or removed when necessary. (Feed contact surfaces)					
3.3.3	Feed contact surfaces not cleaned and sanitized before use, after interruptions, or as necessary.					
3.3.4	Concentrations of cleaners and sanitizers are not effective or routinely checked.					
3.3.5	Other areas covered by the Current Good Manufacturing Practices.					
3.4.0	Prevention of Cross Contamination	m	M	S	C	P
3.4.1	Grounds condition can permit contamination to enter the facility.					
3.4.2	Facility					
3.4.2.1	Design, layout, or materials used cannot be readily cleaned or sanitized; does not preclude contamination. Insufficient lighting for the applicable operation.					
3.4.2.2	Insufficient separation by space or other means allows product to be adulterated or contaminated.					
3.4.3	Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.					
3.4.3.1	Areas directly affecting product or primary packaging material.					
3.4.3.2	Other.					
3.4.4	Cleaning methods permit adulteration or contamination.					
3.4.5	Finished product/primary packaging material not properly covered or protected.					
3.4.6	Equipment and utensils not maintained in proper repair or removed when necessary. (Non-food contact surfaces)					
3.4.7	Non-feed contact surfaces not cleaned before use.					
3.4.8	Processing or feed handling personnel do not maintain a high degree of personal cleanliness.					
3.4.9	Processing or feed handling personnel do not take necessary precautions to prevent adulteration or contamination of feed.					
3.4.10	Other areas covered by the Current Good Manufacturing Practices.					
3.5.0	Hand Washing, Hand Sanitizing, and Toilet Facilities	m	M	S	C	P
3.5.1	Hand washing and hand sanitizing stations not present or conveniently located.					
3.5.2	Improper disposal of toilet waste or sewage.					
3.5.3	Inadequate supplies/signs for employees.					
3.5.4	Insufficient number of functional toilets.					
3.5.5	Other areas covered by the Current Good Manufacturing Practices.					
3.6.0	Protection from Adulteration	m	M	S	C	P
3.6.1	Condensation and other deleterious sources present.					
3.6.2	Adequate air exchange does not exist.					
3.6.3	Other areas covered by the Current Good Manufacturing Practices.					
3.7.0	Proper Labeling, Storage, and Use of Toxic Compounds	m	M	S	C	P
3.7.1	Chemical(s) improperly used or handled.					
3.7.2	Chemical(s) improperly stored.					

3.7.3	Chemical(s) improperly labeled.					
3.7.4	Material Safety Data Sheets (MSDS) not available for all chemicals in use at the facility.					
3.7.5	Other areas covered by the Current Good Manufacturing Practices.					
3.8.0	Control of Employee Health Conditions	m	M	S	C	P
3.8.1	Facility management does not have in effect measures to restrict people with known disease from contaminating the product.					
3.8.2	Other areas covered by the Current Good Manufacturing Practices.					
3.9.0	Exclusion of Pests	m	M	S	C	P
3.9.1	Harborage and attractant areas present.					
3.9.2	Pest control measures not effective.					
3.9.2.1	Exclusion					
3.9.2.2	Extermination					
3.9.3	Improper disposal of processing waste.					
3.9.4	Inadequate housekeeping.					
3.9.5	No written pest control program.					
3.9.6	Pesticides not applied by a licensed individual.					
3.9.7	Other areas covered by the Current Good Manufacturing Practices.					

Feed Audit Template

Seafood Inspection Program
U.S. Department of Commerce
National Oceanic & Atmospheric Administration
1315 East West Highway
Silver Spring, MD 20910

REPORT

INFORMATION

Applicant Name:	
Est. (FEI) Number:	
Physical Address:	
Mailing Address:	
Contact & Title:	
E-mail Address:	
Phone Number:	
Auditor(s):	
Audit Date(s):	
Corrective Action Required:	
Audit Type:	
Audit Objective:	To determine if the feed safety system meets U.S. Food and Drug Administration (FDA) requirements (21 CFR part 123 and 21 CFR 507) and if the system meets USDC NOAA Seafood Inspection Program Fishery Byproducts (not for human consumption) requirements.

Audit Criteria:	• 21 CFR part 123 Fish and Fishery Products • 21 CFR 507 (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.) • 21 CFR part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food • 21 CFR 509 Unavoidable Contaminants in Animal Food and Food Packaging Material • Fish and Fisheries Product Hazards and Controls Guidance 4th Edition June 2021 • NOAA Manual 25 Seafood Inspection Program
Audit Scope:	All program requirements, documentation, records, work procedures, and facility operations under the firm's financial and operational control and as referenced in their HACCP plan for the applicable fishery products.

The auditor, an employee of the Seafood Inspection Program of the United States Department of Commerce, was requested to verify the accuracy, validity, and the implementation of the feed safety plan at the [*FACILITY NAME*] facility in [*STATE of COUNTRY*]. The request was made and the audit performed on behalf of the Seafood Inspection Program.

Upon arrival at the firm, the opening meeting was performed by procedure and was attended by the auditor and *[LIST ATTENDEES].* The firm's feed safety plan was received and reviewed. The audit plan included evaluation of the firm's hazard analysis, critical control points (implementation, accuracy, and efficacy), sanitation standard operating procedures, verification procedures, and record keeping. The audit included an evaluation of plant and food hygiene, and final product evaluation. Where possible, observations were verified by interviews, records, photographs, or testing. After gaining all necessary objective evidence, findings were developed and are listed below. A closing meeting was conducted and the audit findings discussed. The meeting was attended by *[LIST ATTENDEES].*

Corrective action is necessary to improve the process or to bring the system back into control. Please provide a written corrective action to the findings listed in the report. Be certain to include both short-term solutions as well as long term more permanent solutions to each issue. *[AUDITOR DISCRETION TO ADD TIME LINE EXPECTATIONS]*

As no findings exist, no corrective action is necessary.

(Keep which corrective action statement above is applicable)

The USDC Seafood Inspection Program conducted an audit on *[FACILITY]* located in *[CITY, PROVINCE, COUNTRY] on [DATE(S) OF AUDIT]*. This audit included an examination of the company's feed safety plan for the receipt, processing, and packaging of *[PRODUCTS and product forms]* and the operation of the plan, including sanitation standard operating procedures, for compliance. Based on this audit we have concluded that the firm is in compliance with NOAA Seafood Inspection Program requirements and applicable requirements and regulations of the U.S. FDA. *[THIS SENTENCE MAY CHANGE DEPENDING ON THE FINDINGS NOTED IN THE AUDIT]*

The USDC Seafood Inspection Program can only provide such attestations on an audit-by-audit basis, as an audit is a picture in time. This report, or any statements therein, is not a certification or approval of a specific lot of product. It is only a report on the viability of the system and the processes in place.

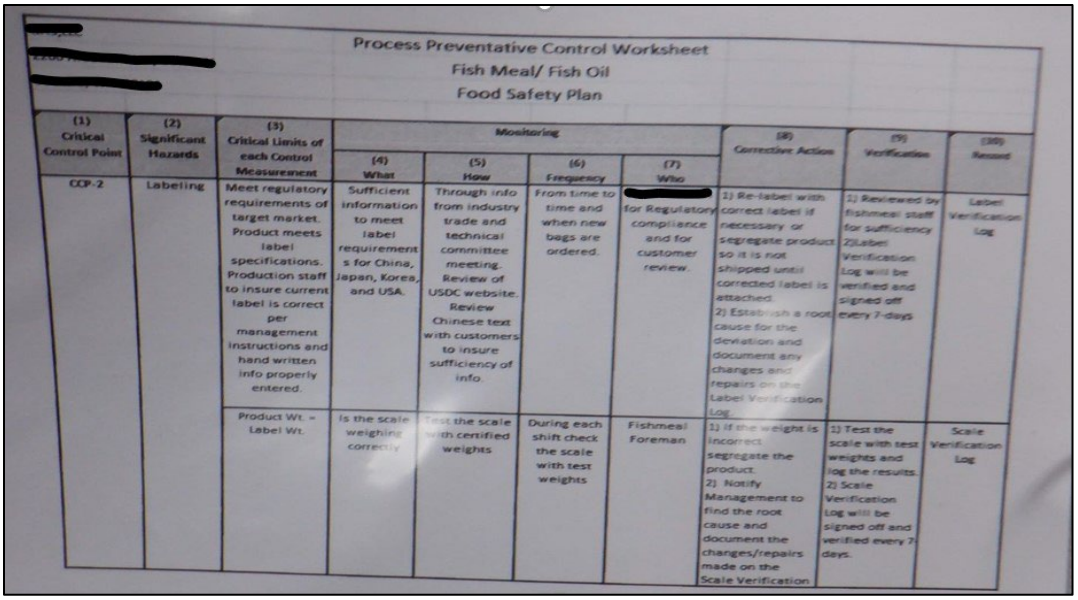
FINDINGS *(LISTED IN ORDER OF SIGNIFICANCE)*

(In this section list out the findings providing sufficient information in which to lead a reader to understand the scope of the issue, the evidence found, and the conclusions of the auditor, including why the decision was made to assess a deficiency or not. An example of a write up is found below. Photographs can be placed in a way to illustrate and define the issue. Be sure to caption the photograph and keep the statements to fact. Justify paragraph margins for the entire report to both sides and keep margins to a minimum of 1 inch.)

Finding 1: Monitoring Procedure Stated in Plan is Inadequate

Monitoring procedures shall be established for each critical limit. The results of monitoring will indicate whether the CCP is reliable. The system shall include all scheduled measurements or observations relative to the critical limit(s). The monitoring system shall consist of relevant procedures, instructions and records that cover the following: a) measurements or observations that provide results within an adequate time frame; b) monitoring devices used; c) applicable calibration methods; d) monitoring frequency; e) responsibility and authority related to monitoring and evaluation of monitoring results; f) record requirements and methods. The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

During the records review, it was noted that the frequency stated in the monitoring procedure of the HACCP plan for the labeling step is not specific: "From time to time and when new bags are ordered" is not adequate to determine monitoring frequency within a feed safety plan. The auditor also notes the person who will be monitoring the labeling step is stated to be: "Jim Smith for Regulatory compliance and for customer review." However, Jim Smith is not present during processing and is unable to monitor the proper labeling of the product. The monitoring procedures stated in the HACCP plan must reflect actual monitoring procedures and frequencies conducted on board the vessel. **2.3.8 – SERIOUS**



Process Preventative Control Worksheet
Fish Meal/ Fish Oil
Food Safety Plan

(1) Critical Control Point	(2) Significant Hazards	(3) Critical Limits of each Control Measurement	Monitoring (4) What	(5) How	(6) Frequency	(7) Who	(8) Corrective Action	(9) Verification	(10) Record
CCP-2	Labeling	Meet regulatory requirements of target market. Product meets label specifications. Production staff to insure current label is correct per management instructions and hand written info properly entered.	Sufficient information to meet label requirements for China, Japan, Korea, and USA.	Through info from industry trade and technical committee meeting. Review of USDC website. Review Chinese text with customers to insure sufficiency of info.	From time to time and when new bags are ordered.	[redacted] for Regulatory compliance and for customer review.	1) Re-label with correct label if necessary or segregate product so it is not shipped until corrected label is attached. 2) Establish a root cause for the deviation and document any changes and repairs on the Label Verification Log.	1) Reviewed by fishmeal staff for sufficiency 2)Label Verification Log will be verified and signed off every 7-days.	Label Verification Log
		Product Wt. – Label Wt.	Is the scale weighing correctly	Test the scale with certified weights	During each shift check the scale with test weights	Fishmeal Foreman	1) If the weight is incorrect segregate the product. 2) Notify Management to find the root cause and document the changes/repairs made on the Scale Verification	1) Test the scale with test weights and log the results. 2) Scale Verification Log will be signed off and verified every 7-days.	Scale Verification Log

Monitoring procedures are inadequately defined in the food safety plan

Remarks: *(include this section if applicable)*

(This section is for those observations that are not significant but should be noted. They do not need to be as prominent as findings, therefore using tables in the document to place text next to any photographs is more appropriate.)

Chapter 6 -Certification

Requests for export certification of aquatic animal by-products not intended for human consumption are processed by the Seafood Inspection Program. Certificates are issued after verification that all U.S. requirements are met along with any specific requirements of the importing country. Certification must be issued prior to export from the U.S.

For certification to China please use the Seafood Inspection Program Online Services Portal (SISP): https://seafoodinspection.nmfs.noaa.gov/customer/customerlogin.html

For export certification to all other destinations please Send the export request form (see below in Additional Resources) to nmfs.nsil.fm.export@noaa.gov.

There are three approaches used for certification

1. End item sampling and testing is required by certain export destinations. In this case, all certification requests must be accompanied by satisfactory lab results performed by NSIL or an approved third party laboratory.

2. NOAA SIP Fishery By-product Approved Establishment based on the system of control at the firm. The system must be validated by a NOAA SIP audit and the collection of verification samples.
3. Annual Consultative Audit Inspection - NOAA SIP audits may be requested to meet country specific export requirements. Under this type of service, a facility receives an audit report that can be used by USDC or other government agencies to verify specific compliance for export certification.

Chapter 7 -Destination Specific Requirements

European Union (EU)

The EU requires facilities exporting fishmeal or oil under Regulations 1069/2009 and 142/2011 to be listed on TRACES. Fishmeal and oil must be produced and shipped from facilities listed on TRACES in order to be imported into the EU. Inclusion of US fishmeal and oil facilities on TRACES requires participation as an Approved Establishment for Fishery By-products in the NOAA Fisheries Seafood Inspection Program, and an approved process validation.

TRACES listing information is available on the EU's website at:

https://webgate.ec.europa.eu/tracesnt/directory/publication/establishment/index#!/search?countryCode=US&sort=classificationSection.translation.

Exporters should have their importers confirm with the pertinent EU border inspection post (BIP) authorities that all requirements for entry of the consignment have been met prior to shipment. This includes verifying that all necessary information (in the interpretation of the BIP related to the specific

materials to be in the consignment) is posted on TRACES and that all required documentation (e.g. export certificates) is available and satisfactory to the BIP. Individual EU countries may have different or additional requirements than EU requirements.

DG Sante

- Proposes legislation on additives, microbiological criteria, colorings, antibiotics, and labeling
- In charge of EU food and feed legislation
- Handles import controls for food and feed
- Includes the Food & Veterinary Office (FVO)

A certificate "for processed animal protein not intended for human consumption," according to the model listed in Regulation 1069/2009 and its implementing Regulation 142/2011 (Chapter 1 certificate), must accompany U.S. exports of fishmeal. For U.S. exporters, NSIL issues this certificate. Fishmeal exports intended for the EU must be produced by EU - approved establishments. The list of U.S. approved animal by-products establishments can be found through the link: ttps://www.fisheries.noaa.gov/national/seafood-commerce-certification/foreign-approved-lists

Shipments of fish oil not intended for human consumption are controlled by different legislations and must be accompanied by a certificate according to the regulation described in Regulation 142/2011 - Chapter 9 certificate - mentioned above. For a complete overview of fish oil import requirements into the EU, see link below:
https://ec.europa.eu/food/sites/food/files/animals/docs/bips_guidance_fish-oil_en.pdf

EU Export Health Certificates for fisheries products not intended for human consumption will only be issued if the product meets the following minimum requirements based upon audit findings of the Seafood Inspection Program.

Minimum EU Export Requirements for Fish Meal:

To meet regulations for export of processed proteins to the EU, the processed animal protein or product must contain exclusively processed animal protein not intended for human consumption that:

- has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Regulation (EC) No 1069/2009;
- has been prepared exclusively with the animal by-products of aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;
- has an approved process validation method 7 in Chapter III of Annex IV to Regulation (EU) No 142/2011 ;
- each lot or consignment has been examined by the competent authority, where a random sample is taken immediately prior to dispatch and found to comply with the following standards:
    - Salmonella: Absence in 25g: n=5, c=0, m=0, M=0
    - Enterobacteriaceae: n=5, c=2, m=10, M=300 in 1 g;
- the product has undergone all precautions to avoid recontamination with pathogenic agents after treatment
- the end product has been packed in new or sterilized bags or transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use which bear labels indicating "NOT FOR HUMAN CONSUMPTION"; and
- The end product was stored in enclosed storage.

Minimum EU Export Requirements for Fish Oil:

To meet the regulations for export of fish oil to the EU, the fish oil must:

- consist of fish oil that satisfy the health requirements below;
- contain exclusively fish oil not intended for human consumption;
- be prepared and stored in a dedicated fish plant approved, validated and supervised by the competent authority in accordance with Regulation (EC) No 1069/2009;
- has been prepared exclusively with fish or other aquatic animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals or animal by-products of aquatic animals originating from plants or establishments manufacturing products for human consumption;
- the fish oil has been subjected to processing in order to kill pathogenic agents and has not been in contact with other types of oils including rendered fats from other animal species;
- the fish oil must be traceable to laboratory analysis indicating compliance with the following standards:
    - *Salmonella*: Absence in 25g: n=5, c=0, m=0, M=0
    - *Enterobacteriaceae*: n=5, c=2, m=10, M=300 in 1 gram.
- is packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination or where bulk transport is intended, the pipe, pumps, and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the product from the manufacturing plant either directly on the ship or into shore tanks or directed to plants have been inspected and found to be clean before use; and
- bears labels indicating “NOT FOR HUMAN CONSUMPTION”

Canada

Canada requires facilities that intend to export animal products and by-products defined as rendered products by CFIA to complete a CFIA facility questionnaire. The purpose of the Questionnaire is to identify ruminants and/or SRM cross contamination risks. An annual on-site audit by the endorsing NOAA SIP is required to verify that the information provided within the questionnaire is complete and accurate as presented. The audit to facilitate issuance of the questionnaire must be done both within 6 months of the questionnaire request and within the same calendar year. The facilities management controls and responsibilities; feed safety programs; sanitation and prerequisite programs will be audited according to the Policies, Procedures, and Requirements for the Approval of Facilities and Systems (available on the SIP website). During the audit, a minimum of 5 verification samples collected randomly from multiple lots of finished product will be collected aseptically by SIP auditors and sent to the National Seafood Inspection Laboratory to test for Salmonella and Enterobacteriaceae.

Please read and follow the instructions found within the CFIA Facility Questionnaire for Animal Products and Animal By-Products (APABP) document and submit the completed questionnaire to the appropriate CFIA office, along with the import permit application required.

http://www.inspection.gc.ca/animals/terrestrial-animals/imports/policies/animal-products-and-by-products/2002-10/facility-questionnaire/eng/1448237170015/1448237170920

> ***Note:*** *No questionnaire is required for fish oil. A completed questionnaire is required for all other commodities listed as "rendered products" within the import policy: TAHD-DSAT-IE-2002-10-10 Animal Health Import Requirements for Raw Inedible Products and Rendered products.*

Directions for completing the Questionnaire:

- The requestor should fill out the latest PDF version of the questionnaire, which can be found in the link above. The requesting firm must provide the questionnaire to the auditor when they arrive at the facility for the audit. Additional copies of the questionnaire can be completed for the cost of $145.00 per copy.
- The facility audit and verification of the information on the questionnaire will be billed by the SIP auditor. This is separate from the completion of the questionnaire which will be finalized and billed by NSIL.
- The auditor will review and verify the information provided on the questionnaire. After verifying the information the auditor will fill out Page 6: Date of annual inspection.
- The auditor does not sign the fields for the full-time, salaried veterinarian or apply a stamp to the questionnaire.
- The auditor will get the following information from the requestor for NSIL to complete and bill for the questionnaire.
    - Bill information
    - Address for completed questionnaire to be mailed to
- The auditor will send the questionnaire, billing information, and forwarding address to the address below via FedEx or UPS. Also notify the NOAA veterinarian via email (NMFS.NSIL.FM.EXPORT@NOAA.GOV) that a questionnaire will be sent.

    National Seafood Inspection Laboratory

    ATTN: NOAA Veterinarian

    3209 Frederic Street

    Pascagoula, MS 39567

- NSIL will review the questionnaire and submit the final bill before the Veterinarian signs, stamp and send the completed questionnaire and any additional copies requested, and a copy of the final NSIL bill to the requestor.

Testing for ruminant protein: For facilities that handle only fisheries products, PCR testing (by a laboratory approved by APHIS or NSIL) for ruminant protein will be required annually. For facilities that handle other animal proteins as well as fisheries products, PCR analysis for ruminant proteins will be required for each shipment of fishmeal to Canada.

Certificate Requirements

All fishmeal, fish oil, and other aquatic animal proteins (used as feed and feed additives) to be exported from the United States to Canada must meet the requirements listed above. A statement indicating “no cross contamination with proteins other than fish” is required on each certificate issued. For facilities that only handle or store fishmeal for export to Canada, certificates may be based upon an USDC annual audit program.

Export certification to Canada for reprocessing and re-export to EU requires the firm must have a current Questionnaire and be listed in traces.

Chile

The export requirement for Chile is a Certificate of Origin. The firm must be in good standing with the U.S. FDA. In addition, if the raw materials are foreign sourced, then the firm must provide Legal Harvest documentation.

Chile does not require an Export Health Certificate. Upon request, export health certification will be provided to SIP Approved Establishments for Fishery By-products.

China

China requires facilities to implement HACCP and have a system to ensure the recall and traceability of products. Products must meet the requirements of the United States and be allowed for free sale. Effective July 1, 2012 all fish meal, fish oil, and other aquatic animal proteins (used as feed and feed additives) to be exported from the United States to the People's Republic of China (PRC) must meet the requirements of General Administration of Customs People's Republic of China (GACC) No. 118 Decree. According to this decree all manufacturing facilities that produce feed and feed additives must be registered with GACC. In order to be registered with GACC, a facility must SIP Approved Establishment for Fishery By-products and be approved to export to PRC. Approval will only be given if all hygiene and quarantine requirements of the PRC for imports of fish oil, fish meal and other aquatic animal proteins are met. Upon approval, the SIP will add the facility to the list of approved facilities provided to GACC.

https://www.fisheries.noaa.gov/national/seafood-commerce-certification/foreign-approved-lists

SIP Requirements:

Facilities wishing to export fish meal, fish oil, and other aquatic animal proteins to the PRC must be a SIP Approved Establishment for Fishery By-products not intended for human consumption and must provide the required laboratory analysis for each shipment.

Certification Requirements

Export certificates for fishery by-product to the PRC will only be issued by SIP if the facility is approved for export based upon compliance with PRC requirements as indicated by audit reports and laboratory testing results including five randomly selected samples (200g of dry product or 8oz of liquid product each) collected from each lot/consignment of product designated for export. The request for inspection and results from third party laboratories must be submitted via email to **NMFS.SI.Fishmeal@noaa.gov** prior to any export documentation being issued. All laboratory results and audit reports will be reviewed by the SIP Regional Office responsible for issuing export certification to verify compliance with all PRC and SIP requirements.

How to obtain certification to China

For certification to China please use the Seafood Inspection Program Online Services Portal (SISP): https://seafoodinspection.nmfs.noaa.gov/customer/customerlogin.html

- Obtain the appropriate laboratory analysis for shipment. Verification that each shipment meets the import country regulations will be done by SIP prior to issuance of the export documentation.
- Obtain and complete the Request for Certification / Fishmeal Exports (available online or from the local SIP inspection office).

- Forward the completed form to: NMFS.SI.Fishmeal@noaa.gov within the same email forward all 3rd party laboratory reports or NOAA/NSIL reports that support the shipment requirements to the destination country. All reports must identify "Lots sampled to the Lots being shipped."
- When submitting the request, make sure to use the following instruction to label the subject line in the email message: Company Name AND Facility FEI Number, country of destination, then use A-Z to mark multiple shipments on a single day. Example: Roberts Fish House, #3014244321, China, A Please make sure to use the correct FEI or CFN # listed officially on the Country of Destination Approved Fishmeal Exporter List
- Allow up to 72 business hours for completion of documentation.
- All certificates will be delivered overnight via UPS unless otherwise noted.

Product Requirements

Raw materials used to produce fish oil, fishmeal or other aquatic animal proteins may be aquatic animals caught in domestic waters or in the open sea; aquaculture animals; or by-products from plants manufacturing aquatic products for human consumption.

Aquatic animals killed for disease eradication cannot be used as raw materials.

The product must not contain any ingredients of non-aquatic animals and must not be contaminated by any products of animal origin from third countries. Products must be subjected to a heat treatment of at least 85C for 15 minutes or other time/temperature combinations that have been validated to be equivalent. Effective measures must be taken to prevent contamination both during and post processing.

Fish oil, fishmeal must not contain hazardous substances which pose a risk to public or animal health and must be in compliance with the safety and hygiene standards listed below. All fish oil, fishmeal or other aquatic animal proteins intended for export to the PRC must be tested and found to be negative for ruminant proteins by PCR or other effective methods. Products for export must meet the following microbiological requirements: Salmonella: Absent in 25 g: n=5, c=0, m=0, M=0, Enterobacteriaceae: n=5, c=2, m=10, M=300 in 1 g.

The end product must be packaged in new, clean, sealed, impermeable, moisture resistant and not easily broken materials and labeled in compliance with standards set by the PRC; or for bulk shipments, the containers or other means of transport should be thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use.

Each shipment must be accompanied with an original export health certificate.

Laboratory Testing Requirements:

Fishery By-product for export to the PRC must be in compliance with the PRC Hygiene standards listed below and be tested at the frequency indicated. These tests may be performed by a third party laboratory that has been recognized by the National Seafood Inspection Laboratory as a laboratory accredited against ISO standards for the specific analyses being performed.

TESTING REQUIREMENTS FOR MEAL:

Test	Criteria	Frequency
Mercury	≤ 0.5 mg/kg	Annually
Cadmium (Cd)	≤ 2.0 mg/kg	Annually
Lead	≤ 10 mg/kg	Annually
Chromium (Cr)	≤ 8 mg/kg	Annually
Arsenic (As)	≤ 10 mg/kg	Annually
Total count of mold	≤ 20000 cfu/g	Annually
Salmonella	Absence in 25 g: n = 5, c = 0, m = 0, M = 0 *	During audits & Each Lot/Consignment
Shigella	Not detected	Annually
Enterobacteriaceae	n = 5, c = 2, m = 10, M = 300 in 1 g (Results may be expressed as CFU/g or MPN/g depending upon method of analysis) *	During audits & Each Lot/Consignment
Total plate count	≤ 2,000,000 cfu/g	Annually
Melamine	≤ 2.0 mg/kg	Annually
Malachite green	Not detected	**
Dioxin	≤ 1.25 ng/kg	Annually

TESTING REQUIREMENTS FOR OIL:

Salmonella	Not detected in 25g; n=5, c=0, m=0, M=0 *	Each Audit
Enterobacteriaceae	n = 5, c = 2, m = 10, M = 300 in 1 g *	Each Audit
Malachite green	Not detected	**
Dioxin	≤ 6.0 ng/kg	Each audit

*** n** = number of samples to be tested; **m** = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m; **M** =maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and **c** = number of samples the bacterial count of which may be between m and M, the samples still being considered acceptable if the bacterial count of the other samples is m or less.

** Not required for wild caught fish. Annually for aquaculture fish.

Note: As long as fish oil has been properly heat treated and processing CCPs are met, microbiological testing is not required for facilities intending to ship to PRC.

Testing for ruminant protein: For facilities that handle only fisheries products, PCR testing (by a laboratory approved by APHIS) for ruminant protein will be required annually. For facilities that handle other animal proteins as well as fisheries products, PCR analysis for ruminant proteins will be required for each shipment of fish meal to the PRC.

Verification Testing and Monitoring: In addition to third party laboratory testing, verification sampling/testing and monitoring will be conducted in Federal Laboratories. The National Seafood Inspection Laboratory (NSIL) will analyze verification samples collected by SIP auditors for microbiological analysis including Salmonella, Enterobacteriaceae, Mold, and Total Plate Count. Test results from the Food and Drug Administration's Feed Contaminants Program, Feed Manufacturing compliance Program, Illegal Drug Residue Program, and BSE/Ruminant Feed Ban Inspections will also be used as additional verification of the safety and wholesomeness of the feed supply.

Japan

Japan export certification requires fishmeal to be produced in a processing plant dedicated only to fishmeal production where no material of animal origin other than fish and shellfish protein of U.S. origin is being processed and the fishmeal must be transported in a manner to avoid commingling with other animal proteins. In addition, export health certification for fishery by-products not intended for human consumption will only be provided to facilities that are NOAA SIP fishery By-product Approved Establishments.

Peru

Peru export certification for fishery by-product requires that the facility produce aquatic animal products **only**. Export health certification for fishery by-products not intended for human consumption will only be provided to facilities that are NOAA SIP fishery By-product Approved Establishments.

In addition, the facility audit scope must determine compliance with the below statements. If the firm ships without export health certification then the audit frequency is reduced to annual.

The fishery by-product

- material is derived only from animals that have never been in any region listed in9 CFR 94.18(A): SEC. 94.18 restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy. See link https://www.ecfr.gov/cgi-bin/text-idx?SID=f82aa5c70f867dbef6169c9299b93e23&mc=true&node=se9.1.94_118&rgn=div8
- were caught and handled on board vessels and were landed, handled and where appropriate prepared, processed, frozen, thawed, packaged, marked, stored and transported hygienically and in compliance with the relevant United States public health standards requirements of the Code of Federal Regulation which have been recognized for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC,
- have satisfactorily undergone health controls and organoleptic, parasitological, chemical, and microbiological checks laid down for certain categories of fishery in compliance with the relevant United States public health standards requirements of the Code of Federal Regulation which have been recognized for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC,
- do not come from toxic species or species containing biotoxins;

Chapter 8 - Sample Collection and Submission of Aquatic Animal By-products (not intended for human consumption) to NSIL for Laboratory Analysis

Note: For questions regarding by-products sample collection and/or submission, please contact:
Judy Stone (228) 762-8964 or
*Johnathan Likens **NSIL.Sample.Custodian@noaa.gov***

Introduction

The USDC Aquatic Animal By-Products Inspection Program is a cooperative effort between the Seafood Inspection Program (SIP) and the National Seafood Inspection Laboratory (NSIL). Surveillance samples of fisheries by-products (not intended for human consumption) are collected from facilities participating in the program and sent to NSIL as verification of the facilities sanitation and HACCP plans. Also, in order to meet federal regulatory and foreign country import requirements, **the collection of samples will be conducted two times a year or within an operation season of product to be certified for export**. This document describes the procedure for submission of fisheries by-product samples to NSIL by SIP inspectors. NSIL will email the results to the CSOs/CSIs collecting the samples and their immediate supervisor and attach to the appropriate row in SmartSheets within 21 calendar days of receipt.

Samples are collected aseptically by SIP inspectors and submitted to NSIL via overnight carrier, U.S. Postal Service, or delivered to the NSIL in person. Samples submitted to the NSIL for bacteriological analyses provide a level of assurance regarding the absence or amount of certain possible hazards that may be associated with the production of aquatic animal by-products. All samples are analyzed for *Salmonella* and Enterobacteriaceae. Once a year, samples from each facility participating in the program are also analyzed for Total Plate Count, Yeast & Mold and ruminant proteins. The objective for the CSOs/CSIs is to obtain a representative sample of the product present at the time of the audit using care and techniques to avoid sample contamination by microorganisms during the sampling procedures.

CSOs/CSIs should be familiar with aseptic sampling techniques through previous training, i.e. FDA satellite downlink video entitled "Food Microbiological Control" and review these techniques prior to collecting samples. The Technical Services Branch Training Section has made these videos available to the field offices. Appropriate measures must be taken to prevent any sample contamination and microbial growth or death during the handling, storage and transport of the samples to the laboratory. Specific sampling technique questions should be directed to the NSIL.

CSOs/CSIs should observe all safety precautions implemented by the facility when collecting samples and all other safety regulations of the Seafood Inspection Program. All samples shipped to NSIL should be shipped following any relevant Department of Transportation regulations.

General Directions and Supplies

The supervisory offices in each Region will purchase and store the items necessary to collect samples as well as sterile bags/jars to ship samples to NSIL. For sampling of liquid products such as fish oil, the company may need to supply sampling equipment to collect samples from large containers or tanks. The CSO/CSI should make sure that all sampling equipment is sanitized appropriately before use.

Standard or typical items needed for aseptic sampling include:

Sterile Containers - Sterile single use whirl-pak bags, jars or other suitable vessel capable of holding at least 200g of dry product or 8oz of liquid product each for shipping samples. (New, non-sterile jars for fish oil collection may be used if no other are available).

Collecting Equipment - Sterile scoops, sterile gloves, sterile probes, or other suitable sample collection tools, sterile knives or scalpels, disposable sterile scalpel blades.

Shipping Boxes

Plastic Bags – Plastic bags for packing each lot of samples and for collecting trash during sampling.

Labels and marker – Permanent markers and waterproof labels

Sterilizing agents – Alcohol wipes, other disinfectant wipes, solution for sanitizing hands or surfaces, alcohol container with screw-type lid with isopropyl alcohol

Sample Numbers and Sample Sizes

Verification Samples: Verification samples are collected at each audit where finished product is available. A minimum of 5 random samples **(200g of dry product or 8oz of liquid product each)** must be collected. The samples should be representative of the product available at the facility.

Lot Samples: Five randomly selected samples **(200g of dry product or 8oz of liquid product each)** are collected from each lot/consignment of product designated for export.

Sample Collection

Prior to sample collection, the responsible company representative should be notified of the intent to collect samples and be told why it is a necessary verification aspect of the program. The CSO/CSI should offer to take duplicate samples for the company.

After requesting to sample product, the CSO/CSI should make sure that all sample collection equipment is available; should don clean protective clothing such as a lab coat, hat or hairnet; and wash and sanitize hands.

Bulk Product: When sampling product stored in bulk, samples should be representative of the finished product in the warehouse/storage container or specific lot to be tested. For dry, bulk product, using a sterile scoop, scrape the surface (approximately 6 inches) of dry product away to allow access to product a few inches into the pile. Collect product from the designated area and place in a sterile sampling container. The sample collection location should be recorded on the warehouse map provided by the company or designated by the CSO/CSI. A new sterile scoop and sample collection container must be used for each sample collected. If possible, for liquid products stored in bulk, samples should be collected using sampling devices provided by the company. If suitable sterile sampling devices are not provided, the CSO/CSI should make arrangements to order appropriate disposable sterile sampling equipment for the tank or vessel holding the liquid.

Packaged Product: If possible, samples should be collected of finished product prior to bagging or packaging. If collecting samples in storage, collect from different pallets and pallet locations. When collecting samples “on-line” , pre-label the sterile containers and have “on-line” personnel place the sample from the line into the sterile container without touching the inside of the container. On completion of filling, the sterile container should be closed and stored as appropriate. If product material is not available before packaging, the CSO/CSI must collect the required number of samples aseptically. Randomly collect the required number of larger packages from the storage area and move them to a clean location, such as the QC lab. Place the package upon a previously cleaned and sanitized counter top. The package surface to be opened should be wiped with an alcohol wipe to remove surface contamination. Carefully open the cleaned area of the package with a sterile knife or scalpel. Remove product using sterile gloves or scoops and place in sterile sample bags. Care should be taken to avoid contact of the product with the outside of the container or non-sterile handling equipment. After filling the collection container, promptly seal it to avoid contamination. Place all sample bags collected

from the facility or a specific lot of product into a separate large plastic bag prior to shipping. Gloves and knives or scalpel blades and collection equipment should be changed between each sample being collected. Prepare samples for shipment to the laboratory and return the opened packages to the processing line or responsible company personnel.

NOTE: *Due to the changing types of aquatic animal by-products requiring microbiological analysis, the sample collection guidelines listed here may not be suitable for all types of samples and all storage conditions. It is advisable to discuss the storage conditions of the product and determine the appropriate sampling equipment needed prior to the audit. Contact NSIL if there are questions concerning how to collect the samples.*

Labeling Sample Containers

Labels should be filled out prior to sampling with the following information:

a. Company name
b. Product lot/code number
c. Sample number
d. Sample Date
e. Name of individual collecting samples

If sample containers are "write-on" sterile plastic bags, this information can be written directly on the bags without using labels.

Information Form

The individual collecting the samples must completely fill out the National Seafood Inspection Lab Sample Information Form for Aquatic Animal By-Products Not Intended for Human Consumption using the following instructions:

Company Information

Company Full Name: Write the company's full name (include vessel or plant name if applicable) as it appears in the USDC Approved Establishments. If the company does not appear in the list, write the company's full name so that it will appear correctly in the NSIL database.

Company Contact's Full Name: The company contact should be the company's contact to address any questions concerning the samples collected.

Company Location Address: Write the **facility's physical sampling location** address as written in the USDC Approved Establishments. If not on the list, write the address of the specific facility location from which the samples were collected.

Company Contact's Title, Phone Number and email address: Questions concerning the sample and laboratory results will be submitted to the CSO/CSI collecting the samples, but we would also like to have the contact information for someone at the company from which the samples were collected.

Full Name and Signature of Company's Representative Acknowledging Samples were collected for Analysis: Print the name and have the individual from the company that is present during the sampling sign the form to acknowledge that samples were collected.

Product Information

Product State (√): Indicate the condition of the sample when it was shipped to NSIL.

Reason for Sample Submission (√): Indicate the reason for sample submission such as audit/surveillance, lot/export certification, or other.

Product's Full Description: Provide as much information about the product as possible including the type (fish meal, fish oil, frozen fish scrap, etc.).

Product Packaging (√): Place a check mark next to the appropriate packaging.

Ingredient Statement (or attach label to back of information form): Include all ingredients listed.

Pack Date: Indicate the date the product was packaged.

Lot Size: Indicate units of mass (i.e. kg or MT)

Lot Number(s): It is important that the lot or code numbers provided allow trace back of the product in case the submitted samples fail analysis.

Sample Information

Sample Date: Include the date the sample was collected.

Sample Size: Indicate the number of sub sample provided.

Sample Unit: Indicate the approximate number of grams of dry product or ounces of liquid product collected of each sample **(200g of dry product or 8oz of liquid product)**.

Name of CSO/CSI's Immediate Supervisor: Write the name of your immediate supervisor. If a submitted sample fails analyses, it is the laboratory's responsibility to contact the supervisor in order that he/she can take appropriate action.

Immediate Supervisor's Telephone/email address: Write your immediate supervisor's telephone and email address. If a submitted sample fails analyses, it is the laboratory's responsibility to contact he supervisor via telephone and to forward analytical results via fax or email in order that he/she can take appropriate action

Full Name of CSO/CSI Collecting Samples: Write your full name.

CSO/CSI's Telephone/email address: Include your telephone and email address so that we can contact you if there are questions about the samples.

Signature of CSO/CSI Collecting Samples: Sign the form to indicate that you collected the samples and that the information on this form is accurate.

Packing Samples and Shipping Containers

Samples to be shipped to NSIL should be packed by the CSO/CSI collecting the samples. If samples are shelf-stable, they can be shipped at ambient temperature in a sealed box or suitable container. If samples require refrigerated or frozen storage, they should be held under these conditions and packaged with gel packs or dry ice to maintain appropriate temperatures during transport.

When possible, samples should be shipped to the NSIL via overnight carrier or some other means to assure a timely delivery to the NSIL.

Prior to shipping samples to NSIL, please notify the Sample Custodian via email NSIL.Sample.Custodian@noaa.gov or call 228-762-8964 that you will be shipping samples.

All samples should be shipped to:
Sample Custodian
National Seafood Inspection Laboratory
3209 Frederic Street
Pascagoula, MS 39567

ADDITIONAL RESOURCES

A list of FDA Regional Laboratories may be found at http://www.fda.gov/ICECI/Inspections/IOM/ucm124067.htm.

Verification testing for aquatic animal diseases and BSE will be done by USDA/APHIS approved laboratories http://www.aphis.usda.gov/animal_health/lab_info_services/approved_labs.shtml and http://www.aphis.usda.gov/animal_health/nahln/labs.shtml.

NOAA SIP website access to foreign approval lists https://www.fisheries.noaa.gov/national/seafood-commerce-certification/foreign-approved-lists

ATTACHMENTS

National Seafood Inspection Lab Sample Information Form for Aquatic Animal Products Not Intended for Human Consumption.

NATIONAL SEAFOOD INSPECTION LAB
SAMPLE INFORMATION FORM

For Aquatic Animal By-Products Not Intended for Human Consumption

Prior to sending samples, please send a copy of this form to:
NSIL.Sample.Custodian@NOAA.gov
3209 Frederic Street
Pascagoula, MS 39567
Phone (228) 762-8964

COMPANY INFORMATION

Company's **Full** Name including vessel or plant name (if applicable):	Company Contact's **Full** Name:(Dr./Mr./Mrs./Ms.)

Facility's physical sampling location where the samples were pulled:

City: State: Zip Code:

Company Contact's Title:	Phone Number:

Company Contact's email address:

Full Name and Signature of Company's Representative Acknowledging Samples Collected for Analyses:

Full Name _____ Signature _____

PRODUCT/SAMPLE INFORMATION

Product State (√): ___Fresh ___Frozen ___Shelf-Stable ___Other

Reason for Sample Submission (√): ___Audit/Surveillance ___Lot Inspection/Export Certification ___Other

Product's **Full** Description:

Product Packaging (√):
_____Bag _____Tote _____Box _____Can _____Jar _____Bulk _____Other

Ingredient Statement (or attach label to back of information form):

Product Pack Date (mm/dd/yy):	Lot Size (kg or MT):	Lot Number(s):

Sample Date (mm/dd/yy):	Sampled (√): _____On-Line _____In-Storage

Sample Size (Number): _____5 _____6 _____9 _____10	Sample Unit:_____ Grams or Ounces

Name of CSO/CSI's Immediate Supervisor:	Immediate Supervisor's Contact Information: Phone: Email:
Name of CSO/CSI Collecting Samples:	CSO/CSI's Contact Information: Phone: Email:
Signature of CSO/CSI Collecting Samples	Comments:

NATIONAL MARINE FISHERIES SERVICE
NATIONAL SEAFOOD INSPECTION LABORATORY

EXPORT CERTIFICATE INFORMATION

Production/Storage Information	
Name & Address of Producer:	Name & Address of Storage Facilities: (List all facilities where product was stored or handled prior to export)
Type of Product: Fish Meal _____ Fish Oil _____ Fish Solubles _____ Frozen Fish _____ Fish Bones _____ Other _____	
Lot Number(s):	
Date(s) of Production:	
Country of Origin:	
Shipping Information	
Name & Address of Consignor: Contact Person: Phone:	Name & Address of Consignee: Contact Person: Phone:
Port of Export:	Shipped To:
Shipped Via: Truck _____ Ship _____ Airplane _____ Other _____	
Name of Export Vessel/Trucking Company/Airline Information:	
Estimated Departure Date:	
Entry BIP in EU (for EU shipments only):	
Total Marked Weight:	
Type of Container(s) (Packages):	
Number of Containers/Packages:	
Container/Seal Numbers: (attach additional pages, if needed)	
End Use of Product:	
Billing Information	
Billing Address:	
Name and Address where certificate should be sent: (Include UPS Account Number and Billing Zip Code)	