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

Contents

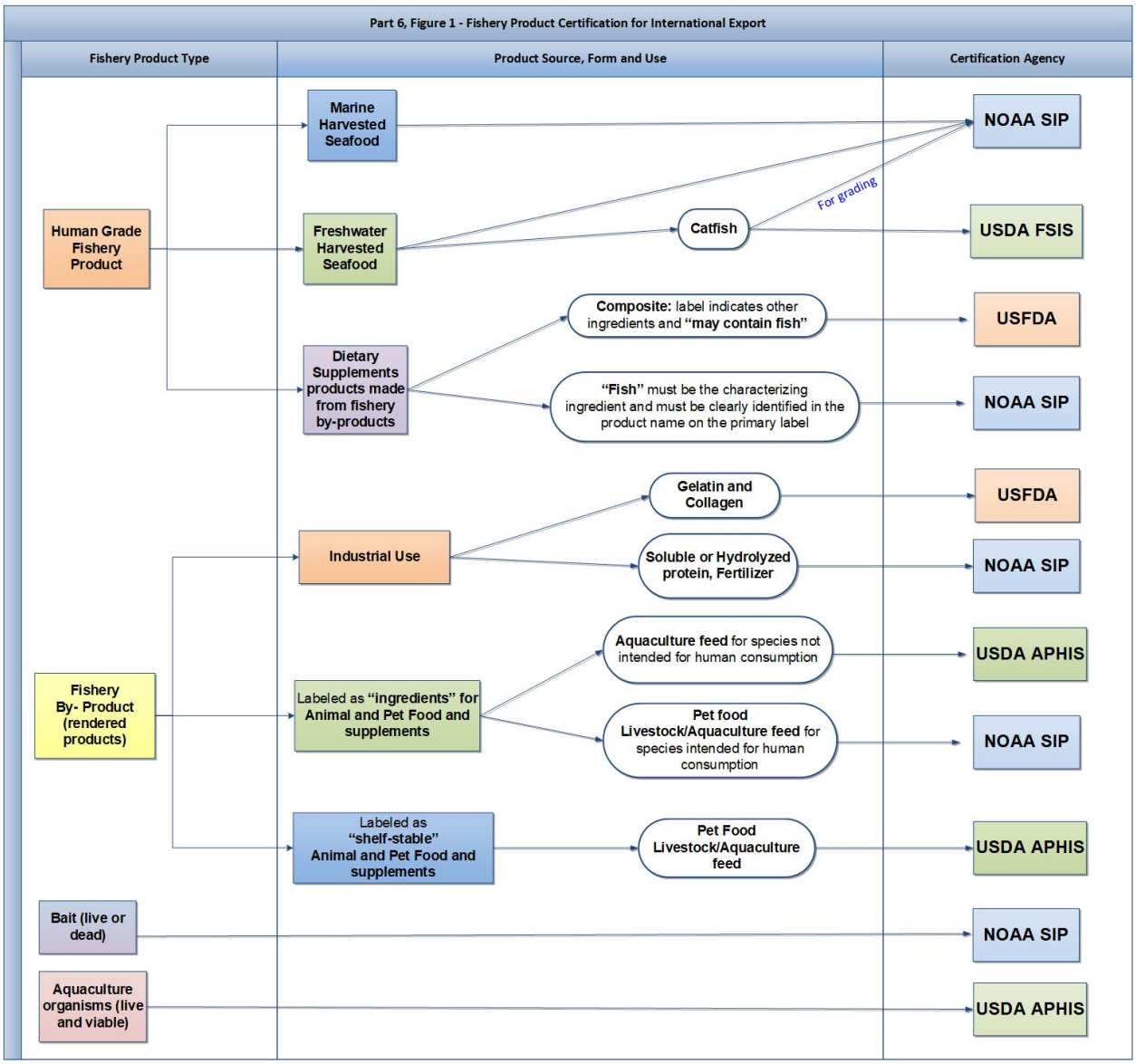
Chapter 1 - Authority

Authority for the Seafood Inspection Program of National Oceanic and Atmospheric Administration (NOAA) Fisheries, U.S. Department of Commerce (USDC) to provide these services can be found within the Agricultural Marketing Act of 1946, the Fish and Wildlife Act of 1956, and the regulations promulgated under these authorities (i.e., 21 CFR 507 and 509, 50 CFR Part 260).

Chapter 2 - Introduction

The NOAA Fisheries Seafood Inspection Program (SIP) offers several types of inspection and product certification services on a fee-for-service basis for the processing and trade of 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 and regulatory changes, SIP has expanded its services to include assistance in the control of additional hazards associated with rendered fishery by-products, such as fishmeal, krill meal, bone meal, fish oil, frozen fish by-products, hydrolyzed fish proteins, and fish solubles. NOAA's National Seafood Inspection Laboratory (NSIL) in Pascagoula, Mississippi, works together with SIP to offer testing of fishery by-products. NSIL is an accredited ISO 17025 analytical laboratory and provides testing services including for bacterial pathogens, chemical contaminants, and other health hazards to meet country specific import requirements.

Innovation has sparked the development of novel uses for fishery by-products, especially as a source of protein in animal feed and industrial products. As a result, export certification may involve multiple agencies. The figure below represents a decision-tree designed to aid in identifying the fishery product certification scope of the various U.S government agencies.



Chapter 3 - Terms and Definitions

The following terms used in this Part of the NOAA SIP Inspection Manual are defined as follows:

Rendered Fishery By-products include the following:

- **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 fish during the production of fish meal.
- **Bone Meal** is a mixture of finely or 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 heat processed, ground, dried Krill,(a small shrimp like crustacean), that is used as a specialty feed ingredient.

- **Hydrolyzed fish proteins** are 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). Example, salmon protein concentrate.
- **Collagen** is the bioavailable protein derived from fish skin, scales, and bones.
- **Gelatin** is a form of collagen made by boiling animal bones, cartilage, and skin for several hours and then allowing the liquid to cool and set. The breakdown of these connective tissues produces gelatin.

Chapter 4 - Program Requirements for USDC Approved Establishments Producing Fishery By-Products

In accordance with 21 CFR 123, 507 and 509 and NOAA Handbook Parts 2 (Policies and Procedures for System Audits) and 3 (Policies, Procedures and Requirements for the Approval of Facilities and Systems), the following apply to fishery by-products not intended for human consumption:

1. The firm must be a USDC NOAA SIP Approved Establishment (AE) for Producing Animal Foods in good standing and appear in the USDC Approved Establishments document under the section titled "Establishments Approved for Producing Animal Foods".
2. USDC Approved Establishments must be audited and in compliance at a minimum of every 6 months or twice during an operation season.
    - for AE that process both human grade and by-products, audit trips should be designed in advance to combine sampling efforts (i.e., sample fishery products and by-products)
3. During the audits, appropriate samples must be collected by an SIP inspector and tested by NSIL, and results uploaded into SIP's internal data system.
    - More frequent sampling and testing may be required depending on country specific requirements. See Chapter 8 in this Part for more details on sampling.
4. In the case of storage facilities not on the Approved Establishment list, an "Annual Consultative Audit Inspection" can be requested to meet country-specific export requirements. Under this type of service, a firm receives an audit report that can be used by USDC or other government agencies to verify specific compliance for export certification.

Chapter 5 - System Compliance Rating Criteria for Fishery By-product (not for human consumption) facilities.

The following are criteria and deficiency descriptions applicable to facility management controls and responsibilities; feed safety programs; sanitation and prerequisite programs; and quality systems:

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 the 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. Training received must fulfill the requirements outlined by 21 CFR part 123.10. In addition, copies of all trained personnel's certificates must be 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 measures 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 workstation, 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 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

Chapter 6 – Validation Process for the European Union (EU)

The following section refers to the requirements for approval of a facility to export fish meal, fish oil, and other animal by-products to the European Union in Regulation (EC)No. 1069/2009 and Commission Regulation (EC) No 142/2011. Prior to issuing an approval for a processing plant/facility for export of animal by-products to the EU, the competent authority (i.e., NOAA Seafood Inspection Program) must check that a validation of the processing plant has been carried out by the operator in accordance with specific procedures. **NOTE: Please submit the proposed sampling protocol to the National Seafood Inspection Laboratory (NSIL) for approval before beginning the validation. Protocols should be emailed to nmfs.nsil.fm.export@noaa.gov. See package requirements at the end of this chapter.**

Overview of EU Process Validation

Specific processing requirements for processing of Category 3 material can be found in Chapter II, Section 4 of Annex IV of Commission Regulation (EC) No. 142/2011. These requirements include the following:

1. The critical control points that determine the extent of the heat treatments applied in processing shall include for each processing method as specified in Chapter III:
    a. Raw material particle size;
    b. Temperature achieved in the heat treatment process;
    c. Pressure, if applied to the raw material;
    d. Duration of the heat treatment process or feed rate to a continuous system. Minimum processing standards must be specified for each applicable critical control point.
2. In the case of chemical treatments which have been authorized by the competent authority as processing method 7 in accordance with point G of Chapter III, the critical control points that determine the extent of the chemical treatments applied shall include the pH adjustment achieved.
3. Processing records shall be maintained for at least two years to show that the minimum process values for each critical control point are applied.
4. Category 3 material shall be processed in accordance with any of the processing methods 1 to 5 listed in the regulation or processing method 7, or, in the case of material originating from aquatic animals, with any of the processing methods 1 to 7, as referred to in Chapter III.

Standard processing methods approved by the EU are found in Chapter III of Annex IV of Commission Regulation (EC) No 142/2011. If a facility chooses to use method 7 (i.e., any method that differs from methods 1-6), the process must be validated by demonstrating the following:

- The identification of relevant hazards in the starting material, in view of the origin of the material, and of the potential risks in view of the animal health status of the Member State or the area or zone where the method is to be used;
- The capacity of the processing method to reduce those hazards to a level which does not pose any significant risks to public and animal health;
- The sampling of the final product on a daily basis over a period of 30 consecutive production days in compliance with the following microbiological standards;
- Details of the critical control points under which each processing plant satisfactorily complies with the microbiological standards must be recorded and maintained so that the operator and the competent authority can monitor the operation of the processing plant. The information to be recorded and monitored must include the particle size, and, as appropriate, the critical temperature, the absolute time, pressure profile, raw material feed rate and fat recycling rate.

Sampling Protocol for EU Process Validation:

The analytical sampling of product required by the EU is two-fold which requires samples to be collected immediately after the heat treatment/critical control point and tested for *Clostridium perfringens*. Additional samples are to be collected during or upon withdrawal from storage and tested for *Salmonella* and Enterobacteriaceae.

1. **Immediately after the Critical Control Point**
   In order to meet the EU process validation requirements, samples must be collected as soon after the heat treatment as feasibly possible (may vary according to individual processing methods, plant design and equipment). One sample should be collected each day for a total of 30 production days and tested for *Clostridium perfringens* ***(All 30 samples to be analyzed individually – Do not composite)***

2. **During or upon withdrawal from storage**
   Five individual samples must be collected on each of 30 days during storage and tested for Enterobacteriaceae and *Salmonella****. (All 150 samples to be analyzed individually – Do not composite)***

Package Requirement for NSIL Review

Approval of a firm's process requires a complete validation package submitted to NSIL for review. Please contact NISL (**nmfs.nsil.fm.export@noaa.gov**) prior to beginning validation. The package should include the following:

- A copy of your process flow diagram including Critical Control Points (CCPs) and processing times and temperatures,
- Particle size of product entering cooker/dryer and how measured
- Processing temperature and processing rate for each of the 30 days
- How processing temperature and minimum time are monitored
- Corrective actions to be taken when deviations from processing times and temperatures are observed
- Sampling Protocol during Validation Study including:
  a. How the samples were collected
  b. Date each sample was collected
  c. How each sample can be traced back to process batch/production day
- Laboratory results table should include the following:
  a. Sample location
  b. Date collected
  c. Identification number of the sample that can be traced back to processing date and time
  d. Processing date
  e. Laboratory results (Enterobacteriaceae*, Salmonella, Clostridium perfringens*)

The validation package should remain at the processing facility and be available for audits by the Seafood Inspection Program auditors or EU auditors. At least two years of processing

records should also be available for auditors to verify methodology for validation. Any changes to the processing method including equipment changes will require a new validation.

Chapter 7 – General Instructions for Certification

Certificate Requests

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

- **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 completed export request form (see appendix below) in PDF format to nmfs.nsil.fm.export@noaa.gov. Export certificate requests must be submitted before the consignment departs the US.
    1. All sections of the request form must be complete and accurate. Certificates will not be issued for incomplete request forms.
    2. The stamp date on the certificate is the date the request form is received by the SIP.

Unless otherwise indicated for a specific destination, general export health certification for rendered product not intended for human consumption will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products, are in good standing with program requirements, and have had their product tested within the last 12 months

Instructions for Certificate Numbering

These instructions establish and implement procedures that will assure national uniformity in the numbering of certificates.

I. Export Certificates:
Use two character country ISO codes at the following link.
http://www.iso.org/iso/english_country_names_and_code_elements

II. Domestic Certificates:
Use 2-character country code “US”.
III. Enter Four-Digit Inspector/Officer number.
IV. Enter Five-Digit numerical reference number starting new with each inspector/officer. Each inspector/officer would begin with 00001 and proceed in numeric order until reaching 99999, then begin again at 00001.
V. Enter 2-digit year code.
VI. Add extension “RP” to the end of the numbering sequence, preceded by a dash.

*****A PERIOD (.) SHOULD BE ADDED BETWEEN THE BEGINNING 2 LETTERS, THE INSPECTOR NUMBER, THE 5-DIGIT NUMERIC REFERENCE NUMBER AND THE 2-DIGIT YEAR CODE*****

Example: CR.4023.00001.23-RP. This is a sample of a Southwest region export certificate for rendered products to Costa Rica issued by Officer 4023 in 2023.

Certificate Superseding

Effective April 1, 2019, certificates may be superseded for previously certified product that has left the US to rectify certificates that have been for example, lost, damaged, contain errors, or where the original information is no longer correct. These supersede certificates must be clearly marked to indicate that they are replacing the original certificate. A supersede certificate shall reference the number of the original certificate that it supersedes and the date the original was signed.

Management requirements

- Regional SIP supervisory staff is expected to do random verification of issued supersede certificates to ensure policy effectiveness and implementation. Supersede certificates issued through the Seafood Inspection Services Portal (SISP) provide a "supersede values" page which documents any changes.
- If a replacement certificate is issued in deviation from written policy, SIP supervisory approval is required. A log shall be kept documenting reasons for deviation and corrective action taken.

Scenarios where a supersede may be appropriate

- A split load under the following conditions: If a shipment is split into two or more certificates, the species cannot change and the total net weight of all new certificates must be less than or equal to the original net weight of the one certificate. There is a limit of one time supersede per consignment for this issue, any requests beyond that must be routed through HQ.
- Change of country. Note: If this is ***from*** outside EU ***to*** an EU country, then the customer assumes the risk of possible rejection of the shipment.
- Change of consignee.
- Change of processor if within the parent company only (EX. Listed processor changes from one vessel or plant to another vessel or plant that is owned and operated by the same company). NOTE: Change of Processor is NOT allowed for EU certificates.
- Minor typographical errors. In particular, EU will accept minor changes to container/seal number but not an entire container/seal number change.
- For changes in logistics (EX. port, shipping vessel name).

Scenarios where a supersede is not appropriate

- USDC will not supersede shipments that have been accepted at a foreign border inspection post. It is the customer's responsibility to work with the 'landed' country (NEW COMPETENT AUTHORITY) for continued export.
- Seal number change.
- To convert multiple certificates into fewer (EX. combining the contents of 2 certificates onto 1 certificate).
- Amend additional product or weight values.
- To change the country of origin of the product.
- Product changes for species, including common name, type code, intermediate code or end product code.

- Product that has not departed the US will have the original certificate voided and a new certificate issued.

Chapter 8 - Destination Specific Requirements

European Union (EU)

The following are requirements in accordance with the Commission Regulations (EC) No. 1069/2009 and Commission Regulation (EC) No 142/2011:

1. The EU requires facilities exporting fish meal or oil (including storage facilities) to be listed on TRACES. Inclusion of US fish meal and oil processing facilities on TRACES requires participation as an "Approved Establishment" for Fishery By-products under the NOAA Fisheries Seafood Inspection Program, and an approved Process Validation as described in Chapter 6 of this Part.

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

2. The EU requires exporting firms and storage facilities to have completed an audit and surveillance sampling and provide NSIL with the following documentation for verification:
   a. For dried rendered fishery by-products (fish meal, krill meal, bone meal etc.):
      i. process validation for that specific commodity, an audit and surveillance sampling that has been conducted within the last 12 months, and lot-specific testing
      ii. each lot or consignment has been examined by the competent authority, where a random sample is taken immediately prior to dispatch (within 60 days of departure) and found to comply with the following standards:

1. *Salmonella*: Absence in 25g: n=5, c=0, m=0, M=0
2. Enterobacteriaceae: n=5, c=2, m=10, M=300 in 1 g;

iii. each lot or consignment has undergone testing to ensure that it contains no products of ruminant origin.

iv. laboratory reports that support the shipment requirements to the destination country must identify "Lots sampled to the Lots being shipped."

b. For oil (fish oil, krill oi) and fish solubles, Salmate®, salmon protein concentrate l) - a process validation for that specific commodity, a current audit, and samples submitted to the NSIL within the last 12 months that meet the same Salmonella and Enterobacteriaceae requirements identified above for dried animal by-products.

c. For frozen animal by-products - an audit has been performed within the last 12 months to verify requirements for hazards and sanitation controls and HACCP are met.

3. 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.

4. Certification of ingredients (including frozen aquatic animal by-products) for the manufacture of pet food is done using the EU Chapter 3(F) certificate (For animal by-products for the manufacture of pet food, intended for dispatch to or for transit through the European Union). The minimum requirements are as follows:

a. Animal by-products must have been obtained in the United States from animals killed in the wild in an area:

i. In which within 25 km there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot-and-mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days; and

ii. That is situated at a distance that exceeds 20 km from the borders separating another territory of a country or part thereof, which is not authorized at these dates for exporting this material to the European Union; and

b. Have been obtained and prepared without contact with other material not complying with the conditions required above, and it has been handled so as to avoid contamination with pathogenic agents
c. Have been packed in new packaging preventing any leakage and in officially sealed containers bearing the label indication "RAW MATERIAL ONLY FOR THE MANUFACTURE OF PET FOOD' and the name and address of the EU establishment of destination
d. Consists only of animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption
e. Have been deep-frozen at the plant of origin or have been preserved in accordance with EU legislation in such a way that they will not spoil between dispatch and delivery to the plant of destination.

5. **Minimum Requirements for animal by-products to be used for purposes outside the feed chain or for trade samples is done using the EU Chapter 8 Certificate (For animal by-products to be used for purposes outside the feed chain or for trade samples intended for dispatch to or for transit through the European Union).**

   Laboratory samples or small quantities of aquatic animal by-products that are intended to be used as laboratory or trade samples and will not be consumed, may be certified using this certificate and the product must bear the label "TRADE SAMPLE NOT FOR HUMAN CONSUMPTION"

6. **Minimum Requirements for processed aquatic animal by-products that will be used as ingredients in further processed products that will be exported to the EU**:

   If aquatic animal by-products are sold to facilities in the U.S. or Canada and will be used as an ingredient in pet food or animal feed for export to the EU, the product must meet the same requirements as those intended for export to the EU. The EU certificate for the finished pet food or animal feed will not be issued by NOAA, but if the ingredients are produced in U.S. facilities as an Approved Establishment for Fishery By-products under in the NOAA Fisheries Seafood Inspection Program, NSIL will provide the necessary attestations for the aquatic animal by-product ingredients that can then be used by the competent authority issuing the certification of the finished product.

Australia

Australian export health certification for rendered product not intended for human consumption will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products, are in good standing with program requirements, and have had their product tested within the last 12 months

The export certificate will contain the following general certificate statements:

1. During the course of commercial manufacture, the product is heated for such times and temperatures so as to preclude the survival of Salmonella and Enterobacteriaceae.
2. The physical plant design is such to preclude contamination of final product with raw fish.
3. The processing, handling, and storing of the product is in accordance with U.S. requirements for aquatic animal by-products promulgated by the U.S. Department of Commerce.
4. This product is free of meat, blood and bones originating from mammals.

Additionally, the certificate will further state:

1. The product does not contain any material derived from plants or algae (including microalgae).
2. Raw (fish species name) are processed in indirect steam cookers.
3. All products are cooked at a minimum temperature of 185°F/85°C.
4. All products have a retention time in the cooker at a minimum of 15 minutes.
5. Products are handled in a way as to not expose them to contamination after processing.
6. Products are packed in clean and new packaging.
7. Raw materials for these products have not been derived from terrestrial animals or avians. This includes egg products, dairy products, and feathers.
8. Raw materials for these products have not been derived from fish of the family Salmonidae (i. e. salmon, trout, or related species).
9. Raw materials for these products are derived from (scientific name of fish species).

Canada

Annex 3 Canadian Food Inspection Agency (CFIA) Facility Questionnaire: An *Annex 3 CFIA Facility Questionnaire for Export of Rendered Products to Canada* (CFIA Questionnaire) must be completed by any facility that wishes to export rendered fishery by-products to Canada in accordance with *Animal Health Import Requirements for Raw Inedible Products and Rendered Products* (TAHD-DSAT-IE-2002-10-10). The CFIA Questionnaire is not required for fish or krill oil. The completed CFIA Questionnaire is required to obtain a Canadian import permit. The purpose of the CFIA Questionnaire is to identify ruminant and/or specified risk material (SRM) cross contamination risks. An annual on-site inspection by the endorsing Central Competent Veterinary Authority (e.g., USDC SIP), along with samples for testing, is required to verify that the information provided within this questionnaire is complete and accurate as presented. The annual audit should be done within 6 months of questionnaire request of the same calendar year.

Directions for completing the Questionnaire:

- **The facility manager initiates completion of the** latest PDF version of the questionnaire (CFIA Facility Questionnaire) which is endorsed by the NOAA Seafood Inspection Program (SIP) auditor and Veterinary Medical Officer (SIP VMO). The physical address of the premises being inspected is required.
- Audit sampling:
    - The SIP auditor will collect a minimum of 5 verification "random" samples from multiple lots of finished product and submit to the National Seafood Inspection Laboratory for EACH intended fishery by-product (not oil) listed on the questionnaire to be exported to Canada.
    - Sampling and testing is required annually and should be done during a NOAA SIP facility audit.
- Facility and Representative Information (Page 1): Include the physical and mailing address of the facility, the name of the facility staff filling out the questionnaire and present during the annual SIP inspection.
- Competent Authority Veterinarian or Inspector Information (Page2): Include the names and title of the NOAA SIP auditor conducting the facility inspection and NOAA SIP VMO endorsing the questionnaire following the audit.
- Table (Page 2): List the type of fishery by-products intended to be exported to Canada, include species, country of origin, and product source (i.e., NOAA SIP Approved Establishment).
- Question 2.0 (Page 2): This question relates to potential for "cross contamination" with ruminant protein known as Specific Risk Material.
    - The answer for 2.1 should be "No" because these facilities do not process ruminant animals. Therefore, the remaining questions are not applicable. Skip to questions 3.
- Question 3.0 (Page 4): This question pertains to facility sanitation and safety (i.e., HACCP principles).
- Question 4.0 (Page 4): This question asks about separation protocols of products eligible for export to Canada from those not eligible.
- Question 5.0 (Page 4): This question relates to the moisture content of dry rendered products (e.g., fish meal, krill meal, bone meals).
- Question 6.0 (page 4): This question pertains to liquid products (i.e., fish protein hydrolysate) and asks if the product is for further processing in Canada. If this question does not apply, the SIP VMO will line through the question, initial and date as appropriate.

- Questions 7.0 and 8.0 (Page 5): These questions pertain to oils, fats, and mixed products of bovine origin and it does not apply to fishery by-products. These questions are not applicable, the SIP VMO will line through the question, initial and date as appropriate.
- Question 9.0 (Page 5): This question asks about the certifying government agency or Competent Veterinary Authority. SIP recommends writing in "USDC NOAA SIP".
- Signatures and Endorsements (Page 6): Be sure that the Facility Official verifies, signs, and dates in this space. Document the date of the latest NOAA SIP facility audit n with sampling. Nothing else needs to be filled out on this page. The SIP VMO will not fill this section out since they are typically not present during the inspection. The SIP VMO makes the final review and endorsement of the questionnaire, signs and stamps on page 7.
- NOAA SIP auditor and VMO will fill out Page 7. Under the "Inspector" field, the SIP auditor will complete. Under the "salaried veterinarian of the CCVA", the SIP VMO will complete and stamp.
- Costs: 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.
    - Additional copies of the questionnaire can be completed for a fee

- **Steps for Review and Completion of the Questionnaire:**
    1. Draft document review - The SIP auditor will email a copy of the DRAFT questionnaire, billing information and physical address to send the final stamped questionnaire to NMFS.NSIL.FM.EXPORT@NOAA.GOV for review, **prior** to sending the original questionnaire to the SIP VMO.
    2. The SIP VMO will review the DRAFT questionnaire for accuracy and program compliance including verification (i.e., via SIP audit log) that NSIL has received the appropriate samples of each fishery by-product listed in the questionnaire with compliant testing results within the last 6 months.
    3. The SIP VMO will follow up with a confirmation email to the SIP auditor.
    4. The SIP auditor or facility manager will send the completed questionnaire to the SIP VMO via express US mail carrier to the following address

        National Seafood Inspection Laboratory
        ATTN: NOAA Veterinarian
        3209 Frederic Street
        Pascagoula, MS 39567
    5. The SIP VMO will review, endorse and stamp the document and send the completed questionnaire and DRC (i.e., invoice) back to the requesting firm via express US mail carrier. The SIP VMO will also email a copy of the paperwork to the requesting firm, SIP auditor, and NSIL.

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 fish meal to Canada.

Certificate Requirements

1. **The production firm has been audited, with the appropriate samples tested and found to be compliant,** within the last 12 months.

   NOTE: *Audits can be "consultative" in association with the completion of the Annex 3 CFIA Questionnaire. It is not necessary for the facility to be an "Approved Establishment."*
2. The facility provides a valid import permit with matching importer to Consignee, exporter to Consignor, producer, product description, and all storage facilities listed on the request form.

NOTE: *Export certification to Canada for reprocessing and re-export to the EU requires the firm to meet all the requirements listed under the EU requirements. The EU certificate will have the statement "This Document is for use by CFIA only and should not be used for direct export to the EU" included in the header.*

The export certificate will contain the following statements:

1. The fish meal/bone meal/krill meal/solubles was only produced at (Facility Address) and were only exported to Canada from (Facility/Storage Address);
2. The certified rendered products contain the following: fish meal/bone meal/krill meal/solubles.
3. The moisture content of the finished product is less than 10%.
4. None of the animals from which any of the animal origin products and/or by-products used to manufacture the rendered products were culled or eradicated as part of a disease response for any disease of concern defined by CFIA.
5. The finished product is placed in tightly sealed waterproof/leak proof bags or cleaned and disinfected containers that prevent cross contamination with any unfinished product, and is stored and otherwise handled in a manner to avoid contamination with any animal origin material that does not meet the requirements of this certificate.
6. The product label bears the following statements "the product does not contain prohibited material, as defined by section 162 of the Health of Animals Regulations. Feeding this product to cattle, sheep, deer, or other ruminants is permitted under the Health of Animals Act."
7. If shipping in bulk, the container is dedicated to transport only non-ruminant material and every precaution was taken during the handling, processing, packaging, storage and

shipping to prevent direct or indirect contact of the product with any animal origin material that does not meet the requirements of this certificate.

Chile

The export requirement for Chile is a Certificate of Legal Origin. To obtain the Chile Certificate of Legal Origin, the firm must be in good standing with the Office of Legal Enforcement (OLE) but does not require USDC Approved Establishments for Fishery By-products status. 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 but one can be provided upon request. Export health certification for fishery by-products not intended for human consumption will only be provided to facilities that are USDC Approved Establishments for Fishery By-products, are in good standing with program requirements, and have had their product tested within the last 12 months.

The export certificate for fishery by-products will contain the following general certificate statements:

1. During the course of commercial manufacture, the product is heated for such times and temperatures so as to preclude the survival of Salmonella and Enterobacteriaceae.
2. The physical plant design is such to preclude contamination of the final product with raw fish.
3. The processing, handling, and storing of the oil/meal is in accordance with "Sanitation Guidelines for the Control of Salmonella in the Production of Fish oil/meal" promulgated by the U.S. Department of Commerce.
4. This product is free of meat, blood and bones originating from mammals.

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 be an NOAA 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

NOAA Seafood Inspection Program Requirements

Facilities wishing to export fish meal, fish oil, and other aquatic animal proteins to the PRC must be a NOAA SIP Approved Establishment for Producing Animal Foods and must provide the required laboratory analysis for each consignment. The facility must be audited twice per calendar year or within production season and surveillance samples must be taken for testing by NOAA Fisheries National Seafood Inspection Laboratory (NSIL) or an approved third party laboratory. NOAA SIP and NSIL will accept results from a third par ty laboratory if it meets NSIL requirements, including accreditation by the International Organization for Standardization relevant to specific analytical protocols. For dry products, the sampling requirement is twice a year (12-month period), frequency for seasonal operations depends on timing between operation seasons and risk. For oil, the sampling requirement is once a year (12-month period), the frequency for seasonal operations depends on timing between operation seasons and risk. See Chapter 9 for more information regarding sampling for NSIL.

Certification Requirements

Export certification for fishery by-products to the PRC will only be issued by NOAA SIP if the facility is approved for export based upon compliance with PRC requirements. In addition, acceptable laboratory testing results, from an approved laboratory, are required for each designated lot/consignment of product for export. The sampling requirement for each designated lot/consignment includes five randomly selected samples (200g of dry product or 8oz of liquid product each. 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 consignment meets the import country regulations will be done by SIP prior to issuance of the export documentation.
- Allow up to 72 business hours for completion of documentation.
- All certificates will be delivered overnight via UPS unless otherwise noted.

Product Requirements

- Each shipment must be accompanied with an original export health certificate.
- Raw materials used to produce fish oil, fish meal 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.
- 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.
- Fish oil and fish meal 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, fish meal 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

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. NOAA SIP and NSIL will accept results from a third party laboratory if it meets NSIL requirements including being accredited by the International Organization for Standardization for the standards for the specific analyses being performed.

Tables 1 and 2 represent the testing requirements for fishery by-products. **Tables 3 and 4** represent the minimum standards for Enterobacteriace and *salmonella* testing.

Table 1. 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 (aquaculture source only)	Not detected	Annually
Dioxin	≤ 1.25 ng/kg	Annually

Table 2. TESTING REQUIREMENTS FOR OIL

Test	**Criteria**	**Frequency**
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 (aquaculture source only)	Not detected	Annually
Dioxin	≤ 6.0 ng/kg	Each audit

Table 3. Testing for *Salmonella* requirements **Desired result = Absent in 25 g.** This is the detection limit. The reporting laboratory must be able to detect at least 1 CFU/g in 25 grams of sample. Result record as "not detected (n.d.)"	
n = 5	N is the number of samples that need to be tested. In this case, it needs to be 5 random samples.
c = 0	c is the number of samples where the result "detected" is allowed. In this case, none of the 5 samples can have the result of "detected".
m = 0	m is the threshold value for the number of bacteria. In this case, none of the 5 samples can have the result of "detected".
M = 0	M is the maximum value for the number of bacteria. In this case, the result is considered unsatisfactory if the number of bacteria in any of the samples is "detected".

Table 4. Testing for Enterobacteriaceae requirements **Desired results in 1 g of sample (see below)**. The reporting laboratory must be able to detect at least 10 CFU/g in 1 gram of sample.	
n = 5	n is the number of samples. The requirement is 5 random samples.
c = 2	c is the number of samples where the bacterial count can be between m (10 CFU/g) and M (300 CFU/g). In this case, 2 of the 5 samples can be 11–299 CFU/g. Results are still considered acceptable/compliant if the bacterial count of the other 3 samples is m (10 CFU/g) or less.
m = 10	m is the threshold value for the number of bacteria. The results are considered acceptable/compliant if the number of bacteria in all samples does not exceed m (10 CFU/g).

M = 300	M is the maximum value for the number of bacteria. The results are considered unacceptable/noncompliant if the number of bacteria in one or more samples is M (300 CFU/g) or more.

Testing for ruminant protein: For facilities that handle only fisheries products, PCR testing (by a laboratory approved by 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 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, total plate count, and ruminant proteins. 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.

The export certificate will contain the following statements:

1. The products described above were manufactured in a facility approved and supervised by the competent U.S. authority; registered with GACC; and are in compliance with the national or regional requirements and may be freely sold in the United States.
2. The raw material may be either aquatic animals caught in the country or region's domestic sea or in the open sea or farming aquatic animals or aquatic animals by-products from plants manufacturing aquatic products for human consumption. The products do not contain any ingredients of non-aquatic animals and should not be contaminated by any products of animal origin from third countries.
3. The products are fit for animal consumption and were manufactured in accordance with U.S. laws and regulations. The products do not contain any hazardous substances which pose a risk to public or animal health and are in compliance with the safety and hygiene standards of the People's Republic of China concerning fish oil, fish meal and other aquatic animal proteins.
4. The products have been subject to a heat treatment of at least 85℃ for 15 minutes throughout its substance or have been treated with other means which are recognized by GACC to be equivalent.
5. Adequate precautions were taken both during and after processing to prevent contamination of the products with pathogens or other harmful substances.

6. The products have been subject to tests by official approved laboratory using PCR or other effective methods with negative results to ruminant ingredients.
7. The competent authority or officially approved laboratory examined a random sample prior to dispatch and confirmed that the consignment met the requirements:

   Salmonella: Absence in 25 g: n=5, c=0, m=0, M=0

   Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 g;

   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.

8. The products were packed in new, clean, sealed and impermeable packaging materials or were 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.
9. The products are labeled in compliance with relevant standards of the People's Republic of China. Label of bulk products was sent along with the invoice.

Costa Rica

Costa Rica export health certification for fish oil not intended for human consumption will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products, are in good standing with program requirements, and have had their product tested within the last 12 months. In addition, Costa Rica requires all fishmeal to meet the following requirements.

1. Fish used for the production of fishmeal in the United States is a fish byproduct that has been caught for human consumption and therefore it is subject to histamine controls for less than 400 ppm; or, comes from an establishment that performs analysis at the final product stage and meets the 400 ppm requirement.

2. The raw materials used to produce fish meal meet U.S. standards for organochlorines, PCBs and heavy metals.

The export certificate will contain the following general certificate statements, written in Spanish and English:

1. During the course of commercial manufacture, the product is heated for such times and temperatures so as to preclude the survival of Salmonella and Enterobacteriaceae.
2. The physical plant design is such to preclude contamination of the final product with raw fish.
3. The processing, handling, and storing of the product is in accordance with U.S. requirements for aquatic animal by-products promulgated by the U.S. Department of Commerce.
4. This product is free of meat, blood and bones originating from mammals.

India

India export health certification for fishery by-products not intended for human consumption will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products that are in good standing with program requirements, and have had their product tested within the last 12 months.

The export certificate will contain the following general certificate statements:

1. During the course of commercial manufacture, the product is heated for such times and temperatures so as to preclude the survival of Salmonella and Enterobacteriaceae.
2. The physical plant design is such to preclude contamination of final product with raw fish.
3. The processing, handling, and storing of the product is in accordance with U.S. requirements for aquatic animal by-products promulgated by the U.S. Department of Commerce.
4. This product is free of meat, blood and bones originating from mammals.

Indonesia

Indonesia export health certification for fishery by-products not intended for human consumption will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products and are up to date on their audits.

The export certificate will contain the following statements:

1. The Product from each batch described above have been processed, inspected and graded in (an) establishment(s) that has been approved by and under the control of the Competent Authority.

2. The product from each batch described above have been handled, prepared or processed, identified, stored and transported under a competent HACCP and sanitary programme consistently implemented and in accordance with the requirements laid down in Codex Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).
3. The Product from each batch has been found to be free of disease based on sampling and testing method recognized by the World Organisation for Animal Health (OIE) for demonstrating absence of disease and inspected according to the appropriate procedures and subsequently found, at the time of inspection:
    a. for crustaceans declared free from AHPND, IHHNV, YHV, TSV, WSSV, WTD, IMNV, LsNV and Crayfish plague.
    b. for cyprinidae declared free from SVC, KHV, RSD and Furunculosis
    c. for tilapia or oreochromis declared free from TiLV, IPNV, RSIVD, VNN, RSD, ESC and Furunculosis
    d. for catfish declared free from CCVD, VHSV, RSD, Furunculosis, ESC and EUS.
    e. for other fish species, declared free in accordance with the list of fish diseases of OIE relevant to the susceptible species.
    f. to show no visible/clinical signs of diseases
    g. The fish must be packaged in shipping containers, holding units and/or conveyances that are either new or cleaned and disinfected. The shipping containers and/or holding units must prevent release of the shipping contents (e.g. water or animals) while en route.

4. For non-edible products have been handled, prepared or processed, stored, transported based on biosecurity principles.

Japan

Japan export health certification for fishery by-products not intended for human consumption will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products in good standing with SIP program requirements, and have had their product tested within the last 12 months.

The export certificate will contain the following general certificate statements:

1. During the course of commercial manufacture, the product is heated for such times and temperatures so as to preclude the survival of Salmonella and Enterobacteriaceae.
2. The physical plant design is such to preclude contamination of final product with raw fish.

3. The processing, handling, and storing of the product is in accordance with U.S. requirements for aquatic animal by-products promulgated by the U.S. Department of Commerce.
4. This product is free of meat, blood and bones originating from mammals.

Additionally the certificate will further state:

1. The fish meal/bone meal/fish oil was produced in processing plants dedicated only to fish meal/bone meal/fish oil production where no material of animal origin other than fish and shellfish protein of U.S.A origin is being used; and
2. The fish meal/bone meal/fish oil was transported in a manner to avoid commingling with other animal proteins.

Peru

Peru export health certification for fishery by-products not intended for human consumption will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products in good standing with SIP program requirements and have had their product tested within the last 12 months.

The export certificate will contain the following general certificate statements:

1. During the course of commercial manufacture, the product is heated for such times and temperatures so as to preclude the survival of Salmonella and Enterobacteriaceae.
2. The physical plant design is such to preclude contamination of final product with raw fish.
3. The processing, handling, and storing of the product is in accordance with U.S. requirements for aquatic animal by-products promulgated by the U.S. Department of Commerce.
4. This product is free of meat, blood and bones originating from mammals.

Additionally the certificate will further state:

5. The material was derived only from animals that have never been in any region listed in 9 CFR 94.18(A): SEC. 94.18 restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

    (1) Bovine spongiform encephalopathy exists in the following regions: Austria, Belgium, Canada, The Czech Republic, Denmark, Finland, France, Germany, Greece, The Republic of Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Oman, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland or and The United Kingdom.

(2) The following regions, because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance, present an undue risk of introducing bovine spongiform encephalopathy into The United States: Albania, Andorra, Bosnia-Herzegovina, Bulgaria, Croatia, The Federal Republic of Yugoslavia, Hungary, The Former Yugoslav Republic of Macedonia, Monaco, Norway, Romania, San Marino, and Sweden.

(3) The material did not originate in and was never stored, rendered, or otherwise processed in or otherwise associated with a facility in any region listed in 9 CFR 94.18(A) (see above)

(4) The material was not otherwise associated with any of the materials listed in 9 CFR 94.18

(A) (Below which have been in a region listed in 9 CFR 94.18(A) (ABOVE) Sec. 95.29 Certification for certain material;

(B)(1) Processed animal protein, tankage, offal, and tallow other than tallow derivatives, unless, in the opinion of the administrator, the tallow cannot be used in feed, regardless of the animal species from which the material is derived;

(2) Glands and unprocessed fat tissue derived from ruminants;

(3) Processed fats and oils, and derivatives of processed animal protein, tankage, and offal, regardless of the animal species from which the material is derived;

(4) Derivatives of glands from ruminants; and

(5) Any product containing any of the materials listed in paragraphs A(1) through A(4) of this section.

Taiwan, Thailand, Vietnam, Korea

For these countries, export health certification for fishery by-products not intended for human consumption will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products, are in good standing with SIP program requirements, and have had product tested within the last 12 months.

The export certificate will contain the following general certificate statements:

1. During the course of commercial manufacture, the product is heated for such times and temperatures so as to preclude the survival of Salmonella and Enterobacteriaceae.
2. The physical plant design is such to preclude contamination of the final product with raw fish.
3. The processing, handling, and storing of the product is in accordance with U.S. requirements for aquatic animal by-products promulgated by the U.S. Department of Commerce.
4. This product is free of meat, blood and bones originating from mammals.

Certification of Krill Products Produced Outside of the United States (e.g., Norway) Designated for Export:

Health certification for krill by-products produced outside of the U.S. (i.e., typically by Norway) will be provided to requesting facilities that are USDC Approved Establishments for Fishery By-products, are in good standing with NOAA SIP program requirements, and have had product tested within the last 12 months. The facility must provide a request form and a copy of the Norwegian sanitary certificate(s) issued for the lot(s) of product getting exported. The Norwegian sanitary certificate(s) must also accompany the export certificate to the BIP of the importing country.

Along with the normal attestations on the destination country specific certificate, additional attestations will be added:

This further certifies that:

1. The krill meal was produced on a processing vessel and was legally imported into the United States using Sanitary Certificates _____ issued by the Norwegian Food Safety Authority; and

2. The krill meal was handled and transported in the United States in a manner to avoid commingling with other animal proteins.

3. THIS CERTIFICATE MUST BE ACCOMPANIED BY THE SANITARY CERTIFICATES ISSUED BY THE NORWEGIAN FOOD SAFETY AUTHORITY.

Chapter 9 Sample Collection and Submission of Aquatic Animal By-products (not intended for human consumption) to the NSIL for Laboratory Analysis

***NOTE**: For questions regarding by-products sample collection and/or submission, please contact NSIL Sample Custodian (228-769-8964) nsil.sample.custodian@noaa.gov*

Introduction

The USDC Seafood Inspection Program provides inspection, verification/surveillance sampling, and certification of fishery by-products. The National Seafood Inspection Laboratory (NSIL) provides analytical services to verify and maintain that the SIP Program participants meet the federal regulatory, importing country, and Program's requirements. These analytical services provide a level of assurance regarding the absence or amount of certain possible hazards that may be associated with the fishery by-product. In most cases, samples are taken for bacteriological analysis (e.g., Salmonella and Enterbacteracea).

General Directions and Sample Supplies

The SIP inspector typically samples fishery by-products during routine surveillance audit visits. The objective of the SIP inspector is to obtain a representative sample of the identified fishery by-product and submit the sample to NSIL in a condition bacteriologically unchanged from that existing within the product at the time of sampling. Aseptic sampling technique must be used to avoid sample contamination by microorganisms during collection, storage, and transport of the samples to NSIL.

Acceptable sampling equipment and tools include but are not limited to:

Sample Container - clean, dry, sterile, leak-proof sample collection containers. IMPORTANT - containers must be tightly closed to prevent spillage during transport.

- for dry product (i.e., fish meal, shellfish meal, bone meal)
    - plastic 24 oz Whirl-pak bags,
    - with waterproof labels

- for liquid products (i.e., fish oil, shellfish oil, Salmate®, or hydrolyzed fish proteins)
    - plastic 8oz wide mouth Jars with screw-top caps
    - with waterproof labels

Collecting equipment

- sterile latex or latex free gloves (check expiration date)
    - sterile gloves
- sterile scoops
    - 4 oz scoops and/or 2 oz scoops

Cutting instruments

- knives and/or scissors for opening packages. For microbiological sampling, sterile these instruments with alcohol wipes.

Sterilizing agents

- Alcohol wipes, other disinfectant wipes, solution for sanitizing hands or surfaces, alcohol container with screw-type lid with isopropyl alcohol 91%, and lighter.
    - Alcohol wipes

Labels and markers

- Waterproof labels for containers that are appropriate for the containers (i.e., adequately stick to containers). Consider purchasing labeled containers (i.e., labels already applied).
- Black or Blue permanent markers for labeling (two per kit)

Containers/sealable plastic bags

- Containers must be appropriately packaged to avoid breakage during transport (e.g., styrofoam packing material, bubble wrap, etc.). Sealable plastic bags for completed information forms (i.e., to keep documents clean and dry).
- One gallon ziplock bags:
    - Dry products - Consolidate a set of five sample bags of dry product into a large one gallon ziplock bag to prevent cross contamination if leakage occurs.
    - Liquid products - Place one to two sample containers of liquid product into a large one gallon ziplock bag to prevent cross contamination if leakage occurs.

Sample Numbers and Sample Sizes

Verification/Surveillance Samples for SIP Approved Establishments: Verification/Surveillance samples are collected following the predetermined sampling plan. Five random samples (200 g of dry product or 8 oz of liquid product per sample) must be collected for each type of fishery by-product available at the facility.

Individual Lot Samples: Five randomly selected samples (200 g of dry product or 8 oz of liquid product per sample) must be collected during a lot inspection from each lot/consignment of product designated for export.

Sample Collection

The objective is to obtain a representative sample of the product at the time of the audit or lot inspection. Prior to sample collection, the SIP inspector will check the internal database for planning purposes and notify the responsible company representative of the intent to collect samples and explain why it is necessary. The SIP inspector should offer to take duplicate samples for the company, but the firm can decline if they choose.

The inspector will use sterile technique to avoid sample contamination by microorganisms during handling, storage and transport of the samples to NSIL. SIP Inspectors will observe safety

precautions implemented by the facility when collecting samples and all other safety requirements of the Program. Prior to shipping samples to NSIL, the SIP inspector will notify NSIL with an estimated delivery time and if other issues arise (nsil.sample.custodian@noaa.gov or 228-769-8964). Send samples to NSIL by a common carrier (i.e. Federal Express, UPS) to arrive during the work week (do not ship for delivery on a weekend or holiday) or delivered to the NSIL in-person.

NOTE: *If the samples arrive at NSIL in unacceptable conditions (i.e. leaking or broken containers), NSIL will contact the SIP inspector that collected the samples and their immediate supervisor to describe the discrepancy and suggest follow-up actions.*

The following is a description of the sampling and testing scheme of SIP Approved Establishments for fishery by-products:

- **Fishmeal Bone Meal, Shellfish meal (i.e., crab, shrimp, or krill)**
    - Twice a year (12 month period), frequency for seasonal operation depends on timing between operation seasons and risk. Samples are tested for Enterobacteriaceae, Salmonella, aerobic plate count, yeast/mold, and ruminant DNA if requested (i.e., China, Canada).
    - All fishmeal lot inspections are tested for Enterobacteriaceae, Salmonella and ruminant DNA.
- **Fish oil, Krill oil, Salmate® (spray-dried fish oil) and hydrolyzed fish proteins**
    - Once a year (12 month period), frequency for seasonal operation depends on timing between operation seasons and risk. Samples are tested for Enterobacteriaceae and Salmonella.
- **Fish solubles**
    - Once a year (12 month period), frequency for seasonal operation depends on timing between operation seasons and risk. Samples are tested for pH. The pH must be less than 4.5 to be compliant. This product does not go through any other testing unless specifically requested by the company. This is usually done through lot inspection.
- **Frozen fish by-products** - at this time, no testing is performed on these products.

Additional considerations for sampling fishery by-products

- **Sampling Bulk Product**
    - When sampling products stored in bulk (i.e., dry or liquid form), samples should be representative of the finished product in the warehouse/storage container or specific lot to be tested.

- For dry bulk product, use a sterile scoop to scrape the surface (approximately 6 inches) of product away to allow access to the product a few inches into the pile. Collect product from the designated area and place it in a sterile sampling container. The sample collection location should be recorded on the warehouse map provided by the company or designated by the SIP inspector. A new sterile scoop and sample collection container must be used for each sample collected.
- For liquid products stored in bulk, samples should be collected using sterile methodology including sampling devices and collection containers.

- **Sampling Packaged Product**
  - If possible, samples of finished product should be collected prior to bagging or packaging.
  - If collecting samples in storage, collect from different pallets and pallet locations.
  - On completion of filling, the sterile container should be closed and stored as appropriate.
  - If product material is not available before packaging, the SIP inspector 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 on 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 a sterile sample container. 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 collection equipment should be changed between each sample being collected.
  - Prepare samples for shipment to the NSIL and return the opened packages to the processing line or responsible company personnel.

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

Labeling Sample Containers

Waterproof labels (i.e., containers with pre-affixed labels or separate adhesive labels) should be filled out prior to sampling (when possible). Use waterproof marker for labeling with the following information:

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

Information Form

The SIP inspector collecting the samples must completely fill out the NSIL Information Form for Aquatic Animal By-Products Not Intended for Human Consumption (see appendix below - QMS5.7b). Place the completed form in a ziplock bag to prevent soiling the document. Use the following instructions for filling out the form:

Company Information

Company Full Name: Provide the company's full name as it appears in the USDC Participants List for Establishments Approved for Producing Animal Foods. 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. Must include the vessel name if applicable.

Company Contact Full Name: Provide the company point of contact designated to address any questions concerning the samples collected.

Company Location Address: Provide the address of the location from which the samples were collected, as it appears in the USDC Participants List for Establishments Approved for Producing Animal Foods. Do not use the company headquarter address unless collecting from a vessel that has no permanent location. If not in the list, write the address of the specific facility from which the samples were collected.

Company Contact's Title, Phone Number and email address: Provide the company POC's title, phone number and email address.

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

Product Information

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

Reason for Sample Submission: Indicate the reason for sample submission such as audit, lot inspection, other (i.e., CFIA questionnaire, corrective action). Consultative audits are considered audits.

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

Product Packaging: Tick or mark the appropriate box for packaging.

Sub-Sample Identification: For each sub-sample collected, provide the Lot/Code Number, Lot Size, and Packed Date. It is important that the lot or code numbers provided allow for "trace back" of the product in case the submitted samples fail the analysis.

Sample Information

Sample Date: The date the sample was collected.

Sample Location: Tick or mark box for appropriate sampling location.

Sample Type: Tick or mark box for appropriate sample type.

Sample Size: Indicate the number of sub-samples provided.

Name of SIP Inspector's Immediate Supervisor: Provide the name of the SIP inspector's immediate supervisor. If a submitted sample fails analysis, it is the laboratory's responsibility to contact the supervisor so they can take appropriate action.

Immediate Supervisor's Telephone/email address: Provide the telephone number and email address of the SIP inspector's immediate supervisor. If a submitted sample fails analysis, it is the NSIL's responsibility to forward the analytical results via email to the SIP supervisor so they can take appropriate action.

Full Name of SIP Inspector Collecting Samples: Provide the full name of the SIP inspector.

SIP Inspector's Telephone/email address: Provide the telephone and email address of the SIP inspector.

Signature of SIP Inspector Collecting Samples: Signature of the SIP inspector.

Packing Samples and Shipping Containers

Samples shipped to the NSIL should be packed by the SIP inspector collecting the samples. If samples are shelf-stable, they can be shipped at ambient temperature in a sealed box or other suitable container following Department of Transportation (DOT) requirements. 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 following DOT requirements. When possible, samples should be shipped to the NSIL via overnight carrier or some other means to assure a timely delivery to the NSIL. Do not ship overnight samples on a Friday for Saturday delivery or for delivery on a holiday.

Prior to shipping samples to the NSIL, please notify the Sample Custodian, either via email to NSIL.Sample.Custodian@noaa.gov or by phone (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

APPENDIX

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) 769-8964

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 (lb, kg or MT):	Lot Number(s):
Sample Date (mm/dd/yy):	Sampled (√): _____In-Storage	
Sample Size (Number): _____5	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:	

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By-Product Certificate Request Form

NATIONAL MARINE FISHERIES SERVICE

EXPORT CERTIFICATE INFORMATION

Production/Storage Information	
Type of Certificate needed: Provide type of certificate needed - what product is being certified	Name & Address of Storage Facilities: (List all facilities where product was stored or handled prior to export) Provide name and address of the storage facility (may be the same as consignor or processor)
Name & Address of Producer: Provide name and address of processor	
Approval/CFN/FEI Number# Provide FEI number of processor	Approval/CFN/FEI Number# Provide FEI number of the storage firm listed above
Type of Product: Fish Meal ☐ Fish Oil ☐ Fish Solubles ☐ Frozen Fish ☐ Fish Bones ☐ Other	
Lot Number(s): Provide the lot number(s), place a comma between multiple lot numbers	
Date(s) of Production: Provide date(s) of production	
Country of Origin: US ISO Code US	
Shipping Information	
Name & Address of Consignor: Provide name and address of consignor	Name & Address of Consignee: Provide name and address of consignee
Contact Person: Provide name a POC for consignor Phone: Consignor phone Import Permit Number Provide Import Permit number if applicable	Contact Person: Provide name of POC for consignee Phone: Consignee Phone number
Port of Export: Provide port of export or embarkation	Shipped To: provide port of import or debarkation
Shipped Via: Truck ☐ Ship ☐ Airplane ☐ Other	
Name of Export Vessel/Trucking Company/Airline Information: Provide name of vessel, airline etc.	
Documentation References: bill of lading or booking reference number Identification: vessel name or flight number	
Date of Departure: date leaving the US For transit through EU to third country (EU Only): Provide EU country of transit Transit country ISO Code ISO	
Country of destination: Provide destination country ISO Code: ISO Export barge information Barge information	
Entry BIP in EU (for EU shipments only): Provide Entry BIP for EU exports only	
HS Commodity Code: HS Code for product Nature of Commodity: Please specify farmed or wild	
Total Marked Weight: Provide total weight Temperature: Please provide Ambient, Chilled, or Frozen	
Type of Container(s) (Packages): Provide type of packaging	
Number of Containers/Packages: Provide number of packages	
Product Scientific Name (Genus species) Provide scientific name Common Name: Provide common name of product	

Description of Commodity Provide detailed description of product
Transportation Company Provide the name of the transportation company
Container/Seal Numbers: (attach additional pages, if needed) Provide container and seal numbers (do not click enter, please use commas to separate multiple entries)
End Use of Product: Not for human consumption
Foreign Source Certificate(s): Provide the country and certificate number(s) for any foreign-sourced product, separated by commas
Billing Information
Billing Address: Please provide billing party name & address
Name and Address where certificate should be sent: (Include UPS Account Number and Billing Zip Code) Please provide name and address for mailing of certificates