U.S. FOOD & DRUG ADMINISTRATION

Report Summary: Aquaculture Product Determination In Ecuador's Subsecretaría De Calidad E Inocuidad

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Background

In 2019, the United States (U.S.) Food and Drug Administration (FDA) developed the Strategy for the Safety of Imported Foods aimed at addressing the complex challenges to ensure food safety amid the complexity of global supply chains, varying food safety systems, and differing levels of regulatory oversight among the more than 200 countries and territories from which the U.S. imports food. As part of this strategy, FDA has been exploring the potential for leveraging a foreign country's aquaculture food safety programs to ensure food safety measures are applied through the supply chain including feed, hatcheries, farms, and processors. The Consolidated Appropriations Act of 2021 Section 787, directed FDA to explore and develop a program for enhancing the safety of imported shrimp products to assure appropriate controls are applied through the entire supply chain. Through this appropriations act, Congress directed FDA to explore the potential for partnerships with those countries exporting a high volume of shrimp to the U.S. The directive was to focus on the top three countries with the highest volume of shrimp exports to the U.S.

Ecuador was identified as one of the principal exporters of shrimp to the U.S. based on volume. As a result, FDA approached the Ecuadorian government to participate in the Regulatory Partnerships (RP) program in 2021. Ecuador identified the Subsecretaría de Calidad e Inocuidad (SCI) as the primary competent authority overseeing the safety of aquaculture shrimp throughout the entire supply chain. FDA and Ecuador agreed to explore an international arrangement through the RP program. The process for the RP: AP program includes identifying the competent authority, signing a confidentiality commitment between the FDA and competent authority, discussing and implementing capacity building, and determining if a Regulatory Partnership Arrangement should be pursued by assessing the participating country's food safety system utilizing the Regulatory Partnerships, Aquaculture Products Assessment Tool.

Purpose

A RP aims to allow FDA and competent authorities in other countries to work together to effectively strengthen the enforcement of food safety measures through the supply chain. A Regulatory Partnership will allow FDA to leverage another country's food safety programs for a specific commodity or program area, for example aquaculture shrimp and shrimp products. Through the exchange of data and information, both partners can inform regulatory decisions and focus their limited resources on the firms and areas that represent the highest risk. These efforts proactively ensure the safety of shrimp imported into the U.S. from Ecuador.

Process

The Regulatory Partnership: Aquaculture Products Assessment Tool is used to determine whether the systems in place contain the essential regulatory elements and levels of oversight needed to ensure effective food safety and public health outcomes. The following are the key areas identified and assessed as necessary for a robust shrimp food safety system: legal and regulatory foundation; inspection, compliance and enforcement programs and capabilities; aquatic animal disease prevention and surveillance program; program performance self-assessment; food-related illness and outbreaks responses; training and resources; and laboratory support.

The assessment process involves a thorough review (desk assessment) of information and supporting documentation submitted by the Sub-Secretariat of Quality and Safety (S*ubsecretaría de Calidad e Inocuidad* (SCI)), Ecuador's seafood food safety authority to FDA using the RP: APAT to define their food safety authority and food safety programs currently in place. An in-country verification assessment is subsequently conducted to verify that the programs described in the desk assessment documentation are implemented effectively.

As Ecuador was the first country to participate in this program, FDA intends to apply experience gained from this process to inform future assessments conducted by FDA under the Regulatory Partnership program.

The Assessment Tool

The RP: APAT contains nine standards identifying the key areas required of a commodity specific program and a robust aquaculture food safety system. These are: Legal and Regulatory Foundation; Inspection Program; Aquatic Animal Disease Prevention and Surveillance Program; Program Performance Self-Assessment; Food-related Illness and Outbreaks; Compliance and Enforcement Program; Training Program; Program resources; and Laboratory Support. The competent authority is requested to fill out the tool in its entirety.

Standard 1: Legal and Regulatory Foundation

The Legal and Regulatory Foundation Standard identifies the laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of an aquaculture food safety control system, which are used by the competent food safety authority to define and ensure compliance with aquaculture regulations. To meet the fundamentals of the standard, the competent authority must demonstrate:

The legal authority and regulatory provisions to perform inspections and investigations;

Gather evidence, collect, and analyze samples; and

Take enforcement actions to ensure the safety of the aquaculture seafood supply.

Standard 2: Inspection Program

The Inspection Program Standard seeks to understand the competent authority's food safety inspection program. To meet the fundamentals of this standard, the competent food safety authority provides information regarding their current inspection program that reduces the likelihood of the occurrence of foodborne illness or injury. This standard identifies the competent authority's basic inspectional functions that are necessary to:

Maintain and implement basic surveillance and control along the seafood supply chain for those veterinary medical products used in aquaculture seafood production, including aquaculture farm operations, raw material supplier(s) to processor(s), processing, and transportation;

Establish criteria and implement procedures to classify higher risk facilities including those at aquaculture farm operation(s), raw material supplier(s) to processor(s), processing, transportation, veterinary medical products supply, and/or distribution facilities;

Obtain immediate corrections and long-term improvements of facilities; and

Respond efficiently and effectively to prevent unsafe seafood from being exported to the U.S.

Individual elements that should be in place include, but are not limited to, an establishment inventory list, risk categorization, registration or certification program for facilities, inspection protocol(s), food recall response, consumer complaint response, and a system for maintaining inspection-related documentation.

Standard 3: Aquatic Animal Disease Prevention and Surveillance Program

The Aquatic Animal Disease Prevention and Surveillance Program Standard considers the key elements of the competent authority's effective aquaculture food safety program to prevent, monitor, and report the occurrence of diseases aiming to minimize the need or inclination for the use of unapproved veterinary drugs or misuse of approved/authorized veterinary drugs, and to prevent contamination of the product with unsafe residues. To meet the fundamentals of this standard, the competent food safety authority needs to demonstrate that their current program reduces the likelihood of aquatic animal diseases through prevention, surveillance, disease outbreak response and implementation of interventions and compliance actions for containing or minimizing the spread of disease. This standard identifies the competent authority's basic functions for an aquaculture animal disease prevention and surveillance program that are necessary to:

Maintain and implement a basic surveillance and control of aquatic animal diseases on the farm, including a contingency plan for disease outbreak management and coordination of the response, and the expertise and infrastructure for early detection and control of current and emerging diseases;

Establish criteria and implement procedures for inspection of conditions at hatcheries and farms to ensure basic biosecurity, disease surveillance, and food safety requirements are met;

Maintain a list of registered and/or approved facilities (i.e., hatcheries, farms, brood stock import, and live animal holding and transportation); and

Establish communication and dissemination of information to the industry and other groups in a timely manner when a disease occurs in order to implement interventions for containing or minimizing the spread of disease.

Standard 4: Program Performance Self-Assessment

The Program Performance Self-Assessments assesses whether the food safety, prevention and inspection programs are designed to identify the strengths and weaknesses of the current program. This standard identifies the competent authority's basic quality assurance program specific to the aquaculture seafood products that are necessary to:

- Evaluate the effectiveness of the food safety disease prevention, and inspection programs for the aquaculture seafood;
- Recognize trends in program implementation and compliance;
- Identify areas for improvement in the implementation of the inspection and support programs; and
- Identify that growing conditions are safe and sanitary as well as the safe use of veterinary drugs.

Standard 5: Food-Related Illnesses and Outbreaks

The Food-Related Illness and Outbreaks Standard assesses key components of the competent authority's effective system for surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies that may result in illness, injury, or outbreaks associated with the consumption of aquaculture seafood products. To satisfy the fundamentals of this standard, the competent authority provides information regarding their current system for surveillance, investigation, response, documentation, analysis, communication and follow-up of alleged food-related illnesses, injuries, and unintentional or deliberate food contamination. For this standard, the competent authority identifies the basic food-related illnesses and outbreak functions that are necessary to:

- Report and track illnesses and outbreaks and conducting trace-back and trace-forward investigations of aquaculture seafood products implicated in an illness, injury, or outbreak;
- Utilize epidemiological information and inspection reports supplied by other authorities (e.g., local, regional, national, international) to detect incidents or outbreaks of foodborne illness or injury associated with the consumption of aquaculture seafood products;
- Communicate public information effectively to consumers, industry, and exporters; and
- Develop and maintain written procedures and policies to include timeframes for processing complaints based on public health impact.

Standard 6: Compliance and Enforcement Program

The Compliance and Enforcement Program Standard considers the competent authority's ability to enforce food safety laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program. To satisfy the fundamentals of this standard, the competent authority must have a compliance and enforcement program that provides procedures to ensure that policies are supported by sound judgment, adequate evidence, and appropriate documentation. For this standard, the competent authority identifies the basic compliance and enforcement functions with real life examples that are necessary to:

- Maintain written protocols and procedures for enforcement strategies;
- Demonstrate an ability to track compliance issues, violations, and violators, and corrective actions;
- Establish and implement a system to communicate verbally and in writing the policy and guidance(s) to managerial and non-managerial staff; and
- Establish and implement a mechanism for responding efficiently and effectively to prevent unsafe aquaculture seafood products from entering commerce, enable the removal of potentially unsafe aquaculture seafood products from commerce, as well as prevent them from being exported.

Standard 7: Training Program

The Training Program Standard seeks to understand the key elements of the competent authority's training program for its personnel in support of the food safety program for aquaculture seafood products. To satisfy the fundamentals of this standard, the competent authority must have and provide information on their training program that ensures all food safety personnel (e.g., investigators, inspectors, auditors, compliance officers) and technical support staff (e.g., laboratory personnel) receive the training required to adequately perform their work assignments. The program should provide for basic and advanced food inspection training as well as continued training for professional development and documentation of staff training must be maintained.

Standard 8: Program Resources

The Program Resources Standard assesses the competent authority to assess the adequacy of resources (staff, equipment, and funding) available to support their food safety regulatory program. To satisfy the fundamentals of this standard, the competent authority must ensure resources such as appropriate tools, equipment, and personnel are available to support a comprehensive food safety program.

Standard 9: Laboratory Support

The Laboratory Support Standard considers key elements of the competent authority's laboratory support for the food safety regulatory program for the aquaculture seafood products. To satisfy the fundamentals of this standard, the competent authority's laboratory services should be available, accessible, and applied appropriately in support of program functions. Documented laboratory capabilities should include standard operating procedures and written agreements with external laboratories when applicable. This Standard identifies the competent authority's basic laboratory functions that are necessary for:

- Operating a quality assurance program such as a Quality Assurance Program (QAP) or a Quality Management Systems (QMS) by government and private/contracted laboratories utilized for regulatory testing of aquaculture seafood products to ensure the quality, accuracy, and reliability of their measurement procedures;
- Acquiring and maintaining an accreditation to ISO/IEC 17025 standards of government and private/contracted laboratories utilized for regulatory testing of aquaculture products;
- Establishing the requirements for government and private/contracted laboratories regarding the use of standard laboratory methodologies for analysis including microbiological, veterinary drug residues and environmental contaminants in aquaculture products;
- Establishing and implementing the regulatory programs such as National Residues Monitoring Program for conducting testing for veterinary drug residues and environmental contaminants in aquaculture products; and
- Maintaining records/documentation of services for regulatory and non-regulatory analyses.

Desk Assessment

In April 2022, SCI submitted their completed RP: APAT including supporting documentation. In May 2022, an inter-disciplinary team of FDA subject matter experts (SMEs) were assembled to assess Ecuador's RP: APAT submission. During the desk assessment, the FDA workgroup evaluated the information provided by the competent authority for each element of each standard. The workgroup also identified questions for the competent authority regarding the program based on the information submitted to seek clarity and better understanding. During the assessment process, FDA and SCI were in continual communication exchanging additional information to obtain clarity of the information between both partners. Additionally, the FDA workgroup searched SCI's publicly available website for information to support the responses in the RP: APAT submission for example, Ecuador's registration and certification lists. The FDA workgroup also assessed the SCI responses provided for each element and identified additional program areas to leverage as part of a formal partnerships, for example, their regulatory oversight of aquaculture farm activities.

A determination for each element and subsequent standard was made as to whether to proceed to the next phase of the assessment, which was the in-country verification assessment. Each team member gained familiarity with the country's laws, regulations, programs, and processes to apply during the in-country verification assessment.

In-Country Verification Assessment

The FDA subsequently conducted the in-country verification assessment to validate that the programs described in the desk assessment documentation are implemented effectively and as described. The FDA in-country verification assessment teams were selected from the larger desk assessment workgroup to ensure those conducting the in-country implementation verification were knowledgeable and understood the competent authority's current food safety controls for aquaculture shrimp and associated programs.

In August and September 2022, five FDA teams of multi-disciplinary subject matter experts conducted the in-country verification assessment of SCI's headquarters, laboratories', and field programs. Selected locations were based on the application of the food safety controls for aquaculture shrimp in Ecuador and included the hatcheries, aquaculture farms, manufacturing firms, feed manufacturing facilities, laboratories where analysis of aquaculture products occurred, and where administrative work was accomplished. SCI, in consultation with FDA, developed the in-country assessment plan and agenda for FDA's verification assessment teams to meet its objectives.

The in-country verification assessments were scheduled for one week each per field teams and one week for the headquarters team and laboratory team. At the time, SCI employed 29 Verifying Officials (inspectors) with 25 new hires in training country wide. The Field teams assessed Verification Officials (VO) implementing their program at food manufacturing facilities, feed mill facilities, hatcheries, and aquaculture farms. Each team was responsible for verifying the aquaculture food safety program through observation and questions in support of the implemented program. Each team was also supplied with outstanding issues from the desk assessment to clarify and evaluate. This ensured the teams obtained the necessary information to address potential outstanding issues upon completion of the process.

Conclusion

The overall findings from the assessment for the aquaculture food safety program implemented by Ecuador's SCI meets the expected threshold of a set of food safety controls to develop a Regulatory Partnership Arrangement (RPA) for shrimp. In other words, Ecuador's food safety controls for shrimp is science-based; is comprised of key elements of a basic food safety system; has ongoing processes to ensure the sustainability of preventive controls; provides competent oversight throughout the supply chain; and has a public health focus. The assessment also concluded that the SCI's food safety program for shrimp implemented through the supply chain to include aquaculture farms could be leveraged to help ensure the safety of aquaculture shrimp imported into the U.S. Ultimately, the findings from this assessment support FDA pursuing a Regulatory Partnership Arrangement with SCI and the agency would benefit from leveraging their export aquaculture food safety system for the safety of U.S. food imports.