

**REGULATORY PARTNERSHIP ARRANGEMENT
BETWEEN
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
WITHIN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE REPUBLIC OF ECUADOR VICE MINISTRY OF AQUACULTURE AND FISHERIES
WITHIN THE MINISTRY OF PRODUCTION, FOREIGN TRADE, INVESTMENTS AND
FISHERIES
ON THE SAFETY OF SHRIMP EXPORTED
FROM ECUADOR TO THE UNITED STATES OF AMERICA**

The United States Food and Drug Administration (FDA) within the Department of Health and Human Services, and the Republic of Ecuador Vice Ministry of Aquaculture and Fisheries (VAP) within the Ministry of Production, Foreign Trade, Investments and Fisheries, hereinafter collectively referred to as the “Participants,” desire to safeguard public health by enhancing oversight related to the safety of shrimp. The Participants desire greater regulatory cooperation, collaboration, coordination, and information exchange between the VAP and FDA and recognize the importance of leveraging FDA’s and the VAP’s respective seafood safety systems to assure the safety of shrimp. The Participants note that this Regulatory Partnership Arrangement (“Arrangement”) is an important tool for enhancing the safety of shrimp exported to the United States of America (“United States”) from Ecuador.

**SECTION I
Purpose**

The purpose of this Arrangement is to leverage FDA’s and the VAP’s respective seafood safety systems to assure that shrimp exported from Ecuador to the United States are safe for human consumption, and meet applicable U.S. requirements, including relevant provisions of the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, and Title 21 of the U.S. Code of Federal Regulations.

This Arrangement sets out the areas of cooperation between FDA and VAP with respect to public health and consumer protection relating to shrimp exported from Ecuador to the United States and to shrimp safety-related areas of mutual interest.

SECTION II

Areas of Cooperation

The Participants intend to:

- a. Develop a collaborative partnership on shrimp safety under which the Participants plan to establish and implement work plans to enhance the safety of shrimp for human consumption exported from Ecuador to the United States and facilitate regular communications related to each Participant's respective shrimp food safety system;
- b. Share information on best practices, food safety policies, and regulatory approaches to address shrimp food safety issues and challenges, including collaborating and exchanging information to evaluate implementation efforts to enhance shrimp food safety oversight;
- c. Ensure prompt notification and response to adverse food safety events such as illnesses, outbreaks, sample findings, or regulatory action such as a recall, import refusal, product detention, or inspection, where the use of, or exposure to, shrimp exported from Ecuador to the United States may cause negative health consequences for humans;
- d. Promote and facilitate training according to specific work plan activities and timeframes that are mutually decided upon by the Participants;
- e. Participate in shrimp inspections, audits and investigations as set forth in the work plan and mutually decided upon by the Participants and where resources allow;
- f. Establish a mechanism for VAP to provide FDA with inspection and registration information, including establishment certification information regarding shrimp exported from Ecuador to the United States or vice versa, as resources allow;
- g. Ensure that only establishments across the entire supply chain certified by Ecuador are exporting shrimp to the United States; and
- h. Establish mechanisms for regular meetings and other types of engagements to develop work plans for implementing this Arrangement, exchanging information, capacity building, and strengthening regulatory cooperation.

SECTION III Information Exchange

The Participants intend to share technical expertise, provide assistance, and exchange information on regulatory and scientific issues related to shrimp safety. Such cooperation may include, but is not limited to the following:

- a. Scientific exchange and collaboration on seafood safety hazards associated with shrimp, including emerging hazards. Exchange and collaboration may include scientific reviews, development of surveys/monitoring, and procedures for sampling and analysis;
- b. Exchange of data regarding shrimp and seafood safety through the supply chain; and
- c. Exchange of regulatory assessments, pertinent laws, regulations, policies and guidance information, where appropriate.

SECTION IV Implementation

1. The Participants intend to develop and implement work plans to carry out the activities under this Arrangement.
2. The Participants intend that exchanges of non-public information pursuant to this Arrangement be done in accordance with established confidentiality commitments and any other legal requirements of the Participants.
3. The Participants intend to review the Arrangement periodically and may carry out an assessment of shrimp food safety systems for shrimp exported from Ecuador to the United States. It is intended that the content and extent of any such review and assessment will be based on discussions and suggestions that will be mutually determined and coordinated through the Contact Points.

SECTION V Contact Points

1. The Participants intend to identify Contact Points for the activities associated with this Arrangement.
2. Each Participant intends to provide written notification to the other Participant within 30 days of relevant changes in the names of its organization, the structure of its organization, and/or its Contact Points. The updating of such administrative aspects does not constitute a change to the provisions of this Arrangement.

**SECTION VI
Nonbinding**

This Arrangement does not create legally binding obligations under domestic or international law. The Participants intend that activities under this Arrangement be in accordance with applicable domestic laws, regulations and policies that might be updated throughout the years, and subject to the availability of personnel and resources.

**SECTION VII
Duration, Commencement, Modification and Discontinuation**

1. Cooperation under this Arrangement is intended to commence on the date of the last signature of the Participants and is intended to continue for a period of five (5) years. Thereafter, the Participants may extend this Arrangement by mutual decision in writing for successive five-year periods.
2. A Participant may withdraw from this Arrangement or discontinue an activity under this Arrangement at any time but is expected to give at least 60-days' prior written notice to the other Participant's Contact Points.
3. The Participants understand that withdrawal from this Arrangement or discontinuation of an activity under this Arrangement is not intended to affect ongoing cooperative activities not under this Arrangement.

Signed, in duplicate in two originals, in the Spanish and English Languages.

FOR THE UNITED STATES OF AMERICA
FOOD AND DRUG ADMINISTRATION,
DEPARTMENT OF HEALTH AND HUMAN
SERVICES:

FOR THE REPUBLIC OF ECUADOR
VICE MINISTRY OF AQUACULTURE AND
FISHERIES, MINISTRY OF PRODUCTION,
FOREIGN TRADE, INVESTMENTS AND
FISHERIES:

_____/s/_____
Mark Abdo
Associate Commissioner
Global Policy and Strategy

_____/s/_____
Andres Arens Hidalgo
Viceminister of Aquaculture and Fisheries

Date: August 17, 2023
Location: Silver Spring, MD

Date: August 24, 2023
Location: Guayaquil, Ecuador