



Office of Global Policy and Strategy

OGPS STATEMENT

August 18, 2022

FDA Signs Confidentiality Commitment with Ecuador

Today, the U.S. Food and Drug Administration (FDA) signed a [confidentiality commitment](#) (CC) with Ecuador's Vice Ministry of Aquaculture and Fisheries (VMAF) in Guayaquil, Ecuador.

The CC will allow for the exchange of confidential information, including inspection records, draft rulemaking and guidance, and other non-public documents and is an important step in preparing Ecuador for participation in a three-country pilot program designed to ensure the safety of shrimp imported to the United States.

In FY 2021 and FY 2022, Congress provided \$6 million to develop and implement options for regulating shrimp imports, including imports from the three largest exporting countries by volume over the last three calendar years. Currently, these countries are India, Ecuador, and Indonesia.

FDA is preparing to evaluate the effectiveness of using a new form of arrangement — a Regulatory Partnership — in these countries. The [partnership](#) aims to leverage commodity-specific oversight systems — in this case, involving shrimp — along with data and information, to strengthen food safety before and at the port of entry.

Mark Abdo, the FDA's Associate Commissioner for Global Policy and Strategy, signed the CC on behalf of the FDA. Andrés Arens Hidalgo, Ecuador's Vice Minister of Aquaculture and Fisheries, signed the CC on behalf of VMAF.

Also attending today's meeting was Don Prater, the FDA's Associate Commissioner for Imported Food Safety.

Below are comments made by Mr. Prater and Mr. Abdo before the CC signing.

Don Prater

Remarks for Delivery at CC Signing with Ecuador's Vice Ministry of Aquaculture and Fisheries

August 18, 2022

Guayaquil, Ecuador

Thank you everyone for the warm reception as well as all the hard work and preparation that went into this day. It's great to be with you in person and connect with so many of the food safety professionals in Ecuador who we've had the opportunity to collaborate with over the past year. We look forward to our discussions over the next couple of days and to learn even more about the robust regulatory systems and organizations in this beautiful country.

As you know, FDA oversees the safety of most of the human and animal food consumed in the United States. In 2021, the US Congress highlighted the importance of food safety related to shrimp imported from all over the world and mandated that FDA consider and develop new options for enhancing the regulation of imported aquacultured shrimp.

An important aim of the agency's strategy for addressing this mandate is to ensure the safety of imported food is held to the same food safety requirements as food produced domestically so consumers can be confident in the safety of the food they eat. In the past, FDA's imported food safety system focused mainly on intercepting unsafe food at the border and preventing its entrance into the U.S. marketplace.

As the volume of imports increased, however, the FDA has adapted new strategies and we've developed new a framework to address the ever-changing food safety challenges in the world.

This strategy is guided by four principal goals:

First, we want to ensure that all food offered for import meets U.S. food safety requirements; preventing food safety issues before product reaches our ports is one of the most effective ways to protect consumers and speed safe products into the U.S. marketplace.

Second, FDA will continue to conduct examinations and sampling of imported shipments at the ports to verify safety and prevent the entry of unsafe foods. We are using predictive tools, including artificial intelligence to help identify shipments with the highest probability of adulteration for examination.

Third, that we react quickly through corrective measures such as food recalls or destruction of the food shipment when we learn unsafe food has been imported. This includes tracing the product back to the source, identifying the source of contamination, and ensuring corrective measures are taken to prevent future illnesses are prevented.

And fourth, to ensure we have an effective and efficient food import program looking at the whole supply chain from farm to table. This is where gleaning insight and using the institutional knowledge of partners such as the Vice Ministry of Aquaculture and Fisheries as well as the Ecuadorian Shrimp Industry is paramount to our food safety goals.

Ultimately, the overall goal is to prevent problems from happening rather than simply catching them after the fact. To do this, we are using a range of tools in the international arena that complement each

other, such as Regulatory Partnership Agreements and Confidentiality Commitments to help establish a framework for FDA and our regulatory partners to collaborate. These agreements allow us to share and rely on various types of data and information, including, as necessary, certain kinds of non-public information.

The FDA recognizes the importance of establishing strong partnerships with all stakeholders along the farm-to-table continuum, including foreign governments, given the importance of foreign sourcing in U.S. food consumption. The principal goal of the Regulatory Partnership will be to establish a forum with Ecuador where we can learn about our respective regulatory authorities and how we can work together to effectively strengthen the enforcement of food safety measures around shrimp.

Over the past few years, FDA and Shrimp Industry partners in Ecuador have maintained a strong relationship through industry and government training programs. We hope to continue to build on this relationship and view a partnership between our agencies as mutually beneficial and could help meet both of our respective interests for advancing food safety and facilitating trade.

Thank you.

Mark Abdoo

Remarks for Delivery at CC Signing with Ecuador's Vice Ministry of Aquaculture and Fisheries

August 18, 2022

Guayaquil, Ecuador

Today more than ever we are observing the effects of living in a globalized world with interconnected supply chains. That's certainly the case for food. Russia's unprovoked invasion of Ukraine is jeopardizing the food supply of several countries in the world, with strong repercussions on their economies and food security.

In the United States, we're certainly reliant on imported food. Approximately 13 percent of the U.S. food supply, including 52 percent of the fresh fruit, 29 percent of the vegetables, and 93 percent of the seafood is imported and much of this food comes from Latin America — including Ecuador.

Ecuador may be a small country, but it has become an important supplier of food to the United States. In 2021, Ecuador exported \$3.2 billion in food to the United States. Half of that amount was seafood, including shrimp, tuna, Mahi Mahi, and swordfish. In addition, Ecuador supplies the United States with bananas, plantains, mangoes, vegetables like broccoli, and, of course, cocoa and coffee products.

No matter where our food comes from, whether from a tomato grower in California or an aquaculture farm in Ecuador, our food must also be safe to eat.

While the U.S. food supply is among the safest in the world, there are still about 48 million cases of foodborne illness annually — the equivalent of sickening 1 in 6 people in the United States — and each year these illnesses result in an estimated 128,000 hospitalizations and 3,000 deaths.

To address this challenge, the FDA has revamped its approach to food safety over the last decade, moving from response to prevention. In 2020, the FDA took another step to modernize its approach by

rolling out a blueprint for a New Era of Smarter Food Safety that looks to tech-enabled traceability, using smarter tools and approaches for prevention and outbreak response, meeting the challenge of new business models such as e-commerce, and adopting a culture of food safety.

Given today's interconnected food supply chains, however, the United States can't achieve its food safety goals alone.

The FDA maintains foreign offices in important trading markets around the world including Latin America to help ensure the safety, quality, and effectiveness of both the food and medical products that we regulate. These offices serve as the FDA's eyes and ears in a country or region and help us build partnership with countries — such as the one we are building with Ecuador — industry, academia, and civil society to help us protect and promote public health through more robust oversight of FDA-regulated products exported to the United States

The FDA's Latin America Office was established in 2009 to serve as the lead for the FDA's on-site presence in the 44 countries and territories that span Latin America, from the U.S. border with Mexico to the tip of South America, Central America, the Caribbean, and Mexico.

Much of what our Latin America Office — or LAO — does involves assessment, information sharing, cooperation and collaboration with our regulatory counterparts and other stakeholders. For example, LAO provides Ecuador and other countries with information, tools, training, and exchange programs that contribute to building or strengthening their approach to risk management, regulation, and food safety practices so that together we can bend the curve on foodborne illness.

Information sharing is essential as we interact with our regulatory partners to assess food safety risks and devise solutions.

But there are limits to what we can share without a Confidentiality Commitment that allows for the sharing of non-public information.

That's why today's event is so important. The FDA's signing of a confidentiality commitment with Ecuador's Vice Ministry of Aquaculture and Fisheries demonstrates the importance of our partnership and the trust we place in the Vice Ministry, and it will surely lead to food safety benefits for consumers in both of our countries. It will allow the sharing of confidential information about inspection records, draft rulemaking and guidance, and other non-public files. In short, it will allow us to take our ongoing relationship to a higher level, consulting in a frank and transparent way to achieve important food safety goals for shrimp imported into the United States.

With Ecuador, the FDA has been lucky enough to find open doors, a strong food safety culture and a willingness to work together to build this regulatory partnership. We appreciate the collaboration and hard work that brought us to this point, and we look forward to many future projects together.

Thank you.