

U.S. Food and Drug Administration sent this bulletin at 09/22/2022 11:54 AM EDT

For best experience [view as a webpage](#).



September 2022

[Global News](#) | [Briefs](#) | [Staff News](#) | [Staff on the Move](#)
[Dear Int'l Colleague](#) | [Events](#)

In this issue



Abdo visits Latin America



EO+OECD vs. illicit products



Hampton named Deputy Dir.



CC signed with Ecuador



U.S.-Mexico FSP progress



INO visits shrimp farm

...and much more inside...

FDA Leads International Workshop on Combating Illicit Health Products

More than 100 persons from government, multilateral international organizations, industry, and civil society participated in a September 15-16 workshop in Paris on combating the trade in illicit health products.

The two-day event was co-hosted by the FDA and the Organisation for Economic Co-operation and Development (OECD) who have partnered under the auspices of the OECD's Task Force on Countering Illicit Trade to promote a whole-of-governments approach to protect consumers from illicit products.

Over the last few years, criminal networks have become increasingly sophisticated, capable of exploiting regulatory, legal, and other gaps to ship and or transship illicit and potentially dangerous health products. These may even include drugs intended to treat serious and life-threatening conditions, such as various forms of cancer, and that require strict temperature controls to be administered safely. Many of these products are being ordered online by consumers and shipped in small packages.

“When criminals are intent on probing for potential weaknesses, there’s a risk they’ll succeed, and products will slip through,” said Mark Abdoo, associate commissioner for global policy and strategy, in [opening remarks](#). “However, these gaps are less likely to occur if multiple countries and their arsenals of authorities that crosscut multiple sectors of government coordinate their efforts in what we call a whole-of-governments approach.”

The FDA's Office of Criminal Investigations has been piloting that approach with the United Kingdom through a series of five initiatives called Operation Lascar. The latest initiative involved the U.S. FDA's Office of Criminal Investigations (OCI is a component of the Office of Regulatory Affairs), U.S. Customs and Border Protection, the U.S. Patent and Trademark Office, the U.S. Embassy in London, and the United Kingdom's HM Revenue & Customs, Border Force, and Intellectual Property Office. Taken together, these five initiatives were responsible for the initiation of more than 80 new FDA criminal investigations and the identification of more than 3,000 violative shipments of illicit medicines intended for the United States. Operation Lascar was discussed by OCI's Kerry Mannion as a case study at the workshop.



The FDA's Mark Abdo and Andi Fristedt, at left, participate on the Executive Panel at the OECD workshop.

During the Executive Panel, the first session of the event, Andi Fristedt, FDA deputy commissioner for policy, legislation, and international affairs, discussed the importance of global cooperation to address shared threats, as demonstrated during the COVID-19 pandemic, when long-standing relationships with foreign regulatory counterparts proved essential to facilitating rapid exchanges of information and concerted approaches. “The FDA has taken an active part in many multilateral initiatives to address illicit health products,” she said. “Valuable lessons learned, and best practices can be drawn from these examples. One common theme is the need for global leadership to promote coordinated action at the international level and cross-sector collaboration.”

The topics covered in the other workshop sessions included:

- Operation Stop, organized by the World Customs Organization (WCO) with the support of a number of international organizations, which targeted illegal trafficking of COVID-19-related products such as illicit and substandard medicines, and vaccines, as well as PPE and other COVID-related medical devices such as masks, gloves, COVID-19 test kits, thermometers, and gowns. A total of 502 million pieces were seized during Operation STOP II from April 2021 to May 2022.
- Data gathering and other efforts by multilateral organizations, including Interpol, Europol, the World Health Organization, the World Trade Organization, the MEDICRIME Committee of the Council of Europe, and the International Narcotics Control Board, in addition to the WCO.

- How to foster international, bilateral, and plurilateral collaboration (greater use of confidentiality commitments, data sharing, communications).
- The potentially positive role that could be played by intermediaries such as online stores, social media platforms, internet providers, and the application of varying postal policies of nations around the world.
- Building partnerships with the private sector, including pharmaceutical companies, which may possess actionable information.

What caught everyone's attention was the scale, magnitude, and underlying causes of transshipments — when illicit products enter the U.S. marketplace after first being shipped to a country in the European Union as an intermediate destination, usually without entering customs — a practice that has increased during the COVID-19 pandemic.

A review of recent FDA data suggests a worrisome uptick in detentions from certain European Union member states and a relationship between bad actors transshipping products to the United States from more than one European country, said Catherine Hermsen, FDA assistant commissioner for criminal investigations, during the session on this topic. Recently, the FDA examined 100 mail detentions appearing to originate from an EU member state, which were found to contain 40 different products, intended for five countries, and that were associated with 33 online pharmacies. Every shipment was associated with the same return address in this EU member state, she said. One issue identified in the session: the potential regulatory gap of the world's 3,500 (according to 2019 OECD data) free-trade zones, which offer lighter regulations and controls and are therefore vulnerable to abuse by illicit traders. The OECD has made progress toward a certification scheme for these zones that could help address this issue.



After two days, it was clear that much is already going on in this sector, however what is needed is greater communication, coordination, and cooperation toward a strategic multisectoral effort, according to Ritu Nalubola, director of the FDA's Europe Office. From information-sharing mechanisms and interoperable data platforms for effective real-time *communication to coordination* of capacity-building efforts and regulatory *cooperation*, the experts at the workshop provided substantive insights for the FDA to consider next steps in building on the momentum gained thus far. A mapping of activities and key stakeholders to get a better understanding of who is doing what to address this globally shared problem was of interest to many.

Just hearing what others are doing is a good start, participants said.

Assistant FDA Commissioner Hermsen stressed the expandability of partnerships and the importance of obtaining and maintaining executive level buy-in when approaching multisectorial work. "Further, even in your own sector, the most critical component of effective engagement is identifying what is important for each stakeholder involved."

Greater focus on the patient is also needed, according to OCI's Mannion. "We've lost the debate over price," he said. "We need to focus on the health and safety aspect, capturing the real-world stories [affecting patients] so that consumers will think twice before buying products on the internet."

Next steps are still under discussion. Participants are likely to establish a core group of experts to address identified issues.

Whatever approach emerges from the workshop "should translate into a path toward prevention rather than response," said OGPS' Abdo. That means, he said, not only getting to the source on supply but addressing the demand for these products.

"The fact is — the stakes are high," he said. "Illicit trade is a severe threat that not only damages economic growth but also undermines national security, good governance, the rule of law, and trust in government. And for the FDA and our regulatory counterparts, illicit goods that enter our marketplaces can pose serious health and safety consequences, including death."

Head of Australia's Therapeutic Goods Administration Visits FDA Headquarters



John Skerritt, head of Australia's Therapeutic Goods Administration (TGA), visited the FDA's White Oak Campus September 19-20 for a series of conversations with his FDA counterparts, including a commissioner's meeting with Principal Deputy Commissioner Janet Woodcock, M.D., Deputy Commissioner for Policy, Legislation, and International Affairs Andi Fristedt, and Chief of Staff Julia Tierney, in addition to FDA Commissioner Robert M. Califf, M.D.

Since the TGA oversees human medical products as well as nicotine and vaping products, separate sessions were arranged with the senior leadership from the Centers for biologics, devices, drugs, and tobacco. Skerritt also met separately with the leadership of the Office of Women's Health and with the leadership of the Oncology Center for Excellence.

To mark the visit, the Office of Global Policy and Strategy [published an interview](#) with Professor Skerritt, "Australia's Robust Strategy for Regional and Global Medical Product Engagement," under the OGPS series called ***From a Global Perspective***.

"We've found that close interactions with each of the center directors and senior staff has been tremendously valuable during COVID and will continue to be in the future," he said in the interview.



(Left to right) Julia Tierney, Andi Fristedt, Dr. Robert Califf, Dr. Janet Woodcock, and John Skerritt.

[Read Skerritt's interview](#)

FDA Signs Confidentiality Commitment with Ecuadorean Seafoods Agency

On August 18, the Food and Drug Administration signed a confidentiality commitment (CC) with Ecuador's Vice Ministry of Aquaculture and Fisheries (VMAF) in Guayaquil, Ecuador.

Associate Commissioner for Global Policy and Strategy Mark Abdoos 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 the VMAF.

The CC will allow for the exchange of confidential information, including inspection records, draft rulemaking and guidance, and other nonpublic

documents. It 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 2021, 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.

The 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.

“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,” said Don Prater, the FDA’s Associate Commissioner for Imported Food Safety, before the CC signing. “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.”

Although Ecuador is a small country, it is an important supplier of food to the United States, with \$3.2 billion in exports in 2021. 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 cocoa and coffee products.

“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 countries,” said Abdoo. “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,” he said.

India Office Learns about Shrimp Farming

Forty percent of shrimp consumed in the United States are from India, making it important to ensure government officials, farmers, shrimp processors, and academia understand principles of seafood safety on the farm. Toward that end, FDA India Office (INO) personnel — including Director Dr. Sarah McMullen, Deputy Director Dr. Natalie Mickelsen, and Food Safety Coordinator Dr. Pankaja Panda, along with International Policy Analyst CDR Nicole Conklin, from the FDA’s OGPS/Office of Global Operations — attended the Good Aquaculture Practices Training for farm-raised shrimp, hosted this summer by the government of India’s (GOI) Marine Products Export Development Authority (MPEDA) at their headquarters in Kochi, in the state of Kerala. The course was presented by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), an FDA-supported international training partner that is organized under the University of Maryland.



FDA Staff visit a modern shrimp farm located in the state of Kerala, India. From left to right: Nicki Conklin, Pankaja Panda, farm owner Anish George, Sarah McMullen, and Natalie Mickelsen.

Why the interest in learning best practices for raising shrimp? Because growing practices significantly impact the safety of aquacultured seafood products. In India, MPEDA works alongside other central government authorities including: the Coastal Aquaculture Administration, Export Inspections Council, and Indian state-level fisheries departments to ensure the safety and quality of India's aquacultured shrimp. FDA inspections of aquacultured shrimp products begin with the primary processor who is responsible for assuring control of food safety hazards on the farms. The agency's investments in partnership with the GOI will provide greater oversight on the farms and will enhance the safety of shrimp exported to the U.S. consumer.

In response to provisions outlined in the U.S. Consolidated Appropriations Act 2021, the FDA is exploring a first-of-its-kind partnership agreement with the GOI regulatory authorities to further ensure shrimp safety. The FDA and MPEDA recently signed a confidentiality commitment that facilitates the ability to share nonpublic information between these agencies. The FDA and MPEDA are also working together on assessments, joint training, and conferences to ensure safer shrimp products for consumers in India and the United States.

To enhance their understanding about aquaculture safety, the training participants visited a shrimp farm in nearby Alappuzha, Kerala. The farm's owner, who was in the information technology industry before taking up aquaculture, has converted a few village ponds into what is now a modern shrimp farm.

The INO participants learned that for any farm, the two most important food safety considerations are the feed and water quality:

- **Feed** is the most expensive component of shrimp farming and can take up to 60% of operating costs per harvest cycle. Fish meal and soybean-based feeds are the most commonly used and need to be sourced from reliable suppliers, as any contamination with pesticides, other chemicals, or veterinary drugs, puts the shrimp at risk of containing unsafe post-harvest residues. Proper supply controls, storage, and testing of feed are critical to ensure safe shrimp.
- **Water** is just as important as feed. Shrimp sourced from contaminated water can lead to pathogens in the final food product, so a clean water source is important. Also, shrimp need dissolved oxygen in the water to breathe, and more dissolved oxygen is needed as they grow. Oxygenation of water in ponds is done by aerator paddles at timed intervals during the day. Dissolved oxygen levels are frequently tested by farm employees. Records for all water and feed testing are required and need to be maintained for inspections by state and central government agencies.

Biosecurity of farms is also vital if the farmer is to avoid contamination of the shrimp ponds by animals, people, or equipment. In fact, biosecurity addresses anything that comes from outside the farm. One of the ways to protect the shrimp from disease spread and wild animal predation is the placement of nets over the top of ponds to prevent birds from entering, and nets along the pond edges to prevent entrance of crabs, both of which can bring outside diseases to the farm. Another common practice is for workers and visitors to wash their hands in a sanitizing solution and rinse their footwear in a sanitizing footbath before entering the pond area. These practices prevent diseases — sometimes deadly — from entering the ponds and infecting the shrimp, resulting in huge losses to the farmer. If diseased shrimp are detected at a global port of entry, the shipment may be refused by the importing country, leading to the required destruction of the shrimp or having the shipment sent back to India.



The workings of a shrimp farm. Upper Left: INO's Sarah McMullen sanitizes her footwear in a chlorinated foot dip to prevent tracking disease vectors to the pond area. Note behind her the netting above and surrounding the pond used to stop wildlife from getting into the pond. Center: Farm worker checks shrimp for size and health. Upper right: Aeration paddles are used to increase oxygenation in the ponds. Lower right: Storage of bags of soybean meal and fish meal, for feed. Lower left: Test kit for chlorine content of foot dip and oxygen content of pond water.

This glimpse into the operations and challenges facing India's 77,000+ shrimp farms will help expand agency insight regarding the challenges that face shrimp farmers and why it is important for the FDA to collaborate with the GOI to ensure the safety of imported shrimp.

India Office Supports Seafood Import Training

The FDA India Office and India's Export Inspection Council (EIC) co-hosted a series of FDA Import Trainings during late August, which were held in four cities across India: Delhi, Mumbai, Kolkata, and Chennai. The FDA India Office has a long-standing relationship with the EIC, strengthened by a confidentiality commitment signed in 2016 by both agencies. Historically, the FDA and EIC have also partnered to provide training to the Indian seafood industry on a variety of topics including seafood safety, seafood HACCP (Hazard Analysis and Critical Control Points), and preventive controls.



Views of India Office personnel, FDA/ORA instructors, and the many students attending import trainings held in cities across India.

Last month's training was targeted at seafood exporters and Government of India regulators and featured three instructors from the FDA's Office of Regulatory Affairs — Consumer Safety Officers Cindy Ford and Anna Brannen, and Program Analyst Owais Tomhe. India Office staff — Director Dr. Sarah McMullen, Deputy Director Dr. Natalie Mickelsen, and Food Safety Coordinator Dr. Pankaja Panda — took turns providing the opening remarks.

Over 300 attendees — both in person and remote — received critical information on the FDA's import program and how to ensure that their products are compliant with FDA regulations when offered for import to the United States. Participants also learned where to find additional information and guidance.

The India Office receives multiple inquiries each week regarding the intricacies of the FDA import process and were instrumental in suggesting that the FDA develop a [video](#) on the process. Additional import topics are currently under development by staff at ORA and OGPS.

Tangible Progress Reported at Second Annual Food Safety Partnership Meeting

The FDA and its regulatory counterparts in Mexico — the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) and the National Service of Agro-Alimentary Health, Safety, and Quality (SENASICA) — reported progress in advancing food safety in both countries during the second annual meeting of their Food Safety Partnership (FSP) on August 25 in Mexico City.

The three regulators established the FSP in August 2020, expanding the scope of their previous 6-year-old produce safety partnership to include the safety of all human food. During this year's meeting, the agencies reported tangible progress involving the FSP's workgroups and discussed plans for the coming year.



(Left to right) Francisco Javier Trujillo Arriaga, director in chief of SENASICA; Mark Abdo, FDA's associate commissioner for global policy and strategy; Frank Yiannas, FDA's deputy commissioner for food policy and response; and Alejandro Svarch Pérez, federal commissioner for COFEPRIS.

“We are building on the long-standing partnership for the U.S. and Mexico to work together to contain outbreaks of foodborne illness and lessen consumer exposure to foodborne hazards. As we approach the 200th anniversary of U.S.-Mexico relations, keeping this partnership strong is more important than ever,” Frank Yiannas, the FDA's deputy commissioner for food policy and response said in a same-day press release issued by the FDA.

Reported progress and outcomes included:

- **Work Group One – Strategic Priorities (addressing commodity-specific issues):** Exchanged key information and plans that guided

efforts to address a 2021 Salmonella outbreak linked to **bulb onions** from the State of Chihuahua, Mexico. The three agencies collaborated to share information on their respective onion plans to guide response and prevention efforts such as: SENASICA's mobile laboratory for assessing field samples from inspections; the FDA's Foreign Supplier Verification inspections for onion importers; and technical meetings hosted with Mexican onion growers and packers to learn more about their production practices. The FDA and SENASICA also collaborated with the **papaya** industry on the verification of the papaya checklist, a tool to further encourage the adoption of food safety best practices for papaya.

- **Work Group Two – Laboratory Collaboration:** Discussed progress on the implementation by SENASICA and COFEPRIS of the FDA's Cyclospora methodology distance training plan, which is based on the Bacteriological Analytical Manual, or BAM, Chapter 19b method for detecting *Cyclospora cayetanensis* in produce samples. Competency in the methodology will expand international capacity for detecting this pathogen. SENASICA also committed to a data-sharing agreement with the FDA to upload 100 genomic sequence data sets (food and environmental) to the GenomeTrakr network. This is an important contribution to the GenomeTrakr network and will allow both Mexico and the United States to identify and respond to outbreaks faster and with more precision, helping to minimize the number of consumers impacted.
- **Work Group Three – Enhancing Outbreak Response:** Established a revised Binational Outbreak Notification Protocol to improve timely and effective communication by sharing genomic sequence data (including a reference to the laboratory methodology for its detection) and using the FDA CORE Investigation Table to share publicly available epidemiologic information. The table was introduced in 2020 to share information on the FDA's investigations of foodborne illness outbreaks, even in their early stages, and as soon as the FDA begins its response to an outbreak. As a next step, the FDA, SENASICA, and COFEPRIS are working together on a new model for conducting inspections that would involve the participation of all three regulatory agencies where a food safety issue is suspected.
- **Work Group Four – Food Safety Training:** During this year's meeting, the FDA, SENASICA, and COFEPRIS reviewed Produce Safety Rule (PSR) trainings they had facilitated, including those with cilantro growers in Puebla, avocado growers in Jalisco, and bulb onion growers in Chihuahua. The three agencies also worked with EMEX, a mango association, to conduct three PSR trainings for mango

producers in the states of Sinaloa, Nayarit, and Jalisco. The FDA also provided outreach to SENASICA and COFEPRIS personnel about the FDA's proposed rule for agricultural water: "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water."

Mexico is a primary supplier of fresh fruits and vegetables to the United States. FDA data shows that about one-third of all agency-regulated human food imported into the United States is from Mexico, including 60% of our fresh produce imports.

"Within the framework of the celebration of 200 years of diplomatic relations between Mexico and the United States, we are honored to be FDA partners," Francisco Javier Trujillo Arriaga, director in chief of SENASICA was quoted as saying in the FDA's press release. "We know the importance of what is at stake, and we are convinced that the success stories we have had with producers and marketers of different types will generalize to other environments."

"In this annual meeting, various activities were carried out that have contributed to a better understanding of the safety systems of both countries," said Federal Commissioner for COFEPRIS, Alejandro Svarch Pérez in the same press release. "In addition, they highlighted that they have allowed for a greater rapprochement between the main actors in the food production chain, with the aim of coordinating efforts and taking advantage of the experience and knowledge available."

Besides the partnership meeting, officials from the FDA, SENASICA, and COFEPRIS toured a tomato greenhouse to observe Mexico's growing and harvesting practices. They also met with Mexican produce associations to hear about their advanced food safety measures — including traceability protocols, produce safety training, and commodity-specific guides — and the challenges they currently face.

Other FDA participants, besides Yiannas, included: Don Prater, the FDA's associate commissioner for imported food safety; Mark Abdo, the FDA's associate commissioner for global policy and strategy; Mike Rogers, assistant commissioner for human and animal food operations in the Office of Regulatory Affairs; Doug Stearn, deputy director for regulatory affairs in the FDA's Center for Food Safety and Applied Nutrition; and Katie Serrano, director of the FDA's Latin America Office.

Imported Foods: FDA's Pesticide Residue Monitoring Report

The enticing array of fruits, vegetables, grain products, and other food items on display at your local grocer are the end result of a managed process from farm to retailer. As part of the process, growers, both in the United States and abroad, often use pesticides to protect their crops and products from insects, weeds, fungi, and other pests.

The Food and Drug Administration works with the Environmental Protection Agency (EPA) to ensure that food treated with a pesticide is safe to eat. The EPA sets limits called “tolerances,” which are based on safety standards, for any residues that remain in or on food; and the FDA monitors for the presence of such residues. (The U.S. Department of Agriculture, or USDA, is responsible for monitoring pesticides in meat, poultry, catfish, and certain egg products — those foods that are under USDA’s jurisdiction.)

The FDA employs a threefold strategy to enforce the EPA’s tolerances for pesticide chemical residues in human and animal food. The FDA’s [pesticide residue monitoring program](#) selectively tests for the presence of nearly 800 pesticide residues and selected industrial compounds in a broad range of imported and domestic human and animal food. For specific commodities or selected pesticide chemical residues of special interest, the FDA may also carry out focused sampling surveys. In addition, the FDA monitors the levels of pesticide chemical residues in foods prepared for consumption in its [Total Diet Study](#), an ongoing program that monitors contaminants and nutrients in the average U.S. diet.

The FDA has been issuing annual reports of its pesticide residue monitoring program since 1987. Its latest report, for fiscal year 2020, summarizes results from testing during the onset of the COVID-19 pandemic. (We've included some interesting tables and graphs from the report, in this article.)

From October 1, 2019, through September 30, 2020, the FDA tested 2,078 human food samples (316 domestic and 1,762 import samples). Agency staff collected domestic human food samples from 35 states and imported human food samples from 79 countries/economies. The findings show that the pesticide residues in most foods are in compliance with the EPA’s [pesticide tolerances](#). (A tolerance is the EPA established maximum residue level of a specific pesticide chemical that is permitted in or on a specific human or animal food in the United States. Anything above that level and it’s an “over-tolerance” violation.)

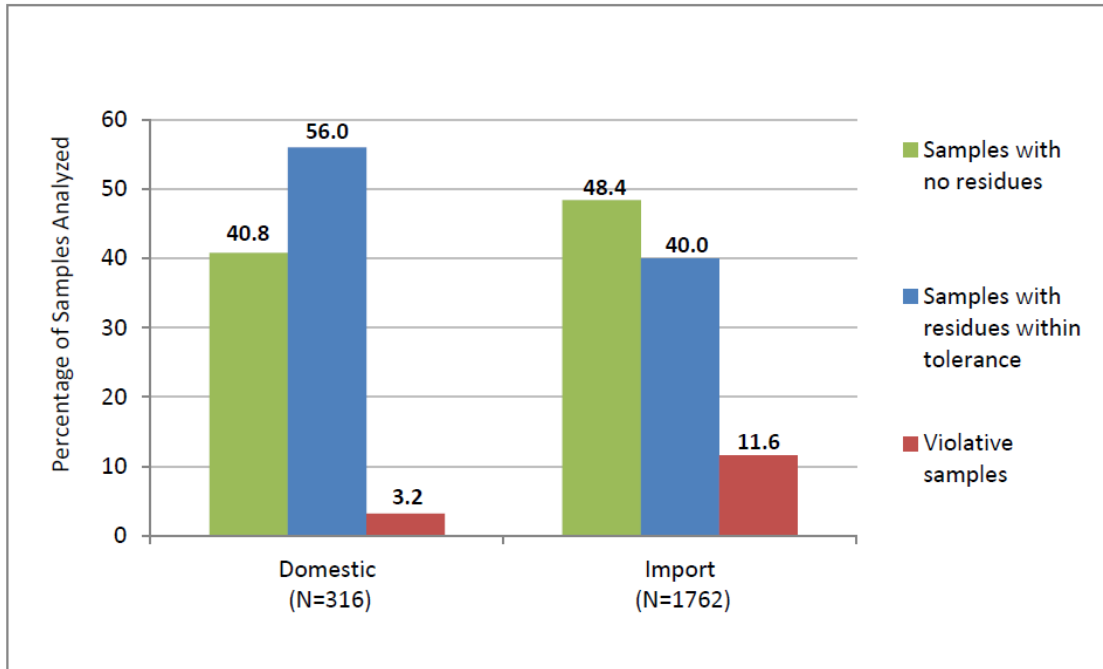
IMPORT SAMPLES PER COUNTRY/ECONOMY OF ORIGIN FOR WHICH TEN OR MORE SAMPLES WERE ANALYZED

Country/Economy	Samples (N)	Country/Economy	Samples (N)
Mexico	582	Argentina	28
Canada	164	Costa Rica	26
China	130	Thailand	24
India	118	Honduras	20
Chile	74	Korea, Republic Of (South)	17
Peru	44	United Arab Emirates	15
Dominican Republic	41	Bulgaria	14
Italy	37	Spain	13
Turkey	36	Egypt	12
Guatemala	33	Taiwan	12
United States*	32	Brazil	11
Vietnam	31	Greece	11
Ecuador	30	South Africa	11
Pakistan	30		

*Indicates import samples collected while in interstate commerce.

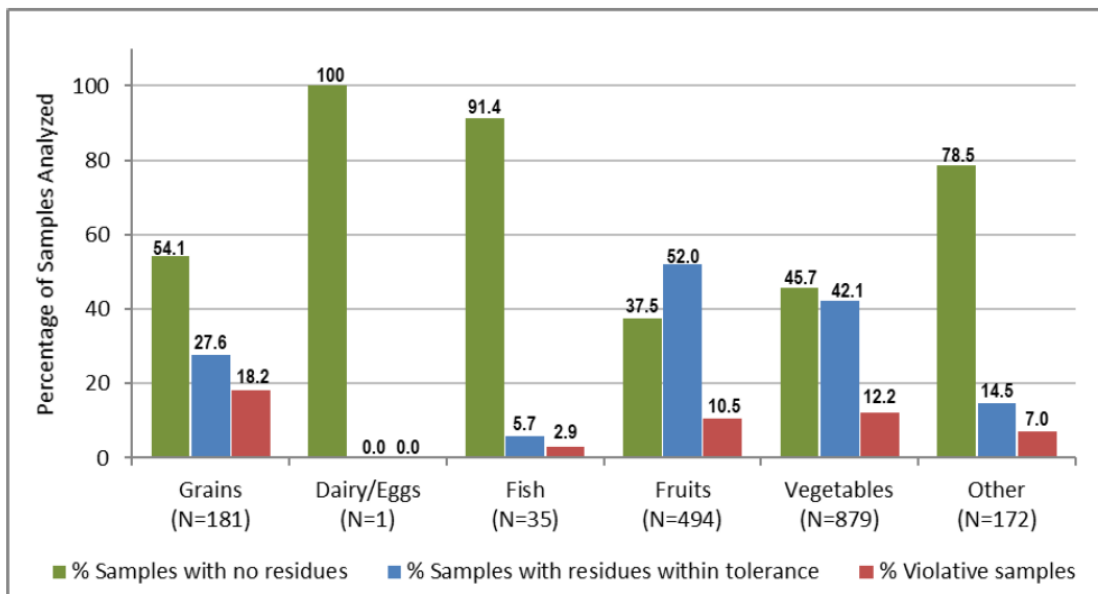
The FDA found that 96.8% of the samples of domestic human food and 88.4% of samples collected from imported human food were compliant with the pesticide tolerances set by the EPA. No pesticide residues were found in 40.8% of the domestic samples and 48.4% of the import samples. In the human food commodity groups, the violation rate in each group was higher for import samples. The higher violation rate affirms the validity of the sampling design in targeting import commodities more likely to contain violative pesticide residues.

SUMMARY OF RESULTS OF DOMESTIC AND IMPORT HUMAN FOOD SAMPLES



N = Number of samples analyzed for commodity group

RESULTS OF IMPORT HUMAN FOOD SAMPLES BY COMMODITY GROUP



N = Number of samples analyzed for commodity group

Of the 205 violative import samples, 182 had no-tolerance violations* and 53 had over-tolerance violations; 30 samples had both no-tolerance and over-tolerance violations for different pesticides contained in the same sample.

Across both domestic and import samples of human foods, 185 different pesticides were detected. The top 15 most detected pesticides are listed in the following table:

Pesticide (No. samples found)		
Azoxystrobin (146)	Imidacloprid (143)	Boscalid (124)
Fludioxonil (124)	Cypermethrin (98)	Thiamethoxam (92)
Pyraclostrobin (87)	Tebuconazole (85)	Carbendazim [†] (80)
Acetamiprid (77)	Chlorantraniliprole (76)	Pyrimethanil (71)
Chlorpyrifos (70)	Bifenthrin (69)	Cyprodinil (67)

The FDA also analyzed 102 animal food samples — 40 domestic and 62 import — for pesticides. The agency found that for animal food 100% of the domestic samples and 96.8% of import samples were compliant with federal standards. No pesticide residues were found in 30.0% of the domestic samples and 48.4% of the import samples.

The FDA's sample collection and analysis for the FY 2020 report was impacted by the pandemic. Approximately 50% fewer human food samples and 70% fewer animal food samples were collected in FY 2020 compared to FY 2019. And more import samples were collected in FY 2020 relative to domestic samples than in previous years; however, in future years, the agency expects to return to its pattern prior to the pandemic years. Nevertheless, the results from samples collected and analyzed in FY 2020 demonstrated a rate of compliance similar to what had been shown in previous years.

The FDA pesticide program is designed to focus on products that have a history of violations or are suspected of violations, based on information such as reports from other agencies and pesticide usage data. Historically, the violation rate for imported foods is higher than for domestic foods; and FY2020 continues that trend. The violation rate for imported foods (11.6%) was over three times higher than the rate for domestic foods (3.2%). The majority of the violations for imported commodities are no-tolerance violations, with approximately 78% of the violative residues less than 0.1 parts per million.

Examination of the FY 2020 pesticide data from the analysis of imported human foods indicates that the commodities listed in the below table may warrant increased sampling of import products in the future.

IMPORT COMMODITIES THAT MAY WARRANT SPECIAL ATTENTION

Commodity [†]	Samples Analyzed (N)	Violation Rate (%)
Blackeye peas	7	42.9
Celery*	20	10.0
Corn, vegetable	24	12.5
Dates*	22	27.3
Dragon fruit*	13	53.9
Ginger root	13	23.1
Jackfruit	15	26.7
Lime	21	19.1
Mango	35	11.4
Mushrooms and fungi*	42	16.7
Olives	12	33.3
Onions, leeks, scallions, shallots	51	23.5
Peas*	44	13.6
Pepper, hot*	64	21.9
Pepper, sweet*	42	19.1
Radish*	25	24.0
Rice*	131	22.9
String beans*	31	19.4
Taro, Dasheen*	30	20.0
Tomatoes	31	12.9

*These specific commodities were selected if they had a 10% violation rate or higher, and with either at least 20 samples analyzed or a minimum of three violations. *Commodity was also on the FY 2019 table of import commodities warranting special attention. †Data listed for commodities in this table are based upon specific product definitions and may not be directly comparable to product summary subcategories listed in Appendix C of the FY2020 Report.*

ENDNOTE: *By “no-tolerance” violations, we refer to circumstances where a given commodity doesn’t have an EPA-assigned tolerance for a specific pesticide chemical or an exemption from the need for such a tolerance. All the EPA tolerances for various commodities are described in [40 Code of Federal Regulations \(CFR\) Part 180.](#)]

Latin America Office Hosts First Hybrid Workshop on Software as a Medical Device

The FDA's Latin America Office (LAO) recently hosted the first hybrid virtual/in-person workshop focused on the topic of Software as a Medical Device (SaMD), that is, software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.



The LAO medical products team convened the meeting in Mexico City on August 29, drawing 50 in-person attendees and approximately 400 participants who joined virtually. Many of those who attended in person represented either industry or Mexico's Federal Committee for Protection from Sanitary Risks (COFEPRIS).

The daylong event centered on SaMD implementation by the FDA and other regulatory bodies based in the Americas — as well as how to harmonize the related guidance documents that were developed by the International Medical Device Regulators Forum (IMDRF). These SaMD-focused

documents help regulators identify commonalities, establish a common vocabulary, and develop approaches for appropriate regulatory controls that promote prospective convergence in areas of advanced and innovative technologies in this topic area. Regulators who participated in the workshop took the opportunity to share their professional experiences, as well as insights into how they incorporated the IMDRF documents into their own regulatory frameworks.

Workshop attendees discussed the necessity of practices such as regulatory jurisdiction to demonstrate compliance and the inclusion of device risk in the regulatory framework. Similarly, the importance of harmonizing documentation and procedures to demonstrate that a device complies with specific requirements relating to the product, process, and system — i.e., device

conformity assessment — was highlighted by the participants. Attendees also advocated for transparency and initiation of dialogue between regulators and industry to achieve more efficient regulatory convergence and streamline authorizations of products.

Joining the FDA and COFEPRIS at the workshop were Argentina’s National Administration of Drugs, Foods, and Medical Devices (ANMAT), the Brazilian Health Regulatory Agency (ANVISA), and Colombia’s National Institute of Drug and Food Surveillance (INVIMA).

FDA, AdvaMed Meet to Discuss Regulatory Updates in India

Potential changes are underway in how India regulates medical products. If finalized, the bill would replace the Drugs and Cosmetic Act of 1940 and provide updates to the regulatory oversight of medical devices, clinical trials, and counterfeit and illicit drugs.

In July 2022, India’s Ministry of Health and Family Welfare (MoHFW) published a draft of the Drugs, Medical Devices, and Cosmetics Bill 2022 with a 45-day comment period, closing on August 22, 2022. To date, medical products sold and distributed in India have been largely regulated nationally through the Drugs and Cosmetics Act of 1940, with two recent rules — the New Drugs and Clinical Trials Rules, 2019, and the Medical Devices Rule (MDR 2017).



FDA representatives from the Office of Global Policy and Strategy and the Center for Devices and Radiological Health met with colleagues from the Advanced Medical Technology Association (AdvaMed) in August to discuss the potential impact of this draft bill, which, for the first time, would create a separate category for medical devices, as separate from drugs.

India has around 37 agencies overseeing medical products at the central and state level: one in each state and union territory, and nationally with the Central Drugs Standard Control Organization (CDSCO), which is under the MoHFW. The CDSCO issues product licenses to both domestic producers and importers of regulated products; State regulatory authorities issue manufacturing licenses to domestic firms, while the CDSCO issues manufacturing licenses to importing firms. The CDSCO also establishes standards and regulates clinical trials of medical products in India.

The draft bill proposes other significant changes for medical devices:

- Expanding regulatory coverage to include diagnostic equipment and their software, implants, devices for assistance with disabilities, devices as life support systems, instruments used for disinfection, and reagents or kits.
- Creating a “Medical Devices Technical Advisory Board,” similar to “Drug Technical Advisory Board” to advise on approvals.
- Establishing new medical device testing centers at the state and central levels.

In addition to its proposed changes for medical devices, the bill proposes time-bound review for clinical trials and prioritizes indigenously developed drug applications. It also would clarify compensation for clinical trial subjects who experience adverse events and further define local clinical trial waiver conditions.

The legislation also creates a definition for over-the-counter drugs and expands the definition of spurious drugs to include products lacking the intended active pharmaceutical ingredient.

Both the FDA’s India Office and the Office of Trade, Mutual Recognition, and International Arrangements plan to continue to monitor the development of the bill and its accompanying measures.

Seven Business Days – Three Countries – OGPS Leadership Visits Latin America

FDA Associate Commissioner for Global Policy and Strategy Mark Abdoos held a series of meetings in Ecuador, Costa Rica, and Mexico over the course of seven business days and two time zones in late August. During that period, he met with staff from the Latin America Office (LAO), with regulators and government officials, with industry, and with civil society, and touched on a variety of issues that impact both FDA's food and medical products work.



The highlight of Abdoos's first stop, to Guayaquil, Ecuador, was the signing of a confidentiality commitment with the Vice Ministry of Aquaculture and Fisheries (see separate story) followed by a visit to the two Undersecretary of Quality and Food Safety Laboratories (the Aquaculture Pathology Testing Laboratory and the Laboratory for Chemical and Microbiological Analysis of Food). He ended the day by meeting with the leadership of the National Chamber of Aquaculture, Ecuador's most prominent private organization in the aquaculture sector. While in Guayaquil, Abdoos and staff also met with the CORDEX Export Corporation, established just last year to represent the sectors of the Ecuadorian export chain, and with the National Agency for Sanitary Regulation, Control, and Surveillance, which has many of the same regulatory responsibilities as the FDA.



Since most of the FDA's LAO staff are assigned to the post in San José, Costa Rica, part of Abdoo's visit there was devoted to meeting with staff and with officials with the U.S. Embassy, within which the FDA office is co-located. In addition, Abdoo and staff met with the leadership of the Costa Rican National Commission for the Prevention and Fight against Counterfeit and Illegal Products of Sanitary Interest to discuss the FDA's evolving whole-of-governments approach to combatting illicit health products (see separate story about the September meeting in Paris on that topic). In addition, he met with officials from the Costa Rican Coalition of Development Initiatives, a private, nonpolitical, and nonprofit organization that provides proactive advocacy for investment in Costa Rica in strategic sectors; and with Lloyd Day, deputy director general of the Inter-American Institute for Cooperation on Agriculture (IICA), the specialized agency for agriculture of the Inter-American System. IICA, which supports the efforts of its more than 30 Member States to achieve agricultural development and rural well-being, has been an essential FDA partner, supporting the agency's efforts to educate exporting food producers in the region so they can comply with the many provisions of the FDA's Food Safety Modernization Act. A recent [OGPS blog](#), timed for release on the day of Abdoo's IICA meeting, describes the FDA's partnership with the organization.

Abdoo's last stop was to Mexico City to participate in the second annual meeting of the Food Safety Partnership between the FDA and its two regulatory counterparts in Mexico — the Federal Commission for the Protection from Sanitary Risks and the National Service of Agro-Alimentary Health, Safety and Quality (see separate story). While in Mexico City, Abdoo also participated in a panel discussion with medical product industry associations — the Mexican Pharmaceutical Council, the National Chamber of the Pharmaceutical Industry, and the Asociación Mexicana de Industrias Innovadoras de Dispositivos

Médicos — discussing supply chains, challenges accessing the U.S. market, International Council for Harmonisation guidelines, and opportunities for collaboration.

IICA: An Essential FDA Partner

For 75 years, the Inter-American Institute for Cooperation in Agriculture — or IICA — has been working to advance the agricultural development and rural well-being of countries across the Americas.

Last month, Katie Serrano, director of our Latin America Office, [wrote an article](#) discussing the many ways in which IICA has become an essential educational partner for the FDA in that region, as the agency began rolling out the FDA Food Safety and Modernization Act, or FSMA. Latin America is an important food exporter to the United States, so IICA has served an important role in keeping the region's agricultural industry informed of FSMA's many requirements.

The article, one of the latest in the OGPS series [From a Global Perspective](#), was originally published in English but will also be translated into Spanish for broader distribution.



[Read Serrano's article on IICA](#)

The GDPR: An Impactful European Data Law

A law enacted by the European Union in 2018 requires that organizations put in place certain measures if they collect, use, or store personal data originating from persons in the European Economic Area (the 27 EU member states plus Iceland, Norway, and Lichtenstein) to ensure that the data is protected, even if transferred out of the area.

The FDA's Europe Office has been closely following the potential impact of the General Data Protection Regulation, or GDPR, on the agency's public health activities. So far, the FDA's bioresearch monitoring program, which oversees the conduct and reporting of FDA-regulated research, has been most impacted by the law, [writes](#) Heather Messick, J.D., who tracked the GDPR while assigned to the Europe Office as an international policy analyst.

Messick's "How a European Data Law Is Impacting FDA" is one of the latest articles to be published by OGPS as part of its [From a Global Perspective](#) series, occasional thought pieces on international topics written by FDA experts across the agency.



[Read Messick's article on EU Data Law](#)

Staff News

Kristi Hampton Named as First OGPS Deputy Director



The person chosen to become the first deputy director of the Office of Global Policy and Strategy is a familiar face in the office — Kristi Hampton, who previously served as the senior advisor to Associate Commissioner Mark Abdo.

“In this new role, Kristi will continue to lead the development and implementation of OGPS’ Organizational Excellence Action Plan and will guide certain crosscutting functions for the office,” said Abdo in his announcement on August 24.

“I am honored to be selected as the first Deputy Director of OGPS and am dedicated to establishing a strong foundation for this role that serves the needs of the office,” Hampton said.

As deputy director, Hampton will focus on ensuring that the organization’s strategic and programmatic activities are thriving. She plans to continue building on the positive momentum that OGPS has gained toward achieving its strategic priority of fostering an inclusive, supportive, high performing organization that values people.

Hampton’s work will expand on OGPS’ current organizational excellence activities by further integrating those activities throughout the office. These activities include everything from recruiting to interviewing, onboarding, offboarding, professional and career development, leadership presence and engagement, employee engagement, workplace culture, strategic alignment,

operational planning, quality management, continuous improvement feedback systems, and more!

In many respects, Hampton's career journey has helped her prepare for this new role. She has over 22 years of extensive experience at the FDA from regulatory enforcement-compliance oversight and policy development to leading crosscutting organizational excellence initiatives such as change and transition management, strategic planning alignment, organizational culture activities, and employee engagement efforts.

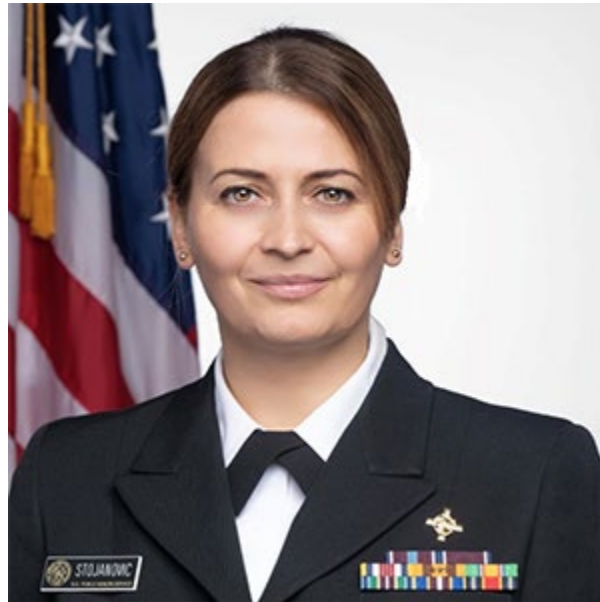
Hampton has a bachelor's degree in biology, master's degree in executive leadership, master's certification in comprehensive evidence-based coaching, and is a professional certified coach through the International Coaching Federation.

"I look forward to partnering with my OGPS colleagues to ensure that our diverse, globally dispersed staff is well positioned to seize the opportunities ahead of us and overcome any challenges that may come our way," Hampton said.

Staff on the Move



On detail



LCDR Danijela Stojanovic

Lieutenant Commander Danijela Stojanovic joined the Europe Office (EO) on a 90-day detail beginning July 31. Stojanovic will serve as an international policy analyst based at the White Oak campus and will support the European Medicines Agency (EMA)-FDA Liaison program, the FDA's work with the EMA on the Parallel Scientific Advice program, and the many international clusters on special topics and therapeutic areas that the agency maintains with the EMA and other regulatory authorities.

Stojanovic joins us from the CDER's Office of Surveillance and Epidemiology (OSE), where she serves as an epidemiologist on the FDA's Sentinel Initiative, the FDA's national electronic system designed to monitor the safety of FDA-regulated medical products. In that role, she has overseen Sentinel's day-to-day operations, which includes leading and coordinating activities to improve medical product safety, identifying gaps in the Sentinel system's capabilities, providing guidance to OSE leadership related to funding and implementation of additional tools, and interfacing with the myriad internal and external stakeholders, including the Centers for Disease Control and Prevention, the National Institutes of Health, and the EMA. Stojanovic is the Sentinel's team principal representative on maternal and pediatric health projects, COVID-19 rapid response inquiries, racial disparities projects, and drug safety issues in the areas of cardiopulmonary and infectious disease. Prior to taking on this role in

2018, she served as a primary reviewer for neurology products in both the Division of Pharmacovigilance and the Division of Epidemiology within OSE.

Stojanovic received a bachelor's degree in chemistry and a doctorate in pharmacy from the University of Texas in Austin and a Ph.D. in pharmacoepidemiology from the University of Florida. She is an officer in the U.S. Public Health Service Commissioned Corps.

lateral



Janete Guardia

Janete Guardia has jumped continents from the India Office to the China Office to serve as the agency's sole medical device investigator stationed in China. Her work will involve conducting complex and highly technical inspections of medical device manufacturers located across the Chinese mainland. Guardia will utilize her extensive knowledge of the FDA's medical device regulations and draw upon her many years of field experience to assess the compliance of medical device manufacturers and ensure that products that are manufactured in China for export to the United States are both safe and effective.

Prior to her arrival in Beijing, Guardia served for six years with the India Office as a bioresearch monitoring (BIMO) investigator, monitoring all aspects of the conduct and reporting of FDA-regulated research. While there, she completed over 65 foreign inspections and foreign remote regulatory assessments. Her work was critical in revealing data integrity concerns — which resulted in

blocking unsafe product from reaching the U.S. market. She also presented at numerous outreach and capacity-building events for researchers and regulators involved with clinical trials. Prior to joining the India Office, Guardia was stationed at the Office of Regulatory Affairs' Dallas District Office. There she served as a domestic investigator covering medical devices and BIMO inspections, and later as one of the investigators in ORA's Dedicated Foreign Cadre, conducting medical device inspections across Europe, Asia, and Central America.

Departing



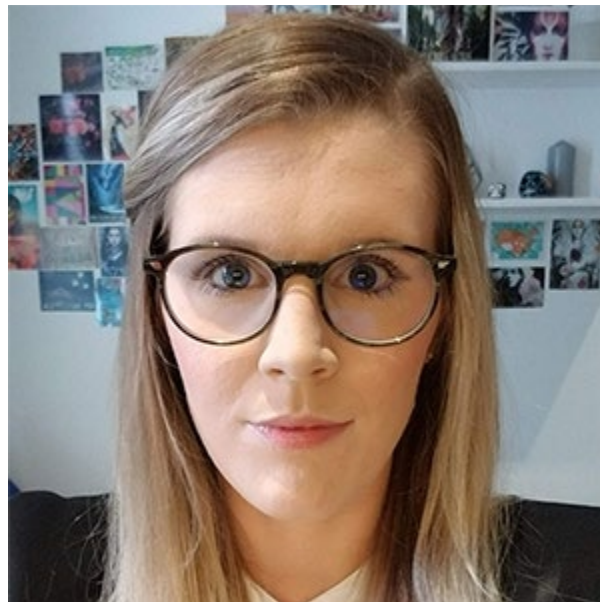
Jason Cornell

Jason Cornell's tour as a foods-focused international relations specialist for the Latin America Office (LAO) ended in August. He began his assignment with LAO in November 2017, stationed in San José, Costa Rica. But in September 2020, during the height of the COVID pandemic, Cornell voluntarily transferred to the LAO's post in Santiago, Chile, to fill a critical vacancy there. The move posed challenges for Cornell and his family because it meant they would be living in a country with some of the most restrictive COVID-19 policies in the region, allowing residents to leave their houses no more than a few hours a week.

Despite the many hurdles he faced along the way, Cornell was a dedicated LAO team member. He was instrumental in advancing the adoption of whole genome sequencing (WGS) technology across the region, helping the FDA form WGS strategic partnerships with key stakeholders in Mexico, Costa Rica, Chile,

Argentina, and Brazil and build their technical capacity to use this promising technology. Cornell also led LAO's response to emerging situations like outbreaks, helping LAO build better connections, and improve communications between the Center for Food Safety and Nutrition's Office of Coordinated Outbreak Response and Evaluation, and the Office of Regulatory Affairs to ensure a collective response in a more agile and comprehensive manner. Most recently, he has been critical in developing the LAO's policy portfolio as it relates to aquaculture, leading OGPS' efforts to lay the groundwork for establishing a regulatory partnership with Ecuador focused on shrimp.

Cornell is excited to begin a new chapter with the FDA: He now holds a position as a policy analyst with the Office of Food Policy and Response, working with the Associate Commissioner for Imported Food Safety Don Prater on New Era of Food Safety and Imported Food Safety projects.



Dana Kappel

ORISE Fellow Dana Kappel has accepted a position in CDER's Office of New Drugs, starting September 26. Over her two years as a fellow in OGPS, Kappel has been remarkable in her diligence, curiosity, and passion for the FDA's public health mission. She has been willing to take on research assignments of all shapes and sizes, including supporting country and regional analyses, evaluating comparative data between the FDA and the European Medicines Agency, scoping out opportunities to advance health equity in the global space,

and coordinating with the Latin America Office on foodborne illness outbreak and response, whole genome sequencing, and aquaculture. Despite this workload, Kappel defended her thesis, outside her workday, to complete her online Master of Science degree in epidemiology from Imperial College London. She also practices Spanish, Navajo, and Mandarin, and was certified as an EMT — a skill she will use volunteering in her community — after months of evening classes. At CDER, Kappel will be a regulatory project coordinator working on oncology drug applications.

Retired



Edna Hidalgo

Sadly — but also happily — Edna Hidalgo, Human and Animal Food Consumer Safety Officer with the FDA China Office (CNO), has retired and returned to the United States. She began her FDA career at the San Francisco District in October 2007. Throughout her 15-year tenure with the agency she remained a food investigator, conducting inspections regarding low-acid canned food, acidified food, produce and farms, HACCP (hazard analysis and critical control points) for juice and seafood, preventive controls/good manufacturing practices, and dietary supplements.

Starting in 2011, she began venturing out on yearly foreign trips during which was able to conduct inspections in Brazil, France, Italy, Japan, Malaysia, the Philippines, South Korea, Taiwan, and the United Kingdom. According to

Hidalgo, these foreign inspections allowed her to gain knowledge and self-confidence, which she later used at her post in Beijing.

Hidalgo arrived in the CNO in September 2020 and was excited to go from city to city even throughout tribulations caused by the pandemic. During this period, trips were limited, trips were canceled, and trips were redirected — despite this, she was still able to carry out many much-needed inspections and came to be regarded as a fixture in the office. Aside from the field work, Hidalgo will be remembered by the CNO for her unflappable, calming presence, her emotional support to all coworkers, and her wonderful, tasty baked goods.

Dear International Colleague

Recent communications from OGPS to our international stakeholders (list does not include twice-weekly FDA International Roundup summaries), August 4 through September 20.

- [Monkeypox Update: FDA Authorizes Emergency Use of JYNNEOS Vaccine to Increase Vaccine Supply](#)
- [COVID-19 Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose](#)
- [Monkeypox Update: FDA Takes Significant Action to Help Expand Access to Testing](#)

Events

September 27-30 World Trade Organization Public Forum

October 19-21 Annual Global Summit on Regulatory Science

[Read our Global Blog](#)

Read thought-provoking pieces covering international topics in ***From A Global Perspective***.

[Follow OGPS on Twitter](#)

Please follow [@FDA_Global](#).

Subscribe to *Global Update*

Don't miss out on future issues of *Global Update* or other international news from OGPS. To sign up, click "Manage Subscriptions" in the below footer then follow the prompts and select the "International Programs" box.

