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September 2023

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Global News

First-of-Its-Kind Regulatory Partnership Arrangement Signed Between FDA and Ecuador's VMAF

The U.S. Food and Drug Administration (FDA) has concluded the signing of a Regulatory Partnership Arrangement (RPA) with Ecuador's seafood regulatory authority to enhance the safety of shrimp imported to the United States.

A first of its kind, the RPA serves as an arrangement between the FDA and the Vice Ministry of Aquaculture and Fisheries (VMAF) to work more closely to reinforce food safety practices along the entire supply chain. Such arrangements aim to leverage commodity-specific oversight systems — in this case, imported aquacultured shrimp — along with data and information, to strengthen food safety before and at the port of entry.

In remarks during the signing ceremony on August 24, Don Prater, Acting Director of the FDA's Center for Food Safety and Applied Nutrition (CFSAN) described the RPA as the "culmination of a lot of work and relationship-building between both of our agencies."

To prepare for the RPA, the FDA and VMAF signed a confidentiality commitment (CC) in August 2022 that allows for the exchange of confidential information, including inspection records, sample findings, and other nonpublic documents. In addition, the FDA conducted a rigorous assessment of Ecuador's

aquacultured seafood safety system and examined important parts of VMAF's programs and capabilities.

The FDA found that Ecuador's food safety controls for shrimp are science-based; include the key elements of a basic food safety system; have ongoing processes to ensure the sustainability of preventive controls; provide competent oversight throughout the supply chain; and have a public health focus.

Through this assessment, the FDA became confident that Ecuador has key components of a food safety oversight system for shrimp and shrimp products intended for export to the United States.

As a result, the FDA will be able to leverage data and information from Ecuador for the FDA's regulatory decision making. And, vice versa, Ecuador will leverage data analytics from the FDA to inform their regulatory activities.

Since 94% of the seafood consumed by volume in the United States is imported, one of the agency's tasks has been to ensure that imported seafood is held to the same food safety requirements as food produced domestically. In the past, that's primarily meant intercepting unsafe food at the border and preventing its entrance into the U.S. marketplace.

In 2021, the U.S. Congress highlighted the importance of food safety related to shrimp — the most popular seafood in the United States — by mandating that the FDA consider and develop new options for enhancing the regulation of imported aquacultured shrimp, including an RPA with the three largest shrimp-exporting countries by volume. Ecuador is one of those countries.

Large scale shrimp farming in Ecuador. (Getty Images)

Such an arrangement would provide an opportunity for the FDA and its regulatory counterpart to proactively learn about each other's regulations and

food safety initiatives, identify potential areas for collaboration, prioritize activities, and engage in specific regulatory and program evaluations.

With the signing of this first RPA with Ecuador, the FDA is delivering on this congressional mandate and has been making progress on implementing the mandate with the two other countries, India and Indonesia.

“Ecuador may be a small country, but it is an important supplier of food to the United States, especially of seafood,” FDA Latin America Office Acting Director Michelle Rodriguez said at the signing ceremony. “To achieve our joint food safety goals, collaboration and information sharing is essential.”

The new RPA with Ecuador sets forth how the FDA and VMAF intend to collaborate with one another to:

- Share information on best practices, food safety policies, and regulatory approaches to address the safety of shrimp.
- Ensure prompt notification and response to adverse food safety events such as illnesses, recalls, and outbreaks.
- Promote and conduct training, including FDA Import Operations, Basic HACCP, Train-the-Trainer HACCP, Good Aquaculture Practices, Good Fishing Vessel Practices, and seafood decomposition detection.
- Participate in shrimp inspections, audits, and investigations.

The FDA is already sharing information with VMAF as a result of the 2022 CC, including import refusals, compliance actions, outbreak investigation information, and detailed sampling results. In response, VMAF has provided the FDA with information on Ecuador’s regulatory follow-up to these events.

“This free flow of information yielded important food safety benefits for consumers in both of our countries, while demonstrating the trust we place in the Vice Ministry,” Rodriguez said.

FDA Associate Commissioner Mark Abdoo signed the RPA on behalf of the FDA while Vice Minister Andrés Ahrens signed the arrangement for VMAF. Both an **English** and a **Spanish** language version of the RPA have been posted on the FDA’s website.

The RPA signing was scheduled so it would coincide with a daylong commemoration of the sixth anniversary of the creation of the Undersecretariat for Quality and Safety (S*ubsecretaría de calidad y inocuidad* or SCI). The commemoration featured a series of presentations on scientific and technical topics, including presentations by Julie Moss, Director of CFSAN’s Office of

International Engagement, and Steve Bloodgood, Director of CFSAN's Office of Seafood Safety.

SCI is the office within VMAF that is responsible for ensuring the health of fishery and aquaculture products, including those intended for export.

For more information:

Enhancing the Safety of Imported Shrimp Through Regulatory Partnerships

International Cooperation on Food Safety

Imported Seafood Safety Program

US-Mexico Food Safety Partnership Nets Progress for Third Year

The U.S. Food and Drug Administration (FDA) and its regulatory counterparts in Mexico reported continued progress in strengthening food safety at the third annual executive meeting of the Food Safety Partnership (FSP), held in Mexico City on September 13. The partnership includes the FDA, Mexico's National Service of Agro-Alimentary Public Health Safety and Quality (SENASICA) and the Federal Commission for the Protection from Sanitary Risks (COFEPRIS).

The FSP seeks to ensure the safety of food for consumers in both countries, by using modern approaches and preventive practices based on technical and

scientific evidence, health surveillance, and verification measures. Roughly one-third of all FDA-regulated human food imported into the U.S. is from Mexico, including 60% of fresh produce imports to the United States.

Laboratory collaboration, food safety training and outreach to industry, as well as outbreak prevention and response, were the focal points of this FSP annual meeting. Accomplishments were described in all categories, which has resulted in greater knowledge of food safety practices among growers and processors and increased technical and response capacities for regulators. Some highlights of these activities include:

- **An in-person meeting with growers of bulb onions in Chihuahua.** The meeting was led by LAO staff to introduce growers to food safety concepts and learn about challenges and opportunities within the sector. This meeting opened the door for a virtual technical workshop with approximately 70 bulb onion producers in Chihuahua on the food safety practices of the FDA, SENASICA, and COFEPRIS. The focus was the FDA's Produce Safety Rule (PSR), SENASICA's SRRC (System for the Reduction of Contamination Risks), and COFEPRIS' regulatory standard for the safe processing of food, beverages, or food supplements (NOM 251). At the workshop, the International Fresh Produce Association also presented their Best Practice Guide for Bulb Onions and encouraged the Mexican onion industry to share growing and harvesting practices that may differ from U.S. production practices, including those addressed in the guide.

- **A Whole Genome Sequencing (WGS) data-sharing agreement between the three agencies to identify pathogens.** In August 2023, the FDA provided in-person laboratory training for SENASICA and COFEPRIS staff on how to use WGS technology and also provided the chemical reagents needed to sequence the DNA of the pathogens. Both agencies are using the technology to upload 100 genomic sequences to the GenomeTrakr network (a database open to government and academic labs to share genomic data). These important contributions to the GenomeTrakr network have allowed both countries to identify and respond faster and with more precision to outbreaks, helping to mitigate their impact on consumers.

- **A shipment of *Cyclospora cayetanensis* DNA reference material to SENASICA and COFEPRIS laboratories.** This FDA effort, aided by the LAO, will help Mexico implement new analytical methodology that can help detect the parasite's presence in a food sample, thus supporting efforts to reduce its existence in the food supply. Additionally, in July 2023 the FDA provided in-person training on the agency's Bacterial

Analytical Manual Chapter 19b molecular detection method for *Cyclospora,* to support SENASICA and COFEPPRIS in demonstrating their required competency on this methodology for detecting this parasite.

- **Trainings for growers on the FDA's Produce Safety Rule.** The FDA, collaborating with SENASICA and COFEPRIS and in partnership with the Produce Safety Alliance, provided 15 trainings in Mexico. Over 400 growers who produce onions, mangos, melon, berries, and papaya participated in the trainings.

- **A Produce Safety Summit and an On-Farm Readiness Review (OFRR) in Guanajuato, Mexico.** The April 2023 trainings were hosted by the FDA with the participation of SENASICA and COFEPRIS. Over 200 farmers, Mexican state inspectors, and other industry stakeholders participated in the summit; and 25 producers participated in the OFRR. Topics covered at the summit included the FSMA PSR, SENASICA's SRRC, COFEPRIS' sanitary control for fresh and minimally processed agricultural products, potential risks surrounding adjacent land use, the Food Safety Modernization Act's Traceability Rule, and the FDA's prevention strategies.

- **Outbreak information exchange under the three agencies' standing Binational Outbreak Notification Protocol.** Over the last year, the protocol ensured the timely and effective communication of information on a Hepatitis A outbreak linked to imported frozen strawberries from certain farms in Baja, Mexico, and a Cyclospora outbreak linked to romaine lettuce. The LAO facilitated the FDA's participation in accompanied unannounced inspections with Mexico. Two took place over the last year, one with SENASICA in response to the Hepatitis A outbreak, and another with COFEPRIS at a broccoli producer in Puebla. Mexico is the only country that has a protocol in place with the FDA to conduct these types of inspections.

Leadership from the three agencies participated in the meetings, with the FDA's delegation led by Don Prater, Acting Director of the Center for Food Safety and Applied Nutrition, and Mike Rogers, Acting Deputy Assistant Commissioner for Regulatory Affairs for the Office of Regulatory Affairs. The delegation also included the Office of Global Policy and Strategy's (OGPS) Principal Advisor for Global Policy Ravi Bharwani, and Acting Director Michelle Rodriguez of the FDA's Latin America Office (LAO), which is managed by OGPS. Although the annual meeting is an opportunity for leadership to come together to recap their accomplishments over the last 12 months, the FDA benefits year-round from having LAO staff located in Mexico's capital city who can collaborate with COFEPRIS and SENASICA in person and on a regular basis.

A day before the FSP annual meeting, the three regulatory agencies hosted a daylong meeting with industry focusing on two FDA regulations — the Food Traceability Rule and the proposed Agricultural Water Rule — which the agency expects to finalize in early 2024. As the FDA moves toward the compliance date for the Food Traceability Rule on January 20, 2026, the FDA supports Mexican farmers, producers, and manufacturers in understanding the full scope of the rule through collaborative industry outreach and education.

Next steps for the FSP include continued discussions to better understand Mexico's food safety supply chain controls, continued outreach and training for producers, and collaboration in testing for Hepatitis A, especially in the event of a possible outbreak. The agencies also plan to discuss a process for guiding rapid communication and reciprocal information exchange when adverse weather events occur that may have an impact on food safety. Such information exchange would allow both countries to consider preventative measures to reduce food safety risks and better protect consumers on both sides of the border.

CURE ID Application Expanded Through OGPS-Supported Collaboration

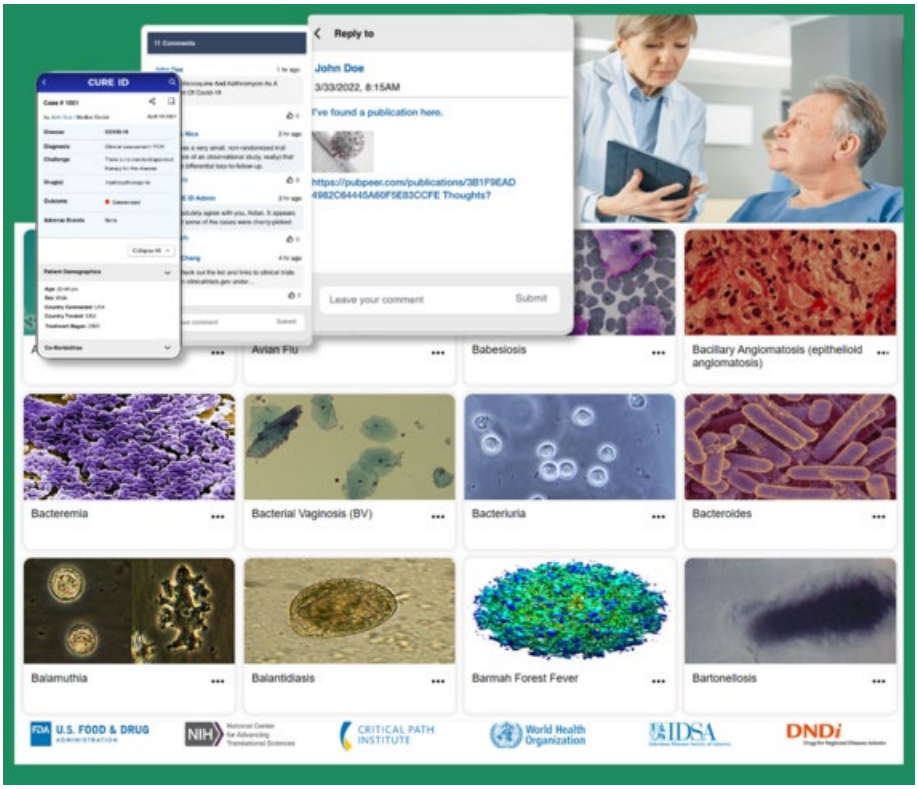
A partnership between the World Health Organization (WHO) and the FDA — funded by the agency's Office of Global Policy and Strategy (OGPS) — has helped to expand the variety of uses of CURE ID, an internet-based repository that allows the global community to report novel uses of existing drugs for difficult-to-treat diseases through a website, a smartphone, or other mobile device. Since late 2019, OGPS support through a cooperative agreement, totaling roughly $200,000 a year, has allowed both the FDA's Center for Drug Evaluation and Research (CDER) and the WHO to use the CURE ID platform in novel disease areas.

CURE ID itself is a collaboration between the FDA and the National Center for Advancing Translational Sciences, part of the National Institutes of Health (NIH). The repository lists de-identified real-world treatment experiences with repurposed drugs including cases when drugs have been used for new conditions, in new populations, in new doses, or in new combinations. Users may even discover through CURE ID that unapproved uses do not work or are even harming patients. Health care professionals may choose to prescribe or use a legally marketed human drug or medical device for an unapproved or

uncleared use when they judge such an unapproved use is appropriate for a patient.

Due to funding limitations related to user fees, the FDA's product centers may not always be able to directly engage with global partners and will ask OGPS to step in and help with engagement. Seeking such assistance, Heather Stone, FDA health science policy analyst in CDER's Office of Medical Policy, brought CURE ID to the attention of OGPS staff, who began working with CDER to expand the use of the application through engagement of the WHO.

By conducting a critical landscape analysis of the diseases where CURE ID would be most useful and qualitative research with many global experts, the FDA-WHO team was able to identify disease spaces to work in that they had not previously considered, Stone said. "Our collaboration with the WHO, thanks to the generous support of OGPS, has been one of our most successful partnerships in the 10-year history of the CURE ID program."



It is through this partnership, according to Stone, that CURE ID has successfully obtained the first large collection of cases, contributed by clinicians globally, with her team's program on implantation mycoses. These are a group of fungal diseases (and one bacterial infection) that develop at the site of trauma entering or passing through skin. Some implantation mycoses affect muscles, fascia, cartilage and bones, beyond the skin and the subcutaneous tissues. Earlier this

year, Stone co-authored with collaborators from the WHO an article on this work, published in the journal *PLOS Neglected Tropical Diseases.*

The same group is also working with national authorities such as the Centers for Disease Control and Prevention, UK National Health Security Agency, and Health Canada to develop a case report form that will allow users to collect and share cases for drug-resistant sexually transmitted infections. Data use agreements are being established with partner agencies, and they hope to receive cases from the cooperating institutions within the next year.

After having successfully identified two priority therapeutic areas where CURE ID could be especially useful (implantation mycoses and drug-resistant gonorrhea/mycoplasma treatment failures), Stone's team recently identified in collaboration with the WHO a third therapeutic area, antimicrobial-resistant fungal and bacterial pathogens. Stone and her colleagues are now in the process of selecting specific priority diseases within this space through an existing group of WHO experts who also developed the WHO fungal priority pathogens list and will publish the results of this survey in the coming year. that was published in the journal *PLOS Neglected Tropical Diseases.*

Additionally, since the collaboration began the team has received case reports from clinicians in Madagascar, Brazil, and Mexico. The resulting data is being combined with cases extracted from published literature and will be presented at a meeting of medical mycology experts in Brazil in November. They are now considering translating the platform into other languages such as French, Portuguese, and Spanish.

Though the current FDA-WHO collaboration on CURE ID is coming to a close, OGPS is working on the next cooperative agreement, to be launched sometime in 2024. FDA experts will continue to work collaboratively with WHO and global health experts to use the application to identify additional priority diseases and engage WHO stakeholders who would like to participate in developing tools to collect cases for these conditions. Future diseases under consideration include cutaneous leishmaniasis (a parasitic, neglected tropical disease), Balamuthia and other amoebic causes of meningitis, and more specific antimicrobial resistance organisms.

"By facilitating our collection of case reports for diseases with high unmet medical need globally, the WHO-FDA partnership has created an important public resource through open data sharing about potential repurposed drugs," said Stone. "The collaboration has also led to important discussions among regulators and other public funders from many international agencies about drug repurposing and how the regulatory ecosystem must evolve to improve access for patients to effective treatments."

Regulatory Benchmarks, Capacity Building Highlighted at FDA Science Forum

Reflections on Dr. Murray Lumpkin's Bill & Melinda Gates Foundation Keynote Address

To avoid or mitigate public health crises, the global health community is engaging in the use of a standard objective tool developed by the World Health Organization (WHO) that can help competent authorities access and develop plans for strengthening their regulatory systems

The Global Benchmarking Tool (GBT) enables regulatory authorities to conduct self-assessments and the WHO to evaluate strengths and areas for improvement; facilitates formulation of an institutional development plan to build upon these strengths, address identified gaps, and prioritize interventions; and assists in monitoring progress, the WHO's regulatory strengthening team wrote in a 2020 journal article in Frontiers in Medicine.

More than a simple checklist, the GBT features almost 300 indicators and sub-indicators that evaluate an agency's ability to perform effectively in nine different areas of regulation during a medical product's life cycle. A range of crucial functions are evaluated by the GBT, including clinical trials oversight, product authorization, pharmacovigilance, inspections, and lot release.

Using the GBT involves three steps. First, a country conducts a self-assessment using the tool to determine what functions they are fulfilling adequately, identify areas of opportunity, and determine which maturity level its regulatory authority thinks it is has reached. Next, an informal WHO assessment is done, which will form the basis of an institutional development plan to address the deficiencies found in the informal assessment. Finally, after the country has attempted to address these deficiencies — usually with support from WHO and other partners — and thinks it's ready, it requests a formal assessment by the WHO. All three steps in this process — the self-assessment, the informal WHO assessment, and the formal WHO assessment — are carried out under confidentiality arrangements.

Table courtesy World Health Organization

List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3)[1] and maturity level 4 (ML4)[2] (as benchmarked against WHO Global Benchmarking Tool (GBT)

(in alphabetical order) - As of November 2022

Country	Regulatory authority	Maturity Level (ML)	Scope of products	Year of announcement
China	National Medical Products Administration (NMPA)	ML3	1. Vaccines (producing)	2022
Egypt	Egyptian Drug Authority (EDA)	ML3	1. Vaccines (producing)	2022
Ghana	Food and Drugs Authority (FDA)	ML3	1. Medicines 2. Vaccines (non producing)	2020
India	Central Drugs Standard Control Organisation (CDSCO)	ML3	1. Vaccines (producing)	2017
Indonesia	National Agency of Drug and Food Control (BADAN POM)	ML3	1. Vaccines (producing)	2019
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	ML3	1. Medicines 2. Vaccines (non producing)	2022
Republic of Korea	Ministry of Food and Drug Safety (MFDS)	ML4	3. Medicines 4. Vaccines (producing)	2022
Serbia	Medicines and Medical Devices Agency (ALIMS)	ML3	1. Vaccines (producing)	2019
Singapore	Health Sciences Authority (HSA)	ML4	1. Medicines 2. Vaccines (non producing)	2022
South Africa	South African Health Products Regulatory Authority (SAHPRA)	ML3	1. Vaccines (producing)	2022
Thailand	Food and Drug Administration (FDA)	ML3	1. Vaccines (producing)	2021
United Republic of Tanzania	Tanzania Medicines and Medical Devices Authority (TMDA)	ML3	1. Medicines 2. Vaccines (non producing)	2018
Viet Nam	Vaccine regulatory system in Vietnam represented by: a) The Drug Administration of Viet Nam (DAV), b) Administration of Science, Technology and Training (ASTT), c) National Institute for the Control of Vaccines and Biologicals (NICVB) and d) General Department of Preventive Medicine (GDPM)	ML3	1. Vaccines (producing)	2020

The list will be updated regularly as new information becomes available.

[1] Meaning "stable, well-functioning and integrated regulatory systems".

[2] Meaning "regulatory systems operating at advanced level of performance and continuous improvement"

List of national regulatory authorities operating at ML3 or ML4, as benchmarked against the WHO Global Benchmarking Tool. Credit: World Health Organization.

Get WHO's List of NRAs

The GBT was piloted in 2018 and used for the first time in spring 2019, in El Salvador and Ghana. Before the GBT, there were several different overlapping assessment tools; users found these confusing and burdensome, according to the WHO regulatory strengthening team.

Developing the many metrics in the GBT involved multiple rounds of public consultation with many of the world's foremost regulatory agencies from all regions of the world, "including much appreciated input and thought leadership from colleagues here at the FDA," said a former FDA senior official, Dr. Murray Lumpkin, director of health of global regulatory systems initiatives for the Bill and Melinda Gates Foundation, in a keynote lecture at the 2023 FDA Science Forum.

And the FDA's Center for Biologics Evaluation and Research (CBER) continues to support use of the tool for regulatory systems strengthening globally. Under a cooperative agreement with the WHO, CBER has provided funding support for pre-visits, training, and other support for self-assessments; formal benchmarking by the WHO team; development of institutional development plans, trainings, and other means of addressing gaps; follow-up activities to monitor progress; trainings for regulators; and the development of standards.

Assessment tools have been a catalyst for advancing regulatory systems in Latin America. More than 15 years ago, the Pan American Health Organization (PAHO) introduced the idea of using a benchmark to assess national regulatory authorities in the region. Using its assessment tools, PAHO found eight regulatory authorities in the Americas to be competent and efficient in their performance of their health regulation functions needed to guarantee the safety, efficacy, and quality of medicines. These eight were recognized as National Regulatory Authorities of Regional Reference (or NRArs). These NRArs – Argentina, Brazil, Canada, Chile, Colombia, Cuba, Mexico, and the United States – were to serve as a reference for best practices for other regulatory authorities in the region. PAHO is now transitioning to the GBT, which incorporates PAHO's experience and uses the same conceptual framework.

Strengthening national regulatory authorities through mechanisms such as the WHO's Global Benchmarking Tool can help nations address public health threats posed by substandard and falsified medications. Photo by FDA's Office of Regulatory Affairs, Health Fraud Branch.

Patty Pineda, International Regulatory Analyst at the FDA Latin America Office, attended a PAHO meeting in Washington, D.C., in July that included a discussion of the GBT transition. “For these NRAr countries in Latin America, the Global Benchmarking Tool has been crucial,” she said. “The tool has served to identify areas of opportunity to improve their regulatory processes and, more importantly, to realize their actual maturity levels.”

Without such standards, countries with nascent or weak regulatory authorities can experience tragedy, Lumpkin warned. “When you work in places where there is no equivalent to our FDA and you experience what that reality looks like, it is generally not pretty,” he said. “Regulation is not just a technique, it's not a technicality — it has very real, very critical consequences in people's lives.”

One way that the WHO’s Global Benchmarking Tool addresses the public health threat of substandard and falsified medications is by helping national regulatory authorities determine their ability to meet the various GBT indicators and then classifying the agencies into one of four maturity levels (ML): ML1, ML2, ML3, or ML4. An agency with the history and experience of the FDA, for example, should easily fall into the ML4 level.

The World Health Assembly, the decision-making body of the WHO, recommends that all agencies should aspire to the ML3 level if they wish to meet the minimal standards of an effective, well-functioning regulatory agency. As of last December, said Lumpkin, only 57 of the WHO’s 194 member states have regulatory agencies that meet the ML3 or ML4 standard.

To help countries build their regulatory capacity and raise their maturity level, the WHO developed the Coalition of Interested Parties — made up of both public and private entities —which can offer technical and financial assistance to help a country address the deficiencies identified through benchmarking using the GBT, and development of an institutional development plan. The Gates Foundation is one of those parties. The coalition has already been supportive of Bangladesh, Ghana, and Senegal — all countries that are working diligently to improve their maturity levels, Lumpkin said.

Photo Album: Dr. Califf in Singapore and India

FDA Commissioner Robert Califf led an FDA delegation to South and Southeast Asia this month for meetings in India and in the island nation of Singapore, organized by the Office of Global Policy and Strategy. The trip

wrapped up just as Global Update went to press, so more information will be available in our next issue. These photos appeared on X, the social media platform formally known as Twitter. For real-time information, don't forget to follow @FDA_Global on X.

Above: Califf and FDA Staff in Singapore.

Below: Califf meeting with Government of Indian officials in New Delhi and clinicians in Hyderabad.

Briefs

FDA Researchers Take New Look at Global Pharmacovigilance for Generic Drugs

An August 2023 article by FDA staff in the journal *Therapeutic Innovation & Regulatory Science* provides a novel look at global pharmacovigilance for generic drugs. The pilot study collected and compared available information from a sample of international regulatory agencies, with the goal of examining each agency's signal detection and decision-making processes for postmarket generic drug safety and surveillance.

Despite the recognized need for generic drug pharmacovigilance harmonization efforts, few studies have compared generic drug postmarket safety and surveillance methods adopted by regulatory agencies in different countries. This study featured a structured four-part questionnaire of open-ended and multiple-choice questions, along with a semi-structured interview, all designed to solicit detailed responses. The authors found commonalities in processes for signal

identification, evaluation, and action in each agency's decision-making procedure for a generic drug safety concern — although variations do exist in processes appropriate for each agency's regulatory environment.

The research was conducted by several FDA experts, including co-author Sarah Ibrahim, Associate Director for Stakeholder and Global Engagement at the Office of Generic Drugs, FDA Center for Drug Evaluation and Research. The FDA, Health Canada, U.K.'s Medicines and Healthcare products Regulatory Agency, and Swissmedic provided the information used in the research.

The findings do not provide a roadmap toward future harmonization; rather, they represent an important initial step to identify challenges and support future research related to pharmacovigilance processes from a generic drug perspective. While the authors noted that most vigilance procedures are not unique to generic drugs, there are opportunities for regulators to work together to "promote cross-collaboration between global regulatory agencies."

Global Efforts to Address Plastic Pollution: An FDA Perspective

The world produces around 460 million tons of plastic a year. Globally, 46% of plastic waste is landfilled, 22% is mismanaged and becomes litter, 17% is incinerated and 15% is collected for recycling, with less than 9% actually

recycled after losses. According to one UN Environment Programme (UNEP) study, more than 14 million metric tons of plastic enters and damages aquatic ecosystems annually.

Responding to these concerns, the United Nations Environment Assembly, UNEP's supreme governing body, issued a resolution in 2022 that has touched off efforts to address this problem through an international legally binding instrument.

Matt Scherer, an international policy analyst in the FDA's Office of Global Policy and Strategy (OGPS), who's tasked with monitoring the agency's day-to-day work on this instrument, talks about this process in the latest ***From a Global Perspective***, OGPS' blog consisting of occasional thought pieces on international topics from FDA experts across the agency.

Read the interview

Matt Scherer attending the Second Intergovernmental Negotiating Committee meeting. Background image shows plastic pollution on a Newport, Oregon, beach this past August (photo by OGPS Comms staff).

FDA Officials Meet with South African Health Products Regulatory Authority

Officials from the South African Health Products Regulatory Authority (SAHPRA) met with an FDA delegation led by Mark Abdoo, Associate Commissioner for Global Policy and Strategy, at the FDA's White Oak Campus on August 29.

SAHPRA's Chief Executive Officer Boitumelo Semete-Makokotlela and Portia Nkambule, Chief Regulatory Officer, led the South African delegation.

Established in 2017 as a successor to the Medicines Control Council (MCC), SAHPRA is an independent entity of the South African National Department of Health and is responsible for regulating, monitoring, evaluating, investigating, inspecting, and registering health and medical products (including drugs, biologics, devices, and veterinary drugs) and clinical trials.

The FDA has a long history of engagement with SAHPRA and its MCC predecessor and collaborates with the South African regulatory authority in a variety of international harmonization venues.

SAHPRA's visit to the FDA was part of a U.S. Trade and Development Agency-funded project aimed at increasing the efficiency of pharmaceutical, medical

device, and in-vitro diagnostic product registrations and approvals in South Africa.

The SAHPRA delegation spoke about regulatory priorities for the next three years, which include strengthening and reengineering reliance practices, strengthening its role on the continent to support African-based manufacturing, building capacity and capabilities, pandemic preparedness, and digitalization efforts.

During the meeting, the FDA and SAHPRA discussed plans to continue to engage in multilateral forums and international harmonization efforts. FDA officials also provided information on the agency's emergency management operations that ensure the agency's preparedness for crises and emergencies and the FDA's work on information technology, data, and cybersecurity.

Produce Safety Train-the-Trainer Event in Brazil

The Inter-American Institute for Cooperation on Agriculture (IICA) and the FDA offered a produce safety Train-the-Trainer event August 7-10 in São Paulo, Brazil, to leverage the availability of the Produce Safety Alliance's (PSA) Grower Training curriculum in Portuguese. This was the first time IICA has conducted a Train-the-Trainer event in Portuguese.

Brazil is a country of over 200 million where Portuguese is the official and national language so creating a cadre of Portuguese-speaking lead trainers will, in turn, create more training opportunities in Brazil. There were 21 Brazilian participants at the event, 14 from federal and state governments, and seven from industry involved with exporting produce such as mango, ginger, grapes, and melon/cantaloupe.

Brazil accounts for around 10% of the fruit and fruit products imported into the United States, as well as around 14% of coffee and tea products, according to the FDA's Office of Regulatory Affairs' Profile of Regulated Imports from FY 2015-2019.

The FDA holds a cooperative agreement with IICA to support implementation of the Food Safety Modernization Act (FSMA) in Latin America and the Caribbean, by developing a cadre of professionals trained on the PSA curricula (Trainers and Lead Trainers) to promote produce safety practices and food safety culture development in the Americas.

As a precursor to the Train-the-Trainer event, IICA and the Brazilian Ministry of Agriculture, Livestock, and Food Supply (MAPA) held a virtual Grower Training at the end of June 2023, which was supported by two Brazilian trainers and attended by 52 government and industry participants.

A PSA Train-the-Trainer Course provides students with detailed information on how trainers can effectively deliver the PSA Grower Training Course, as well as information on Good Agricultural Practices, co-management of natural resources and food safety, and FSMA Produce Safety Rule requirements, as well as an overview of the various topic modules within the PSA Grower Training curriculum. The curriculum was developed by the PSA under the auspices of Cornell University, through a cooperative agreement with the FDA and U.S. Department of Agriculture.

The manuals for the PSA's Grower Training curriculum are currently offered in English, Spanish, Chinese, Korean, and Portuguese. The FDA also has a Portuguese version of the FSMA Produce Safety Rule available.

Attendees at the PSA Train-the-Trainer event in Brazil.

India Office Presents at Global Food Regulators Summit

The Food Safety & Standards Authority of India (FSSAI), part of the Ministry of Health & Family Welfare (MoHFW), held its first Global Food Regulators Summit July 20-21 in New Delhi.

Food regulators from 40 countries — around 1,500 delegates — participated in the event, as well as representatives from five international organizations and 11 International Food Research Institutes. The summit gave regulators an opportunity to exchange knowledge and strategies for ensuring safe food throughout the food value chain, with sessions on establishing robust international standards and best regulatory practices for food, a global regulatory framework for food, international standard setting, antimicrobial resistance, animal feed, and organic foods.

The FDA's Dr. Pankaja Panda and Dr. Phil Nguyen presenting at GFRS 2023.

Staff from the FDA India Office (INO) represented the FDA at the summit, presenting materials provided by FDA colleagues at the Center for Food Safety and Nutrition's Office of International Engagement and the Center for Veterinary Medicine's Office of International Affairs. Dr. Phil Nguyen, international relations specialist with INO, discussed the FDA's thinking about good regulatory practices as part of a panel discussion on a global regulatory framework for food, while Dr. Pankaja Panda, the INO's senior technical advisor for food, presented on the FDA's safety approaches for animal feed, an area where regulations and oversight are still evolving within India.

Dr. Mansukh Mandaviya, Minister of MoFHW, inaugurated the summit and launched a new informational tool — the Food-O-Copoeia, a single-point digital

guide on food safety standards for use by domestic and international stakeholders, including information on all food related items produced, imported, and sold in India. These monographs are intended to provide reference for India's "applicable standards for a specific product category specifying quality and food safety standards, labeling and claim requirements, specific packaging requirements, test methods, and any other regulatory provisions."

Also launched at this time, was SaNGRAH ("Safe Food for Nations – Global Food Regulatory Authorities Handbook"), an international food authority digital directory in both flipbook and dashboard format, offered in English and various Indian languages. Designed for the benefit of Indian exporters, the directory lists for each major trading country their local contact information for food regulators, WTO enquiry points, and Codex contacts; plus their trade authorities and information on their respective regulations and standards.

Photo Brief: Califf Meets with Health Canada

On August 26 in Halifax, FDA Commissioner Robert Califf met Health Canada's Health Products and Food Branch Assistant Deputy Minister Pamela Aung-Thin for the first time since she assumed that role and laid the groundwork for future collaborations between their two agencies.

Kerry Mannion Joins FDA Europe Office and Fight Against Illicit Health Products

The FDA's Europe Office (EO) recently welcomed Kerry Mannion, a senior liaison officer from the FDA's Office of Criminal Investigations (OCI), to their team. Part of the agency's Office of Global Policy and Strategy, the EO is partnering with OCI in support of a series of ongoing initiatives targeting illicit health products.

Mannion led and shaped OCI's response to global distribution of illicit pharmaceuticals and other FDA-regulated products by transnational criminal groups — including the FDA's first bilateral initiative focused on the movement of illicit FDA-regulated products, with the government of the United Kingdom, known as Operation Lascar; and the first joint international enforcement operation executed by the government of India, referred to as Operation Broadsword, targeting violative inbound shipments of FDA-regulated products originating from India.

Drawing on that background, OCI and the EO partnered with the Organisation for Economic Co-Operation and Development's (OECD) Task Force on Countering Illicit Trade to execute a series of workshops in 2022, which advocated for a whole-of-governments approach to address the complex health threats of today. The program culminated in a large two-day in-person event in Paris that brought together more than 110 multinational representatives from law enforcement, public health, intellectual property, trade, policy organizations and agencies, and private industry.

Mannion's work within the EO will focus on engagement with partner agencies at the USEU, various European Union-related entities, and multinational organizations to address threats to global public health through multifaceted and coordinated approaches. Additionally, Mannion will be working with his FDA colleagues to strengthen international regulatory frameworks and enforcement capabilities to enhance the effectiveness of global public health policies and advancing a series of crosscutting initiatives building upon the joint FDA and OECD program.

Mannion joined the FDA in 2009, and his most recent assignments included serving as the Special Agent in Charge of OCI's Office of Internal Affairs and Headquarters Operations. Mannion earned a Bachelor of Science in education from The Citadel, and a Master of Science in organizational leadership from Johns Hopkins University.

US Embassy India Hosts HHS Secretary Becerra at Townhall

Ambassador Eric Garcetti and Secretary Xavier Becerra.

Health and Human Services (HHS) Secretary Xavier Becerra included a trip to the U.S. Embassy in New Delhi last month, in addition to participating in a G20 Ministerial-level meeting on health.

During his Embassy visit, Becerra toured HHS offices, met with HHS, FDA, and Centers for Disease Control and Prevention leadership, and participated with Ambassador Eric Garcetti in a town hall discussion for the embassy community, including the U.S. consulates in India who participated via Zoom.

In opening remarks, the Secretary talked about his humble beginnings as a child of Mexican immigrants, the globalization of health care, and the many successes and challenges for HHS and the world with pandemics like COVID-19.

During a Q & A session, Dr. Phil Nguyen, an international relations specialist in the FDA's India Office, asked about the HHS collaborations with the White House and other U.S. government partners to help strengthen medical supply chains in order to avoid drug shortages.

The Secretary agreed there was a need for more robust supply chains, and shared his personal observation that some Americans were "hoarding products" — as occurred, he said, when infant formula was in shortage. The U.S. government currently lacks the authority to direct companies to manufacture more products when shortages occur, he noted, so that granting the FDA that authority would require new legislation.

The highlight of the event was a group photograph of the embassy's HHS staff (department level and FDA) with the Secretary and Ambassador, taken at the end of the townhall meeting. In the front row, Ambassador Eric Garcetti and Secretary Xavier Becerra are 5th and 6th from the left, respectively, while INO Director Sarah McMullen is 9th from the left.

The INO participated in the advance team to prepare for the Secretary's visit.

India is serving as President of the G20 this year, and Ministerial-level meetings were held for various sectors culminating in the G20 leadership meeting September 9-10. The G20 meeting held immense significance as it brings together the world's major economies to address critical global economic issues.

Advance team with the FDA's Kamal Kishore and Amrita Kaur (2nd and 3rd from left, respectively).

Dear International Colleague

Recent communications from OGPS to our international stakeholders (list does not include twice-weekly FDA Roundup summaries).

- FDA Takes Action on Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants

Events

September 29	World Heart Day
October 10-13	US-India Health Dialogue
October 19	Conversations on Cancer: Living with Metastatic Breast Cancer (organized by FDA's Oncology Center for Excellence and the European Medicines Agency)
December 1	World Aids Day

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