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GLOBAL NEWS

U.S. Hosting Asia-Pacific Economic Cooperation in 2023

The U.S. will host the annual meeting of the [Asia-Pacific Economic Cooperation](#) (APEC) in 2023, the White House announced on February 10.

"President [Joe] Biden and Vice President [Kamala] Harris offered to host APEC next year because of our focus on expanding and deepening economic ties in the region — and we thank our fellow APEC economies for supporting the U.S. offer to host," press secretary Jen Psaki said in a statement.

APEC is a regional economic forum established in 1989 to leverage the growing interdependence of the Asia-Pacific economies. It has a variety of sector-specific committees and sub-groups with engagement from the executive to the technical levels of government. The forum has 21 members, referred to as Member Economies, and is hosted by a different one every year.



Asia-Pacific Economic Cooperation

The U.S. last hosted the APEC meeting in 2011.

The FDA participates in a variety of working groups within APEC that touch on both medical products and food and traditionally leads the U.S. delegation to APEC's Food Safety Cooperation Forum (FSCF), co-chaired by Australia and China. The FSCF was established in 2007 in response to rising food safety concerns in the APEC region. Its purpose is to improve and strengthen food safety information sharing and to identify, prioritize, and coordinate the region's capacity-building efforts. To achieve this purpose, the FSCF created the Partnership Training Institute Network, to engage the food industry, scientific societies, and academia in innovative ways to strengthen capacity and enhance and streamline technical assistance efforts in food safety.

The FDA also leads the United States' engagement on the APEC Regulatory Harmonization Steering Committee (RHSC) as co-chair of the RHSC alongside Japan. Through 29 established Centers of Excellence across nine economies and collaboration with multi-sectoral partners, the RHSC contributes to early access to safe and effective medical products and contributes to the stable supply of medical products in APEC regions.

APEC's original founding members were Australia, Brunei, Darussalam, Canada, Indonesia, Japan, Korea, Malaysia, New Zealand, the Philippines, Singapore, Thailand, and the U.S. Other nations — including China in 1991, Mexico in 1993, and Russia in 1998 — joined the organization following its formation.

Thailand is scheduled to host APEC this year, while Peru hosts in 2024. A location for the U.S. meeting has yet to be determined.

Trade in Molluscan Shellfish to Resume

Trade in bivalve molluscan shellfish between the U.S. and the European Union (EU) could begin as early as February 27.

The Office of the U.S. Trade Representative announced on February 4 that the U.S. and the EU had concluded negotiations to allow for the resumption of shellfish trade. For the first time since 2011, U.S. producers, beginning in the states of Massachusetts and Washington, will be eligible to export live, raw, and processed bivalve molluscan shellfish to the EU, including oysters, clams, mussels, and whole or roe-on scallops. EU producers in Spain and the Netherlands will also be eligible to export live and raw bivalve molluscan shellfish to the U.S.

The FDA played a role in the resumption of trade. In September 2020, the agency issued an equivalence determination that found that the adoption and implementation of the EU's system of food safety control measures for raw bivalve molluscan shellfish by both Spain and the Netherlands, along with their application of additional measures specifically adopted for export to the United States, provided at least the same level of sanitary protection as comparable food safety measures in the United States — and was therefore equivalent.



Associate Commissioner Mark Abdoo discussed that decision in an [FDA Voices article](#) with Dr. Susan Mayne, director of the Center for Food Safety and Applied Nutrition.

In a follow-up From a Global Perspective [blog](#), Anne Kirchner, in the OGPS Office of Trade Mutual Recognition and International Arrangements, and Ritu Nalubola, director of the OGPS Europe Office, further elaborated on the process of arriving at the equivalence decision.

The final administrative step, after the equivalence determination, was for the European Commission to adopt and publish an export health certificate, which it did on February 7. The certificate will be issued by the Seafood Inspection Program at the National Oceanographic and Atmospheric Administration and must accompany shellfish exported to the European Union. The certificate will become effective on February 27, 2022, which is the date that bilateral trade between the United States and the EU can begin.

LAO Staff Provides Timely Updates on AgWater Rule

When the FDA proposes changes to food safety rules, the Office of Global Policy and Strategy is quick to tell its international stakeholders about it.

On January 27, OGPS' Latin American Office participated in a webinar on the FDA's proposed agricultural water rule, just one month after its release. The virtual webinar, offered in both Spanish and English, was sponsored by the Inter-American Institute for Cooperation (IICA).

“At LAO, we are happy to emphasize the FDA’s approach to making the rules around agricultural water simpler and more practical to implement. Given that 40% of U.S.-consumed produce is imported and that most of those imports come from Latin America, it is critical that stakeholders in our region understand and have the opportunity to engage in this process,” said LAO Director Katie Serrano.

FDA subject matter experts Mauricio Castelo, Ph.D., and Kruti Ravaliya, of the Center for Food Safety and Applied Nutrition’s (CFSAN’s) Division of Produce Safety, were the speakers at the webinar, which drew a maximum capacity of 1,000 attendees. A recording will be available soon via IICA.



CFSAN has also been trying to educate stakeholders more broadly. It scheduled two virtual public meetings to discuss the proposed rule. The first meeting took place February 14. The second is set for February 25. To register for the second public meeting, click on the link in the Upcoming Events calendar below.

The proposed “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” would replace the pre-harvest microbial water quality criteria and testing requirements in the 2015 Produce Safety Rule with requirements for a systems-based pre-harvest agricultural water assessment for covered produce other than sprouts. This approach was developed following hundreds of farm visits and meetings with stakeholders and reflects findings from several recent produce outbreak investigations that offered additional insights into potential routes of contamination.

The agricultural water compliance dates in the 2015 rule were set to begin in January 2022, but in issuing the draft rule, the FDA said it intended to exercise enforcement discretion and would begin work on a rule for a targeted compliance date. While this work is going on, covered farms should implement good agricultural practices to maintain and protect the quality of their water sources.

“We look forward to working across the region to enhance stakeholder participation and compliance with the Agricultural Water Rule,” said Katie Serrano.

STAFF NEWS

Investigator Found Her Calling Through Field Experience

“When I was a kid, I was always fascinated by science,” said former India Office (INO) Consumer Safety Officer Rita Kabaso as she explained why she chose her career.

Born in Lubumbashi, the second largest city in Democratic Republic of the Congo, Rita was exposed to a predominantly subtropical climate, a close-knit family, and an abundance of wildlife. She recalls an inquisitive young girl who was “curious about how human bodies function, especially when sick.”



Rita at the Mukuni Big Five Safari in Livingstone, Zambia

The Kabaso family immigrated to Bowie, Maryland, when Rita was 15 years old, and it was her high school biology teacher who encouraged a deeper dive into the sciences.

Upon graduation, Rita enrolled in pre-med at McDaniel College in Westminster, Maryland. However, while working in a lab during her second year, she fell in love with research.

Yearning for more science, Rita spent her summers as an undergraduate student in an Immunology lab working on Toll-like receptors, which play a role in innate immune response.

After earning her bachelor's degree, she began studies toward a master's in biotechnology at Johns Hopkins University in Baltimore. While in school, Rita worked full-time as a research technologist at Johns Hopkins School of Medicine in an infectious disease lab. Rita worked on HIV and Hepatitis C blood samples, DNA sequencing, plasmid research, and writing lab protocols for implementation. Rita made the decision to obtain a doctorate degree in virology with a concentration in biodefense. Soon after, however, she unexpectedly had another change of heart.

"I felt burnt out and wanted to take a break and get a job," she said.

It was during one of her final courses for her masters that a representative visited her class to talk about opportunities at the FDA. She said to herself, "Well, let me give FDA a trial." Her plan was to work at the agency for two years and then go back to school.

Now six years later, “I just ended up loving it,” she said.

Coming to FDA

Rita’s first assignment was with the Office of Regulatory Affairs (ORA) in their Kansas City District Office, as a [consumer safety officer](#) (CSO) for drugs — covering Iowa, Kansas, Missouri, and Nebraska.

After noticing an internal job posting for a foreign investigator, Rita reached out to her ORA colleague, Kellia Hicks, to learn more about the work. Kellia was then on detail as a CSO at OGPS’ India Office. After hearing how much Kellia loved both India and working overseas for FDA, Rita decided to apply to become part of ORA’s cadre of foreign CSO’s. She was accepted and soon was being sent overseas to conduct ORA inspections in Germany, Finland, Italy, Taiwan, and India.

“My overall experience was great, and I absolutely loved it,” Rita said. Her next career move was to seek and be approved for an OGPS detail in an FDA foreign office. She served two separate details as a CSO in India in 2019: 90 days beginning May 2019, where she completed three inspections; and 30 days beginning August 2019, completing two inspections, before applying for a two-year tour there. Rita was accepted and after undergoing clearance, reported to India in February 2020.

Inspecting on Another Continent

Given her arrival date, Rita managed to complete just one inspection before the country implemented COVID-19 lockdowns in March 2020. Inspections resumed again in January 2021.

Most of her travel was by air, since so many facilities are located far from INO’s offices in New Delhi, and her days while on the road were long. It required juggling a workload that included examining products and facilities, writing reports, collecting evidence, and citing violations.

Many facilities she inspected made sterile finished dosage drug products, and their inspection required a week-and-a-half of field work before Rita could head back to the office to write up the report. For these inspections, she would begin in the facility’s microbiology laboratory where she observed microbial analyses; familiarized herself with the firm’s equipment and software; and, when available, extracted raw data from their database. Rita also observed the prepping and testing of samples before results are read, a process that could last two or more hours.

Investigators often use a regulatory diary to record their notes, especially while on the production floor. When she could, Rita would use her computer to take electronic notes via the FDA’s electronic inspection tools (eNSpect). This application allows users to upload exhibits and attachments; send reports to their

supervisor; and generate the Form FDA 483. This form is issued to company management at the conclusion of the inspection, if necessary, should the investigator observe any conditions that may constitute violations.

The Many Perks of Living in India

Memorable experiences. Cultural competence. Greater sense of self.



Rita visiting Lodhi Gardens in New Delhi

Rita was able to take many trips while stationed abroad. Her most memorable ones included a bird sanctuary in Bharatpur, Rajasthan; hiking in Shimla, Himachal Pradesh; city park gardens in New Delhi; and touring South-Indian temples. “The art in the temples left me in awe. You just can’t believe it,” she said.

Always on her travel list were centuries-old stepwells, a type of well where water can be fetched by walking on a set of steps. In India, stepwells were originally used as an art form by Hindus. “Whenever I went to a new city, I would always look for a stepwell. They were just amazing,” Rita said.



An avid hiker, Rita took in nature while visiting Shimla

Volunteerism in Abu Dhabi

In mid-November of last year, Rita served on a Department of Health and Human Services' detail for a month in Abu Dhabi, United Arab Emirates, to assist in the resettling of Afghan refugees after the drawdown in Afghanistan. Rita's assignment was to help interview an estimated 10,000 Afghan evacuees at the Emirates Humanitarian City camp.

She gathered information from individuals and families, via translators, to be captured on applications for U.S. visas. "It was very challenging and emotional," she said. "Many people did not have shoes, were crying, or needed medication." The experience made Rita grateful for the life she has.



Rita in Abu Dhabi

Back at ORA



Now back with ORA, Rita accepted a promotion to be a team lead in the Division of Foreign Pharmaceutical Quality Inspections. In this role she will be involved in the review of work products for ORA's dedicated foreign drug cadre and the OGPS foreign offices.

When asked why she chose her path, she replied, "When I look back 70 years from now at the different careers that I have held, I will know that I did the best that I could in protecting public health. I just always want to do the best that I can."

Additional resources

[India Office](#)

[Consumer Safety Officer](#)

[Inspection Observations](#)

FDA, OGPS Assist in HHS China History Project

As the 2022 Winter Olympics in Beijing capture the attention of millions worldwide, HHS employees working in China are welcoming the new Mission China leadership, Ambassador Nicholas Burns. To support that effort, the Department of Health and Human Service's operating divisions in China, including FDA's China Office (CNO), have been developing material to contribute to an HHS History in China project. The project will feature agency information and key one-pagers outlining accomplishments by all HHS agencies with a presence in China, including the Centers for Disease Control and Prevention, FDA, the National Institutes of Health, and the HHS/Office of Global Affairs.



The ribbon cuttings at the U.S. Embassy in Beijing, Nov. 19, 2008 Secretary of Health and Human Services Michael Leavitt, Former CFDA Commissioner Shao Mingli, FDA commissioner Andrew von Eschenbach

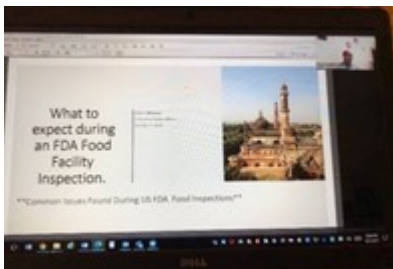
The FDA historical fact sheets, which will include an overview, information on personnel, and key issues sections, will help orient Ambassador Burns to agency activities in China and apprise him of current challenges and past successes. Country Director Vanessa Shaw-Dore, Deputy Country Director Latasha Robinson, and Lixia Wang, M.D., China Office Medical Research Scientist — all working within the CNO — have been key contributors to the project. Jeff Gray from OGPS' Communication Team has been providing writer-editor support on the project.

Some of the topics to be covered in the new FDA fact sheets include past drug and food recalls, China's data security laws, addressing problematic medical devices imported from China, and the two Implementing Arrangements that created the framework for the FDA China Office. The 2007-2008 tragedies involving diethylene glycol, melamine, and adulterated heparin that led to the creation of the FDA foreign offices in 2008 will also be delineated.

BRIEFS

INO Concludes 'What to Expect During an FDA Inspection'

The India Office (INO) has wrapped up its multipart webinar on food safety. Last year in February, the INO's Human and Animal Food team, led by Sarah McMullen, Ph.D., now INO director, began brainstorming about how to provide information to industry and local government on improving food safety practices in India.



To reach the largest possible target audience, the team decided to conduct a six-part webinar that would address the needs of firms in India and invite their 4,600 listserv members and 130 Government of India counterparts. The team was both surprised and pleased with the strong attendance.

The presentations were focused on what to expect during an FDA food inspection, and covered regulatory information, practical scenarios, and INO's personal experiences. At the conclusion of each webinar, the presenter(s) engaged in a robust question and answer session with participants.

Sessions included:

- General Food Facility Information and Inspections.
- Preventive Controls for Human Foods.
- Dietary Supplements.
- Low Acid Canned Food Inspections.
- Fish and Fishery Products.
- Commons Issues Found During FDA Inspections.

Other team participants included Denise Connelly, Natalie Mickelsen, D.V.M., Eric Milstead, M.S., Pankaja Panda, Ph.D., and Chris Priddy, who has since left CNO.

TRANSITIONS



Betsy Newcomer joins the OGPS Immediate Office (IO) after spending close to seven years in the FDA's Office of Regulatory Affairs, managing its response to performance audits by the U.S. Government Accountability Office (GAO) and Office of Inspector General. This included developing a communication strategy, assigning programs, overseeing the quality of ORA's responses, and monitoring ORA's implementation of performance improvements in response to the audit recommendations.

Newcomer came to the FDA from the Office of Management and Budget (OMB) where she worked to shape federal agency management policies with the support of several federal agency management councils. While at OMB she helped lead implementation of the Government Performance and Results Modernization Act by writing guidance for agencies regarding strategic planning and performance management. In addition, she was responsible for managing work on the GAO's High-Risk list for OMB.

Earlier, Newcomer was a Presidential Management Fellow at the Small Business Administration and worked for seven years in the nonprofit sector administering public health and affordable housing programs. She also served in the Peace Corps in Mali, West Africa.

As an advisor in the IO, her work will focus on cross-agency policy coordination and various strategic priorities.



John (Girard) Griggs has accepted the role of international policy analyst on the Program and Policy Team in the Office of Global Operations' (OGO) Immediate Office. His work will focus on OGO's medical product portfolio and liaising with the medical product centers and our foreign offices.

Griggs previously worked as a medical device importation expert at the Center for Devices and Radiological Health where he provided support for a countrywide import alert compliance program and was a member of a team developing a new informatics program and evaluating key bioresearch monitoring programs.

Recently, Griggs volunteered for several months to help 5,000 unaccompanied children from Central America who were being housed at the Fort Bliss Emergency Intake Site in El Paso. Prior to coming to the FDA, he worked for the Minnesota Department of Health, managing a state-wide taskforce that developed public health policy for HIV/AIDS prevention.

Griggs received his Master of Public Health in environmental health from the University of Minnesota and earned a second master's degree in medical product regulatory affairs and services from Saint Cloud State University. He holds a bachelor's degree in engineering and received his Regulatory Affairs Certification for drug/device/biologic regulatory pathways. He also earned a Six-Sigma Yellow Belt Certification for Organizational Quality from the American Society for Quality.

Dear International Colleague

Following are the most recent Dear International Colleague Letters:

[FDA Roundup: January 11, 2022](#)

[FDA's Upcoming Webinar on a Global Topic: A Focus on Biologics](#)

[FDA's Upcoming Webinar on a Global Topic: A Focus on Biologics \(govdelivery.com\)](#)

[FDA Roundup: January 14, 2022](#)

[FDA Roundup: January 18, 2022](#)

[FDA Roundup: January 21, 2022 | FDA](#)

[Coronavirus \(COVID-19\) Update: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant](#)

[FDA Roundup: January 25, 2022](#)

[FDA Roundup, January 28, 2022](#)

[FDA Takes Key Action By Approving Second COVID-19 Vaccine](#)

[FDA Takes Key Action By Approving Second COVID-19 Vaccine](#)

[FDA Roundup: February 4, 2022](#)

[Announcing Public Meeting on FDA's Agricultural Water Requirements in Produce Safety Rule](#)

[FDA Roundup: February 8, 2022](#)

[FDA Roundup: February 11, 2022](#)

[Coronavirus \(COVID-19\) Update: FDA Authorizes New Monoclonal Antibody for Treatment of COVID-19 that Retains Activity Against Omicron Variant](#)

[FDA Postpones Advisory Committee Meeting to Discuss Request for Authorization of Pfizer-BioNTech COVID-19 Vaccine for Children 6 Months Through 4 Years of Age](#)

UPCOMING EVENTS

- February 25 [Proposed Changes to AgWater Requirements in the PSR](#)
- March 7-9 [FDA, MHRA, and Health Canada Good Clinical Practice](#)
- March 16 [FDA-EMA Parallel Scientific Advice \(PSA\) Program](#)

March 24 [World TB Day](#)

March 31 3rd anniversary of OGPS

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