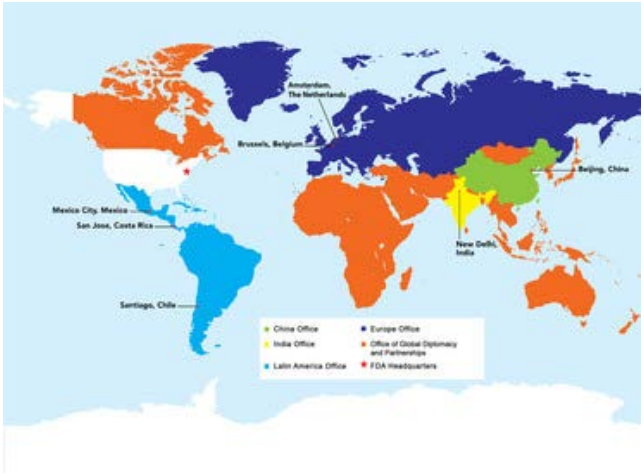
U.S. FOOD & DRUG ADMINISTRATION

OGPS Monthly Update

September 2020



Molluscan Shellfish Determination Finalized

For the first time, FDA has used a mechanism known as equivalence to begin reopening markets in raw and processed molluscan shellfish that have been closed to trade between the United States and the European Union (EU) since 2010.

Getting there took several years and involved scientific, policy, legal, and trade experts in FDA's Office of Global Policy and Strategy, the Office of the Chief Counsel and the Center for Food Safety and Applied Nutrition, with input from the Office of the U.S. Trade Representative.

Molluscan bivalve shellfish – such as oysters, clams, mussels and roe-on and whole scallops – are filter feeders, taking nourishment by filtering water containing plankton and food particles through their gills, which raises the importance of the safety of the water through which they eat. The U.S. shellfish industry follows a variety of rigorous food safety steps both during and after harvest to ensure the safety of its product and the FDA has specific procedures in place to ensure compliance.

As a leader in food safety standards, the FDA has a variety of import controls to ensure that food coming from outside of the United States is safe for American consumers. The FDA stopped accepting raw shellfish imported from EU countries in the 1980s due to public health concerns. In 2010, the EU, which uses different safety controls for several aspects of their food control system, stopped accepting U.S. exports of raw and processed bivalve molluscan shellfish after the European Commission (EC) conducted an audit and determined that the U.S. food safety controls were different from and did not comply with EU requirements.

In an effort to resume molluscan shellfish trade, the FDA and the EC decided to independently assess each other's food safety controls for molluscan shellfish using an approach spelled out in the Veterinary Equivalency Agreement signed by the United States and the EU in 1999. That agreement reaffirmed Article 4 of one of the foundational agreements establishing the World Trade Organization (WTO) in 1995, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). Article 4 of the SPS Agreement provides a mechanism for facilitating trade

between countries that use different food safety control measures to achieve the same level of public health protection.

Technical experts in CFSAN's Division of Seafood Safety conducted an assessment of the EU system and, initially, reached a tentative positive determination on two of the Member States after those Member States had agreed to implement additional safety controls. This technical assessment took several years and culminated in a proposed equivalence determination published in the Federal Register in 2018. FDA proposed to find equivalent raw molluscan shellfish harvested from specified growing areas in Spain and the Netherlands where additional controls were implemented for the U.S. market. Establishments interested in shipping raw product to the United States also would have to be listed by FDA on the Interstate Certified Shellfish Shippers List.

Around the time of FDA's proposed determination, the EU's food safety regulatory authority separately determined the U.S. food safety control system for raw molluscan shellfish to be equivalent to the EU system, beginning with accepting shellfish from certain growing areas in Massachusetts and Washington.

In addition, since 2018, FDA and the EC have been working to set up an implementation process for assessing additional EU Member States and U.S. States. OGPS's Office of Trade, Mutual Recognition, and International Arrangements (OTMRIA) and the Europe Office joined these efforts to lead negotiations with the EU. Their efforts resulted in an Administrative Arrangement signed by FDA and the EU's food safety regulatory authority, DG SANTE, that specifies a streamlined process for allowing exports from additional U.S. States participating in the National Shellfish Sanitation Program, and for recognizing additional EU Member States seeking to export to the United States under equivalence. That was signed at the end of July 2020. The FDA's final equivalence determination was published in the Federal Register on Sept. 24, the agency's first-ever final equivalence determination.

While negotiating the Administrative Arrangement for raw molluscan shellfish, OGPS also led negotiations with the EC to design an expedited equivalence assessment of the U.S. national food safety controls for processed shellfish. Using this mechanism, the EC planned to reach a final determination in a total of 12 months. The EC has made significant progress on this assessment, which they expected to conclude in mid-2021, but the timeframes had to be adjusted due to the global pandemic. A positive determination would open the EU market to processed shellfish on a nationwide-basis from all 50 States.

These and other understandings, memorialized in the Administrative Arrangement and related documents signed by the FDA and EC, provide the framework for important work still to be done. In the coming weeks, both FDA and DG SANTE will be taking the final operational steps necessary to start trade under the equivalence determinations. CFSAN's Division of Seafood Safety will be holding webinars for States and U.S.

industry interested in shipping to the EU and both agencies will be standing up electronic systems for this process and producing lists of firms eligible to export to the other.

Additional information:

FDA Voices blog

Constituent Update: FDA Publishes Final Equivalence Determination to Resume Shellfish Trade with Spain and The Netherlands

Federal Register Notice: Food and Drug Administration Equivalence Determination Regarding Implementation by Spain and the Netherlands of the European Union System of Food Safety Control Measures for Raw Bivalve Molluscan Shellfish with Additional Controls.

Questions and Answers on Shellfish Traded Between the United States and Certain Member States of the European Union

LAO Meets with Mexico on Papaya

On Aug. 20, the Latin America Office (LAO) hosted a virtual meeting with Mexico's ProExport Papaya trade association. The goal was to learn more about the association's composition, membership status, and the education/outreach activities with fresh papaya producers in Mexico.

The association includes about 85% of papaya producers in Mexico in at least five producing Mexican States. The grower association seeks to ensure that their members have completed the Produce Safety Alliance (PSA) Produce Safety Rule grower course, of which 95% of their members have completed thus far.

ProExport Papaya continues to be heavily involved in the implementation of the Texas International Produce Association's (TIPA) Papaya Best Practices Guide and has formed a working group with SENASICA to do the same with their Papaya Action Plan. ProExport Papaya is committed to a strong food safety culture, supporting training opportunities for producing safe papayas.

This current intense focus on increasing papaya safety is due to the occurrence of eight outbreaks since 2011 tied to the consumption of imported fresh papayas, causing more than 100 hospitalizations and two deaths in the United States.

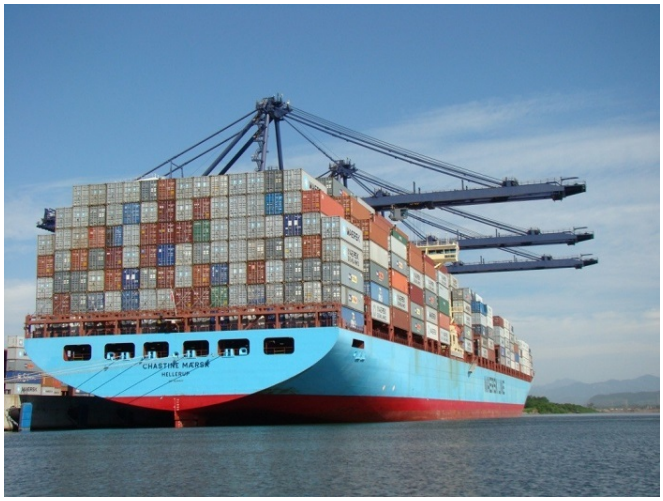
LAO staff worked diligently to ensure the creation of the industry-led Papaya Best Practices Guide included the input and participation of SENASICA, and that the

document aligned well both with FDA expectations as well as the SENASICA System for the Reduction of Contamination Risks (SRRC) program.

ProExport Papaya continues to conduct outreach activities for the 15% of papaya producers who are not yet members. They plan to coordinate efforts when SENASICA presents their SRRC and Papaya Action Plan programs to industry.

At the August meeting, LAO also shared information about the agency's New Era of Smarter Food Safety Blueprint initiative, which places emphasis on a strong and pervasive food safety culture – a goal that ProExport Papaya, SENASICA, and other papaya-involved associations mutually recognize and actively seek.

Medical Product Supply Chain Under Review



The safety and security of the drug and medical product supply chain is a hot topic. A few weeks ago, the Congressional Research Service issued FDA's Role in the Medical Product Supply Chain and Considerations During COVID-19. They noted that the COVID-19 pandemic has underscored the importance of understanding the supply chain—in particular, U.S. reliance on foreign sources of medical products and the federal government's ability to oversee the supply chain and mitigate future disruptions.

Also, the recently-enacted Coronavirus Aid, Relief, and Economic Security Act, known as the CARES Act, directed the Department of Health and Human Services (HHS) to commission a study by the National Academies of Science, Engineering and Medicine (NASEM) on the security of the U.S. medical product supply chain. The study will assess and evaluate U.S. dependence on critical drugs and devices sourced or manufactured outside of the United States and provide recommendations on improving the supply chain's resiliency.

The HHS Office of the Assistant Secretary for Preparedness and Response has been tasked with serving as the sponsor of the study. The NASEM *Committee on Security of*

America's Medical Product Supply held its kick-off meeting for this project just last week. Experts from our FDA's Center for Drug Evaluation and Research and the Center for Devices and Radiological Health were represented at the meeting.

The U.S. drug supply chain remains one of the safest in the world. However, protecting the integrity of this supply chain has become more complex as we increasingly rely on the global marketplace for drugs to treat patients and keep consumers healthy. Threats such as counterfeiting, diversion, cargo theft, and importation of unapproved or otherwise substandard drugs, could result in unsafe, ineffective drugs in U.S. distribution.

New Import Screening Tool Launched

When we talk about FDA as a scientific, data-driven agency, most people likely think about the data we analyze before approving an FDA-regulated medical product. But data is essential across FDA – including our efforts to ensure the safety of the U.S. food supply.

Some data sources – including information on food imports - are large and complex. To help us collect, review and analyze this wealth of information, FDA has begun employing artificial intelligence (AI) -, in particular a category of AI known as machine learning (ML) which uses an algorithm to learn from and act on data.

In the spring of 2019, FDA launched a pilot program to employ machine learning l to help screen data on food imports. It was thought that machine learning could automatically identify connections and patterns in data that people or even our current rules-based screening system cannot see.

To begin the "proof of concept," involved retrospective data from seafood shipments. The ML screening tool was "trained" by sorting years of data from past seafood shipments that were refused entry or subjected to additional scrutiny, such as a field exam, label exam or laboratory analysis of a sample. Over time the tool then "learns" to flag a potentially hazardous food shipment by analyzing such factors as food type and supplier. Seafood was chosen for the pilot because the U.S. imports so much of it — upwards of 94 percent of the seafood Americans consume each year.

The next step for the pilot is to apply the AI/ML model algorithm to actual field conditions, again with imported seafood. The model will be applied to the screening methods used to help FDA staff decide which shipments to examine, including which

food in the shipment should be sent for laboratory testing. The results will then be compared to the recommendations made by the current, non-AI, review system.

The pilot addresses two important new initiatives at the FDA. In addition to the priorities embodied in the Technology Modernization Action Plan (TMAP), it also reflects the New Era of Smarter Food Safety and its recently released Blueprint which outlines how the agency plans to leverage new technologies and approaches to create a more digital, traceable and safer food system.

The pilot is revealing the specific, immediate benefits that this technology could have in helping to ensure the safety of imported foods. FDA can learn how to gain the knowledge needed from the enormous volume of data collected via millions of import shipments each year. In 2019, the FDA screened nearly 15 million food shipments offered for import into the U.S. for sale to American consumers. Last year, the U.S. imported about 15% of its food, and that percentage continues to increase.

"We believe that we can use the knowledge that ML provides to know where best to concentrate our resources to find potentially unsafe products, said FDA Commissioner Stephen M. Hahn, M.D. "In addition to improved import surveillance resources, the intelligence that ML can extract from the stores of data the FDA collects can also inform decisions about which facilities we inspect, what foods are most likely to make people sick, and other risk prioritization questions," he continued.

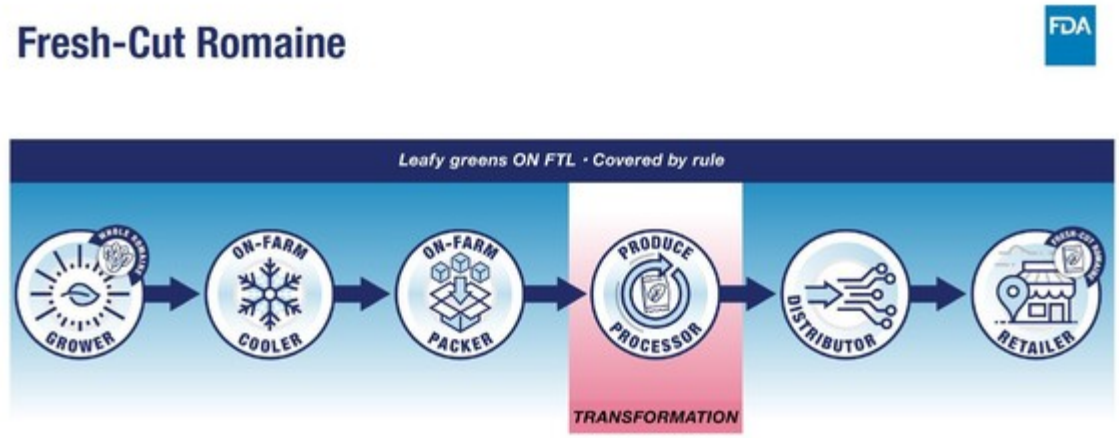
Proposed Rule Will Enhance Food Traceability, if Finalized

The FDA is proposing to establish additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the agency has designated for inclusion on the Food Traceability List.

The proposed rule, "Requirements for Additional Traceability Records for Certain Foods," was opened for public comment on Sept. 23. The proposed requirements would help the FDA more rapidly and effectively identify recipients of suspect problem foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death.

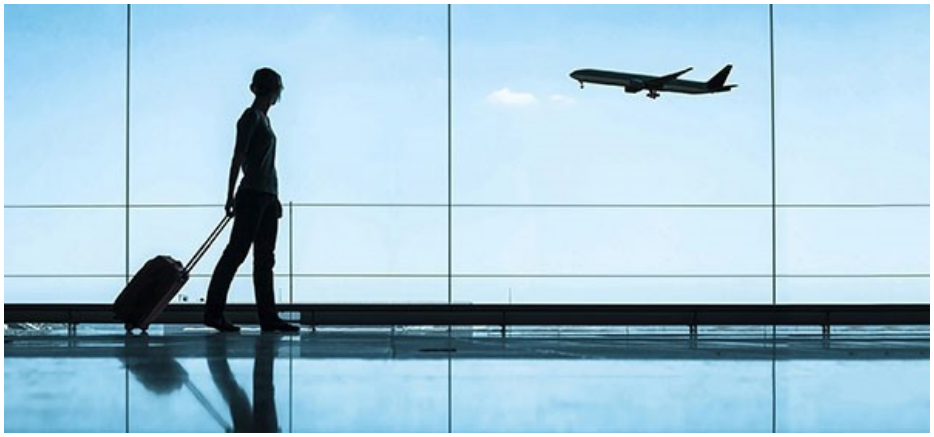
Current FDA regulations require much of the food industry to establish and maintain records that document one step forward to where food has gone and one step back to its immediate previous source. These existing FDA traceability requirements do not apply to farms and restaurants, meaning that a large part of the supply chain is excluded from keeping these important traceability records. With the proposed rule, key players in the supply chain not already required to keep traceability records — like the growers — will now be included.

T*he below example is via the **First Receiver Factsheet (PDF)**.*



The ultimate goal is a modern, coordinated approach to traceability that can be used and understood throughout all stages of the food supply chain. Such approach will go further to reduce foodborne illness, build consumer trust, and avoid overly-broad recalls. The proposed rule, when finalized, would establish a standardized approach to traceability recordkeeping, paving the way for industry to adopt, harmonize, and leverage more digital traceability systems in the future.

China Staff Return to Post to Continue the OGPS Mission



OGPS staff and family from the Office of Global Operations (OGO) China Office (CNO) have displayed dedication and resilience throughout the COVID-19 pandemic.

In early February 2020, CNO staff left Beijing to various safe-haven locations in the United States after receiving an authorized/ordered departure from the State Department on Jan. 29 “due to restricted transportation options and limited availability of

appropriate health care" related to the outbreak of what was then called the novel coronavirus. It was the first time FDA had ever evacuated a foreign office post.

After arriving in the U.S., 18 staff and 35 family members followed U.S. Centers for Disease Control and Prevention (CDC) guidance and self-quarantined. Because the authorized/ordered departure prompted U.S. Direct Hires (USDH) and Eligible Family Members (EFMs) to temporarily return to the U.S., the China Office's locally engaged staff were instrumental in ensuring continuity of operations and working across time zones with USDH staff who had returned to the U.S. During this interim period, the FDA moved to a 100% telework model, yet remained committed to leveraging available resources to continue its efforts in-country to ensure the safety of imported goods.

"We've been immersed in this pandemic for nearly nine months. While it may seem like forever, that's a relatively short period of time, particularly when it relates to our understanding of a new disease that, as of the beginning of this year, a large part of our nation and our planet was virtually unaware of," said OGO Director Bruce Ross.

Once conditions became more stable in-country, the U.S. Embassy in Beijing created a homecoming taskforce to return USDH and EFMs to post.

CNO began its phased return to Beijing on May 31 with the return of Deputy Country Director **Latasha Robinson** and Program and Policy Analyst **William (Bill) Sutton**, for the 30+ hour, multiple-stop journey. Subsequent State Department chartered flights returned remaining CNO staff and their families to Beijing. Upon their return to China, all U.S. Government travelers were tested for COVID-19 by the China CDC and entered a mandatory 14-day isolation period. On day 13 of isolation another COVID-19 test was administered, to ensure a negative result prior to clearance by the China CDC to leave quarantine and return to work and life in China.

Most recently, the State Department chartered flights were used to bring four new staff and their families to China as they begin their two-year tours: China Office Director **Vanessa Shaw-Dore**, and Consumer Safety Officers **Marcus Ray**, **Edward Potter** and **Edna Hidalgo**.

Transitions

Welcome

Dana Kappel is the new ORISE Fellow assigned to the Immediate Office, but she will work on a variety of projects across OGPS. She will assist the Latin America Office with outbreak epidemiology; help analyze drug data for the Europe Office and the European Medicines Agency; and help Policy Advisor **Ravi Bharwani** in the Immediate Office on long-term research and analytical projects.

Kappel recently graduated from Imperial College London with a Master of Science degree in epidemiology with a focus on infectious diseases. Additionally, she

received a Bachelor of Arts in classical studies and Master of Arts in world history from Seton Hall University.

Eloisa Noriega has been selected for a 120-day detail as an international policy analyst in the Office of Trade, Mutual Recognition, and International Arrangements, working on the disclosures and arrangements portfolio. Noriega comes from the Center for Drug Evaluation and Research, Office of Management, Division of User Fee Management and Budget Formulation where she has served in several roles – both in the Immediate Office and in the Generics Branch, determining and assessing Generic Drug User Fee Amendments fees.

She joined the federal government in 2013 after graduating from the University of Maryland with a degree in communication.

Dhruv Shah is a medical product safety coordinator with the India Office. Prior to joining FDA, Shah worked in research and development with major pharmaceutical companies. He brings roughly nine years of experience in formulation development of solid oral drug products intended for the U.S., EU, and other regulated markets. His expertise includes product development using Quality by Design (QbD) concepts, process development, optimization, scale-up, validation, and technology transfer. Shah holds a Master of Pharmacy degree with specialization in pharmaceutical technology and pharmaceutics from Gujarat Technological University.

Publication on Remdesivir Emergency Approvals Released

FDA Europe Office's **Sandy Kweder, M.D.**, has coauthored an article with representatives from the European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), comparing how they used their emergency pathways for the first regulatory approvals of the antiviral remdesivir to treat patients infected with SARS-Cov2, the virus that causes COVID-19.

They concluded that while the regulatory approvals were clearly based on evidence, regulators used agile methods to speed up approval, and make the first antiviral with reliable data available to patients in their constituencies on a very short time frame.

See: Remdesivir emergency approvals: a comparison of the US, Japanese and EU systems

Food and Drug Law Institute Annual Meeting Welcomes FDA Experts

On Tuesday Oct. 6, Associate Commissioner Mark Abdoo will join FDA Commissioner Stephen M. Hahn, M.D., Principal Deputy Commissioner Amy P. Abernethy, M.D., Ph.D., FDA Chief Counsel Stacy Cline Amin, as one of the speakers at the Food and Drug Law Institute (FDLI) Annual Conference: *Exploring Advanced Topics in Food and Drug Law*.

The FDLI conference was supposed to be held in early May but was moved to become a virtual event in Oct. due to COVID-19.

Abdoo will participate in the panel: *The Global Economy of FDA-Regulated Products Under Stress*, from 4:00 – 5:00 p.m. ET, where experts will discuss recent challenges regarding supply chain demands related to imports and exports.

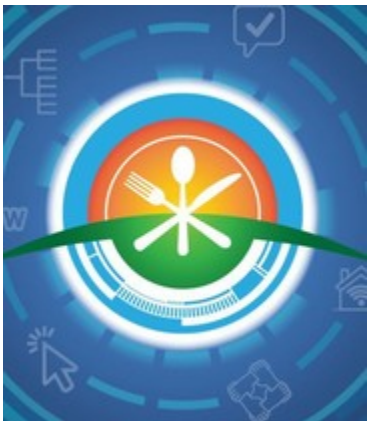
They will also explore the current status of FDA's mutual recognition program, how FDA works with agencies in other countries, and the state of FDA inspections outside of the United States. Other panelists include Benjamin L. England of Benjamin L. England & Associates LLC/FDAImports.com, LLC; John A. Murphy of the Biotechnology Innovation Organization; Kimberly A. Trautman of Medical Device International Services, NSF International. The panel will be moderated by Carla Cartwright of Johnson & Johnson.

The Food and Drug Law Institute (FDLI), founded in 1949, is a nonprofit membership organization that offers education, training, publications, and professional engagement opportunities in the field of food and drug law. FDLI brings together stakeholders to inform innovative public policy, law, and regulation.

FDLI's scope covers all industries regulated by the U.S. Food and Drug Administration (FDA) and related agencies and authorities in the U.S. and globally, including drugs, medical devices, biologics, food, dietary supplements, cosmetics, veterinary, tobacco, and cannabis-derived products.

The upcoming meeting will feature over 30 breakout sessions covering the latest in legal, regulatory, compliance, policy, marketing, and related issues and will have consecutive FDA Center Director sessions.

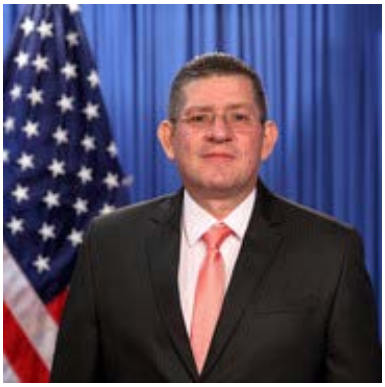
Gonzalez Presents Training on the New Era of Smarter Food Safety



Educating our regulatory partners about FDA's activities is one of the major tasks of our foreign offices. Sometimes that requires looking for the most effective and efficient way to leverage resources.

When the Guatemalan Ministry of Agriculture, Livestock and Food sought a briefing for ministry officials on the New Era of Smarter Food Safety, FDA's Latin America Office instead contacted the Guatemalan Association of Exporters and proposed that the training be conducted as part of the virtual forum, *InnovAcción 2020*.

Consequently, the training was available to attendees from an important group of Central American exporters and/or potential exporters of food to the United States, plus a small group of Competent Authorities from other countries in the region plus the officers from the Guatemalan Ministry. Around 400 people attended the forum to hear **Allan Gonzalez**, an international regulatory analyst in Costa Rica, discuss the core elements of the New Era blueprint and discussed FDA's new approach to traceability.



Gonzalez has participated in inspections in the areas of both food and medical devices, and has provided training on good agricultural practices, the process of exporting food and medical devices to the U.S., and the Food Safety Modernization Act.

Prior to joining FDA, he gained extensive experience working in the private food industry, in positions involving production, quality assurance, occupational health and environmental management. He has also worked in university research, in the management of wastewater treatment plants, and as an instructor in food safety issues.

LAO Hosts Cyclospora Cyentanensis Webinar

On Sept. 18, LAO co-hosted a webinar on Cyclospora cayetanensis, along with The Center for Food Safety and Applied Nutrition and counterparts from the Mexican food regulatory authorizes: SENASICA, COFEPRIS, and UnaComex.

The event was planned in conjunction with the Cyclospora taskforce and was focused on getting good information to growers about prevention techniques for Cyclospora contamination of fresh produce.

The event was targeted to growers, packers and distributors of fresh aromatic herbs (e.g., cilantro and basil) in the state of Puebla, Mexico. In addition to industry, federal and state government officials as well as academia and students from agri-foods programs were invited to participate.

Participants of the webinar received a special certificate of participation from FDA.

September is National Preparedness Month

Planning for a disaster is more important now more than ever this year due to COVID-19. This year your shelter options may be different due to the pandemic. Follow the guidance of your local public health or emergency management officials on when and where to shelter.

While at the shelter following these CDC recommendations:

Bring your disaster kit with you, which should include cloth face masks, hand sanitizer and soap, and disinfecting wipes.

- Stay at least 6 feet from anyone who is not from your household.
- Take CDC-recommended precautions to protect those who are at higher risk for severe illness from COVID-19.
- Avoid touching high-touch surfaces like stair rails and wash your hands often.
- Keep your living area in the shelter clean and disinfect frequently touched items.
- If you start to feel sick, tell shelter staff immediately.

Dear International Colleague

The Dear International Colleague Letter (DICL) is a letter sent via email to a list-serve of about 20,000 subscribers – both DC-based embassies and international stakeholders. The DICL is intended to inform these stakeholders of any FDA announcements that are relevant to an audience with international interests. Here are the most recent DICLs:

CDER Small SBIA Drug Registration and Listing Workshop

Advancing Innovative Science in Generic Drug Development Workshop

FDA finalizes framework that will resume shellfish trade with EU

FDA Announces FSMA Rule to Advance Food Traceability

Upcoming Activities

October 6-8	Food and Drug Law Institute Annual Meeting
October 29-30	WHO Member State Mechanism Plenary Meeting
November 11-12	INOFOOS & IAFP's 7th Latin American Symposium