

**COMMITTEE ON STRONGER FOOD AND DRUG
REGULATORY SYSTEMS ABROAD**

Academy of Sciences of Costa Rica
Los Yoses, San Pedro, Costa Rica

FEBRUARY 25, 2019

9:00-9:15	Welcome and Introductions Catherine Woteki , <i>Committee Chair</i>
9:15-9:30	Opening Remarks Pedro Leon , Academy of Sciences of Costa Rica
9:30-9:45	Introduction to FDA Latin America Katherine Serrano , <i>Director, Latin America Office</i> , Food and Drug Administration
9:45-10:00	Break

**SESSION 1- OPEN
FOOD SAFETY SYSTEMS**

10:00-10:25	FAO and WHO Food Control Assessment Tool Marisa Caipo , <i>Food Safety and Quality Officer</i> , FAO Regional Office for Latin America and the Caribbean
10:25-10:50	New Food Safety Management System for Ecuador Rommel Anibal Betancourt Herrera , <i>General Coordinator of Food Safety</i> , Agency for Regulation and Control of Plant and Animal Health (AGROCALIDAD)
10:50-11:15	The Effects of the US Food Safety Modernization Act on Local Markets Ana Marisa Cordero , <i>Specialist</i> , Agricultural Health and Food Safety, IICA
11:15-11:40	The Effect of Codex Standards on Local Food Markets Tatiana Cruz Ramirez , <i>Head, Department of Technical Regulation and Codex</i> , Ministry of Economy, Industry and Commerce, Costa Rica
11:40-12:40	Lunch
12:40-2:20	Panel Discussion on Food Safety (All Session 1 Speakers) Joshua Sharfstein , <i>Moderator</i> <ul style="list-style-type: none">• <i>Latin American countries generally have large agricultural sectors that employ a lot of people. Do you see a tension between food regulation for the promotion of trade and food regulation for domestic consumption?</i>

- *Most food safety systems emphasize choosing priorities based on risk. What are the barriers to doing this?*
- *What factors aide or hold back your ability to work with other countries in the region on foodborne disease, outbreaks and emergencies? How would you say this has changed over the last 5 to 10 years?*

2:20-2:35

Break

<p style="text-align: center;">SESSION 3- OPEN</p> <p style="text-align: center;">MEDICAL PRODUCT SAFETY SYSTEMS</p>
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2:35-3:05

Strengthening Medicines Regulation in Central America
Jose Vicente Coto Ugarte, *Regional Consultant, Medicines, PAHO*

3:05-3:35

Approval and Registration of Biotherapeutics
Emilio Medina *Technical and Scientific Director, Development and Research Processes, National Polytechnical Institute of Mexico*
Mayra Perez-Tapia, *Executive Director & Research Professor, Unit for Development and Research in Bioprocesses, National Polytechnical Institute of Mexico*

3:35-4:05

Licensing and Inspection of Drug Manufacturer, Import, and Wholesale
Jean Carlo Apuy, *Enforcement, College of Pharmacy of Costa Rica (COLFAR)*

4:05-4:35

Staff and Agency Development Planning
Maria Angelica Sanchez Herrera, *former Head, Office of International Affairs, National Institute for Drug and Food Surveillance (Invima)*

4:35

Adjourn

FEBRUARY 26, 2019

9:00-9:15 Welcome
Catherine Woteki, *Committee Chair*

SESSION 4 - OPEN
INDUSTRY AND CONSUMER PERSPECTIVES

9:15-11:00 Panel Discussion on Openness and Industry's Role in Regulatory Systems
Maria Elena Bottazzi, *Moderator*

- *How would you describe the relationship between public confidence in your products and the strength of the regulatory agency?*
- *How do you see industry's role in building strong regulatory agencies in the countries where you work?*
- *Can you share examples of times when you found regulatory action to be predictable and objective and times when it was not?*
- *What is your experience of the regulatory agencies ability to respond to new technologies?*

Rivelino Flores, *Director of Regulatory Affairs and Innovation*, National Chamber of the Pharmaceutical Industry
Monique Collaço de Moraes Stávale, *Vice Director of Quality*, Bio-Manguinhos, Oswaldo Cruz Foundation
Paula Vargas, *Regulatory Leader*, Pfizer, Central American and the Caribbean
Lissy Cruz, *Regulatory Manager*, Fedefarma
Mario Montero, *Executive Vice President*, CACIA, the food industry association of Costa Rica

11:00-11:15 Break

11:15-11:45 Open Sharing of Government Data
Ana Gabriel Zuniga, *Specialist in Open Government and Accountability*, HIVOS

11:45-12:15 Information, Education, and Communication with Consumers
Carolina Paz, *Center for Consumer Defense*, El Salvador

12:15-1:15 Lunch

SESSION 5 - OPEN
THE CHALLENGES FACING REGULATORY AGENCIES

In their brief introductory comments speakers are asked to describe their agency, its responsibilities, when it was founded, and how it is funded.

1:15-1:30 Introduction to ARSA
Iris Galeano, *Commissioner*, Sanitary Regulatory Agency (ARSA) Honduras

1:30-1:45	<p>Introduction to ARCSA</p> <p>Juan Carlos Galarza, <i>Executive Director</i>, National Agency for Health Regulation, Control, and Surveillance (ARCSA), Ecuador</p>
1:45-2:00	<p>Introduction to Anvisa</p> <p>Dirceu Barbano, <i>former Director General</i>, National Health Surveillance Agency (Anvisa) Brazil</p>
2:00-2:15	Break
2:15-3:45	<p>Panel Discussion with Session 6 Speakers</p> <p>Mikel Arriola, <i>Moderator</i></p> <ul style="list-style-type: none"> • <i>What are the main challenges facing your agency with regards to food safety, medicine and vaccine safety?</i> • <i>Would you say staff retention is a problem, and if so, what do you think would help retain talented workers?</i> • <i>Is the food and drug regulatory agency a priority for heads of government, ministers of health, and ministers of finance? If not, what might persuade them to make it one?</i> • <i>What are the main barriers to persuading heads of government to invest in regulatory systems?</i>
3:45	Adjourn Public Meeting
<div> <div>SESSION 6 – CLOSED</div> <div>COMMITTEE DEBRIEF</div> </div>	
3:45-4:30	Committee Debrief
4:30	Adjourn