

# Modernizing the Regulatory System for Biotechnology Products

## Public Meeting

October 30, 2015  
9:30 AM – 1:00 PM

FDA's White Oak Campus  
Building 31 Conference Center, the Great Room (1503-B&C)  
10903 New Hampshire Ave., Silver Spring, MD 20993-002

**Docket No. FDA-2015-N-3403**

### AGENDA

- 8:30 AM**      **Registration Begins**
- 9:30 AM**      **Welcome**  
Ritu Nalubola, Ph.D.  
*Senior Policy Advisor*  
*Office of Policy*  
*U.S. Food and Drug Administration*
- 9:40 AM**      **Opening Remarks**  
John Holdren, Ph.D.  
*Director*  
*White House Office of Science and Technology Policy*
- 9:55 AM**      **Modernizing the Regulatory System for Biotechnology Products**  
Roberto Barbero, Ph.D.  
*Assistant Director for Biological Innovation*  
*White House Office of Science and Technology Policy*
- 10:20 AM**      **Federal Regulation of Biotechnology Products**
- 10:20-10:40      **USDA-APHIS Role in the Regulation of Products of Biotechnology**  
John Turner, Ph.D.  
*Director*  
*Biotechnology Risk Analysis Program*  
*Animal and Plant Health Inspection Service*  
*U.S. Department of Agriculture*
- Lisa Ferguson  
*National Director, Policy Permitting and Regulatory Services*  
*National Import Export Services*  
*Animal and Plant Health Inspection Service-Veterinary Services*  
*U.S. Department of Agriculture*

**10:40 AM**      **Break**

10:50-11:10    **Environmental Protection Agency Role--Biotechnology Pesticide Oversight**

Mike Mendelsohn  
*Senior Regulatory Specialist*  
*Office of Pesticide Programs*  
*U.S. Environmental Protection Agency*

11:10-11:30    **Toxic Substances Control Act and Genetically Engineered Microorganisms**

Mark Segal, Ph.D.  
*Senior Microbiologist*  
*Office of Pollution Prevention and Toxics*  
*U.S. Environmental Protection Agency*

11:30-11:50    **FDA Regulation of Products Derived from Genetic Engineering**

Leslie Kux, J.D.  
*Associate Commissioner for Policy*  
*U.S. Food and Drug Administration*

**11:50 AM**      **Break**

**12:00 PM**      **Public Comment Session**

Registered Speakers:

- Alexis Baden-Mayer, Organic Consumers Association (on behalf of Steven Druker, Alliance for Bio-Integrity)
- Richard Engler, Bergeson & Campbell, P.C.
- Doug Gurian-Sherman, Center for Food Safety
- Michael Hansen, Consumers Union
- Tim Schwab, Food & Water Watch
- Sapna Brown, Governance Solutions
- Kelly Drinkwater, iGEM Foundation
- Val Giddings, Information Technology & Innovation Foundation
- Jaydee Hanson, International Center for Technology Assessment
- Randy Gordon, National Grain and Feed Association
- Marek Cuhra, Norway - University of Tromso
- Nina Fedoroff, OFW Law
- Alexis Baden-Mayer, Organic Consumers Association
- Megan Parker
- Megan Palmer, Stanford University
- Terry Medley, DuPoint
- Tyrone Spady, American Society of Plant Biologists

## **Meeting Adjournment**

If you would like to be kept up to date on future activities related to modernizing the regulatory system for biotechnology products, please sign up at: <https://www.whitehouse.gov/webform/stay-connected-modernizing-biotech-regulatory-system>.