

**Progress on
Modernizing the Regulatory System for Biotechnology Products**

—Second Public Meeting—

March 9, 2016
9:30 AM - 1:30 PM

EPA Region 6 Main Office
1445 Ross Avenue, Oklahoma Room, 12th Floor
Dallas, TX 75202

Docket No. FDA-2015-N-3403

The primary purpose of this meeting is to illustrate current Federal roles and responsibilities regarding biotechnology products. This will be accomplished by reviewing case studies of hypothetical products. There will be several question and answer sessions to clarify the information presented during the case studies. The information presented at this meeting about the current Federal roles and responsibilities regarding biotechnology products will be made available for public comment in the Federal Register later this year. The agenda for this meeting provides time for public comments. Commenters should email their intention to comment, as well as their name and affiliation to mendelsohn.mike@epa.gov prior to the meeting. Public comments made at this meeting will be submitted to the docket as part of the official meeting transcript.

AGENDA

- 8:30 AM** **Registration Begins**
- 9:30 AM** **Opening Remarks**
Robert McNally
Director, Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
US Environmental Protection Agency
- 9:35 AM** **Welcome**
Jeffrey Morris
Deputy Director, Office of Pollution Prevention and Toxics
US Environmental Protection Agency
- 9:40 AM** **Review Agenda**
Robert McNally
Director, Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
US Environmental Protection Agency

- 9:45 AM** **Modernizing the Regulatory System for Biotechnology Products—Background and Progress Made to Date**
 Robbie Barbero
Assistant Director for Biological Innovation
White House Office of Science and Technology Policy
- 10:10 AM** **Regulation of Biotechnology Products—Clarifying Roles of and Coordination among USDA/APHIS, EPA, and FDA through a Discussion of Case Studies**
 Robbie Barbero
Assistant Director for Biological Innovation
White House Office of Science and Technology Policy
 Neil Hoffman
Science Advisor
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
US Department of Agriculture
 Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs
US Environmental Protection Agency
 Mark Segal
Senior Microbiologist
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
 Ritu Nalubola
Senior Policy Advisor
Office of Policy, Office of the Commissioner
US Food and Drug Administration
- 10:15 AM** **Case Studies: Products for Human Food and Animal Feed**
 Hypothetical Plant-Incorporated Protectant (PIP) Corn
 Hypothetical Herbicide-tolerant plant
- Q&A**
- 10:55 AM** **Case Study: Products for Biomedical Applications**
 Hypothetical GE rabbit (produces insulin for human use)
- Q&A**
- 11:15 AM** **20-min Break**
- 11:35 PM** **Case Studies: Microbial Products for Pesticide or Industrial Applications**
 Hypothetical Microbial Pesticide
 Hypothetical Algae for Biofuels (not intended for use in food for animals)

Q&A

12:15 PM **Case Study: Products with Other Applications**
Hypothetical GE Rose

Q&A

12:35 PM **Discussion of Third Public Meeting on March 30, 2016 in Davis, CA**
Robbie Barbero
Assistant Director for Biological Innovation
White House Office of Science and Technology Policy

12:40 PM **Public Comment**

Meeting Adjournment