

Total Burden Hours: 28.

Ruth Brown,

*Departmental Information Collection
Clearance Officer.*

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0024]

Modernizing the Regulatory System for Biotechnology Products; Notice of Third Public Meeting

AGENCY: Animal and Plant Health
Inspection Service, USDA.

ACTION: Notice.

SUMMARY: Under the auspices of the National Science and Technology Council, USDA, along with the White House Office of Science and Technology Policy, the Environmental Protection Agency and the Food and Drug Administration (FDA) are holding the third public meeting related to the memorandum entitled, “Modernizing the Regulatory System for Biotechnology Products,” issued by the Executive Office of the President in July 2015. The purpose of the third public meeting is to illustrate current Federal roles and responsibilities regarding biotechnology products. The docket, FDA-2015-N-3403, established by FDA prior to the first public meeting, will continue to be used for this interagency effort.

DATES: The meeting will be held on March 30, 2016, from 9:30 a.m. to 1:30 p.m. PDT.

To request accommodation of a disability, please immediately contact the person listed under **FOR FURTHER INFORMATION CONTACT** to give USDA as much time as possible to process your request.

ADDRESSES: The meeting will be held at the University of California, Davis Conference Center, Davis, CA 95616.

FOR FURTHER INFORMATION CONTACT: For general questions about the meeting, contact Mr. Sidney W. Abel, Assistant Deputy Administrator, Biotechnology Regulatory Services, APHIS, 4700 River Road, Unit 147, Riverdale, MD 20737-1236; (301) 851-3896. For questions about the memorandum entitled, “Modernizing the Regulatory System for Biotechnology Products,” or related activities described in that memorandum, contact the National Science and Technology Council: Emerging Technologies Interagency

Policy Coordination Committee, Office of Science and Technology Policy, Executive Office of the President, Eisenhower Executive Office Building, 1650 Pennsylvania Ave., Washington, DC 20504; (202) 456-4444; online: [https://www.whitehouse.gov/webform/contact-emerging-technologies-interagency-policy-coordinating-committee-national-science-and-](https://www.whitehouse.gov/webform/contact-emerging-technologies-interagency-policy-coordinating-committee-national-science-and-technology-policy)

SUPPLEMENTARY INFORMATION:

I. Background

Under the auspices of the National Science and Technology Council, the Environmental Protection Agency, Food and Drug Administration (FDA), United States Department of Agriculture (USDA) and the White House Office of Science and Technology Policy (collectively referred to as “we” in this **Federal Register** document), held a public meeting on October 30, 2015, to discuss the Executive Office of the President (EOP) memorandum entitled, “Modernizing the Regulatory System for Biotechnology Products,” that was issued in July 2015. The purpose of the October 2015 meeting was to inform the public about the activities described in the July 2015 memorandum, invite oral comments from interested parties, and provide information about how to submit written comments, data, or other information to the docket. The October meeting was the first of three public engagement sessions on this topic.

A second public meeting was held on March 9, 2016, in Dallas, TX. Transcripts and materials from this meeting can be found in the docket [FDA-2015-N-3403] on www.regulations.gov.

On February 1, 2016, we announced the date and location for the third public engagement session: <https://www.aphis.usda.gov/biotechnology/modernizing-framework>.

The third public meeting will be held on March 30, 2016, at the University of California’s Davis Conference Center in Davis, CA.

There are two draft documents available that will be the basis for discussion at the March 30 meeting: A document with eight case studies of hypothetical biotechnology products, and a table of oversight authorities related to biotechnology products. These documents can be found in the docket [FDA-2015-N-3403] on www.regulations.gov and on the USDA Web site at <https://www.aphis.usda.gov/biotechnology/modernizing-framework>, along with the final meeting agenda as soon as it is available.

II. How can I participate in the March 30th meeting?

There will be several opportunities for questions and answers to clarify the information presented during the case studies. The agenda for this meeting provides time for general public comments from those attending the meeting in person. Those planning to provide comment are asked to indicate their desire to comment when they register on USDA’s Web site prior to the public meeting. Public comments made at this meeting will be submitted to the docket as part of the official meeting transcript.

To participate in person or view the webinar, please register in advance online at <https://www.regonline.com/builder/site/default.aspx?EventID=1824027>. Those registered will receive detailed instructions with their confirmations that explain how to access the meeting via webinar or in person.

III. Meeting Materials, Transcripts and Recorded Video

Any additional information and data submitted voluntarily to us will become part of the administrative record for this activity and will be accessible to the public in the docket [FDA-2015-N-3403] on www.regulations.gov. The transcript of the proceedings from the public meeting will become part of the administrative record for this activity and will also be included and accessible in the docket as soon they are available. Additionally, we will live webcast and record the public meeting. Once the recorded video is available, it will be accessible on USDA’s YouTube channel.

Transcripts and meeting materials may also be viewed in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 23rd day of March 2016.

Michael C. Gregoire,

*Acting Administrator, Animal and Plant
Health Inspection Service.*

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