

USDA's Proposed Biotechnology Regulatory Revisions Available for Public Comment

Biotechnology Regulatory Services (BRS), a program within the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), is proposing to revise its existing regulations regarding the importation, interstate movement and environmental release of certain genetically engineered (GE) organisms. APHIS is proposing changes to its biotechnology regulations—based on BRS' extensive experience implementing the current regulations—in order to stay ahead of advances in biotechnology. The proposed rule outlines the potential changes and allows for public input.

The proposed revisions include aligning the regulations with the plant pest and noxious weed provisions of the Plant Protection Act (PPA) of 2000 to ensure that GE organisms posing a risk as a plant pest or noxious weed are appropriately regulated. The revisions would clarify which GE organisms are regulated and provide continued protection to agriculture and the environment as technology advances and more complex GE organisms are developed.

APHIS is also considering additional changes, including developing a multiple-category permitting system based on the potential environmental risk of the GE organism. This risk-based system will improve APHIS' ability to provide more flexible, risk-appropriate oversight, better regulatory enforcement and improved transparency. The proposed regulations would improve and clarify the petition procedure to approve nonregulated status, whereby a GE organism is no longer subject to APHIS' biotechnology regulations. APHIS used public input along with the latest science in developing the proposed rule. The public is a key partner in the rulemaking process, and APHIS has encouraged public involvement throughout the entire rulemaking process.

The first opportunity for public comment occurred in January 2004 when APHIS published a notice of intent (NOI) to prepare an environmental impact statement (EIS) in connection with potential changes to

federal regulations regarding GE organisms. This notice identified potential issues and alternatives to be studied in the EIS and requested public comment to further shape the scope of the EIS. In July 2007, APHIS published a draft EIS, seeking public comment on the regulatory alternatives that were currently under consideration and the potential environmental effects of the proposed regulatory changes. APHIS also held a series of stakeholder meetings to discuss issues associated with the proposal.

These comments contributed to the issues APHIS considered in the formulation of the proposed rule. APHIS continues to value comments from the public and stakeholders. APHIS will consider comments from the public and stakeholders prior to publishing new regulations (a final rule).

On Oct. 7, 2008, announced the availability of the proposed rule and the public comment period. The public comment period on the proposed rule begins Oct. 9, 2008. You may submit your comments by any of the methods outlined below. Consideration will be given to all comments received on or before Nov. 24, 2008.

How to Submit Comments

1. Postal mail or commercial delivery:
Please send two copies of written comments to:
Docket No. APHIS-2008-0023, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238. Please state in the body of your comment that it refers to Docket No. APHIS-2008-0023.
2. Internet:
If you wish to submit a comment using the Internet, go to the federal eRulemaking portal at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0023>; then click on "Add Comments." This will also allow you to view public comments and related materials available electronically. Please do not use alternative means to send comments through the Internet. Using the federal eRulemaking portal is the best way to ensure that your comments will be associated with the correct docket and reviewed.

Comments are posted on the Regulations.gov Web site and may also be reviewed at USDA, Room 1141, South Building, 14th St. and Independence

Ave., S.W., Washington, D.C., between 8 a.m. and 4:30 p.m., Monday through Friday, excluding holidays. To facilitate entry into the comment reading room, please call (202) 690-2817.

3. Written and oral comments will also be accepted at scheduled public meetings. Using designated comment stations at the meetings, individuals can submit prepared written comments, record comments on forms provided or enter comments electronically. A court reporter will be available to take oral comments.

Dates and Locations of Public Meetings:

Oct. 28, 2008, from 4 p.m. to 7 p.m., local time. Walter A. Buehler Alumni & Visitors Center, Alpha Gamma Rho Hall, University of California, Davis, Calif. 95616. For directions or facilities information, call (530) 754-9195 or visit <http://www.alumnicenter.ucdavis.edu/>

Oct. 30, 2008, from 4 p.m. to 7 p.m., local time. Hilton Kansas City Airport, Shawnee Room A, 8801 NW 112th Street, Kansas City, MO. 64153. For directions or facilities information, call (816) 891-8900 or visit <http://www.hiltonkci.com/>

Nov. 13, 2008, from 4 p.m. to 7 p.m., local time. USDA Riverside, Oklahoma City Memorial Conference Rooms B, C, and D, 4700 River Road, Riverdale, MD, 20737. For directions or facilities information, call (301) 734-8010.

For more information, please visit these Web sites:

Proposed Rule: <<http://www.aphis.usda.gov/.shtml>>
Overview of the EIS and the EIS process:
< http://www.aphis.usda.gov/biotechnology/EIS/EIS_index.shtml >

Draft EIS: < http://www.aphis.usda.gov/brs/pdf/complete_eis.pdf>

Federal Register notices related to EIS: NOI, Jan. 23, 2004 <http://www.aphis.usda.gov/brs/fedregister/BRS_20040123a.pdf>

Notice of Availability, July 17, 2007: <http://www.aphis.usda.gov/brs/fedregister/BRS_20070717a.pdf>

For further information regarding the proposed rule, contact

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To obtain copies of the proposed rule, contact

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