

 **NEWS RELEASE**

United States Department of Agriculture • Animal and Plant Health Inspection Service • Legislative and Public Affairs
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USDA SEEKS PUBLIC COMMENT ON PROPOSED RULE FOR BIOTECHNOLOGY REGULATIONS

WASHINGTON, Oct. 6, 2008--The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) proposes to revise existing regulations regarding the importation, interstate movement and environmental release of certain genetically engineered (GE) organisms under the Plant Protection Act (PPA) of 2000. These proposed revisions to the regulations are in response to emerging trends in biotechnology. New regulations will address the current and future needs of the agency and provide a high level of environmental protection.

“This is the most comprehensive review and revision of our biotechnology regulations since they were first developed in 1987,” said Cindy Smith, administrator of APHIS. “Revising these regulations now will allow us to ensure effective oversight for years to come.”

The proposed changes will also improve regulatory processes so they are more transparent to stakeholders and the public, make more efficient use of agency resources and eliminate unnecessary regulatory burdens. The proposed rule also addresses several provisions from the 2008 Farm Bill regarding the improvement of the management and oversight of GE organisms regulated under the PPA of 2000. This proposal does not cover vertebrate animals.

Proposed changes include aligning the regulations with the plant pest and noxious weed provisions of the PPA of 2000. Under the proposed rule, certain GE organisms would be subject to the regulations if they could pose a plant pest or noxious weed risk, or their plant pest or noxious weed risk is unknown.

APHIS proposes to discontinue the notification procedure but retain the permitting procedure for authorizing the importation, interstate movement or environment release of those GE organisms that fall within the scope of the regulations. The proposed permitting system could be adapted to address a wide variety of different species and genetic modifications.

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. All previous determinations of nonregulated status made under the current regulations would continue to have nonregulated status under the revisions being proposed.

The proposed regulations would also establish a new petition procedure for APHIS to approve new conditional exemptions from the requirement to obtain a permit, which is currently done by amending the regulations. The proposed procedure would be more efficient, yet still allow for public comment.

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APHIS is seeking public comment on the proposed rule. APHIS will consider all public comments submitted during the comment period before any regulatory changes are put in place. Because the public is a key partner in the rulemaking process, APHIS is scheduling three public meetings that will take place in California on Oct. 28, in Missouri on Oct. 30 and the Washington, D.C., area on Nov. 13, to allow interested parties to express their views in person. Meeting dates and locations will be published in the same *Federal Register* notice announcing the proposed rule.

APHIS' broad biotechnology regulatory authority falls under the scope of the PPA of 2000, which combined and modernized the authorities under which APHIS regulates certain GE organisms, including the Federal Plant Pest Act, the Plant Quarantine Act and the Noxious Weed Act.

The proposed rule is available on the APHIS Web site at <http://www.aphis.usda.gov>. Notice of this proposed rule is scheduled for publication in the Oct. 9 *Federal Register*. Consideration will be given to comments received on or before Nov. 24. Send two copies of postal or commercial delivery 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. Comments can be submitted on the Federal eRulemaking portal at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0023>. Click on "Add Comments," to view public comments and related materials available electronically.

Comments received are posted on the Regulations.gov Web site and also can be viewed 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.

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