

# Questions and Answers: Withdrawal of Proposed Rule Regarding the Introduction of Certain Genetically Engineered Organisms (340 Regulations)

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is advising the public that we are withdrawing a proposed rule, published October 9, 2008, that would have amended the regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered (GE) organisms. The most significant parts of the 2008 rule were the proposed changes to the scope of GE organisms that would be subject to regulation and the proposed use of the noxious weed provisions of the Plant Protection Act (PPA). Currently, APHIS only uses the PPA's plant pest provisions to regulate GE organisms.

**Q: When was the proposed rule first announced by APHIS, and is it still available to view?**

**A:** APHIS announced the proposed rule on October 9, 2008, and it is available [here](#).

**Q: Why did APHIS originally propose revisions to its biotechnology regulations?**

**A:** The proposed rule was the result of a comprehensive review of APHIS' biotechnology regulations and was an attempt to improve regulatory processes by focusing on risks to plant health while increasing transparency, making more efficient use of agency resources and eliminating unnecessary regulatory burdens.

**Q: What were some of the proposed changes?**

**A:** APHIS proposed a number of significant changes including aligning biotechnology regulations with provisions of the PPA, eliminating the current notification

and permitting procedures and developing a multiple-category permitting system in its place, and changing the petition procedure for deregulating GE organisms.

**Q: How many comments did the proposed rule receive?**

**A:** We received over 88,300 comments by the close of the comment period. These were received in 5,580 submissions that included unique comments, form letters, and signatories to petitions. Stakeholders expressed significant concerns with several key aspects of the proposal.

**Q: Who submitted comments?**

**A:** Comments were from a variety of stakeholders, including advocacy groups; State, Tribal, and foreign governments; university researchers; trade associations; regulated entities; and private citizens.

**Q: What were the main concerns with the rule?**

**A:** Commenters were especially concerned about the lack of details surrounding the proposed risk-based system that would determine what organisms fell under APHIS oversight as well as the proposed multi-tiered permit system, and perceived expansion of agency authority.

**Q: What will happen to the comments submitted in response to the 2008 proposed rule?**

**A:** Previously submitted comments will be retained and considered as the agency undertakes future discussions and decision making on this subject.

**Q: Did the comments on the proposed rule impact APHIS' decision to withdraw the proposal?**

**A:** Yes. APHIS' decision to withdraw the rule is based on the scope of the comments received as well as the experience we have gained over the past 28 years, and our recognition of the continuing advances in biotechnology. We look forward to beginning a new stakeholder engagement effort aimed at exploring alternative policy approaches.

**Q: When can stakeholders and the public begin to share their input?**

**A:** Once the 2008 proposed rule is officially withdrawn, APHIS can begin having conversations with stakeholders about regulatory issues that were not possible due to ex parte communication rules that apply during rule-making. These rules are designed to prevent unequal access or the perception of favoritism during the active rulemaking period after a new rule is proposed.

**Q: Will APHIS present a platform for stakeholder input?**

**A:** We look forward to engaging stakeholders on this subject. In the near future, APHIS will announce plans for a series of webinars that will provide for initial stakeholder feedback.

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