Questions & Answers: APHIS Requests Public Input on Next Steps Towards Revision of Its Biotechnology Regulations

APHIS is issuing its proposed revisions to its biotechnology regulations. The proposed rule updates the regulations in a number of areas, all within the Agency's current statutory authority under the Plant Protection Act (PPA) passed into law in 2000. The proposed rule is based on the best available science, will better enable APHIS to focus its resources on regulating genetically engineered (GE) organisms that may pose plant pest or noxious weed risks, and will enhance regulatory flexibilities that foster innovation. In developing the proposed rule, APHIS carefully considered comments received during public scoping and comment periods related to withdrawal of the 2008 proposed rule as well as comments relative to the notice of intent (NOI) to conduct a programmatic environmental impact statement (PEIS), recommendations made in two Office of the Inspector General (OIG) audits, recent advances in biotechnology, provisions in the 2008 Farm Bill, and the Agency's accumulated experience in implementing the current regulations. This would be the first comprehensive revision of the regulations since they were established in 1987.

APHIS' proposed rule will be available for public review and comment for 120 days, until DATE.

Q: What is prompting this revision?
A: Since 2000, when the Plant Protection Act was passed, we never lost sight of the need to update our regulations to protect plant health in the United States. Outside reviewers, including the Office of the Inspector General and the General Accountability Office and provisions in the 2008 Farm Bill have urged us to update the biotechnology regulations that were originally promulgated in 1987 and modified only slightly since then. We have gathered and considered input from stakeholders and have developed a proposed rule that is now ready to be shared for further input.

Q: What are APHIS' goals with this revision?
A: Our goals are to protect plant health, improve regulatory processes to be more transparent to stakeholders and the public, to regulate at a level more commensurate with risk, to eliminate unnecessary regulatory burdens and to enhance development opportunities for small companies and universities who cannot afford to go through our current deregulation process.

Q: What is APHIS proposing to regulate?
A: Currently, GE organisms that fall under APHIS regulation are required to have APHIS authorization via permit or notification in order to be imported, moved interstate, or released into the environment (meaning regulated, controlled outdoor use such as field trials), until it can be shown that they do not pose plant pest impacts. APHIS is proposing a regulatory program in which it first assesses GE organisms to determine if they pose plant pest or noxious weed risks. If APHIS concludes that a GE organism does not pose a plant pest or noxious weed risk, then APHIS would not require a permit for movement of the GE organism. On the other hand, if APHIS determines, based upon the risk analysis that controls on movement are needed, APHIS will work with the requestor to establish appropriate permit conditions to manage identified risks to allow safe movement. By "movement" we mean import, interstate movement, or environmental release (regulated controlled outdoor use such as in field trials.)

There are four categories of GE organisms we are proposing to regulate. They are:

- GE organisms that belong to a taxon (group) that is or contains plant pests, and that meet the Plant Protection Act (PPA) definition of plant pest themselves. This would most often pertain to known plant pests that have been subject to genetic engineering.
- GE organisms where the genetic material that was engineered in the organism was derived from a plant pest and either confers plant pest traits, or the inserted DNA engineers the organism to produce compounds which are typically produced by pathogens and involved in

producing disease symptoms.
- GE plants that have crop and trait combinations that we have not previously evaluated for plant pest or noxious weed risks.
- GE organisms determined by APHIS to be plant pests or noxious weeds.

APHIS would also regulate a GE biological control (biocontrol) agent if we determine that it is a plant pest or noxious weed. Biocontrol involves the reduction of plant pest and weed populations through the use of natural enemies such as predators, pathogens, or competitors to suppress plant pest and weed populations.

Q: How is the noxious weed authority involved with this proposal?
A: The current biotechnology regulations have not been changed substantially in nearly 30 years, and do not incorporate the PPA's noxious weed authority. Under the proposed rule, we would incorporate the noxious weed authority using a risk-based approach to determine whether a GE plant poses a noxious weed risk before deciding to require a permit for movement. This is an important facet of the proposed regulation, and we invite stakeholders to provide us with their input and information during the comment period.

Q. What does APHIS mean by "genetic engineering"?
A. APHIS is proposing to update its definition of genetic engineering to mean techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome. APHIS considers synthetic nucleic acids to be nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules.

APHIS would exclude from the definition of genetic engineering traditional breeding techniques (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion) or chemical or radiation-based mutagenesis. APHIS would do so because the Agency has never considered such techniques to constitute genetic engineering. Accordingly, organisms created through such techniques are currently excluded from regulation under 7 CFR part 340, and would continue to be excluded.

Q. What categories of GE organisms is APHIS proposing to exclude?

A. Three categories of GE organisms would be excluded under the proposal. They are:

- The genetic modification in the organism is solely a deletion or single base pair substitution which could otherwise be obtained through the use of chemical- or radiation-based mutagenesis.
- The genetic modification in the organism is solely the result of introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion).
- The GE organism is the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny.

Q: How would this proposal affect APHIS' regulatory approach?
A: The proposal would change APHIS' regulatory approach by shifting from a "regulate first/analyze later" system to first assessing new GE organisms to determine if they pose plant pest or noxious weed risk to U.S. agricultural plants, before regulating through permitting such organisms.

Under the proposed new regulatory approach, for those GE organisms that do need to be regulated, APHIS will subject them to compliance requirements consistent with risks identified in the risk analysis.

One of the major departures from our current regulatory approach is that we would no longer regulate strictly on the basis of whether a GE organism was created using genetic material from a plant pest. Our experience has shown that the use of genetic material from plant pests has not resulted in the creation of plant pest risks in recipient organisms. We would only regulate if the GE organism itself posed a plant pest or noxious weed risk.

Q: How does the proposed rule address new genome-editing techniques?
A: APHIS regulates the products of biotechnology and not specific biotech techniques. Products of the so-called "new genome-editing techniques" would be regulated under this part only if they pose plant pest or noxious weed risk.

Consistent with the Coordinated Framework for the Regulation of Biotechnology, APHIS continues to work closely with EPA and FDA on various issues related to biotechnology, including on genome editing. We intend to work cooperatively with other relevant agencies that may also be considering their policies or approaches related to genome editing applications within their jurisdictions.

Q: Have you sought input from stakeholders before drafting this proposed rule?
A: Yes. We have considered over 88,300 comments received on a rule we proposed in 2008, which we withdrew in 2015. In addition, in 2015 APHIS received over 200,000 comments when we opened a comment period regarding the regulation of biotechnology. These comments have also been considered. Finally, APHIS leadership engaged in one-on-one meetings with a broad range of stakeholders over the past two years. Altogether we had over 50 engagements with stakeholders before the development of the proposed rule. These opportunities were offered to all stakeholders.

Q: Have you considered the economic impact of the proposed rule?
A: Yes. APHIS has conducted a Regulatory Impact Analysis (RIA) and Initial Regulatory Flexibility Analysis as required by law. Among other things, the analysis found that under the proposed rule, savings to the regulated community would result from a reduced need to collect field data, fewer reporting requirements, and lower management costs when compared to current costs of applying for permits and petitions. The RIA will be posted to regulations.gov with the new proposed rule upon publication of the Federal Register notice regarding the new rule, and will also be posted to the BRS website.

Q: Would APHIS regulate more GE organisms if this rule is enacted?
A: The rule is likely to result in a broader range of GE organisms being required to come in for review, but fewer would be subject to regulatory controls by APHIS over movement via permitting. Whether APHIS determines a GE organism is regulated by APHIS (requires a permit) or not, the organism would still need to comply with any and all applicable FDA and EPA requirements for safe food for humans and animals and pesticide use.

Q: Does the proposed rule change APHIS' role in food safety?
A: No.. Food safety falls under the Federal Food, Drug and Cosmetic Act and is regulated by the Food and Drug Administration.

APHIS's authority under the Plant Protection Act of 2000 is to protect plant health. Whether APHIS determines a GE organism is regulated by APHIS (requires a permit) or not, the organism would still need to comply with any and all applicable FDA requirements for safe food for humans and animals.

Q: Under the proposed rule, how will developers be able to show that their product has been reviewed by APHIS?
A: Once APHIS has completed its review of an organism and made a decision about regulatory status, we will provide documentation indicating the results of the weed and/or plant pest risk analysis that can be used to verify APHIS review. We will also provide the information to the public.

Q: Would developers still be required to comply with EPA and FDA regulations?
A: Yes. Whether APHIS determines a GE organism is regulated by APHIS (requires a permit) or not, the organism would still need to comply with any and all applicable FDA and EPA requirements for safe food for humans and animals and pesticide use.

In cases where APHIS determines an herbicide resistant plant is not regulated under the Plant Protection Act but the herbicide product specifically designed for use on those crops has not completed EPA's registration process, it will be illegal to use the herbicide on these crops until the specific herbicide completes registration with EPA.

Q: If a final rule is published, will there be a transition process from the current rule to the new rule, should it be adopted?
A: Yes. As there would be products in process under the current rule should a new rule be finalized, APHIS will work with stakeholders to ensure a smooth transition should we implement a new rule. We welcome comments during the public comment period that will help us develop a strong transition plan for both domestic and international stakeholders.

Q: Will APHIS engage internationally to explain its proposed rule?
A: Yes. We have been informing trading partners over the past year or so of our intention to publish a proposed rule and will continue to engage them in a variety of ways including venues such as the U.S.-Canada and Mexico Technical Tri-Lateral and the international Organization for Economic Cooperation and Development. In addition, we will have targeted engagements with key trading partners. We will continue to actively inform and work with the international community to ensure understanding

of our proposed rule and its science-based focus on regulating only those GE organisms that present a plant pest or noxious weed risk. We are aware that other countries look to the US for leadership in the regulation of agricultural biotechnology, and we are committed to communicate the proposed rule to the international community to build understanding and enhance trade.

Q: Are you aware that FDA is also publishing draft guidance and a Request for Information regarding genome editing?
A: Yes. FDA has recently published for comment a new draft guidance on the regulation of intentionally altered genomic DNA in animals (GFI #187).

In addition, FDA has solicited comments in a Request for Information (RFI 1248) on the use of genome editing techniques to produce new plant varieties used for human or animal food.

While FDA, USDA, and EPA will continue to coordinate responsibilities under the Coordinated Framework for the Regulation of Biotechnology, FDA's actions under the FD&C Act are separate and distinct from APHIS's proposal of a new rule under the Plant Protection Act.

Q: What are the next steps?
A: We will carefully review public comments on the proposed revisions to our biotech regulations. We will decide how or whether to finalize the regulations based on our evaluation of public comments to the proposed revisions. Additionally, we will make available a draft programmatic Environmental Impact Statement (EIS) that we intend to publish for public comment soon, and we look forward to stakeholder comment and input on the EIS. We also intend to have public meetings on the proposed rule during the comment period.