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# Remarks

**Remarks as Prepared for Associate Administrator Michael Gregoire**
**American Soybean Association Action Partnership Meeting**

WASHINGTON, DC, March 16, 2016—USDA's Animal and Plant Health Inspection Service's (APHIS) biotechnology regulations date back to 1987, and haven't been updated in more than two decades.

As you may know, in March 2015, APHIS announced the withdrawal of its 2008 proposed rule that would have amended our regulations for certain genetically engineered (GE) organisms.

When we withdrew the proposed rule, it had generated over 88,000 comments. The feedback we gathered was incredibly valuable and provided useful information that has shaped our thinking.

It's also worth noting that withdrawal of the 2008 proposed rule has allowed us to actively engage with stakeholders in a way that we haven't been able to over the past 8 years. Prohibitions on ex parte communication during rulemaking had limited our ability to do this until that rule was withdrawn.

We're drawing on 29 years of experience regulating GE organisms to inform our new approach on how to best regulate the organisms produced through biotechnology and updating our regulations will allow us to put that experience to better use.

On February 5, APHIS published a notice of intent (NOI) in the Federal Register announcing our plan to prepare a programmatic environmental impact statement (EIS) related to revisions of our biotechnology regulation.

Due to many requests for more time to consider the issues in the NOI, we decided to keep the comment period open for an additional 45 days and it will now close April 21, 2016.

We will carefully review and consider all comments received during this time.

In drafting the programmatic environmental impact statement and the new proposed rule —which we hope to publish for comment later this year—we'll use the comments we received on the 2008 proposed rule, our 29 years of experience, and the feedback we're gathering through active engagement with stakeholders.

***Rationale***

The original biotechnology regulations were implemented in 1987. The fundamental basis of the regulations has not changed since then.

Updating our regulations will allow us to incorporate all of our authorities, under the Plant Protection Act (PPA), including noxious weed authority.

We also realize that there have been significant advances in biotechnology over the past three decades and new issues have emerged. Our regulations need to reflect these changes.

In our current system, we regulate first and analyze later. Moving forward, we want to analyze first and only regulate when necessary—that is, when we determine that the organism presents a plant pest or noxious weed risk.

APHIS has developed a Weed Risk Assessment (WRA) tool to help support decisionmaking regarding potential noxious weed risks presented by new plant varieties. The WRA is currently in peer review.

We intend to publish our WRA in a peer-reviewed, scientific journal to ensure it is scientifically sound and rigorous, and also to help stakeholders better understand the assessment and how we will use it on the front end of the process.
We believe this will bring regulatory relief for many stakeholders along with increased transparency.

Universities, for example, tell us they can perform regulated field trials, but cannot afford the time and expenses of moving a GE organism through the deregulation process.

This shift will allow those creating biotechnology organisms determined not to pose a risk to American agriculture to proceed with their development plans.

These are the reasons we want to bring regulatory change: increase transparency and provide regulatory relief to our stakeholders.

The new proposed process will also enable us to focus our resources and scientific expertise on those new GE plants that truly pose a plant pest or noxious weed risk to agricultural crops.

***Coordinated Framework***

APHIS, the Environmental Protection Agency, and the Food and Drug Administration are currently working with the Executive Office of the President (EOP) to modernize a number of issues and activities related to the oversight of the products of biotechnology.

Although APHIS' evaluation of its own regulations is distinct from the EOP effort, the two processes are compatible and complimentary.

More immediate goals of the update to the Coordinated Framework include:

- clarifying the roles and responsibilities of the Agencies,
- formulating a long-term strategy to ensure the Federal regulatory system is equipped to efficiently assess risk, and
- commissioning an external, independent analysis of the future landscape for biotechnology products.

***Notice of Intent Highlights***

In the NOI we list four alternatives. The first—No Action alternative—is required to be included by the National Environmental Policy Act (NEPA). Under this alternative the regulations remain as they exist today.

The second alternative would create regulatory review criteria for a system in which we analyze before we regulate. We are seeking input on the following review criteria:

- Implement both the plant pest and noxious weed authority from the Plant Protection Authority as part of 7 CFR part 340.
- Move away from the term "genetically engineered organisms" towards the term "biotechnology organisms."
- Consider exemptions for certain "biotechnology organisms."
- Analyze plant pest and noxious weed risks first; regulate when appropriate through a permitting system.
- Eliminate notifications and the existing process for deregulation.

The third alternative would increase oversight and resources that would enable APHIS to become, to the extent permitted by its authorities, an all-encompassing, wide-scale regulatory permitting authority which would:

- regulate all "biotechnology organisms" under permit,
- remove exemptions for certain "biotechnology organisms," and
- eliminate notifications and the existing process for deregulation.

The fourth alternative would completely withdraw current regulations and provide a voluntary, nonregulatory consultative process.

For the three alternatives that would involve changes to the regulations, we have posed some specific questions, and are seeking input on each alternative. We would like to specifically hear reactions to eliminating notifications and petitions (included in alternatives two, three, and four).

Additional input is requested on definitions provided in the NOI that would be used in the EIS, as well as on how public health and safety objectives might be achieved for pharmaceutical or industrial products of biotechnology.

***Closing***

We welcome and look forward to a continued dialogue with you and other stakeholders. Any regulatory proposal we issue will be available for a lengthy public review process before we make final decisions.

By working together and sharing information, I'm confident we can create new regulations that protect plant health and allow new and innovative products to get to market.

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