

**Statement of Michael Gregoire  
Associate Administrator  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture**

**Before the**

**Senate Committee on Agriculture, Nutrition and Forestry**

**October 21, 2015**

Chairman Roberts, Senator Stabenow, and members of the Committee, thank you for the opportunity to appear before you today to discuss an important topic to American agriculture – the complex issues surrounding biotechnology and the federal government’s role in regulating it.

I am Michael Gregoire, Associate Administrator of the U.S. Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS is responsible for ensuring that new biotechnology advances do not inadvertently harm plant health. Prior to becoming Associate Administrator, I led APHIS’ Biotechnology Regulatory Services program.

In support of USDA’s efforts to expand U.S. agriculture, we at APHIS must ensure that our regulatory oversight is timely, consistent, effective, and grounded in sound science. We must ensure that we keep pace with the latest scientific developments, and that we do so transparently. The Plant Protection Act gives APHIS, through the delegated authority of the Secretary, the ability to prohibit or restrict the importation, exportation, and interstate movement of plants, plant products, certain biological control organisms, noxious weeds, and plant pests. It is under these authorities that APHIS regulates the importation, interstate movement, and field testing of genetically engineered (GE) organisms. Today, I am going to discuss how we use these authorities, and the steps we have taken and are taking to ensure a robust process.

APHIS’ Role in Biotechnology

APHIS’ specific role is to ensure that new GE crops don’t pose a plant pest risk—such as causing disease or damage to other crops or plant products in the United States. If a GE product requires USDA oversight, developers must apply for an APHIS permit or notification and adhere to APHIS’ regulations to maintain adequate confinement of a regulated organism during field trials.<sup>1</sup> We require applicants to submit detailed information for thorough review by our scientists before any regulated activities are allowed.

After developers have the scientific information which they believe is sufficient for us to conclude that a GE organism is unlikely to pose a plant pest risk, they can petition APHIS for non-regulated status. We then prepare the appropriate environmental analysis, as required under the National Environmental Policy Act, as well as an assessment of the potential plant health risks to agriculture, including changes to agronomic practices. APHIS makes these draft

---

<sup>1</sup> 7 C.F.R. § 340.

assessments available to the public for review and comment. Then, if our officials conclude that a GE organism does not pose a plant health risk, APHIS deregulates it and the GE organism may be freely moved or planted without APHIS permits or other APHIS regulatory oversight. However, additional regulatory oversight and/or consultation with the other Federal agencies may be necessary if the GE product has a pesticidal quality or will be commercialized as a food or feed product.

### Biotechnology Petition Improvement

Over the past several years, APHIS has undertaken a process to significantly improve the timeliness of its biotechnology regulatory decisions—with great results. We have been able to provide a more timely review process that doesn't sacrifice the thoroughness or quality of our scientific reviews, while also giving the public an earlier opportunity to provide us with input and information that can help our scientific review of new GE products.

In 2010, APHIS' biotechnology program began a business process improvement to help address concerns about the length of time it takes the Agency to deregulate GE products. Based on the results of that review, in March 2012, APHIS implemented a new process for petitions that require an environmental assessment (EA) and not an Environmental Impact Statement (EIS). The new process created two paths for these petitions: one for products which APHIS has familiarity with and that raise no new issues, and one for new products or products that may raise new concerns. Prior to the change in process, it often took USDA three or more years to complete a determination. Now, the target timeframes for reaching a determination are 13 months and 15 months, respectively. We have also given the public an additional and earlier chance to provide comments when we first publish a petition, in addition to when we publish our draft EA and plant pest risk assessment, which also provide opportunities for review and comment.

APHIS has made significant progress in reaching the goals we set out, while maintaining our robust scientific and environmental reviews. Of the 23 pending determinations when the new process was put in place, only one remains – and it requires an EIS, which falls outside the scope of the process improvement. APHIS has received 14 new petitions since the process was put in place. Of those, eight have been deregulated, and three of the remaining six should be complete by the end of calendar year 2015. In summary, APHIS has completed 30 of the 37 pending and new petitions since implementing our new process in March 2012, and plans to complete 3 more by the end of the year.

Since March of 2012, we also cut the time down for review of new petitions from between three to five years, to just over 18 months. We have a process in place that we believe will allow us to soon reduce that review period further down to 15 months.

Lastly, while not part of the business process improvement effort, we have made strides with products that require a full environmental impact statement (EIS) and thus require a longer period of time to complete. Over the last few years, APHIS has devoted additional staff to complying with these environmental regulations. While completing an EIS still takes additional

time, that last two we completed were done in about half the time of previous EISs, all while improving the quality of the analysis.

### Which Products Are Regulated?

As previously mentioned, APHIS' authority to regulate GE products is based solely on their potential plant pest risk; we do not regulate GE products per se. We regulate any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent is a plant pest as defined in our regulations; or if it is or contains an unclassified organism, as well as any other organism or product altered or produced through genetic engineering which we determine is a plant pest or have reason to believe is a plant pest. APHIS does not consider any specific method of plant development to be inherently safer than any other technique. As envisioned by the Coordinated Framework, we regulate based on the specific product and the environment into which it is being introduced, not the production process that created it.

In some cases, developers may seek a written determination from APHIS if they are unsure whether or not their product requires APHIS regulatory oversight. Through this process, known as "Am I regulated?", the developer must provide scientific data, the technology used, and other information about the GE organism. APHIS will then evaluate whether the product itself is a plant pest, whether a plant pest was used during the genetic engineering process, and whether the final product contains genetic material from a plant pest to determine if it is regulated. If the product is not subject to our biotechnology regulations, APHIS issues a letter to the developer indicating such and publishes it on our Web site. GE organisms not regulated under our regulations may still be subject to other APHIS regulations as well as Environmental Protection Agency (EPA) and/or Food and Drug Administration (FDA) regulations.

### Coordination with FDA and EPA

APHIS works regularly with FDA and EPA to ensure that the development, testing, and use of biotechnology products happens in a way that is safe for plant and animal health, human health, and the environment. FDA has primary responsibility for ensuring the safety of human food and animal feed, as well as proper labeling and safety of all GE plant-derived foods and feeds. EPA regulates pesticides, including crops with plant-incorporated protectants (pesticides intended to be produced and used in a living plant) to ensure public safety. EPA also establishes tolerances for pesticide residue on food and these tolerances are then enforced by FDA.

Depending on the characteristics of a biotechnology product in question, it may be subject to the jurisdiction of one or more of our three agencies. APHIS officials regularly communicate and exchange information with FDA and EPA to ensure that any safety or regulatory issues that may arise are appropriately resolved. We have great confidence in the safety of GE crops approved under the current U.S. regulatory system.

Recently, on July 2, 2015, the Executive Office of the President (EOP) released a memo that directed EPA, FDA, and USDA to work with the EOP to update the Coordinated Framework of 1986, (elaborated in 1992), that guides the U.S. Government in regulating products of modern

biotechnology. The Coordinated Framework establishes the U.S. Government policy on how the regulatory agencies work together effectively and establishes high level policy on how to regulate. It does not specify regulations themselves.

APHIS is working closely with the EOP and its interagency partners as we work to clarify the current roles and responsibilities of the three regulatory agencies, develop a long-term strategy to ensure that the system is prepared for the future products of biotechnology, commission an expert analysis of the future landscape of biotechnology products to support this effort, and work with the EOP and relevant budgeting authorities to ensure a plan to support implementation of this effort. Recently, on October 6, 2015, the National Science and Technology Council issued a request for information, soliciting data and information to assist as we undertake this effort.

#### Updating USDA's Biotechnology Regulations (7 CFR Part 340)

Complementing the interagency effort to update the Coordinated Framework is our renewed effort to revise APHIS' regulations. This effort will support the current regulatory policy described by the Coordinated Framework, the White House guidance of 2011 on 'Principles for Regulation and Oversight of Emerging Technologies', and any future changes that come out of efforts related to updating the Coordinated Framework.

In 2008, we published a proposed rule to significantly revise our biotechnology regulations under the Plant Protection Act. The proposed revisions were extensive and included significant changes to the scope of the regulations and the mechanics of APHIS' regulatory oversight. In March 2015, APHIS withdrew the 2008 proposed rule. This decision was based primarily on our review and consideration of more than 88,300 comments received on the proposed rule; our experience in regulating GE organisms over the past 28 years; and the Agency's desire to begin fresh stakeholder engagement aimed at exploring alternative policy approaches to regulation. To initiate our public engagement, in May 2015, we conducted 3 webinars and took comments via Regulations.Gov to gain insight into the public's current thinking. We are currently analyzing the over 221,000 comments received.

In addition, late this year we plan to publish a Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) to analyze the impacts of our proposed new rule. Through the EIS scoping process, we will get public input on the proposed action and alternatives to determine the breadth of issues that should be considered in the EIS. We will use the best available science, and incorporate our past 28 years of experience in developing a new proposed rule for risk-based regulation.

While we are still working out the specifics and examining public input, we expect the new proposed rule to modernize our regulations in a number of areas, all within our current statutory authority. We plan to align our regulations with current authorities and regulate GE organisms that pose plant pest or weed risks in a manner that balances oversight and risk, and that is based on the best available science. We plan to continue to engage the public throughout the rulemaking process and provide ample opportunity for the public to participate in the process. The next opportunity will be during a meeting on November 18 to update stakeholders on our progress.

Based on these efforts, hopefully it is apparent that USDA and the federal government overall is committed to a sound, science-based, and modern approach to the regulation of products derived from biotechnology. We at APHIS will continue to work with our federal partners and with stakeholders as we build upon our many years of work in this area. This concludes my testimony. I would be happy to answer any questions.