

BRS Stakeholder Meeting Agenda
November 7, 2018
10:00 am - 3:30 pm EST

9:30am-10:00 am	Registration for Onsite Attendees	
10:00 am	<i>Welcome</i>	Dick George BRS Communications Branch Chief
10:05-10:35 am	<i>BRS: Reflections on FY18 and a Look Forward to FY19</i>	Mike Firko APHIS Deputy Administrator for BRS
10:35-10:45 am	<i>International Engagement & Outreach</i>	Ibrahim Shaqir, Associate Deputy Administrator for BRS
10:45-11:10 am	<i>International Strategy for Plant Breeding Innovation</i>	Paul Spencer, Director, New Technologies and Production Methods Division, USDA FAS
11:10-11:20 am	Break	
11:20-11:40 am	<i>Biotechnology Research Supported by the Biotechnology Risk Assessment Grants (BRAG) Program</i>	Sally McCammon, BRS Scientific Advisor
11:40-11:55 am	<i>"Am I Regulated?"- Implementation of Process Improvements</i>	Bill Doley, BRS Government Relations Specialist
11:55am-12:15 pm	<i>Agricultural Biotechnology Education and Outreach Initiative</i>	Sid Abel, Assistant Deputy Administrator for BRS
12:15 pm-1:30 pm	Lunch on Your Own	
1:30-3:30 pm	<i>APHIS eFile Demonstration & Discussion</i>	eFile Change Management Team
3:30 pm	Adjourn	

Secretary Perdue Issues USDA Statement on Plant Breeding Innovation

Release & Contact Info

Press Release

Release No. 0070.18

Contact: USDA Press

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(Washington, D.C., March 28, 2018) – U.S. Secretary of Agriculture Sonny Perdue today issued a statement providing clarification on the U.S. Department of Agriculture’s (USDA) oversight of plants produced through innovative new breeding techniques which include techniques called genome editing.

Under its biotechnology regulations, USDA does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests. This includes a set of new techniques that are increasingly being used by plant breeders to produce new plant varieties that are indistinguishable from those developed through traditional breeding methods. The newest of these methods, such as genome editing, expand traditional plant breeding tools because they can introduce new plant traits more quickly and precisely, potentially saving years or even decades in bringing needed new varieties to farmers.

“With this approach, USDA seeks to allow innovation when there is no risk present,” said Secretary Perdue. “At the same time, I want to be clear to consumers that we will not be stepping away from our regulatory responsibilities. While these crops do not require regulatory oversight, we do have an important role to play in protecting plant health by evaluating products developed using modern biotechnology. This is a role USDA has played for more than 30 years, and one I will continue to take very seriously, as we work to modernize our technology-focused regulations.”

“Plant breeding innovation holds enormous promise for helping protect crops against drought and diseases while increasing nutritional value and eliminating allergens,” Perdue said. “Using this science, farmers can continue to meet consumer expectations for healthful, affordable food produced in a manner that consumes fewer natural resources. This new innovation will help farmers do what we aspire to do at USDA: do right and feed everyone.”

USDA is one of three federal agencies which regulate products of food and agricultural technology. Together, USDA, the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) have a Coordinated Framework for the Regulation of Biotechnology that ensures these products are safe for the environment and human health. USDA’s regulations focus on protecting plant health; FDA oversees food and feed safety; and EPA regulates the sale, distribution, and testing of pesticides in order to protect human health and the environment.

USDA continues to coordinate closely with its EPA and FDA partners to fulfill oversight responsibilities and provide the appropriate regulatory environment. This ensures the safety of products derived from new technologies, while fostering innovation at the same time.

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Details on USDA Plant Breeding Innovations

Last Modified: Mar 28, 2018

USDA is committed to helping farmers produce healthy, affordable food in a sustainable manner that protects this country's natural resources and offers more choices for consumers. Through innovative methods, plant scientists can now create new plant varieties that are indistinguishable from those developed through traditional breeding methods. These new approaches to plant breeding include methods like genome editing and present tremendous opportunities for farmers and consumers alike by making available plants with traits that may protect crops against threats like drought and diseases, increase nutritional value, and eliminate allergens.

In keeping with our responsibility to protect plant health, USDA has carefully reviewed products of these new technologies to determine whether they require regulatory oversight.

As USDA works to modernize its biotechnology regulations, the vision and direction of this Department will be to continue to focus regulatory initiatives on the basis of risk to plant health.

Under its biotechnology regulations, USDA does not currently regulate, or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are developed without the use of a plant pest as the donor or vector and they are not themselves plant pests. This can include plant varieties with the following changes:

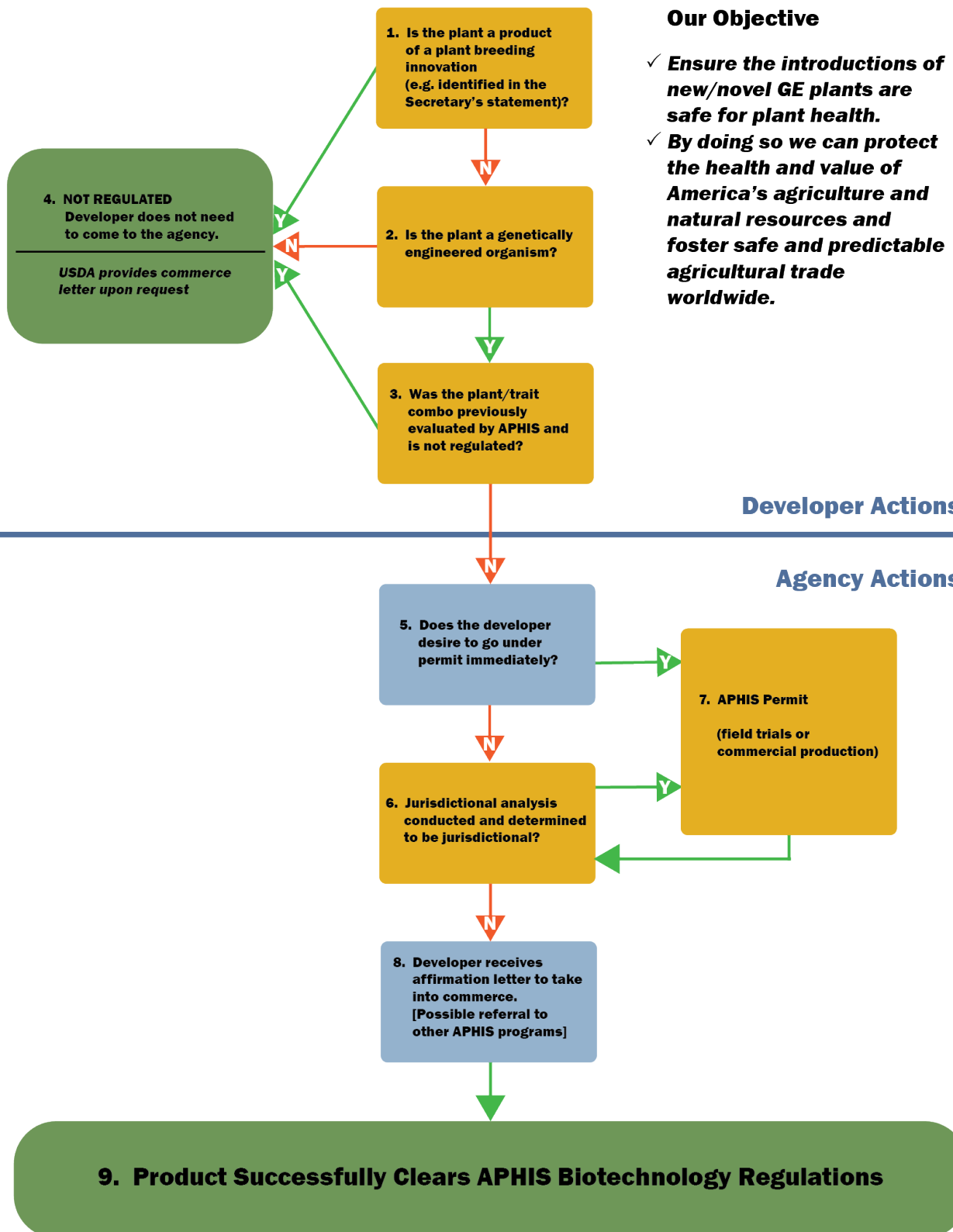
- **Deletions**—the change to the plant is solely a genetic deletion of any size.
- **Single base pair substitutions**—the change to the plant is a single base pair substitution.
- **Insertions from compatible plant relatives**—the change to the plant solely introduces nucleic acid sequences from a compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding.
- **Complete Null Segregants**—off-spring of a genetically engineered plant that does not retain the change of its parent.

USDA will continue working with other Executive Branch Departments, our domestic stakeholders, trading partners and international organizations to advance this science-based and practical approach that protects plant health while allowing for technological advancements in accordance with the Report of the Interagency Task Force on Agriculture and Rural Prosperity (<https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf>).

Potential Biotechnology Regulatory Process

for Plants Developed through Biotechnology

DRAFT, DELIBERATIVE, PRE-DECISIONAL





INTERNATIONAL STATEMENT ON AGRICULTURAL APPLICATIONS OF PRECISION BIOTECHNOLOGY

COMMUNICATION FROM ARGENTINA, AUSTRALIA, BRAZIL, CANADA, THE DOMINICAN REPUBLIC,
GUATEMALA, HONDURAS, PARAGUAY, THE UNITED STATES OF AMERICA AND URUGUAY

Revision

The following communication, received on 26 October 2018, is being circulated at the request of the delegations of Argentina, Australia, Brazil, Canada, the Dominican Republic, Guatemala, Honduras, Paraguay, the United States of America and Uruguay.

1 OVERVIEW

1.1. Precision biotechnology techniques, as a whole, constitute an essential tool for agricultural innovation. Their use provides farmers with access to products that increase productivity while preserving environmental sustainability.

1.2. Global environmental challenges, pest and disease pressures, food insecurity, and changes in consumer preferences, among other factors, have made the use and fostering of tools such as precision biotechnology vital for increasing the production of safe food.

1.3. In this light, in April 2018, the countries participating in the "Seminar on Genome Editing for Regulators", organized by the Inter-American Institute for Cooperation on Agriculture (IICA), shared a draft statement on the applications of precision biotechnology.

1.4. The primary objective is to coordinate efforts to ensure that the regulatory approaches for these techniques, which include gene editing, are scientifically based and internationally harmonized.

1.5. The final text of the international statement is non-binding on supporting countries, but provides the necessary guidelines for preventing regulatory asymmetries and, in turn, potential trade disruption.

2 TEXT OF THE "INTERNATIONAL STATEMENT ON AGRICULTURAL APPLICATIONS OF PRECISION BIOTECHNOLOGY"

2.1. Agricultural innovation has played an essential role in increasing yields and productivity in support of growing, prosperous civilizations. Innovations in precision biotechnology, such as gene editing, have brought the promise of major improvements in terms of the ease and precision of introducing desirable traits into agricultural organisms, as compared to other breeding methods. Farmers continually need to broaden access to new tools to improve productivity, plant and animal health, and environmental sustainability, and need to help address global challenges such as climate change, pest and disease pressures, and the safety and security of worldwide food supplies, as well as meet consumer preferences and demands for healthier, higher quality foods at affordable prices. Government policies must continue to foster innovation, including in the public sector and by small and medium-sized enterprises (SMEs), and mitigate unintended, unnecessary barriers to the entry of agricultural products.

22. In some cases, precision biotechnology, such as gene editing, may generate organisms with characteristics similar to those obtainable through conventional breeding. In other cases, the organisms generated may have characteristics similar to those introduced into organisms using recombinant-DNA technologies. In either case, the food, animal, and environmental safety of such products can be adequately addressed by existing regulatory frameworks for agricultural products and existing safety standards based on the characteristics of the product or organism.

23. Governments are engaging in policy discussions on regulatory frameworks and global regulatory compatibility to encourage cross-border research collaboration and minimize potential disruptions to trade. Differing domestic regulatory approaches for products derived from precision biotechnology may result not only in international asynchronicity in approvals, but also in asymmetry in regulatory approaches, and create potential trade issues that could impede innovation. Recognizing the potential positive contributions of precision biotechnology to global agriculture, and emphasizing the importance of early action to identify avenues to minimize the trade impacts of differing regulatory approaches, the undersigned governments acknowledge that:

- Precision biotechnology products have the potential to play a critical role in addressing the challenges facing agricultural production, including by contributing to increasing the supply of foods and other agricultural products, in a sustainable way;
 - Collaborative research efforts and the ability to introduce useful products into the market, especially by SMEs and public sector researchers, are necessary to fully realize the potential of precision biotechnology;
 - Given the differences internationally in approaches used to assess agricultural biotechnology, due consideration should be exercised by governments to avoid arbitrary and unjustifiable distinctions between end products derived from precision biotechnology and similar end products obtained through other production methods;
 - To ensure appropriate science- and risk-based approaches consistent with the protection of human, animal and plant health and the environment, due consideration should be given to available scientific and technical information when updating existing regulatory frameworks or applying these frameworks to products of precision biotechnology, and when using available flexibility within existing regulatory frameworks for agricultural products;
 - Regulatory approaches necessary to help ensure safety (of humans, animals, plants, and the environment) in respect of products derived from precision biotechnology should be science- and risk-based, transparent, predictable, timely, and consistent with relevant international trade obligations;
 - Cooperative work by governments to minimize unnecessary barriers to trade related to the regulatory oversight of products of precision biotechnology, including the exploring of opportunities for regulatory and policy alignment, should be pursued where possible;
 - This collaborative work should promote constructive dialogue with trading partners and agricultural stakeholders on potential trade issues related to precision biotechnology, so as to support open and fair trade and encourage research and innovation;
 - Public communication efforts can build trust in regulatory frameworks and improve the acceptability of future agricultural innovations that will help farmers address global challenges with a view to the production of abundant, safe and affordable food, feed, fibres, and energy in the 21st century.
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BRS Stakeholder Meeting
November 7, 2018
Afternoon Session, 1:30 - 3:30 pm EST
APHIS eFile Demonstration Agenda

Modernizing APHIS Permitting: <i>Learn Why APHIS is Transitioning Permitting Systems</i>
APHIS eFile Demo: <i>A Preview of the APHIS eFile Customer Portal and BRS Applications</i>
Demo Q&A: <i>Question and Answer Session Following the Demonstration</i>
Preparing for APHIS eFile: <i>Learn How APHIS Will Transition From ePermits to APHIS eFile</i>
Preparing for APHIS eFile Q&A: <i>Question and Answer Session About Transition Plan</i>

Questions? Reach out to us at eFile.Communications@aphis.usda.gov

Transition Plan ePermits to eFile: New Applications

