

November 1, 2016

National Science and Technology Council
Emerging Technologies Interagency Policy Coordination Committee
Office of Science and Technology Policy
1650 Pennsylvania Avenue NW
Washington, DC 20504

RE: Docket FDA-2015-N-3403-0916, Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology.

Dear Sir or Madam,

The National Corn Growers Association, American Soybean Association, National Sorghum Producers and the American Farm Bureau Federation appreciate the opportunity to respond to questions posed by the Office of Science and Technology Policy regarding the clarification of roles and responsibilities in the Coordinated Framework. We commend OSTP's review of the framework to help improve the functionality, transparency, and clarity of roles and responsibilities of the agencies involved.

The Coordinated Framework has allowed for the commercialization of important modern biotechnology products that have had a positive impact on U.S. agriculture. Through strong adoption by growers, these tools have revolutionized weed and insect management, opened new conservation practices, and increased the efficiency of farming operations. Farmers use less pesticides and less fertilizer per bushel, and are able to withstand variability in the weather to produce record crops year after year. The increased options for crop management through these current technologies keep U.S. agriculture as the global leader in production efficiency.

We are pleased with the Administration's support for good regulation, reflected in *Modernizing the Regulatory System for Biotechnology Products: An Update to the Coordinated Framework for the Regulation of Biotechnology*. If this technology is to continue to be available for growers, then the principles from the 1986 Coordinated Framework must continue to guide the agencies as they move into the regulation of future biotechnology products.

While growers are not directly regulated under the Coordinated Framework, the impacts of regulation on technology providers and the registration of their products do impact growers. Maintaining clear coordination on how these products navigate through the agencies should provide companies the ability to efficiently bring products to market through a robust, scientifically based review.

1. *What additional clarification could be provided regarding which biotechnology product areas are within the statutory authority and responsibility of each agency?*

The Coordinated Framework and the participating agencies should provide clarity on what is and what is not a regulated product. While the current suite of products on the market today is relatively established, as new technologies develop, it will remain critical that this clarity be maintained. This will allow developers to innovate with a clear path to market and foster the development of the next generation of products for growers.

- 2. What additional clarification could be provided regarding the roles that each agency plays for different biotechnology product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment?*

Crossover in responsibilities between agencies has been difficult in recent years. Stronger coordination should be supported to avoid unnecessary delays in the approval and availability of new products across traditional biotechnology and crop protection products. Asynchrony between agencies can cause confusion in the marketplace and delay effective implementation of new tools for growers. Every effort should be made to ensuring that the agencies work together to bring the appropriate products to market without delay.

- 3. What additional clarification could be provided regarding communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function?*

We are encouraged by the development of the Interagency Biotechnology Working Group and hope it will be able to foster coordination while maintaining the autonomy of each agency. Making sure that the agencies are in consistent communication while reviewing new products will hopefully increase efficiency and timing of new products. Additionally, this will provide a forum for agencies to address new technologies on a planned basis and not rely on ad-hoc coordination.

- 4. What additional clarification could be provided regarding the mechanism and timeline for regularly reviewing, and updating as appropriate, the Coordinated Framework to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology.*

Consistent transparency of the roles and responsibility of each agency while reviewing any inefficiencies that may arise should, we hope, minimize delays and maintain a clear path to market. We are encouraged by the open dialogue OSTP has engaged in to allow growers' voices to be a part of this review, and continue to encourage the agencies to maintain that openness. The broad engagement and clarity aid in our common goal of clarifying the benefits of the technology to the public.

We would add that decisions made by U.S. regulatory agencies are closely watched by their counterparts in foreign exporting and importing countries. The potential impacts of changes in how the U.S. regulates products, and how different products are regulated, can affect regulatory approvals abroad, and could have adverse impacts on international trade. It is important, therefore, that our regulatory agencies consult with other governments and with the Office of the U.S. Trade Representative to ensure minimal potential trade disruptions.

In summary, U.S. regulatory oversight of modern biotechnology products needs to maintain our global leadership role. Maintaining the scientific basis of our oversight, while providing transparency to technology developers, growers, and the general public is critical and needs to occur while minimizing delays and improving efficiency. Growers look forward to continued access to the current and next generations of technology. Access to these technologies will allow us to continue to provide a sustainable, safe, and secure food supply for the world.

Thank you for the opportunity to respond.

American Farm Bureau Federation

American Soybean Association

National Corn Growers Association

National Sorghum Producers