



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

Submitted Electronically via Federal eRulemaking Portal (<http://www.regulations.gov>)

Re: Food and Drug Administration Docket No. FDA-2015-N-3403-0916; Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology

Dear Sir or Madam:

These comments are being submitted in response to Docket FDA-2015-N-3403-0916.

Founded in 1883, the American Seed Trade Association (ASTA), located in Alexandria, Virginia, is one of the oldest trade organizations in the United States. Its membership consists of over 700 companies involved in seed production and distribution, plant breeding, and related industries in North America. ASTA members research, develop, produce and distribute all varieties of seeds – including grasses, forages, flowers, vegetables, row crops, and cereals. ASTA member seed products support agricultural producers of food products and farm commodities in the United States and around the world.

ASTA is appreciative of the Office of Science and Technology Policy (OSTP)'s effort to review and update the Coordinated Framework for the Regulation of Biotechnology, and we are glad to offer these comments on the Administration's completed report.

Plant breeding innovation is based on an increased understanding of plant genomes, refinements in breeding techniques, and identification of new characteristics so that farmers have a wide array of high quality, high producing seed varieties available when making their planting choices. Such innovation is crucial for both the U.S. seed sector and global food security, particularly at a time when the global population continues to grow rapidly and many developing nations can ill-afford food shortages.

A fundamental principle articulated in the Coordinated Framework was the use of existing Federal laws to regulate biotechnology research and products. These laws provide authority to various agencies to regulate particular products and product uses (e.g., food, pesticides). Because the uses and potential risks posed by products developed through modern biotechnology would be the same as existing products otherwise developed with similar traits, the developers of the Coordinated Framework determined that existing laws would provide adequate oversight for protecting the public and the environment. Using existing laws helped to ensure that other central regulatory principles were

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adhered to—that similar products be treated the same by regulatory agencies and that new products meet the same safety standards and criteria as existing products. Thus, a new food crop must be as safe to grow and as safe to eat as those food crops already on the market.

In agriculture, most new plant varieties are introduced without a specific pre-market safety assessment, given the long history of safe application of the methods breeders use to develop new plant varieties. Acknowledging the first principle of appropriate regulation, the Coordinated Framework focused on only those plants that presented a potential risk, when compared to similar plant/trait combinations that have a history of safe use and consumption. ASTA appreciates the Administration’s initiative in undertaking its review of the Coordinated Framework. Another principle articulated in the Coordinated Framework is that regulations should evolve and take into account new scientific advances and experience. In the intervening 30 years since the Coordinated Framework was operationalized, significant experience and familiarity with new plant/trait combinations has accrued. Scientists and regulators can predict more precisely which products and product uses require more or less stringent oversight and which could be exempted from premarket review.

It is also heartening that the Administration recognizes the need for increased communication between the three regulatory agencies and the biotechnology industry. Regulations have a large impact on the number of products being brought to market and a key issue is open and transparent coordination among the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). An excellent example already occurring would be USDA’s Biotechnology Regulatory Service annual stakeholder meeting.

Recently, we have been concerned at the lack of policy coordination between the three federal agencies involved in the Coordinated Framework. Even before the Administration’s review was completed and published for public comment, USDA published a notice in the Federal Register announcing plans to update its biotechnology regulations at CFR part 340. This action was taken independently of the review of the Coordinated Framework.

The National Strategy for Modernizing the Regulatory System for Biotechnology Products released as a companion to the Update to the Coordinated Framework acknowledges that all three agencies have room to improve in the area of coordination. ASTA and the seed industry are committed to working with USDA, FDA, and EPA as they explore additional ways to enhance both external and interagency collaboration. In the end, it is imperative that when the agencies move forward with any changes to their regulatory policy that they communicate with industry stakeholders, other federal agencies, and our international trading partners.

As part of the released report, ASTA was glad to see the creation of the Interagency Biotechnology Working Group under the guidance of the Emerging Technologies Interagency Policy Coordination Committee. Other interagency groups were critical in creating and implementing the 1986 Coordinated Framework and ensuring its functionality. We have seen regulatory delays and lack of coordination between agencies due to the lack of an active interagency working group for biotechnology, and we feel

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this is a step in the right direction. The United States is a global leader in biotechnology-based innovation and, as such, the White House needs to take a strong leadership role in ensuring strong communication among the three agencies. Furthermore, we agree with the Strategy's point that any updates to federal regulatory authority must be based on the best available science. As instructed in the July 15 Executive Order, EPA, FDA, and USDA are expected to produce a report documenting the steps that are taking to implement the Strategy. Through these annual reviews, any future updates to the Coordinated Framework can be conducted alongside the evolution of agricultural biotechnology instead of reviewing and updating after new technologies have come and gone.

The U.S. is watched closely by governments and regulators in other countries. It is therefore important that the three agencies remain coordinated in their regulations of products of biotechnology, and that their oversight is consistent with the principles articulated in the Coordinated Framework. Given the global nature of the seed industry and the agriculture sector as a whole, it is also critical that our regulatory agencies consult with other key governments and with the Office of the U.S. Trade Representative to minimize potential disruptions to trade. ASTA stands ready to provide any additional information as needed by the Agency.

Sincerely,

Andrew W. LaVigne
President & CEO
American Seed Trade Association

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