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Via: regulations.gov

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: Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology. Docket No. FDA-2015-N-3403.

The National Cotton Council (NCC) is the central organization of the United States cotton industry. Its members include producers, ginners, cottonseed processors and merchandizers, merchants, cooperatives, warehousers and textile manufacturers. A majority of the industry is concentrated in 17 cotton-producing states stretching from Virginia to California. The NCC represents producers who cultivate between 10 and 14 million acres of cotton. Annual cotton production, averaging approximately 16 to 20 million 480-lb bales, is valued at more than \$5 billion at the farm gate. The downstream manufacturers of cotton apparel and home furnishings are located in virtually every state. Farms and businesses directly involved in the production, distribution and processing of cotton employ more than 230,000 workers and produce direct business revenue of more than \$27 billion. Accounting for the ripple effect of cotton through the broader economy, direct and indirect employment surpasses 420,000 workers with economic activity well in excess of \$120 billion. In addition to the cotton fiber, cottonseed products are used for livestock feed, and cottonseed oil is used as an ingredient in food products as well as being a premium cooking oil.

Biotech cotton was first introduced in 1996 and U.S. cotton farmers adopted the new technology rapidly. Currently, approximately 90% of U.S. cotton is planted with insect resistant or herbicide tolerant genetically enhanced cotton varieties. The latest estimates of the benefits of these insect resistant varieties are 185 million lbs/year increase in production; 1.9 million lbs/year decrease in insecticide use; and \$103 million/year increase in net revenue for U.S. cotton farmers.¹ The benefits of herbicide tolerant biotech cotton in the U.S. include a 6.2 million lbs/year decrease in herbicide active ingredients applied and \$133 million/year savings in weed control costs.²

¹*Plant Biotechnology: Current and Potential Impact For Improving Pest Management In U.S. Agriculture: An Analysis of 40 Case Studies* by Leonard P. Gianessi, Cressida S. Silvers, Sujatha Sankula and Janet Carpenter, National Center for Food and Agricultural Policy, June 2002.

²*The Potential for Biotechnology to Improve Crop Pest Management in the U. S.:40 Case Studies* by Leonard P. Gianessi, Cressida S. Silvers, Sujatha Sankula and Janet Carpenter National Center for Food and Agricultural Policy, June 2002.

While the current Federal regulatory system for biotechnology products effectively protects human health and the environment, advances in science and technology have altered the product landscape in recent years. In addition, the complexity of the current regulatory system can make it difficult for the public to understand how the safety of biotechnology products is evaluated and creates challenges for small and mid-sized businesses to navigate the regulatory process for these products. To address these challenges, on July 2, 2015, the Executive Office of the President (EOP) issued a memorandum (July 2015 EOP Memorandum) directing the primary agencies that regulate the products of biotechnology — the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—to accomplish three tasks, but to primarily update the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302; June 26, 1986).

As part of that process, on September 22, 2016, the White House Office of Science and Technology Policy published a document titled, “*Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology*” which asked commenters to respond to any or all of four questions.

U.S. cotton farmers have a vested interest in the continued availability of new biotechnology products under a regulatory system that is efficient and streamlined while protecting the health and safety of the American public and environment. The NCC appreciates the efforts of the agencies to upgrade their Coordinated Framework of biotechnology regulations and this opportunity to provide input on the questions raised.

COMMENTS:

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

The NCC encourages USDA’s Animal and Plant Health Inspection Service (APHIS) to ensure that they are clearly identified as having the lead role and primary responsibility for regulatory assessments consistent with the Federal Coordinated Framework for the Regulation of Biotechnology. The NCC urges APHIS to maintain the risk-based scientific approach while reflecting advanced understanding for the development and commercialization of biotechnology products, including new methods of gene editing and altering.

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?

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates the sale, distribution, and use of all pesticides, including those produced through genetic engineering.³

³ 40 C.F.R. Parts 700, 720, 721, 723, and 725

In recent non-genetically engineered pesticide registrations, EPA has been using epidemiological studies to assess risk, without providing those studies for public review and comment and without providing guidelines regarding how EPA uses those studies in their assessments, despite repeated requests from stakeholders to make them available.

The NCC is concerned about how this new, non-transparent assessment method will translate into the framework for regulating genetically engineered pesticides such as plant-incorporated pesticides.

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?

The process, as described in the document, appears to be circular in nature without prescribed beginning and end points. How long will agencies wait on one or more of the other agencies to complete their review and assessment? Can one agency hold up the entire process indefinitely? For example, the similar consultation framework for endangered species between EPA and the U.S. Fish and Wildlife Service and the National Marine Fisheries Service is fraught with stalled and uncompleted reviews.

The NCC is concerned that a similar process will occur within the coordinated framework unless specific timetables are spelled out in order to keep the process moving forward.

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 products?

The July 2015 EOP Memorandum requires an annual report five years after the release of the *Strategy*. The NCC believes that the report will enhance transparency and efficiency if it provides real-world case studies of regulatory assessments that were successful and timely as well as those that were not successful.

The NCC appreciates this opportunity to provide comments concerning the regulatory framework for technologies of critical importance to the U.S. cotton industry. Please do not hesitate to contact Steve Hensley with any questions or concerns at shensley@cotton.org or (202) 745-7805.

Sincerely,



Steve Hensley
Senior Scientist, Regulatory and Environmental Issues