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July 30, 2018

Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8,
4700 River Road Unit 118,
Riverdale, MD 20737-1238

RE: Docket No. APHIS-2018-0034. Notice of Intent to Prepare an Environmental Impact Statement; Movement and Outdoor Use of Certain Genetically Engineered Organisms

The National Cotton Council (NCC) appreciates the opportunity to provide input in response to the USDA Animal and Plant Health Inspection Service's (APHIS) request for public comments on the proposed revisions to its biotechnology regulations in 7 CFR part 340.

The NCC is the central organization of the United States cotton industry. Its members include producers, ginners, cottonseed processors and merchandizers, merchants, cooperatives, warehousemen and textile manufacturers. A majority of the industry is concentrated in 17 cotton-producing states stretching from California to Virginia. U.S. cotton producers cultivate between 9 and 12 million acres of cotton with production averaging 12 to 18 million 480-lb bales annually. 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 125,000 workers and produce direct business revenue of more than \$21 billion. Annual cotton production is valued at more than \$5.5 billion at the farm gate, the point at which the producer markets the crop. Accounting for the ripple effect of cotton through the broader economy, direct and indirect employment surpasses 280,000 workers with economic activity of almost \$100 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 and/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

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.

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

Biological breakthroughs are enabling farmers to confront the overarching challenge for agriculture: doing more with less. Society still faces the challenge of clothing and feeding an ever-expanding population, which will reach nine billion by 2050 and require at least a 70 percent increase in food, fiber, feed and fuel production. Advancing the adoption of innovations and technology for agricultural production and long-term, sustainable rural development is a key goal in the White House's recently published directive promoting U.S. agriculture and rural prosperity. A regulatory climate that fosters innovation in agricultural biotechnology will be an important component in meeting that goal, by continuing to provide a set of precise, yet flexible, tools for meeting the challenges facing U.S. farmers today.

During the past 30 years, there have been major advances in the science of biotechnology, and new issues have been brought to APHIS' attention by a range of stakeholders. Over this period, APHIS has also gained considerable experience in assessing the plant health risks of genetically engineered (GE) organisms. Accordingly, APHIS is considering amending the regulations pertaining to movement and outdoor use of certain GE organisms to address the advances in biotechnology and APHIS' understanding of the issues raised by stakeholders. The proposed revisions would allow APHIS to more effectively protect plant health under the Plant Protection Act (PPA) by focusing APHIS' regulations in 7 CFR part 340 on risks that may be posed by certain GE organisms rather than on the methods used to produce the products and would also make the regulatory processes more transparent while removing unnecessary regulatory burdens.

APHIS plans to prepare a programmatic environmental impact statement (EIS) in connection with the proposed revisions to APHIS' biotechnology-related, 7 CFR part 340 regulations that are being considered. Aspects of the human environment that may be affected by the proposed regulatory changes and that APHIS has preliminarily identified for evaluation in the EIS will include potential impacts on:

- U.S. agriculture and forestry production (*e.g.*, conventional, biotechnology-based, and organic);
- Current and future uses of certain GE organisms in agriculture and forestry;
- Agronomic practices employed in GE crop production that may have environmental consequences or effects (*e.g.*, tillage, crop rotation, weed and pest control, and agronomic inputs);
- Aspects of the physical environment, including soil quality, water resources, and air quality, with consideration given to the effects of dynamic climate conditions;
- Aspects of the biological environment, such as animal and plant communities, the development of weed, pathogen, and insect resistance to pesticides, the potential gene flow from certain GE organisms to sexually compatible species, the weediness of GE crop plants, and biodiversity;
- Consumer health and agricultural worker safety; and
- Animal feed safety, availability, quality, and animal health.

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.

APHIS will also examine socioeconomic considerations, such as the potential impacts of crop plants that are GE organisms on the domestic economic environment, international trade, and coexistence among all forms of U.S. agriculture—conventional, biotechnology-based, and organic—and on market demand for food, feed, fiber, and fuel.

The NCC commends APHIS for this latest attempt to develop an improved regulatory system for agriculture biotechnology. The last proposed revisions were not considered adequate by NCC. Therefore, we ask that in this revision APHIS strive for transparency and clarity, simplified regulations on the research and development phase of products, consistency with other APHIS programs and other agencies' programs, and a concern for impacts to domestic and international markets.

In addition, we encourage APHIS to explore policy options that make implementation of its existing regulations more consistent with the risks posed by the activities it oversees, such as: 1) meet its 2011 regulatory timelines for making final determinations on petitions, in order to improve the timeliness and predictability of its reviews; 2) expand the use of the extension process for products similar to those already reviewed; 3) exclude or exempt from regulation categories of organisms that are unlikely to be plant pests; and 4) oversight of field trails should be proportionate to the actual risk posed by the organism.

NCC appreciates this opportunity to provide comments on proposed revisions to APHIS biotechnology regulations, and please do not hesitate to contact us with any questions or concerns. We look forward to working with APHIS during the comment phase for the EIS, and beyond.

Sincerely,

A handwritten signature in cursive script that reads "Steve Hensley".

Steve Hensley
Senior Scientist, Regulatory and Environmental Issues