National Cotton Council of America

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August 5, 2019

United States Department of Agriculture
Animal Health and Plant Inspection Service
Regulatory Analysis and Development, PPD, APHIS
Station 3A–03.8
4700 River Road Unit 118
Riverdale, MD 20737–1238

RE: Proposed Rule –Doc. No. APHIS–2018–0034

The National Cotton Council (NCC) appreciates the opportunity to comment on APHIS' regulations regarding the movement, which includes the importation, interstate movement, and environmental release, of certain genetically engineered (GE) organisms that fall under 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests" (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, warehousers 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 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.[i] 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.[ii]

Based on the feedback APHIS received from stakeholders and on their internal Agency deliberations, APHIS is proposing to revise the regulations in accordance with a new regulatory framework. The new framework will provide a clear, predictable, and efficient regulatory pathway for innovators while facilitating the development of new and novel GE plants that are unlikely to pose a plant pest risk.

APHIS' new regulatory approach is intended to prepare the Agency for future advances in the genetic modification of plants. Where genetic modifications are similar in kind to those modifications made through traditional breeding, the plant pest risks should also be similar. These types of plants are considered to be equivalent to those that have a history of safe use and would be exempted from the proposed regulation. On the other hand, genetic modifications made in the future may result in increasingly complex products which, in turn, may pose new types of risks with which the Agency has less familiarity. This latter category of engineered plants would be subject to review under the new regulations. Once products are reviewed by the Agency and found unlikely to pose a plant pest risk, similar products would be exempt from further review.

The proposed approach would differ from the current regulatory framework in that regulatory efforts would focus on the properties of the GE organism itself rather than on the method used to produce it. APHIS believe that this new approach, which reflects their current knowledge of the field of biotechnology, would enable the agency to evaluate GE organisms for plant pest risk with greater precision than the current approach allows. GE organisms that pose a plant pest risk would fall within the scope of the proposed regulations and require permits for movement. Plant pest risk is defined in this proposed rule as "[t]he possibility of harm resulting from introducing, disseminating, or exacerbating the impact of a plant pest."[iii]

APHIS will continue to regulate GE organisms that are, in and of themselves, plant pests, as well as other GE non-plant organisms that pose plant pest risks. Such organisms would require permits for movement. Other GE non-plant organisms that do not pose a plant pest risk would not fall under the scope of the regulations and therefore would not require permits for movement.

Under the current system, when making decisions regarding regulatory oversight of GE plants, APHIS assesses each transformation event (also sometimes referred to as the individual transformed line, transgenic line, or GE line) separately, even though the inserted genetic material may be identical or very similar to transformation events already assessed. This has sometimes been referred to as an "event-by-event" approach.

Under the proposed rule, developers would have the option of requesting a permit or a regulatory status review of a GE plant that has not been previously reviewed and determined to be nonregulated. Decisions on regulatory status would be based on the agency's assessment of plant pest risk. If movement of a GE plant is found to be unlikely to pose a plant pest risk, APHIS would not have authority under the PPA to regulate the plant in accordance with part 340. If the agency were unable to reach such a finding, APHIS would regulate the subject plant, which would be allowed to move only under permit.

Under § 340.1(b) of the proposed rule, certain categories of modified plants would be exempted from the regulations in part 340 because they could be produced through traditional breeding

techniques and thus are unlikely to pose a greater plant pest risk than traditionally bred crops, which APHIS has historically not regulated. These products of biotechnology are likely to pose no greater plant pest risk than their traditionally bred comparators.

Proposed § 340.1(c) would exempt GE plants with plant-trait-mechanism of action (MOA) combinations that have already been evaluated by conducting a regulatory status review and found to be unlikely to pose a plant pest risk. MOA refers to the biochemical basis for the new trait. The results of all completed regulatory status reviews would be publicly accessible on the APHIS website.

> **COMMENT:** NCC believes that this section dealing with formerly evaluated MOA combinations will facilitate an increase in new events as well as facilitating innovation from new, smaller companies.

Under the proposed new regulatory framework, a developer would have the option to make a self-determination as to whether their GE plant belongs to one of the categories listed under § 340.1(b) or (c) and is therefore exempt from the regulations. A developer who determines that his or her GE plant belongs to an exempted category would have the option under proposed § 340.1(d), to request written confirmation from APHIS that the self-determination is valid. These confirmation letters would provide a clear and succinct statement about the regulatory applicability of the GE plant and the nexus to plant health. APHIS anticipates a timely turnaround in developing and providing these confirmation letters to developers. Allowing for self-determinations would provide developers and APHIS with more time to devote to innovations that must be further reviewed due to potential plant pest risk.

> **COMMENT:** While NCC appreciates the option for self-determination NCC believes it may be in the best interest of transparency, legal-certainty and global adoption of GE traits that seeking agency confirmation of a self-determination of an exempted plant be mandatory. We believe that most developers will apply the option to seek a confirmation letter anyway, therefore we don't believe that making it mandatory will dramatically increase the workload of the agency and the benefits of moving forward with assurance will outweigh the costs.
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> The agency will also need to set a response time to affirm or deny the exemption, probably with the caveat that no response by the deadline will be automatic affirmation. This procedure should take place prior to commercialization.

In the proposal, APHIS would define *genetic engineering (GE)* as techniques that use recombinant or synthetic nucleic acids to modify or create a genome. They consider that this proposed definition is clearer than the existing one. They state that "the current definition could also be construed, contrary to our intentions, <u>to exclude</u> the use of synthetic DNA, *in vivo* DNA manipulation, and <u>genome editing</u>." (emphases added)[iv]

> **COMMENT:** NCC believes that genome editing should not be defined as genetic engineering. By labeling gene editing as such, the agency brings huge, negative perception issues into play as well as regulatory challenges that will defeat the promise of

this new science. In addition, U.S. cotton's smaller acreage, compared to other crops, makes it difficult to justify the costs associated with 'genetic engineering'.

Currently it takes 20 to 40 years to bring new traits from diploid cottons into Upland or Pima cotton through traditional breeding. Gene editing can do the same function in 2 years, but that's only if the process can be allowed to work free of the delays and road blocks created by misunderstandings in the public arena and the slow regulatory regime. In the U.S., wild cotton relatives have valuable alleles (for resistance to drought, disease, etc.) that the industry hopes to swap out with Upland alleles using gene editing. These are traits needed to insure the continuation of fiber, food and feed for the growing population and they can be edited into Upland cotton in a timely fashion if they are not considered GMO by the U.S. regulatory agencies.

U.S. cotton relies heavily on Australia for breeding – lots of germplasm starts there. Of the main commercial cotton-breeding countries, only Australia[v] and the U.S. are considering gene editing to not be genetic engineering and the industry needs the two countries to align.

In conclusion, the NCC would like to commend APHIS for its attempt to develop a better regulatory system for agriculture biotechnology as well as for recognizing the long history of scientific evidence that supports the safety of products developed using these methods. 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 current regulatory system has operated quite successfully for decades and has resulted in no adverse plant health impacts to U.S. agriculture. In the end, we believe that making the proposed strategic improvements to the current regulatory system will engender broader support, prove easier to implement, and have a much more immediate impact with fewer unintended consequences.

Finally, we appreciate the strong position APHIS is providing regarding pre-market review of products of newer techniques like genome editing, and the similarity of many products derived from these techniques to conventional plant breeding. NCC would like to point out that consistent policies globally for products of plant breeding innovation are essential to avoid trade disruptions. Therefore, U.S. government agencies should be encouraged to actively engage with our trading partners around these policies as soon as possible to work toward consistent, science-based policies across countries.

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.

Sincerely,

Steve Hensley
Senior Scientist, Regulatory and Environmental Issues

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[i] *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.

[ii] *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.

[iii] Federal Register / Vol. 84, No. 109. June 6, 2019. *Movement of Certain Genetically Engineered Organisms.* Pg. 26516.

[iv] Ibid: pg. 26522

[v] Nature. 23 April 2019. *Australian gene-editing rules adopt 'middle ground': Updated regulations allow scientists to use some genome-editing techniques in plants and animals without government approval.*