



August 5, 2019

Biotechnology Regulatory Services
Animal Plant Health Inspection Service
United States Department of Agriculture
4700 River Road Unit 146
Riverdale, MD 20737-1236

RE: The National Corn Growers Association comments on the Proposed Rule regarding Movement of Certain Genetically Engineered Organisms. Docket ID: APHIS-2018-0034-0037

Dear Sir/Madam:

The National Corn Growers Association (NCGA) appreciates the opportunity to comment on the proposed update to 7 CFR 340. Founded in 1957, NCGA represents nearly 40,000 dues-paying corn farmers nationwide and the interests of more than 300,000 growers who contribute through corn checkoff programs in their states. NCGA and its 48 affiliated state organizations work together to create and increase opportunities for corn growers.

Decades of research and cultivation demonstrate the environmental and economic benefits of genetically engineered (GE) organisms, and today more than 90 percent of the field corn planted annually in the U.S. utilizes GE technology. NCGA greatly appreciates USDA's recognition of the impeccable safety record of GE organisms and its efforts to streamline the oversight and regulatory framework for these products. A simplified pathway for bringing these product innovations to market will bring benefits to farmers and consumers alike. NCGA believes reduced regulatory hurdles for GE products will allow new technology to reach the market in less time and in a more cost-effective manner, enabling increased innovation across a wide spectrum of players and encouraging new participants in the market.

We appreciate USDA's intention to focus on the plant pest risk of each product, instead of the method used to create that product. NCGA believes this change positively reflects recent advancements in plant breeding and will funnel resources to those products still requiring review. We are also supportive of USDA's decision to review only once those plant-trait-mechanisms of action requiring oversight. However, we ask that USDA explicitly state in the rule that those plant-trait-mechanisms of action that have previously received approval will not be subject to additional or new review due to process and rule changes.

Overall, we support and trust USDA's scientifically based regulatory system, and appreciate the agency's commitment to continuing to use such an approach. We believe this system leads the world in fair and comprehensive reviews that enable new and innovative products to safely come to

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the market. While NCGA is largely supportive of the proposed rule, we believe several amendments to the current language would strengthen it and enable broader support.

Definitions

NCGA believes USDA would benefit from further clarifying the definitions of “genetic engineering” and “genetically engineered organism” used in the rule.

“Genetic engineering” is defined in Section 340.3 of the Proposed Rule as “techniques that use recombinant or synthetic nucleic acids to modify or create a genome.” NCGA recommends that USDA provide more clarity around what is meant by “synthetic nucleic acids” by stating that, for the purposes of Part 340, “synthetic nucleic acids” are those that are non-naturally occurring.

Because the term “genetic engineering” is often used synonymously with terms like “biotechnology,” “modern biotechnology,” and “genetic modification,” we recommend further definition for the term “genetically engineered organism.” Defining the term “genetically engineered organism” as recommended would make clear that plants derived from applications of genome editing that could be achieved through traditional breeding would not be treated as genetically engineered organisms subject to Part 340. We suggest the following definition be used to provide greater clarity around which “organisms” would and would not be subject to Part 340 regulations:

“An organism developed using genetic engineering, excluding those offspring that do not retain the genetic modification of the parent. For the purposes of this part, a plant will not be considered a genetically engineered organism if it meets any of the criteria outlined in 340.1(b)(1)-(3).”

Use of more consistent and widely accepted definitions will aid in increasing acceptance of these products domestically and globally, and reduce the risk of commerce and trade disruptions.

Exemptions

We encourage USDA to reflect the Secretary’s statement from March 28, 2018 on [Plant Breeding Innovation](#), which said, “USDA does not plan to regulate plants that could otherwise have been developed through traditional breeding techniques.” To better reflect that statement, NCGA recommends that proposed §340.1(b)(3) be modified by revising the exemption to read as follows:

(3) The genetic modification is introducing nucleic acid sequences:
(i) from within the plant’s gene pool;
(ii) from editing nucleic acid sequences to correspond to a sequence in that plant’s gene pool; or
(iii) otherwise accessible through traditional plant breeding methods such as, but not limited to, induced or somaclonal mutagenesis, tissue culture, protoplast, cell or embryo fusion, wide and bridging crosses, haploid induction, or other methods that enable efficient movement or rearrangement of genes within the plant’s gene pool.

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Self Determination

Under §340.1(d), USDA establishes the option to request confirmation from APHIS that the plant belongs to one of the categories listed under §340.1(b) or (c) and thus get an official confirmation from the Agency that the self-determination is valid. We understand that USDA will receive comments supporting a compulsory notification system for all new products intended for commercialization from a variety of groups, including product registrants. We support all seed providers in executing their due diligence and market risk assessments, in the same way these organizations commit to undertaking voluntary consultations with FDA as part of their assessments. NCGA encourages the agency to consider how a mandatory notification system might be perceived in international markets that share USDA's regulatory approach based on scientific assessment, and if or how such a requirement would hinder global acceptance of products developed using advanced breeding techniques.

Plant-Incorporated Pesticides Oversight

The majority of corn acres in the U.S. are planted with seeds that have plant-incorporated pesticides (PIPs). The access to this technology and continued innovation for corn farmers is essential to long-term corn farmer profitability and sustainability. To prevent disruptions in innovative new products containing PIPs coming to the market, NCGA encourages USDA to continue playing a role in PIP oversight on those plantings less than 10 acres.

We understand that many of the GE PIP-producing plants currently under the authority of USDA would no longer require this oversight under the proposed rule. However, products with a mechanism of action not previously reviewed by USDA will require oversight. A wholesale transfer of responsibilities to EPA will thus require the development of a new system for review, staff training and more, and in turn create the potential for increased regulatory burden and delays for years as this new system becomes familiar. This change therefore contradicts the intent of the President's June 11, 2019 Executive Order, [Modernizing the Regulatory Framework for Agricultural Biotechnology Products](#), to streamline regulatory processes.

Instead of an outright transfer of responsibilities to EPA, NCGA asks that USDA retain responsibility for implementing the review of PIP plantings in coordination with and oversight from EPA.

We also encourage USDA to provide reasonable, defined timelines for processes listed in the rule. A lack of these timelines may stall innovation and puts trait providers and farmers at a disadvantage, as they will be unable to adequately anticipate and plan for the introduction of new, beneficial material.

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**NATIONAL
CORN GROWERS
ASSOCIATION**

Finally, NCGA asks USDA to closely coordinate with EPA and FDA on the broader topic of GE organism regulation to avoid duplicate or unnecessary review, or diminish the potential benefits of a streamlined approach as outlined in the proposed rule.

NCGA appreciates USDA's consideration of our submission and the continued opportunity to work together to provide a consistent, sustainable and safe food supply to the nation and to the world.

Sincerely,

Lynn Chrisp
President, National Corn Growers Association

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