



August 5, 2019

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

*Submitted via [www.regulations.gov](http://www.regulations.gov)*

RE: Proposed Rule –Doc. No. APHIS–2018–0034 (84 Fed. Reg. 26514 (June 6, 2019))

Thank you for the opportunity to comment on the proposed rule changes to USDA’s regulations in 7 CFR part 340, “Introductions of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests”.

The National Association of Wheat Growers (NAWG) is a federation of 20 state wheat grower associations that works to represent the needs and interests of wheat producers before Congress and federal agencies. Based in Washington, D.C., NAWG is grower-governed and grower-funded, and works in areas as diverse as federal farm policy, trade, environmental regulation, agricultural research and sustainability. Our members feel it is important to provide comments on this Docket as it impacts wheat research aimed at improving wheat productivity for our producers and, potentially, the rule changes could impact the marketability of wheat to our foreign customers.

NAWG believes USDA APHIS is correct in its efforts to update and revise the current regulations. APHIS should be commended in its attempt to streamline the process. APHIS can point to its learnings from over 20 years of documented risks to plant health within its authority related to plant pests and noxious weeds when making these rule changes.

Modern biotechnology (transgenesis and gene editing) helps achieve an increase in food production without the need for more land area for agriculture. It has demonstrated its ability to sustainably improve productivity by reducing pesticide use and increasing conservation practices available to growers since their commercial introduction over 20 years ago. It is expected to continue contributing to achieving global food production necessary to feed world population and thus it is necessary for this technology to be used by researchers for further crop improvement and for these improved crops to be widely accepted.

Our members believe science-based decisions should be used to develop regulatory framework. Regulation needs to be rational and not burden research investment with unnecessary costs or delays. The history of GE crops, after rigorous testing and arduous

regulation, have shown the risks are similar to those of traditional crops. Government authorities rarely assess traditional crops due to their remarkable safety records. As a result of these learnings, wheat grower members will support the APHIS goal to streamline its process and find ways to reduce regulation on plant products produced through biotechnology that pose little, if any, plant pest risk. NAWG encourages USDA APHIS to be vocal about the safety of GE technology, aiming their messaging at every opportunity to the U.S. consumer.

These are the areas proposed by APHIS in its Docket which are supported by NAWG:

- Focus on the properties of the GE organism itself, rather than on the method used to produce it. NAWG believes it is the end result plant organism needing the assessment of risk, not the process used to develop it.
- Re-defining plant pest risk as “the possibility of harm resulting from introducing, disseminating, or exacerbating the impact of a plant pest”
- Under proposed Part 340.4 (a), providing developers the option of “requesting a permit”; or, a “regulatory status review” of a GE plant that has not been previously reviewed based on its plant-trait-Mechanism Of Action (MOA) combination.
  - (MOA refers to the biochemical basis for the new trait.) The MOA may cause desired phenotypes and undesired phenotypes. APHIS must evaluate the MOA to determine the risk of undesired phenotypes that may occur within the organism of interest.
  - As gene editing research is expanded in wheat, NAWG is concerned for permit issuance bottlenecks from the increase in plant products undergoing testing. Having the option of a regulatory status review could serve to avoid potential delays with permit issuance.
- Under Part 340.1 (c), exempting GE plants with plant-trait-MOA combinations that have already been evaluated.
  - It is important to note NAWG encourages USDA APHIS to monitor its areas of exemption, providing regular updates to the exempted list. This would include removing previously exempted technologies that prove to contain plant pest risk, while adding technologies proving to be safe after their review.
- Under Part 340.4, categories of GE plants exempted from regulation that would otherwise have been developed through traditional breeding techniques
- Under proposed Part 340.2, NAWG is supportive of the categories of GE organisms listed as subject to the regulatory permits.
  - The GE organism is a plant that has a plant-trait-MOA combination that has not been subjected to a regulatory status review
  - The GE organism meets the definition of a plant pest in Part 340.3
  - The GE organism is not a plant but has received DNA from a plant pest and the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease
  - The GE organism is a microorganism used to control plant pests and could pose a plant pest risk.
- Under proposed Part 340.5, NAWG is supportive of requiring permits of any GE organism subject to regulation in Part 340, thus removing the former “notification”

process. Permitting provides APHIS with more information and ability to enforce adherence to rule provisions.

These are areas NAWG feels the need for USDA-APHIS continued oversight:

- Regulation of plants producing industrials and pharmaceuticals
  - Products from these plants are subject to FDA oversight. However, FDA has no regulations governing planting of such crops and developers do not have to go to the FDA until they are ready to begin clinical trials with the pharmaceutical derived from the plant. Since this timeframe could be years after the first planting of the crop, NAWG prefers USDA-APHIS provide oversight of the planting of such crops (under 7 CFR part 360) because of its expertise in this area. This would serve wheat growers by providing the integrity and quality of wheat needed to serve its customers domestically and abroad. USDA APHIS has a stellar history of preventing contamination of commercial grain with regulated, unapproved GE grain products.
- Prefer APHIS continue oversight of small-scale testing of Plant Incorporate Protectants (PIPs) until such time as a regulatory status review be completed or the developer has completed the regulatory review and approvals are granted.
  - Similar to Plant Made Industrials and Pharmaceuticals, PIPs are under oversight of an outside agency, in this case, the EPA since these plants are developed to produce pesticides. APHIS has provided oversight on plantings of PIPs on 10 acres of land or less, until they are de-regulated. Under the proposed rule, APHIS may not classify these plants as regulated if the plant-trait-MOA has been previously been evaluated. Again, NAWG prefers USDA-APHIS provide oversight of the planting of PIPs because of its expertise in this area and urges a coordination to address this concern with the EPA. This would serve wheat growers by providing the integrity and quality of wheat needed to serve its customers domestically and abroad.

#### **NAWG's Concern: Foreign Trade Partners Accepting USDA APHIS's Rule Changes to 7 CFR Part 340**

Since a large percentage (approximately 50%) of wheat produced in the United States is marketed for export on an annual basis, any rule change contemplated by the USDA APHIS needs to consider its impact to importing countries of US produced grain. This is NAWG's highest priority concern with the proposed change in the regulation. NAWG encourages USDA APHIS to develop and execute an international engagement strategy that defines USDA's rationale on pre-market regulatory approaches. U.S. government agencies should be encouraged to actively engage with our trading partners as soon as possible to work toward consistent, science-based policies across countries to avoid trade disruptions. All foreign customers expect the continued oversight by USDA to ensure consistent food safety, which is fundamental to their confidence in purchases of U.S. wheat.

Wheat growers are interested in any technology improvements aimed at increasing productivity. This includes GE improvements to the wheat plant. Regardless, however, of the technology and its productivity improvement, wheat growers will not purchase the technology if the marketplace

will not accept it. Wheat growers will proactively secure customers for their grain prior to planting any wheat containing a new trait developed with GE processes.

USDA indicates its proposed rule change is based on the following principles: **Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient or SECURE**. NAWG believes the new proposed rule can allow plant health to be protected while agricultural innovation thrives at the same time, if implemented with this goal as its guide. NAWG desires regulatory flexibility for genetic engineering improvement, which lets regulators oversee plant pest risk based on the best available science.

Thank you for the opportunity to provide comments.

Sincerely,

A handwritten signature in blue ink that reads "Chandler Soule". The signature is written in a cursive style with a large initial 'C'.

CEO  
National Association of Wheat Growers