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June 19, 2017

Docket No. APHIS-2015-0057
Regulatory Analysis and Development, PPD, APHIS
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Proposed Revised Regulation Governing the Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms

On January 19, 2017, APHIS published in the Federal Register requests for comment on the proposed revised regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. This is the first comprehensive revision to the regulations since they were established in 1987. The stated goal is to reduce the burden for regulated entities whose organisms pose no plant pest or noxious weed risks.

The National Association of Wheat Growers (NAWG) has provided input below on several of the areas potential to change by USDA APHIS. NAWG appreciates the opportunity to provide comment on these potential changes to APHIS biotechnology regulations (7 CFR 340).

Encourage International Communication and Coordination

Since a large percentage (approximately 50%) of wheat produced in the United States is marketed for export on an annual basis, any change contemplated by the USDA APHIS needs to consider its impact to importing countries. This is NAWG's highest priority concern with the proposed change in the regulation. USDA is encouraged to develop and execute an international engagement strategy that defines USDA's rationale on pre-market regulatory approaches, including its approach to oversight of products developed with genome editing tools. 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 to avoid trade disruptions. All foreign customers expect the continued oversight by USDA to insure consistent food safety, which is fundamental to their confidence in purchases of U.S. wheat.

Regulatory Relief and Exclusions Are Welcomed

NAWG is encourage to see exclusions to the proposed rule will include double haploid and marker assisted breeding techniques, currently used broadly in wheat breeding. This was a concern mentioned in NAWG's comments of April 21, 2016 on APHIS Notice of Intent Docket No. APHIS-2014-0054. The proposal also recognizes that some applications of gene editing result in plant varieties that are essentially equivalent to varieties developed through traditional breeding methods. Under the proposed rule, these plant varieties would not be considered "genetically engineered organisms" and thus would be excluded from USDA's pre-market

regulatory review. The proposal makes the strong argument that these products have genetic changes that can occur naturally or through long-standing breeding methods. We support this up-front exclusion which upholds the regulatory principle that similar products should be treated similarly. NAWG is excited to see the scope of products and technologies included in the proposed list of exclusions.

Regarding APHIS's proposal on plant-incorporated protectant GE plants (PIPs), NAWG again is encouraged that the intent would be only to regulate a PIP if the plant/trait combination had never been evaluated for plant pest and/or noxious weed risk. If APHIS had experience with the plant/trait combination, there would be no regulatory oversight by APHIS. NAWG understands PIPs would need to be evaluated by EPA under the coordinated framework and that EPA may decide to require permits to enable them to be evaluated. (EPA would need to develop a program to oversee small scale testing of PIPs and oversee potential regulations.) But this proposed change sends a positive signal about the need to foster innovation by insuring regulatory oversight is proportional to actual risk.

Proposed Rule Places Risk Early in Development Stage

APHIS's proposal will shift the regulatory burden from pre-launch commercialization stages to the early research/pre-development phase of product innovation. Each new plant variety must undergo a complex risk assessment and endure public comment BEFORE out-of-the-greenhouse, field scale trials can be held. Researchers will not have proven field efficacy of the product before incurring costs to produce data needed for APHIS's risk assessment. Researchers risk incurring cost without knowing the plant variety meets the product concept for commercialization.

NAWG is concerned the current posting of the proposed regulation does not include more detail of the risk assessment model, nor data/information requirements needed from the researcher. Also, the decision criteria and APHIS timeline to perform the risk assessment has not been communicated in the proposal. The process outlined in the proposal lacks transparency and clarity, and risks arbitrariness in the scope of regulation.

NAWG is also concerned the assessment process is unlikely to have the throughput capacity to accommodate the scale of US research and development, which potentially could result in many products being in a holding pattern while their regulatory statuses are being assessed. NAWG encourages APHIS to be cognizant of this "capacity to assess" issue, as it directly influences the motivation to innovate among all plant researchers.

Other Rule Change Commentary

NAWG believes USDA APHIS is correct in its efforts to revise the current regulations. APHIS should be commended in its attempt to streamline the process. APHIS SHOULD be focused on its learnings from 20 years of documented risks to plant health within its authority related to plant pests and noxious weeds.

NAWG is concerned with the proposed rule which describes a confusing process on what the agency will consider as a noxious weed. Identifying “indirect damage a plant may cause to the interest of agriculture” can be subjective, which lacks clarity on how the rule will be applied in placing a plant on the Federal noxious weed list.

APHIS indicates the definition of “genetic engineering would mean techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome”. NAWG believes a genome can be altered without changing the natural presence of a known protein or proteins within the plant or without adding new proteins. This could involve more than one or two base pairs, in either deletion or substitution within the genome. This could affect the expression of the protein already present, more or less, but may not change the structure of the protein. In this example, NAWG feels this should NOT fall within the proposed “genetic engineering” definition even though the genome would be altered. As long as the protein (or proteins) produced by the plant have not been altered through any technology, it should not be regulated.

At the request of APHIS in the posting, NAWG does not support defining “traditional breeding techniques” or “chemical or radiation-based mutagenesis”. These terms are well understood by the breeding industry, and do not warrant a new definition within the proposed rule.

Build International Support

Because wheat growers are very dependent on exports, NAWG will end this commentary with a similar recommendation as the beginning of the letter. USDA must develop and execute an international engagement strategy that explains USDA’s latest thinking on pre-market regulatory approaches, including its approach to oversight of products developed with genome editing tools. 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 to avoid trade disruptions.

Finally, USDA should engage with EPA and FDA to ensure consistent domestic policy and regulatory treatment for GMOs and products derived from other precision tools, like gene editing for use in food and agriculture.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Schemm", with a long horizontal line extending to the right.

David Schemm, President
National Association of Wheat Growers