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Submitted electronically

June 22, 2015

Animal and Plant Health Inspection Service
U.S. Department of Agriculture
1400 Jefferson Drive, S.W.
Washington, D.C. 20250

Re: Docket No. APHIS-2015-0036:
New Stakeholder Engagement on APHIS Biotechnology Regulations

Dear Reviewing Official:

The National Grain and Feed Association (NGFA)[1] and North American Export Grain Association (NAEGA)[2] respectfully submit the following statement to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) for consideration as it initiates a new round of stakeholder engagement on the agency's regulation of agricultural crop biotechnology. We commend the agency for its March 4, 2015 ***Federal Register*** announcement withdrawing its 2008 proposed rule that would have amended the regulations regarding the introduction of certain genetically engineered organisms, in recognition of the technological advancements, market developments and experiences that have been gained over the past 28 years. We also appreciate APHIS's stated willingness to explore alternative policy approaches as it looks to develop an updated and effective biotechnology regulatory approach that fosters both continued innovation of this safe, sustainable and environmentally sound technology, while at the same time fulfilling the agency's core mission to protect the health and economic value of

[1] NGFA, established in 1896, is a U.S.-based nonprofit trade association that consists of approximately 1,050 grain, feed, grain processing, export and other grain-related firms that operate more than 7,000 facilities and handle more than 70 percent of the U.S. grain and oilseed crop. Affiliated with NGFA are 26 state and regional grain, feed and agribusiness associations**.** Given the diversity of NGFA's membership, the views expressed in this statement may not necessarily reflect the views of every NGFA associate or affiliate member.

[2] NAEGA, a not-for-profit trade association established in 1912, consists of private and publicly owned companies and farmer-owned cooperatives that are involved in and provide services to the bulk grain and oilseed exporting industry. NAEGA-member companies ship and support the vast majority of the highly competitive, sustainable and fungible U.S. grain export supply.

U.S. agriculture, which we respectfully submit includes preserving and enhancing U.S. agriculture's unfettered access to domestic and export markets in ways that recognize, respect and preserve the fungibility of the U.S. grain and oilseed supply.

NGFA and NAEGA-member companies store, handle, process and export the vast majority of grains and oilseeds used in human and animal food, and are affected directly by marketability-related issues associated with the commercialization of crop biotechnology and other cropping systems. Our comments reflect this perspective.

In this statement, the NGFA and NAEGA wish to provide the following initial thoughts and concepts that we believe warrant strong consideration by APHIS as it considers its future biotechnology regulatory framework.

- First, we believe APHIS does have a role to play in devising a regulatory approach that protects the marketability of U.S. crops while at the same time fulfills its statutory responsibilities under the Plant Protection Act to adhere to sound science in its procedures for deregulating biotech-enhanced events that have been found not to present a plant pest or noxious weed risk.

- Second, we believe APHIS should consider whether, how and to what extent its regulatory review should apply to new plant breeding technologies that do not involve transgenisis, and whether utilizing the definition of "modern biotechnology" adopted by the Codex Alimentarius Commission would assist in that process and foster international harmonization.

- Third, we believe APHIS should reevaluate the scientific basis for its current 660-foot buffer zone requirement that applies to regulated field trials of biotechnology-enhanced events, based upon evidence that the current requirement is insufficient to protect against pollen drift from certain commodities, particularly corn.

- Fourth, we encourage APHIS to examine its current oversight of regulated field trials to determine if sufficient oversight is being exerted, given the isolated discovery of regulated wheat plant material on research plots in recent years.

- Fifth, we encourage APHIS to work with other U.S. and foreign government entities and market stakeholders to develop and implement a U.S. policy that addresses the low-level presence (LLP) of biotech-enhanced events that have been scientifically reviewed and approved as safe by a competent government authority in the country of export, but not yet by the importing country. We believe this is an essential component of a suite of policies that would enhance the marketability of U.S. crops produced with or derived from safe technologies, but which are subject to trade impediments resulting from differences in regulation and the timing of regulatory consideration by governments in different markets.

Before expanding on each of these recommendations, it is important to stress that our organizations support utilization of biotechnology and other safe technologies and modern agricultural practices that enhance the production of safe, affordable and sustainable food and energy for U.S. and world consumers. But achieving that objective of feeding a growing world population and providing for an abundant supply of agricultural products also necessitates that the grain handling and marketing industry be able to competitively, cost-effectively and seamlessly source and market U.S. agricultural products in domestic and foreign markets.

In that regard, significant dialogue is ongoing between agricultural stakeholders on: 1) domestic and export supply chains, as it relates to securing international market approvals for genetically engineered (GE) crops; and 2) commercialization of products with unique functional characteristics (PUFCs) and their impact on commodity and specialty supply chains. These two issues have generated discussion within the value chain on how new traits are assessed, approved, commercialized and handled domestically and internationally, and highlight the pressing need for the development and adoption of responsible standards and practices by technology owners to protect access to markets for all growers and other participants in these commodity supply chains.

APHIS's Role in Protecting the Economic Value of U.S. Agriculture

The combination of a growing lack of coherence in national regulation regarding safety reviews and approval of new biotech-enhanced events, as well as the increasing practice of biotechnology owners to release into commerce new biotechnology-enhanced events prior to obtaining import approvals from governments in importing countries (as has occurred in several notable instances), prevented or reduced the access of U.S. crops to markets and resulted in very significant reductions in economic value to U.S. agriculture.

Documented incidents in which GE events have been detected – and commodity shipments rejected – in major U.S. export markets for which they have not yet been approved point to the fact that it is commercially impossible to effectively channel products with 100 percent certainty, despite best efforts. For this reason, NGFA and NAEGA have supported greatly expanded efforts by APHIS and others to provide for much more timely and predictable regulatory actions regarding applications for approval of new traits. Likewise we do not support premature, aggressive commercialization in advance of export market approvals unless technology owners concurrently agree to accept and bear the risks and liabilities associated with their company-specific business decisions, given the lack of global regulatory coherence and compatibility of regimes addressing the life cycle of crop biotechnology.

Governments, including the U.S. government and APHIS, need to provide for practical regulation that is science-based, predictable and transparent to provide for increased synchronization of biotech regulatory regimes and the management of low-level presence of recombinant DNA plant materials that have undergone and passed adequate food safety reviews in one or more countries, but may on occasion be present in food imported by countries where the safety of the relevant recombinant-DNA plants has not been determined yet.

However, we also believe technology owners, who ultimately make the business decision to commercialize their products and provide for regulatory compliance, properly should bear the market-related risks and responsibilities associated with their respective decisions.

Similarly, significant issues exist between traditional commodity supply chains and the emergence of PUFCs, which can materially affect the nutritional, functional, compositional and other characteristics of a food or feed if present in quantities above certain levels. These products typically are intended to be handled within fully segregated supply chains. However, given the fact that an agricultural supply chain cannot be managed to achieve 100 percent segregation, the introduction of PUFCs also could have significant impacts on the quality (i.e. specifications) of existing commodity supplies. All sectors of the agricultural supply chain, from technology owners to end users, have recognized that the mismanagement of PUFCs can have significant adverse impacts on these existing commodity supply chains. Given these challenges, downstream stakeholders have asked technology owners to take additional responsibility to ensure the appropriate introduction, handling and use of PUFCs.

Responsible commercialization of PUFCs includes determining the level of impact that the presence of PUFCs could have on the nutritional, functional and compositional characteristics of a food or feed, and development of a corresponding plan to manage the PUFC in a way that does not negatively impact stakeholders in the United States and major foreign markets. The level of impact of the commingling of PUFCs with the fungible commodity supply must be examined on a case-by-case basis because some products may have little to no impact, while others may have significant impacts. Technology owners should continue working with downstream stakeholders to ensure that both the commodity and specialty supply chains are aware of such impacts. Further, we believe technology owners have a responsibility to protect the supply chain so it can be operated effectively and efficiently.

For the aforementioned reasons, the NGFA and NAEGA believe the following three elements are essential if biotech-enhanced traits are to be commercialized in a responsible way to minimize adverse market impacts on the U.S. agricultural value chain and food and feed system:

- ***Risk Assessment:*** Technology owners should assess, in collaboration with affected value-chain stakeholders, the market risk and threshold of impact, if any, that may be associated with the commercialization of biotech-enhanced crops. In the case of PUFCs this assessment should include a determination of the trait's level of impact (i.e., impact threshold) in a commodity that will have significant negative impacts on the commodity and its supply chain. Once this data is developed, it should be a matter of public record. We believe accepting responsibility will further enhance and assure positive outcomes from the technology owner's stewardship efforts.

- ***Risk Management:*** Once the market risk-assessment is completed, technology owners should establish and implement sufficiently robust and effective stewardship plans and supply chains that are appropriate and commensurate with the degree to which the given trait poses a risk to U.S. export markets or, in the case of biotech-enhanced products with unique functional characteristics (PUFCs), to keep the product segregated in a manner

that ensures it does not escape into the commodity supply chain above the impact level/threshold.

- ***Risk Responsibility:*** When the technology owner, producer or other parties in the technology owner's trait-specific risk-management supply chain fail to effectively assess and/or manage a given biotech-enhanced trait's adverse impacts, they should accept responsibility for direct economic damage incurred by downstream stakeholders resulting from their failure to manage the trait.

We raise these issues because commerce in grains and oilseeds are tied to global sourcing, and given the irrefutable fact that achieving a sustainable supply of these basic commodities depends upon adequate fungibility – that is, supply of a given crop having a degree of substitutability and relatively comparable value regardless of the geographic production area from which it originates. Grain supplies that can be comingled without concern over regulatory status can be accessed in a timely and efficient manner in response to buyer demands, providing time-and-space utility that is essential to achieving supply integrity and food security. Production and logistics systems that benefit from a fungible supply of grains and oilseeds are critical.

In its regulation of biotech-enhanced traits, we believe APHIS, too, has a role to play, given its stated mission "to protect the health and **value of American agriculture** and natural resources." *[Emphasis added.]* Further, the NGFA and NAEGA believe that several provisions of the "findings" section (Sec. 402) of the Plant Protection Act expressly state Congress's intent that the statute be utilized "for the **protection** of the agriculture, environment and **economy o**f the United States." *[Emphasis added.]* In addition, §402(5) of the Plant Protection Act contains the congressional finding that "the **smooth movement** of enterable plants, plant products, biological control organisms or other articles into, **out of, or within the United States is vital to the United States' economy and should be facilitated to the extent possible**." *[Emphasis added.]*

Recommendation: Given APHIS's mission statement and the previously cited provisions of the Plant Protection Act, we encourage the agency to consider whether it is appropriate to create a different category of "deregulation" – namely "conditional deregulation" – expressly for biotech-enhanced events that the agency has found do not present a plant pest or noxious weed risk, but which have not received approvals in significant U.S. export markets and as such represent a risk of disrupting domestic and/or export markets if they become present in the commingled supply chain. For biotechnology-enhanced events subject to "conditional deregulation," technology owners could be directed to implement sufficiently robust and appropriate trait-specific stewardship plans and associated responsibility to protect the value of U.S. crops until such approvals are granted. We submit that the same "conditional deregulation" approach should apply to PUFCs, whose presence could disrupt domestic and international supply chains if they become present above specified threshold levels. This potential suggested approach would recognize and respect both the "sound-science" requirement that should solely govern whether a biotech-enhanced event is determined to be a plant pest or noxious weed risk, while also recognizing the importance of addressing APHIS's mission to protect the value and economic well-being of crop-based U.S. agriculture.

Organizations like the Biotechnology Industry Organization and CropLife International, which represent plant science and biotechnology companies, have developed standards and policies for coexistence and stewardship. In these standards, technology owners are expected to communicate promptly, broadly and in a transparent manner with stakeholders. We support the position that companies commercializing biotech-enhanced traits, including PUFCs, should be responsible in their introduction and management of the impacts on overall supply chains, and believe that APHIS's regulatory approach can play a constructive role in making that happen.

Scope of APHIS Regulation of Crop Biotechnology

Second, as it looks to the future, we believe it is appropriate for APHIS to consider whether, how and to what extent (if any) it should regulate new crop breeding technologies that do not involve transgenisis, but which can present the same marketability risks as GMOs given the current lack of regulatory synchronization or of comparable or consistent international regulatory approaches. The types of new plant breeding technologies of which we are aware include Cisgenesis/ intragenesis, reverse breeding, grating (non GM-scion/GM rootstock), RNA-dependent DNA methylation, Oligo-directed mutagenesis and zinc-fingernucleases (mutagenesis).

The NGFA and NAEGA are engaged in ongoing discussions with international and domestic organizations representing the seed and biotechnology industries in an attempt to determine a positive path forward in trying to achieve a more harmonized international approach to this complex issue. The NGFA and NAEGA are hopeful that perhaps a recognized international body, such as the Codex Alimentarius Commission, could be looked to as a way to bring about some consistency regarding regulatory approach toward these new breeding technologies. In that vein, Codex, in its Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, which was adopted in 2003 and subsequently amended in 2008 and 2011, defined modern biotechnology as meaning: "...the application of (i) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or (ii) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection." We believe APHIS may wish to consider this definition as it determines the future scope of its regulation of crop biotechnology.

Reevaluation of Biotech Research Trials

The NGFA and NAEGA also urge APHIS to use this opportunity to reevaluate two aspects of the rigor of its regulation of field trials involving biotech-enhanced crops:

- First, we believe APHIS should reanalyze the adequacy of its current 660-foot buffer zone and other measures that are designed to isolate regulated field trials of biotech-enhanced crops from non-regulated fields. Given the zero tolerance for the presence of unapproved events that currently exists in the United States and other countries, we are concerned about anecdotal examples that the current buffer zone is insufficient to adequately protect against cross-pollination of nonregulated fields, particularly for corn.

- Second, once its investigations is completed into the post-field-trial emergence of biotech-enhanced wheat plant material on research fields operated by Montana State University, we encourage APHIS to reevaluate and further strengthen, as necessary, its protocols for overseeing such research trials.

Pursue Adoption of Global LLP Policy

Finally, we encourage APHIS to work with other U.S. and foreign government entities and market stakeholders to develop and implement a U.S. policy that addresses the low-level presence (LLP) of biotech-enhanced events in both imports and exports that have been scientifically reviewed and approved as safe by a competent government authority in the country of export, but not yet by the importing country. We believe this is an essential component of a suite of policies that would enhance the marketability of U.S. crops produced with or derived from safe technologies, but which are subject to trade impediments resulting from differences in regulation and the timing of regulatory consideration by governments in different markets. Such a suite of policies should support least-trade-distortive commercial and public measures for both imports into and exports from the United States, and provide for adequate fungibility throughout the supply chain, which as explained previously is a critical component of U.S. competitiveness.

Practical approaches are needed for the management of LLP that are science-based, predictable and transparent, and that will encourage the use of international science-based guidelines on LLP. One example is the Codex Alimentarius Commission's Annex 3: Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food. A practical approach to LLP management must address each crop biotechnology event or trait individually, beginning with the planting of seeds that contain that event or trait. It is impractical to manage LLP with a testing-based clearance mechanism for commodity shipments. The use of process controls to appropriately limit exposure, starting with the planting of seeds, may provide for LLP management when responsibility for the controls is established and maintained.

To address the current lack of synchronized approvals for biotech-enhanced crops globally and comprehensively, NGFA and NAEGA stand ready to work with APHIS and others to encourage adoption of an LLP policy to facilitate marketability of such traits for the United States and all relevant global regulatory regimes.

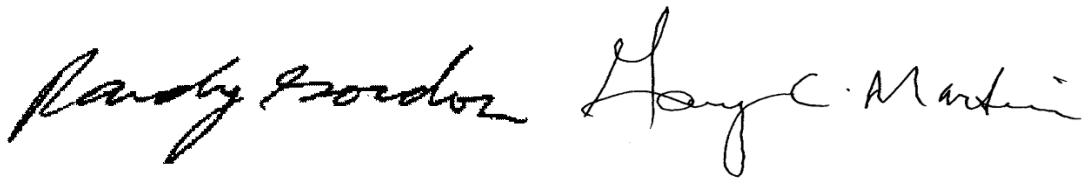
Conclusion

To conclude, the NGFA and NAEGA believe that commercial seed products currently on the market have enabled growers to increase crop yields while at the same time protecting the environment by decreasing crop inputs and expanding the use of conservation tillage. These technological advances largely have been successful in enhancing the productivity and competitiveness of U.S. growers, grain handlers, processors and exporters, and accrued substantial benefits for consumers.

Going forward, our organizations support the use of balanced biotechnology policies – including policies that effectively address marketability risks and impacts – to ensure the successful development and processing of foods for humans and animals from all agricultural cropping systems.

Thank you for the opportunity to comment on this important issue.

Sincerely,



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