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October 13, 2015

Regulatory Analysis and Development
Plant Protection Division
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Station 3A—03.8
4700 River Road, Unit 118
Riverdale, MD 20737

Re: Docket No. APHIS-2015-0048: Monsanto Company –
Availability of Petition for Determination of Nonregulated Status for Maize Genetically Engineered for Resistance to Dicamba and Glufosinate (MON 87419)

Dear Reviewing Official:

The National Grain and Feed Association (NGFA)[1] and North American Export Grain Association (NAEGA)[2] respectfully submit this statement to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) in response to its request for comments on the petition submitted by Monsanto Company seeking a determination of nonregulated status for maize designated as MON 87419, which has been genetically engineered for resistance to the herbicides dicamba and glufosinate.

Concerning this petition for deregulation, NGFA and NAEGA reiterate their belief that APHIS needs to balance the need to foster a science-based biotechnology regulatory policy that encourages both continued innovation of this safe, sustainable and environmentally sound

[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.

technology, while at the same time fulfilling the agency's core mission to protect the health and economic value of U.S. agriculture, which we respectfully submit includes preserving and enhancing the marketability of U.S. crops and U.S. agriculture's unfettered access to domestic and export markets in ways that recognize, respect and preserve the fungibility and commingled nature 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.

The NGFA and NAEGA believe APHIS must evaluate both plant and environmental safety and the economic impacts on U.S. agriculture when making a determination as to whether to grant a determination of nonregulated status for crop biotechnology events like MON 87419. APHIS's decision should consider the impacts on the marketability of U.S. crops, while at the same time fulfilling the agency's 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. In this regard, in comments submitted previously to APHIS in response to its request for comments from stakeholders on a prudent future biotech regulatory framework, NGFA and NAEGA have encouraged the agency to work with other U.S. and foreign government entities and market stakeholders to develop and implement trade-facilitation policies, including 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 of 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 expounding upon these principles and their application to the nonregulated status petition associated with MON 87419, 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 the objective of feeding a growing world population and providing an abundant supply of competitively priced 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 supply chain stakeholders on: 1) domestic and export supply chains, as they relate to securing international market approvals for genetically engineered (GE) crops; and 2) commercialization of products with unique functional characteristics (PUFCs) and their impacts on commodity and specialty supply chains. These two issues have generated significant discussions 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 increasing lack of coherence in various nations' regulatory systems regarding safety reviews and approval of new biotech-enhanced events – combined with the increasing practice of biotechnology owners to release into commerce new biotechnology-enhanced events before obtaining import approvals from governments in importing countries (as has occurred in several notable instances) – have indeed prevented or reduced access of U.S. crops to markets and resulted in very significant downward pressure on prices paid to farmers and reduced the economic value of U.S. agricultural production.

Documented incidents involving the detection of GE events that have not been authorized yet by the importing country – and subsequent rejection or disruption of commodity shipments – in major U.S. export markets point to the fact that, despite best efforts, it is commercially impossible to effectively manage the presence of GE events in commodity shipments to a zero tolerance or to non-detectable levels. This lack of global regulatory coherence and compatibility of regimes for addressing the life cycle of crop biotechnology not only results in negative impacts on the marketability and acceptance of all U.S. crops, but also affects access to important production technology.

As a result, NGFA and NAEGA have supported greatly expanded efforts by APHIS and others to provide for more timely and predictable regulatory actions regarding applications for approval of new traits. However, we likewise support prudent practices by the entire value chain regarding the commercialization and utilization of GE production technology. 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.

Government entities, including the U.S. government and APHIS, need to provide for practical regulation that is science-based, predictable and transparent to facilitate 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 commodities or co-products imported by countries where the relevant recombinant-DNA plants have not been approved yet.

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

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/economic impacts on the U.S. agricultural value chain and food and feed system, and have relevance to this petition:

- ***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. We believe accepting responsibility will further enhance and foster 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 that are designed to prevent escapes into the commodity supply chain.

- ***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. It is an irrefutable fact that achieving a sustainable supply of these basic commodities depends upon adequate fungibility – that is, the ability to source supplies of a given crop that have 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, NGFA and NAEGA 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, we believe that several provisions of the "findings" section (§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.]*

APHIS Plant Pest Risk and Environmental Assessments: For these reasons, we urge APHIS to assess and consider the status of Monsanto's obtaining of import approvals in key U.S. export markets as part of its forthcoming plant pest risk and environmental assessments associated with this petition. Unfortunately, APHIS' previous draft environmental assessments associated with petitions granting nonregulated status for biotech-enhanced traits have demonstrated an alarming lack of recognition of the significant economic impacts that trade-related disruptions involving biotech-enhanced crops can have – and indeed have had – on domestic markets and U.S.

farmgate prices of corn, as well as other crops where trace amounts of the event are likely to be present given the commingled nature of the fungible U.S. commodity system.

A significant and all-too-recent case-in-point involves the decision by Syngenta Seeds Inc. to commercialize its Agrisure Viptera™ MIR 162 corn seed in the United States prior to obtaining import approval from the People's Republic of China. An analysis completed by NGFA in early April 2014 and updated in August 2014 estimated that the total economic damage to U.S. sellers of corn, distillers dried grains with solubles (DDGS) and soybeans resulting from Syngenta's commercialization of Viptera MIR 162 prior to Chinese import approval – and the trade disruptions that ensued after China detected MIR 162 and rejected shipments under its zero-tolerance policy – ranged from **$1.5 billion to $4 billion for the 2013/14 marketing year**. Using a mathematical model that forecasts the national average corn price based upon U.S. corn ending stocks, NGFA estimates that the trade disruption depressed U.S. corn prices by 11 cents per bushel, and reduced U.S. soybean prices by an estimated 15 cents per bushel. The negative price impact was even more severe for DDGS. For instance, between May and August 2014, DDGS prices in Iowa declined $68 per metric ton, whereas corn prices in Iowa declined by $21 per metric ton. The poor price performance of DDGS relative to corn was largely attributable to China's decision to stop issuing import permits for U.S. DDGS in the near term, and its subsequent request for official test reports for all future U.S. DDGS shipments. Prior to the interruption in trade, China was accounting for 13 percent of total demand for 2013/14 U.S. DDGS production. The impact of temporarily losing China as a DDGS trading partner was a primary reason for the 50 percent drop in DDGS prices between May and August 2014, NGFA's analysis found. Importantly, these economic losses only reflect 2013/14 marketing year impacts, and do not reflect the loss of U.S. export sales to China that occurred following the Viptera MIR 162-related disruption in export shipments and sales.

NGFA-NAEGA Recommendations

Given APHIS's mission statement, the previously cited provisions of the Plant Protection Act, and our aforementioned comments on the severe adverse economic impacts that can result from the granting of non-regulated status for biotech-enhanced events, the NGFA and NAEGA recommend that APHIS create and apply a different category of "deregulation" – namely ***"conditional deregulation"*** – expressly for MON 87419 and for other biotech-enhanced events that the agency determines 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, present 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 should 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. Our suggested approach recognizes and respects both the "sound-science" requirement that solely should govern whether a biotech-enhanced event is determined to be a plant pest or noxious weed risk, while also recognizing and respecting 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 should be responsible in their introduction and management of the impacts on overall supply chains, and believe that use by APHIS of a "conditional deregulation" approach can play a constructive role in making that happen.

Pursue Adoption of Global LLP Policy

Finally, we again take this opportunity to encourage APHIS to work with other U.S. and foreign government entities and market stakeholders to develop and implement trade facilitation policies, including 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.

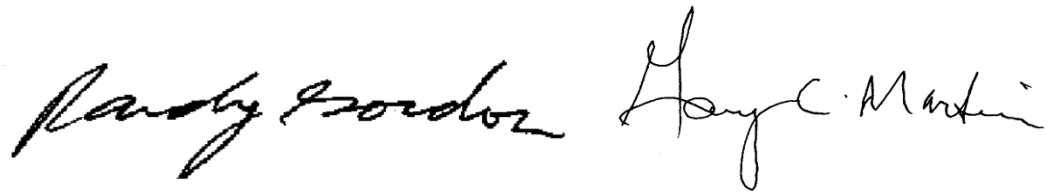
Conclusion

To conclude, the NGFA and NAEGA believe that commercial seed products currently on the market have enabled growers to increase yields of safe crops for use as food, feed and for further processing, while at the same time protecting the environment by decreasing crop inputs and expanding the use of conservation tillage. These technological advances also 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, NGFA and NAEGA 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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