



National Grain and Feed
Association



North American Export
Grain Association

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April 29, 2013

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 20737-1238

Re: *Docket No. APHIS-2012-0026*
Availability of Petition, Plant Pest Risk Assessment and Environmental
Assessment for Determination of Nonregulated Status of Maize Genetically
Engineered for Herbicide Tolerance and Insect Resistance (DP-ØØ4114-3)

Dear Sir/Madam:

The North American Export Grain Association (NAEGA) and National Grain and Feed Association (NGFA) submit this joint statement in response to the notice published in the February 27, 2013 edition of the *Federal Register* seeking comment on the petition Pioneer Hi-Bred International, Inc., (Pioneer) seeking nonregulated status of its biotechnology-enhanced maize event (DP-ØØ4114-3) that has been genetically engineered to provide agronomic benefits through resistance to certain lepidopteran and coleopteran pests and tolerance to the herbicide glufosinate.

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's mission is to promote and sustain the development of commercial export of grain and oilseeds and their primary products. Through a reliance on member action and support, NAEGA acts to accomplish its mission from its office in Washington D.C., and in markets throughout the world. NAEGA members are engaged in the vast majority of U.S. grain and oilseed exports, whose value exceeds \$50 billion annually.

NGFA is comprised of 1,050 member companies that operate more than 7,000 facilities and handle more than 70 percent of the U.S. grain and oilseed crop. NGFA membership encompasses all sectors of the industry, including country, terminal and export grain elevators;

commercial feed and feed ingredient manufacturers; biofuels producers; cash grain and feed merchants; end-users of grain and grain products, including grain and oilseed processors, corn and flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries.

As organizations whose member companies represent the U.S. grain and oilseed handling and marketing system, with deep interest in the production of safe and healthful agricultural commodities, we strongly support agricultural biotechnology and other scientific and technological innovations that contribute to agricultural production efficiencies. These advances are crucial to enabling the United States to meet the growing demand to provide a safe, abundant and high-quality food, feed and fiber supply for U.S. and world consumers.

To achieve this worthy objective, issues concerning how crop biotechnology is managed need to be addressed to facilitate the efficient marketing of U.S. crops and avoid the costly and far-reaching disruption of the integrity of the domestic and export supply chain. Biotech-enhanced events can disrupt the supply chain if and when such biotech events: 1) have not been approved or authorized in U.S. export markets; and/or 2) express unique functional characteristics that make their presence in either the domestic or export supply chains inappropriate above certain levels.

For these reasons, NGFA and NAEGA believe biotechnology providers have several inherent responsibilities associated with the commercial introduction of biotechnology-enhanced events intended for the U.S. commodity system. Consistent with this belief, we urge the following three commitments be met by biotechnology providers as part of their responsible commercialization of biotech events:

- **Risk Assessment:** The biotechnology provider should be required to determine a level, if any, at which it is inappropriate for such traits to be present in the general commodity stream because of potential adverse export market access and/or food/feed functionality economic impacts. This critical risk assessment and related risk communication must be completed at an early stage through active, joint consultation with producers, grain handlers, grain processors, exporters and other market participants. One option for making this critical information available is to include the assessment and current and complete factual information related to international import approvals and/or functionality impacts as part of the public rulemaking record.
- **Risk Management:** Based upon the results of the risk assessment, the biotechnology provider should be required to develop, implement and enforce binding stewardship programs and supply chain management, under which the technology provider is obligated to comply in a manner that is: 1) appropriate for the given biotech-enhanced trait; and 2) sufficient to prevent such traits from becoming present in the general commodity stream above levels determined as part of the risk-assessment process described previously.
- **Risk Responsibility:** Biotechnology providers should be required to accept liability to compensate parties for economic damage resulting from a failure to adequately

implement and enforce binding risk-management (stewardship) and supply chain management plans deemed sufficient and effective in preventing biotech events from becoming present in the general commodity stream at levels that could disrupt efficient commerce.

One of the most important of these commitments is to voluntarily restrict commercialization (marketing of seeds) under corporate stewardship plans until such time as the technology provider has obtained sufficient import authorizations from foreign governments. It is imperative that such import authorizations be in place to provide U.S. grains and oilseeds with competitive, reliable and efficient access to international markets. The reality is that bulk grain and oilseed shipments “may contain” a biotech-enhanced event that has been made available to producers for commercial production. Any biotechnology trait present in such shipments that lacks approval in a country of import will confront an impossible-to-achieve zero tolerance in that country. The consequences of such occurrences are dire, including impeding the ability of importing countries to provide for food security, imperiling present and future market opportunities for U.S. farmers, and unrecoverable and extensive product and shipment-rejection costs to the U.S. production and grain marketing system.

These international authorizations need to be in place at the time seed containing the event first is purchased by producers. U.S. corn producers often make their initial seed purchase decisions in the fall prior to spring planting – about the same time as international buyers begin substantial contracting for delivery of the next year’s harvest. Given that such contracts are contingent upon receiving authorizations for all biotech-enhanced events that may be present in the commodity shipment, NAEGA and NGFA believe import authorizations need to be in place at least one year prior to harvest-time deliveries from U.S. farms.

However, we recognize that technology providers may find the opportunity for economic reward attractive enough to avoid completing U.S export market approvals prior to product launch in the United States. In such cases, appropriate restraints and responsibility for risks imposed on downstream stakeholders when and after a crop biotechnology event is in production must be part of all technology providers’ product stewardship commitments. Such restraint and risk responsibility is critically important when crop biotechnology is deployed under regulatory systems like the science-based U.S. coordinated regulatory framework, which does not apply an international merchantability or marketability test prior to commercialization of the genetically engineered event. Under no circumstances can or should the grain handling, processing or export industry sectors in the United States or abroad be expected to shoulder the financial risks associated with market disruptions that they have little, if any, ability to control or manage. Rather, the technology providers that do have the ability to control such exposure – and reap the economic reward of commercialization prior to authorization of their products in international markets – must be held responsible. Doing otherwise creates market risk, and undermines the ability of U.S. agriculture to contribute to global food security, as well as to U.S. economic growth and job creation.

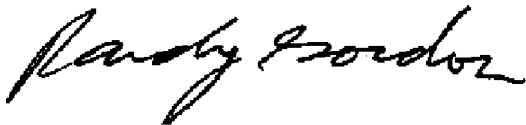
To this point, Pioneer has not shared with us its plans for obtaining sufficient international authorizations for import of DP-ØØ4114-3. Failing to do so in such key grain and oilseed importing markets as Canada, China, the European Union, Japan, Mexico, Philippines, South

Korea and Taiwan would create a risk of significant economic losses to U.S. grain and oilseed producers and markets if this event becomes present in shipments intended for such countries. We do believe it is important, as part of the rulemaking docket associated with this petition, for the technology provider to specify the foreign country governments whose authorizations it intends to secure prior to commercialization, and to commit to doing so. Further, we urge Pioneer to commit publicly through this docket to develop and implement sufficient risk-management (stewardship) commitments commensurate with the extent to which import authorizations ultimately are obtained from foreign governments so as to protect the integrity of the general commodity stream, as well as risk-responsibility commitments in the event its risk-management protocols subsequently prove to be inadequate and result in rejections of shipments in U.S. export markets.

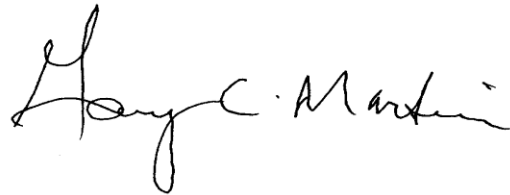
We encourage APHIS to take into full account Pioneer's commercialization plans for DP-ØØ4114-3 prior to granting deregulation of this event. Doing so is consistent with APHIS's mission of to "protect the health and value of American agriculture and natural resources."

We appreciate APHIS's consideration of these viewpoints on DP-ØØ4114-3, and would be pleased to receive and respond to any questions the agency or Pioneer may have.

Sincerely,



Randall C. Gordon
President
National Grain and Feed Association



Gary C. Martin
President and Chief Executive Officer
North American Export Grain Association