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Regulatory Analysis and Development  
PPD, APHIS, Station 3A-03.8,  
U.S. Department of Agriculture  
4700 River Road, Unit 118,  
Riverdale, MD 20737-1238

**RE: Docket ID Number** APHIS-2020-0098; Pioneer Hi-Bred International, Inc.: Petition for the Determination of Nonregulated Status for Insect-Resistant and Herbicide-Tolerant Maize

Dear Reviewing Official:

The National Grain and Feed Association<sup>1</sup> (NGFA) and North American Export Grain Association<sup>2</sup> (NAEGA) submit these comments in response to the U.S. Department of Agriculture Animal and Plant Health Administration's (APHIS) notice, published in the November 3, 2020 *Federal Register*, regarding Pioneer Hi-Bred International's "Petition for the Determination of Nonregulated Status for Insect Resistant and Herbicide-Tolerant Maize (DP23211)." We urge that this petition be given full, fair and prompt consideration by the agency.

In so doing, 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

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<sup>1</sup> Established in 1896, the NGFA is a U.S.-based nonprofit trade association that consists of approximately 1,000 grain, feed, grain processing, export and other grain-related firms that operate more than 7,000 facilities and handle more than 75 percent of the U.S. grain and oilseed crop. Also affiliated with NGFA are 33 state and regional grain, feed and agribusiness associations. Given the diversity of NGFA's membership, which includes biotechnology owners and providers, the views expressed in this statement may not necessarily reflect the views of every NGFA associate or affiliate member.

<sup>2</sup> NAEGA promotes and sustains the international trade of grain and oilseeds from the United States. Established in 1912, NAEGA's members include private and publicly owned companies and farmer-owned cooperatives serving the bulk grain and oilseed exporting industry. NAEGA represents the industry in communications with foreign buyers, U.S. and foreign governmental bodies, and before international institutions. NAEGA-member companies ship and support the vast majority of the highly competitive and fungible U.S. grain export supply.

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 U.S. agriculture, which 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 adequate fungibility and efficient marketing of the abundant and competitive 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 Critical Nature of Value Chain Communication**

We commend Corteva, Pioneer Hi-Bred's parent company, for the recent launch of its public Seed Product Directory (<https://www.corteva.com/transparency.html>), which provides a level of transparency about the breeding technology used to create each variety of its corn, soy and canola portfolio sold in North America. We also commend Pioneer for submitting for consultation a voluntary safety and nutritional assessment of DP23211 maize to the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA CFSAN) in 2019 and a registration application to the U.S. Environmental Protection Agency's Biopesticides and Pollution Prevention Division (BPPD) under FIFRA Section 3.

These actions are consistent with our organizations' overarching belief that technology providers bear a responsibility to lead comprehensive educational efforts to inform other stakeholders and consumers about the benefits and risks, if any, associated with plant-breeding innovation. When technology providers proactively reach out to our associations to share information and begin the dialogue on biotechnology traits and grain marketability as early as possible in the pipeline process, our organizations can better fulfill our member companies' responsibility to communicate back to them regarding issues or concerns about developments in markets our members serve. This is particularly important for preserving U.S. export markets, where foreign government authorities may have different approaches for providing regulatory oversight of all gene-edited, as well as transgenic, seeds that are created with biotechnology that rightfully should affect technology providers' plans and schedules for seeking trait approvals/authorizations, as well as decisions about whether and when to release the seed for such traits for planting in the United States.

Early and constant communication between technology providers and stakeholders – from producers to grain handlers to consumers – has never been more critical given APHIS' decision to finalize its so-called "SECURE" rule on May 14, 2020. Under this rule, technology providers soon will be granted the unilateral authority to "self-determine" whether their plants are exempt from APHIS regulatory oversight. This regulatory decision comes without any obligation for the technology provider to notify the agency, the marketplace or consumers about the event(s) being commercialized. Therefore, it is quite possible there could be genetically engineered, including gene-edited, crops in the market without the knowledge of USDA, other federal agencies and/or the remainder of the food value chain within the United States or internationally. Unfortunately, APHIS decided not to require pre-market notification to the agency of a genetically engineered/gene-edited plant that the developer has determined meets one or more of Part 340's new exemptions prior to introduction into the marketplace – contrary to the wide support for such notification from more than a dozen trade associations representing technology providers, bakers, food companies, processors, grain handlers, millers and consumers, which would have

helped alleviate trade concerns and promoted consumer trust. Despite APHIS's failure to do so, we urge all technology providers to commit to bringing their products through APHIS' voluntary regulatory status review process (RSR) and obtaining a letter confirming that the product is exempted from USDA/APHIS oversight before commercializing such traits.

### **NGFA and NAEGA Support Biotechnology, Marketability and Responsible Commercialization**

As we have stated repeatedly in previous filings with the agency, our organizations support utilization of plant breeding innovation 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. 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 the use of 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 resulted in substantial benefits for consumers.

However, 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.

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 they originate. Grain supplies that can be comingled without concern over their regulatory status can be accessed in a timely, efficient and competitively priced 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 an adequately fungible supply of grains and oilseeds are critical.

Therefore, 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.

In that regard, it is important that APHIS be aware that 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 all – transgenic and gene-edited included – genetically engineered (GE) crops; and 2) commercialization of products with unique functional characteristics (of which DP23211 is not) and the need for responsible commercialization to enable coexistence between different crop technologies and the needs and requirements to enable U.S. agricultural products to be marketed.

Given these considerations, NGFA and NAEGA believe biotechnology providers introducing such events should take the following steps to address marketplace risks:

- **Risk Assessment:** Biotechnology developers, prior to releasing biotechnology-enhanced events into the marketplace – including prior to any pre-commercialization or test production and marketing activities associated with such products – should determine if

there is a threshold level at which it is inappropriate for such events to be present in the general commodity stream because of potential adverse economic, market or food/feed functionality impacts. (We would stress that in the absence of key export market approvals, this threshold currently is zero.) These risk assessments should be discussed with appropriate stakeholders in the value chain prior to approval of such biotech-enhanced events.

- **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:** In instances of a failure to adequately assess and/or manage a biotechnology-enhanced event's adverse market impacts, the biotechnology provider should accept responsibility for the impacts and resulting costs incurred by other stakeholders in the supply chain that are directly associated with the release of the event.

In addition, organizations like Excellence through Stewardship, the Biotechnology Innovation Organization and CropLife International, which represent plant science and biotechnology companies, have developed standards and policies for coexistence and stewardship. Under these standards, technology owners are expected to communicate promptly, broadly and in a transparent manner with stakeholders. Again, 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.

In this regard, we would note and commend the fact that Pioneer Hi-Bred's petition does include Corteva's responsible regulatory approach for DP23211 maize:

*“Corteva is committed to robust product stewardship prior to launch and continuing through product discontinuation. Corteva is a member of Excellence Through Stewardship® (ETS). Pioneer products are commercialized in accordance with Corteva policies regarding stewardship of those products and with ETS Product Launch Policy Stewardship Guidance.”*

NGFA and NAEGA appreciate the willingness of Corteva/Pioneer to engage in an ongoing dialogue with us and our member companies on the important issues of product stewardship and securing the necessary foreign market approvals to avoid trade disruptions.

### **Conclusion**

To reiterate, NGFA and NAEGA recommend that Pioneer's Petition for a Determination of Nonregulated Status for Insect Resistant and Herbicide-Tolerant Maize be given full, fair and prompt consideration by the agency.

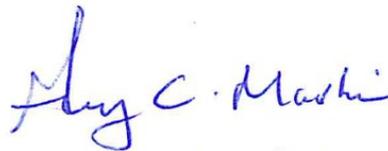
NGFA and NAEGA support the use of balanced biotechnology policies – including policies that effectively address marketability risks and impacts – to ensure the successful development and processing of foods for humans and animals from all agricultural cropping systems.

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

Sincerely,



**Randall C. Gordon**  
President  
National Grain and Feed Association



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