National Grain and Feed Association

North American Export Grain Association

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March 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-2012-0033***
Preliminary Decision for Extension of Determination of Nonregulated Status of Corn Genetically Engineered for Herbicide Tolerance (HCEM485)

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 from Stine Seed Farm Inc. seeking nonregulated status of its biotechnology-enhanced corn event (HCEM485) that has been genetically engineered for tolerance to the herbicide glyphosate.

Specifically, Stine Seed Farm requests the U.S. Department of Agriculture's Animal and Plant Health Inspection Service to extend its determination of nonregulated status of Roundup Ready® corn line GA21 to apply to its maize line HCEM485. For the reasons explained subsequently in this statement, NAEGA and NGFA emphatically object to Stine Seed Farm's petition, and urge APHIS to maintain regulated status for HCEM485 until such time as Stine Seed provides verified information that it has obtained sufficient international import authorizations for HCEM485 to avoid roiling export markets.

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 our country 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 voluntary restrict commercialization (marketing of seeds) under corporate stewardship plans until such time as the technology provider has obtained sufficient authorizations from key 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, import authorizations need to be in place at least one year prior to harvest-time deliveries from U.S. farms.

Technology providers may find the economic opportunity attractive enough to avoid completing key international approvals prior to product launch in the United States. However, appropriate restraints and responsibility for risks imposed on downstream stakeholders when and after a crop biotechnology product is in production must be part of all technology providers' product stewardship. 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 do 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.

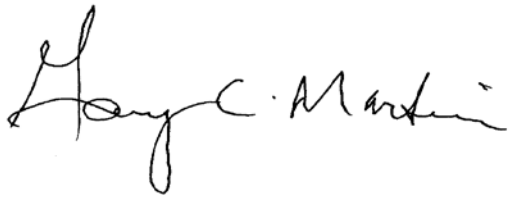
We believe HCEM485 is a unique genetic event that requires approvals and authorizations from foreign government competent authorities for import for use in food, feed and processing. To our knowledge, Stine Seed Farm Inc., as of this date, either has not made application nor been successful in obtaining any international authorizations for import of HCEM485. Further, we have not been made aware of – nor can we find – any public information on Stine Seed Farm's plans to control exposure of commodity corn to the HCEM485 trait – corn that is subject to export to significant U.S. international markets. Failing to obtain such authorizations in such key corn import markets as Japan, Canada, China, Mexico, the European Union, the Philippines, South Korea and Taiwan would create a risk of significant economic losses to U.S. corn producers, grain handlers, exporters and others in the value chain if this event becomes present in shipments intended for such countries.

Given the apparent lack of actions and commitment by Stine Seed Farm to be responsible for international approvals and authorizations for HCEM485, NGFA and NAEGA strongly object to a determination of nonregulated status for this biotech-enhanced corn trait.

We would be pleased to receive much-needed factual information from Stine Seed Farms Inc., APHIS or other credible parties on how the responsibilities associated with the commercial introduction HCEM485 are being met by Stine Seed Farms. But until that happens – and the information provided can be verified – NAEGA and NGFA urge APHIS to take into full account what appears to be Stine Seed Farm's total lack of responsibility in assessing export market risk as part of its commercialization plans for HCEM485 prior to granting deregulation of this event. Doing so is consistent with APHIS's mission to "protect the health and value of American agriculture and natural resources."

We appreciate APHIS's consideration of these viewpoints on HCEM485, and would be pleased to receive and respond to any questions the agency or Stine Seed Farms may have.

Sincerely,



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