



National Grain and Feed
Association



North American Export
Grain Association

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February 27, 2012

Regulatory Analysis and Development
PPD, APHIS
Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Re: *Docket No. APHIS-2011-0095*
Determination of Nonregulated Status of Soybean Genetically Engineered
to Produce Stearidonic Acid (MON 87769)

Dear Sir/Madam:

The National Grain and Feed Association (NGFA) and North American Export Grain Association (NAEGA) submit this joint statement in response to the notice published in the December 27, 2011 *Federal Register* by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). The notice requests comments on the petition from Monsanto Company seeking a determination of nonregulated status for its biotechnology-enhanced soybean event (MON 87769) that has been genetically engineered to produce high levels of stearidonic acid, an omega-3 fatty acid not found in conventional soybeans.

The 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 operations; biofuel producers; cash grain and feed merchants; end-users of grain and grain products including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries.

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.

Our organizations understand the prospective benefits of this new event – MON 87769 – and generally support the development of products with unique functional characteristics (PUFC). However, such new products that are not functionally equivalent to commodity grains and oilseeds present unique regulatory and marketing challenges, which need to be addressed carefully prior to deregulation by APHIS.

The NGFA and NAEGA believe biotechnology providers have several corporate responsibilities pursuant to the commercial introduction of biotechnology events, including PUFCs, that may be introduced into the U.S. commodity stream.

The first of these is the voluntary restriction of commercialization (marketing of seeds) under corporate stewardship plans until such time as the technology provider has obtained sufficient authorizations from foreign governments with functioning, predictable systems for approving biotech-enhanced events in U.S. export markets to avoid causing significant market disruptions. In this regard, it is our understanding that Monsanto intends to commercialize, under controlled conditions of a closed-loop supply chain, prior to obtaining such authorizations from competent authorities of foreign governments in important U.S. export markets. That imposes on grain handlers, exporters and others in the value chain the risk of attaining a zero tolerance for unauthorized events. The NGFA and NAEGA believe that it is imperative that technology providers extend concrete commercial assurances to downstream stakeholders to compensate for economic damages if the technology provider decides to knowingly commercialize a biotechnology-enhanced trait prior to approval or authorization of a biotechnology-enhanced trait in one or more key export markets, thereby creating regulatory-compliance risk for others in the value chain if the technology provider's risk-management system proves to be deficient.

While a closed-loop system might envision controls and incentives that will encourage growers to segregate and deliver the crop appropriately, there is always the potential occurrence of human error or weather and marketing disruptions that could arise that create incentives for such PUFCs and all biotechnology-enhanced events lacking sufficient international authorizations to move outside the closed-loop system. If this were to occur, U.S. exporters could face rejection at importing countries, and domestic grain handlers, soybean processors and food companies could confront additional risks and costs of addressing food-grade commodity oil impacts.

Therefore, until such commercial assurances are provided by Monsanto with respect to MON 87769, NAEGA and the NGFA respectfully urge that APHIS maintain the regulated status of this product.

A second corporate responsibility of technology providers applies to situations involving commercial introduction of PUFCs not intended to be commingled in the general commodity stream. That, in turn, also involves putting in place comprehensive and effective risk-management practices that prevent the introduction of such events in commodity streams where the PUFC's presence is inappropriate.

Concerning this key aspect, our understanding – based upon consultations with the National Oilseed Processors Association (NOPA), which has had access to data to which our organizations have not – is that accidental or intentional commingling of MON 87769 with oil

produced from commodity soybeans can affect adversely the functional characteristics of commodity soybean oil, as well as the nutritional labeling claims and the accuracy of labels.

Monsanto itself has recognized the potential for damage to the existing oilseeds complex, and has responded by proposing to APHIS that MON 87769 soybeans be managed through the closed-loop supply chain system cited previously. It is the view of NAEGA and the NGFA that prior to deregulation of this product by APHIS, such information should be made publicly available to stakeholders in the value chain, including our members, so that they may assess the impact of this product and the sufficiency of Monsanto's closed-loop risk-management plan.

Further, it is our understanding from NOPA that Monsanto has accepted responsibility and liability for overall risk management for MON 87769 soybeans in the supply chain only for a limited time period – namely, prior to major international market approvals, and not through the product's entire life cycle. The NGFA and NAEGA do not believe the oilseed handling, marketing and processing sector should be expected to shoulder the market risks and financial costs associated with a failure of a closed-loop system to control PUFCC events adequately, as well as the costs of testing programs at origin and/or product rejection at destination in either export or domestic markets at any time during the product's entire lifecycle.

As this and other PUFCC events are introduced into the market, there is a need for involvement of the commercial grain/oilseed export, handling and processing sectors to improve the chances for market success. But to accomplish this, these industry sectors cannot be expected to shoulder the risks of market disruptions. Rather, it is those companies that develop such products – the technology providers – that must be willing to provide reasonable commercial assurance for such products, and clearly state that they are willing to stand behind the products and ameliorate the risks they may pose. Doing otherwise creates market risk, and undermines the ability of U.S. agriculture to contribute to global food security, as well as U.S. economic growth and job creation.

Within the U.S. grain and oilseed handling, marketing and processing system, each company makes its own determinations as to whether to accept various commodity crops – including those containing biotech-enhanced events – driven by customer preferences, regulatory regimes, contractual commitments and the respective markets they serve. Given the nature of the U.S. grain marketing system, these business decisions extend to the first point of sale from the producer. This fundamental freedom inherent in our industry's ability to operate fosters the coexistence of the diverse interests involved in the production, marketing and consumption of U.S. agricultural products.

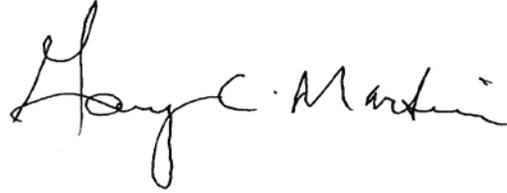
In summary, the NGFA and NAEGA cannot support deregulation of MON 87769 until such time as Monsanto provides written assurances to value-chain stakeholders and as part of the public record of this proceeding that it will commit to implementing its closed-loop system and accept such commercial responsibility for supply chain disruptions throughout the lifecycle of this biotechnology-enhanced event once the trait is deregulated and commercialized.

The NGFA and NAEGA appreciate APHIS's consideration of these viewpoints on MON 87769, and would be pleased to respond to any questions the agency may have.

Sincerely,



Randall C. Gordon
Acting President
National Grain and Feed Association



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