National Grain and Feed Association

NAEGA North American Export Grain Association

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August 29, 2011

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

Re: Docket No. APHIS-2011-0046
Genetically Engineered Soybean MON 87705

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 June 28, 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 87705) that has been genetically engineered to have a modified fatty acid profile and for tolerance to the herbicide glysophate.

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 healthful benefits of this new event – MON 87705 (Vistive® Gold) – 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.

Biotechnology providers have several corporate responsibilities pursuant to the commercial introduction of biotechnology events that may be introduced into the U.S. commodity stream. First 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. A second corporate responsibility applies to situations involving commercial introduction of PUFCs not intended to be commingled in the commodity stream; that involves putting in place comprehensive and effective quality-assurance practices that prevent the introduction of such events in either domestic or export commodity streams where the PUFC's presence is unauthorized or inappropriate.

This particular biotech-enhanced product (MON 87705) presents two primary challenges with respect to entering the market for food and feed products. First, according to the biotechnology provider (Monsanto) and based upon a separate submission to this record by the oilseed processing industry (which has had access to data to which our organizations have not), accidental (or intentional) commingling of commodity soybean oil with oil derived from MON 87705 soybeans can affect adversely the functional characteristics of commodity soybean oil, as well as the nutritional labeling claims and the accuracy of labels. Second, the MON 87705 soybean has not yet received international approvals in major export markets for soybeans and soy products. Monsanto has indicated it is pursuing regulatory review in all major markets, and has projected a timeline for acceptance internationally. However, we urge Monsanto to make available as part of the public record at least summaries of both its expectations about the timing of such international approvals, as well as its evaluations of the potential impacts of comingling of MON 87705 with commodity soybeans and soybean products under each of the stewardship scenarios it plans to employ, as well as under an unrestricted commercialization regime.

To minimize the risk of inadvertent mixing of MON 87705 with commodity soybeans, soyoil, or soymeal, Monsanto has proposed a closed-loop system to operate in 2012 and 2013 with very limited acreage, a single processing plant and a very limited number of growers and buyers that agree to deliver such specialty biotech-enhanced soybeans within the closed loop. Depending upon market response to this new product (demand, progress with approvals, etc.), tentative plans are to expand the program in 2014 and change the marketing system from closed-loop to identity-preserved, with markets driving premiums. However, if there are other risk factors that still need to be addressed at that time (i.e., such as non-approvals, or other problems that surface during commercialization), the company has informed us that it is willing to extend the closed-loop system an additional year into 2014, as well.

NAEGA and NGFA believe that Monsanto's design of a closed-loop system (as verbally described by Monsanto to our organizations during a meeting in late August 2011) – if implemented as intended – holds promise to appropriately manage the potential for commercial disruption in U.S. domestic commodity soybeans, processed products and in international trade. However, we wish to reiterate that until sufficient international authorizations are in place – most likely at least two years after the proposed non-regulated status is initiated – Monsanto's closed-loop system will have the added responsibility of preventing the presence of MON 87705 in U.S. export shipments.

In any case, 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 grain handlers, soybean processors and food companies could confront additional risks and costs of addressing food-grade commodity oil impacts.

Within the U.S. grain and oilseed handling and marketing 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. We believe Monsanto recognizes this fundamental freedom to operate with respect to our industry's work to provide for coexistence of the diverse interests involved in the production, marketing and consumption of U.S. agricultural products.

As this and other PUFCs 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 over which they have little, if any, ability to control or manage. 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.

We are pleased that as a result of our on-going experiences, and recent communications with Monsanto, that it accepts overall responsibility for supply chain disruptions that may be caused by negligence on its part, or through the fault of parties contracted to be in the closed loop. Likewise, we believe Monsanto has made commitments to responsible actions related to the product's entire lifecycle. We do believe it would be helpful if Monsanto were to make its commitment to corporate responsibility public to all stakeholders in the value chain.

The NGFA and NAEGA appreciate APHIS's consideration of these viewpoints on MON 87705, and would be pleased to respond to any questions the agency may have.

Sincerely,

Kendell W. Keith
President
National Grain and Feed Association

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