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

RE: DOCKET NO. APHIS-2017-0096
(Nuseed B0050-27)

Dear Sir/Madam:

The National Oilseed Processors Association (NOPA)¹, the National Grain and Feed Association (NGFA)² and the North American Export Grain Association (NAEGA)³ appreciate the opportunity to comment to the United States Department of Agriculture's (USDAs) Animal and Plant Health Inspection Service (APHIS) on the Nuseed Americas Inc. [Nuseed] event B0050-027. This event has been developed (genetically engineered) to accumulate the long chain omega-3 fatty acid known as docosahexaenoic acid in seed. We would consider this to be a Product with Unique Functional Characteristics (PUFC).

Commercial seed products currently on the market have allowed growers to increase crop yield, decrease crop inputs and increase the use of conservation tillage. These technological advances have been largely successful for U.S. growers, processors and exporters, and going forward NOPA, NGFA, and NAEGA support the use of balanced biotechnology policies to ensure the success of trade and processing of grains and oilseeds and their derivative products.

The recent emergence of a new class of Genetically Engineered (GE) products that have unique functional characteristics (hereafter referred to as PUFCs) have the potential to create additional value-added specialty product supply chains in the United States, if/when they map to true market needs and are effectively pulled by downstream stakeholders in the supply chain (processors, ingredient manufacturers, branded food companies).

¹ **National Oilseed Processors Association** (NOPA), represents the U.S. soybean, sunflower seed, canola, flaxseed and safflower seed crushing industries. NOPA's 13-member companies crush approximately 95% of all soybeans processed in the United States. NOPA member companies process more than 1.8 billion bushels of soybeans annually at 64 plants located throughout the country, including 58 plants that process soybeans.

² **National Grain and Feed Association** (NGFA), established in 1896, is a U.S.-based nonprofit trade association that consists of approximately 1,050 grain, feed, grain processing, export and other grain-related firms that operate more than 7,000 facilities and handle more than 70 percent of the U.S. grain and oilseed crop. Affiliated with NGFA are 26 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.

³ **North American Export Grain Association** (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-member companies ship and support the vast majority of the highly competitive, sustainable and fungible U.S. grain export supply.

Functionally unique products are intended to be delivered through fully segregated supply chains to both preserve the integrity of the novel product and to minimize the negative impacts of the comingling of PUFs with existing commodity supply chains. All partners in the product-specific supply chain as well as technology owners have recognized that the mismanagement of PUFs can have significant impacts on existing commodity supply chains.

Since there is an inherent risk an agricultural supply chain cannot be managed to achieve 100% segregation, the responsible commercialization of PUFs requires a comprehensive review of the potential for significant impacts to the quality (specifications) of the existing fungible, commingled commodity supply. Generally, the goal should be to determine the level of impact of the unintended presence of PUFs and a corresponding plan to manage the PUF in a way that does not negatively impact stakeholders in the United States and foreign markets.

The level of impact of the comingling of PUFs with the commodity supply must be examined on a case-by-case basis, as some products may have little impact while others have significant impact. On this basis, downstream stakeholders have asked the technology developers to commit to responsible commercialization in the introduction of PUFs to ensure that both the commodity and specialty supply chains can coexist effectively and with a clear understanding of the PUFs' value and the potential risk prior to commercialization.

We believe that there must be widely available information and a strong commitment to work transparently with stakeholders in addressing three key areas: (1) a proper risk assessment of the impacts of the product on existing food and feed processes and products; (2) the development of a sufficient risk management plan based on the assessed risks to food and feed processes and products; and (3) a commitment by the developer of the new technology that their responsibility for proper handling and use of the product extends beyond the seed sale. These areas must be addressed adequately with continued follow up and communication to impacted industries through all phases of commercialization.

In recent years when technology providers have submitted grain and oilseed petitions to APHIS, they have reached out to our associations and provided the opportunity for a dialogue and sharing of information and in some instances, commitments to product launch stewardship. This has been a particularly valuable dialogue with several companies who have introduced PUFs to properly define the threshold of impact for comingling, ensure stakeholders understand the rigor of the risk management system to be deployed, and understand the risks being placed on the market. Unfortunately, Nuseed made no attempt to communicate any information or commitments to product launch stewardship to NOPA, NGFA or NAEGA. Therefore, due to the lack of dialogue and communication and no understanding or commitment to responsible commercialization, we cannot support a determination of nonregulated status of Event B0050-27.

We believe agricultural biotechnology providers have several inherent responsibilities associated with the responsible commercial introduction of their biotechnology-enhanced events intended for the U.S. commodity system. Consistent with this belief, as part of their commercialization of biotechnology events in cases where a product-specific value chain is employed either to manage a product with unique functional characteristics (PUFs) supply chain or address export market risks, we expect the following three commitments to be met by agricultural biotechnology providers:

- **Risk Assessment:** Agricultural biotechnology providers/owners should characterize at what level of comingling their new product will negatively impact either export market access or the functional characteristics of the commodity ingredient (level of impact). For example, at what threshold is there a significant negative impact on the commodity supply chains? This data, once developed, should become a matter of public record.
- **Risk Management:** Once the level of impact is determined, agricultural biotechnology providers/owners should establish a product-specific supply chain to keep the product segregated and tracked to ensure that the novel product does not escape into the commodity supply chain above the impact level/threshold.
- **Risk Responsibility:** When the agricultural biotechnology provider/owner fails to effectively assess and/or manage their product's impacts, they should accept responsibility for economic damages to downstream stakeholders caused by their failure to manage the novel product.

Importantly, APHIS has a responsibility to carefully review products of modern biotechnology ahead of deregulation on a case-by-case basis to clearly understand the direct and indirect impacts on the diverse interests of U.S. agriculture. APHIS must provide careful review and should consider scientific data assessing the risks to food functionality, risk mitigation and risk responsibility in its review of such traits as Event B0050-27.

Our organizations remain committed to and believe that the responsible use of biotechnology can play an important role in production agriculture. To that end, we expect biotechnology providers to deploy prudent and comprehensive risk management through effective and responsible stewardship programs.

A key element for our support of any request for a "determination of nonregulated status" by APHIS will be based upon the technology provider's commitments to the responsible commercialization of the product and U.S. oilseed, grain, and feed stakeholders specifically relating to: (1) Risk Assessment, (2) Risk Management and (3) Risk Responsibility.

In some cases, the agricultural biotechnology provider/owner may decide to "pre-commercialize" these traits ahead of U.S. export market approvals, justified by the inherent need to test-market the products prior to full commercialization. Since no supply chain can effectively channel products with 100% precision, there is an inherent risk that an escape of the unapproved event will be detected in a U.S. export market and that significant market disruptions will occur given the zero-tolerance applying to U.S. export cargoes.

As stated earlier, irresponsible commercialization of Genetically Engineered (GE) traits without first obtaining the necessary approvals in U.S. exports markets has led and will continue to result in commercial impacts/disruptions in domestic supply chains and this will be unacceptable by international customers of U.S. grains and oilseeds. Disruptions caused by these products will damage the image of many U.S. products in international markets and all such products, irrespective of their value or degree of involvement, will be regarded negatively. It is thus likely that buyers will require exclusions from export shipments of such products.

We do not support commercialization prior to export market approvals and consider a “pre-commercial release” no different than a product commercialization, since the potential risks and impacts are the same. Our organizations cannot support this approach and we urge agricultural biotechnology developers to fully bear the risks and liabilities associated with any commercialization of their products should market disruptions occur prior to obtaining approvals in U.S. export markets.

NOPA, NGFA and NAEGA member companies will make their own independent business decisions regarding the commercialization of any specific GE crops or PUFs, based on that company’s individual assessment of the risks and rewards.

NOPA, NGFA and NAEGA appreciate the opportunity to comment on this proposed deregulation; however, we cannot support USDA /APHIS moving this product forward under these circumstances.

Sincerely,



Thomas A. Hammer
President
National Oilseed Processors Association



Randy Gordon
President
National Grain and Feed Council



Gary C. Martin
President/CEO
National American Export Grain Association