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To Whom It May Concern:

The North American Grain Export Administration (NAEGA) is pleased to submit comments to Docket No. APHIS-2006-0112, "Introduction of Organisms and Products Altered or Produced through Genetic Engineering; Notice of availability of draft environmental impact statement and request for comments." 72 FR 39021; July 17, 2007.

NAEGA is a not for profit trade association, established in 1912, consisting 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 oilseed trade from the United States. NAEGA acts to accomplish this mission from its office in Washington D.C. and in markets throughout the world. NAEGA therefore has a keen and obvious interest in regulations and policy affecting the production and trade of grains and oilseeds of all types, including those improved through biotechnology. The proposed regulatory and policy changes covered in the docket cited above are of great interest to our members and we offer the following comments and suggestions.

NAEGA believes that grains and oilseeds improved through biotechnology are an increasingly important and critical part of the provision of food, feed and fuel from global agricultural systems. To be competitive in global markets the United States must continue to lead the way not only in research and development and marketing of new production increasing and value added products, but also in adopting effective, efficient, science-based policies and regulations to deal with such products. We support APHIS' intent to improve and adapt the current regulations to the products and issues that are relevant today as well as those we can anticipate by looking ahead. In particular, we support APHIS in moving to more closely match the degree of oversight and regulatory review to the level of risk entailed in the products covered. The rapid entry of new products into the marketplace over the past decade, and burgeoning experience with these new products, mean such rationalization is timely and due. Many of the changes proposed by USDA in the docket go toward improving policies and regulation in this way.

We wish to point out and emphasize that it is critical to ensure that unauthorized biotechnology not be present in the food and feed supply. All modifications to crops commercially used for food or feed must have regulatory approval that recognizes their exposure to food and feed. Such regulatory approval must include a sound science based approach to the potential Adventitious Presence (AP) of such modification in the supply destined for food and feed use. In the absence of a comprehensive regulatory structure to manage AP, all modifications to crops commercially used for food or feed must have complete regulatory approval for use as food and feed. Marketing biotechnology in crops in advance of critical international authorizations is of great concern for

US exports of grains and oilseeds – indeed all crops - that are exposed to crops produced using modern biotechnology. It is important that all stakeholders understand that US farmers and the grain export industry have relied on the commercial responsibility of technology providers to maintain access to major export markets as new biotechnology derived events become commercialized. One of the principle measures of maintaining access has included the voluntary restriction of commercialization until such time as the technology provider has obtained export market authorizations that are adequate to avoid significant disruption of markets. Over the last several years, we believe this process has eroded and subsequently failed US agriculture several times. We are encouraged by recent efforts of the biotechnology industry to institute good practices to improve this process and we seek to minimize government interference with commercial activity related to meeting customer needs. NAEGA believes that commercial solutions are the most effective and preferable means to meet customer needs for unique commodities, including those that have requirements related to biotech content. The best way to overcome global controversy and trade disruption in bulk commodity shipments due to products derived from modern biotechnology is the adoption of a comprehensive, harmonized, global regulatory approval and authorization process that addresses key issues like AP. Until such a process is in place, commercialization of new biotech products without prior approval by the governments in the major international markets for such products should be avoided.

More directly to the dEIS, NAEGA notes that one cumulative impact APHIS does not consider in the dEIS should be addressed: that is the cumulative impact on the environment resulting from an artificial prolongation of market dominance by obsolete varieties or agricultural practices due to the retarded introduction of newer and safer alternatives as a consequence of excessive regulation. After more than 20 years experience with crops improved through biotechnology the wisdom of numerous studies by panels of the US National Academy of Sciences and other competent expert bodies has been reaffirmed that such crops are at least as safe as their conventional counterparts, if not safer, and there is no science-based reason to single them out for special or severe regulatory attention. We understand there is a wide sense of frustration among the research community that regulatory oversight for transgenic crops is significantly more burdensome than can be justified on any scientific grounds. APHIS should consider in the dEIS the environmental opportunity costs of new varieties being slowed due to regulation that imposes such disproportionate burdens.

Specific comments on the issues framed by APHIS follow.

ISSUE 1 -- REGULATORY SCOPE -- “APHIS is considering the broadening of its regulatory scope beyond genetically engineered organisms that may pose a plant pest risk to include genetically engineered plants that may pose a noxious weed risk and genetically engineered organisms that may be used as biological control agents. Do regulatory requirements for these organisms need to be established?”

- NAEGA supports the proposal to expand APHIS authority under noxious weed provisions of the PPA of 2000 as described. We note, however, the terms used in the statute lend themselves to potential misunderstanding and abuse. We encourage APHIS to be prepared to explain and justify the proposal in language that is not possible to convert to inappropriate use, and actively to counter and correct such when it occurs;
- NAEGA supports the proposal to expand authorities to deal with biological control organisms;

- The proposed shift from event based to trait based oversight is highly praiseworthy. NAEGA supports this proposal and encourages APHIS to move as rapidly and as far in this direction as possible;
- NAEGA supports, with the conditions of further clarification, the proposal to exempt certain organisms under specified conditions of demonstrated safety.

ISSUE 2 -- RISK BASED CATEGORIES -- “APHIS is considering revisions to the regulations to increase transparency and to address advances in technology that may create new products and concerns. Should a new system of risk based categories be designed to deal with new products and new concern? If so, what criteria should be used to establish the risk-based categories?”

The suggestion that for plants that present unresolved risk concerns, the Agency should be in a position to adopt appropriate risk mitigation measures to allow commercial planting to occur is consistent with the goal of ensuring adequate protection of health, safety and the environment. This would represent a departure from current USDA /APHIS practice for food and feed crops, where commercialization follows a determination of non-regulated status by the Agency that applies to a particular plant, but not to any particular company. The concept of some sort of commercial approval, commercial permit, or commercial authorization does appear to be adequately supported by the Plant Protection Act and such an authorization would only be granted if the unresolved risk concerns have been addressed to the Agency’s satisfaction. This seems to be consistent with the way EPA and FDA act under their respective licensing statutes.

The key issue will be how USDA/APHIS carries out enforcement under this approach. If a plant is "approved, but still regulated" then USDA /APHIS would be responsible for enforcing the conditions of use. Those conditions might include managing commercial practice and controls such as isolation distances, stewardship and quality management programs, etc. We understand EPA and FDA hold the licensee (developer/manufacturer) responsible under similar circumstances and most often the licensee handles that responsibility by educating its licensees, distributors and users and ultimately holding them responsible through contractual arrangements. Presumably this commercial solution will work for USDA/APHIS enforcement.

Hence, the proposal to adopt a tiered approach to reviewing and regulating biotech materials is supported in concept by NAEGA.

Further:

- Alternative 4 seems best suited to facilitating innovation in plants;
- APHIS should follow the data wherever they lead, which argues for a more aggressive move toward expanding the low risk tiers more rapidly than APHIS proposes;
- APHIS should increase transparency with regard for how much increased familiarity it takes to move a regulated article from a higher tier to a lower one;

ISSUE 3 -- REGULATORY FLEXIBILITY AT COMMERCIAL SCALE -- “Issue 3 -- APHIS is considering ways to provide regulatory flexibility for future decisions by accommodating the commercialization of certain genetically engineered organisms while continuing, in some cases, to regulate the organisms based on minor unresolved risks. Other regulated articles could be treated as they have been under the current system, in

which all regulatory restrictions are removed. What environmental factors should be considered in distinguishing between these kinds of decisions?

- NAEGA supports APHIS' proposal to enable APHIS to partially or conditionally deregulate an article;
- We remind APHIS that while the purpose of this additional flexibility is to reduce regulatory burdens and speed products to commercialization and, absent compelling cause, not to erect additional and disproportionate obstacles (as in cases restricting the use of stacked trait plants in breeding programs) it is of paramount importance that unauthorized biotechnology not be present in the food and feed supply. APHIS has stated a commitment more closely to align the level of oversight with that of risk, and this is a good place to bring that commitment to life.
- Although APHIS has framed this issue largely in terms of PMP/PMIPs, there is no reason that multi-year permits should not also be available for crops in other areas of R&D as well.
- In re APHIS' example of a possibly conditional deregulation for a stacked combination of deregulated biotech traits produced through conventional breeding (as on p. 30, line 14ff), it should be noted that while acquiring the ability to issue conditional deregulations is a good idea, this example is not a good one; to do as it suggests would be to depart in a significant way from the precedent APHIS has set in holding more closely to the science than other regulatory regimes around the world in dealing with stacked traits. This is not something that should be contemplated without far more compelling justification than is laid forth in the dEIS.

ISSUE 4 -- PMP/PMIP REGULATION -- "Are there changes that should be considered relative to environmental review of, and permit conditions for, genetically engineered plants that produce pharmaceutical and industrial compounds?"

- NAEGA is concerned with APHIS' inclination to significantly reduce the regulatory constraints it imposes on many PMP/PMIPs . We acknowledge that unless significant impacts would result from an environmental exposure, it does not matter if a confinement approach fails ($Risk = Hazard \times Exposure$; when $Hazard = 0$, exposure is moot). Experience has abundantly confirmed that exposure per se is not equivalent to hazard. Hence under certain conditions APHIS might be able to move forward on this basis.
- In some cases, when confinement measures less severe than contemplated might be justified, we do not agree with regulation that is restrictive to a degree not supported by science. However until such justification is more apparent and internationally accepted, the APHIS' comment on p. 147 that they are "not considering any alternatives that propose a less rigorous system than the one currently in place" represents an appropriate mindset.
- A single risk tier for all PMP/PMIPs would logically be inadequate. In moving to a tiered system, experience demonstrates APHIS might incorporate multiple tiers including a tier or tiers less restrictive for PMP/PMIPs than the baseline level now in place.
- If and only if agreed standards for adventitious presence are implemented on an international scale, medicines and industrial compounds that are already derived from a number of food/feed crops and existing production systems might be produced with

an acceptable method of segregation and prevention from exposure to the food and feed supply.

ISSUE 5 – NOXIOUS WEED AUTHORITY -- “The definition of noxious weed in the PPA includes not only plants, but also plant products. Based on that authority, APHIS is considering the regulation of nonviable plant material. Is the regulation of nonviable material appropriate, and if so, in what cases should we regulate?”

- As stated above, with caveats, NAEGA supports the proposal to expand APHIS authority under noxious weed provisions of the PPA of 2000.

ISSUE 6-- MULTI-YEAR PERMITS FOR COMMERCIALIZATION OF PLANTS NOT INTENDED FOR FOOD OR FEED USE -- “APHIS is considering establishing a new mechanism involving APHIS, the States, and the producer for commercial production of plants not intended for food or feed in cases where the producer would prefer to develop and extract pharmaceutical and industrial compounds under confinement conditions with governmental oversight, rather than grant non-regulated status. What should be the characteristics of this mechanism?”

- NAEGA believes APHIS could, when international acceptance is established, put in place policies consistent with their admission that it is “even likely, that many of these substances do not pose a human-health risk in food and also that they do not pose a risk to agriculture or the environment” (page 34, line 36-7) with containment/management measures that are proportional to this low level of risk (i.e., “very stringent” containment/confinement measures are clearly disproportionate).

ISSUE 7 – LOW-LEVEL PRESENCE/ADVENTITIOUS PRESENCE -- “The current regulations have no provision for the low-level presence of regulated articles in commercial crops, food, feed, or seed of GE plant material that has not completed the required regulatory processes. Should the low-level occurrence of a regulated article be exempted from regulation?”

- We support APHIS putting in place a risk-based policy that accounts for the inevitability of AP/LLP and avoids disruptions to trade that are not justified on the basis of hazard or science.
- We are concerned with the lack of clarity of APHIS’s intent and the level of international acceptance with regard to options for a low-level presence of regulated articles in commercial crops.
- APHIS discusses the issue of coexistence and the impact of their proposed changes in regulations on the USDA Organic Standard, but the discussion is incomplete and in some ways obfuscatory. APHIS should explicitly address the conclusions of the USDA Organic Standards board that the unintentional LLP/AP of biotech material in organic harvests is of no relevance to organic certification under the USDA standard (see http://www.ams.usda.gov/NOP/Q&A.html#Production/Handling_esp_entry_dated_1/14/05).

- APHIS' discussion of safety criteria to enable non actionable treatment of PMP/PMIPs under appropriate conditions should be vetted and proposed for policy and regulations.

ISSUE 8 -- EXPEDITED REVIEW OF LOW RISK IMPORTS INTENDED FOR FFP --
“Should APHIS provide expedited review or exemption from review for certain low-risk, imported GE commodities intended for food, feed, or processing that have received all necessary regulatory approvals in their country-of-origin and are not intended for propagation in the United States?”

- NAEGA supports APHIS' preferred alternative on this issue.

ISSUE 9 – ARABIDOPSIS MOVEMENT EXEMPTION -- “Currently, genetically engineered *Arabidopsis* spp. are exempt from interstate movement restrictions under 7 CFR 340.2 because they are well understood and extensively used in research. Should the movement of genetically engineered *Arabidopsis* spp. or other GE organisms be exempted from movement restriction?”

- NAEGA endorses the proposal, in principle, but reserves judgment in specific cases contingent on particulars of the case, until they can be reviewed in detail.

ISSUE 10 -- PERFORMANCE BASED CONTAINER REQUIREMENTS -- “What environmental considerations should be evaluated if APHIS were to move from prescriptive container requirements for shipment of GE organisms to performance-based container requirements, supplemented with guidance on ways to meet the performance standards?”

- NAEGA supports the proposed shift from prescriptive to performance-based criteria for shipping containers for regulated articles.

Thank you for the opportunity to present these comments. We look forward to working with you on these issues in the future.

Sincerely,



Gary Martin
President & CEO
NAEGA