

March 20, 2009

Mr. Richard Coker
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Comment on Docket No: Docket No. APHIS-2008-0023 Re: USDA Scoping Session on Introduction of Organisms and Products Altered or Produced Through Genetic Engineering

Thank you for the opportunity to comment on the proposed scope and format of the April public meetings on the APHIS proposed rule, "Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms."

The undersigned associations are encouraged by the agency's ongoing efforts in keeping with the goal of streamlining the regulatory system while ensuring the continuation of the rigorous science-based approach to its responsibilities. A broadened scope, increased transparency, rigorous oversight, and enhanced public involvement incumbent in any changes to 7 CFR part 340 (part 340) regulations and the programmatic Environmental Impact Statement (EIS) should serve to increase the credibility of the regulatory system and benefit US agriculture and the nation. In combination with an effective and well developed international communication and coordination with stakeholders, the proposed rule can help US agriculture overcome and prevent numerous trade restrictions related to the innovation of crop biotechnology.

In addition to the many issues already included in the scope of your review, we believe it is important for USDA to address the deregulation process for events created through the use of modern crop biotechnology; where an event is determined to be safe for use in food and feed, but contains functional characteristics that are unique from the more traditional agronomic biotech traits or conventional counterparts.

Specifically, we believe the agency should consider including in the public record an appropriately comprehensive scientific analysis of the material and functional impacts that the event may have on existing food and feed processes and products that is sufficient in scope and rigor to allow downstream stakeholders to determine the level of inclusion or commingling that can occur without negatively impacting product quality/functionality and thus rendering it a plant pest or noxious weed. This we believe would better position the agency to meet its obligations under National Environmental Procedures Act (NEPA).

The Agency should also consider what other information should be provided regarding risk management and risk abatement mechanisms that will be required from the petitioner

to ensure the food and feed sectors are not harmed by a deregulation of an event with unique functional characteristics.

Since the products of GM crops with unique functional characteristics, when found out of place, can render such products a plant pest, of key concern is the need for the regulatory process to clearly address questions concerning the effects of these products presence on the processing industry. Processing concerns such as milling characteristics, feed quality attributes, and impacts on existing food processing systems may need to be addressed in the regulatory process. It is important to understand the impact of the functional difference on downstream stakeholders or related industries.

For example, the current regulatory framework does not provide for the data necessary for the affected industries to determine whether a specific, proposed closed loop channeling program is sufficient to mitigate potential risks. Therefore, USDA should consider requesting information from meeting participants regarding the public disclosure of details on the risk management and risk abatement considerations that are necessary to ensure the appropriate utilization of closed loop systems for handling the specific genetically altered commodity.

There should also be consideration by the Department, as to whether or not the petitions for deregulation of these types of products lack adequate scientific data or documentation necessary to evaluate the possible impacts on food and feed functionality should this type of event be comingled with other supplies of the commodity.

We further suggest that respect to the deregulation and commercialization of all GM events, an adequate risk assessment, risk management, and risk responsibility plan must be put in place by the technology provider. Consideration for such measures and the degree to which they should be included in the APHIS process is needed. In the case of deregulation of those events that contain unique functional characteristics that in turn may result in plant pest that extends damages downstream to users of the commodity for food, feed and processing as well as consumers. USDA might consider posing as part of its quest for transparency and inclusion of stakeholders questions like:

- 1) How much depth of analysis should be required from and be understood by the applicant requesting deregulation regarding “functionality” effects when the product is found out of place;
- 2) What are the appropriate risk assessment, risk management, and risk responsibility mechanisms that should be established and made available to the public prior to a deregulation of this class of products;
- 3) How could differences in functionality have negative impacts on ready-to-eat cereals, snack foods, blended products used for food aid, beverages, as well as livestock feed if such products are not adequately characterized and managed and at what cost;

- 4) How could these unknown effects also negatively affect the exports of U.S. products; and
- 5) Without adequate assessment and risk mitigation actions would the U.S. be subject to the establishment of regulatory and commercial restrictions on U.S. products in international markets?

Thank you for the opportunity to comment and we look forward to working with the agency on these critical issues to help ensure the benefits of agricultural biotechnology are fully realized.

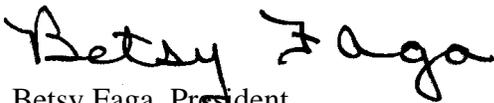
Sincerely,



Kendell Keith, President
National Grain and Feed Association



Gary C. Martin, President and CEO
North American Export Grain Association



Betsy Faga, President
North American Miller's Association