

April 21, 2016

Regulatory Analysis and Development  
Plant Protection Division  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture  
Station 3A—03.8  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

**Re: Docket No. APHIS-2014-0054: Environmental Impact Statement;  
Introduction of the Products of Biotechnology**

Dear Reviewing Official:

The Corn Refiners Association (CRA)<sup>1</sup>, National Grain and Feed Association (NGFA)<sup>2</sup>, National Oilseed Processors Association (NOPA)<sup>3</sup>, North American Export Grain Association (NAEGA)<sup>4</sup> and North American Millers Association (NAMA)<sup>5</sup> respectfully submit this statement in response to the U.S. Department of Agriculture Animal and Plant Health Inspection Service's (APHIS) request for comments on its notice of intent to prepare a programmatic environmental impact statement (EIS) regarding potential changes to its regulations under 7 CFR Part 340 ("Part 340") applicable to the importation, interstate movement and environmental release of certain genetically engineered organisms.

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<sup>1</sup> Corn Refiners Association (CRA) is the national trade association representing the corn refining industry of the United States. CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts, corn oil and feed products from corn components such as starch, oil, protein and fiber.

<sup>2</sup> 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.

<sup>3</sup> NOPA, established in 1930, assists the U.S. soybean, canola, flaxseed, sunflower seed and safflower seed processing industries to be the most competitive and efficient in the world by utilizing the combined expertise, knowledge and resources of its members to foster market- and science-based policies. NOPA represents 12 member companies who process over 1.8 billion bushels of oilseeds annually at 63 plants in 19 states.

<sup>4</sup> 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.

<sup>5</sup> North American Millers' Association (NAMA) represents millers of wheat, corn, oats and rye in the United States and Canada. NAMA members take the raw grain and, through grinding and crushing, create flour and other products that are used to make such favorite foods as bread, pasta, cookies, cakes, and snack foods. NAMA member companies represent more than 90 percent of total industry production capacity.

We appreciate the extension of the comment period by the agency to enable us and other stakeholders to more thoroughly consider the agency's potential regulatory changes. This is a critically consequential rulemaking for all sectors of the agricultural value chain and, therefore, should not be rushed to completion.

Our organizations begin by reiterating our strong belief that APHIS needs to take an outcome-based focus when developing its Part 340 programmatic environmental impact statement. We respectfully submit that the desired outcome should be to develop a sound future regulatory policy that accomplishes the twin goals of encouraging continued innovation of biotechnology as a safe, sustainable and environmentally sound crop-production technology, but does so in ways that are comparable and compatible, to the maximum extent possible, with regulatory approaches used by competent government authorities in important U.S. export markets so as to minimize or avoid the risk of market and trade disruptions. We submit that this latter goal clearly is within the purview of both USDA and APHIS, which we believe have the responsibility and obligation to protect both the health and *economic value* of U.S. agriculture. Maintaining economic value includes safeguarding the marketability of U.S. crops and protecting U.S. agriculture's unfettered access to domestic and export markets in ways that recognize, respect and preserve the efficiency and competitiveness of a fungible and commingled U.S. grain and oilseed supply.

Our member companies store, handle, process and export the vast majority of grains and oilseeds used in human and animal food, and are affected directly and acutely by marketability-related issues associated with the commercialization of crop biotechnology and other cropping systems. Our comments reflect this perspective.

At the outset, and for the reasons explained later, CRA, NAEGA, NAMA, NGFA and NOPA believe it is premature and ill-advised for APHIS – with the exception of the conditional deregulation concept discussed herein – to proceed with a proposal to amend its existing Part 340 regulations pertaining to introductions of certain GE organisms – at this time.

Our organizations strongly support utilization of biotechnology and other safe crop-production technologies and modern agricultural practices that enhance the availability and distribution of a safe, affordable and sustainable food and energy supply for U.S. and world consumers. But achieving the objective of feeding an ever-growing world population and providing an abundant supply of competitively priced agricultural products also necessitates that the grain handling, processing and marketing industry be able to competitively, cost-effectively and seamlessly source and market fungible U.S. agricultural products in domestic and foreign markets.

In this regard, we believe USDA must consider both plant and environmental safety *and* the potential economic impacts on U.S. agriculture of commercialization of biotechnology traits in the absence of export market approvals or in the case of biotech events with functionally different output traits. We believe this can be done using a concept we call “conditional deregulation” – described later in this statement – while at the same time allowing APHIS to fulfill its statutory responsibilities under the Plant Protection Act (PPA) to adhere to sound science in its procedures for deregulating biotech-enhanced events that have been found not to present a plant pest or noxious weed risk under Part 340.

Organizations like the Biotechnology Innovation Organization and CropLife International, which represent plant science and biotechnology companies, have developed standards and policies for coexistence and stewardship. In these standards, technology owners are expected to communicate promptly, broadly and in a transparent manner with stakeholders. We support the position that companies commercializing biotech-enhanced traits should be responsible for their introductions and management of the impacts on overall supply chains, and believe that use by USDA of a “conditional deregulation” approach can play a constructive role in making that happen.

Further, we urge APHIS not to pursue changes to its existing Part 340 regulations in a vacuum. In this regard, we are deeply troubled by APHIS’s statement that its consideration of changes to Part 340 are being done distinct and separate from the White House Office of Science and Technology Policy’s current initiative examining ways to modernize the existing U.S. regulatory system for biotechnology products under the so-called Coordinated Framework. We believe any revisions to Part 340 regulations should be done within the context of the Coordinated Framework review. At a minimum, this must include discussions and coordination with the other two U.S. government agencies – the Food and Drug Administration and Environmental Protection Agency – that have regulatory responsibilities over agricultural biotechnology.

Our organizations also are extremely alarmed about what appears to this point to be a lack of outreach by APHIS or on its behalf by other USDA agencies (e.g., the Foreign Agricultural Service) concerning changes being contemplated to Part 340. To create a truly workable biotech regulatory framework for the future, APHIS necessarily must take the necessary time and make the necessary effort to address the challenge of achieving regulatory coherence and compatibility in the global market. Competent government authorities in significant U.S. export markets need to be approached and consulted. This is even more important currently, given ongoing and potentially productive dialogue occurring between the private sector and foreign government officials on whether and how to address the regulatory treatment of new and important breeding technologies, such as those encompassed under the broad phrase of “gene editing.”

In addition, in comments submitted previously to APHIS in response to its request for comments from stakeholders on a prudent future biotech regulatory framework, our organizations have encouraged the agency to work with other U.S. and foreign government entities and market stakeholders to develop and implement trade-facilitation policies, including a U.S. policy that addresses the low-level presence (LLP) of biotech-enhanced events that have been scientifically reviewed and approved as safe by a competent government authority in the country of export, but not yet by the importing country. We believe this is an essential component of a suite of policies that would enhance the marketability of U.S. crops produced with or derived from safe technologies, but which are subject to trade impediments resulting from differences in regulation and the timing of regulatory consideration by governments in different markets (i.e., asynchronous approvals). But this highly important initiative, on which significant progress is being made, also could be short-circuited if APHIS adopts a regulatory approach under Part 340 that is incongruous or at odds with those used by competent regulatory authorities in other countries.

## **APHIS's Role in Protecting the Economic Value of U.S. Agriculture**

The increasing lack of coherence in various nations' regulatory systems regarding safety reviews and approval of new biotech-enhanced events – combined with the increasing practice of biotechnology owners to release into commerce new biotechnology-enhanced events before obtaining import approvals from governments in importing countries (as has occurred in several notable instances) – have indeed prevented or reduced access of U.S. crops to foreign markets and resulted in very significant downward pressure on prices paid to farmers and reduced the economic value of U.S. agricultural production.

Documented incidents involving the detection of genetically engineered (GE) events that have not been authorized yet by the importing country – and subsequent rejection or disruption of commodity shipments – in major U.S. export markets point to the fact that, despite best efforts, it is commercially impossible to effectively manage the presence of GE events in commodity shipments to a zero tolerance or to non-detectable levels. This lack of global regulatory coherence and compatibility of regimes for addressing the life cycle of crop biotechnology not only results in negative impacts on the marketability and acceptance of all U.S. crops, but also affects access to important production technology.

We also believe APHIS should develop a clearly defined, specific regulatory process for agricultural products that have unique functional characteristics (e.g., output traits) that may adversely affect the functionality and/or compositional and nutritional integrity of the product and downstream users if the trait becomes present in the commingled, fungible commodity stream at levels exceeding certain thresholds. Such a process should include a requirement that the biotechnology provider or other applicant petitioning APHIS be responsible for establishing and enforcing an appropriate supply chain to keep the product segregated based upon fact-based threshold levels established through the risk-assessment process.

Our organizations have supported greatly expanded efforts by APHIS and others to provide for more timely and predictable regulatory actions regarding applications for approval of new traits. However, we likewise support prudent practices by the entire value chain regarding the commercialization and utilization of GE production technology. We do not support premature commercialization in advance of export market approvals unless technology owners concurrently agree to accept and bear the risks and liabilities associated with their company-specific business decisions.

A significant and all-too-recent case-in-point involves the decision by Syngenta Seeds Inc. to commercialize its Agrisure Viptera™ MIR 162 corn seed in the United States prior to obtaining import approval from the People's Republic of China. An analysis completed by NGFA in early April 2014 and updated in August 2014<sup>6</sup> estimated that the total economic damage to U.S. sellers of corn, distillers dried grains with solubles (DDGS) and soybeans resulting from Syngenta's commercialization of Viptera MIR 162 prior to Chinese import approval – and the trade disruptions that ensued after China detected MIR 162 and rejected shipments under its zero-

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<sup>6</sup> A copy of this study is available from NGFA.

tolerance policy – ranged from **\$1.5 billion to \$4 billion for the 2013/14 marketing year**. Using a mathematical model that forecasts the national average corn price based upon U.S. corn ending stocks, NGFA estimated that the trade disruption depressed U.S. corn prices by 11 cents per bushel, and reduced U.S. soybean prices by an estimated 15 cents per bushel. The negative price impact was even more severe for DDGS. For instance, between May and August 2014, DDGS prices in Iowa declined \$68 per metric ton, whereas corn prices in Iowa declined by \$21 per metric ton. The poor price performance of DDGS relative to corn was attributable largely to China’s decision to stop issuing import permits for U.S. DDGS in the near term, and its subsequent request for official test reports for all future U.S. DDGS shipments. Prior to the interruption in trade, China was accounting for 13 percent of total demand for 2013/14 U.S. DDGS production. The impact of temporarily losing China as a DDGS trading partner was a primary reason for the 50 percent drop in DDGS prices between May and August 2014, NGFA’s analysis found. Importantly, these economic losses only reflect 2013/14 marketing year impacts, and do not account for the loss of U.S. export sales to China that occurred following the Viptera MIR 162-related disruption in export shipments and sales.

We raise these issues because commerce in grains and oilseeds is inextricably tied to global sourcing. It is an irrefutable fact that achieving a sustainable supply of these basic commodities depends upon adequate fungibility – that is, the ability to source supplies of a given crop that have a degree of substitutability and relatively comparable value regardless of the geographic production area from which they originate. Grain supplies that can be comingled without concern over regulatory status can be accessed in a timely and efficient manner in response to buyer demands, providing time-and-space utility that is essential to achieving supply integrity and food security. Preserving production, storage, marketing and logistics systems that benefit from a fungible supply of grains and oilseeds is critical.

In its regulation of biotech-enhanced traits, our trade associations A believe APHIS, too, has a role to play, given its stated mission “to protect the health and **value of American agriculture** and natural resources.” *[Emphasis added.]* Further, we believe that several provisions of the “findings” section (§402) of the PPA Act expressly state Congress’s intent that the statute be utilized “for the **protection** of the agriculture, environment and **economy** of the United States.” *[Emphasis added.]* In addition, §402(5) of the PPA contains the congressional finding that “the **smooth movement** of enterable plants, plant products, biological control organisms or other articles into, **out of, or within the United States is vital to the United States’ economy and should be facilitated to the extent possible.**” *[Emphasis added.]*

### **Recommendations in Response to EIS Notice**

For the reasons provided hereafter, our organizations believe it is premature and ill-advised for APHIS at this time – with the exception of the conditional deregulation concept discussed herein – to proceed with a proposal to amend its existing Part 340 regulations pertaining to introductions of certain GE organisms. To proceed with such sweeping and far-reaching changes without significant consultations with domestic stakeholders and competent government authorities in foreign markets is ill-advised and could result in trade disruptions that have grave economic consequences.

Our organizations offer the following specific comments on the definitions, alternatives and other aspects raised by APHIS in its notice.

**Definitions:** As indicated previously in this statement, we believe it is premature and ill-timed for APHIS to propose an expansive new definition for “biotechnology,” particularly given ongoing global discussions that are occurring regarding the pre-market regulatory scope that may apply to new breeding techniques. A new APHIS definition also runs counter to the current internationally accepted definition developed through the Codex Alimentarius Commission.

While we do not support doing so at this time, were APHIS to adopt a new definition of “biotechnology” it likely would need to make it as broad as possible to encompass current and future technologies that may require government review and oversight under the PPA and the agency’s noxious weed authority. The APHIS-proposed definition reads: *“Biotechnology. Laboratory-based techniques to create or modify a genome that results in a viable organism with intended altered phenotypes. Such techniques include, but are limited to, deleting specific segments to the genome, directed altering of the genome, creating additional genomes, or direct injection and cell fusion beyond the taxonomic family that overcomes natural physiological reproductive or recombinant barriers. This definition does not include and is intended not to include traditional breeding, marker-assisted breeding, or chemical or radiation-based mutagenesis.”*

Likewise, APHIS proposes to define “*Product of biotechnology*” as “*an organism developed using biotechnology*” and to define “*Regulated organism*” as “*an organism developed using biotechnology that poses plant pest or noxious weed risks as documented in an APHIS risk analysis that APHIS has determined to regulate.*”

But we again caution that this approach runs the risk of subjecting to at least initial regulatory review a broad range and large number of biotechnology-enhanced traits that APHIS would be ill-equipped to handle in a timely manner, creating regulatory uncertainty for all segments of the value chain, including the grain and oilseed handling, processing and export sector. As noted previously, it also risks undercutting current efforts to build a more harmonized and rational, and less cumbersome and costly, regulatory system for addressing gene editing and other new non-transgenic breeding techniques.

We grant that the proposed definition would provide the agency with the latitude to exercise prudent risk-assessment and risk-management to determine the extent of regulatory review – or whether regulatory review is required at all – under the PPA for biotech-enhanced traits that may emerge from current and future technological innovation. Under its proposed definition, APHIS would have the flexibility to focus its regulatory oversight more narrowly on a subset of biotechnologies that should be reviewed and assessed prior to deregulation. This approach also would minimize the potential need for APHIS to amend the definition in the future to respond to unanticipated or unforeseen innovations in technology that could warrant review under the PPA.

Conversely, however, this definitional approach also poses a risk of signaling to competent regulatory authorities in other countries that the United States is expanding – rather dramatically

– the potential scope of its regulatory review, thereby contravening ongoing and potentially productive international efforts to do just the opposite.

Given current international approaches, APHIS might choose to use this flexibility to narrow its scope by applying the current Codex Alimentarius definition of “*Modern Biotechnology*,” which reads as follows: “*Biotechnology means the application of: i) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or ii) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.*” Doing so, at least for the time being, would improve regulatory coherence with the vast majority of countries currently regulating agricultural biotechnology; including significant U.S. export markets.

But before proceeding down this path, we urge APHIS to examine carefully whether its current regulatory tools under Part 340 are sufficient for the time being. These tools include the transparent “extension” process that allows it to evaluate new biotech-enhanced traits and make a determination as to whether they warrant regulatory review based upon whether they are identical or sufficiently similar to other technologies that previously have been determined by APHIS not to pose a plant pest or noxious weed risk, and therefore have been deregulated by the agency.

**Regulatory Approach:** We offer the following comments on the four alternatives APHIS proposes to examine under the EIS:

- **Alternative #2:** The agency’s presumably preferred alternative would revise current Part 340 regulations to provide for a process to review and regulate certain products of biotechnology to protect plant health; analyze potential plant pest and/or noxious weed risks first; and thereafter regulate only when appropriate and necessary. But to our knowledge, this alternative is inconsistent with any trait-specific biotech regulatory-approach adopted under international risk-assessment standards (i.e., Codex), which are utilized by a vast majority of countries, including by competent government authorities in significant U.S. export markets. Adopting this approach would pose a considerable risk of increasing the number of costly trade disruptions, which is inconsistent with APHIS’s stated mission and the requirements of the PPA to protect the **economic value** of U.S. agriculture.

We also adamantly oppose the proposal by APHIS in Alternative #2 to eliminate **both** the petition process and notification procedure, which currently is utilized by the agency to alert the public and other countries about its evaluation of whether a given biotech-enhanced trait poses a plant pest or noxious weed risk. The lack of transparency that would result from such action is alarming, and would not engender respect or trust of the U.S. regulatory system by foreign governments, nor domestic and world consumers of products derived from such biotech-enhanced traits.

While many details and specifics are not provided by APHIS in its notice, it also is our understanding that Alternative #2 would end the current practice of the technology provider supplying a “data package” on the biotech-enhanced trait as part of the petition process.

That, we believe, would be detrimental and raise significant questions and concerns about the thoroughness of the agency's regulatory review under this proposed approach.

Further, APHIS itself recognizes that Alternative #2 is deficient in that it fails to adequately address crops that have pharmaceutical and/or industrial output traits – which may not pose plant pest or noxious weed risks, but certainly pose grave disruption-to-commerce issues that argue for a strict permit-controlled conditional deregulation approach (e.g., restricted to being grown in greenhouses).

- **Alternative #3:** Under this option, the agency proposes to issue permits and conduct regulatory oversight of biotechnology-enhanced traits that could pose a plant pest or noxious weed risk, using the existing plant pest or noxious weed “analysis trigger” to classify plants produced through biotechnology as potential plant pests or noxious weeds. APHIS notes that this alternative would require permits and the application of conditions for import, interstate movement or “outdoor” use.

We believe that this type of permit-based approach could be used to protect against premature commercialization of biotech-enhanced events that pose a risk to the economic value of U.S. agriculture, consistent with assertions made earlier in this statement regarding APHIS's responsibility “to protect the health and **value of American agriculture** and natural resources.” It also would be suitable for biotech-enhanced events with pharmaceutical or industrial output traits.

Given APHIS's mission statement and the previously cited provisions of the PPA, we support APHIS establishing and applying a different category of “deregulation” – namely “**conditional deregulation**” – subject to permits expressly for biotech-enhanced events that the agency determines do not present a plant pest or noxious weed risk, but which have not received approvals in significant U.S. export markets or have functionally different output traits and, as such, present a risk of disrupting domestic and/or export markets if they become present in the commingled, fungible supply chain. Under this approach, for biotechnology-enhanced events subject to “conditional deregulation,” technology owners would be required to implement sufficiently robust and appropriate trait-specific stewardship plans and assume associated risk-responsibility if their defined risk-management plans fail to protect the value of U.S. crops until such approvals are granted. This approach recognizes and respects both the “sound-science” requirement that solely should govern whether a biotech-enhanced event is determined to be a plant pest or noxious weed risk, while also recognizing and making operational APHIS's mission to protect the value and economic well-being of U.S. agriculture.

Under this approach, APHIS should be required to provide notice that a given trait is under review and solicit public comment. This would enable affected industry and producer stakeholders to meet at an early stage with technology owners/providers to assess the adequacy of their risk-management (stewardship) and risk-responsibility (liability) plans if – and during the time that – the trait is subject to conditional deregulation status. Stakeholders then could provide timely and relevant feedback to APHIS on whether the technology



owner's/provider's plans are sufficient, while preserving confidential business information that may be part of such plans.

As noted previously, we support the proposition that companies commercializing biotech-enhanced traits should be responsible for identifying the risks associated with their introduction, managing the impacts on overall supply chains, and being responsible if those risk-management plans fail. Our organizations believe that use by APHIS of a "conditional deregulation" approach would play a constructive role in making that happen.

- **Alternative #4:** This alternative would abandon the current APHIS regulatory process altogether and replace it with a voluntary consultation process akin to what the FDA currently has in place with biotech providers to assess food/feed safety risks of biotech traits. We oppose this alternative because it would reduce the existing transparency and opportunity for public comment by stakeholders, and would be inconsistent with the approach taken by competent government authorities in the rest of the world, further ostracizing the U.S. regulatory system internationally and creating increased potential for costly market-related trade disruptions.

**Lack of Consultation with Competent Government Authorities in Foreign Countries:** We believe that *any* changes to U.S. biotech regulatory processes – including Part 340 – should be considered *only after* advance, robust and thorough discussions with competent government authorities in countries that represent important U.S. export markets, during which alignment in regulatory approaches is achieved to the maximum extent possible. To our knowledge, that has not occurred to date with respect to: 1) the four proposed regulatory alternatives; and 2) the new definitions for Part 340 proposed by APHIS in this notice. We urge the agency not to proceed further with the EIS or proposed revisions to Part 340 unless and until such consultations are conducted and completed.

**Adverse Impacts on LLP Policy and Trade Accommodation:** Our associations also believe APHIS's proposed approach to its Part 340 rulemaking risks undermining the considerable time and effort invested by the U.S. government and private sector to gain support for a low-level presence (LLP) policy and to encourage use of the concept of trade accommodation to help overcome current asynchronous-approvals of biotech-enhanced traits around the globe. Specifically, we are gravely concerned that APHIS may adopt a regulatory review process under Part 340 that is out-of-step with major U.S. trading partners – based upon a flawed assumption that the rest of the world will simply follow suit. The history of biotechnology regulation is replete with examples of this not occurring, often with devastatingly adverse economic repercussions. In the absence of sufficiently robust international consultation and "buy-in" by competent governmental authorities in foreign countries, this approach puts the United States at risk of becoming even more of an international outlier when it comes to regulating biotech-enhanced traits. In addition to posing the potential for severe and costly market disruptions in the trade of grains, oilseeds and other grain-based products, such an approach would undermine U.S. participation in the Global LLP Initiative (GLI) and exclude U.S. agricultural companies from benefits of emerging LLP policies being developed for important U.S. export markets.

These considerations also argue for APHIS taking the time necessary to develop a prudent, well-conceived and consultative approach.

**Pursuit of a Global LLP Policy:** Finally, we want to take this opportunity to again encourage USDA and other relevant U.S. government agencies to work with other U.S. and foreign government entities and market stakeholders to develop and implement “trade facilitation<sup>7</sup>” policies, including a U.S. policy that addresses the low-level presence (LLP) of biotech-enhanced events in both imports and exports that have been scientifically reviewed and approved as safe by a competent government authority in the country of export, but not yet by the importing country. We believe this is an essential component of a suite of policies that would enhance the marketability of U.S. crops produced with or derived from safe technologies, but which are subject to trade impediments resulting from differences in regulation and the timing of regulatory consideration by governments in different markets. Such a suite of policies should support least-trade-distortive commercial and public measures for both imports into and exports from the United States, and provide for adequate fungibility throughout the supply chain, which as explained previously is a critical component of U.S. agricultural competitiveness.

Practical approaches are needed for the management of LLP that are science-based, predictable and transparent, and that will encourage the use of international science-based guidelines on LLP. One example is the Codex Alimentarius Commission’s Annex 3: Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food. Any practical approach to LLP management must address each crop biotechnology event or trait individually, beginning with the planting of seeds that contain that event or trait. It is impractical and costly to attempt to manage LLP with a testing-based clearance mechanism for commodity shipments. However, the use of process controls to appropriately limit exposure, starting with the planting of seeds, may provide for a workable LLP management mechanism when responsibility for the controls is established and maintained.

To address the current lack of synchronized approvals for biotech-enhanced crops globally and comprehensively, our organizations stand ready to work with APHIS and other U.S. government agencies to encourage adoption of an LLP policy to facilitate marketability of such traits for the United States and all relevant global regulatory regimes.

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<sup>7</sup> In this context, trade accommodation refers to the availability of mutually agreeable practices to manage in consignments intended for import the presence of certain substances, including but not limited to biotechnology-enhanced traits, so that the likely resulting presence is acceptable to the point regulatory action does not prohibit entry and use of the imported goods. Most often, trade accommodation is an outcome of consultations with appropriate government authorities and commercial stakeholders.

## Conclusion

To conclude, for the reasons cited herein, CRA, NAEGA, NAMA, NGFA, and NOPA believe it is premature and potentially harmful to U.S. agriculture for APHIS – with the exception of the “conditional deregulation” concept discussed herein – to propose significant revisions to its Part 340 regulations at this time.

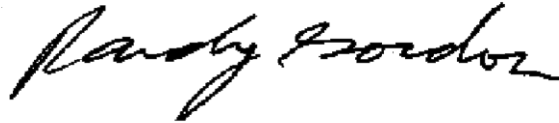
Going forward, we support the use of balanced biotechnology policies – including policies that effectively address marketability risks and impacts – to ensure the successful development and processing of foods for humans and animals from all agricultural cropping systems to enhance world food security.

Thank you for the opportunity to comment on this important issue, and our organizations stand ready to meet with APHIS to discuss the critical issues raised in its Part 340 review and in our comments.

Sincerely,



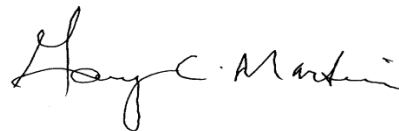
John W. Bode  
President and Chief Executive Officer  
Corn Refiners Association



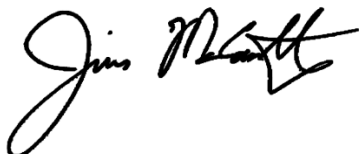
Randall C. Gordon  
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Thomas A. Hammer  
President and Chief Executive Officer  
National Oilseed Processors Association



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



James A. McCarthy  
President and Chief Executive Officer  
North American Millers Association