



**Corn Refiners Association
National Grain and Feed Association
National Oilseed Processors Association
North American Export Grain Association
North American Millers' Association**

Submitted Electronically

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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-2015-0057: Interstate Movement and Environmental Release of Certain Genetically Engineered Organisms

Dear Reviewing Official:

The undersigned national organizations¹ respectfully submit this joint statement in response to

¹ **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.

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.

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.

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.

the U.S. Department of Agriculture Animal and Plant Health Inspection Service's (APHIS) request for comments on proposed revisions to regulations under 7 CFR Part 340 ("Part 340") applicable to the importation, interstate movement and environmental release of certain genetically engineered organisms.

Our organizations' member companies are engaged daily in storing, handling, processing, marketing and exporting the vast majority of America's grain and oilseed production to domestic and world consumers. As such, our organizations strongly support the utilization of biotechnology and plant-breeding innovation, including genome editing, as well as other safe cropping technologies and practices that enhance the production of safe, affordable and sustainable food and energy for U.S. and world consumers.

We recognize APHIS's efforts to attempt to modernize its regulations to ensure they are updated, risk-based and proportional to reflect best-available science and the agency's experience since 1987 in reviewing biotech-enhanced events for potential plant pest and noxious weed risks.

However, feeding an ever-growing world population and providing an abundant supply of competitively priced agricultural products necessitates that the grain handling, processing, marketing and export industry be able to competitively, cost-effectively and seamlessly source and market fungible U.S. agricultural products in domestic and foreign markets. For APHIS to execute the "first comprehensive revision of the regulations" in three decades without first engaging in broad international discussion and collaboration with regulatory authorities in important U.S. export markets and securing international acceptance and the buy-in of our trading partners would be a horrific mistake and must be avoided. Further, as we cite later in this statement, such engagement and consultation also is needed with U.S. state government authorities.

As our organizations outlined in comments to APHIS on April 21, 2016 (Docket No. APHIS-2015-0057: Notice of Intent to Prepare Environmental Impact Statement Under 7 CFR Part 340), we continue to believe that APHIS must take an outcome-based approach when developing revisions to Part 340. We respectfully submit that an overridingly important outcome is for APHIS to create a science- and risk-based regulatory approach that not only fosters continued innovation of biotechnology, but is comparable, compatible, and recognized as acceptable by government authorities in important U.S. export markets to minimize or avert the risk of costly market and trade disruptions that undermine the export competitiveness of U.S. agriculture and subvert its tremendous contribution to U.S. job creation, economic growth and world food security.

In this regard, we note that building upon U.S. agriculture's success in export markets is a principal focus of the Trump Administration as it seeks to modernize the North American Free

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.

Trade Agreement and engage in bilateral negotiations with Asia-Pacific nations in the aftermath of the Trans-Pacific Partnership trade accord. USDA data show that the food and agricultural sector supports more than 15 million U.S. jobs, creates more than \$423 billion in annual U.S. economic activity, and constitutes the single largest U.S. manufacturing sector – accounting for 12 percent of all U.S. manufacturing jobs. Every dollar in U.S. agricultural exports has a multiplier effect that generates an additional \$1.27 in U.S. economic activity. Above all else, APHIS needs to “do no harm” by avoiding prematurely implementing a regulatory approach under Part 340 with respect to advancements in genetic engineering technology that puts U.S. grain and agri-bulk exports at risk. APHIS should not be working at cross-purposes to undercut the Administration’s focus on trade and exports.

Thus, given insufficient interaction with – and to our knowledge the total absence of acceptance by – government authorities in important U.S. export markets of the new regulatory approach under Part 340 being contemplated by the agency, as well as the existence of several significant flaws in the proposal itself that are articulated subsequently in this statement, we urge APHIS to withdraw the proposed rule.

Instead, we submit that a much higher priority now is for APHIS, in consultation and cooperation with other appropriate U.S. government agencies (including USDA’s Foreign Agricultural Service and the Office of the U.S. Trade Representative), as well as value-chain stakeholders, to develop a comprehensive engagement strategy with regulatory agencies in other countries to build international regulatory compatibility and acceptance around a new, more science- and risk-based approach that ensures genetically engineered plants do not pose a plant pest or noxious weed risk. To be clear, this does not mean that other countries need to adopt a regulatory approach to new plant-breeding techniques that is identical to a future approach employed by APHIS. But, emphatically, it *does* mean that APHIS’s regulatory approach must be recognized by, and acceptable to, government regulatory authorities in U.S. export markets so as not to trigger regulatory action against U.S. commodities produced using genetic engineering or plant-breeding innovation, including gene-editing, in international commerce.

There also is a need for APHIS to engage and consult adequately with relevant U.S. state governmental bodies concerning its proposed new regulatory approach to avert situations in which individual states may attempt – in the absence of APHIS regulatory oversight – to exercise their own regulatory control over field trials or commercial cultivation of plant-breeding innovation techniques. Acceptance by states of any new APHIS regulatory approach will be essential to avoid the threat of a patchwork of state regulatory policies that could disrupt even interstate commerce within the United States.

Further, until such time that APHIS has achieved broad-based acceptance through such international and domestic engagement of its new regulatory approach so as not to endanger the marketability of U.S. agricultural products, we urge the agency not to repropose the rule. We believe the agency has other tools at its disposal to improve its existing science-based risk-assessment process to avoid impeding responsible innovation of new plant-breeding techniques while at the same time preserving U.S. farmers’ access to foreign markets.

Need for Comprehensive Engagement at the International and State Levels

One of the principal advantages of withdrawing the proposed rule is to remove the rulemaking restrictions that have prevented APHIS from actively engaging with its international counterparts in a much-needed dialogue on creating a new science- and risk-based approach. As noted previously, the need for consultation and acceptance also extends to state governmental bodies to avert varying approaches to oversight of field trials and cultivation and the threat of a patchwork of state regulatory policies that could disrupt even interstate commerce within the United States. To create a truly workable biotech regulatory framework for the future, APHIS must take the necessary time and make the necessary effort to address the challenge of achieving regulatory compatibility in domestic and global markets.

In particular, government regulatory authorities in significant U.S. export markets need to be contacted and consulted. This is even more urgent given the ongoing dialogue now occurring between private sector value-chain stakeholders and foreign government officials regarding the degree of regulatory oversight that may be appropriate for new plant-breeding innovation techniques (i.e., gene editing). We urge APHIS to withdraw its proposed Part 340 rule until there is sufficient international regulatory compatibility and acceptance among exporting and importing countries around any future regulatory approach the U.S. government contemplates using ***before*** changes are made so as not to disrupt trade. Proceeding with such sweeping and far-reaching changes as contained in the Part 340 proposed rule in the absence of significant consultations and alignment with domestic value-chain stakeholders and state and foreign government authorities is ill-advised and could result in disruptions in commerce that would have grave economic consequences.

In addition, in previous statements submitted to APHIS in response to its request for comments from stakeholders on a prudent future biotech and plant-breeding innovation regulatory framework, our organizations have encouraged the agency to work with other U.S. and foreign government entities and value-chain 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 the appropriate government authority in the country of export, but not yet by the importing country. We take this opportunity to reiterate our belief that 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 plant-breeding 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 with those used by regulatory authorities in other countries.

In short, there needs to be international recognition and acceptance among importers of U.S. agricultural products that any new USDA/APHIS regulatory approach is science- and risk-based, and will not further encumber international approvals or acceptance of imports for food, feed or for further processing of U.S. products developed using plant-breeding innovation technology. To achieve this, USDA needs to develop and execute, in consultation and cooperation with other

appropriate U.S. government agencies and value-chain stakeholders, an international engagement strategy that explains APHIS's latest thinking on pre-market regulatory approaches, including its approach to oversight of products developed with genome-editing tools. The first step in making such a dialogue possible is to withdraw the proposed rule.

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

There continues to be an increasing lack of compatibility in global regulatory systems regarding safety reviews and approval of new biotech-enhanced events. There currently also is considerable uncertainty over whether and how various countries will approach the regulatory oversight of agricultural commodities produced using new plant-breeding techniques. The increasing practice of several significant biotechnology owners to release into commerce new biotechnology-enhanced events before obtaining import approvals from governments in important U.S. export markets (as has occurred in several notable instances with transgenic traits) – and the exponentially greater number of plant breeders expected to become involved in developing new plant-breeding techniques – raise the specter of even greater and more severe disruptions in the marketability of U.S. crops unless international regulatory compatibility and acceptance is achieved. As the experience of transgenic biotechnology has demonstrated all too well, the lack of international regulatory compatibility and premature commercialization of biotech traits that combine to prevent or reduce access of U.S. crops to foreign markets result in very significant downward pressure on prices paid to farmers and reduce 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 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 adversely affects access of growers to important production technology.

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 bear the market 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 2014² 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 Vipitera MIR 162 prior to Chinese import approval – and the trade disruptions that ensued after China detected MIR 162 and rejected shipments under its zero-tolerance policy – ranged from **\$1.5 billion to \$4 billion for the 2013/14 marketing year alone**. 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 even was 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 accounted 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 Vipitera 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. It is critical to preserve production, storage, marketing and logistics systems that benefit from a fungible supply of grains and oilseeds.

In its regulation of biotech-enhanced traits, our associations believe APHIS, too, has a role to play in not encumbering the marketability of U.S. crops, 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 Plant Protection Act (PPA) expressly state congressional 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.]*

² A copy of this study is available from NGFA.

The APHIS Proposed Rule is Flawed in Multiple Respects

Our organizations also offer the following additional specific comments on aspects raised by APHIS in its proposed rule:

- **Risk Assessment:** As part of APHIS’ proposed revisions to Part 340, the agency has provided focus areas for noxious weed risks on the APHIS BRS Weed Risk Assessment System for Genetically Engineered Plants webpage (<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/2016-340-rule/weed-risk-assessment>). To protect plant health, APHIS states it will consider if the GE plant or GE relative would be expected to: “Negatively affect the production or quality of an agriculturally important plant” as well as “cause damage to other plants or plant products when there is mixing of the GE plant, GE relative or plant products with other plants or plant products.”

Our organizations strongly believe that the weed risk assessment raises marketability concerns and questions. For instance, does APHIS consider marketability when evaluating whether the “quality” of an agriculturally important plant is negatively affected? We believe the agency should. Similarly, does “damage” encompass adverse economic damage, including downward pressure on prices paid to farmers? Again, our organizations argue that APHIS does have a role in protecting the economic value of U.S. agriculture.

- **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 accommodation⁴ to help overcome current asynchronous-approvals of biotech-enhanced traits globally. Specifically, we are gravely concerned that APHIS may adopt a regulatory review process under its proposed revisions to 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 consequences.

In the absence of sufficiently robust international consultation and “buy-in” from 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

⁴ 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.

important U.S. export markets. These considerations also argue for APHIS taking the time necessary to develop a prudent, well-conceived and consultative strategy whose end-objective is a science- and risk-based regulatory approach compatible with or acceptable to other countries that constitute important U.S. export markets.

- Pursuit of a Global LLP Policy:** Finally, we again encourage USDA and other relevant U.S. government agencies to work with other U.S. and foreign government entities and value-chain stakeholders to develop and implement “trade facilitation”³ 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 government authority in the country of export, but not yet by the importing country. As noted previously, 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 in 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, other U.S. government agencies and private-sector partners to encourage adoption of an LLP policy to facilitate marketability of such traits for the United States and all relevant global regulatory regimes.

Additional Concerns: In addition to the paramount concerns cited previously regarding achieving compatibility and acceptance prior to adoption of any new regulatory approach to Part 340, other concerns with the APHIS proposal have been identified by the broad U.S. value chain, with which our organizations concur. These include the following:

- Researchers and technology product developers cannot about learn the regulatory status of new genetically engineered organisms without undergoing complex and lengthy risk assessments, providing little transparency and clarity to them or to the value chain, including marketers, as well as consumers, about which products will be subject to regulation, and

raising the prospect of arbitrary regulatory determinations that may be incompatible with or unacceptable to international markets, thereby risking further market uncertainty and restrictions in innovation.

- The APHIS-proposed assessment process is unlikely to have the band width to accommodate the scale of U.S. research and development of plant-breeding innovation techniques, potentially resulting in many products being suspended in regulatory limbo while their regulatory status is being assessed.
- The APHIS-proposed system would be a significant expansion of the authorities under Part 340, creating a redundant weed risk regulatory process that currently works well under USDA's Part 360 regulations. The merging of the Part 360 authority into Part 340 would add significant complexity and raise barriers to innovation, as well as litigation risk. We join in recommending that USDA maintain the distinction between these two authorities.
- The significant departure from the current regulatory system may have unintended consequences for other regulatory agencies, and domestic and international markets, and lead to significant new litigation risks.

Conclusion

For the reasons cited herein, our organizations urge APHIS to withdraw its proposed Part 340 regulations because they are premature, contain fundamental flaws and likely would result in disruptions in international trade, and potentially even U.S. interstate commerce. Instead, we urge APHIS to pivot to develop an effective international and state engagement strategy to build understanding, alignment and acceptance around a new science- and risk-based regulatory approach appropriate for addressing plant pest and noxious weed risk, if any, posed by genetically engineered organisms and the products of new plant-breeding techniques, with the goal of preserving the marketability of agricultural products and avoiding disruptions in domestic and international trade.

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

Sincerely,



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