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

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Regulatory Analysis and Development
Plant Protection Division
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
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Dr. Alan Pearson
Assistant Deputy Administrator
Biotechnology Regulatory Services
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U.S. Department of Agriculture
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Docket No. APHIS-2018-0034, Proposed Rule on Movement of Certain Genetically Engineered Organisms

Dear Dr. Pearson and Reviewing Officials:

The undersigned national organizations[1] respectfully submit this joint statement in response to

[1] **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 33 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.

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.

the U.S. Department of Agriculture (USDA) 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 movement of certain genetically engineered organisms.

This joint statement pertains to the application of the proposed Part 340 regulations to grains, oilseeds and products derived therefrom for human and animal food uses, and not for other products to which the proposed rule may apply.

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, we strongly support the utilization of biotechnology and plant-breeding innovation, including genome editing, under appropriate government oversight determined through prudent scientific risk-assessment, as well as other cropping technologies and practices that enhance the production of safe, affordable and environmentally sustainable food and energy for U.S. and world consumers.

A cornerstone of U.S. agriculture's competitiveness is its ability to efficiently and cost-effectively market America's agricultural abundance with our key export market customers as part of a global food system. It's our sector's ability to both leverage new agricultural innovations while at the same time providing safe, competitively priced food and feed supply for global consumers that ultimately allows the benefits of agricultural biotechnology to be realized. Put succinctly, if government policies create an environment that disrupts the efficient, seamless movement of agricultural products, these enhanced production technologies will have little utility for the value chain or the American farmer. It is through this dual lens – support for technological innovation while ensuring the continued efficient marketability of crops in which it is used – on which these comments are based.

It also is why we jointly urged APHIS to go back to the drawing board in response to its 2017 proposed rule to modernize its biotechnology regulations under Part 340, citing, among other things, the lack of concurrence regarding the agency's proposed new regulatory approach among governmental authorities in important U.S. export markets. We believed this pause would enable APHIS and its colleagues with other U.S. government agencies to build international regulatory compatibility and recognition around its proposed regulatory approach to ensure genetically engineered plants do not pose a plant pest or noxious weed risk. Our organizations also urged APHIS not to re-propose the rule until such a broad-based recognition of a new regulatory approach was achieved so as not to endanger the marketability of U.S. agricultural products,

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National Oilseed Processors Association (NOPA), is a national trade association that represents 13 companies engaged in the production of food, feed and renewable fuels from oilseeds, including soybeans. NOPA's member companies process more than 1.9 billion bushels of oilseeds annually at 65 plants located in 21 states throughout the country, including 59 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.

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.

particularly grains and oilseeds. We commend APHIS for responding to that and other input from a wide range of stakeholders – including those representing the seed and agricultural biotechnology sectors – in agreeing to withdraw that proposed rule in November 2017.

Our organizations also appreciate the outreach in which USDA and other U.S. government agencies engaged during the ensuing time period to collaborate with and gather additional perspectives regarding regulatory approaches on genome-editing from other countries and domestic stakeholders, including representatives of our organizations. Among the tangible outcomes of the international collaboration was the issuance of a non-binding statement on "Agricultural Applications of Precision Biotechnology" signed by a dozen countries that states, among other things, "Precision biotechnology products have the potential to play a critical role in addressing challenges facing agriculture production…" and encouraged pursuit, wherever possible, of "cooperative work by governments…including by exploring opportunities for regulatory and policy alignment…." But while a laudable aspirational statement of intent, this document has not yet been translated into tangible recognition or support for the largely deregulatory approach that APHIS is proposing in its revised Part 340. To the contrary, several key U.S. grains and oilseeds trading partners, such as Japan, have adopted or are in the process of adopting mandatory consultation requirements, tiered food safety risk assessment models, and enhanced transparency requirements for gene-edited products, putting the APHIS approach largely out of step with key international markets and governments. Further, the European Court of Justice's decision last year to require gene-editing techniques to go through the same regulatory and approval process as transgenics (genetically modified plants) presents additional significant marketability headwinds – a factor that needs to be considered before APHIS develops a final rule on Part 340.

Plant breeding innovations like gene-editing are very promising. But making such fundamental regulatory changes before knowing how major U.S. trading partners will treat these products, or whether they will accept APHIS's regulatory approach as sufficient, could negatively affect U.S. exports.

Our organizations believe that APHIS's new proposed rule is fundamentally flawed, and is inconsistent with the agency's obligation to protect the economic value of U.S. agricultural and food exports. We believe the rule, as proposed, could create further impediments that would undermine our industry's ability to fulfill its indispensable role of marketing grains and oilseeds, and the products derived therefrom, in global markets, as well as undermine consumer confidence in the U.S. regulatory system to provide appropriate oversight of this promising, but nascent, technology.

We cite the following significant deficiencies:

- **Inadequate Transparency and Implications for the Credibility and Integrity of U.S. Biotechnology Review Process:** First and foremost, APHIS's proposal would fundamentally undermine the absolutely essential need for transparency, as well as potentially undercut the credibility and integrity of the U.S. biotechnology regulatory review process, by providing unprecedented authority for technology developers to self-

> determine whether even to seek regulatory review by APHIS of their gene-edited technologies, without ever notifying the agency.
> In this regard, the proposal would outright exempt from APHIS regulatory oversight four broad categories of genome editing: 1) sole deletions "of any size"; 2) single base-pair substitutions; 3) genetic modifications resulting solely from inserting nucleic acid sequences from within the same plant's "natural gene pool" or from editing of nucleic acid sequences in a plant to correspond to a sequence known to occur in the plant's natural gene pool; and 4) null segregants that do not retain genetic modification from the genetically engineered parent. To preserve the integrity of its regulatory decision-making process, we believe APHIS needs to provide the necessary – and available – scientific justification for these categorical exemptions, which the proposed rule does not. We submit that simply stating in the explanatory text of the proposed rule that these exemptions are being granted "because they could be produced through traditional plant breeding techniques and thus are *unlikely* to pose a greater plant pest risk than traditionally bred crops, which APHIS has historically not regulated" is insufficient scientific justification for granting broad exemptions. *[Emphasis added.]*

In addition, APHIS proposes to exempt genetically engineered plants with plant-trait-mechanisms-of-action combinations previously evaluated by the agency and found unlikely to pose a plant pest risk. This kind of categorical exemption directly contradicts the well-established international norms of case-by-case risk-assessment models and guidance adopted by the Codex Alimentarius Commission (CODEX) for products of modern biotechnology (including many forms of gene-editing). As such, this APHIS proposal radically deviates from existing and long-established biotechnology regulatory frameworks adopted by the vast majority of countries that do business with U.S. agricultural companies.

> But APHIS proposes to go still further by giving technology developers *"the option"* of requesting a permit or regulatory status review of a genetically engineered plant that has not been previously reviewed and deregulated by the agency. *[Emphasis added.]* While APHIS under §340.1(d) of the proposed regulations provides *"the option"* for the technology provider to request written confirmation from the agency that its self-determination is valid and to obtain so-called "confirmation letters" from APHIS attesting to the "regulatory applicability" of the genetically engineered plant and its nexus to plant health, there is no assurance they will do so.

This is a significant issue given that the advent and commercialization of genome editing and other plant-breeding innovations will lower the barriers to entry, ushering in a host of new technology providers from the public and private sectors – many of which will have no knowledge or experience with the U.S. ***"Coordinated Framework for Regulation of Biotechnology"*** (Coordinated Framework) or the respective authorities thereunder of APHIS, the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA). APHIS appears to be banking on the cudgel of "remedial measures" and "criminal and/or civil penalties" proposed in §340.6 (c) to encourage technology providers to seek such confirmation. But it is difficult to envision when, if at all, such an "after-the-fact" remedy would be deployed by the agency or be legally defensible given the broad discretion and self-determination that APHIS grants to technology providers throughout the proposed rule.

As an aside, we would note that the aviation industry currently is experiencing significant turmoil and scrutiny over the safety certification process where the federal government leaned heavily on self-determinations by an aircraft manufacturer.[2]

> Promulgating this rule in a manner that allows technology developers to self-determine whether their GE traits are exempt from regulation and without providing any notification lacks transparency and risks undermining consumer acceptance and international regulatory recognition of APHIS's regulatory oversight, and is the wrong approach. The fact that APHIS would allow these new technology-provider entrants to self-determine whether their products should be subject to the agency's regulatory oversight while also not requiring any sort of notification to the marketplace would make the already difficult job of knowing what is present in the fungible and commingled commodity supply almost impossible.

- **Flawed Concept and Questionable Acceptability of "Confirmation Letters":** In the "Supplementary Information" section of its rulemaking – but importantly, not in the actual proposed rule itself – APHIS states that it would be willing to issue what it calls "confirmation letters" to technology providers that voluntarily exercise *the option* to seek the agency's affirmation that a given genetically engineered trait does not pose a plant pest risk. APHIS states that such letters "would provide a clear and succinct statement about the regulatory applicability of the GE plant and the nexus to plant health, (and) may be useful to developers wishing to market their products domestically or overseas by allowing them to provide verification to an importing country or other party that APHIS concurs with their self-determinations."

This concept is flawed on several levels. First, in the case of grains, oilseeds and many other plant products, it is our member companies – not the technology providers – that buy, process and market the agricultural commodities produced and derived from genome editing and other forms of plant breeding innovation.

Second, as such, it is our member companies and their customers that need sufficient information about which GE traits are being commercialized as part of diverse supply chains, frequently and necessarily involving fungible and commingled commodity logistics. It is these market participants that need to be in a position to request such attestations from APHIS to enable them to continue to efficiently purchase and market raw grains, oilseeds and derived products to domestic and global customers. Yet, with no requirement for technology providers to notify APHIS of the GE traits they are introducing into the commercial supply, our members and their customers will not have the necessary access to information on what traits are present in the grain and oilseed supply, making it nearly impossible to know when and on what products to request such "confirmation letters." This is a disconnect that we repeatedly and emphatically pointed out to APHIS in discussions prior to issuance of the proposed rule.

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[2] "How the FAA allows jetmakers to 'self certify' that planes meet U.S. safety requirements" A Washington Post Investigation, March 15, 2019 (https://www.washingtonpost.com/investigations/how-the-faa-allows-jetmakers-to-self-certify-that-planes-meet-us-safety-requirements/2019/03/15/96d24d4a-46e6-11e9-90f0-0ccfeec87a61_story.html?utm_term=.3dc10090a017)

Third, to our knowledge, there is no assurance at this time that such APHIS "confirmation letters" will be acceptable to or recognized by upstream and downstream customers in the United States, let alone by foreign government authorities. There also is no assurance that foreign countries would consider such attestations as an acceptable substitute for a CODEX risk assessment. That is a significant and inherent deficiency of APHIS not granting an *official* regulatory attestation that a GE trait does not represent a plant pest risk.

- **Implications for Disruptions of Field Trials:** Our organizations also are concerned about the degree to which individual states or localities will intervene to disrupt necessary field trials of GE traits given APHIS's largely deregulatory approach. Just as we supported the National Bioengineered Food Disclosure Standard (P.L. 114-216) to provide for federal preemption and avoid a patchwork of individual state labeling requirements for bioengineered food, we do not want to see a patchwork of state or local laws or restrictions developed that would disrupt field trials or the interstate movement of GE-derived agricultural commodities and products. In its proposed rule, APHIS has not adequately addressed the degree to which its rule would preempt such state or local incursions.

- **Lack of International Acceptance or Recognition of APHIS's Regulatory Approach:** As noted previously, it is absolutely essential that whatever regulatory approach is developed by APHIS to address plant pest risks of GE be recognized and accepted by government authorities in important U.S. export markets. To be clear, this does not mean that other countries need to adopt the same regulatory oversight or approach to new plant-breeding techniques as APHIS. But it emphatically *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 disadvantage U.S. commodities in the highly competitive global market.

Our joint submission dated June 19, 2017 provided ample and persuasive evidence of the adverse impacts and devastating costs imposed upon U.S. agricultural producers, our industry sectors and the U.S. economy when agricultural trade is disrupted because of the lack of import approvals in foreign markets. As noted in that statement, this was demonstrated most recently when Agrisure Viptera MIR 162 corn was commercialized in the United States prior to receiving Chinese import approval, triggering shipment rejections and resulting in between $1.5 billion and $4 billion in economic damage to U.S. sellers of corn and distillers dried grains with solubles (DDGs). APHIS's proposal risks compounding that risk by promulgating a rule that lacks international compatibility, recognition or acceptance for an entire class of innovative, promising and much-needed GE technology.

In our 2017 joint statement, our organizations also expressed grave concerns – which we still have – that in the absence of such international acceptance/recognition, APHIS's Part 340 regulatory approach could undermine progress being made in the Global Low-Level Presence Initiative (GLI), in which countries (including the United States) are striving to achieve a science- and risk-based approach that would allow for a commercially achievable tolerance for the presence of a biotechnology-enhanced trait that has been approved as safe by a country based upon scientific analysis and CODEX-adopted risk assessment principles, but not yet by an

importing country. Indeed, the U.S.-Mexico-Canada Agreement expressly commits all three countries to develop a low-level presence policy for imports.

For these reasons, we respectfully submit that obtaining such international recognition or acceptance in significant U.S. export markets should be a precondition before APHIS proceeds with a final rule. Doing otherwise could trigger significant trade disruptions.

- **Need for Coordinated Action by U.S. Government Agencies in Promulgating Rules and Guidance on Genome Editing and Other Forms of Plant Breeding Innovation:** Our organizations also believe APHIS's proposed rule needs to be developed and considered within the context of the Coordinated Framework. We are aware that FDA is in the process of developing updated guidance regarding its voluntary consultation process with respect to genome editing and other plant-breeding innovation to ensure the continued safety of human and animal food. Likewise, EPA still is in the process of considering potential changes to its regulatory approach for addressing pesticidal proteins with respect to this technology.

We believe such efforts should be compatible with one another and be coordinated through the White House Office of Science and Technology Policy. APHIS would be ill-advised to issue a final rule on Part 340 until all three agencies have determined and consulted with stakeholders and consumers on their planned path forward.

Major Recommendations

For the previously stated reasons, our organizations first and foremost strongly urge APHIS to amend its Part 340 proposed rule to require *all* technology providers to notify the agency in advance before introducing gene-edited or other plant breeding innovation traits for commercialization – even those within APHIS's expressly exempted categories – so that the agency can issue an *official* letter for all traits attesting that they do not present a plant pest risk. Under this recommendation, APHIS still could adopt a prudent science- and risk-based approach for determining the level of regulatory oversight warranted – with the important caveat that it needs to obtain recognition and acceptance of that approach from governmental authorities in significant U.S. export markets.

We believe requiring notification by technology providers followed by a formal APHIS response would solve a host of major flaws inherent in the agency's current proposal by:

- Enabling APHIS and its sister agencies; the industry sectors our organizations represent; manufacturers and retailers of human and animal food; and consumers and other stakeholders to know what technologies are being commercialized and utilized in various crops present in the grain and oilseed supply.

- Providing our industry with the necessary *official* U.S. government attestation that the traits do not pose a plant pest risk, thereby providing an important tool to efficiently market U.S. agricultural products.

- Perhaps limiting the potential for state or local government actions that could disrupt field trials of genome-edited traits or other forms of plant breeding innovation and the interstate movement of agricultural products.

Second, APHIS should secure international recognition or acceptance of its regulatory approach toward assessing plant pest risk ***before*** proceeding to finalize its Part 340 rule. APHIS's risk-based regulatory approach needs to be accepted and recognized as scientifically sound by government authorities in important U.S. export markets.

Third, we believe APHIS should ***not*** proceed to issue a final rule on Part 340 until its sister agencies – FDA and EPA – develop and issue guidance and/or rules on how they plan to address genome editing and other plant breeding innovation technologies within their respective areas of jurisdiction under the Coordinated Framework. Doing otherwise risks undercutting the Coordinated Framework and potentially promulgating inconsistent, and at worst, incompatible, approaches to regulatory oversight that would further imperil this important technology.

Conclusion

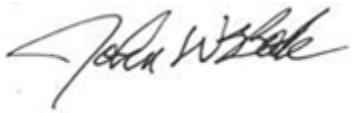
In conclusion, our members support the use of agricultural biotechnology and plant breeding innovation for contributing to an abundant, affordable and environmentally sustainable human and animal food supply, thereby enhancing global food security. However, for the member companies of our organizations, and the farmers and downstream customers they serve, the importance of efficiently and cost-effectively marketing U.S. farmers' agricultural abundance without encountering recurring trade disruptions is paramount.

Our industry, and our farmer-customers emphatically need to avoid the costly trade disruptions that have been associated periodically with transgenic biotechnology. If the U.S. government's regulatory oversight approach to genome editing and other plant breeding innovation is out of step with the domestic food industry or America's trading partners, it will have perilous repercussions for the grain and oilseed value chain, including U.S. farmers. We can "build it," but if U.S. and global consumers "don't come," (i.e., "don't buy it") the acceptance of this valuable technology could be imperiled and undermined irrevocably.

We respectfully believe each of the recommendations we offer are essential to avoiding such an undesirable outcome, and urge that they be adopted by APHIS.

Sincerely,

Randall C. Gordon
President and Chief Executive Officer
National Grain and Feed Association



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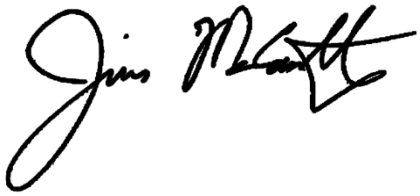

Jim McCarthy
President and Chief Executive Officer
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cc: The Honorable Sonny Perdue, Secretary of Agriculture

The Honorable Greg Ibach, Under Secretary of Agriculture for Marketing and Regulatory Programs

White House Office of Science and Technology Policy