

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

November 1, 2016

Docket Clerk  
National Science and Technology Council  
Emerging Technologies Interagency Policy Coordination Committee  
Office of Science and Technology Policy  
1650 Pennsylvania Avenue N.W.  
Washington, DC 20504

***RE: Docket No. FDA-2015-N-3403; Clarifying Current Roles and Responsibilities  
Described in the Coordinated Framework for the Regulation of Biotechnology***

The undersigned national organizations<sup>1</sup> representing member companies involved in the grain and oilseed storage, handling, processing, feed manufacturing and export industries respectfully

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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.

**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)**, 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.

submit these comments in response to the Office of Science and Technology Policy’s proposed update of the *Coordinated Framework for the Regulation of Biotechnology* (“*Coordinated Framework*”). In so doing, we also reference a few key provisions in the accompanying *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (“*National Strategy*”) dated September 2016 that we believe have a direct bearing upon the updated draft *Coordinated Framework*.

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 other safe cropping technologies and practices that enhance the production of safe, affordable and sustainable food and energy for U.S. and world consumers. As we have expressed previously, the competence and objectivity of the science-based U.S. regulatory framework that ensures the safety of biotech-enhanced products for humans, animals and the environment is well proven.

Instead, what is of overriding importance in our view are the serious issues related to the marketability and current lack of international regulatory coherence regarding the premarket regulatory review of crops produced through modern biotechnology, and the negative impact those factors have in facilitating access to U.S. crops. While it acknowledges public comments made by our organizations and others about the tremendous significance of these issues, the updated draft *Coordinated Framework* only briefly references and then summarily dismisses them. Instead, the updated draft *Coordinated Framework*, regrettably in our view, confines itself to “clarifying the current roles and responsibilities of the (U.S.) agencies that regulate biotechnology products<sup>2</sup>.” Unfortunately, we believe this represents a significant missed opportunity. More importantly, it fails to recognize the underlying fact that nothing is gained if crops produced through modern biotechnology and other safe cropping technologies cannot be marketed.

In addition, and as discussed subsequently herein, we are concerned about the decision by the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) to move forward with rulemaking to revise its 7 CFR Part 340 regulations without the benefit of an updated *Coordinated Framework*. While APHIS states that the two efforts are distinct yet “entirely compatible,” common sense suggests that two “distinct” efforts occurring in isolation likely are not “coordinated.”<sup>3</sup>

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**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.

<sup>2</sup> *Coordinated Framework*, page 51.

<sup>3</sup> See 81 Fed. Reg. 6225, 6226 (February 5, 2016), “Currently, the Federal agencies are in the process of working with the Executive Office of the President to modernize a number of *Coordinated Framework* issues and activities;

Given the *Coordinated Framework* is reviewed only periodically, we believe the better and more prudent course of action would be for the interagency Biotechnology Working Group to revise the updated draft *Coordinated Framework* to identify specific issues and “gaps” that exist in the current U.S. approach for providing regulatory oversight of modern biotechnology, and to identify potential options for addressing them – including instances where new statutory authority may be needed.

Instead, the *Coordinated Framework* declines to take a more comprehensive approach, stating that “[s]ome responses raised issues that are more appropriately addressed under the *Strategy*, and those will continue to be considered as part of future work related to the implementation of that *Strategy*.”<sup>4</sup> Yet, it fails to identify any specific “issues” it is referencing. We acknowledge that the *National Strategy* cites the importance of the Environmental Protection Agency, Food and Drug Administration and U.S. Department of Agriculture “**continu(ing) to provide leadership in international fora to promote scientific competency, understanding of the U.S. regulatory approach, and regulatory compatibility worldwide for biotechnology products.**”<sup>5</sup> [*Emphasis in original.*] We recognize and commend the increased emphasis by the U.S. government in engaging and taking more of a leadership role in chairing key working groups within the Organization for Economic Cooperation and Development (OECD) on scientific and technical issues underpinning regulatory approaches for products of agricultural and industrial biotechnology. As an extension of such efforts, we urge a redoubling of U.S. government efforts to fully engage and coordinate with competent regulatory authorities of key U.S. trading partners, and to explicitly highlight in the *National Strategy* the specific steps it plans to take to foster international regulatory coherence for products of modern biotechnology.

However, we also note that this same section of the *National Strategy* is revealing in that it further states that U.S. initiatives are directed at “supporting **greater regulatory predictability** and reducing impediments to U.S. innovation and products worldwide” [*Emphasis added.*] Regulatory predictability (which to date largely has been limited to the U.S. government urging competent government authorities in important U.S. export markets to “fix” their biotech regulatory-approval systems) is far different, and we would submit far less likely to succeed, than having the U.S. government work collaboratively to achieve **regulatory coherence and compatibility** with U.S. trading partners to the maximum extent possible. It also is curious that the *National Strategy* – both in this and other sections, does not envision any role for the Office of the U.S. Trade Representative, which we believe is a serious omission and which we hope is not revealing of the narrow scope of the planned U.S. approach.

By failing to address issues surrounding the marketability of U.S. crops produced through modern biotechnology, the newly updated *Coordinated Framework* continues to ignore the “elephant in the room.” The U.S. regulatory system has never operated in a vacuum. And the marketability of crops matters – for U.S. producers and agribusinesses, the U.S. agricultural economy and ultimately to world food security, the latter of which is linked directly to the

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that effort is distinct from and entirely compatible with APHIS' effort to revise its biotechnology regulations at 7 CFR part 340.”

<sup>4</sup> Ibid, page 52.

<sup>5</sup> National Strategy, page 11.

bounty of U.S. agriculture. Marketability considerations have become of paramount importance given the increasing lack of coherence in various nations' regulatory systems regarding safety reviews and approval of new biotech-enhanced events. As our organizations have pointed out repeatedly, there are no shortages of documented cases in which U.S. export customers' access to U.S. crops has been disrupted or halted entirely – leading to significant downward pressure on farmgate prices, severe economic damage to U.S. exporters and reduced economic value of U.S. agricultural production – as a result of commercialization of biotech-enhanced crops prior to commensurate approval by competent government authorities in significant U.S. export markets.

We raise these issues because commerce in grains and oilseeds is tied inextricably to global sourcing, and because of the irrefutable fact that achieving a sustainable supply of these basic commodities depends upon fungibility – the principle that the supply of a given crop has a degree of substitutability and relatively comparable value, regardless of the geographic production area from which it originates. Grain and oilseed supplies that can be comingled without concern over regulatory status can be accessed in a timely, cost-effective and efficient manner in response to buyer demands, providing time-and-space utility that is essential to achieving supply integrity and food security. Production and logistics systems that benefit from a fungible supply of grains and oilseeds are critical to the efficient movement of these essential commodities to global consumers.

In addition, the updated draft *Coordinated Framework* fails to address appropriate government oversight of biotech-enhanced traits that have functionally different output characteristics than their conventional counterparts (e.g., Enogen® corn containing alpha amylase) that can affect nutritional, compositional or other end-use properties, thereby making their presence in the food or feed system inappropriate above certain threshold levels. Should one or more federal agencies have a role in providing regulatory oversight or third-party audits of private-sector stewardship programs to avoid the disruption and adverse economic impacts on the food or feed system – both domestically and internationally – if such traits become present in the fungible, commingled commodity system? Again, the updated *Coordinated Framework* is troublingly silent.

We respectfully submit that within the overall U.S. government regulatory oversight of modern biotechnology, USDA's APHIS does have a role to play, given that agency's 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 (Sec. 402) of the Plant Protection 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 Plant Protection Act 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.*] Yet, as noted previously, the updated *Coordinated Framework* again fails to consider this important APHIS Mission as it relates to the overall marketability of crops produced through modern biotechnology.

Given APHIS's Mission Statement and the previously cited provisions of the Plant Protection Act, we encourage the interagency Biotechnology Working Group to evaluate whether it is appropriate to create a different category of "deregulation" – namely "conditional deregulation"

– expressly for biotech-enhanced events that the agency has found do not present a plant pest or noxious weed risk, but which have not received approvals in significant U.S. export markets and as such represent a risk of disrupting domestic and/or export markets if they become present in the commingled supply chain. We submit that the same “conditional deregulation” approach should apply to biotech-enhanced events that have functionally different output traits whose presence in the fungible, commingled commodity system could disrupt domestic and international supply chains if they become present above specified threshold levels.

For biotechnology-enhanced events subject to “conditional deregulation,” technology owners could be directed to implement sufficiently robust and appropriate trait-specific stewardship plans, in consultation with affected value-chain stakeholders, to protect the marketability and value of U.S. crops. This potential suggested approach would recognize and respect 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 the importance of addressing APHIS’s mission to protect the value and economic well-being of plant- and animal-based U.S. agriculture. Further, USDA’s Agricultural Marketing Service could be looked to as a credible third-party auditor, through its “Process Verified Program,” of sufficiently rigorous stewardship programs to prevent or minimize the presence of such traits in the commodity stream.

Importantly, these marketability-related and global regulatory coherence issues that are given short shrift in the updated *Coordinated Framework* and *National Strategy* promise to become even more crucial given the advent of plant breeding innovation techniques that involve new non-transgenic – but nonetheless genetic engineering – breeding technologies. These new technologies raise the prospect of even greater divergence in international regulatory approaches in the future, unless the United States and its international partners adopt a different model appropriate to these new technologies going forward. We join our colleagues in the biotechnology, seed and agricultural producer and commodity value chain in stressing the importance of the U.S. government doing all it can to provide the leadership necessary to achieve alignment with significant U.S. trading partners on sound, science-based criteria for determining which of these new plant breeding innovation techniques warrant regulatory review.

To create a truly workable biotech regulatory framework for the future, we believe both the *Coordinated Framework* and *National Strategy* must more adequately address the challenge of achieving regulatory coherence and compatibility in the global market. This includes the development of a U.S. regulatory policy for the low-level presence (LLP) of genetically engineered products in food, feed and seeds, as well as consideration of compatibility with implicated U.S. laws<sup>6</sup>. Again, the *National Strategy* mentions that this LLP issue was raised by our organizations in public meetings and subsequent written comments, but is silent about whether or how the interagency Biotechnology Working Group intends to address it.

To reiterate, if the interagency Biotechnology Working Group believes current statutory authority does not permit the U.S. government to address the marketability and trade-disruption concerns cited in this statement, we believe it has a responsibility to identify them as significant “gaps” in the current *Coordinated Framework* and propose a specific outcome-based strategy

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<sup>6</sup> Coordinated Framework, page 51.

for addressing them. Further, we urge that the *National Strategy's* Goals and Objectives Section on Increasing Predictability and Efficiency be amended in bullet #3 to include a specific reference to marketability-related issues.<sup>7</sup> Specifically, we recommend that this bullet be amended to read: “*Identify changes to authorities, regulations, and policies that could improve agencies’ abilities to assess expeditiously the potential impacts and risks – **including marketability-related risks** – arising from future products of biotechnology and to ensure the transparency, predictability and efficiency of regulatory oversight for such products. [New language boldfaced and underscored.]*”

With respect to the request for input on questions associated with facilitating communication across agencies and ensuring there is public trust in the U.S. regulatory system for biotechnology products, we believe the creation under Presidential Executive Order 12866 of the interagency Biotechnology Working Group under the auspices of the Emerging Technologies Interagency Policy Coordination Committee is a positive development.

However, in this regard, we and other stakeholders have been concerned over what apparently is a lack of such policy coordination between affected federal agencies involved in the *Coordinated Framework*. As noted previously, a case in point is APHIS’s publication of a *Federal Register* notice announcing plans to update its 7 CFR Part 340 regulations, an action taken independently of the review of the *Coordinated Framework*. We concur with the American Seed Trade Association in believing it is imperative that when agencies move forward with significant changes such as this in their biotechnology regulatory policies, that they engage in two-way communication well in advance with other federal agencies, industry stakeholders and our international trading partners. The APHIS 7 CFR Part 340 rulemaking appears to be proceeding in a manner that is out of step with the Coordinated Framework activities, apparently by design. This raises significant concerns among our respective memberships that a proposed rule to update 7 CFR Part 340, prior to the conclusion of the Coordinated Framework activities, will result in confusion in the international marketplace and with key U.S. trading partners, potentially damaging the U.S. economy and running the risk of requiring additional rulemaking in the future. Thus, we recommend that the interagency Biotechnology Working Group complete an assessment as soon as possible of both 7 CFR Part 340 and the *Coordinated Framework* to determine their compatibility and coherence with counterpart global regulatory regimes.

To enhance stakeholder certainty and public trust, we also encourage agencies to develop and publish clear guidance on the scope of regulations, data requirements, regulatory processes and bases for decision-making for regulatory reviews of biotechnology-enhanced products, as well as oversight of field trials and other regulatory activities.


Finally, given the rapidly advancing science and innovation in genetic engineering, we strongly recommend that the U.S. government commit to reviewing the *Coordinated Framework* and the *National Strategy* at least every five years, and more frequently if needed, to keep them current and maintain their relevance.

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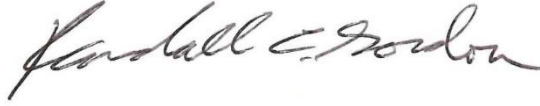
<sup>7</sup> National Strategy, page 9.

The undersigned national organizations again appreciate the opportunity to provide our views, and would be pleased to respond to any questions the interagency Biotechnology Working Group may have.

Sincerely,



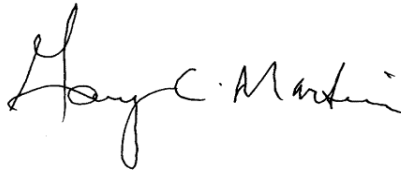
**John Bode**  
President and Chief Executive Officer  
Corn Refiners Association



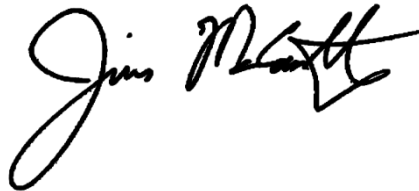
**Randall C. Gordon**  
President  
National Grain and Feed Association



**Thomas A. Hammer**  
President  
National Oilseed Processors Association



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



**Jim McCarthy**  
President and Chief Executive Officer  
North American Millers' Association