May 11, 2015

The Honorable Tom Vilsack
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Filed electronically at: http://www.regulations.gov/#/docketDetail;D=APHIS-2013-0047

Re: Docket No. APHIS-2013-0047: U.S. Department of Agriculture Stakeholder Workshop on Coexistence

Dear Mr. Secretary:

The Corn Refiners Association (CRA)\(^1\), National Grain and Feed Association (NGFA)\(^2\), North American Export Grain Association (NAEGA)\(^3\), National Oilseed Processors Association

---

\(^1\) CRA, established in 1913, is the national trade association representing the U.S. corn refining industry. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts, corn oil and feed products from corn components such as starch, oil, protein and fiber.

\(^2\) 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.

\(^3\) 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.
Joint Comments to USDA on Coexistence
May 11, 2015
Page 2

NOPA\(^4\) and North American Millers’ Association (NAMA)\(^5\) respectfully submit the following statement to the U.S. Department of Agriculture for consideration in response to its request for comments on issues and proposals discussed during the workshop on agricultural coexistence conducted on March 12-13, 2015. We appreciate the extension of the comment period to give more stakeholders an opportunity to address this important topic. Our member companies handle, process and export the vast majority of grains and oilseeds used in human and animal food, and are affected directly by marketability-related issues associated with the commercialization of crop biotechnology and other cropping systems.

At the outset, it is important to note that our organizations support biotechnology and other sound scientific innovations that enhance the production of safe, high-quality, affordable and sustainable food for U.S. and world consumers. But achieving that objective requires that our industry sectors be able to competitively, cost-effectively and seamlessly market U.S. agricultural products in domestic and foreign markets.

In that regard, it is our observation that the coexistence conversation unfortunately continues to remain focused on only one of three important coexistence discussions: the coexistence between commodity and organic agriculture. However, significant dialogue also is ongoing between agricultural stakeholders on coexistence between 1) domestic and export supply chains, as it relates to major market approvals for GE crops; and 2) commodity and specialty supply chains, as it relates to commercialization of products with unique functional characteristics (PUFCs).

These two additional coexistence issues represent the root cause for the ongoing advocacy of development of a policy for addressing low-level presence (LLP) of biotech materials and the promotion of standards concerning how new traits are assessed, approved, commercialized and handled domestically and internationally. All three coexistence issues highlight the pressing need for the development and adoption of responsible standards and practices by technology owners to enable coexistence. Thus, we urge USDA to continue to engage the public on the broader range of coexistence issues and leverage the ongoing dialogues underway between agricultural value-chain stakeholders in U.S. agriculture.

**Premature Release of GE Traits**

The increasing emergence of a new business model by biotechnology owners involving new forms of commercial releases of biotech-enhanced events (e.g., “pre-commercial release,” etc.) has caused increasing friction between various sectors of the agricultural value chain, and heightened market risk for U.S. agricultural exports. In effect, technology owners increasingly have adopted business strategies in which they partially introduce GE traits in various U.S. geographic areas before they are fully commercialized for cultivation on a widespread basis, yet do so before they have secured approvals in significant U.S. export markets.

---

\(^4\) NOPA is a national trade association that represents 13 companies engaged in the production of vegetable meals and oils from oilseeds, including soybeans. NOPA’s member companies produce more than 1.6 billion bushels of oilseed products annually at 63 plants located in 19 states, including 57 plants that process soybeans.

\(^5\) NAMA is the trade association representing the wheat, corn, oat and rye milling industry. Its 47 member companies operate 170 mills in 38 states and Canada. Their aggregate production of more than 175 million pounds per day is approximately 95 percent of the total industry capacity.
However, documented incidents in which GE events have been detected — and commodity shipments rejected — in major U.S. export markets for which they have not been approved yet, point to the fact that it is virtually impossible to effectively channel products with 100 percent certainty, despite best efforts. Therefore, we do not support premature commercialization in advance of market approvals unless technology owners concurrently agree to accept and bear the risks and liabilities associated with their company-specific business decisions, since such strategies pose the same potential risks and adverse market impacts as full product commercialization given the lack of a globally accepted, attainable LLP. Technology owners, who ultimately make the business decision to commercialize their products, should properly bear the market-related risks and liabilities associated with their decisions. These responsibilities of technology owners include: 1) the implementation of sufficiently robust and effective production, stewardship and marketing systems designed prevent the introduction of the technology to other U.S. commodity crops in the fungible supply chain if they have not been approved yet in export markets; and 2) the acceptance of liability associated with the failure to adequately manage the trait.

**Products with Unique Functional Characteristics**

Similarly, significant issues exist between traditional commodity supply chains and the emergence of biotech-enhanced products with unique functional characteristics (PUFCs). These products are intended to be handled within fully segregated supply chains. However, given the fact that an agricultural supply chain cannot be managed to achieve 100 percent segregation, the introduction of PUFCs could have significant impacts on the quality (i.e. specifications) of existing commodity supplies. All sectors of the agricultural supply chain, from technology owners to end users, have recognized that the mismanagement of PUFCs can have significant adverse impacts on these existing commodity supply chains. Given these challenges, downstream stakeholders have asked the technology owners to take additional responsibility to ensure the appropriate introduction, handling and use of PUFCs.

Responsible commercialization of PUFCs includes determining the level of impact that the presence of PUFCs could have on the nutritional, functional and compositional characteristics of a food or feed, and development of a corresponding plan to manage the PUFC in a way that does not negatively impact stakeholders in the United States and major foreign markets. The level of impact of the commingling of PUFCs with the fungible commodity supply must be examined on a case-by-case basis; some products may have little to no impact, while others may have significant impacts. Technology owners should continue working with downstream stakeholders to ensure that both the commodity and specialty supply chains are aware of such impacts. Further, we believe technology owners have a responsibility to protect the supply chain so it can be operated effectively and efficiently.

**Core Elements for Coexistence**

The following three elements are essential if biotech-enhanced traits are to be commercialized in a responsible way to minimize adverse market impacts on the U.S. agricultural value chain and food and feed system:
Joint Comments to USDA on Coexistence
May 11, 2015
Page 4

- **Risk Assessment:** Technology owners should assess, in collaboration with affected value-chain stakeholders, the market risk and threshold of impact, if any, that may be associated with the commercialization of biotech-enhanced crops. In the case of PUFCs this assessment should include a determination of the trait’s level of impact (i.e. impact threshold) in a commodity that will have significant negative impacts on the commodity and its supply chain. Once this data is developed, it should be a matter of public record.

- **Risk Management:** Once the market risk-assessment is completed, technology owners should establish and implement sufficiently robust and effective stewardship plans and supply chains that are appropriate and commensurate with the degree to which the given trait poses a risk to U.S. export markets or, in the case of PUFCs, to keep the product segregated in a manner that ensures it does not escape into the commodity supply chain above the impact level/threshold.

- **Risk Responsibility:** When the technology owner, producer or other parties in the technology owner’s trait-specific risk-management supply chain fail to effectively assess and/or manage a given biotech-enhanced trait’s adverse impacts, they should accept responsibility for direct economic damage incurred by downstream stakeholders resulting from their failure to manage the trait.

Organizations like the Biotechnology Industry 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, including PUFCs, should be responsible in their introduction and management of the impacts on overall supply chains.

Finally, we believe that the commercial seed products currently on the market have allowed growers to increase crop yield, decrease crop inputs and increase the use of conservation tillage. These technological advances largely have been successful in enhancing the productivity and competitiveness of U.S. growers, grain handlers, processors and exporters, and accrued substantial benefits for consumers. Going forward, our organizations 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 practices.

Thank you for the opportunity to comment on this important issue.

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