June 12, 2017

Office of the U.S. Trade Representative
600 17th Street, NW
Washington, D.C. 20006

Submitted Electronically via Federal eRulemaking Portal (http://www.regulations.gov)

Re: Docket No. USTR-2017-10603 - Request for Comments on Negotiating Objectives Regarding Modernization of the North American Free Trade Agreement With Canada and Mexico

Dear Sir or Madam:

The U.S. Biotech Crops Alliance appreciates the opportunity to provide comments in response to USTR's Request for Comments on negotiating objectives regarding modernization of the North American Free Trade Agreement with Canada and Mexico (82 FR 23699).

The U.S. Biotech Crops Alliance (USBCA) is a broad-based group of organizations encompassing the value chain dedicated to improving the environment for technology innovation and the marketability for U.S. crops produced using modern biotechnology. The goal of USBCA is to implement consensus positions on key policy issues to improve the introduction, stewardship, domestic and international regulatory policy, and distribution in U.S. and export markets of commodities and processed products containing or derived from modern biotechnology. USBCA members consist of 13 leading national organizations representing U.S. biotechnology providers; seed, grain and oilseed producers; grain handlers, feed manufacturers, grain processors and millers; exporters; and other end-users.

The North American Free Trade Agreement (NAFTA) came into force two years prior to the commercialization of the first biotech crops in 1996. Since that time, biotech acreage across multiple crops has grown rapidly because of the increased productivity and, environmental benefits associated with this technology.

Since the NAFTA entered into force, the global regulatory framework for biotech crops has expanded, sometimes resulting in redundant measures, leading to an unpredictable, and time-consuming global regulatory environment, which in turn has imposed high barriers to efficient trade. Corn and soybean products often are evaluated for their safety by 20 or more governments, all generally following the same standards for assessment and evaluating the same data. The timing of approval of these products affects the entire crop value chain. If a product is commercialized in one plant crop in the absence of globally synchronized regulatory approvals, trade disruption may occur in multiple crops and processed products used for food, feed and further processing, even though the product has completed a risk assessment and been approved in one or more countries. Similarly, asynchronous approvals have contributed to the delayed introduction of new technologies for use by agricultural producers, resulting in lost opportunities for farmers and

product developers, as well as other participants in the value-chain, to capitalize on the introduction of new biotech traits.

The USBCA seeks to ensure the unencumbered marketability of U.S. crops and improve international biotechnology regulatory policy, including through trade agreements like NAFTA. To this end, we seek to achieve enhanced cooperation between regulatory agencies and prevent trade disruptions related to agricultural production technologies like biotechnology.

Under a modernized NAFTA, USBCA requests that the U.S. government: (1) enter a mutual recognition agreement with Canada and Mexico on the safety determination of biotech crops intended for food, feed and for further processing, and (2) develop a consistent approach to managing low-level presence (LLP) of products that have undergone a complete safety assessment and are approved for use in a third country (ies) but not yet approved by a NAFTA member.

Mutual Recognition of Safety Determinations for Food and Feed

Asynchronous approvals of biotechnology products by regulatory authorities in exporting and importing countries may restrict innovation and create enormous risk to the international trade of commodities, such as corn and soybeans. The most effective way to reduce the risk of trade disruptions and enable farmers to access the most advanced technologies within a reasonable time is to eliminate the gap in product approvals through an agreement on mutual recognition of safety determinations of biotech-enhanced commodities for use as food, feed or for further processing. Such an agreement, in addition to reducing risk to international trade and enabling innovation, would be consistent with existing international obligations and the current direction that the U.S. government and others are taking in the area of regulatory cooperation.

As an example, the Food and Drug Administration (FDA), to meet its obligations under the Food Safety Modernization Act (FSMA), has entered into food safety agreements thus far with Australia, Canada, and New Zealand that recognize the comparability of the countries' respective food safety systems as a means of resource-sharing and prudent risk-management to achieve safety outcomes and better enable trade. This concept of "systems recognition" is granted to countries where FDA has determined that the country's food safety system offers a similar, though not necessarily identical, system of protections as does the FDA food safety system. While similar to equivalence, systems recognition properly puts relatively more focus on the outcomes of food safety systems and whether other systems are achieving comparable safety outcomes as FDA's, rather than determining whether or not countries are following the same processes, as can be the case with some equivalence assessments.

For products of modern biotechnology, the regulatory agencies of the United States, Canada, and Mexico have demonstrated to each other time and time again that while their systems for regulating such products may differ in some areas, the regulatory agencies consistently arrive at the same conclusions regarding the human and animal food safety of products that are evaluated by all three governments. In the years prior to and following the commercial introduction of biotech crops in

1996, regulators in the United States, Canada, and Mexico have collectively reviewed and approved 660 products for food and feed safety.

The Governments of the United States, Canada, and Mexico also have collaborated to help develop international standards for the safety assessment of food derived from biotechnology. In March 2000, the Codex Alimentarius *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (TFFBT) held its first session, in which the U.S. and Canada were participants. The Government of Mexico joined TFFBT for the second session in 2001, and TFFBT went on to produce *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (CAC/GL 44-2003) and *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* CAC/GL 45-2003), among other standards. The idea of regulatory cooperation – specifically that governments may use the "risk assessment undertaken by other regulatory authorities to assist in the risk analysis and avoid duplication of work" – was articulated in CAC/GL 44-2003.

In 2002, the United States proposed the creation of the North American Biotechnology Initiative (NABI), which conducted its first meeting that same year. The objective of NABI was to discuss issues of common interest, as well as identify areas for further cooperation ranging from scientific research, collaborations, market access, and regulatory regimes. At the outset, working groups on science, marketing, and regulatory were established to identify: priority issues, existing collaborations amongst the three countries, and those areas where work could be undertaken on a trilateral basis. To date, NABI has achieved several successes, notably the Trilateral Arrangement on the Documentation Requirements for Living Modified Organisms for Food or Feed, or for Processing, which helped Mexico achieve its obligations to the Cartagena Protocol on Biosafety without disrupting intra-regional trade.

USBCA believes that a trilateral mutual recognition agreement regarding the safety of agricultural products intended for use as food, feed or for further processing under a modernized NAFTA agreement is consistent with the progression of NABI and other multilateral dialogues involving NAFTA members and is the most effective means of ensuring the marketability of U.S. crops and improving international biotechnology regulatory policy.

Agreement on a Policy Framework for Low-Level Presence (LLP)

While mutual recognition of safety determinations for agricultural products intended for use as food, feed and for further processing is our priority objective, USBCA requests that this administration seek to establish common practice to manage LLP incidents. U.S, Canada, and Mexico are expected to continue to provide for uniformity on approvals but common official and commercial practice still are needed, especially to respond to situations when the biotechnology product is authorized for use in a non-NAFTA member country with a competent national authority that has completed a food safety assessment.

The participating countries of the Trans-Pacific Partnership (TPP) negotiations recognized that asynchronous biotechnology approvals and the resulting LLP incidents are a threat to trade; however, the TPP language had several deficiencies in that it was non-binding and did not achieve

any improvement in the predictability of trade in the absence of synchronous approvals of biotechnology products. USBCA believes the modernization of NAFTA creates an opportunity to take a much bolder step than what was possible in TPP and build upon other existing dialogues on LLP involving NAFTA members.

The United States, Canada, and Mexico are all members of the Global LLP Initiative (GLI), and as such, are signatories to the *International Statement on LLP*. Though non-binding, this statement recognizes the need for action and the importance of developing practical approaches for the management of LLP that are science-based, predictable, and transparent. To date, however, only the Government of Canada among these three countries has taken visible steps to develop and try to integrate practical approaches to LLP into its existing legal framework.

While the Government of Canada's leadership in this space and progress on LLP policy development should be commended, inconsistent approaches to LLP by NAFTA members create risk to intra-regional trade. Therefore, a consistent LLP policy by NAFTA-member countries is needed to address cases where the product is approved by a third country following a safety assessment.

In addition to facilitating regional trade, a NAFTA policy framework for LLP can serve as a model policy for other countries that enables trade in the absence of synchronous biotechnology approvals. , USBCA expects the U.S. government to be a leader in developing policies to better enable innovation and trade, including LLP policy, and stands ready to provide input to the administration in this regard.

Conclusion

USBCA believes modernizing NAFTA is an excellent opportunity to improve domestic and export marketability of U.S. crops. We encourage the completion of an agreement that provides for n mutual recognition of approvals and common practice for LLP situations. Inclusion of these principles in a "modernized" NAFTA also could contribute to their adoption in future trade accords beyond North America.

USBCA appreciates your consideration of these recommendations, and stands ready to work together with you and our NAFTA partner countries during the consultation process and throughout the upcoming negotiations.

Sincerely,

The U.S. Biotech Crops Alliance