AMERICAN SEED TRADE ASSOCIATION

May 10, 2013

Mr. Douglas Bell
Chair, Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th St, N.W.
Washington, D.C. 20508

Re: Docket USTR-2013-0019 (*Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement*)

Dear Chairman Bell:

Please find below comments from the American Seed Trade Association regarding *Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement*.

Background

The U.S. seed industry is a thriving science-based industry that exceeded an estimated $12 billion market value in 2011. It is both the largest market for seeds in the world, with a value that contributed approximately 26% to the global commercial seed sales in 2011, and the largest global exporter of seeds, with an annual export value of over $1.25 billion. Innovation is fundamental to the U.S. and global seed industry. The focus of this innovation is on an increased understanding of plant genomes, refinements in breeding techniques, and identification of new traits so that farmers have a wide array of high quality, high producing seed varieties when making their planting choices. The continuation of such innovation is crucial for both the U.S. seed industry and global food security, particularly at a time when the global population continues to grow rapidly and many developing nations can ill-afford food shortages.

Founded in 1883, The American Seed Trade Association's (ASTA) mission is to enhance the development and movement of quality seed worldwide. Many ASTA members are research-intensive companies engaged in the discovery, development, and marketing of seed varieties with enhanced agronomic characteristics and characteristics related to end-use quality. In addition, ASTA's membership is extremely diverse. We represent all manners of seed produced for planting, from conventional, to biotechnology, to organic. Our members research, develop, produce and distribute all varieties of seeds – including grasses, forages, flowers, vegetables, row crops, and cereals. Our members' seed products support agricultural producers of food products and farm commodities in the United States and other countries.

ASTA welcomes the opportunity to provide comments in response to *Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement* (78 Fed. Reg. 19,566 (Monday, April 1, 2013)). The seed industry is a global industry with the movement of seed across national borders an integral component of variety development and seed distribution and sales. Together the seed industries in the United States and the European Union (EU) represent approximately half of the market value of the world

seed industry. The importance of seed movement between the United States and the European Union is vital to the continued growth of the industry and ultimately to global agriculture productivity and food security. The proposed Transatlantic Trade and Investment Agreement (TTIP) has the potential to provide a useful mechanism to both resolve issues and identify opportunities important to the U.S. seed industry and to the mutual benefit of U.S.,EU, and global agriculture.

While ASTA welcomes the launch of the TTIP negotiations, ASTA is concerned about certain trade-distorting EU policies that are neither based on science nor conducive to scientific development or agricultural productivity, which undermines both the interests of the U.S. seed industry and agricultural producers that rely on our products in the United States and other countries. Specifically, ASTA's comments will focus on regulatory issues and non-tariff barriers, including sanitary and phytosanitary (SPS) issues and issues related to the WTO Agreement on Technical Barriers to Trade (TBT). ASTA agrees with the final report of the High Level Working Group on Jobs and Growth (February 11, 2013) that the United States and the EU should negotiate "ambitious SPS-plus and TBT-plus" chapters. Robust intellectual property protection is a key priority for the seed industry and these comments raise Intellectual Property Rights (IPR) issues of importance to U.S. seed industry. ASTA strongly encourages the United States to work toward an equally ambitious negotiation on IPR issues.

Intellectual Property Rights

EU Unitary Patent System

The introduction of the Unitary European Patent package will, once it enters into force, enable applicants to choose between three patent regimes in Europe: (i) national patents (protection granted by the national authorities), (ii) European Patents (granted by the European Patent Office and validated in EU member states), and (iii) new Unitary Patents that need no further validation and offer protection in all Participating States on the basis of a single application. After a period of time, the Unitary Patent is expected to be the only option for member countries.

Issue: One of the exemptions included in the Unitary Patent Scheme states that the protection provided by the unitary patent ". . . shall not extend to the use of biological material for the purpose of breeding, or discovering and developing other plant varieties." The breeder's exemption provision is inconsistent with the principles of exclusive rights to patent holders and non-discrimination underlying the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Impacts: This "breeder's exemption" is broader than the breeder's exemption of the International Convention for the Protection of New Varieties of Plants (UPOV) that is already codified in national laws to include plant varieties that are or could be covered by a patent. The exemption creates an imbalance between the United States and the EU, such that many research, development and breeding activities that must be undertaken under a license in the United States would be obligation-free in the EU. Additionally, European patent-holders would still have fully enforceable patents in the United States, whereas U.S. patent-holders would have no such rights in the European Union.

Proposed Solution: ASTA strongly recommends the TTIP contain a robust section on Intellectual Property Rights and that discussions include the impact of the Unitary European Patent System on intellectual property protection of materials and methods related to plants, with the objective to safeguard patent holders' rights consistent with principles under the TRIPS Agreement and those provided by the U.S. to European patent-holders.

Availability of All Intellectual Property Protection Systems

Issue: Traits are the characteristics of an organism, the expression of which is controlled by one or more specific segments of DNA. The ability to identify specific traits at the genetic level and so to more efficiently select for and alter their expression are becoming increasingly available to plant breeders. These advances in plant breeding provide enhanced opportunities for effective evaluation and characterization of the vast complexity of genetic diversity that underlies the genomes of well-adapted varieties, in less adapted varieties or wild species. Use of such approaches enables the breeding community to allow farmers to increase agricultural productivity in an environmentally sustainable manner.

The past few years there have been efforts in the EU to restrict the granting of patents on these traits (sometimes referred to as "native traits") and to limit the form of intellectual property protection available for such traits to plant variety protection rights under UPOV. Although at this point legislation has not been introduced to impose these limitations, two matters pending before the European Patent Office Enlarged Board of Appeals squarely raise the issues of the patentability of these traits.

Impacts: All forms of intellectual property protection systems, including patents and PVP and other methods of protection, should be available to allow new inventions to be protected in the most appropriate manner as determined by the inventor, in this case the breeder. Placing off-limits certain protections for particular inventions will discourage investment in these inventions and undermine the growth of agricultural productivity. Additionally, should restrictions be placed on the type of intellectual property protection that can be utilized for the discovery of specific traits in a plant's genome, again, there would be an imbalance in the availability of protections between the United States and Europe.

Proposed Resolution: Patent claims on native traits should neither have higher nor lower requirements on patentability than other inventions. The TTIP should provide a mechanism to ensure a robust dialogue between U.S. and EU patent authorities on these types of patents.

Regulatory Issues and Non-Tariff Barriers

International Seed Standard

Issue: Strong support is needed by both the United States and the EU in the development of an international seed standard under the International Plant Protection Convention (IPPC), the international body responsible for establishing international phytosanitary standards.

Impacts: Together, the United States and the EU make up over one-third of the global seed trade. The U.S. and EU seed industries are expressly linked with many U.S. seed companies having subsidiaries in the EU and vice versa; therefore, there is a need for seed phytosanitary policies and programs that are equivalent and harmonized based on scientific principles in order to achieve a predictable trade environment that enhances the economies of both the United States and the EU.

Proposed Resolution: The United States and the EU should serve as examples for how seed phytosanitary matters should be addressed, resolved, and implemented. TTIP provides an opportunity for both parties to work together to strongly support science-based, harmonized phytosanitary measures, support (and participate in) the development of the international seed standard by the IPPC, and then apply this and other IPPC standards to address phytosanitary aspects of seed trade. Overall, both parties should reaffirm the IPPC principle of trust in the international phytosanitary export certification system.

Seed Re-Export

Issue: Phytosanitary restrictions that that unnecessarily impede seed re-export not only have a negative impact on seed trade between the United States and the EU, but also negatively impact the movement of seed to many other countries in the re-export chain and global agricultural productivity.

Impacts: Seed re-export is normal practice by the seed industry and is a critical issue for both the United States and the EU. Seed in the form of research and breeding material, parental seed lines for the development of hybrids, seed for research trials and evaluation of performance under varying environmental conditions, and commercial seed for sale are routinely moved between the United States and EU member states. In addition, both the EU and the United States act as intermediaries in re-export to other non EU and US destination countries.

Proposed Resolution: The TTIP provides an opportunity to set up a mechanism for the United States and the EU to develop a common scheme for seed re-export that also preserves phytosanitary security for both parties.

Minimizing Differences in Seed Diagnostics and Testing Methodologies

Issue: Minimizing phytosanitary measures such as seed diagnostic and testing methodologies and protocols for phytosanitary pests of concern is needed to prevent unnecessary shipment rejections and trade disruptions. Mutual recognition of these methodologies and protocols will enable the development and adoption of standardized language needed for additional declarations on phytosanitary certificates for specific pests of concern that will resolve many issues with seed re-export and international seed movement in general.

Impacts: The EU represents one-quarter of the total U.S. seed exports and is the second largest regional importer of U.S. seed. In 2012, U.S. seed exports to the EU were valued at over $355 million.

Proposed Resolution: Efforts should focus on methods that are not only scientifically accurate and reproducible, but simple and economically feasible so that when countries elect to re-test incoming shipments, they get the same (correct and credible) results. In addition, both parties should commit to recognize equivalency among the basic categories of phytosanitary measures for as many seed quarantine pests of concern; namely phytosanitary field inspections, pest free areas and pest free places of production, seed diagnostic and testing methodologies, and seed visual inspection.

Biotechnology

EU's policies toward biotechnology products are not only unreasonable given the economic, environmental and human health benefits associated with biotechnology, but also inconsistent with the WTO requirement that sanitary and phytosanitary measures be based on scientific evidence and scientific risk assessments. These unscientific, WTO-inconsistent EU policies have severely restricted the U.S. seed industry's access to the EU market for seeds and many crops grown in the U.S., as the vast majority of soybeans, cotton, and corn acres in the United States are planted with seeds improved with modern biotechnology. Additionally, these EU policies have served to impede the utilization of new scientific advances that improve agricultural productivity, particularly in developing countries that depend on access to Europe for their farm exports.

Marketing of Non-Biotech ("Conventional") Seed with Trace Amounts of Biotechnology Material

Issue: There is legal uncertainty around the export of non-biotechnology seed (sometimes called "conventional" seed) to the EU. There is essentially an "absolute zero" standard for any biotechnology material in these seed shipments.

Impacts: Some level of variability is inherent in any biological reproductive system and is reflected in applicable quality programs and standards. As a result, thresholds and tolerances are a component of most seed quality standards. The impact of such a zero standard has been three-fold for U.S. seed companies seeking to ship seed, primarily corn seed, to Europe. First, it has meant that some companies have moved their production of corn seed bound for Europe from the United States to

Europe, primarily Eastern Europe. This shifting of seed production to Europe creates economic and job losses in the United States. Second, for those companies that continue to try to ship corn seed to Europe, the testing of that seed for any trace amounts of biotechnology material has become prohibitive.

Proposed Resolution: The EU has established a "technical solution" to address trace amounts of biotechnology material in feed, essentially technically defining zero for these shipments. The EU should extend this technical solution for seed in those cases where the seed has not yet been approved for cultivation in the EU. A commercially viable threshold based on science, using existing seed standards as a guide, should be set for those circumstances when the seed has been approved for cultivation in the EU. Additionally, a standardized and predictable lot approval process that includes accreditation of third party labs and private company labs should be established to provide predictability to the implementation of a threshold.

Delays in the EU Approval Process

Issue: Avoidable delays in the EU food and feed approval process have created major barriers to trade, and forced delays in commercial cultivation plans in the United States.

Impacts: The increasing delays in the EU food and feed approval process, which is largely due to political factors rather than science-based risk assessments, means a growing asynchrony between the necessary authorizations for commercialization of a biotech event in the United States and the import approval for that event in the EU. It is well documented that this increasing regulatory gap between the two sides has had a negative impact on U.S. agriculture exports to the EU. The EU's regulatory process for import approvals takes close to 3 ½ years on average while the United States has invested resources in reducing the timelines in its approval process.

Proposed Resolution: The EU should follow the timelines already established in their regulatory process. The EU Commission can take numerous steps to reduce administrative delays and improve the efficiency of the European Food Safety Agency (EFSA) safety assessment process. Types of efficiency improvements include clear timelines for each application, limiting the scope of applications to products and their intended uses and limiting referrals to EFSA that are not part of the approval process. Following a positive opinion of an application by EFSA, the European Commission should act within the timeframe (3 months) laid out by the regulation covering imports and food and feed use (Article 7 of Regulation 1829/2003).

Review and Approval of Stacked Products

Issue: The EU requires a separate approval for each individual stacked product, creating further risk for disruption of trade, a greater gap between approvals in the United States and the EU.

Impacts: Stacked products are produced through bringing single biotech events into a variety through traditional breeding techniques. Even if the individual biotech events in a stacked product are approved in the EU, each combination of stacked events needs a separate EU approval. Commercial seed containing stacked biotech traits are now increasingly the norm in the United States. Requiring a new approval for each stack, coupled with the redundant data requirements for these stacks, has created an unnecessary regulatory burden and a regulatory requirement that will become unsustainable.

Proposed Resolution: A mechanism should be established in the TTIP so that U.S. regulators can begin discussions with their European counterparts on how the U.S. regulatory agencies approach stacked products.

Variety Registration

Issue: The variety registration system in the EU creates a significant time and expense factor for breeders and slows the process of bringing a variety to market. In effect, the EU system restricts competition by limiting the number of variety cultivars that can be commercialized.

Impacts: The additional time to complete registration requirements can slow a variety to market by 2-3 years after entering the U.S. market, creating a burdensome cost to the breeder from an inventory management perspective. The registration system is not implemented consistently across EU Member States and it can take several years to register a variety. Depending on how a Member State implements the registration system, company breeding and testing records are often not recognized. Additionally, varieties with value added traits can be denied a registration because of the type of tests used to determine eligibility for registration.

Proposed Resolution: The United States and the EU are the leaders in world seed trade, and as such, should serve as a model for how varieties are introduced to the market, a model that can, for example, be readily adopted by developing countries and contribute to global agricultural productivity. It is preferable to offer the market and farmer-consumers ample freedom to make varietal choices and allow the market to drive decisions about agricultural and vegetable seed varieties. The TTIP provides an opportunity to move toward a more market-driven system for making seed varieties available to farmers. It also provides an opportunity for some shorter-term solutions to make the variety registration process in the EU more consistent and fair to all breeders.

New Breeding Techniques

Issue: The EU has initiated discussions on the regulatory status and the risk assessment of new breeding techniques. Some of these techniques are outside the scope of the current EU regulations covering Genetically Modified Organisms (GMOs).

Impacts: As already discussed in these comments, the seed industry is a science-based industry and there have been advances and refinements in breeding techniques to take advantage of the growing knowledge of plant genomes and genetic characteristics. These evolving techniques are enabling a more efficient and precise breeding process. If the EU unilaterally determines that it will begin to regulate some of these advanced breeding techniques there will be potential consequences for both trade in seeds and/or commodities and agricultural productivity.

Proposed Resolution: A mechanism should be established under the TTIP to function as a venue for the United States and the EU to discuss these newer breeding techniques now being utilized and those that are anticipated in the future. This venue should work toward clarification and alignment on which of these techniques are within the scope of the EU GMO regulations. The techniques that are not within this scope and are essentially the same as the techniques used in "conventional" breeding should not come under regulation.

Treated Seed

Issue: The EU crop protection regulation 1107/2009 requires treated seed to be labeled with the name of the active ingredient, the formulation name and the commercial name in the EU Member State where the treated seed is sold.

Impacts: Because U.S. formulations invariably differ from formulations of the same active ingredient in the EU, it is virtually impossible to import treated seeds from the United States into the EU.

Proposal for resolution: A revision of the regulation 1107/2009 has already started and the opportunity exists to amend the legislation to recognize near-identical formulations, as well as U.S. commercial names.

Conclusion

ASTA would like to reiterate its support for a broad-based TTIP and appreciates the opportunity to offer these comments and proposed resolutions for the identified issues. We stand ready to answer any questions concerning these comments. We look forward to working with USTR, USDA, and the other members of the U.S. negotiating team to secure a comprehensive, high-standard FTA that creates new export opportunities for ASTA's member companies and their customers.

Sincerely,

A. W. LaVigne

Andrew W. LaVigne
President & CEO