BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

November 3, 2009

Gloria Blue
Executive Secretary
Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Docket: SPS Measures: USTR-2009-0031

Dear Ms. Blue:

This letter is submitted by the Biotechnology Industry Organization (BIO) in response to the request for public comment with respect to the annual National Trade Estimate Report on Foreign Trade Barriers in the Federal Register on September 24, 2009. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and over 30 nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

In 2006, a World Trade Organization (WTO) dispute panel on the European Union's moratorium on the approval of agricultural biotechnology products concluded that the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) applied to measures related to agricultural biotechnology authorizations. With 92 percent of U.S. soybeans, 86 percent of U.S. cotton and 80 percent of U.S. corn derived from seeds developed through modern biotechnology, tens of billions of dollars of U.S. agricultural exports depend on WTO members to have science-based regulatory systems for agricultural biotechnology products. Within this context, BIO submits the following comments identifying unjustified SPS measures, which result or could result in trade barriers to U.S. agricultural products.

General

The 2009 National Trade Estimate report provides a comprehensive review of SPS barriers to agricultural biotechnology products in countries around the world. Although some progress has been made in some countries, many of these barriers, frequently in the form of authorization or labeling regulations, are not based on science and act as trade barriers. As the Office of the U.S. Trade Representative (USTR) prepares its 2010 National Trade Estimate report, BIO encourages USTR to continue to highlight these barriers in the new SPS report.

The following comments highlight priority issues in key countries.

China

China does not allow biotechnology developers to apply for authorization of a new biotechnology product unless the product has already been authorized in the country of export. This creates the likely scenario of U.S. exports being disrupted due to the low level presence of a product that has been approved in the country of export, but not yet in China. As China moves forward with the development and commercialization of its own agricultural biotechnology products, its authorization system should be applied equally no matter the origination of the product.

European Union

In 2006, a WTO dispute panel found that the European Union's (EU) moratorium on agricultural biotechnology product approvals and several Member State bans on cultivation were inconsistent with the WTO SPS Agreement. As of today, the EU has still made no real progress in meeting its WTO obligations to operate a science-based regulatory authorization process without undue delay. Instead of 40 dossiers awaiting a decision in 2008, over 60 dossiers are now backed up for a decision. As a result, U.S. corn exports are still effectively banned from the EU. This failure to make timely decisions on top of not having a science-based low level presence policy consistently causes major disruptions to trade as experienced for example this year with U.S. soybeans.

The EU further has failed to come into compliance with the WTO dispute panel report regarding Member State bans on cultivating agricultural biotech seeds. In fact, since the issuance of the panel report, additional Member States have banned cultivation of biotech seeds despite repeated scientific conclusions supporting the safety.

USTR and the other agencies of the U.S. government should step up its efforts to resolve the long standing trade disruptions caused by the failure of the EU to abide by its WTO obligations.

A new potential trade barrier to U.S. animal-based exports is the European Parliament's consideration of actions that could result in the prohibition of food from animal clones or their first generation progeny. As confirmed by the European Food Safety Authority, food from clones and progeny is completely safe, and there is no scientific or safety reason to prohibit cloning. Should the Parliament or the Commission act in a way that would affect U.S. dairy or beef exports, such action would clearly be an unjustified trade barrier.

Korea

In 2008, Korea implemented the Living Modified Organisms Act (LMO Act) as an important step in its ratification of the Cartagena Protocol on Biosafety. BIO members are concerned, however, that the new LMO Act contains globally unprecedented regulatory requirements that are both duplicative and burdensome. The area of greatest concern is the new Risk Review Consultation provisions. The new Risk Review Consultation provisions of the LMO Act are excessive, and are not based on science or global consensus of the safety of biotech crops. Although trade disruptions have for the most part been averted due to substantial investment in U.S. government and industry resources, the slowdown in Korea's burdensome review process has a significant impact on getting timely authorizations and therefore potentially can disrupt U.S. exports.

BIO is further concerned with Korea's labeling requirements for products derived from modern biotechnology. In September 2008, KFDA proposed changes to significantly expand mandatory labeling for products of biotechnology to include all products and ingredients derived from biotechnology including food additives and those ingredients derived from genetically modified microorganisms. Enforcement is expected to begin in 2010. These labeling requirements are expected to have a significant adverse impact on U.S. food and agriculture exports, even those products where recombinant DNA or protein is undetectable.

Turkey

On October 26, 2009, the Turkish Ministry of Agriculture and Rural Affairs published a "Regulation on the Import, Processing, Export, Control and Inspection of Food and Feed Products Bearing GMOs and GMO Components". In violation of the WTO SPS Agreement, the regulation was effective immediately and was published without opportunity for comment or notification to the WTO. The regulation establishes a new authorization system for biotech products and establishes new conditions for import, processing and labeling of biotech products, among other provisions. Among the conditions for authorization are that the product must have been commercialized for three years in the country of export. If enforced this single provision could serve as a perpetual barrier to the import of biotech crops as new products are introduced. The regulation also contains a provision that the government of the exporting country must provide documentation of the "lot number, amount, and GMO type" in the shipment. Clearly this will have a significant, negative impact on U.S. exports, since the U.S. government does not and should not provide such documentation.

Conclusion

BIO welcomes USTR's initiative to prepare a separate report on SPS barriers to U.S. agricultural exports. BIO encourages USTR and other U.S. government agencies to renew their efforts to ensure that SPS measures affecting exports of U.S. products derived from modern biotechnology are based on science and consistent with the SPS Agreement.

Sincerely,

Sharon Bomer Lauritsen
Executive Vice President
Food and Agriculture