BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

October 4, 2010

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

Docket: USTR-2010-0020

Dear Ms. Blue:

This letter is submitted by the Biotechnology Industry Organization (BIO) in response to the request for public comments regarding USTR's annual Report on Sanitary and Phytosanitary (SPS) Measures. BIO represents more than 1,100 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 Settlement Body (DSB) 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 93 percent of U.S. soybeans, 93 percent of U.S. cotton and 86 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 to identify SPS measures that are inconsistent or appear to be inconsistent with the WTO SPS Agreement and unnecessarily restrict trade of U.S. agricultural products derived from modern biotechnology.

General

The 2010 Report on Sanitary and Phytosanitary Measures provides a comprehensive review of SPS barriers to agricultural biotechnology products in countries around the world. In some countries progress has been made, while in others the situation has deteriorated. BIO encourages USTR to continue to highlight these barriers as it prepares the 2011 Report.

The following comments highlight priority issues in key countries.

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Peoples Republic of China (China)

China's regulatory framework requires developers of agricultural biotechnology products to delay the submission of applications for the approval of new products for import into China until after the product has been approved in the country of export. This increases the likelihood for U.S. exports to be disrupted due to the low level presence of a product that has been approved in the United States (as the exporting country), but not yet approved for import into China.

In 2010 agricultural biotechnology companies' applications for cultivation in China were denied. The SPS agreement requires that approval procedures be undertaken and completed without undue delay and in no less favorable manner for imported products than for like domestic products. As China moves forward with development and commercialization of its own agricultural biotechnology products, its authorization system should provide foreign biotechnology companies equal consideration for applications.

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.

The dispute remains unresolved and the potential for resolution is increasingly uncertain. In July 2010, the European Commission (EC) unveiled a proposal that would devolve the decision on the cultivation of agricultural biotechnology to the Member States. This proposal is intended to enable Member States to opt-out of EC decisions to allow cultivation, by enacting legislation at the national or sub-national level. Furthermore, the EC proposal suggests that the opt-out could be justified for reasons other than science.

The WTO Dispute Panel ruling was very clear -- EU Member State safeguard measures, and the range of justifications provided, are inconsistent with obligations under the SPS agreement.

With regard to product applications, the EC made some progress on product approvals in 2010. However, as of today, 40 dossiers remain under review – some pending EC approval dating back to 2005. The EC maintains zero tolerance for the low level presence of products approved in the exporting country, but not in the EC. Zero tolerance, coupled with the undue delay in the review and approval of applications consistently results in the disruption of U.S. exports of agricultural products.

A potential barrier to U.S. animal-based exports is the European Parliament's consideration of actions that could result in prohibition of food from animal clones or their first generation progeny. As confirmed by the European Food Safety Authority (EFSA), food from clones and progeny is completely safe; there is no scientific or safety

related reason to prohibit cloning. Should the Parliament or the Commission act in a way to affect U.S. dairy or beef exports, such action would clearly be an unjustified trade barrier.

The Republic of Korea

Since the Republic of Korea implemented the Living Modified Organisms Act (LMO Act) in 2008, BIO members have experienced delays in the approval process. Much of the delay is a result of the requirement that five separate regulatory agencies participate in the consultation review process, and the fact that imports of products for food, feed and processing (FFP) require an environmental risk assessment. Further, as part of a safety package for product approval, regulatory agencies continue to require fish feeding studies, which have no scientific basis.

Biosafety regulations must be objective and science based, and proportionate to the associated risk of the intended use of the process. Although trade disruptions have for the most part been averted as the result of a substantial and sustained investment of U.S. government and industry resources, the slowdown in Korea's burdensome review process has a significant impact on achieving timely authorizations and has the potential to disrupt U.S. exports.

In addition, BIO is 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. Labeling requirements have not been finalized and remain in the Prime Minister's office, however enforcement is expected. 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

The emergence of Turkey's regulatory framework for agricultural biotechnology has created confusion and uncertainty and will likely result an extended disruption to U.S. exports. In October 2009, Turkey published the "Regulation on the Import, Processing, Export, Control and Inspection of Food and Feed Products Bearing GMOs and GMO Components." This Regulation effectively stopped all imports of food and feed derived from biotechnology. Following publication of the Regulation, the Biosafety Law was ratified in Parliament in March 2010, with an implementation date of September 26, 2010. However, following passage of the Law, Turkey faced declining feed stocks and thus allowed imports of a majority of biotech soybeans and corn products approved in the European Union (EU). While this interim import measure temporarily replenished feed

stocks, trade in these commodities has now stopped as the Law became effective on September 26, 2010.

Turkey is fully within its rights under the WTO SPS agreement to require agricultural biotechnology companies to submit applications for product approvals. However, the Biosafety Law also implemented onerous and extraneous liability requirements. Turkey has not provided necessary clarity with respect to application procedures and labeling requirements which makes it impossible for agricultural biotechnology companies to submit product applications.

In addition, the Law bans production of agricultural biotechnology, both plant and animal, in Turkey without scientific justification. Also, without justification, the Law prohibits the use of products derived biotechnology as ingredients in baby food.

Turkey has an obligation to ensure consistency between its SPS measures and WTO rules – the regulatory system established must be transparent, science-based and no more trade restrictive than necessary. BIO and its members fully endorse Turkey's interest in developing a science-based regulatory system consistent with its WTO commitments. However, Turkey's Biosafety Law and implementing regulations do not appear to be consistent with WTO rules.

Conclusion

BIO encourages USTR and other U.S. government agencies to renew efforts to ensure that any SPS measures affecting exports of U.S. products derived from modern biotechnology be based on scientifically verifiable criteria and be consistent with the SPS Agreement.

Sincerely,

Sharon Bomer Lauritsen
Executive Vice President
Food and Agriculture