BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

September 18, 2006

Ms. Gloria Blue
Executive Secretary, Trade Policy Staff Committee
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

RE: Notice of Public Hearing Concerning China's Compliance with WTO Commitments Written Comments (Federal Register Vol. 71, No. 145 July 28, 2006)

Dear Ms. Blue:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to submit comments regarding the notice of public hearing concerning China's compliance with WTO commitments. In addition, in light of the up-coming meeting of the U.S.-China High Level Biotechnology Joint Working Group (BWG) on September 19th and the meeting of the supporting Technical Working Group (TWG) on September 18th, BIO would like to highlight additional concerns regarding agricultural biotechnology in China.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

The Chinese government has listed agricultural biotechnology as one of the six most significant industries on the drive to improve China's economic future. China is also the largest market for U.S. biotechnology crops and is the fifth largest producer of biotechnology enhanced plants based on the total number of acres. As the biotechnology industry in China continues to grow, it is in the mutual interest of China and the United States to have an environment that promotes the technology. There are many significant barriers to trade in agricultural biotech products. BIO has three main areas of concern regarding agricultural biotechnology: responsibilities of the Ministries with regards to agricultural biotechnology, foreign investment and export prohibitions, and regulation of agricultural biotech products. In addition, BIO is concerned with China's protection and enforcement of intellectual property rights (IPR).

Responsibilities of the Ministries

The problems faced by the agricultural biotechnology industry in China are plagued by a regulatory system that is consistently slow and bogged down by political debate rather than based on science. This is due to the fact that the roles and responsibilities of the Ministry of Health (MOH) and the Ministry of Agriculture (MOA) remain unresolved. The MOH issued regulations for food safety assessment of biotech products on April 8, 2002, to be implemented on July 1, 2002. These regulations were never implemented. A subsequent agreement between MOA and MOH, which established that MOA will regulate biotech crops, confused the situation in that the decision has not been officially announced and MOH regulations are still standing. In addition, the State Environment Protection Administration (SEPA) is currently working on a draft biosafety law now that China is a party to the Cartagena Protocol on Biosafety (BSP). A greater effort is needed to harmonize the regulatory requirements among the various

ministries to avoid unnecessary and duplicative requirements and to ensure that a scientific and workable regulatory system is in place.

Prohibitions

Foreign Investment

China still does not allow for non-Chinese companies to own more than 49 percent of a Chinese joint venture. In addition, in 2002 China issued a foreign direct investment catalog and prohibited foreign direct investment in the transgenic seed business in China.

Export prohibition

China also prohibits the export of germplasm. Improved germplasm can be moved freely into China, but it cannot be exported, appearing to not comply with Article 11 of the General Agreement on Tariffs and Trade (GATT).

Agriculture Biotech Regulations

Certain of China's agricultural biotechnology regulations do not appear to be based on science, are not transparent and are more trade restrictive than required to meet its appropriate level of sanitary or phytosanitary protection , taking into account technical and economic feasibility.

Approval Process for Agricultural Biotechnology

China's agricultural biotech approval process impedes the growth of the biotechnology industry. The Ministry of Agriculture has a requirement that a biotech product be approved in the country of development, but it is unclear whether this is to be done before the approval process in China can begin. There is no scientific basis for delaying approvals in China before a product is approved in the country of development.

Another hindrance in the approval of biotech products is the lack of transparency during the regulatory review and approval process. There are only two meetings per year of the Biosafety Committee, which issues production approvals. Companies must submit their applications three months prior to the meeting and do not hear anything again until the product is approved or rejected. The decisions of the Biosafety Committee are anonymous, and there is no opportunity for the applicant to answer any questions by the Committee before a final decision is made.

China needs to have an event-based approvals process, rather than commodity-based, to create a timely and science-based approval process. Currently, each variety containing a biotech trait has to undergo a separate approval. This is very burdensome and costly on the applicant and much of the information provided is redundant. Furthermore, the separate variety registration system is not comparable with the current gene safety approval system, resulting in a cumbersome process that could take more than 7-8 years to commercialize a transgenic product.

Labeling

Currently China requires that agricultural biotech products listed in the regulations be labeled. The listed products include seed, oil and meal from soybeans, corn, cotton, canola and tomatoes. Decree 10 states that the labeling requirement is used to guide production and consumption of the products and for the

consumer right to know. The regulations specify what language is to go on each individual label. There is no scientific health or safety reason justifying the mandatory labeling of these products.

Safety Certificates

WTO notification of regulations by the Ministry of Agriculture (MOA) for obtaining safety certificates for the import of biotech crops involved considerable delays and provided insufficient time for clarification of numerous ambiguities in the regulations. In particular, the regulations' "prior notice" policy requires exporters to notify China six months in advance of a shipment of agricultural biotech products through application for a safety certificate that details the make-up of the shipment. This is very burdensome to trade and costly to the exporter.

Intellectual Property Rights

Intellectual property is the life blood of the biotechnology industry. Development and commercialization of biotechnology products can take decades and sometimes hundreds of millions of dollars to achieve. Biotechnology companies rely on the strength and predictability of their intellectual property rights (IPR) to entice investment in cutting edge projects. Strong and predictable IPR provides the necessary assurance for investors that they may one day recoup their investment. Weak IPR enforcement devalues the biotechnology enterprise and hinders innovation and development.

While China has made strides toward strengthening its intellectual property protections, biotechnology companies have continued to experience problems with counterfeiting and effective enforcement of their intellectual property in certain provinces. In this regard, BIO urges more effective interdiction and enforcement to traffickers and distributors of counterfeit biopharmaceuticals. In addition, BIO notes that Chinese government agencies and municipalities lack the coordination and cooperation necessary to address enforcement issues. A reliable dispute resolution system that produces "objective, enforceable and enforced decisions," coupled with a public record of precedent, would greatly enhance the IPR regime in China.

Our members have also pointed to certain ambiguities inherent in Chinese intellectual property laws, which hinder patent procurement and enforcement efforts. We note that China has attempted to remedy some of these deficiencies by proposing amendments to its patent laws. Some of these amendments will be helpful in clearing ambiguities and strengthening patent laws, yet there are others that may pose unique problems for the biotechnology sector. For a detailed account of BIO's concerns in regard to the Chinese patent law amendments, please see the attached document.

One set of problematic provisions in the Chinese patent amendments are the amendments to Article 25 and 26 to provide a new ground for rejecting claims in a patent application if the completion of the invention depended on the acquisition and exploitation of genetic resources. These amendments would require patent applicants to indicate the source of genetic resources if the completion of the claimed invention depended on the acquisition of genetic resources.

These amendments appear to be intended to promote compliance with the provisions of the Convention on Biological Diversity (CBD) related to access to genetic resources and the equitable sharing of benefits arising from this access. Unfortunately, we believe that these amendments will not significantly enhance fulfillment of the objectives of the Convention, but rather will burden inventors. In addition, we urge China to consider that, by removing the possibility of intellectual property protection on inventions derived from genetic resources, it will remove an opportunity to provide economic value in this area for the providers as well as for the users of the genetic resources. Moreover, it is not clear to us that these

amendments would be consistent with obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights.

Articles 48 and 49 of China's new patent law amendments provide for compulsory licensing, but the considerations that would trigger compulsory licensing as well as the scope and duration of the license need significant clarification. In addition, the new patent law amendments also introduce a so-called Bolar exemption to infringement (Art 63(5)). In other countries where such an exemption has been introduced, it is balanced by a provision to allow extension of patent term to compensate for delays in development of a product due to safety/regulatory requirements. Patent term extension should also be included in the Chinese Patent Law.

In addition, we note that shortcomings of patent and plant variety protection systems also continue to deny BIO members adequate and effective protection of their intellectual property rights. Specifically those members who focus on transgenic plants and animals are unable to protect their inventions because they are ineligible for protection under Chinese patent law.

Conclusion

BIO appreciates this opportunity to comment on China's WTO compliance, and we look forward to working closely with USTR to ensure resolution of these issues.

Sincerely,

James C. Greenwood
President and CEO

CC: Ambassador Karan Bhatia
Ambassador Richard T. Crowder

Attachment