



June 29, 2007

Mr. Michael Yost Administrator Foreign Agricultural Service U.S. Department of Agriculture 1400 Independence Avenue S.W. Washington, DC 20250

Dear Mr. Yost:

In light of the upcoming U.S.-China Joint Commission on Commerce and Trade (JCCT) meeting in August, the American Seed Trade Association (ASTA) and the Biotechnology Industry Organization (BIO) would like to highlight three concerns regarding agricultural biotechnology in China.

ASTA is one of the oldest trade organizations in the United States. Its membership consists of about 850 companies involved in seed production and distribution, plant breeding, and related industries in North America. As an authority on plant germplasm, ASTA advocates science and policy issues of industry-wide importance.

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 identified 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, however, many significant barriers to trade that need to be resolved if this market is to be realized. Three key issues of concern are: 1) China's regulation of agricultural biotech products; 2) protection and enforcement of intellectual property rights (IPR); and, 3) germplasm export prohibitions.

Regulation of Agricultural Biotechnology Products

China's agricultural biotech authorization process impedes agricultural trade through asynchronous authorizations of agricultural biotechnology products. The Ministry of Agriculture has a requirement that a biotech product to be imported into China must be approved in the country of development before the authorization process in China can begin. There is no scientific basis for delaying the start of the authorization process in China solely because a product is not yet approved in the country of export. In addition, such a provision raises questions as to whether the regulation is consistent with China's obligations under the World Trade Organization. We request that the U.S. government seek to amend China's regulations to minimize asynchronous authorizations.

Protection and Enforcement of Intellectual Property Rights

Intellectual property is fundamental to innovation in the seed industry. Patent and Plant Variety Protection (PVP) requirements and expertise in China are key areas for ASTA members who are trying to enter the market in China. The amendments to China's patent law preclude the possibility of patenting plant varieties. Therefore, the seed industry must currently rely on the Plant Variety Protection (PVP) process to protect the intellectual property of seed companies conducting business in China. The manner in which the PVP process in China has been implemented has resulted in little or no security around a plant variety's germplasm. Plant germplasm constitutes the plant's genetic make-up and is essentially equivalent to the product formula for that plant variety. Without adequate security over this germplasm U.S. seed companies would not likely provide elite varieties to China and effectively prevent China from reaping the benefits of the newest technology.

Also during the approval process, China requires that a sample of the biotechnology-derived seed be submitted with no Material Transfer Agreement stating how these samples will be used. This raises concerns around intellectual property protection, which must be seriously considered by a company prior to expansion into the Chinese market.

It is necessary that developers of new plant varieties, including plants produced through biotechnology, be afforded adequate protection under China's patent and PVP systems. We request the U.S. government bring clarity to the PVP process in China and ultimately work toward an IPR framework in China that allows the patenting of plant varieties.

Germplasm Export Prohibitions

China has regulations that restrict the exportation of improved germplasm, including seed and related germplasm, appearing to not comply with Article 11 of the General Agreement on Tariffs and Trade (GATT). Under these regulations, BIO member companies and ASTA members have previously been refused permission to export germplasm, both biotech and non-biotech germplasm. The inability of companies to export certain kinds of germplasm from China severely inhibits their capacity to expand their business throughout the region.

Chinese regulations restrict the import and export of germplasm through the "Seed Law of the People's Republic of China". Seeds categorized as "non-exchangeable with foreign countries" are not allowed to be exported, but there is no transparency as to which types of seeds are so categorized. We request that the U.S. government bring transparency to China's export restrictions and pursue policies that promote trade in germplasm.

Conclusion

China's current systems are unpredictable and non-transparent. ASTA and BIO request that the U.S. government include these issues on the agenda of the next JCCT meeting that will lead to a satisfactory solution.

Thank you for your consideration.

Sincerely,

Andrew W. LaVigne President and CEO

American Seed Trade Association

Sharon Bomer Lauritsen Executive Vice President

Biotechnology Industry Organization

cc: Michael Henney, USDA FAS

Melissa Clarkson, USDA FAS