BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

March 24, 2006

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

RE: United States-Republic of Korea Free Trade Agreement Written Comments (Federal Register Vol. 71, No. 27 February 9, 2006)

Dear Ms. Blue:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to submit comments regarding the public notice of intent to initiate negotiations with the Republic of Korea. BIO supports negotiations between the United States and Korea and hopes that an FTA will provide access for agricultural biotechnology products based on science and ensure Korea's statutes, regulations and policies affecting biotechnology are consistent with Korea's WTO trade obligations.

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.

According to the 2005 International Service for the Acquisition of Agro-biotech Applications (ISAAA) report, the U.S. plants 122.3 million acres or 55% of the global biotech crop acreage. A majority of the crops are exported globally. Some governments have not created science-based policies for the import of biotech products, which has hindered trade of these products. BIO believes the notification of intent to initiate FTA negotiations with the Republic of Korea is particularly timely as the Korean government is preparing to ratify the Cartagena Protocol on Biosafety (the Biosafety Protocol (BSP)).

Intellectual Property Rights

More than 90 percent of BIO members are small businesses that are years away from profitability. It can take decades and hundreds of millions of private dollars for a biotechnology company to commercialize a biotechnology product. This is because of the lengthy research and development timeframe, time to develop regulatory packages, and the rigorous regulatory review process generally associated with biotechnology products. In order to translate an innovative idea into a commercially viable product, companies depend on their patent portfolios to generate

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private investment funding. Patents provide the necessary assurance for investors that they may one day recoup their investment.

The government of Korea recognizes the importance of strong and predictable IP protections and has been an ardent supporter of these protections in the World Trade Organization (WTO) and the Convention on Biological Diversity. Of concern to the biotech industry is Korea's high levels of counterfeiting due in part to non-deterrent penalties. We encourage USTR to address this matter in the upcoming negotiations.

Implementation of BSP

A main concern of the biotechnology industry is Korea's draft regulations to implement the Biosafety Protocol to come into effect when Korea ratifies the Protocol, which is expected in the third quarter of this year. These draft regulations may potentially affect the ability of industry to obtain timely and predictable registrations for biotech products. In January 2006 Korea's Ministry of Agriculture and Forestry (MAF) submitted its draft guidelines to the WTO for comment. BIO urges USTR to address the following issues pertaining to the Republic of Korea's implementation of the BSP to ensure requirements are based on science, do not burden or restrict trade, and are consistent with Korea's obligations under the World Trade Organization.

Pre-Import Approval

MAF's draft regulations for BSP implementation appear to require that Korea give import approval for each shipment prior to export and that approval documentation must accompany each shipment. BIO believes these requirements would add a significant and unnecessary burden to the exporter as well as to MAF.

The draft regulation is unclear as to what approvals are required to ship a product, raising such questions as: Is there a need for import approval prior to the initial shipment of the product or each time an individual shipment is brought into the country? BIO believes that, if these guidelines are implemented as written suggesting that each shipment needs approval, trade in biotech products will be significantly affected by such uncertainties.

Testing

Within the draft regulations, it is unclear on how the proposed testing regime would work in regards to the importation of biotechnology products. National Agri-products Quality Management Service (NAQS) would be the LMOs detection method validation agency in charge of "import approvals," "annulment of import approval," and "handling and management for domestic area." The National Plant Quarantine Service (NPQS) will be primarily responsible for conducting tests to verify whether an imported shipment contains unapproved events. The article mentions living modified organisms (LMOs) validation agencies as having authority to issue import approval certificates and conduct tests to verify whether an LMO is approved or notified. These terms need more definition and reasoning based on science. Testing of shipments at import for authorized products is overly burdensome and more trade restrictive than necessary.

Adventitious Presence

Korea does not currently have a policy regarding adventitious presence (AP) for agricultural biotechnology. AP is defined as the low level incidental presence of biotech material

in food, feed, or grain at levels that could reasonably be expected to be present consistent with generally accepted agricultural and manufacturing practices. BIO would like USTR to work with Korea on a science-based solution to this issue.

Labeling

Korea requires labeling for foods derived from biotechnology. Processed and unprocessed products with biotech ingredients or with a biotech product in the top five ingredients must carry a "GM food" label. Labeling has kept biotech products off the retail shelves in Korea because of the negative connotation that is associated with biotech products by Korean consumers, despite the fact that these products are safe and shown to be substantially equivalent to non-biotech products.

Compliance with GATT and the SPS Agreement

Not only would the requirements above negatively affect trade, they appear not to comply with the General Agreement on Tariffs and Trade (GATT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The method of production is not sufficient justification under the SPS agreement for imposing restrictions on handling, packaging and transport of a product. Also the GATT does not allow a country to discriminate against like products. If a biotech product has been proven safe and approved for food and environment, there is no scientific basis for a country to impose restrictions such as special handling, transport and packaging. Without sufficient science for such restrictions, such measures would be inconsistent with the WTO.

Conclusion

BIO believes that these negotiations are being initiated at a time when the Korean government is preparing to restructure their biotechnology regulations and guidelines. We encourage the U.S. government to engage with the Korean government to ensure that Korea's new regulations are based on science and take into account the impact that overly strict regulations of approved products would have on trade.

BIO appreciates this opportunity to comment on the Korea FTA negotiations and we look forward to working closely with USTR to ensure a successful outcome to the negotiations.

Sincerely,

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cc: Ambassador Richard T. Crowder
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