



May 12, 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 Malaysia Free Trade Agreement Written Comments  
(Federal Register Vol. 71, No. 55 March 22, 2006)**

Dear Ms. Blue:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit comments regarding the public notice of intent to initiate negotiations with Malaysia. BIO supports negotiations between the United States and Malaysia, and hopes a Free Trade Agreement (FTA) will provide enhanced access for U.S. biotechnology products and ensure Malaysia's statutes, regulations and policies affecting biotechnology are science-based and consistent with Malaysia's World Trade Organization (WTO) 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 percent, of the global biotech crop acreage. As the global production of biotech crops increases, the export of these products also will increase. Some governments have not created science-based policies for the import of biotech products, which hinders trade in these products.

BIO believes FTA negotiations with Malaysia are particularly timely as Malaysia has recently launched its new National Biotechnology Policy to promote the development of its biotechnology sector. We respectfully request the U.S. government use the opportunity of the FTA negotiations to ensure Malaysia promulgates science-based, transparent regulations for predictable and timely biotechnology approvals, import requirements and labeling. These regulations should not discriminate against agricultural biotechnology and should be no more trade restrictive than required to achieve Malaysia's appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

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## **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 due to the lengthy research and development timeframe, the 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 private investment funding. Patents provide the necessary assurance for investors that they may one day recoup their investment. Uncertainty and weakened intellectual property (IP) rights can turn investors away from biotechnology research and development; therefore, patent rights must be strong and predictable.

The Malaysian government is beginning to recognize the value of biotechnology, and should be encouraged to strengthen its patent laws to encourage innovation and allow for protection of biotech inventions.

We urge USTR to address two key issues on IP in the negotiations for a FTA with Malaysia to ensure that Malaysian requirements are consistent with the TRIPS Agreement, in particular Article 29. First, the agreement should include protections on new, useful and non-obvious transgenic plant and animal inventions. Second, certain countries have enacted laws requiring special disclosure of genetic source or origin as part of patent applications; these requirements are onerous and nearly impossible to meet. Such special requirements, if unchallenged, will allow countries to deny patent applications on grounds unrelated to the merits of the invention, and they will allow our competitors to mount unjustified attacks on companies' patents. We urge USTR to work with the Malaysian government to ensure understanding of the negative impact of such requirements on biotechnology, and to ensure that such special requirements for biotechnology inventions are not adopted by Malaysia.

## **Implementation of Biosafety Protocol**

The government of Malaysia has strongly advocated the growth of the biotechnology industry, and yet the Malaysian Ministry of Natural Resources & Environment (MONRE) has taken negative positions regarding biotechnology at recent meetings of the Convention on Biodiversity (CBD) and the Cartagena Protocol on Biosafety (BSP). As Malaysia is seen as an influential voice among developing countries in the region, such positions have detrimental effects on the discussions and outcomes of Protocol implementation meetings. For example, the Malaysian delegation has promoted an overly broad definition of "damage" under a proposed liability scheme under BSP. It also has advocated for a strict, rather than fault-based, liability regime, and for imposing extensive obligations on non-Parties to the Protocol regarding liability and redress. BIO believes that these and other proposed measures would significantly inhibit the development of and trade in biotechnology agricultural products.

## **Biosafety Bill**

We understand the Malaysian government currently has a draft biosafety bill that will be presented to the Parliament in the near future. Though the bill is not yet publicly available, we understand the proposed Biosafety Act would require mandatory labeling of biotech food. There are numerous reasons why labeling would be detrimental to the development of biotechnology in Malaysia and inhibit U.S. exports of agricultural biotechnology products, as follow:

- BIO does not believe a mandatory labeling scheme adds value or is scientifically justified.
- Mandatory labeling will be difficult and costly to enforce, with the burden of enforcement falling on resource-limited government agencies, with no added value provided by the labeling.
- Mandatory labeling requirements for biotech foods have the potential to mislead consumers regarding the safety of foods produced through biotechnology.
- Mandatory labels would imply biotech foods are either “different” from conventional foods or present a potential risk even though the food has been determined equivalent and safe.
- Labeling of biotech food products would increase costs for farmers by requiring them to segregate seed, crops and feed, and to use complex record keeping systems.

### **Adventitious Presence**

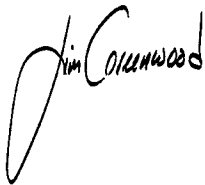
Malaysia does not currently have a policy regarding adventitious presence (AP) for agricultural biotechnology. AP is defined as the low-level incidental presence of biotech material in food, feed, or grain at levels that could reasonably be expected to be present, consistent with generally accepted agricultural and manufacturing practices. BIO recommends USTR work with Malaysia on a science-based solution to this issue.

### **Conclusion**

BIO believes the FTA negotiations are being initiated at a time when the Malaysian government is preparing to restructure its biotechnology regulations and guidelines. We encourage the U.S. government to take advantage of the bilateral negotiations to engage the Malaysian government to ensure Malaysia’s new regulations are science-based and take into account the impact that an overly strict regulatory regime will have on innovation and trade.

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

Sincerely,



James C. Greenwood  
President and CEO

cc. Ambassador Richard T. Crowder  
Ambassador Karan Bhatia  
Under Secretary J.B. Penn