OBAMA-BIDEN TRANSITION PROJECT

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BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

December 5, 2008

TO: Anna Gomez, Transition Team for USTR
Don Abelson, Transition Team for USTR

Dear Ms. Gomez and Mr. Abelson:

Thank you for the opportunity to discuss the range of agricultural trade issues last week. As was highlighted in that discussion, sanitary and phytosanitary (SPS) trade barriers, and specifically impediments to trade of products produced through modern biotechnology, are high on the agenda for agricultural organizations. Many of the trade barriers to agricultural biotechnology products are not based on science, impair U.S. exports and also inhibit farmers in other parts of the world to benefit from the technology for more sustainable agricultural production.

The Biotechnology Industry Organization (BIO) appreciates the opportunity to elaborate on the key international trade issues affecting the agricultural biotechnology industry. The importance of these issues to U.S. agricultural exports cannot be overstated. Eighty percent of U.S. corn and 92 percent of U.S. soybeans are produced using agricultural biotechnology; and the United States exported over $23 billion in corn and corn products and $20 billion in soybean and soybean products in 2007.

The key bilateral issues of concern include:

1) Failure of the EU to comply with the WTO ruling on agricultural biotechnology;
2) Potential trade restrictions resulting from revisions to Korean regulations;
3) Russia's efforts to accede to the WTO;
4) Potential trade barriers with the development of Malaysia's biotechnology regulations;
5) Cultivation approvals and biosafety regulations in Mexico; and,
6) Trade barriers due to non-science based labeling of products derived from biotechnology.

Attached is a briefing paper addressing each issue in more detail.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

Thank you for the opportunity to comment on these matters. Please feel free to contact BIO, should you have any questions or suggestions.

Sincerely,

Sharon Bomer Lauritsen
Executive Vice President
Food and Agriculture

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KEY BIO TRADE ISSUES

EU: Non-Compliance with the WTO Ruling on Agricultural Biotechnology

Since 1998 the European Union (EU) has implemented a *de facto* moratorium on the products of agricultural biotechnology. This moratorium has resulted in lost exports markets for U.S. corn and corn products, e.g., corn gluten feed, and impaired U.S. exports of soybeans.

In September 2006, a WTO dispute settlement panel, with the United States, Argentina and Canada as plaintiffs, issued a final report concluding that the European Communities were not in compliance with its obligations under the WTO agreements on matters related to the approval and marketing of agricultural biotechnology products in the European Union (EU).
Since that time, the plaintiffs have been pressing the European Commission to come into compliance. The U.S. government in particular has engaged in systematic talks with the European Commission according to a set of industry-supported benchmarks that cover product approvals, national bans and thresholds for adventitious presence in seeds and in imported commodities. The Biotechnology Industry Organization and other key U.S. industry stakeholders along with EuropaBio and the European Food, Feed and Farmer Coalition have supported those efforts to normalize trade in agricultural biotechnology products and to achieve a functioning EU approval system for imported biotechnology commodities as well as cultivation of biotechnology crops. The talks between the EU and the plaintiffs have not succeeded in any meaningful progress. Politically the issue of the incapacity to implement the EU regulatory process has reached new heights with the President of the Commission taking the topic to his Commissioners in a specific meeting in May 2008 and then creating his own group of Heads of State sherpas to discuss how to improve the situation. In hard facts, the number of product approvals has decreased as compared with 2007 and rather than being lifted, national bans remain with the addition of a major biotechnology cultivating country, France.

To date the Canadian and Argentinean Governments have extended to the end of 2008 the Reasonable Period of Time (RPT) by which the EU has to demonstrate compliance under WTO procedures. The U.S. government has taken a stronger stance choosing to end the RPT early in 2008 and now has two options to consider: 1) continue the dialogue to try to normalize trade in biotechnology commodities; or 2) undertake next steps to request a WTO compliance review panel to determine whether the EC is in compliance with the original WTO panel report (this would be a first step in the process toward possible retaliation). BIO and its members will continue to cooperate with the Administration on this dispute.

Korea: Revisions to the Korean Food and Drug Administration (KFDA) Food Safety Regulations and New Risk Review Consultation Process under Korea's LMO Act

Korea and the United States have had ongoing discussions on agricultural biotechnology regulatory matters for several years, primarily in the context of the negotiations on the Korea-United States FTA during 2006 and 2007. Within these negotiations, Korea and the United States developed an "Understanding on Agricultural Biotechnology" whereby both governments agreed to a number of commitments with respect to supporting science-based regulatory processes for agricultural biotechnology that would not negatively affect trade. At present,

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Korea is the sixth largest market for U.S. food and agriculture products – with a market of over $1 billion - many of which are biotechnology products or contain biotechnology material. In September 2008, KFDA announced a revision to its food safety guidance regulations that expands upon the types of data required by BIO members for food safety authorizations in Korea. Most of the new data required goes well beyond internationally-accepted standards for food safety assessment. In fact, some of the data required is not requested by any other country in the world.

In addition, in August 2008, Korea released new regulations to its Living Modified Organisms Act (LMO Act), the national legislation implementing the Cartagena Protocol on Biosafety (an international agreement affecting trade in agricultural biotechnology products), which included a new process for risk review consultation. These new risk review consultation procedures impose burdensome requirements on BIO members and, if left unresolved, have the potential to cause disruption in grain trade between the United States and Korea. The new consultation agencies involved in the risk review consultation have started to request redundant and unnecessary information from the BIO member companies for pending authorizations that are related to matters outside the jurisdiction of those agencies. In addition, approvals for pending applications are not occurring within the 270 day statutory timeline for decision-making. As a result, this creates uncertainty and unpredictability about the timing of food and feed approvals in Korea, which could negatively affect U.S. agricultural exports. BIO views the situation in Korea as a very important matter and seeks the assistance of the U.S. Government in working toward a commitment from the Korean Government to establish and maintain a science-based, workable, transparent and predictable regulatory system for agricultural biotechnology products under the new provisions of the LMO Act.

Russia: Accession to the WTO

A strong anti-biotechnology faction exists in Russia influenced by Europe and activists that supports overly burdensome biosafety legislation, which would effectively keep products of agricultural biotechnology out of Russia. As Russia continues its efforts to accede to the WTO, BIO is concerned that it will be even more highly influenced by the EU model of biosafety regulation and these anti-biotechnology voices, and will further structure its biosafety system to not be based on science. For example, the Moscow city government recently promulgated regulations requiring "GMO-free" labeling for food products in Moscow, Russia's largest food market, and provinces are increasingly making declarations that they are "GMO-free" zones. In addition, Russia recently implemented a regulation that defines adventitious presence of biotechnology components in food products as 0.9 percent, the standard followed by the EU. Such actions are not based on any legitimate scientific or food safety concern, but are purely responses to the pressure from anti-biotechnology activists on government officials to limit the potential acceptance of agricultural biotechnology products in Russia.

These types of market access restrictions are occurring within the context of a bilateral agreement between Russia and the United States on agricultural biotechnology that was finalized during the bilateral negotiations on Russia's accession to the WTO. This agreement states, *inter alia*, that policies and measures affecting agricultural biotechnology will be based on science, will be transparent, and will be in accordance with WTO Agreements, to enable the use and trade

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of agricultural biotechnology products. Despite this agreement, it is still illegal to grow biotechnology crops in Russia. Russia is highly influential in the Eastern European and Central Asian region and many of these governments follow the Russian regulatory model when developing their own regulatory systems. BIO therefore encourages the United States to use the ongoing negotiations on Russia's WTO accession to influence Russia's abiding by its bilateral agreement to develop biosafety policy and regulations in a way that would prevent negative impacts on trade of agricultural biotechnology products from the United States to Russia.

Malaysia: Implementation of the Biosafety Act and its Accompanying Regulations

The United States and Malaysia engaged in FTA negotiations through 2007, with significant discussion on agricultural biotechnology trade and regulation as Malaysia was in the process of developing its agricultural biotechnology regulatory framework. While the negotiations did not come to fruition, Malaysia's Prime Minister has recently indicated an interest in re-starting these negotiations during the early days of the Obama Administration.

Malaysia is in the process of finalizing the provisions of a Biosafety Act that would govern all approvals for research, trade and cultivation of agricultural biotechnology products. The most recent version of the Biosafety Act includes onerous, provisions that are not science-based and would extend to "products of" agricultural biotechnology, including labeling and full food and environmental safety authorizations for such "products of". Much of the Biosafety Act's impact will be determined through regulations yet to be developed. BIO is concerned that the anti-biotechnology advocates will use the implementation of the Biosafety Act to prevent products of agricultural biotechnology from entering into Malaysia from the United States, having an immediate impact on all processed food products that contain ingredients made from agricultural biotechnology products. Malaysia is also quite influential in the Southeast Asian region, particularly with other Muslim countries, and it is important that any framework for biosafety regulation be science-based, workable, transparent and predictable. For these reasons, and within the context of comments by Malaysia's Prime Minister and Deputy Prime Minister regarding Malaysia's interest in resuming Free Trade Negotiations with the United States, BIO supports continued U.S. Government discussions with Malaysia as the Biosafety Act and its accompanying regulations are developed and implemented to ensure this occurs in a manner that will not have a negative impact on trade in agricultural biotechnology products.

Mexico: Developing Biosafety Regulations

Mexico is a major market for U.S. agricultural biotechnology exports. In 2007, imports included 7.9 MMT of corn, 2.8 MMT of cracked corn, 3.7 MMT of soybeans, and 343,000 MT of cotton. Mexico has a regulatory framework for agricultural biotechnology products that allows for research and development, for imports for food, feed and processing use, and for cultivation of certain products. However, the country has not yet moved forward on cultivation, despite the fact that the regulations published in March 2008 served as the final steps required to implement controlled plantings. While cultivation has not yet occurred, BIO members are pleased to note support from President Calderón to try to move Mexico forward on cultivation.

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While Mexico has no significant trade barriers affecting biotechnology crops or foods derived from agricultural biotechnology, it is a very influential country both in the region and in international fora. In addition, Mexico, the United States and Canada entered into a trilateral arrangement that serves as a workable model for implementation of the shipping documentation requirements for agricultural commodities under the Cartagena Protocol on Biosafety (Protocol). The provisions behind this trilateral arrangement will be open for discussion by the Parties to the Protocol at their fifth meeting in October 2010, and it is imperative that the arrangement continue to be implemented in these three countries and supported by Mexico as a country importing agricultural biotechnology products. Therefore, BIO is of the view that the United States must continue to prioritize bilateral and multilateral discussions with Mexico to encourage progress in implementation of the Biosafety Law and regulations, as well as continued support of the trilateral arrangement for shipping documentation, to ensure the continued uninterrupted flow of trade between the two countries.

Labeling: Development of Mandatory Biotechnology Labeling Requirements

Many countries are using the development of their national regulatory systems to support mandatory labeling regimes for agricultural biotechnology products and foods derived from agricultural biotechnology products. Such labeling regimes are not based on science and have the immediate effect of preventing import of many food products that contain agricultural biotechnology ingredients. BIO requests that the U.S. Government establish a strategic approach to proactively influence countries to avoid the creation of non-science based mandatory labeling requirements for agricultural biotechnology products and to support the U.S. labeling approach. The United States requires labeling of biotechnology products if there is a material difference in the product compared to its conventional counterpart due to the creation of toxins, changes in nutrients or the creation of allergens. In addition, BIO requests that the U.S. Government consider its opportunities to leverage trade relationships between the United States and those countries that have already established mandatory labeling regimes to minimize the impact of such regimes and allow for open markets for U.S. exports of products of agricultural biotechnology.

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