



November 22, 2010

Ms. Gloria Blue  
Executive Secretary  
Trade Policy Staff Committee  
Office of the United States Trade Representative  
600 17<sup>th</sup> Street, N.W.  
Washington, DC 20508

Docket: USTR-2010-0031

RE: Participation of Malaysia in the Trans-Pacific Partnership Trade Negotiations

Dear Ms. Blue:

The Biotechnology Industry Organization (BIO) is pleased to have the opportunity to comment on the proposed accession of Malaysia to the Trans Pacific Partnership (TPP) negotiations. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and over 30 nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

The TPP is a strategic opportunity for the United States to expand trade within Asia. Comparatively, in terms of gross domestic product the TPP, including Malaysia, would nearly equal the size of the North American Free Trade Agreement (NAFTA). Although, the United States has already negotiated bilateral free trade agreements with a number of TPP countries, the TPP offers an opportunity to expand market access and promote regulatory cooperation in the region.

Specific to agricultural biotechnology, as of 2009, 25 nations actively cultivate genetically engineered (GE) crops, with an additional 32 nations authorizing imports. Parties to the TPP negotiation are a mixture of countries that actively cultivate and import GE crops, as well as those that have yet to develop functioning regulatory systems. Therefore, the TPP offers the potential to achieve a common regulatory approach and disciplines for agricultural biotechnology. This objective is particularly important given the potential for the TPP to expand, via accessions over time.

With regard to the accession of Malaysia to the TPP negotiations, BIO strongly believes that Malaysia should commit to achieve a comprehensive outcome on agricultural biotechnology. Malaysia has a strategic vision to develop its agricultural biotechnology sector and the TPP would give impetus to this objective. According to the Malaysia Biotechnology Corporation, investment in agricultural biotechnology totaled \$287 million in 2009. However, throughout the course of the negotiations of the Cartagena Protocol on Biosafety (Biosafety Protocol) and specifically negotiations on the recently adopted Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, negotiators from Malaysia's environmental ministry actively sought

inclusion of text running counter to the establishment of an environment that would foster growth in the trade of products derived from modern agricultural biotechnology as well as cultivation of genetically engineered crops. Therefore, should Malaysia become a Party to the TPP negotiations, BIO requests the U.S. government seek assurances from all TPP Parties to fully support positions to promote science-based, functioning regulatory systems within the Biosafety Protocol, international standard setting organizations or other international negotiations, and to not advocate for positions which would result in unscientific and unduly burdensome requirements for trade and cultivation of agricultural products derived from modern biotechnology.

With respect to the negotiating objectives for the TPP, BIO believes it is critical to promote the establishment of a science-based regulatory framework that reaffirms the Parties' commitment to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The U.S. government has stated the intention to treat the TPP as a model agreement for the 21<sup>st</sup> century, and therefore BIO believes that sound, objective and science-based approaches to agricultural biotechnology regulation should be a top priority, particularly with respect to the challenges facing global agriculture and energy supplies in the 21<sup>st</sup> century and beyond.

Negotiating text should include a provision for Parties to maintain functioning regulatory systems<sup>1</sup> for genetically engineered agricultural products. For those countries that do not have a framework in place to regulate agricultural biotechnology, negotiations should be aimed at a specified timeframe for the establishment of a functioning regulatory system consistent with the WTO SPS Agreement and guidance from international standard setting bodies.

To the extent practicable, BIO recommends that the U.S. government address the problems associated with asynchronous approvals by developing a common framework and practices for the approval of agricultural products derived from modern biotechnology. Regulatory frameworks should be streamlined, objective, science based and proportionate to the risk of the intended use of the product.

Parties should commit to full cooperation in international standard setting bodies. Specifically, Parties should implement policies for the low level presence of genetically engineered agricultural products consistent with the Codex Alimentarius Commission's *Annex on Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food*.

With regard to labeling of foods derived from agricultural biotechnology, BIO recommends the development of labeling practices consistent with the U.S. Food and Drug Administration (FDA) Draft Guidance. Therefore, any mandatory or required labeling for genetically engineered products should be science based, such as if the product has been significantly changed nutritionally or if there have been changes in other significant health-related characteristics of the

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<sup>1</sup> A "functioning" regulatory system is science-based, with clearly defined timelines and processes for regulatory review and decision-making, and appropriate protection for proprietary information and data. The regulatory decision-making processes must be predictable, completed in a timely manner, and not subject to undue political influence.

food (allergenicity, toxicity, or composition). Voluntary labeling should be truthful and not misleading.

In closing, BIO is fully supportive of a U.S. trade agenda that proactively addresses and removes barriers to trade of agricultural products derived from biotechnology.

Sincerely,

A handwritten signature in black ink, appearing to read "Sharon Bomer Lauritsen", with a horizontal line extending to the right.

Sharon Bomer Lauritsen  
Executive Vice President