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Report Highlights:

The Biosafety Bill is still under review and likely will not be passed until the end of the year. Under the Ninth Malaysia Plan (2006-2010), efforts will be intensified to create a conducive regulatory framework for the development of biotechnology. During the COP/MOP3 in Brazil, Malaysia took a more measured approach although at the end of the day the Malaysian delegation continued to support the more restrictive "does contain" documentation requirement under Article 18.2a. The first two Malaysian scientists have been selected for joint research in the U.S. in the field of ag biotechnology under the Scientists Exchange Program. Malaysia has committed to chair the Steering Committee for the APEC Biotechnology Investment Toolbox.

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Table of Contents

Executive Summary 3

Section II. Biotechnology Production and Trade..... 5

Section III. Biotechnology Policy 6

Section IV. Marketing Issues 8

Section IV. Marketing Issues 8

Section V: Capacity Building & Outreach..... 10

Section VI: Reference Material..... 11

Executive Summary

Malaysia is the 26th largest agricultural export market for the U.S. In 2005, the U.S. exported \$422 million of agriculture, fish and forestry products to Malaysia, mainly bulk grains and oilseeds, feedstuffs, temperate fresh fruits, temperate hardwood lumber, and other high valued consumer products. Almost all of the imported US soybean and corn shipments, valued at \$36 million in 2005, contain GMOs. The other primary sources of soybeans and corn are Argentina, Brazil and China. Having access to this important market is vital to the exports of US biotechnology-related products.

Malaysia has an influential voice among the developing countries as well as in the Islamic world. With its ambition to becoming a global player in the biotechnology industry, Malaysia could be a strong partner with the U.S. in the development of agricultural biotechnology and be a powerful, vocal advocate of biotechnology in the international arena. Malaysia's leadership on 'Halal' issues is also recognized in the Organization of Islam Conferences.

On April 28, 2005, the Prime Minister of Malaysia launched the new National Biotechnology Policy to give impetus to developing the biotechnology sector into a new economic engine to enhance prosperity and wellness of the nation by 2020. The Malaysian Biotechnology Corporation (MBC) was created as a one-stop agency to spearhead the development of the sector, including coordination of regulatory policy among different agencies. Unfortunately, the Ministry of Natural Resources and Environment (MONRE) is taking positions that could have serious negative impacts on biotechnology-related trade at the Convention on Biodiversity's COP/MOP 2 meeting (held May 30 – June 2005 in Montreal).

A more diverse Malaysian delegation went to the COP/MOP3 in Curitiba, Brazil in March 2006. Malaysia took a more measured approach although at the end of the day the Malaysian delegation continued to support the more restrictive "does contain" documentation requirement under Article 18.2a.

The National Biotechnology Policy was re-emphasized in the Ninth Malaysian Plan (9MP) (2006-2010) launched on March 13, 2006. Under the 9MP, the GOM allocated US\$550 million for biotechnology development. The GOM recognizes the importance of a conducive regulatory framework to ensure the success of its biotechnology endeavor. Efforts will be intensified to improve the IP policy and management framework in order to foster innovation and safeguard investment in the biotechnology sector.

Malaysia currently places no restrictions on the import of biotech food or feed, although it does have pending legislation that would regulate imports and labeling of GM food. After numerous revisions and delays, the Biosafety Bill is now under responsibility of the MONRE. Officials at the MONRE are working on the final draft before submitting to the Malaysian Parliament hopefully before the end of 2006. Once the Biosafety Act is in place, the Ministry of Health will amend the Food Regulations of 1985 to require all GM foods be labeled (labeling would be required for products containing over 3% biotech content).

On June 22 2005, the Malaysian Minister of Science, Technology and Innovation, Dr. Jamaludin Jarjis and the USDA's Undersecretary Joseph Jen exchanged letters to embark on an exchange program involving 4 scientists from each country every year to do agricultural research including biotechnology. The first two Malaysian scientists have been selected for joint research with their counterparts in the U.S. in the field of ag biotechnology.

At the APEC Hanoi meeting in January 2006, the Malaysian delegates volunteered to chair the Steering Committee for the APEC Biotechnology Investment Toolbox. The project

should be complete in time for submission at the next Policy Dialogue, which will be in January 2007 in Australia.

Section II. Biotechnology Production and Trade

Production

While Malaysia has not yet produced a biotechnology crop commercially, several genetically modified crops containing traits of value have been produced at the experimental stage. At the Malaysian Agricultural Research and Development Institute (MARDI), rice has been successfully modified to resist the tungro virus and papaya manipulated to resist ring-spot virus infection and to have a prolonged shelf life. Other crop plants such as pineapples are manipulated to resist "black heart", bananas and papaya for delayed ripening and chili for virus resistance.

Malaysia is also developing genetically engineered oil palm, with a focus on increasing value-added products from the palms, such as high oleate and high stearate oil, nutraceuticals (vitamin A and E), bio-diesel and bio-plastics.

In general, food biotechnology is relatively new in Malaysia although food and food ingredients produced by traditional biotechnology like fermentation technology have brought to market products like soy sauce, yogurt and 'tempeh'. Food biotechnology has also produced high quality, clarified fruit juices. Current research focuses on using enzymes to modify palm oil, sago starch and local fruit juices.

Several animal recombinant vaccines have been produced to assist the development of animal husbandry. Marker assisted breeding strategies are also being practiced to increase the efficiency of livestock breeding programs. In order to reduce the high costs associated with imported feed, research is also underway in Malaysia to generate cheaper domestic livestock feed through biotechnology.

Malaysia has collaborated with the Massachusetts Institute of Technology (MIT) since 1999 to discover nutraceuticals from two Malaysian natural products, *Eurycoma longifolia* (Tongkat Ali) and *Centalla asiatica* (Pegaga); and to produce bio-plastic through applying metabolic engineering to oil palm.

Trade

Malaysia currently places no restrictions on the import of biotech food or feed, although it does have pending legislation that would regulate imports and labeling of GM food. To date, the only GM ag product officially approved to be imported into Malaysia is 'Roundup Ready' soybeans. Although the bulk of soybeans imported from the U.S. is GM, there is a niche non-GM market since local soy product exporters need to conform to the EU's GMO requirements when they export processed soy-related food such as soy sauce, canned tuna in soy oil and soy milk to the EU. While Malaysia has not officially approved the imports of GM corn, it has not restricted the importation of GM corn.

Malaysia is not a food aid recipient and is unlikely to become one in the near future. Malaysia does not produce any biotechnology crops that were developed outside the U.S. and have not passed through the U.S. regulatory system.

Section III. Biotechnology Policy

The draft biosafety regulations, initially released for comment in 2001, caused some concern for the USG due to the broad scope combined with an undefined adherence to the "precautionary principle" as well as socio-economic, religious, and cultural "norms" that would be a part of the decision making process. After numerous revisions and delays, the bill is now under the responsibility of the Ministry of Natural Resources and Environment (MONRE). Officials at the MONRE are working on the final draft before submitting to the Malaysian Parliament hopefully before the end of 2006.

Once the Biosafety Act is in place, the Ministry of Health will amend the Food Regulations of 1985 to require all GM foods be labeled (labeling would be required for products containing over 3% biotech content). In general, Malaysian officials closely monitor international practice on GM foods and labeling, and have used Codex Alimentarius discussions as a benchmark in drafting their own regulations. The U.S. has commented on Malaysia's WTO Notification (G/TBT/N/MYS3) on GM labeling in November 2002.

Malaysia ratified the Biosafety Protocol in Dec 02 2003. Malaysian officials at the MONRE claimed that the pending Malaysian biosafety regulations would meet Malaysia's commitments as a full Party to the Protocol. The MONRE led the Malaysian delegation to the Convention on Biodiversity's COP/MOP2 meeting in Montreal (May 30 – June 4 2005). Malaysia's interventions at the Working Group on Liability and Redress (May 25 - 27) included a broader definition of "damage" to cover damage to environment, cultural, spiritual and moral values. Malaysia also wanted to apply a strict liability regime for all biotechnology products and argued against "permit defense" for biotech producers/operators, that limit liability for an activity that has been permitted by the government. Malaysia also took the very strong position that the Parties to the Protocol should impose extensive obligations on non-Parties dealing with Parties relating to liability and redress. At the MOP2, Malaysia supported the NGO's and the African Group's call to change the "may contain LMO" language to "does contain LMOs" on every shipping document for living modified organisms (LMOs) for use as food, feed or for processing.

A more diverse Malaysian delegation went to the COP/MOP3 in Curitiba, Brazil in March 2006. Malaysia took a more measured approach although at the end of the day the Malaysian delegation continued to support the more restrictive "does contain" documentation requirement under Article 18.2a. Apparently, Malaysia is slowly realizing that too strict a stand would have negative impact on its own livestock industry that relies heavily on imported feed and the further development of its domestic ag biotechnology. While still at the negotiation stage, any negative positions could have serious implications on US biotechnology related trade.

On April 28, 2005, the Prime Minister of Malaysia launched the new National Biotechnology Policy to give impetus to developing the biotechnology sector into a new economic engine to enhance prosperity and wellness of the nation by 2020. The Policy recognized the need to create a legislative and regulatory environment conducive to the development of the biotechnology industry. Soon after the announcement, the Malaysian Biotechnology Corporation (MBC) was created as a one-stop agency under the Prime Minister to spearhead the development of the sector, including coordination of regulatory policy among different agencies. Hopefully, with the MBC under the aegis of the Prime Minister, frictions among the various agencies could be eliminated and Malaysia would have a unified voice in the international arena. For further details on the new Policy, please refer to MY5019 dated 5/5/05.

The National Biotechnology Policy was re-emphasized in the Ninth Malaysian Plan (9MP) (2006-2010) launched on March 13, 2006. Under the 9MP, the GOM allocated US\$550 million for biotechnology development. The GOM recognizes the importance of a conducive regulatory framework to ensure the success of its biotechnology endeavor. Efforts will be intensified to improve the IP policy and management framework in order to foster innovation and safeguard investment in the biotechnology sector. For further details, please visit web <<http://www.epu.jpm.my>>, Chapter 6 on Biotechnology.

Section IV. Marketing Issues

The following is the profile of the Malaysian Consumers towards agricultural biotechnology and GM food according to a survey done 2002 by the International Service for the Acquisition of Agri-biotech Applications (ISAAA):

- Moderately to very interested in biotechnology
- Moderately to very concerned about biotechnology issues
- Perceive the risks of biotechnology to be moderate
- Perceive the benefits of biotechnology to be between moderate to high
- Have a high regard for research institutes (76%), university scientists (67%) and consumer groups/NGOs (62%) as being highly concerned about public health and safety issues relating to biotechnology
- Believe that regulatory bodies (86%), research institutes (84%) and university scientists (79%) have total responsibility for conducting risk assessment and risk management on biotechnology.
- Have a very high regard for the role of science in the development of agriculture in Malaysia (89%)
- Rate themselves as having a moderate understanding of biotechnology
- Have moderate score on factual knowledge about biotechnology
- Generally exhibit moderate attitudes toward biotechnology
- *On banning GM foods.* 64% would be in favor being actively involved through either time or money in banning GM foods. Only 14% are not in favor of this action.
- *On labeling GM foods.* 90% believe that GM food should be labeled.
- *On benefits of biotechnology to small farmers.* 62% agree with the proposition that agricultural biotechnology will not benefit small farmers.
- *On the benefits of biotechnology to Malaysia agriculture.* 65% believes that biotechnology is good for Malaysian agriculture.
- *On the adequacy of biotechnology regulations in Malaysia.* 51% disagree with the statement that current biotechnology regulations in Malaysia are sufficient. Only 23% agree about current regulations sufficiency.
- *On paying extra for the labeling of GM foods.* 49% indicated that are willing to pay extra for the labeling of GM foods, where as 29% are not willing to pay extra.
- Average frequency of contact had with the media within a two-month period is extremely low, the tri-media sources 1.42 times, family and other proximate interpersonal sources practically less than once and books and pamphlets less than once also.
- 12% reported using experts and less than ten percent have claimed accessing websites on biotechnology. They have listened to NGOs. They have barely talked to a religious group, regulators or a local politician about biotechnology nor have they attended seminars.
- Are highly trusting of information that comes from University scientists, science magazines and private sector scientists at 67%, 59% and 48% respectively.
- 31% feel that information they have received about biotechnology is useful. 33% feel that it is only somewhat useful and 34%, the highest percentage, feel that it is not useful.
- When asked if they perceive the information they receive about biotechnology, 30% percent feel that the information is highly scientific, 45% feel that the received information is moderately scientific, and 24% thought the information was not at all scientific.
- Types of issues/concerns they have heard or known about biotechnology are as follows: 60% have heard of moral/ethical issues, 32% have heard of religious

- issues/concerns, 20% about cultural and 19% about political issues/concerns.
- Think that moral/ethical issues (76%) will influence most their judgment on biotechnology.

For full details, please refer to the publication entitled 'The Social and Cultural Dimensions of Agricultural Biotechnology in Southeast Asia: Public Understanding, Perceptions and Attitudes towards Agricultural Biotechnology in Malaysia' by Napoleon K. Juanillo.

Section V: Capacity Building & Outreach

Past Activities

1. Over the last 5 years, Post has sent 2 journalists, 3 government officials, 3 science professors and one pro-biotech NGO to the U.S. to participate in the Cochran-funded Biotech short-courses. The US Grains Council has also had an active program of biotechnology outreach.
2. At least 2 Malaysian officials each year have attend the APEC High Level Policy Dialogue on Biotechnology since the first meeting was held in Mexico City in 2002. At the Hanoi meeting in January 2006, the Malaysian delegates volunteered to chair the Steering Committee for the APEC Biotechnology Investment Toolbox. The project should be complete in time for submission at the next Policy Dialogue, which will be in January 2007 in Australia.
3. The Embassy's Public Affairs and USDA have sponsored eminent American experts (including CS Prakash, Bruce Chassy, Shetty Kalidas and Val Giddings) to speak on biotechnology at conferences and seminars in Malaysia over the last five years.
4. The USG was the platinum sponsor of the 'BioMalaysia 2002: Biotechnology Symposium, Exhibition, and Business Partnering' held in Kuala Lumpur at the beginning of October 2002. With funding from EMO/USDA and Public Affairs/State, the U.S. Embassy was able to fully sponsored Dr. Autar Mattoo (Research Leader, Plant Molecular Biology Laboratory, ARS Beltsville) as a speaker; as well as the international travel expenses of three other distinguished American speakers (Prof. Anthony Sinskey, MIT, Prof. C.C. Liew, Harvard and Dr. Hasnah Hamdan, Quest Diagnostics Inc.). To support the organizer's efforts to make the conference "truly international", Post sponsored six journalists and scientists from Romania, Indonesia, the Czech Republic and the Philippines, Vietnam and India. The numerous articles generated after the event, supporting ag biotechnology, were well worth the effort of identifying, sponsoring, and escorting this group throughout the conference.
5. Malaysia has increasingly welcomed international conferences on biotechnology and has shown a willingness to collaborate with the United States to present biotech events. In December 2004, Malaysia co-hosted the APEC "Building a Positive Environment for the Investment of Agricultural Biotechnology" Seminar that was presented in response to priorities identified at the U.S.-chaired APEC High Level Policy Dialogue on Agricultural Biotechnology. Malaysian Minister of Science, Technology and Innovation, Dr. Jamaludin Jarjis, opened the seminar that explored the need for efficient and predictable regulatory environments and development of intellectual property systems as a basis for attracting investment. A list of goals that are necessary for building a positive investment environment was formally presented to the 2005 APEC High Level Policy Dialogue on Agricultural Biotechnology in Seoul, Korea in March 2005.
6. On June 22 2005, the Malaysian Minister of Science, Technology and Innovation, Dr. Jamaludin Jarjis and the USDA's Undersecretary Dr. Joseph Jen exchanged letters to embark on an exchange program involving 4 scientists from each country every year to do agricultural research including biotechnology. The program among others may cover the areas of genomics, crop yield forecasting and feasibility studies for agriculture and agro-based projects. The first two Malaysian scientists have been selected for joint research with their counterparts in the U.S. in the field of ag biotechnology.
7. Post selected two Malaysians to attend the short course on IPR at the University of Michigan in July 2005. Cochran funded the cost of the training.

Section VI: Reference Material

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