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Report Highlights:

No GE crops are approved for planting in Malaysia. Confined GE papaya trials were recently approved. Only a few corn and soybean GE events have been authorized for release on the market, even though approval is technically required for food, feed, and processing. The local food processing sector is quite concerned about the slow pace of approvals, as the 3.6 million tons of annual corn and soybean imports undoubtedly include unapproved GE varieties. Recently published GE labeling guidelines will be enforced starting in July 2014.

Section I. Executive Summary:

Malaysia imports over 3 million tons of corn, about 1.2 million tons of soybean meal, and 600,000 tons of soybeans annually, all of which have a high percentage of genetically engineered (GE) content. In terms of value, soybeans are generally the number one U.S. export to Malaysia. The U.S. also exports about 40,000 tons of corn gluten feed and 60,000 tons of corn distiller by-products to Malaysia annually. In addition, the U.S. exports to Malaysia about \$110 million in snack foods and high-value consumer products that have ingredients (primarily corn syrup and soybean oil) derived from GE crops. Malaysia also imports about 90,000 tons of identity-preserved non-GE soybeans annually, but they are not from the U.S.

According to Malaysia's 2007 Biosafety Law, the National Biosafety Board (NBB) must approve any "living modified organisms" to be released onto the market, including grains for feed or processing, and GE animals and products. As of June 2013, six corn and three soybean events have been approved, and one soybean, BPSCV127-9 (Glycine Max), is currently under review. The local food manufacturing sector is quite concerned about the slow pace of feed and processing approvals as it takes 180 days to process. Furthermore, for the events that have been approved, NBB often attaches unreasonable conditions on the downstream handling of commodities; conditions which are beyond the control and outside the responsibility of the applicants.

Following several months of consultations with relevant stakeholders, in April 2013 the Ministry of Health publicized GE food and ingredient labeling guidelines. The new GE labeling requirements will begin to be enforced in July 2014.

While much research is being done, particularly on oil palm and rubber, no GE crops are approved for commercial planting. Interest exists in the palm oil sector, as Malaysia is the world's second-leading producer, but local palm oil producers are reluctant to embrace GE technology for fear of a backlash from buyers and processors. Nonetheless, domestic consumer awareness and concern over GE content in food is not widespread.

In May 2013, NBB approved the first confined trials of a GE crop, which is a delayed ripening papaya variety. The Malaysian Agricultural Research and Development Institute (MARDI) will conduct the trials in their research facilities.

In general, both the general public and regulators are opposed to using GE in animal production, and no R&D in this area is occurring in Malaysia. However, NBB did approve a request from the Malaysian Institute of Medical Research to do trials on GE mosquitoes for dengue fever control. After doing a controlled release in uninhabited areas in 2010, further developments in this effort have been stalled due to public resistance to release in inhabited areas.

Section II. Plant Biotechnology Trade and Production:

Part A: Production & Trade

Product Development: In May 2013, NBB's Genetic Modification Advisory Committee (GMAC) granted approval for the Ministry of Agriculture's Agricultural Research and Development Institute (MARDI) to conduct confined field trials on GE papaya, whose improved trait is delayed ripening. The evaluation will be limited to evaluating the delayed fruit ripening characteristic within a 24m X 18m X

5.2m confined net-house structure. The papaya has been modified with an ACC Oxidase 2 gene obtained from Eksotika Papaya using antisense technology. To prevent cross-pollination, only female and hermaphrodite transgenic plants will be planted in the trial. The objective of the trial is to collect data in preparation for open field trials; it is still premature to predict when/if commercialization will occur.

Apart from the above, GMAC has not approved any other GE trials, and no GE crops are approved for planting. Nonetheless, within palm oil producing companies, reportedly biotechnology related research is ongoing, and development of varieties with improved traits using GE technology is conceivable in the near future. On the other hand, the industry also uses the fact that palm oil is still “GMO-free” to promote itself as superior to other vegetable oils. The industry is unlikely to seek official approval for confined or field trials now.

Biotechnology in Malaysia tends to have a broad interpretation, much broader than genetic engineering. For example, crop research using tissue culture and molecular markers, as well as research on bio-pesticides, integrated pest management, and natural fertilizers, are often categorized as “biotechnology” in the same context as genetic engineering. It is within that broad definition that the government of Malaysia promotes R&D and investment in “Biotechnology.”

The Biotechnology Corporation (BiotechCorp) is the lead agency for attracting investment and forming public and private sector partnerships in the biotechnology industry. However, most of its focus has been on the promoting investment in healthcare sector, with the agriculture sector lagging behind.

Commercial Production: There is no commercial production of GE crops or products in Malaysia.

Trade:

Exports: Malaysia does not export any GE crops. It is likely that some of Malaysia’s processed food product exports contain ingredients (e.g. soybean oil) derived GE crops.

Imports: Malaysia imports over 3 million tons of corn, about 1.2 million tons of soybean meal, and 600,000 tons of soybeans annually, all of which have a high percentage of GE content. Argentina and Brazil are the sources for about two-thirds of the corn imports, almost all the soybean meal comes from Argentina, and the U.S. supplies about half the soybeans. The U.S. also exports about 40,000 tons of corn gluten feed and 60,000 tons of corn distiller by-products to Malaysia annually. In addition, the U.S. exports to Malaysia about \$110 million in snack foods and high-value consumer products that have ingredients (primarily corn syrup and soybean oil) derived from GE crops.

Malaysia also imports about 90,000 tons of identity-preserved (IP) non-GE soybeans from Canada, and about 10,000 tons of IP corn from the U.S. Both these IP commodities are processed to make foods for human consumption.

No GE seed imports are approved for planting.

Food Aid: Malaysia does not receive food aid, and is not expected to in the future.

Section III. Plant Biotechnology Policy:

Regulatory Framework: The Ministry of Natural Resources and Environment’s (MNRE) Department

of Biosafety oversees GE crop and marketing related issues. The NBB, an inter-Ministerial body, reviews requests for research and marketing; GMAC is a part of the NBB that provides the expertise during the review process. GMAC provides expert advice to NBB based on recommendation by its subcommittee, the Environment, Human Health and Animal Health, which consists of personnel from various government Agencies and Universities. Malaysia's biosafety law requires that the NBB evaluate and approve "living modified organisms" before release onto the market for food, feed, or processing. This would apply to any and all GE events that may be found in the 3.6 million tons of corn and soybeans Malaysia imports annually. The NBB is supposed complete applications within 180 days. Legislation and regulations on the development, use, import and disposal of GE plants and their products can be found at www.biosafety.nre.gov.my.

The Ministry of Health's (MOH) Food Safety and Quality Division handles food safety assessments and labeling (details below) issues.

With no GE crops approved for domestic planting, regulating non-GE crops planted near GE crops has not been an issue, so there are no rules on co-existence. However, in GE corn approvals, NBB has included language regarding concerns of the potential impact on the local sweet corn industry should an unintentional "spill" occur from a bulk shipment.

Approvals: Information on the approval requirements and process is available at:

http://www.biosafety.nre.gov.my/regulatory_process/approval.shtml

The list of approved GM events for food, feed, and processing is available at:

http://www.biosafety.nre.gov.my/country_decision/app_ffp.shtml

Field Testing: As written above, only confined field evaluation of a papaya variety with a delayed ripening trait has been approved.

Stacked Event Approvals: The approval process for single or multi trait "stacked" events is the same. In January 2013, NBB approved TC1507 insect resistant and herbicide tolerant corn through the same process as single trait event application.

Additional Requirements: Malaysia has a seed registry procedure that is only loosely enforced by the Department of Agriculture (DOA), and NBB's approval of a variety would be sufficient to obtain seed registration. NBB's approvals do not mention any limit on the time for which approval is granted.

Coexistence: With no GE crops approved for domestic planting, regulating proximity of non-GE crops planted near GE crops has not been an issue, so there are no rules on co-existence. However, in GE corn approvals, NBB has included language regarding concerns of the potential impact on the local sweet corn industry should an unintentional "spill" occur from a bulk shipment.

Labeling: In April 2013, Food Safety and Quality Division, MOH published new "Guidelines on Labeling of Foods and Food Ingredients Obtained through Modern Biotechnology." The document can be found here:

http://fsq.moh.gov.my/v4/images/filepicker_users/5ec35272cb-

MOH will begin enforcing the guidelines on 8 July, 2014.

Some key elements of the labeling guidelines include the following:

- 1) If the GE content is not more than three percent, labeling is not required, “provided that this presence is adventitious or technically unavoidable.”
- 2) For single ingredient foods, the words “genetically modified (name of the ingredient)” must appear in the main display panel.
- 3) For multi-ingredient foods, the words “produced from genetically modified (name of the ingredient)” should appear in list of ingredients and “contains genetically modified ingredient” must be stated on the main display panel.
- 4) Highly refined foods, defined as those where processing has removed all novel DNA and protein, are exempt from the labeling requirement. (e.g.: vegetable oils, corn syrup, acidic foods, and salty foods).
- 5) Meat from animals fed with GE grains do NOT need to be labeled.
- 6) Only GE crops that have been approved by NBB can be used for foods and food ingredients.

Trade Barriers: Only those GE crop events that have been approved for food, feed, and processing are supposed to be marketed. However, as of June 2013, only 9 corn and soybean events have been approved. Bulk corn and soybean shipments likely contain many more events. When the new labeling requirements enter into force in July 2014, the required approvals are supposed to be more strictly enforced, including for processed food. However, it is still unclear how this is going to be enforced. It is uncertain if processed food, or even bulk grain shipments, will be tested for the presence of unapproved events. The long approval process and unreasonable conditions on the downstream handling of commodities creates additional uncertainty. Approvals for domestic commercial release for food, feed, and processing include conditions which are beyond the control and outside the responsibility of the life science companies who are the applicants. As a result of these unrealistic conditions, some applicants are hesitant to seek additional approvals, and without the approvals, end-users may be reluctant to risk continue using some products as ingredients. This unwieldy approval process may hinder imports.

Intellectual Property Rights: IPR protection is certainly a major concern among policy makers. But Malaysia doesn't have a strong seed development sector, no GE crops are approved for planting, and no institutionally strong seed registry exists.

Cartagena Protocol Ratification: Malaysia is a signed and active member of Cartagena Protocol and recipient of UNDP – GEF funds.

International Treaties/FORA: Malaysia regularly sends representatives to Codex meetings, but has not necessarily taken strong positions on GE plant regulations.

Monitoring and Testing: Neither MOH nor MNRE have a program for testing or actively monitoring GE content.

Low Level Presence (LLP): No stated policy on LLP exists. Any GE crop events on the market are supposed to have cleared NBB approvals.

Section IV. Plant Biotechnology Marketing Issues:

Market acceptance: The market is relatively indifferent regarding GE products: not necessarily rejecting the products, but not exhibiting complete acceptance either. With the exception of a few organized stakeholder groups, consumers are not particularly aware of GE foods and don't show particular concern. Although public awareness of GE products is currently low, enforcement of GE labeling may increase awareness and have an impact on overall acceptance in the future.

Public/Private Opinions: An NRE-UNDP-GEF survey completed in 2012 concluded that awareness and knowledge of the biosafety law and regulatory framework was low. Analysis of the report is available at: <http://www.biosafety.nre.gov.my/newsletter/Newsletter%20vol%204.pdf>

Section V. Plant Biotechnology Capacity Building and Outreach:

Activities: Malaysian officials and NGO representatives have attended courses and conducted independent research related to biotechnology under the Cochran and Borlaug Fellowship programs. Last year State Department funded a seminar on media presentation of scientific information. A follow-up to that program will be conducted in fall of 2013.

In 2011 and 2012, NRE conduct a series of information seminars fund by UNDP-GEF.

Strategies and Needs: It would be beneficial to educate NBB members about bulk grain handling and logistics. With a better knowledge of how grain marketing works, and who actually owns and controls grain transport and handling, they would realize that the conditions and requirements they place on food, feed, and processing approvals are unrealistic and impractical. However, it is unclear whether NBB would be receptive to a dialogue on this matter, and whether they would consider changing the conditions for approval.

Section VI. Animal Biotechnology:

Product Development: In general, both the general public and regulators are opposed to using GE in animal production, and no R&D in this area is occurring in Malaysia. However, in 2010 NBB did approve a request from the Malaysian Institute of Medical Research (IMR) to do trials on GE mosquitoes for dengue fever control. After doing a controlled release in uninhabited areas in 2010, further developments in this effort have been stalled due to public resistance to release in inhabited areas. It is unclear when/if development will be reinitiated.

The October 2010 NBB approval permitted the release of male GE mosquitoes, *Aedes aegypti* OX513A(My1) strain and male non-GM *Aedes aegypti* mosquitoes (wild type). In December 2010, IMR released the GE mosquitoes in an uninhabited area. The mosquitoes were developed by Oxitec a

U.K. biotech firm that aims to fight dengue by releasing massive numbers of "genetically sterile" male *Aedes aegypti* mosquitoes. Public consultation was held in August 2010.

Details of the approval can be found at NRE website:

[http://www.biosafety.nre.gov.my/country_decision/field_trial/aedes_aegypti/nbb%20decision%20\(eng\).pdf](http://www.biosafety.nre.gov.my/country_decision/field_trial/aedes_aegypti/nbb%20decision%20(eng).pdf)

A fact sheet on the field trial is available at:

[http://www.biosafety.nre.gov.my/country_decision/field_trial/aedes_aegypti/fact%20sheet%20\(eng\).pdf](http://www.biosafety.nre.gov.my/country_decision/field_trial/aedes_aegypti/fact%20sheet%20(eng).pdf)

Questions and answers with Media on the field trial can be found at:

http://www.biosafety.nre.gov.my/country_decision/field_trial/aedes_aegypti/question%20and%20answer%20session.pdf

Commercial Production: No commercial production of GE or cloned animals.

Biotechnology Exports: No exports of GE or cloned animals.

Biotechnology Imports: Malaysia is highly dependent on imports for genetics in livestock production, particularly for ruminants. It is conceivable that some of these imports may have been derived from clones.

Regulation: As is the case with plant material, the regulatory framework for GE animals is contained in the 2007 Biosafety Act and 2010 Approval Regulations, which can be found here:

http://www.biosafety.nre.gov.my/act_regulations/biosafety-act2007.pdf

http://www.biosafety.nre.gov.my/act_regulations/biosafety%20regulations%202010.pdf

Depending on the particular animal species involved, the Department of Veterinary Services and/or Fisheries, as well as NRE would be the key government entities involved with the decision making.

Labeling and Traceability: The labeling guidelines listed in the Plant Biotechnology Section also apply to GE animal products. There are no traceability mechanisms in effect.

Trade Barriers: No trade restrictions related to biotechnology issues.

Intellectual Property Rights: Nothing related to animal biotechnologies.

International Treaties/Fora: Malaysia regularly sends officials to Codex and OIE meetings, but representatives have not taken noteworthy positions on GE animals or cloning.

Marketing: To the extent that they are aware, most consumers would be opposed to consuming products from GE or cloned animals.

Capacity Building and Outreach: There have been no activities related to GE animals. And in fact, outreach on GE animals would probably be counter-productive. Any efforts should focus on achieving greater acceptance of GE plants first.

Section VII. Author Defined:

Reference Material

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