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Report Highlights:
There are no significant developments to report since the 2013 report: 1) No GE crops are approved for planting; 2) GE papaya research approved in 2013 is still only for confined trials; 3) Only a few corn and soybean GE events have been authorized for import and market release; 4) The GE labeling guidelines are still not being enforced; and 5) Release of GE mosquitos to fight dengue is still pending.

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Section I. Executive Summary:

In 2013, Malaysia imported 3.4 million tons of corn, 1.34 tons of soybean meal, and 572,000 tons of soybeans, all of which have high percentage of genetically engineered (GE) content. Soybeans were the main U.S. export in 2013, at 213,000 tons, accounting for 37 percent of total soybean imports. In addition, the U.S. exports about 60,000 tons of corn gluten feed, roughly 50,000 tons of corn distiller by-products, and $110 million worth of consumer products, which contain ingredients from GE grains. Malaysia also imports about 90,000 tons of identity-preserved non-GE soybeans, mostly from Canada.

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 2014, NBB had approved six corn and five soybean events, with one soybean event under review. Life science companies complain about the the slow approval process, which can take up to 180 days, and the unreasonable liability conditions placed on product approvals. Food processing companies, on the other hand, are concerned that some of their inputs may contain unapproved GE varieties.

A GE food and ingredient labeling regulation was to take effect on 8th July 2014, but at the time this writing it was still not being implemented, and the Ministry of Health had not made any official announcement when/if it would be.

While the oil palm (Malaysia's most important crop) genome has been mapped, the local sector is reluctant to invest too much in GE research and development in oil palm, fearing a backlash from palm oil buyers and processors. In fact, market leaders point to the non-GE characteristic of palm oil as a marketing advantage vis-à-vis soy and canola oil.

The NBB approved the first confined trials of GE papaya (delayed ripening trait) in May 2013. There is no other progress to report on this effort.

The Government of Malaysia (GOM) released GE mosquitos, designed to control dengue, under controlled field conditions in uninhabited areas in 2010. After these initial trials, GOM has been reluctant to take further action due to local opposition.

Section II. Plant Biotechnology Trade and Production:

Part A: Production & Trade

Product Development: On 29th May 2013, NBB's Genetic Modification Advisory Committee (GMAC) granted approval for the Malaysia Agriculture Research and Development Institute (MARDI) to conduct confined field trails on GE papaya. The confined field trails to be conducted at MARDI facility within a 24m X 18m X 5.2m confined net-house structure. The GE papaya has a delayed ripening trait. MARDI has not yet indicate any plans to pursue field trials.

A U.S. company is partnering with a major Malaysian palm oil company to conduct research and development on using GE yeast in a fermentation process, using palm oil and other palm-based products as feed stock, to produce industrial chemicals.

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 promoting investment in healthcare sector, with the agriculture sector lagging behind.

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

Trade:Trade:

Exports: Malaysia does not export any GE crops. It is likely that some of Malaysia's processed food product exports (e.g. soy milk) contain ingredients derived from 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 60,000 tons of corn gluten feed and 50,000 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 or 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 approve 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-78/Perundangan/Garispanduan/Pelabelan/GUIDELINES-ON-LABELLING-OF-FOODS-AND-FOOD-INGREDIENTS-PRODUCED-FROM-MODERN-BIOTECHNOLOGY_%2012042013-p.pdf

Please take note the above link was inaccessible at a time of report writing

However, as of early July 2014, MOH had still not been implementing the regulation.

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 2014, only 11 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, 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. In 2012, State Department funded a seminar on media presentation of scientific information on GE plant biotechnology.

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: Genetic Engineering in animal production has a negative perception among the public and government. There is no R&D done either by the government or private sectors using Genetic Engineering in animal production. Although the NBB did approve a controlled field release GE mosquitoes in 2010, opposition to the project at that time has halted further efforts to develop GE mosquitos. The GE mosquitoes were developed to fight dengue by releasing massive numbers of "genetically sterile" male Aedes aegypti mosquitoes.

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

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

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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