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Approved By:
Joani Dong
Prepared By:
Abdul Ghani Wahab

Report Highlights:
There have not been any significant developments to report since last year's 2015 report: 1) no genetically engineered (GE) crops have been 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) GE labeling guidelines are not enforced; and 5) there has not been any progress on releases of GE mosquito.

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SECTION I. EXECUTIVE SUMMARY:

In 2015, Malaysia imported 3.6 million tons of corn (mostly for poultry feed), 1.3 million tons of soybean meal (mostly for poultry feed) and 726,586 tons of soybeans (processed into cooking oil while the byproduct of this process is used for poultry and swine feed), all of which have high percentages of genetically engineered (GE) content. Soybeans were the main U.S. export in 2015, at 292,829 tons accounting for 40 percent of total soybean imports. In addition, the U.S. exports about US$31.1 million worth of corn gluten feed (for poultry and swine feed), roughly $8.7 million worth of corn distiller by-products (for poultry feed), 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 (for soy drinks), 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 2016, NBB had approved fourteen corn and seven soybean events.

Life science companies complain about 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 July 8, 2014, but, at the time of this writing, it has still not been implemented, and the Ministry of Health has not made any official announcement when/if it would be.

The genome of oil palm, Malaysia's most important crop, has been mapped. Nonetheless, the 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 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.

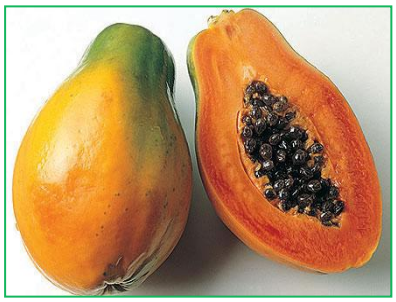
The Government of Malaysia (GOM) released GE mosquitos, designed to control dengue, under controlled field conditions in uninhabited areas in 2010. After these initial trials, GOM has been reluctant to take further action, fearing outcry from environmental groups. In March 2014, the Ministry of Health issued a statement that the trial would not proceed due to the cost associated with the second phase of the trials.

SECTION II. PLANT AND ANIMAL BIOTECHNOLOGY:

CHAPTER 1 PLANT BIOTECHNOLOGY

PART A: PLANT PRODUCTION & TRADE

a) PRODUCT DEVELOPMENT: On May 29, 2013, NBB's Genetic Modification Advisory Committee (GMAC) granted approval for the Malaysia Agriculture Research and Development Institute (MARDI) to conduct confined field trails at its facility on GE papaya with a delayed ripening trait within a 24m X 18m X 5.2m confined net-house structure. MARDI has not yet indicated any plans to pursue field trials. Lack of experience in collecting field trial data and funds to conduct further research hamper the progress of the GE papaya.



Over ripening papaya which has short shelf life.

Ideal papaya.

A U.S. company is partnering with a major Malaysian palm oil company to conduct research and development in using GE yeast in a fermentation process, using palm oil and other palm-based products such 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 research and development 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.

b) COMMERCIAL PRODUCTION: There is no commercial production of GE crops or products in Malaysia.

c) 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.

d) IMPORTS: Malaysia imports over 3.6 million tons of corn, about 1.3 million tons of soybean meal, and 726,000 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 United States 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 States. Both IP commodities are processed to make foods for human consumption.

No GE seed imports are approved for planting.

e) FOOD AID: Malaysia does not receive food aid and is not expected to in the future.

PART B: PLANT BIOTECHNOLOGY POLICY:

a) 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 found in the 3.6 million tons of corn and soybeans Malaysia imports annually. The NBB is supposed to 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 issues (details below).

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.

b) 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
c) FIELD TESTING: As written above, only confined field evaluation of a papaya variety with a delayed ripening trait has been approved.

d) 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.

e) 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.

f) 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.

g) LABELING: In April 2013, Food Safety and Quality Division of the Ministry of Health (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/v5/ms/guidelines-on-labelling-of-foods-and-food-ingredients-obtained-through-modern-biotechnology/

However, as of time of writing, MOH had still not implemented 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.

h) TRADE BARRIERS: Only those GE crop events that have been approved for food, feed, and processing are supposed to be marketed. As of June 2016, 21 corn and soybean events were approved, and there was an increase of 31% from 16 approved in 2015. 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.

i) INTELLECTUAL PROPERTY RIGHTS: IPR protection is a major concern among policy makers. However, Malaysia doesn't have a strong seed development sector. There have not been any GE crops are approved for planting. Also, there is no institutionally strong seed registry.

j) CARTAGENA PROTOCOL RATIFICATION: Malaysia is a signed and active member of Cartagena Protocol and recipient of UNEP – GEF funds.

k) INTERNATIONAL TREATIES/FORA: Malaysia regularly sends representatives to CODEX meetings, but has not necessarily taken strong positions on GE plant regulations.

l) RELATED ISSUES: None.

m) MONITORING AND TESTING: Neither MOH nor MNRE have a program for testing or actively monitoring GE content.

n) LOW LEVEL PRESENCE (LLP): There is no stated policy on LLP. Any GE crop events on the market are supposed to have cleared NBB approvals.

PART C: PLANT BIOTECHNOLOGY MARKETING:

a) MARKET ACCEPTANCE: The market is relatively indifferent about GE products, i.e., not necessarily rejecting 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.

b) PUBLIC/PRIVATE OPINIONS: An NRE-UNEP-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

c) MARKETING STUDIES: None.

PART D: PLANT BIOTECHNOLOGY CAPACITY BUILDING AND OUTREACH:

a) 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, the State Department funded a seminar coordinated by USDA Foreign Agricultural Service (FAS) on media presentation of scientific information on GE plant biotechnology.

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

Malaysia has participated in the last three APEC High Level Policy Dialogue on Agricultural Biotechnology workshops/meetings held in Medan, Indonesia in 2013; in Beijing in 2014; and in Manila in 2015.

On September 7, 2016, USDA/FAS will be organizing a biotech seminar to address issues faced by the Department of Biosafety and a closed door session for GMAC members.
b) STRATEGIES AND NEEDS: The Department of Biosafety highlighted needs to educate NBB members on bulk grain handling and logistics and on low level presence. For these reasons, USDA/FAS will hold a one day seminar on September 7, 2016 entitled "Sustainable Food Security in ASEAN: Role of Genetics and New Technologies" A closed door workshop for regulators, focusing on safety assessment of gene technologies, will be organized for GMAC. The seminar objective were to provide general public on current issues of GM products and how the stakeholders particularly importers and logistic companies handling the transportation of GM grains. As for GMAC members, the objective was to ensure GMAC members has the latest knowledge and update of the current practices in safety assessment.

CHAPTER 2: ANIMAL BIOTECHNOLOGY:

PART E: ANIMAL BIOTECHNOLOGY PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Genetic Engineering in animal production has a negative perception among the public and government. Neither government nor private sector conducts research and development 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

b) COMMERCIAL PRODUCTION: No commercial production of GE or cloned animals.

c) BIOTECHNOLOGY EXPORTS: No exports of GE or cloned animals.

d) BIOTECHNOLOGY IMPORTS: Malaysia is highly dependent upon imports for genetics in livestock production, particularly for ruminants. It is conceivable that some of these imports may have been derived from clones.

PART F: POLICY

a) 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 (DVS) and/or Fisheries, as well as NRE would be the key government entities involved with the decision making.

b) LABELING AND TRACEABILITY: Labeling guidelines listed in the Plant Biotechnology Section also apply to GE animal products. There are no traceability mechanisms in effect.

c) TRADE BARRIERS: No trade restrictions related to animal biotechnology issues.

d) INTELLECTUAL PROPERTY RIGHTS: Nothing related to animal biotechnologies.

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

PART G: MARKETING

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

b) PUBLIC/PRIVATE OPINIONS: None.

c) MARKET STUDIES: None.

PART H: ANIMAL BIOTECHNOLOGIES CAPACITY BUILDING AND OUTREACH

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

b) STRATEGIES AND NEEDS: None.

Reference Material

KEY BIOTECHNOLOGY CONTACTS IN MALAYSIA:

Dato' Sri Dr. Noorul Ainur
Secretary General
Ministry of Science, Technology & Innovation
Level 6, Block C5, Parcel C

Federal Government Administrative Centre
62662 Putrajaya
Tel: (60-3) 8885-8020/8021
Fax: (60-3) 8889-9000
E-mail: dr.noorul@mosti.gov.my
Website: http://www.mosti.com.my

Mr. Letchumanan A/L Ramatha
Director General
Department of Biosafety
Ministry of Natural Resources & Environment
Level 1, Podium 2, Wisma Sumber Asli
No. 25, Persiaran Perdana
Federal Government Administrative Centre
62662 Putrajaya
Tel: (60-3) 8886-1580 Ext: 1579
Fax: (60-3) 8890-4935
E-mail: letchu@nre.gov.my
Website: http://www.nre.gov.my
: www.biosafety.nre.gov.my

Dr. Muhamad Zakaria
Executive Director
National Institutes of Biotechnology Malaysia
NIBM, Level 2, Agro Biotechnology Complex (ABI)
C/O MARDI Headquarters
43400 Serdang Selangor Darul Ehsan
Tel No: (60-3) 8949 5648
Fax No: (60-3) 8940 8692
E-mail: mzak@nibm.my / muhamadzakaria@gmail.com

Dato' Dr. Mohd. Nazlee Kamal
Malaysia Biotechnology Corporation Sdn. Bhd.
Chief Executive Officer
Level 23, Menara Atlan
161 Jalan Ampang
50450 Kuala Lumpur
Tel: (60-3) 2116-5588
Fax: (60-3) 2116-5411

E-mail: info@biotechcorp.com.my
Website: http://www.biotechcorp.com.my/

Dato. Ahmad Zakaria Bin Mohamad Sidek
Director General of Agriculture
Department of Agriculture, HQ
Ministry of Agriculture & Agro-Based Industries
Wisma Tani
No. 30, Level 17, Persiaran Perdana
Lot 4G1, Presint 4
Federal Government Administrative Centre
62624 Putrajaya
Tel: (60-3) 8870-3001 (DL)/ 8870-3000 (G/L)
Fax: (60-3) 8888-5069
E-mail: zakaria@doa.gov.my
Website: http://www.doa.gov.my

Datuk Dr. Mohamad Azmie B. Zakaria
Director General
Department of Veterinary Services
Ministry of Agriculture & Agro-Based Industries
Wisma Tani
Level 2, Lot 4G1, Podium 1A, Presint 4
Federal Government Administrative Centre
62624 Putrajaya
Tel: (60-3) 8870-2001/8170
Fax: (60-3) 8888-8685/6051
E-mail: kp@dvs.gov.my
Website: http://www.dvs.gov.my

Dato' Ahamad Sabki Bin Mahmood
Director General
Department of Fishery (Jabatan Perikanan Malaysia)
Ministry of Agriculture & Agro-Based Industries
Wisma Tani
Level 6, Lot 4G2, Presint 4
Federal Government Administrative Centre
62628 Putrajaya

Tel: (60-3) 8889-5855/ 8870-4008/4009
Fax: (60-3) 8889-2460/8870-4000
E-mail: ahamadsabki@dof.gov.my / kpp01@dof.gov.my
Website: http://www.dof.gov.my

Datin Paduka Nurmala Abdul Rahim
Secretary General
Ministry of Plantation & Commodities
6-13th Floor, Lot 2G4, Presint 2
Federal Government Administrative Centre
62654 Putrajaya
Tel: (60-3) 8880-3334/3333
Fax: (60-3) 8880-3345/3441
E-mail: nurmala@mpic.gov.my
Website: http://www.kppk.gov.my

Datuk Farida Mohd Ali
Secretary General
Ministry of Health
Level 12, Block E7, Parcel E
Federal Government Administrative Centre
62590 Putrajaya
Tel: (60-3) 8883-2539
Fax: (60-3) 8889-5245
E-mail: farida@moh.gov.my
Website: http://www.moh.gov.my

END OF REPORT.