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Report Highlights:

There have not been any significant developments since last year's 2016 report: 1) no genetically engineered (GE) crops have ever been approved for planting; 2) GE papaya research approved in 2013 is still only for confined trials; 3) as of August 2017, 29 events of which 4 are cotton, 1 rapeseed, 15 maize and 9 soybean events were approved for import and market release; 4) GE labeling guidelines are not enforced; and 5) there has not been any progress on release of GE mosquitos.

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SECTION I. EXECUTIVE SUMMARY:

In 2016 Malaysia imported 3.60 million tons of corn (mostly for poultry feed), 1.17 million tons of soybean meal (mostly for poultry feed) and 796,114 tons of soybeans (for processing 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 2016, at 397,877 tons accounting for 50 percent of total soybean imports. In addition, the U.S. exported US\$ 11.9 million worth of corn gluten feed (for poultry and swine feed), roughly \$9.8 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 imported 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 into the market, including grains for feed or processing, and GE animals and products. As of August 2017, the National Biosafety board (NBB) had approved 29 events of which 4 were cotton, 1 rapeseed, 15 maize and 9 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 of inputs which may contain unapproved GE varieties. Responding to these concerns, the Department of Biosafety has shortened its approval process to 90 days and is in constant consultations with stakeholders to streamline the regulation process.

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 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 has been no other progress to report on this effort. Lack of funding and expertise to further research beyond confined trials lead to project standstills.

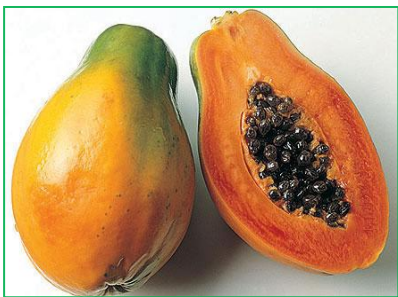
The Government of Malaysia (GOM) released GE mosquitos, designed to control dengue, under controlled field conditions in uninhabited areas in 2010. After these initial trials, GOM has been reluctant to take further action, fearing outcry from environmental groups. In March 2014, the Ministry of Health 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 progress of the GE papaya.



Over ripe papaya with short shelf life.



Ideal papaya.

A U.S. company, Verdezyne, is partnering with a major Malaysian palm oil company, Sime Darby, 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. A ground breaking ceremony was held on July 30, 2017, for Verdezyne's first commercial-scale renewable chemicals manufacturing facility producing 30 million pounds per year of diacids, including dodecanedioic acid (DDDA).

DDDA is a raw material used in the production of nylon or other polymers for use in a variety of applications including: engineering resins, automotive parts, athletic apparel, carpeting and toothbrush bristles, at lower cost than traditional, petroleum-derived nylons.

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 the healthcare sector, with the agriculture sector lagging behind.

1. COMMERCIAL PRODUCTION:

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

2. 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.

3. IMPORTS:

In 2016, Malaysia imported over 3.6 million tons of corn, about 1.17 million tons of soybean meal, and 796,114 tons of soybeans annually, all of which had a high percentage of GE content. Argentina and Brazil were the sources for about two-thirds of corn imports. Almost all the soybean meal comes from Argentina, and the U.S. supplies half of the soybeans. The United States also exported \$11.9 million worth of corn gluten feed and \$9.8 million of corn distiller by-products to Malaysia annually. In addition, the U.S. exported to Malaysia about \$100 million in snack foods and high-value consumer products that have ingredients (primarily corn syrup and soybean oil) derived from GE crops.

Malaysia also imported 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.

4. FOOD AID:

Malaysia does not receive food aid and is not expected to in the future.

5. TRADE BARRIERS:

Only GE crop events that have been approved for food, feed, and processing are supposed to be marketed. As of August, 2017, 29 events of which 4 are cotton, 1 rapeseed, 15 maize and 9 soybean events were approved, an increase of 23.8% from 21 approved in 2016. Bulk corn and soybean shipments likely contain many more events. When new labeling requirements enter into force, required approvals are supposed to be more strictly enforced, including for processed food. However, it is still unclear how this is going to happen.

It is uncertain if processed food or bulk grain shipments would be tested for 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. Given unrealistic conditions, some applicants are hesitant to seek additional approvals, and without the approvals, end-users may be reluctant to risk continue using products as ingredients. This unwieldy approval process may hinder imports.

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 National Biosafety Board (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 recommendations 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 evaluates and approves "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 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 handle food safety assessments and labeling issues (details below).

Since there aren't any 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 about 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 approved GM events for food, feed, and processing is available at:

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

c) **STACKED or PYRAMIDED 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 a single trait event application.

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

e) **INNOVATIVE BIOTECHNOLOGIES:** There is no specific regulatory status of innovative biotechnologies as all biotechnologies are treated the same.

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, the 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 the time of writing, MOH had still not implemented the regulation. 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 the 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 approved by NBB can be used for foods and food ingredients.
- h) **MONITORING AND TESTING:** Neither MOH nor MNRE have a program for testing or actively monitoring GE content.
- i) **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.
- j) **ADDITIONAL REGULATORY 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.
- k) **INTELLECTUAL PROPERTY RIGHTS (IPR):** 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 approved for planting. Also, there is no institutionally strong seed registry.
- l) **CARTAGENA PROTOCOL RATIFICATION:** Malaysia is a signed and active member of Cartagena Protocol and recipient of UNEP – GEF funds.
- m) **INTERNATIONAL TREATIES and FORUMS:** Malaysia actively sends representatives to CODEX and APEC HLPDAB meetings, but has not necessarily taken strong positions on GE plant regulations.
- n) **RELATED ISSUES:** None.

PART C: PLANT BIOTECHNOLOGY MARKETING:

a) **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>

b) **MARKET ACCEPTANCE/STUDIES:** The market is 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.

PART D: PLANT BIOTECHNOLOGY CAPACITY BUILDING AND OUTREACH:

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.



***Aedes aegypti* mosquito, the main cause of dengue fever in Malaysia.**

(Source : Wikipedia)

Details of the approval, field trial and questions and answers can be found at the NRE website under the heading of :

Limited-Mark-Release-Recapture of *Aedes aegypti* (L.) Wild Type & OX513A(My1) Strains
Applicant: **Institute of Medical Research**

Reference Number: **JBK(S) 602-1/1/3**

Date of Decision: **5 October 2010:**

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

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

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

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

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

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 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) **INNOVATIVE BIOTECHNOLOGIES :** There is no specific regulatory status of innovative biotechnologies as all biotechnologies are treated the same

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

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

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

f) **RELATED ISSUES:** None.

PART G: MARKETING

a) **MARKET ACCEPTANCE:** Most consumers would be opposed to consuming products from GE or cloned animals.

b) **PUBLIC/PRIVATE OPINIONS:** None.

c) MARKET STUDIES: None.

Reference Material

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END OF REPORT.