

Required Report: Required - Public Distribution

Date: November 24,2020

Report Number: MY2020-0011

Report Name: Agricultural Biotechnology Annual

Country: Malaysia

Post: Kuala Lumpur

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

Malaysia currently does not have any domestic production of plant biotechnology. However, the country continues to expand the number of approved genetically engineered (GE) products for commercial use. As of August 2020, 46 GE products have been approved for import and market release. This is an increase of 21 percent from the 38 products that were approved as of October 2019. The Malaysian Ministry of Health established mandatory GE labeling guidelines in 2013 but they have yet to be enforced.

EXECUTIVE SUMMARY:

Plant biotechnology product research in Malaysia is minimal and has been limited to just a few unfinished projects to date. As a result, there is no commercial production of GE plants in the country.

The Malaysia livestock feed industry is a significant importer of GE products and as of August 2020, 46 GE products have been officially approved for import and market release. This is an increase of 21 percent from the 38 products that were approved as of October 2019. The country imports feed ingredients from multiple sources, including Argentina, Brazil, Canada and the United States. In 2019, total corn imports surpassed 3.7 million metric tons (MMT), almost all of which originated from Argentina and Brazil. Soybean imports in 2019 surpassed 770,000 metric tons, over 85 percent of which came from the United States. Soybean meal imports in 2019 totaled nearly 1.38 MMT, almost all of which was sourced from Argentina.

The Malaysian Ministry of Health published guidelines on GE labeling in 2013. The stated purpose of these regulations is to ensure food safety and provide guidance to the food industry and consumer. The guidelines stipulate labeling is mandatory for products with GE content over 3 percent. Although this regulation was published seven years ago, it has yet to be enforced.

Malaysia's agricultural community is supportive of the expanded use of biotechnology, as is reflected by the strong import demand for approved GE products within the livestock feed industry. Consumer acceptance is more mixed and market analysts believe sentiment would be further tested if mandatory labeling laws were enforced.

There is no current animal biotechnology product development in Malaysia. In 2010, the Malaysian National Biosafety Board did approve a controlled release of GE mosquitos, but the project was quickly halted due to a lack of funding. The Islamic Development Authority of Malaysia (JAKIM) opposes the production and development of animal biotechnology products for the purpose of consumption in Malaysia.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

Biotechnology in Malaysia tends to have a broad interpretation beyond 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”. It is within that broad definition that the government of Malaysia promotes research in biotechnology.

Plant biotechnology product development in Malaysia is minimal and has been limited to just a few unfinished projects to date.

In 2013, the National Biosafety Board’s (NBB) Genetic Modification Advisory Committee (GMAC) granted approval for the Malaysia Agriculture Research and Development Institute (MARDI) to conduct confined field trials on GE papaya with delayed ripening traits. Due to a lack of funding, the trials were halted after an initial phase and no indication has been given regarding a continuation of this project.

Sime Darby, a major Malaysian palm oil company, had previously partnered with a U.S. company (Verdezyne) in various research projects utilizing byproducts from the palm oil production process. One of their joint projects reportedly used GE yeast in a fermentation process. However, media reports indicate the partnership abruptly came to an end in May 2018.

b) COMMERCIAL PRODUCTION:

There is no commercial production of GE plants in Malaysia.

c) EXPORTS:

Malaysia does not export any GE crops.

d) IMPORTS:

Malaysia imports GE livestock feed ingredients from multiple sources, including Argentina, Brazil, Canada, and the United States. Data on the exact percentage of imported feed ingredients that is genetically engineered is unavailable. In 2019, total corn imports surpassed 3.7 MMT, almost all of which originated from Argentina and Brazil. Soybean imports in 2019 surpassed 770,000 metric tons, over 85 percent of which came from the United States. Soybean meal imports in 2019 totaled nearly 1.38 MMT, almost all of which was sourced from Argentina. Malaysia is also an importer of corn gluten feed and distillers dried grains derived from GE corn from the United States.

e) FOOD AID:

Malaysia does not provide or receive food aid.

f) TRADE BARRIERS:

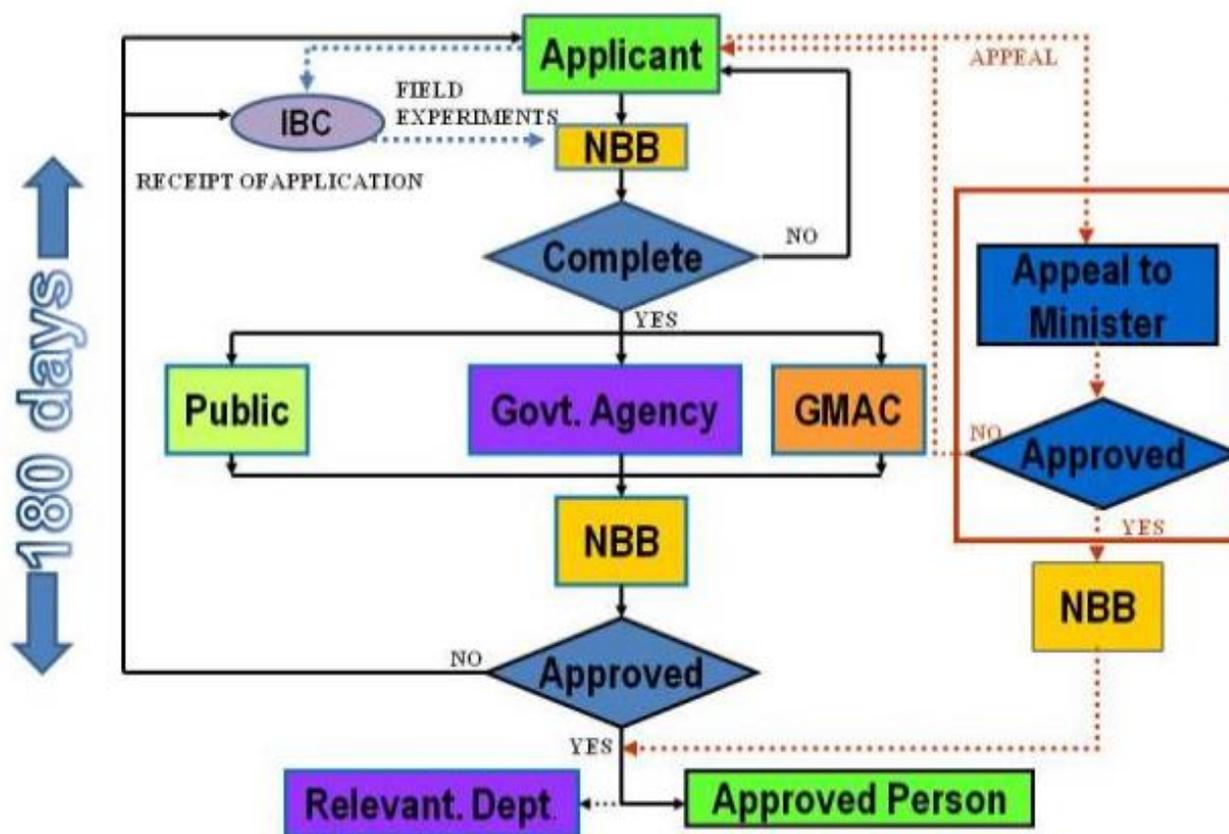
Although the Malaysian Ministry of Health (MOH) published mandatory labeling guidelines for “food and food ingredients obtained through modern biotechnology” in 2013 (please see Labeling Section below), no labeling requirements are currently enforced for foods, seeds, fibers, oils, or feeds that are derived from biotech crops.

PART B: POLICY

a) REGULATORY FRAMEWORK:

The Ministry of Natural Resources and Environment’s Department of Biosafety has authority over GE crop regulations and marketing. The NBB, an inter-ministerial body, reviews new GE product applications for safety before allowing the respective GE product market access. The GMAC is an entity within the NBB that provides technical, legal, and regulatory expertise during the review process. Relevant government agencies and universities can also play a role in providing the NBB with technical, legal, and regulatory expertise depending on the product being reviewed. Although NBB regulations indicate the review process for new GE product applications is meant to occur within 180 days, industry analysts explain that the review process is prone to exceed this time limit due to a lack of resources. Information on the development, import, and use of GE products can be found at <http://www.biosafety.gov.my/en-my/Pages/default.aspx>.

National Biosafety Board GE Product Approval Process



The MOH Food Safety and Quality Division is responsible for food safety assessments and labeling issues. If the mandatory guidelines published in 2013 (please see Labeling Section below) were to be enforced, the MOH would be responsible for ensuring all packaged food products with GE content above 3 percent are labeled.

b) APPROVALS:

As of August 2020, 46 GE products have been approved for import and market release. This is an increase of 21 percent from the 38 products that were approved as of October 2019. The list of approved GE products is available at:

<http://www.biosafety.gov.my/en-my/nbb-decision/Pages/NBB-Decision-Food-Feed-Processing.aspx>

c) STACKED OR PYRAMIDED EVENT APPROVALS:

The approval process for stacked events is the same for single-trait products.

d) FIELD TESTING:

Field trials for approved GE product imports are not required. The only approved field evaluation in Malaysia is for a papaya variety that was halted in 2013.

e) INNOVATIVE BIOTECHNOLOGIES:

There are currently no specific Malaysian guidelines or deliberations on regulating innovative biotechnologies (e.g. genome editing); all biotechnologies are treated the same.

f) COEXISTENCE:

There are no rules on co-existence as there are no GE crops approved for domestic commercial cultivation at this time.

g) LABELING AND TRACEABILITY:

In April 2013, the Food Safety and Quality Division of the Ministry of Health published new “Guidelines on Labeling of Foods and Food Ingredients Obtained through Modern Biotechnology”. The stated purpose of these regulations is to ensure food safety and provide guidance to the food industry and consumer. The guideline is mandatory for all processed, packaged food sold in Malaysia. Although this regulation was published in 2013, it has yet to be enforced. Details on this regulation can be found at: [Guidelines on Labeling of Foods and Food Ingredients Obtained through Modern Biotechnology](#).

Key elements of the labeling guidelines include:

- 1) If the GE content is more than three percent, labeling is required.
- 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, etc.).
- 5) Meat from animals fed with GE grains do NOT need to be labeled.

h) MONITORING AND TESTING:

The NBB and the MOH rely on the Malaysian Department of Chemistry, under the Ministry of Energy, Science, Technology, Environment, and Climate Change for the monitoring and testing of GE products.

i) LOW LEVEL PRESENCE (LLP) POLICY:

There is no stated policy on LLP. Any GE products on the market are required to undergo NBB review and approval.

j) ADDITIONAL REGULATORY REQUIREMENTS:

Malaysia has a seed registry procedure that is enforced by the Department of Agriculture (DOA). However, the NBB's approval of a variety would be sufficient to obtain this seed registration.

k) INTELLECTUAL PROPERTY RIGHTS (IPR):

Market analysts indicate IPR protection is a major concern among domestic policy makers. However, Malaysia does not have a strong seed development sector and there have not been any domestically developed GE crops approved for commercial use.

l) CARTAGENA PROTOCOL RATIFICATION:

Malaysia signed the Cartagena Protocol on May 24, 2000 and ratified it on September 3, 2003. Malaysia is an active member of the group and a recipient of United Nations Environment Program-Global Environment Facility funds.

m) INTERNATIONAL TREATIES and FORUMS:

Malaysia actively sends representatives to Codex Alimentarius (Codex) and the Asia Pacific Economic Cooperation forums on High Level Policy Dialogue on Agricultural Biotechnology.

n) RELATED ISSUES:

None

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

Malaysia's agricultural community is generally supportive of the expanded use of biotechnology, as is reflected by the strong import demand for approved GE products within the livestock feed industry. Consumer acceptance is more mixed and multiple market analysts believe sentiment would be further tested if mandatory labeling laws were enforced. Also, there are at least two consumer advocacy associations (Consumers Association of Penang and the Muslim Consumers Association of Malaysia) who actively lobby against GE products.

b) MARKET ACCEPTANCE/STUDIES:

In 2012, a United Nations Environment Program-Global Environment Facility survey was conducted in Malaysia to gauge public awareness of the country's biosafety law and regulatory framework. The results indicated that while industry and academia were fairly knowledgeable of the biosafety laws and regulatory framework, domestic consumer awareness was significantly lower.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

There is no animal biotechnology product development in Malaysia. In 2010, the NBB did approve a controlled release of GE mosquitos but the project was quickly halted after an initial phase due to a lack of funding.

b) COMMERCIAL PRODUCTION:

There is no commercial production of animal biotechnology in Malaysia.

c) EXPORTS:

None

d) IMPORTS:

None

e) TRADE BARRIERS:

There are no trade restrictions related to animal biotechnology.

PART E: POLICY

a) REGULATORY FRAMEWORK:

As is the case with plant material, the regulatory framework for animal biotechnology is contained in the 2007 Biosafety Act and 2010 Approval Regulations. Details can be found at:

<http://www.biosafety.gov.my/en-my/Corporate-Info/Pages/Legislation-and-Policy.aspx>

b) APPROVALS:

There are no approved animal biotechnology products for commercial use in Malaysia.

c) INNOVATIVE BIOTECHNOLOGIES:

There is no specific regulatory status for innovative biotechnology in animals.

d) LABELING AND TRACEABILITY:

Labeling guidelines listed in CHAPTER 1: PLANT BIOTECHNOLOGY also apply to GE animal products. There are no traceability mechanisms in effect.

e) ADDITIONAL REGULATORY REQUIREMENTS:

None

f) INTELLECTUAL PROPERTY RIGHTS (IPR):

There is no current legislation that addresses IPR for animal biotechnologies.

g) INTERNATIONAL TREATIES and FORUMS:

Malaysia regularly sends officials to Codex and World Organization of Animal Health (OIE) forums.

h) RELATED ISSUES:

None

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

The Islamic Development Authority of Malaysia (JAKIM) opposes the production and development of animal biotechnology products for the purpose of consumption in Malaysia. JAKIM issued two directives to this regard in 1999 and 2011.

b) MARKET ACCEPTANCE/STUDIES:

FAS Malaysia is unaware of any studies on animal biotechnology market acceptance.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION:

Malaysia commercially produces food ingredients that may have been derived from microbial biotechnology. Malaysian companies work on a variety of bacteria, yeasts, fungi, and enzymes for application in food & beverage, pharmaceutical, bio-industrial, and veterinary areas.

b) EXPORTS:

Malaysia exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

c) IMPORTS:

Malaysia imports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS:

There are no known trade restrictions related to microbial biotechnology products at this stage.

PART H: POLICY

a) REGULATORY FRAMEWORK:

Products derived from microbial biotechnology for human consumption are subject to the Malaysian Food Regulations Act of 1985. Details on these regulations can be found at:

<http://fsq.moh.gov.my/v6/xs/page.php?id=72>

b) APPROVALS:

Approval of food ingredients derived from microbial biotechnology is subject to the Malaysian Food Regulations Act of 1985, under the purview of the Malaysian Ministry of Health's Food Safety and Quality Division.

c) LABELING AND TRACEABILITY:

Labeling guidelines for all food ingredients are listed in CHAPTER IV of the Food Regulations Act of 1985.

d) MONITORING AND TESTING:

The MOH relies on the Malaysian Department of Chemistry, under the Ministry of Energy, Science, Technology, Environment, and Climate Change for the monitoring and testing of all food ingredients derived from microbial biotechnology.

e) ADDITIONAL REGULATORY REQUIREMENTS:

None

f) INTELLECTUAL PROPERTY RIGHTS (IPR):

There is no current legislation that addresses IPR for microbial biotechnologies.

g) RELATED ISSUES:

None

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

Currently, in Malaysia, there is no debate on microbial biotechnology.

b) MARKET ACCEPTANCE/STUDIES:

FAS Malaysia is unaware of any studies on microbial biotechnology-derived product market acceptance.

Attachments:

No Attachments