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Report Highlights:

There have been no major changes to Malaysia's biotechnology regulations in the past year. The country continues to review its Biosafety Act, including how it will regulate gene edited products in the future. Malaysia currently has 61 genetically engineered (GE) products approved for import.

EXECUTIVE SUMMARY:

There have been no major developments in Malaysia's biotechnology regulations in the past year. An internal review of the Biosafety Act 2007 and Biosecurity Regulations continues in the Department of Biosafety, and the proposed changes will eventually be published for public comment. Consultation meetings were held in 2023 for certain areas not covered by current Malaysian regulation, including Low-Level Presence (LLP). Malaysia does not currently have a defined policy for products of gene editing technologies.

Plant biotechnology product research in Malaysia has been limited, but is growing with the availability of gene editing technology. Despite interest, there is no commercial production of GE plants in the country. The Malaysian livestock feed industry is a significant importer of GE products, with 61 GE products officially approved for import and market release (the last was approved in November 2023). The full list of approved products are available [here](#). There are a further four products that had been approved for field trials, with the latest approved in 2019. The country imports feed ingredients from multiple sources, including Argentina, Brazil, Canada, and the United States. The Malaysian Ministry of Health (MOH) published regulations on GE labeling in 2013 that stipulate labeling is mandatory for products with GE content over three percent.

Given Malaysian reliance on importation of GE corn and soybeans for animal feeds, the livestock industry is supportive of biotechnology for feed use. There is no current animal biotechnology product development in Malaysia. The Islamic Development Authority of Malaysia (JAKIM) opposes the production and development of animal biotechnology products for the purpose of consumption in Malaysia. JAKIM however, allows the use of GE grains for animal feed.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND 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 (GOM) promotes research in biotechnology.

Plant biotechnology product development in Malaysia is growing with wider availability of gene editing technology and expertise. In particular, there is a significant amount of work on disease-resistant rice varieties. However, this research rarely advances to field trials. 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. However, the trials were halted after an initial phase.

Both palm oil plantation companies and the GOM have invested heavily in research and development of genome sequencing in palm oil, which is not considered development of GE products. The Malaysian Oil Palm Genome Program under the purview of the Malaysian Palm Oil Board runs an advanced research and development program. Plantation companies have successfully developed varieties of new palm tree hybrid seeds through this method.

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 2023, total corn imports were near 3.6 MMT, almost all of which originated from Argentina and Brazil. Soybean imports in 2023 were 640,000 metric tons, with both the United States and Brazil as significant suppliers. Soybean meal imports in 2023 totaled nearly 1.3 MMT, almost all of which was sourced from Argentina. Malaysia is also an importer of corn gluten feed and distiller’s dried grains derived from GE corn from the United States.

e) FOOD AID:

Malaysia does not provide or receive food aid.

f) TRADE BARRIERS:

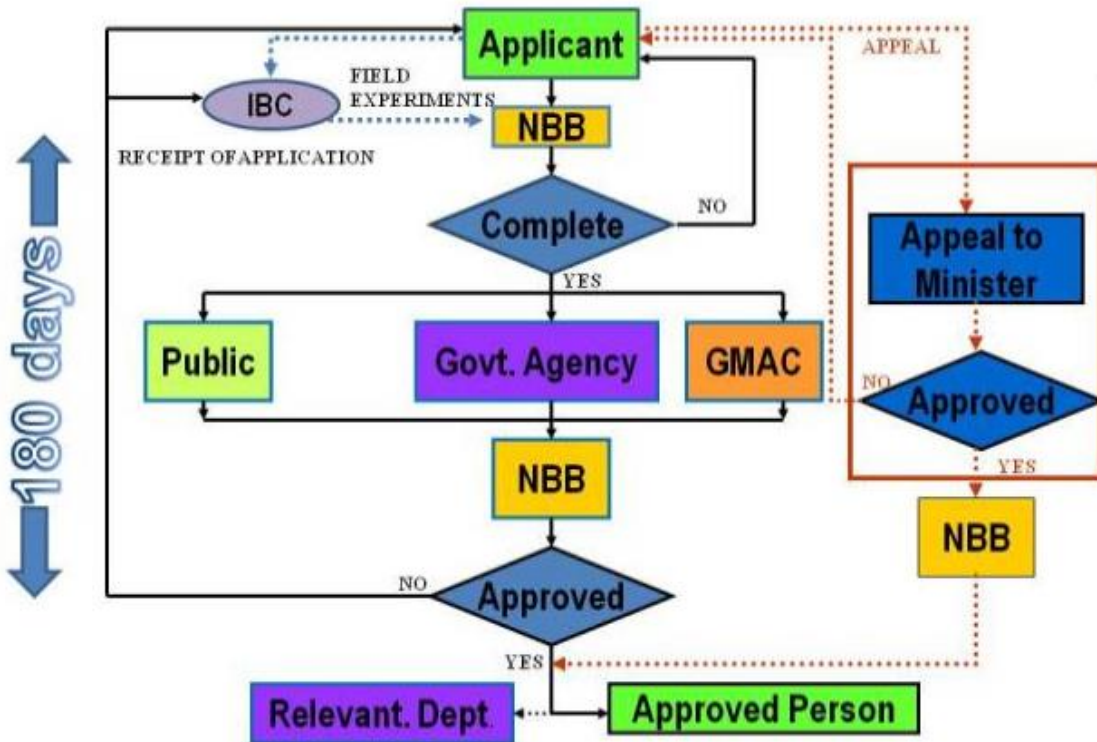
The import permit requirements identify the intellectual property (IP) owner as being liable for cleanup in case of spillage during transportation and transportation condition required the consignment to be transported in a secured and closed container. While these requirements have not been enforced to date, developers note that they do not have direct control over shippers or local importers of their products.

PART B: POLICY

a) REGULATORY FRAMEWORK:

The Ministry of Natural Resources, Environment and Sustainability’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 sources note 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 the Department of Biosafety [website](#). Once approved, there are no requirements for re-registration and no expiry date for the approved events.

National Biosafety Board GE Product Approval Process



Source: Department of Biosafety Malaysia

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 three percent are labeled.

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
<p>Organsima Diubah Suai yang Hidup</p> <p>Bioteknologi Moden</p>	<p>Living Modified Organism (LMO)</p> <p>Modern Biotechnology</p>	<ul style="list-style-type: none"> • Biosafety Act 2007 (Act 678) • National Policy on Biological Diversity 2016-2025 • Biosafety (compounding of offences) Regulations 2018 • Biosafety (Approval and Notification) Regulations 2010 • Animal Act 1953 • Vaccine Registration Procedure 	<p>Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.</p> <p>The application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles; or the fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.</p>
<p>Mikro-Organisma Diubah Suai yang Hidup</p>	<p>Genetically Modified Microorganisms</p>	<ul style="list-style-type: none"> • Biosafety Guidelines: Risk of 	

		Genetically Modified Micro-organisms	
Hasilan Makanan yang Diuban Suai	Genetically Modified Food (GMF)	<ul style="list-style-type: none"> • Guidelines on Labelling of Foods and Food Ingredients Produced from Modern Biotechnology 	Food or food ingredients obtained through modern biotechnology.
Organsima Diubah Suai yang Hidup	Genetically Modified Organism (GMO)		An Organism in which the material has been changed through modern biotechnology in a way that it does not occur naturally by multiplication or natural recombination or both.

b) APPROVALS/AUTHORIZATIONS:

As of October 2024, 61 GE products have been approved for import and market release. There have been no new events approved by the Department of Biosafety. The list of approved GE products is available [here](#).

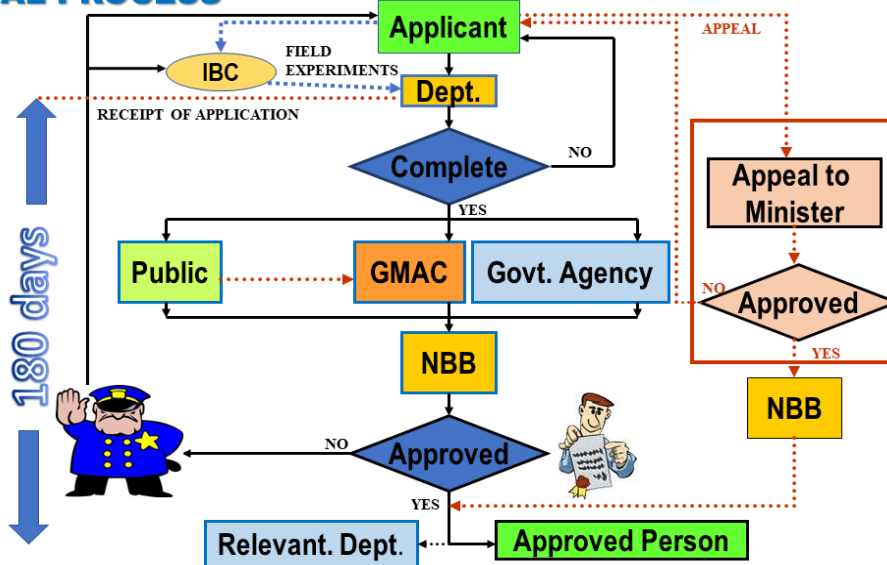
c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS:

The approval process for stacked events is the same for single-trait products. GMAC treats stacked trait products as a new products and re-reviews all the events it contains.

d) FIELD TESTING:

For field trial testing below the process flow of the application process.

APPROVAL PROCESS



Source: Department of Biosafety Malaysia

The fee chargeable by the Department of Biosafety for field trial testing depends on the size of the field experiment sites. For an area less than 5 hectares (ha) the fee is RM 100. For area of 5 ha to 10 ha the fee is RM 250 and for area more than 10 ha the fee is RM 500.

There are three types of form the applicants need to complete either Form A or B and Annex 2.

Form A (Approval for Release Activities of LMO-Research and Development purposes in All Field Experiments or importation of LMO that is higher Plant). This form is used to conduct field experiments involving LMOs consisting high-grade plants and can be either imported or produced locally for the field testing.

Form B (Approval for Release Activities of LMO – Research and Development purposes in All Fields Experiments or Importation of LMO other than Higher Plants). This form is used to conduct field experiments involving LMOS that are not composed of high-grade plants and can be either imported or produced locally for the field testing.

Annex 2 [Institutional Biosafety Committee (IBC) Assessment of Project Proposal involving Modern Biotechnology Activities] – This form should be used when the IBC evaluates the field test activities before submitting the result to the Department of Biosafety. Guidelines on how to set up the IBC is [here](#). Once the approval accepted by the Department of Biosafety, the IBC need to follow the guideline for LMO controlled field experiment which is available [here](#). Guidelines on the risk assessment of modified plants (GM) to the environment (ERA) is available [here](#).

e) INNOVATIVE BIOTECHNOLOGIES:

There are currently no specific Malaysian guidelines on regulating innovative biotechnologies (e.g. genome editing); all biotechnologies are treated the same. This may be further examined during the ongoing review of the Biosecurity Regulations.

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 “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. Details on this regulation can be found [here](#).

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 does 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 Science, Technology and Innovation 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. A public consultation on LLP of Genetically Modified Organisms was held in August 2023. The consultation is to gauge public interest on LLP, GOM did not announce dates for follow-up meetings or intentions for a timeline to pass new regulations and policy on LLP.

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. Malaysia accepted TRIPS on December 10, 2015 and has been an active member of IPPC. There is no record of infringement of copyrights or IP rights reported on GE events.

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), ASEAN Centre for Biodiversity 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. A survey by researchers from the Malaysia National University (UKM) in 2021, titled "[Stakeholders' Attitudes Toward Genetically Modified Rice in Malaysia](#)" shows mixed level of acceptance, with majority of respondents viewing GE rice (the research subject) to have moderate benefits and risks. Lack of information, unfamiliarity of GE products, and disinformation from NGOs on GE products are issues faced by consumers in Malaysia.

There are at least three consumer advocacy associations (Consumers Association of Penang, the Muslim Consumers Association of Malaysia, and the Third World Network) who actively lobby against GE products. Their claims include negative impacts on humans and the environment resulting from genetic contamination from the GE corn and other commodities and products.

In addition to the above NGOs, the Malaysian Agroecology Society for Sustainable Resource Intensification (SRI-Mas) champions the cultivation of organic heirloom rice by disparaging hybrid and GM rice varieties.

b) MARKET ACCEPTANCE/STUDIES:

In 2021, Malaysian National University (UKM) researchers completed a survey titled “ [Stakeholders’ Attitudes Toward Genetically Modified Rice in Malaysia](#)” which shows a mixed level of acceptance in general towards GM rice. Most participants view GM rice to be moderate in benefits and risks. A lack of information, unfamiliarity of GE products, and disinformation from certain NGOs on GE products are issues faced by consumers in Malaysia.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT:

There is no animal biotechnology product development in Malaysia. In 2010, the NBB approved 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. However, the Islamic Development Authority of Malaysia (JAKIM) opposed any development of animal biotechnology for human consumption for Muslim consumers, fearing the use of porcine genetics which is prohibited in Islam.

PART E: POLICY

a) REGULATORY FRAMEWORK:

The regulatory framework for animal biotechnology is the same as for plant biotechnology. Please refer to the above plant biotechnology 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 [here](#).

Products derived from animal biotechnology for human consumption are subject to the Malaysian Food Regulations Act of 1985. Details on these regulations can be found [here](#) (link in Malay, PDFs available in English). In addition, it is also subject to the Malaysian Islamic Department (JAKIM) regulations on Halal requirements especially on the use of porcine genetics which is prohibited in Islam.

b) APPROVALS/AUTHORIZATIONS:

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 specific traceability requirements 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:

None.

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 with a variety of bacteria, yeasts, fungi, and enzymes for application in food and 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 trade restrictions related to microbial biotechnology products at this stage.

PART H: POLICY

a) REGULATORY FRAMEWORK:

The regulatory framework for microbial biotechnology is the same as the plant biotechnology. Please refer to the above plant biotechnology 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 [here](#).

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 [here](#) (link in Malay, PDFs available in English).

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b) APPROVALS/AUTHORIZATIONS:

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. List of approved ingredients derived from microbial biotechnology is available [here](#). As an active member of CODEX ALIMENTARIUS, Malaysia recognized Codex texts based on proven scientific research.

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 Science, Technology, and Innovation 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:

There is no public debate on microbial biotechnology.

b) MARKET ACCEPTANCE/STUDIES:

None.

Attachments:

No Attachments