Required Report: Required - Public Distribution **Date:** December 16, 2025

Report Number: MY2025-0016

Report Name: Biotechnology and Other New Production Technologies Annual

Country: Malaysia

Post: Kuala Lumpur

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

Malaysia continues to depend on imported GE-derived feed ingredients while keeping strict limits on domestic GE crop cultivation. In 2025, regulators began more active discussions on how genome-edited products should be handled, reflecting pressure to modernize policy. Animal biotechnology remained minimal, and discussions continue to focus on public expectations and halal consideration. Microbial biotechnology stayed commercially strong in 2025, supported by steady industry use of fermentation-based ingredients and clear food-safety rules.

EXECUTIVE SUMMARY

Malaysia’s biotechnology landscape continued to develop steadily in 2025, driven by practical needs in food security, industry growth, and scientific capacity. Plant biotechnology remained the most active research area, especially in rice and palm oil, where universities and research institutes focused on disease resistance, climate-tolerant traits, and productivity improvements. Even though Malaysia does not allow Genetically Engineered (GE) crop cultivation, the country relies on GE -derived feed imports for its livestock sector. This reliance, combined with rising production costs, has encouraged regulators to review how genome-edited crops should be managed in the future and whether a more flexible, risk-based approach is appropriate.

Animal biotechnology remained limited, with no development or use of GE animals, genome-edited livestock, or clones. Public and religious sensitivities continue to shape the national stance, with halal considerations playing a major role in how new technologies are viewed. At the same time, Malaysia demonstrated openness to biotechnology in public-health applications, such as ongoing Wolbachia mosquito releases to control dengue; a sign that biotechnology solutions are welcomed when clearly understood and well-communicated. Conservation programs, especially for the Malayan tiger, also expanded their use of genetic tools, though these do not involve genetic modification.

Microbial biotechnology continued to be the area with the most commercial activity. Malaysian firms use a wide range of fermentation-derived enzymes, cultures, and food-processing aids in everyday manufacturing, from dairy and beverages to nutraceuticals and industrial applications. These products are widely accepted and regulated under existing food-safety laws. Discussions on how genome-edited microbes might fit into the current system have begun, but they remain exploratory.

Across all sectors, Malaysia’s overall approach to biotechnology remains cautious but gradually evolving. Investments in testing capacity, interagency coordination, and public-engagement efforts show that the country is preparing for more advanced technologies, even if major regulatory changes are still in the early stages.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

Malaysia's biotechnology research is driven mainly by public institutions, universities, and the palm oil industry. Earlier efforts were centered on tissue culture and molecular markers, and these approaches remain widely used as the foundation of most breeding programs. In recent years, researchers have added gene editing and other precision-breeding tools to complement but not replacing the existing methods. Much of this work focuses on traits such as disease resistance in rice, drought tolerance in vegetables, and higher oil yield in palm.

The Malaysian Palm Oil Board (MPOB) continues to lead genomic research. Its long-running genome sequencing program helps breeders identify desirable traits earlier and select higher-yielding planting materials more accurately. Although this work is not classified as genetic modification, it relies on advanced biotechnology that improves breeding efficiency.

Rice biotechnology is also expanding. Malaysian Agricultural Research and Development Institute (MARDI) and several universities are developing saline-tolerant, disease-resistant, and climate-resilient varieties using molecular techniques. Most projects remain in laboratory or greenhouse stages because field trials face regulatory caution, public concerns, and funding limitations. The discontinued GE papaya trial illustrates these hurdles.

Beyond crop improvement, local research institutions are working on bio-pesticides, biofertilizers, and microbial inoculants. These products support Malaysia's shift toward sustainable farming and help producers meet export-oriented sustainability standards and highlight the general broad interpretation of biotechnology used in Malaysia.

b) COMMERCIAL PRODUCTION

Malaysia has not approved any GE crop for commercial planting. Despite substantial research activity, commercial deployment remains limited by regulatory requirements and cautious policymaking. The current legal framework does not distinguish between Genetically Modified Organism (GMO) and gene-edited crops, contributing to slow progress.

c) EXPORTS

Malaysia does not export GE crops.

d) IMPORTS

Malaysia depends on GE-derived feed ingredients such as corn, soybeans, soybean meal, corn gluten feed, and distillers' dried grains with solubles (DDGS). The United States, Canada, Brazil, and Argentina remain major suppliers. Approval procedures, documentation, and compliance with biosafety rules are essential for maintaining stable feed supplies.

Table 1. Malaysia's Import Volume (Tons) of Corn, Soybeans and Soybean Meal (CY 2022-2024)

Commodity	2022	2023	2024
Corn	3,484,888	3,595,865	4,029,423
Soybean	722,447	640,741	7,037,773
Soybean Meal	1,331,670	1,287,232	1,387,170

Source: Trade data Monitor

Industry stakeholders monitor halal compliance, sustainability certifications, and traceability requirements that influence procurement decisions. Global market conditions, particularly commodity prices and currency exchange rates also affect sourcing patterns.

e) FOOD AID

Malaysia does not provide or receive food aid.

f) TRADE BARRIERS

Import permits require intellectual property owners to take responsibility for accidental spillage and mandate secure, closed transport of GE consignments.

PART B: POLICY

a) REGULATORY FRAMEWORK

Malaysia's biosafety system is anchored in the Biosafety Act 2007 (Act 678) and the Biosafety (Approval and Notification) Regulations 2010 administered by the Department of Biosafety (DOB) under the Ministry of Natural Resources, Environment and Sustainability (NRES).[1] Several political and policy considerations shape Malaysia's approach to regulating GE plant products. Food security remains a dominant factor, especially after recent supply disruptions and Malaysia's reliance on imported feed grains. These pressures have encouraged ministries including the Ministry of Agriculture and Food Security (MAFS) and NRES, to consider more innovation-friendly regulatory options, including clearer pathways for genome-edited crops.

Malaysia is reviewing elements of its biosafety framework under the National Biotechnology Policy 2.0. This includes early discussions on whether genome-edited products without foreign DNA should be regulated differently from GMOs. The DOB plans to release an Issue Paper on Genome Editing, which may guide future updates although no amendments have been formally proposed in Parliament as of 2025.

Decisions on GE products are made by the National Biosafety Board (NBB), an inter-ministerial body that draws representations from key ministries, scientific agencies, and regulatory authorities.

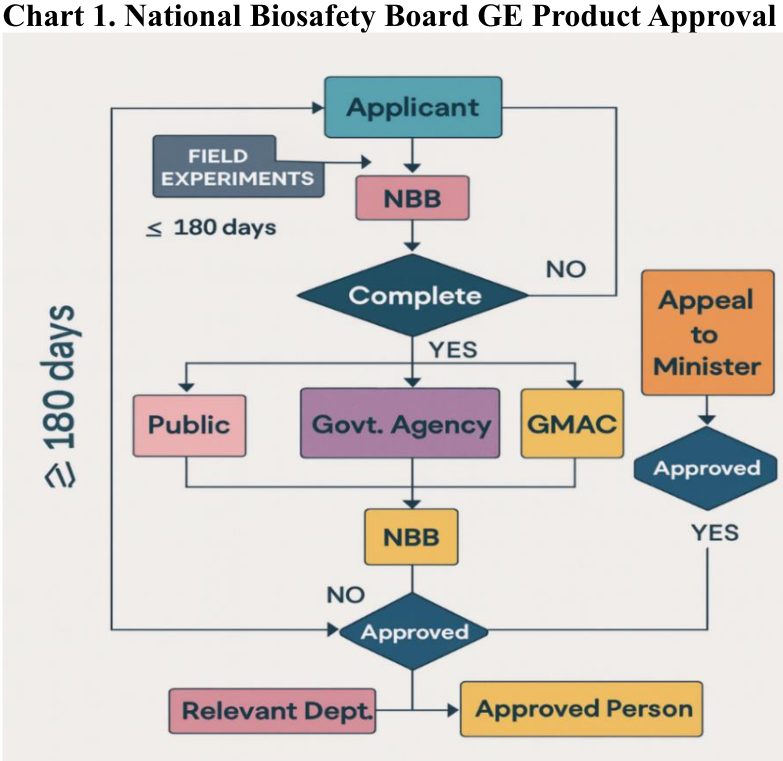
[1] Regulations related to Biosafety in Malaysia

Technical risk assessments are carried out by the Genetic Modification Advisory Committee (GMAC), which reviews dossiers related to environmental safety, food and feed safety, and molecular characterization. GMAC serves as the NBB's technical body which conducts scientific risk assessments covering environmental safety, food and feed safety, and molecular characterization for all GE plant applications. Its recommendations guide the NBB's final decisions. GMAC members include molecular biologists, plant breeders, toxicologists, food scientists, ecologists, regulatory specialists, and external experts for highly specialized evaluations.

The Food Safety and Quality Division (FSQD) under the Ministry of Health is responsible for assessing the food safety aspects of GE plant products. FSQD reviews data on composition, allergenicity, toxicity, and dietary exposure to determine whether a product is safe for human consumption. The division also manages the biotechnology labeling guidelines and enforces these requirements through routine inspections, import checks, and market surveillance. Research institutions and universities maintain Institutional Biosafety Committees (IBCs), which review proposals involving modern biotechnology, ensure containment measures are in place, and verify adherence to national biosafety standards before they are escalated to national regulators.

Although the regulatory framework specifies an approval timeline of 180 days, reviews often extend to a year or longer due to multi-agency consultations and workload constraints. In 2025, the DOB launched BioReg 2.0, a digital submission and tracking system intended to improve dossier management, transparency, and communication with applicants.2.0, a digital submission and tracking system intended to improve dossier management, transparency, and communication with applicants.

Chart 1. National Biosafety Board GE Product Approval Process



Source: Department of Biosafety, Ministry of Natural Resources and Environment Sustainability

Policy discussions on a separate regulatory pathway for gene-edited crops gained momentum in 2025, reflecting regional developments in the Philippines and Indonesia and Malaysia's growing interest in a risk-proportionate regulatory model. This was demonstrated through several formal actions by the Department of Biosafety and the National Biosafety Board. In November 2025, the GMAC Subcommittee on Exemptions (JKG-Pengecualian) convened a dedicated meeting to review exemption criteria, workflow processes, and documentation requirements for genome-editing activities. The session included participation from multiple government agencies, universities, and industry representatives, highlighting the national importance of the issue.

Legal term (in official language)	**Legal Term (in English)**	**Laws and Regulations where term is used**	**Legal Definition (in English)**
Bioteknologi Pertanian	Agricultural Biotechnology	• National Policy on Science, Technology and Innovation (NPSTI) • National Agrofood Policy 2021–2030 (NAP 2.0) • National Biotechnology Policy 2.0 • Related guidelines under Ministry of Agriculture and Food Security (MAFS)	The use of modern biological techniques such as molecular markers, tissue culture, microbial processes, and genomic tools to improve crops, livestock, and agricultural production systems. This includes the application of biotechnology for yield improvement, disease resistance, input efficiency, and sustainability in the agricultural sector.
Kejuruteraan Genetik	Genetic Engineering	• Biosafety Act 2007 (Act 678) • Biosafety (Approval and Notification) Regulations 2010 • Ministry of Health Guidelines on Modern Biotechnology (2013) • Malaysian Standards relating to laboratory containment and molecular work	A set of techniques used to alter the genetic material of an organism through modern biotechnology, including recombinant DNA methods, gene insertion, deletion, or modification in ways that do not occur naturally through mating, reproduction, or natural recombination.
Diubah Suai Secara Genetik or Organisma Diubah Suai Genetik	Genetically Modified or Genetically Modified	• Biosafety Act 2007 (Act 678) • Biosafety (Approval and Notification)	An organism in which genetic material has been changed using modern biotechnology in a way that

(GMO)	Organism (GMO)	Regulations 2010 • Food Regulations 1985 (for certain labeling provisions) • Guidelines on Labelling of Foods and Food Ingredients Produced from Modern Biotechnology (2013)	does not occur naturally through multiplication or natural recombination.
Bioteknologi Inovatif (or sometimes Bioteknologi Baharu)	Innovative biotechnologies	• National Biotechnology Policy 2.0 • National Biosafety Board discussion papers (e.g., Genome Editing Issue Paper) • ASEAN Guidelines on Modern Biotechnology (under development)	New and emerging biotechnology techniques such as genome editing, site-directed nucleases, oligonucleotide-directed mutagenesis, and other precision-breeding methods that enable targeted genetic changes. These technologies may not involve the insertion of foreign DNA and may result in organisms indistinguishable from those produced through conventional breeding.

b) APPROVALS / AUTHORIZATIONS

As of October 2025, Malaysia has 77 approved GE events for import and market release. These approvals cover soybeans, corn, canola, cotton, and sugar beet for food, feed, and processing purposes.[2] No GE crop is approved for cultivation. Event submissions must include molecular characterization, environmental and food safety assessments, detection methods, and reference materials. Reviews follow Codex Alimentarius and Organization for Economic Co-operation and Development (OECD) standards.

c) STACKED OR PYRAMIDED EVENT APPROVALS

Malaysia continues to treat stacked or pyramided events as new applications, even when individual traits have already been approved. GMAC reassesses potential interactions among traits and compiles a fresh risk evaluation before recommending a decision to NBB.

d) FIELD TESTING

[2] List of Approved GE events in Malaysia

Malaysia allows confined field trials (CFTs) under strict conditions set by the Biosafety Act. Field trials require NBB approval supported by an IBC recommendation. Trials are limited in scale and follow containment measures such as isolation distances, controlled access, monitoring protocols, and post-harvest site management.

Application fees range from RM100/USD41.2 for trials under 5 hectares to RM500/USD121.36 for trials above 10 hectares. The 2025 rollout of BioReg 2.0 digitalized applications and monitoring of CFT approvals.[3]

Since the discontinued delayed-ripening papaya project, no new GE field trials have been reported. However, interest is resurfacing as part of the National Biotechnology Policy 2.0, particularly for gene-edited rice and oil palm.

e) INNOVATIVE BIOTECHNOLOGIES

Malaysia currently regulates innovative biotechnologies such as genome editing under the same framework used for transgenic GMOs. Since 2024, however, regulators, researchers, and industry groups have engaged in consultations to explore a differentiated pathway for non-transgenic, gene-edited products.

MPOB and MARDI are already testing gene-edited traits in their research programs, focusing on yield improvements, drought tolerance, and disease resistance. These developments signal a gradual shift toward a tiered, risk-proportionate regulatory approach.

Research institutions such as MPOB and MARDI are actively expanding their work in plant biotechnology beyond conventional breeding. Their programs now include genomic analysis, molecular marker development, trait discovery, tissue culture improvements, and exploratory studies on gene-editing tools aimed at traits like yield enhancement, drought tolerance, and disease resistance. These activities reflect a broader adoption of advanced biotechnology across key Malaysian crop sectors, even though no genome-edited product has yet been submitted for regulatory approval. In parallel, NRES is preparing a draft "Issue Paper on Genome Editing," which is expected to outline potential regulatory principles and trigger future amendments to the current biosafety framework. While no formal decision has been made, policymakers and industry stakeholders generally support a tiered approach that differentiates between edits involving foreign DNA and edits that mimic natural mutations. Malaysia's deliberations are expected to continue through 2025 and may feed into biosafety modernization efforts under National Biotechnology Policy 2.0.

f) COEXISTENCE

Malaysia does not have a coexistence policy because GE crop cultivation is not permitted. Even so, the Department of Agriculture (DOA) and DOB have begun early discussions on coexistence measures in anticipation of future commercial planting of gene-edited crops.

g) LABELING AND TRACEABILITY

[3] Exchange Rate from Bank Negara Malaysia as of Dec 9, 2025

Malaysia continues to use the 2013 Guidelines on Labeling of Foods and Food Ingredients Obtained through Modern Biotechnology as the main reference for GE labeling. Under this guideline, labeling is mandatory when genetically engineered content exceeds three percent of total ingredients.as the main reference for GE labeling. Under this guideline, labelling is mandatory when genetically engineered content exceeds three percent of total ingredients.

Key requirements include:

- Single-ingredient foods must carry the label “Genetically Modified (ingredient name)” in the main display panel.
- Multi-ingredient foods must state “Produced from Genetically Modified (ingredient name)” in the ingredient list and include a front-panel disclosure.
- Highly refined products such as vegetable oils and corn syrup are exempt from labeling.
- Meat, eggs, and dairy from animals fed GE feed do not require labeling.

In 2025, the FSQD began consultations to formalize these guidelines under the Food Regulations 1985, which would make them legally enforceable. Proposed updates include adopting QR-based digital traceability for GE ingredients and aligning labeling templates with Codex Alimentarius. Enforcement is carried out through FSQD inspections supported by DNA testing at the Department of Chemistry.

h) MONITORING AND TESTING

Malaysia conducts routine testing for GE traits, focusing primarily on imported feed ingredients. Testing is carried out by the Department of Chemistry Malaysia, operating under the Ministry of Health (MOH) and the Ministry of Science, Technology and Innovation (MOSTI). Sampling targets high-volume imports, particularly soybean meals, corn grain, DDGS, and canola products, using a risk-based approach at key entry points. Event-specific Polymerase Chain Reaction (PCR) testing remains the standard method, and since 2025, laboratories have expanded the use of digital PCR (dPCR) for greater sensitivity.

Developers are required to submit validated detection methods and reference materials with their regulatory dossiers. If unapproved GE events are detected, consignments are either re-exported or destroyed following NBB verification.

Malaysia’s GE testing network now aligns with ISO 21569 standards, strengthening its position as a reference hub for genetic detection under ASEAN biosafety cooperation initiatives.

i) LOW LEVEL PRESENCE (LLP) POLICY

Malaysia does not currently have a formal LLP policy. The country follows a zero-tolerance approach, meaning any detection of an unapproved event renders a shipment non-compliant.

j) ADDITIONAL REGULATORY REQUIREMENTS

Even after receiving NBB approval, GE-related products must undergo seed registration with the DOA. For imported food and feed, additional permits from Department of Malaysian Quarantine and Inspection Services (MAQIS), MOH, and Department of Veterinary Services (DVS) are required. While these steps do not create technical barriers, they do add administrative burdens for exporters.

The government is working toward establishing a single-window clearance platform projected for rollout in 2026 linking NBB, DOA, MOH, and MAQIS, to reduce delays and streamline approvals for trade partners.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Malaysia's IPR environment is governed by the Patents Act 1983, Trade Marks Act 2019, and the Protection of New Plant Varieties Act 2004. The country complies with WTO TRIPS and participates in ASEAN intellectual property cooperation.

Malaysia is not yet a member of UPOV 1991, but MAFS and the Malaysian Intellectual Property Corporation (MyIPO) are studying the implications of accession. Strengthening plant breeder rights is seen as a key factor in attracting advanced biotechnology investment.

l) CARTAGENA PROTOCOL RATIFICATION

Malaysia ratified the Cartagena Protocol on Biosafety (CPB) in 2003 and implements it through the Biosafety Act. The Department of Biosafety acts as the national focal point and maintains Malaysia's submissions to the Biosafety Clearing House (BCH).

Malaysia participates actively in CPB processes, including the COP-MOP sessions and technical expert groups. During COP-MOP 11 (2024), Malaysia supported balanced approaches on issues related to Digital Sequence Information (DSI) and the classification of gene-edited organisms.
Implementation of CPB obligations mainly affects documentation and transboundary movement of living modified organisms (LMO). These requirements do not restrict trade but reinforce Malaysia's reputation as a compliant and transparent biosafety regulator.

m) INTERNATIONAL TREATIES AND FORUMS

Malaysia participates in a wide range of international and regional biotechnology platforms, including:

- Cartagena Protocol on Biosafety (CPB)
- Convention on Biological Diversity (CBD)
- Codex Alimentarius Commission
- International Plant Protection Convention (IPPC)
- APEC High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB)
- ASEAN Working Group on Biotechnology and Biosafety (AWG-BB)

Through these engagements, Malaysia promotes science-based decision-making, environmental stewardship, and ethical considerations in biotechnology regulation. These positions influence domestic policies and provide transparency for trading partners, including the United States.

n) RELATED ISSUES

None

PART C: MARKETING

a) PUBLIC AND PRIVATE OPINIONS

Malaysia's agricultural and industrial sectors generally view biotechnology positively, especially because the livestock feed industry relies on imported GE soybean meal and corn from the United States, Canada, Brazil, and Argentina. This long-term dependence has made GE feed widely accepted among producers, millers, and integrators.

Consumer attitudes are more mixed and tend to depend on the type of product and its intended use. Feed and fiber applications attract little concern, while consumer-facing foods made from soybean or corn ingredients continue to face some skepticism related to safety, ethics, and perceptions of "naturalness." Acceptance of gene-edited crops is increasing, with many consumers and academics viewing them as modern, non-transgenic tools distinct from conventional GMOs.

Religious considerations remain important. The Department of Islamic Development of Malaysia (JAKIM) and the Halal Development Corporation (HDC) are working to clarify the concept of halal-compliant biotechnology under the Halal Industry Master Plan 2030. Their engagement with industry has helped reduce uncertainty among halal food producers.

Opposition from civil society groups such as the Consumers Association of Penang (CAP), the Muslim Consumers Association of Malaysia (PPIM), and the Third World Network (TWN) continues, though their influence has softened. Government agencies like Department of Biosafety and Ministry of Agriculture and Food Security conduct periodic awareness programs but these remain targeted rather than expansive especially on food security challenges and reducing the impact of anti-GE narratives.

In 2025, the DOB and MAFS launched the PAL Biotech initiative, focused on strengthening public understanding through education campaigns, university cooperation, and targeted engagement with religious and community groups.

b) MARKET ACCEPTANCE AND STUDIES

Market acceptance varies across segments but remains stable overall. Large plantation companies continue monitoring global biotechnology developments and show interest in traits related to disease resistance and climate resilience, even without domestic cultivation approvals.

Importers and feed manufacturers remain dependent on GE ingredients due to cost, availability, and consistency. Their primary concerns relate to approval timelines and regulatory clarity rather than consumer sentiment.

Retailers take a more cautious approach. While they follow the three percent GE labeling threshold, most avoid explicit GMO statements to prevent misinterpretation or controversy. Some premium brands highlight non-GE sourcing for market differentiation, not regulatory requirements.
Despite varying perceptions, public sentiment has not affected trade flows. Malaysia continues to import GE-derived feed ingredients in high volumes, and retailers have not faced disruptions for products containing approved GE components.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

Malaysia does not develop GE or genome-edited livestock, and there are no commercial pipelines for GE animals. Research institutions remain cautious, largely due to regulatory uncertainty, limited funding, and sensitivities surrounding halal compliance. Malaysia's earliest work in animal biotechnology involved a 2010 confined field release of genetically engineered *Aedes aegypti* mosquitoes designed to reduce dengue transmission. Due to funding constraints and community concerns, the project was discontinued. More recently, Malaysia has adopted a different biotechnology approach using Wolbachia-infected Aedes mosquitoes which are not genetically engineered. These mosquitoes are deployed as a public-health tool to suppress dengue transmission and do not involve genetic modification, but they reflect continued interest in biological and biotechnology-supported vector-control methods.

Besides that, currently, one of the few active areas involving biotechnology is wildlife conservation, particularly efforts to protect the critically endangered Malayan Tiger. The National Wildlife Rescue Centre (NWRC), working with Malaysian Palm Oil Green Conservation Foundation (MPOGCF) and Sunway University, uses genomics and immunogenetics assessments to study genetic diversity and identify suitable breeding pairs. These projects rely on DNA sequencing, molecular profiling, and marker-based genetic screening to maintain a healthy captive population and reduce the risk of inbreeding. Conservation teams also apply assisted reproductive technologies when natural mating is not feasible. While these methods do not involve genetic engineering, they demonstrate Malaysia's growing use of advanced biotechnology tools in animal management.

In 2025, Malaysian universities continue to conduct small-scale academic studies on animal genetics, focusing on conventional breeding, disease tolerance markers, and reproductive performance. These activities remain fully within existing biosafety guidelines and do not involve in GE or genome-edited animals.

Overall, Malaysia's animal biotechnology landscape remains exploratory. There are no GE animals, genome-edited livestock, or clones in development, and no indications of near-term commercialization.

b) COMMERCIAL PRODUCTION

Malaysia does not commercially produce genetically engineered animals, genome-edited livestock, cloned animals, or any products derived from such technologies.

c) EXPORTS

Malaysia does not export genetically engineered animals, genome-edited livestock, cloned animals, livestock clones or any products derived from biotechnology.

d) IMPORTS

Malaysia does not import genetically engineered animals, genome-edited livestock, cloned animals, livestock clones, or products derived from these animals.

e) TRADE BARRIERS

Malaysia has no formal trade barriers specific to animal biotechnology as the country does not authorize the development, import or use of GE or cloned animals. However, several factors function as ***de facto barriers*** and could affect future trade.

The most significant influence is Malaysia's halal framework. JAKIM requires clear lineage, traceability, and assurance that no prohibited materials were used. Without halal certification, such products are not commercially viable in Malaysia's domestic market, particularly for poultry, beef, and dairy sectors.

Consumer perception also plays an indirect but important role. Even though GE animals or clones are not present in the market, public views are strongly shaped by halal considerations. Many consumers question if genetic modification is halal and are cautious about the introduction of non-halal elements, such as porcine genes or materials derived from non-halal slaughter.

Malaysia's Biosafety Act and veterinary import guidelines do not contain categories or risk-assessment procedures for biotech animals or cloned livestock. The DOB has not established protocols for evaluating such applications, and DVS has no import pathways for these products.

Taken together, these factors form a strong set of potential trade barriers should biotech animal products emerge in global commerce.

PART E: POLICY

a) REGULATORY FRAMEWORK

Malaysia regulates animal biotechnology under the same legal framework that governs plant biotechnology, principally the Biosafety Act 2007 (Act 678) and the Biosafety (Approval and Notification) Regulations 2010. These laws apply to any LMO, including genetically engineered or genome-edited animals, their offspring, and any activities involving their development, import, contained use, field release, or disposal. The DOB under NRES serves as the national authority responsible for managing approvals and ensuring compliance with biosafety requirements.

Products derived from animal biotechnology intended for human consumption fall under the Food Act 1983 and Food Regulations 1985, administered by FSQD of the MOH. These regulations cover composition, food safety evaluations, and labeling. For products aimed at Muslim consumers, JAKIM regulates halal requirements. This halal dimension is an important political factor and often influences how regulators approach public communication.

There is currently no dedicated legislation addressing cloning or genome-edited animals, and Malaysia has not established a separate regulatory pathway for innovative technologies. Instead, all modern biotechnology techniques like transgenic, cloned, or gene-edited, fall under the same biosafety approval process. Early discussions within NBB and DOB indicate growing interest in modernizing the framework, largely driven by food security considerations and regional developments in the Philippines, Singapore, and Japan. However, no amendments or bills related to animal biotechnology have been tabled in Parliament, and the regulatory system remains unchanged as of 2025.

Malaysia does not require re-registration once an approval is granted, and approvals do not have expiration dates. If an animal biotechnology product were to be commercialized, developers would still need separate permits from DVS and compliance with halal certification requirements where relevant. These overlapping administrative steps could function as non-tariff barriers if not harmonized.

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Organisma Hidup Diubahsuai (OHD)	Living Modified Organism (LMO)	• Biosafety Act 2007 (Act 678) • Biosafety (Approval and Notification) Regulations 2010	Any living organism, including animals, whose genetic material has been altered using modern biotechnology. Applies broadly to GE animals, cloned animals, and genome-edited animals.
Haiwan Terubahsuai secara Bioteknologi	Biotech Animal / Genetically Engineered Animal	• Biosafety Act 2007 • Department of Biosafety Guidelines on Modern Biotechnology • Veterinary import guidelines (DVS)	An animal developed through recombinant DNA, gene insertion, gene deletion, or other biotechnology techniques to express a specific trait not achievable through conventional breeding.
Pengklonan Haiwan	Animal Cloning	• Malaysian Veterinary Guidelines (DVS) • References under	The production of a genetically identical copy of an existing animal using somatic cell nuclear transfer (SCNT) or other cloning

		Biosafety Act (general scope)	technologies. Considered a form of modern biotechnology.
Bioteknologi Haiwan	Animal Biotechnology	• National Biotechnology Policy 2.0 • MAFS strategic policy documents • DVS breeding and genetic improvement guidelines	The application of biological and technological tools including genomics, reproductive technologies, molecular diagnostics, and genetic modification to improve, manage, or reproduce livestock, aquatic species, or wildlife.

b) APPROVALS / AUTHORIZATIONS

Malaysia has no approved animal biotechnology products for commercial use as of 2025. The NBB has not received, evaluated, or authorized any applications involving genetically engineered animals, genome-edited animals, or livestock clones for food, feed, reproduction, or environmental release.

The only recorded case involving an animal biotechnology product was the 2010 controlled release of genetically engineered ***Aedes aegypti*** mosquitoes, which were developed to reduce dengue transmission. This was a research-based, confined field trial and not a commercial product. The project ended after the initial phase due to funding constraints. No further applications have been submitted since then. In contrast, Malaysia's current dengue-control program has used *Wolbachia* infected mosquitoes, which are not genetically engineered and therefore do not fall under NBB's approval framework for GE organisms. This 2025 deployment represents a public health biological intervention rather than a regulated GE activity. As for that, there are no new GE-related applications for animals that have been submitted since the 2010 trial.

c) INNOVATIVE BIOTECHNOLOGIES

Malaysia has not established a dedicated regulatory framework for innovative biotechnologies involving animals.

Techniques such as genome editing, somatic cell nuclear transfer (cloning), or other precision-breeding tools are still governed under the same Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010. In theory, this means any animal produced through modern biotechnology whether transgenic or non-transgenic and would be reviewed under the same regulatory pathway currently applied to genetically engineered organisms.

There are no official consultations, draft papers or policy proposals that outline separate treatment for genome-edited animals. While Malaysia monitors international developments, there has been no indication of regulatory reform in this area as of 2025.

d) LABELING AND TRACEABILITY

Malaysia does not have any specific labeling or traceability requirements for livestock clones, genome-edited animals, or products derived from animal biotechnology. Since there is no genetically engineered or cloned animals that are approved for commercial use, the current system has not been expanded to include these categories.

In principle, animal biotechnology products would fall under the same labeling provisions that apply to genetically engineered food under the 2013 "Guidelines on Labelling of Foods and Food Ingredients Obtained Through Modern Biotechnology." These guidelines only cover packaged food containing more than three percent GE-derived content. They do not explicitly address meat, milk, eggs, or genetic materials (such as semen or embryos) originating from biotech animals.

As of 2025, there are no active proposals to introduce labeling or traceability rules specific to animal biotechnology. Regulators appear to be watching international developments but have not announced any changes.

e) ADDITIONAL REGULATORY REQUIREMENTS

Malaysia does not have explicit regulatory barriers targeting animal biotechnology, clones, or genome-edited animals. However, several indirect regulatory layers may affect potential imports of biotech-derived animal products if such products enter global trade in the future. These include halal compliance requirements, import permit procedures, and the absence of clear risk assessment protocols for biotech animals within DVS and DOB.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

Malaysia does not have legislation specifically addressing intellectual property rights (IPR) for animal biotechnologies. Existing protections fall under general frameworks such as the Patents Act 1983**,** the Copyright Act 1987**,** and the Protection of New Plant Varieties Act 2004. None of these laws directly apply to genetically engineered or genome-edited animals, cloned livestock, or their genetic materials.

Since Malaysia does not develop or commercialize any biotech-derived animals, policymakers have not prioritized IPR mechanisms for this sector. Discussions on biotechnology- related IPR remain focused on plant varieties and pharmaceutical innovations, leaving a regulatory gap for future animal biotechnology products.

g) INTERNATIONAL TREATIES AND FORUMS

Malaysia participates in several international agreements and technical forums related to animal health, food safety, and biotechnology. The country is a member of the World Organization for Animal Health (WOAH/OIE)**,** the Codex Alimentarius Commission**,** the Convention on Biological Diversity (CBD)**,** and the Cartagena Protocol on Biosafety (CPB)**.** These platforms inform Malaysia's approach to biosafety and animal health standards, even though the country does not commercialize animal biotechnology products.

Malaysia regularly sends representatives from DVS, DOB, and MOH to Codex and WOAH committee meetings. Their engagement focuses mainly on food safety, animal welfare, antimicrobial resistance (AMR), and disease surveillance. Malaysia does not actively advocate positions related to animal cloning or GE livestock**,** reflecting its conservative domestic stance and limited research and development activity.

h) RELATED ISSUES

Malaysia has expanded the use of Wolbachia-infected Aedes mosquitoes as part of its national dengue-control program. These mosquitoes are not genetically engineered; instead, they carry the naturally occurring Wolbachia bacterium, which reduces their ability to transmit dengue and other arboviruses. A release of approximately 65,000 male *Wolbachia* mosquitoes was carried out in Putrajaya, where authorities reported a notable reduction in dengue incidence. Although unrelated to agricultural production, this activity reflects Malaysia's broader use of biotechnology-based vector control tools.[4]

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Public attitudes toward animal biotechnology in Malaysia remain cautious, especially when it involves food-producing animals. Most consumers associate cloning, GE animals, or genome-edited livestock with risks to halal integrity, and there is little distinction made between the different technologies.

b) MARKET ACCEPTANCE / STUDIES

Malaysia has no commercial presence of cloned, GE, or genome-edited animals, and there are no market studies on consumer acceptance. Despite the absence of explicit regulatory barriers, industry actors avoid these products because they expect strong consumer resistance, mainly driven by halal concerns. Since these products are also not present in the market, no academic or industry research has been conducted on their acceptance, and there is no indication of near-term demand.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

Malaysia produces a range of food ingredients that rely on microbial biotechnology, mainly through fermentation processes involving bacteria, yeasts, and fungi. These ingredients are used in food manufacturing, beverage processing, nutraceuticals, and enzyme-based industrial applications. Production is carried out by local biotechnology firms, food manufacturers, and several companies operating under Malaysia's Bioeconomy Corporation.

[4] Putrajaya released 65,000 Wolbachia mosquitoes to combat Denggi - Bahasa

Commercial activity focuses on microbial-derived enzymes production (such as amylases, proteases, and lipases), organic acids, bioflavor compounds, fermentation nutrients, and food-processing aids. These products are used in baking, brewing, dairy processing, oil refining, and animal feed formulation. Companies typically use well-established industrial microbes such as *Aspergillus niger*, *Bacillus subtilis*, *Saccharomyces cerevisiae*, and *Trichoderma reesei*, which are standard hosts for enzyme and fermentation-based ingredient production worldwide. These organisms are not genetically modified in most Malaysian applications; they are generally conventional strains selected for stability and high yield. Malaysia also hosts small-scale production of microbial cultures for probiotics and fermented functional foods. These involve lactic acid bacteria such as Lactobacillus and Bifidobacterium, primarily produced for domestic food and nutraceutical markets.

At present, there is no confirmed commercial use of genetically engineered microbes or genome-edited microalgae for food production in Malaysia. Companies rely mostly on traditional fermentation or natural strain improvement rather than transgenesis. Discussions on adopting more advanced microbial technologies are ongoing within research institutions, but products derived from modern biotech methods have not entered commercial manufacturing as of 2025.

b) EXPORTS

Malaysia does not export GE microbes, microbial "seed stock," or modified production strains. However, the country does export a wide range of processed foods, dairy products, bakery goods, confectionery, beverages, and nutraceutical items that may contain microbial-derived food ingredients such as enzymes (e.g., protease, amylase, lactase), fermentation-based flavor enhancers, organic acids, or probiotics.

These microbial-derived ingredients are typically sourced from internationally recognized suppliers and are widely used in global food manufacturing. Malaysia does not require exporters to declare whether a product contains microbial biotech-derived processing aids, and export documentation does not distinguish between conventional and fermentation-derived ingredients.
Some Malaysian-exported food categories including dairy powders, bakery mixes, confectionery ingredients, and functional beverages are eligible for export to the United States. However, Malaysia does not export purified microbial-derived ingredients such as enzymes, sweeteners, or organic acids to the United States as standalone products.
There are no official statistics or estimates on the export volume of microbial-biotech-derived ingredients from Malaysia. Available trade data classifies exports by final product category rather than by the specific use of microbial-derived components.

c) IMPORTS

Malaysia imports a wide range of food ingredients and processed products that use microbial biotechnology, although the country does not publish statistics that isolate these items. Enzymes and fermentation-derived ingredients are commonly used in dairy processing, bakery manufacturing, beverage production, and nutritional supplement formulation. These include microbial-derived proteases, amylases, lipases, lactase, rennet substitutes, flavor enhancers, organic acids, and probiotics, most of which are sourced from major global suppliers in the United States, Europe, China, and Japan.

In addition to standalone ingredients, Malaysia also imports alcoholic beverages, dairy products, baking mixes, confectionery items, and processed foods that may contain microbial biotech-derived components as part of their manufacturing process.

No government agency reports the volume or value of microbial biotech-derived imports, but industry sources note that the use of fermentation-based enzymes and processing aids continues to grow due to expanding food and beverage manufacturing needs. These ingredients are widely accepted and treated as standard inputs within Malaysia's food industry, and there are no specific restrictions that target microbial-derived food components.

d) TRADE BARRIERS

Malaysia does not impose biotechnology-specific restrictions on microbial-derived food ingredients, and there are no formal trade barriers that target products produced using fermentation, enzymes, or microbial processing aids.

Proper documentation and product classification can be considered as one of the trade barriers. Malaysia's Food Regulations 1985 require clear ingredient disclosure for imported food products, but the regulations do not distinguish between conventional and biotech-derived microbial ingredients. As a result, importers sometimes face additional queries from FSQD when products contain enzymes or fermentation-derived additives that are unfamiliar to inspectors or not commonly used in domestic manufacturing.

JAKIM requires verification of microbial-derived inputs when these ingredients are used in products seeking halal certification, particularly in food, beverage, or animal-based applications. In such cases, the production microbe, growth media, and all processing materials must comply with halal requirements.

PART H: POLICY

a) REGULATORY FRAMEWORK

Malaysia regulates microbial biotechnology under the same biosafety system that governs genetically engineered plants and animals. The overarching legal instruments are the Biosafety Act 2007 (Act 678) and the Biosafety (Approval and Notification) Regulations 2010, administered by DOB under NRES. These laws apply to any microorganism modified through modern biotechnology, including bacteria, yeasts, fungi, and microalgae.

For food applications, microbial-derived ingredients fall under the Food Act 1983 and the Food Regulations 1985, enforced by the FSQD of MOH. These regulations govern safety assessment, permissible use, purity standards, and ingredient labeling requirements for enzymes, cultures, amino acids, vitamins, organic acids, and other fermentation-derived components.

Imports of microbial biotech-derived ingredients require clearance from MAQIS and may undergo inspection or laboratory analysis by the Department of Chemistry Malaysia to verify compliance with food safety requirements. Products intended for halal markets must also meet traceability standards established by JAKIM, particularly regarding the microbial strain, fermentation substrate, and processing aids used.

Malaysia has no separate legislation specific to genome-edited microbes, and no distinction is made between transgenic and non-transgenic microbial biotechnology. Any microorganism altered through techniques that meet the Biosafety Act's definition of "modern biotechnology" is regulated as an LMO. Highly purified enzymes and processing aids are generally not regulated as LMOs but remain subject to food safety rules.

b) APPROVALS / AUTHORIZATIONS

Malaysia does not maintain a public database listing each microbial biotech-derived ingredient approved for use. Instead, approvals for enzymes, cultures, and fermentation-derived ingredients fall under the Food Act 1983 and the Food Regulations 1985, which are administered by FSQD. These regulations determine whether an ingredient is permitted in food processing, and they apply regardless of whether the ingredient is produced through conventional fermentation or through modern biotechnology.

Although Malaysia does not publish a list of "approved GM microbes," industry practice and import patterns indicate that the following categories of microbial-derived ingredients are widely accepted and used:

Table 2. Common Microbial Biotech-Derived Ingredients Used in Malaysia

Ingredient Type	Typical Uses	Production Microbe (Common Examples)	Biotech Status
Proteases / Lipases / Amylases	Dairy processing, baking, brewing	*Aspergillus niger*, *Bacillus subtilis*, *Trichoderma reesei*	Often produced using GM strains, allowed if purified and safe
Yeast extracts & flavor enhancers	Savory flavors, snacks, beverages	*Saccharomyces cerevisiae*	Non-GM and GM-derived strains used globally
Lactase	Dairy, lactose-free milk	*Kluyveromyces lactis*	Sometimes GM-derived
Citric acid & organic acids	Beverages, confectionery	*Aspergillus niger*	Typically produced using optimized industrial strains
Vitamins (e.g., B2, B12)	Supplements, fortified foods	*Ashbya gossypii*, *Propionibacterium* spp.	Produced using engineered or enhanced strains

c) LABELING AND TRACEABILITY

Malaysia does not have specific labeling or traceability rules that apply only to microbial biotech-derived food ingredients. Instead, these products fall under the same framework used for other processed food ingredients, as outlined in the Food Regulations 1985 and the 2013 Guidelines on Labeling of Foods and Food Ingredients Obtained Through Modern Biotechnology.

Because microbial-derived enzymes, cultures, and processing aids are highly purified and typically do not contain viable microorganisms or detectable DNA, they are not subject to the GE labeling threshold of three percent. The labeling requirement applies only when genetically engineered material is present in the final food product, which is not the case for most microbial-derived additives such as enzymes, organic acids, or vitamins.

Malaysia does not require traceability documentation that distinguishes between conventional fermentation products and those produced using genetically modified microbes. Instead, traceability is handled through general food safety rules, import documentation, and voluntary halal certification processes. For halal-certified products, producers must disclose the microbial strain and fermentation substrate to ensure the ingredient complies with Islamic dietary requirements, but this is separate from biotechnology regulation.

At present, no new policies have been proposed to introduce GE-specific traceability or labeling for microbial-derived food ingredients. Regulators continue to monitor Codex and international discussions but have not signaled any changes for 2025.

d) <u>MONITORING AND TESTING</u>

Malaysia does not routinely test microbial biotech-derived food ingredients for evidence of genetic engineering. Most enzymes and fermentation-derived additives used in food processing are highly purified and do not contain viable microbes or detectable DNA, so they fall outside the scope of standard GE testing protocols.

Monitoring processed food imports is carried out by FSQD and the Department of Chemistry, but testing is targeted primarily at products that may contain genetically engineered plant ingredients, such as soy- or corn-derived components. Testing is conducted on a risk-based basis rather than as a routine requirement for microbial-derived ingredients.

If genetic engineering is detected in an ingredient or processed product that contains an unapproved GE event, the shipment is handled under the Biosafety Act 2007. In practice, this means the consignment may be held for further verification, and if confirmed to contain an unapproved event, it would typically be re-exported or destroyed at the importer’s expense.
To date, Malaysia has not reported any enforcement cases involving microbial biotech-derived food ingredients, reflecting both the regulatory focus on GE plant events and the nature of microbial products, which generally do not carry detectable recombinant DNA.

e) <u>ADDITIONAL REGULATORY REQUIREMENTS:</u>

No supplementary regulations apply to microbial biotech-derived ingredients outside the standard provisions of the Food Regulations 1985 and the Biosafety Act 2007

f) <u>INTELLECTUAL PROPERTY RIGHTS (IPR):</u>

No dedicated laws currently in place to address intellectual property protection for microbial biotechnology products in Malaysia

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