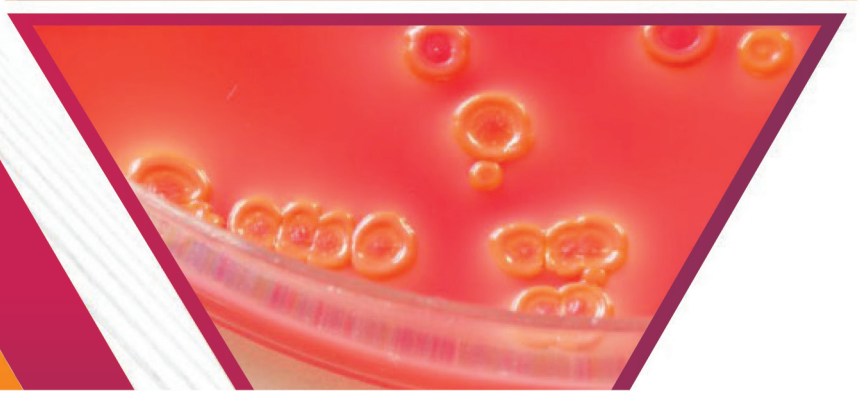
KEMENTERIAN SAINS,
TEKNOLOGI DAN INOVASI
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION

NATIONAL BIOTECHNOLOGY ETHICS GUIDELINES IN MALAYSIA



MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION

**KEMENTERIAN SAINS,
TEKNOLOGI DAN INOVASI**
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION

NATIONAL BIOTECHNOLOGY ETHICS GUIDELINES IN MALAYSIA

**STRATEGIC TECHNOLOGY AND S&T APPLICATION DIVISION
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION
(MOSTI)**

NATIONAL BIOTECHNOLOGY ETHICS GUIDELINES IN MALAYSIA

MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION

Published by:
Ministry of Science, Technology and Innovation (MOSTI)
Strategic Technology and S&T Applications Division (TSA)
Level 3, Block C4, Complex C
Federal Government Administrative Centre
62662, WP Putrajaya Malaysia
Tel: 603 – 8000 8000
Email: enquiry@mosti.gov.my
URL: http://www.mosti.gov.my

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ACRONYMS

4IR	Fourth Industrial Revolution
AI	Artificial Intelligence
CEC	Clinical Ethics Committee
CEM	Clinical Ethics Malaysia
COMEST	World Commission on the Ethics of Scientific Knowledge and Technology
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
ESG	Environmental, Social and Governance
FOMCA	Federation of Malaysian Consumer Associations
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IIM	Malaysian Institute of Integrity
IRB	Institutional Review Board
IKIM	Institute of Islamic Understanding Malaysia
IoT	Internet of Things
JAKIM	Department of Islamic Development Malaysia
KPKM	Ministry of Agriculture and Food Security
MARDI	Malaysian Agricultural Research and Development Institute
MBC	Melaka Biotechnology Corporation
MBeN	National Bioethics Council
MCCBCHST	Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism
MCRCR	Malaysian Code of Responsible Conduct in Research
MDA	Medical Device Authority
MMA	Malaysian Medical Association
MMC	Malaysian Medical Council
MOOC	Massive Open Online Courses
MOH	Ministry of Health Malaysia
MOSTI	Ministry of Science, Technology and Innovation
MPOB	Malaysian Palm Oil Board
MREC	Medical Research and Ethics Committee
mRNA	messenger RNA

MSMBB	Malaysian Society for Molecular Biology and Biotechnology
NBP	National Biotechnology Policy 2.0
NIBM	National Institutes of Biotechnology Malaysia
NGOs	Non-govermental Organisations
NPRA	National Pharmaceutical Regulatory Agency
NRES	Ministry of Natural Resources and Environmental Sustainability
rDNA	Recombinant DNA
RNAi	RNA interference
SDGs	Sustainable Development Goals
UiTM	Universiti Teknologi MARA
UKM	Universiti Kebangsaan Malaysia
UM	Universiti Malaya
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UPM	Universiti Putra Malaysia
USM	Universiti Sains Malaysia
WHO	World Health Organization

FOREWORD

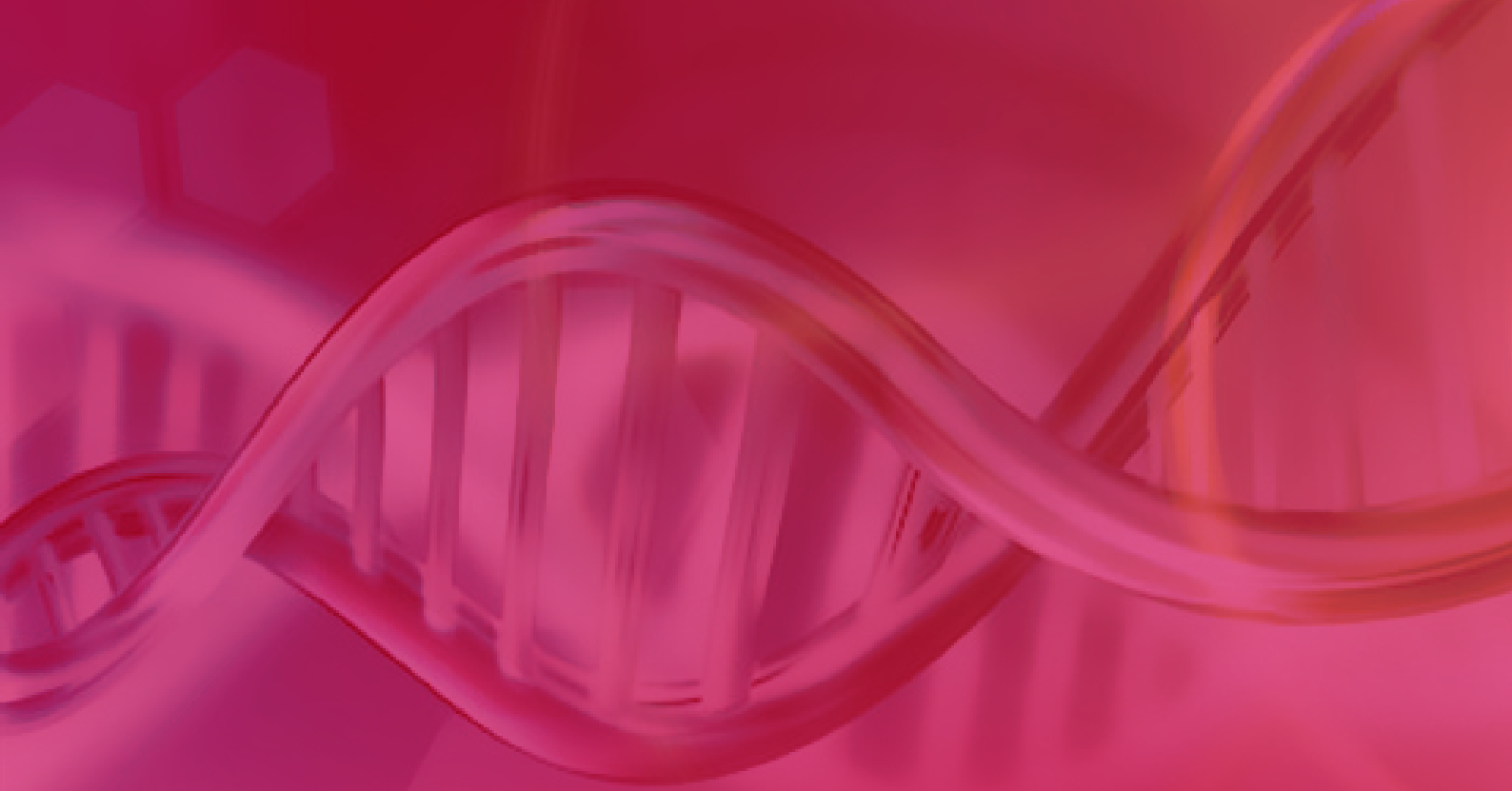
The rapid advancements in biotechnology, including gene editing, cell therapy, synthetic biology, and artificial intelligence, have paved the way for numerous new applications in health, agriculture and industry. However, this wave of innovation also raises complex ethical questions, including issues of genetic data privacy, fairness of access, biosecurity and religious as well as cultural sensitivities. In line with these developments, the nation needs a clear, inclusive and balanced ethical framework that harmonises technological progress with human values.

In line with the aspirations of the National Biotechnology Policy 2.0 (NBP 2.0), the development of the *Biotechnology Ethics Guidelines* in Malaysia represents an important step in strengthening the nation's biotechnology governance ethically and inclusively. These guidelines are designed to guide all parties involved to ensure that biotechnology advancements are carried out responsibly, transparently and with respect for the cultural and religious values of Malaysia's diverse society.

The Ministry of Science, Technology and Innovation, as the secretariat to the National Bioethics Council (MBeN) and the lead agency for NBP 2.0, plays a vital role in ensuring that national practices and policies are developed based on comprehensive ethical principles. As the Chairperson of MBeN, I also believe that these Guidelines can serve as a key reference document to support policy implementation, facilitate informed decision-making and build public trust in the applications of biotechnology.

I would like to express my appreciation to all parties involved in the preparation of these guidelines. It is hoped that this document will continue to serve as a reference in ensuring that the advancement of biotechnology in Malaysia is not only safe and effective but also ethical, fair and founded on human values.

YB TUAN CHANG LIH KANG
Minister of Science, Technology and Innovation



CHAPTER 1
INTRODUCTION

CHAPTER 1
INTRODUCTION

1.1 Introduction

Biotechnology refers to the use of biological systems, living organisms, or their derivatives to produce products or applications that benefit humankind. It is an interdisciplinary field that integrates biology, technology, engineering and computer science across various sectors such as health, agriculture, food, industry and the environment.

Since the 20th century, biotechnology has advanced rapidly and achieved major discoveries that have had significant impacts across various fields, including health, agriculture and industry. The use of techniques such as selective breeding, fermentation, and now advanced technologies like gene editing and cell therapy has brought about remarkable changes in human life and the environment. Biotechnology has contributed to the development of new medicines, improved crop yields and the creation of cleaner and more sustainable industrial processes. Given its potential to address global challenges such as disease, hunger and climate change, biotechnology stands as a promising technology that fosters the well-being of humanity as well as the sustainability of the environment.

The development of modern biotechnology can be divided into several phases, encompassing the discovery and advancement of major biotechnological applications over the past century, as illustrated in **Figure 1.1**.

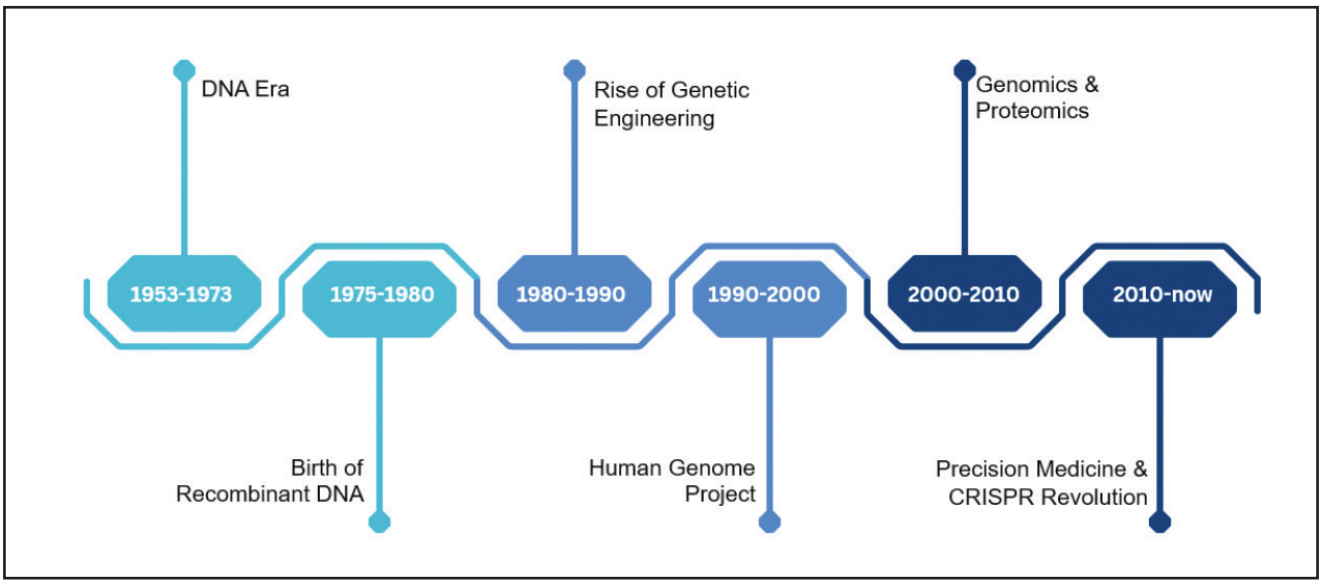


Figure 1.1: Development of Modern Biotechnology

1.2 National Biotechnology Policy 2.0

The Government has consistently demonstrated a strong and continuous commitment to advancing the biotechnology sector as an accelerator of national economic growth and well-being. This commitment was further strengthened through the introduction of the National Biotechnology Policy (NBP) 2005–2020, which served as the strategic framework for the development of biotechnology in Malaysia from 2005 to 2020. The NBP 2005–2020 focused on three main sectors, Agricultural Biotechnology, Healthcare Biotechnology and Industrial Biotechnology, with the goal of building capacity, promoting research and development (R&D), and commercialising biotechnology-based products. This policy also supported ecosystem development through the establishment of agencies such as the Malaysian Biotechnology Corporation (BiotechCorp) and the development of technical infrastructure and other supporting facilities.

As a continuation of these efforts, the government launched the National Biotechnology Policy 2.0 (NBP 2.0) for the period 2022 to 2030. The NBP 2.0 is designed to advance biotechnology in a more strategic and sustainable direction, with an emphasis on positioning Malaysia as a high-technology nation. This policy provides a framework of initiatives and strategies to accelerate investments and the implementation of locally based technologies, thereby aiming to transition Malaysia from being a technology user to a technology creator and exporter.

The NBP 2.0 is also formulated based on the context of more comprehensive national development aspirations, emphasising inclusive growth and sustainable development in line with the Sustainable Development Goals (SDG). Through this policy, the government focuses on strengthening capabilities in molecular biosciences as well as the creation and application of biotechnology that support the country's future needs.

1.3 Rationale

The NBP 2.0 places strong emphasis on strengthening a robust and ethical innovation ecosystem, as well as developing a bio-based industry that contributes to societal well-being and environmental sustainability. Alongside the rapid advancement of biotechnology, various concerns and ethical dilemmas have emerged, which include potential risks to humanity and the environment, the possibility of abuse by irresponsible parties, as well as challenges in defining the boundaries of the use of this technology without stifling progress and innovation.

Apart from technical and safety issues, the use of biotechnology also involves considerations of societal values, cultural norms and religious sensitivities within a diverse community. Without clear guidance, there is a risk of value conflicts among different parties and inconsistencies in the implementation of policies or decisions involving high-impact technologies. Therefore, the development of these ethics guidelines must consider not only universal ethical principles but also local religious and cultural values to ensure public acceptance and the suitability of implementation at the national level.

The need for biotechnology ethics guidelines is also stated under the Strategic Thrust 1: Ecosystem Governance, through Strategy 1.2 in the NBP 2.0, which outlines the importance of enhancing collaboration through the development of information and regulations related to biotechnology. This includes formulating ethics guidelines and reviewing existing regulations concerning the use of biotechnology products and methodologies in identified industries. Therefore, the development of these guidelines represents the implementation of a national policy initiative aimed at strengthening biotechnology governance holistically and contextually.

1.4 Objectives

These guidelines aim to:

a. serve as a guide on ethical practices in biotechnology in accordance with the universal bioethical principles, as well as Malaysia's laws, cultural values and religious beliefs;
b. provide an ethical framework for the research, development, commercialisation and application of biotechnology, particularly in the agricultural, healthcare and industrial sectors in Malaysia; and
c. ensure that the research, development and application of biotechnology are conducted ethically and responsibly.

1.5 Scope and Applications

These guidelines cover ethical considerations in the research, development, commercialisation and application of biotechnology across the three main thrusts outlined in the NBP 2.0, namely:

a. Agricultural Biotechnology & Food Security;
b. Healthcare Biotechnology & Wellness; and
c. Industrial Biotechnology & Circular Economy.

The NBP 2.0 focuses on the application of molecular biosciences and converging technologies, which serve as key accelerators of biotechnological innovation across these three sectors. Therefore, these guidelines also take into account the rapid advancements in molecular biosciences, including cell, genetic and synthetic research, as well as technologies such as Artificial Intelligence (AI) and genetic data, all of which require more comprehensive and up-to-date ethical considerations.

These guidelines are intended for use by various stakeholders within the biotechnology ecosystem, including but not limited to the parties listed in **Figure 1.2**.

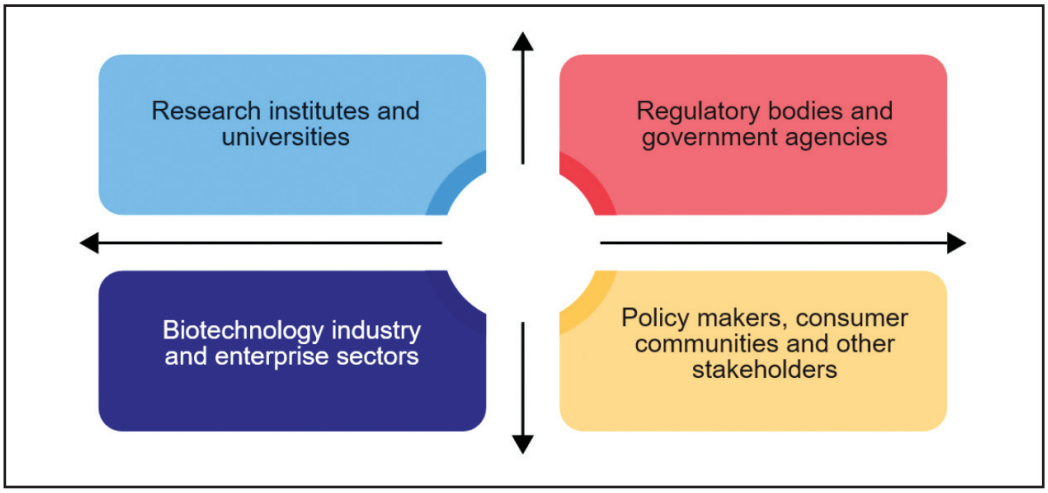


Figure 1.2: Stakeholders in the Biotechnology Ecosystem in Malaysia

Stakeholders may use these guidelines as a reference in formulating internal policies, conducting research and development activities, assessing social and ethical impacts, as well as making decisions that align with national values and principles.

These guidelines are not legally binding and are not intended to replace any existing laws or regulations related to biotechnology in Malaysia. Instead, they are designed to complement and support government policies in the areas of bioethics and biotechnology development.

In line with the universal bioethical principles outlined by international bodies such as the United Nations Educational, Scientific and Cultural Organisation (UNESCO) and the World Health Organisation (WHO), these guidelines also consider the diverse cultural values, religious beliefs and social norms of Malaysian society.

To ensure their relevance in line with current developments, these guidelines will be reviewed periodically in accordance with advancements in science and technology, as well as national policy needs. This approach aims to ensure that the guidelines remain relevant, practical and responsive to the ever-evolving challenges of biotechnology.

1.6 Main Definitions

The key terms used in these guidelines are defined as follows:

a. **Ethics:** Moral principles or values upheld by an individual or a group. It can also be defined as a system of values that determines what is right and wrong, as well as what is appropriate or inappropriate to do.

b. **Bioethics:** An interdisciplinary and multidisciplinary study of ethical issues arising in the life sciences, healthcare, technology, and science and health policies. It examines the ethical, legal and sociocultural implications of issues such as informed consent, artificial intelligence (AI) and genetics in everyday life.

c. **Biotechnology:** Activities or studies that utilise microorganisms, biological systems or biological processes in production and service industries to create products such as antibiotics, vaccines, cheese and others.

d. **Emerging biotechnology:** Refers to areas, techniques or applications of biotechnology that are still in the early stages of development but have high potential to transform or significantly impact health, agriculture, industry and the environment.

e. **Halal:** Defined as something permissible, allowed and lawful to be done, the opposite of *haram* (forbidden). From an Islamic legal perspective, *halal* refers to anything that is permitted and sanctioned under the *Shariah* law.

CHAPTER 2

PRINCIPLES OF BIOTECHNOLOGY ETHICS

CHAPTER 2
PRINCIPLES OF BIOTECHNOLOGY ETHICS

2.1 Introduction

Biotechnology holds the potential to bring various advancements in the fields of health, agriculture, food and industry. However, alongside its vast potential benefits, this technology also raises ethical questions and dilemmas, including issues of justice, safety, data confidentiality and its impact on the environment and society.

In this context, bioethics serves as a multidisciplinary field that guides decision-making processes in the life sciences, including biotechnology, by drawing on principles from various sources such as philosophy, law, religion and the social sciences. Bioethical principles such as respect for autonomy, beneficence, non-maleficence and justice are widely applied to evaluate biotechnology policies, programmes and practices that may pose risks to human health, well-being and the environment.

Apart from assessing the appropriateness of actions, bioethical principles also guide the formulation of policies and laws, evaluate the eligibility of research, resolve value conflicts and enhance public trust in technology. They also serve as a foundation for dialogue among stakeholders and guide researchers and industries towards the development of biotechnology that is responsible, equitable and in line with shared values.

2.2 Issues of Biotechnology Ethics in Malaysia

The principles of biotechnology ethics are formulated in response to the various issues and dilemmas that arise within the field. Therefore, before elaborating further on these ethical principles, it is important to first understand the key ethical issues in the context of biotechnology development and application, particularly emerging biotechnologies in Malaysia. Some of these ethical issues are illustrated in **Figure 2.1**.

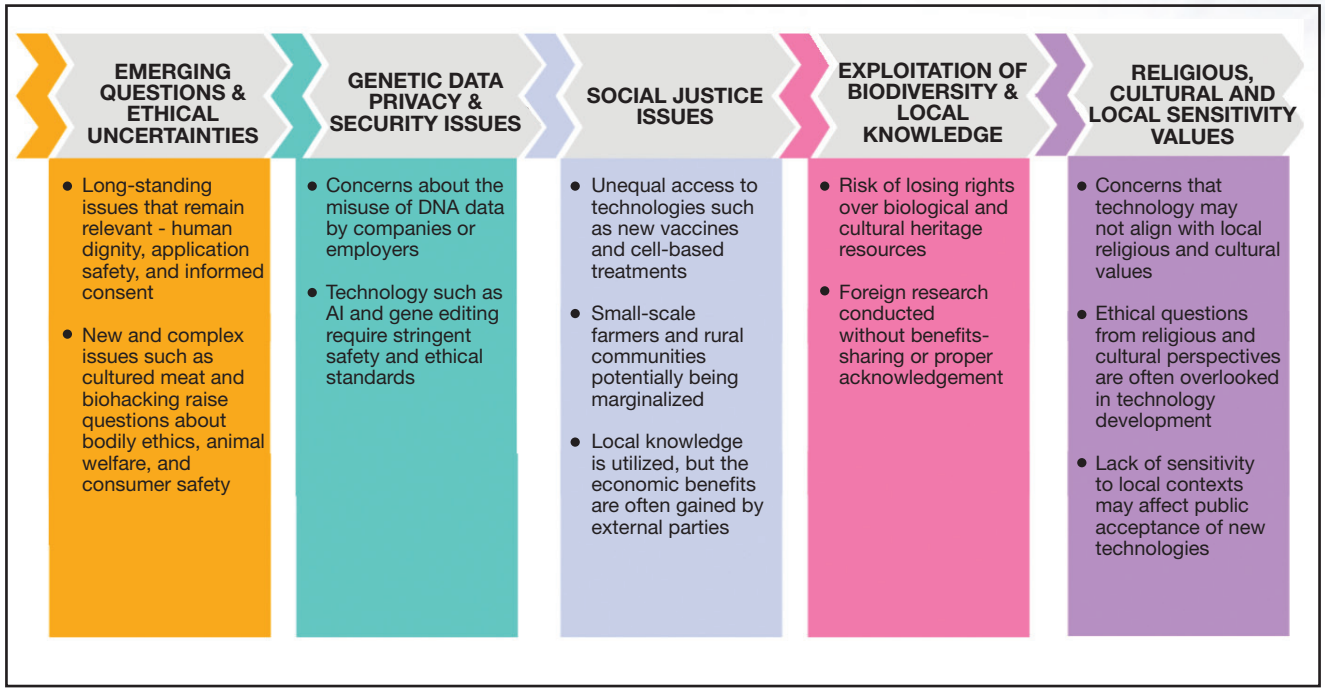


Figure 2.1: Issues in Emerging Biotechnology Ethics in Malaysia

2.3 Principles of Biotechnology Ethics

Table 2.1 outlines the key principles of biotechnology ethics that can guide the ethical conduct of research, development, commercialisation and application of biotechnology in Malaysia.

No.	Principle	Explanation
1.	Respect for Autonomy	The individual's right to make decisions based on clear, complete and fully understood information must be respected.
2.	Respect for Human Dignity and Fundamental Rights	The dignity and fundamental rights of every individual must be respected in all biotechnology research, development, commercialisation and application activities, including ensuring protection from discrimination, exploitation or any treatment that undermines human dignity.
3.	Beneficence	Biotechnology should provide broad benefits to public health, economic growth and environmental sustainability. The technology must contribute to improving the overall quality of life in a holistic and sustainable manner.
4.	Non-Maleficence	The risks arising from the use of technology must be minimised and should not outweigh its benefits. Protection must be provided to individuals, vulnerable groups, as well as the environment and ecosystems from potential harm.

No.	Principle	Explanation
5.	Justice	Justice in access, participation and the distribution of technological benefits must be ensured regardless of gender, age, ethnicity, religion, socioeconomic status or geographical location.
6.	Privacy and Confidentiality	Personal information, biological data and research findings must be protected from unauthorised disclosure or utilisation.
7.	Transparency and Accountability	All processes of research, development and technological implementation must be carried out in an open, transparent and reviewable manner.
8.	Integrity and Responsible Utilisation	Researchers, industry players and policymakers must uphold scientific and social integrity and avoid the abuse of technology for personal gain or unethical purposes.
9.	Respect for Religion, Culture and Local Values	Biotechnology research and development must consider the sensitivity of religious, cultural and local values of Malaysian society to prevent conflicts that may affect public acceptance.
10.	Prevention and Preparedness	Risks to humans, society and the environment must be identified, assessed and addressed proactively from the earliest stages, including through the establishment of monitoring, reporting and policy mechanisms that are prepared to respond to future changes and challenges.
11.	Social Responsibility	The goals of biotechnology development must go beyond commercial profit by ensuring its applications contribute to social well-being and community empowerment.
12.	Benefit Sharing	The benefits arising from the research, development and application of biotechnology must be shared fairly and equitably among stakeholders, including communities and rights holder of genetic resources or related traditional knowledge.
13.	Safeguarding Biosovereignty	The rights of the nation and its people over genetic resources, biological data and traditional knowledge must be fully protected from exploitation, unauthorised appropriation or power imbalances in international collaborations.
14.	Sustainability	The development and application of biotechnology must be carried out in a balanced manner to meet present needs without compromising the ability of ecosystems and natural resources to continue supporting life in the future.
15.	Protection of Future Generations	The long-term impacts of biotechnology development and application on the rights, safety, health and opportunities of future generations must be considered in every decision and action.

Table 2.1: Principles of Biotechnology Ethics

2.4 International Reference Frameworks and Benchmarks

These guidelines are developed based on bioethical principles that are widely recognised at the international level. The primary reference is the Universal Declaration on Bioethics and Human Rights (2005) by the United Nations Educational, Scientific and Cultural Organisation (UNESCO). This declaration outlines 15 fundamental principles related to human dignity, fundamental rights and responsibilities in the life sciences. These principles encompass key aspects such as:

a. Respect for human dignity and human rights;
b. Informed consent and autonomy;
c. Beneficence and non-maleficence;
d. Justice, equity, and solidarity;
e. Social responsibility; and
f. Protection of future generations and biodiversity.

The declaration also emphasises the need to consider cultural contexts and local values in the implementation of bioethical principles. Therefore, it serves as a key reference framework in shaping principles that are not only universal but also relevant to local needs.

In addition to the declaration stated above, other UNESCO publications that serve as important references on biotechnology ethics include the Universal Declaration on the Human Genome and Human Rights (1997) and the International Declaration on Human Genetic Data (2003).

The World Health Organisation (WHO) has also been active in conducting discussions and publishing ethics guidelines in the field of healthcare. Key reference documents include Ethics and Governance of Artificial Intelligence for Health (2021) and the Global Guidance Framework for the Responsible Use of the Life Sciences (2022). These ethical instruments emphasise, among other things, the need for ethical justification, informed consent, protection of vulnerable populations, independent review and scientific validity.

The principles of biotechnology ethics outlined in these guidelines are also supported by the values within the Environmental, Social, and Governance (ESG) framework, which is widely applied in the investment and sustainable development contexts. Elements such as environmental sustainability (Environmental), social justice and well-being (Social), and transparent and accountable governance (Governance) closely align with principles such as beneficence, justice, responsibility and integrity.

Besides that, several countries have published their own bioethics guidelines, which serve as reference instruments and benchmarks in the development of these biotechnology ethics guidelines. Among them are the Tri-Council Policy Statement Ethical Conduct for Research Involving Human (TPCS2) published by Canada in 2022, the General Ethical Guidelines for Biotechnology Research published by South Africa in 2008 and the Victoria Statement of Ethical Principles for Biotechnology published by Australia in 2006.

In addition, ethics guidelines from ASEAN countries such as Indonesia, Thailand, the Philippines and Singapore were also referenced in the preparation of these guidelines. Although the published guidelines primarily focus on human research ethics, their principles are consistent with the broader bioethical framework, particularly in addressing issues such as autonomy, justice and non-maleficence. **Figure 2.2** illustrates the relevant documents on biotechnology ethics and human research ethics in these countries.

Figure 2.2: Guidelines Related to Bioethics in Selected Countries

CHAPTER 3

BIOTECHNOLOGY ETHICS GOVERNANCE IN MALAYSIA

CHAPTER 3
BIOTECHNOLOGY ETHICS GOVERNANCE IN MALAYSIA

3.1 Introduction

Governance of biotechnology ethics refers to the structures, mechanisms and practices that ensure the use and development of biotechnology are aligned with moral values, public interests and applicable regulations. It is not only essential for protecting individual safety and rights but also plays a vital role in maintaining public trust in scientific and technological advancement.

Governance of biotechnology ethics in Malaysia involves various institutions, policies and regulations that play a role in ensuring that biotechnology research, development and application are conducted ethically, responsibly and in alignment with the public interest. In line with the aspirations of the National Biotechnology Policy 2.0, which emphasises responsible innovation and sustainability, an effective governance system is also essential to support the development of the biotechnology sector in the country.

3.2 Structure of Biotechnology Ethics Governance in Malaysia

Governance of biotechnology ethics in Malaysia operates within a multi-layered and decentralised structure involving ministries, government agencies, institutional ethics committees, professional regulatory bodies and legal frameworks. **Figure 3.1** illustrates the structure of bioethics governance in Malaysia and the stakeholders involved.

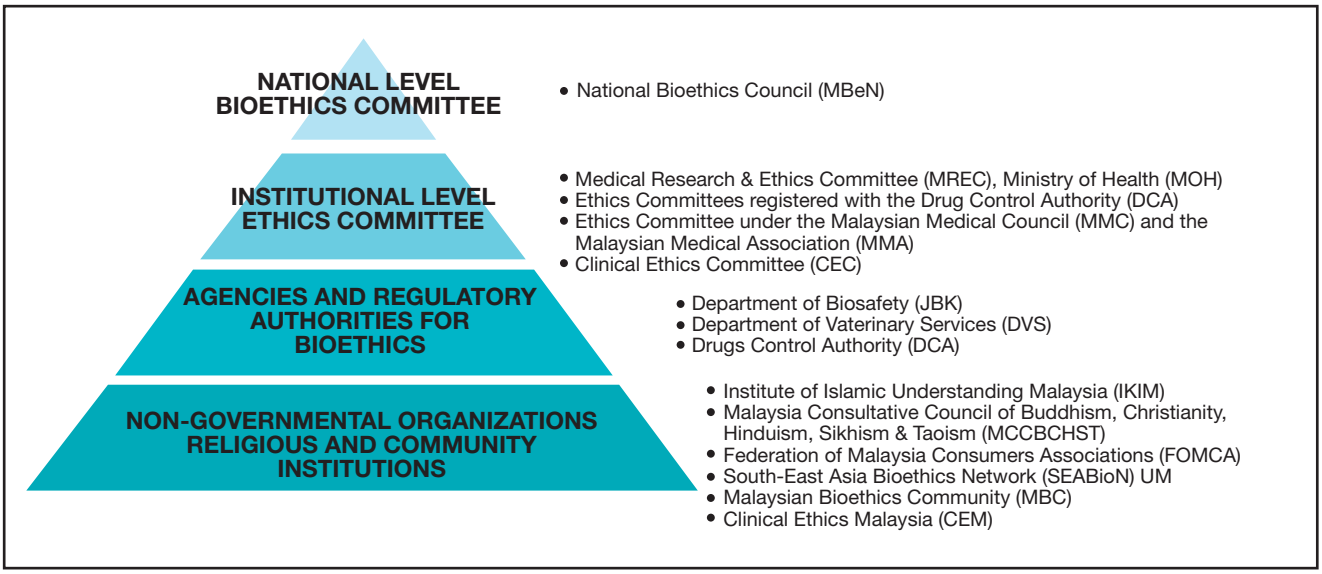


Figure 3.1: Structure of the Biotechnology Ethics Governance in Malaysia

Note: The list of entities under each category of stakeholders serves as examples and is not limited to those listed, except for bioethics committees at the national level.

3.3 Stakeholders in Biotechnology Ethics in Malaysia

In Malaysia, stakeholders in the biotechnology ethics include ministries and government agencies, institutions of higher learning, healthcare providers, industry players, religious and community institutions, professional and regulatory bodies, non-governmental organisations (NGOs) and the general society. **Figure 3.2** illustrates the main categories of stakeholders in biotechnology ethics in Malaysia.

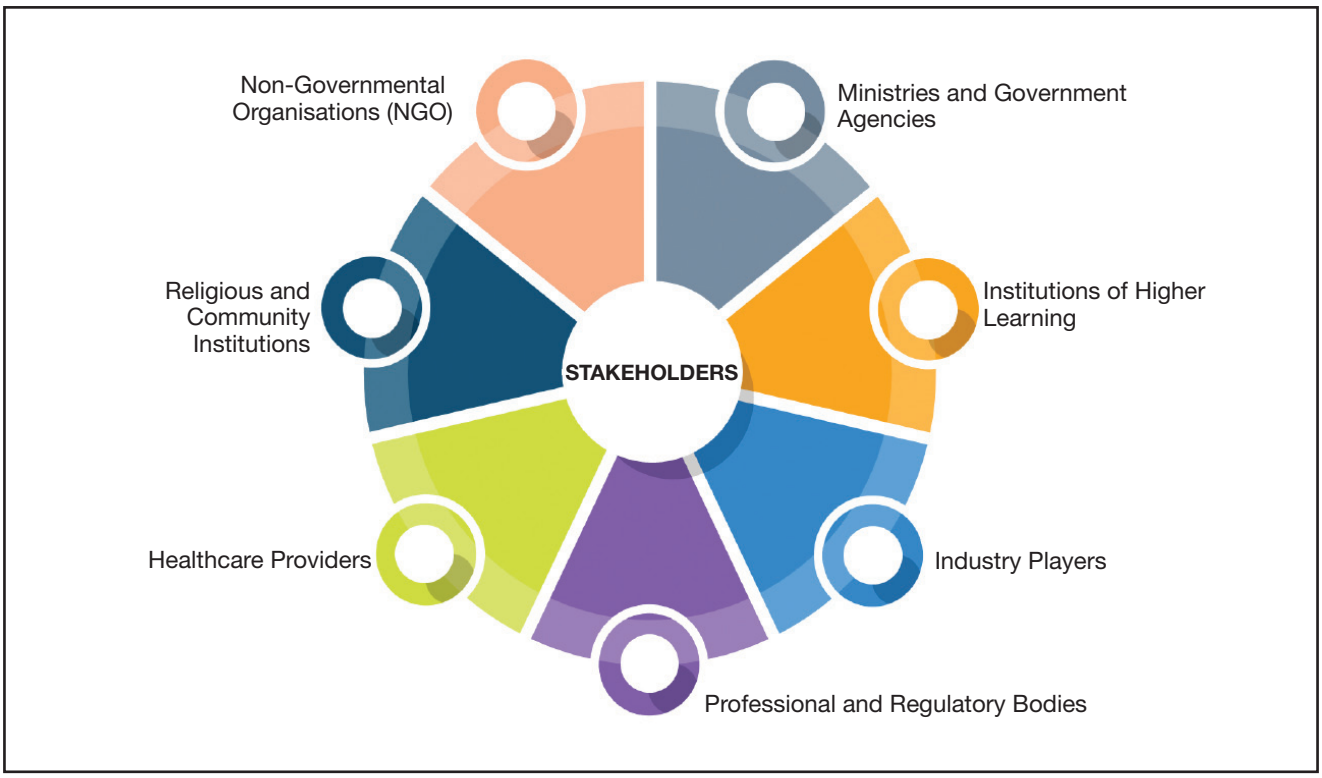


Figure 3.2: Stakeholders in the Biotechnology Ethics in Malaysia

3.4 National Bioethics Council

The National Bioethics Council (MBeN) is an advisory body established by the Government of Malaysia to discuss and formulate policies related to bioethical issues arising from advances in the life sciences, including biotechnology. The MBeN was officially launched in May 2012. The idea for its formation came about on 19 June 2009 during a workshop held in conjunction with the 6th Meeting of the International Commission on the Ethics of Scientific Knowledge and Technology (COMEST), jointly organised by the Ministry of Science, Technology and Innovation (MOSTI) and the Ministry of Women, Family and Community Development (KPWKM). On 9 July 2010, the establishment of the MBeN was approved by the Cabinet and placed under the administration of MOSTI. **Figure 3.3** illustrates the membership composition of the MBeN, while **Figure 3.4** outlines the council's roles and responsibilities.

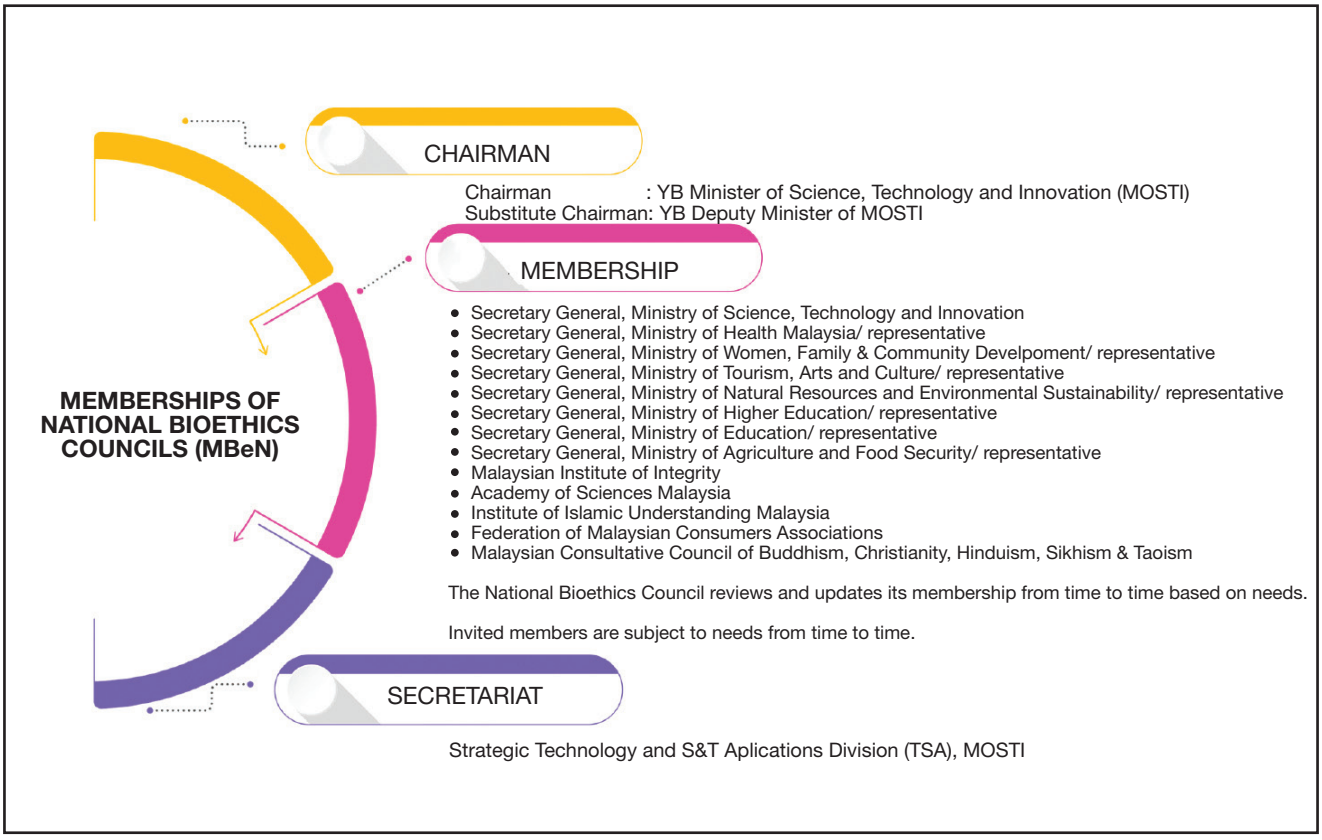


Figure 3.3: Membership of the National Bioethics Council (MBeN)

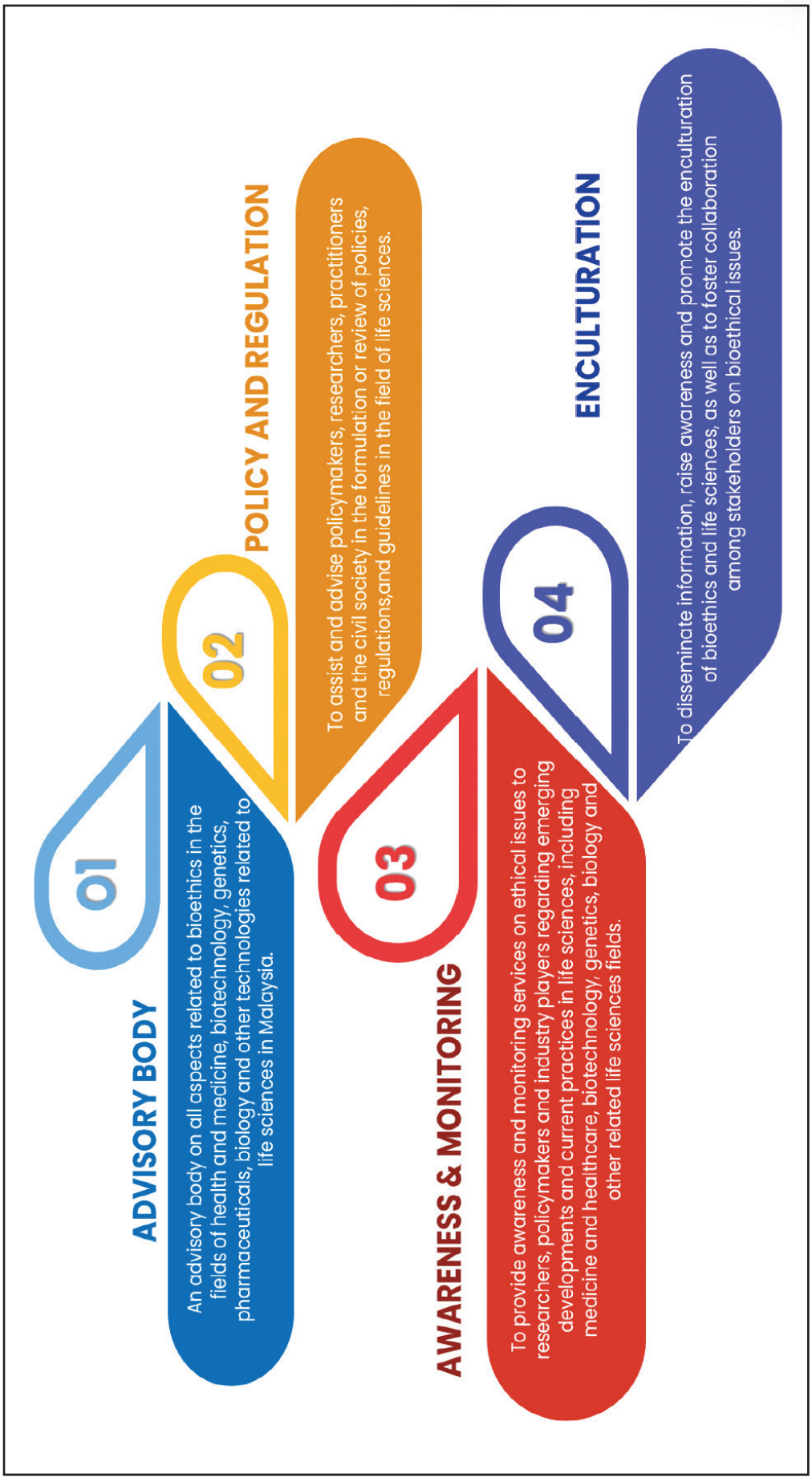


Figure 3.4 Roles and Responsibilities of the National Bioethics Council (MBeN)

3.5 Reference Instruments

Existing reference instruments on biotechnology ethics in Malaysia are generally specific to a particular field and technology. Therefore, these biotechnology ethics guidelines are complementary to existing reference instruments that span various sectors such as agriculture, food, industry and the environment. **Table 3.1** lists several acts and guidelines related to biotechnology ethics in Malaysia.

No.	Acts/Guidelines	Responsible Agencies
1.	Patent Act 1983 [Act 291]	Ministry of Domestic Trade and Cost of Living (KPDN)
2.	Biosafety Act 2007 [Act 678]	Department of Biosafety, Ministry of Natural Resources and Environmental Sustainability (NRES)
3.	Personal Data Protection Act 2010 [Act 709]	Department of Personal Data Protection (JPDP), Ministry of Digital
4.	Animal Welfare Act 2015 [Act 772]	Department of Veterinary Services, Ministry of Agriculture and Food Security (KPKM)
5.	Access to Biological Resources and Benefit-Sharing Act 2017 [Act 795]	Biodiversity Management Division, Ministry of Natural Resources and Environmental Sustainability (NRES)
6.	Malaysian Guideline for Good Clinical Practice (Fourth Edition) (2018)	National Pharmaceutical Regulatory Division, Ministry of Health Malaysia (MOH)
7.	Guidelines on Ethical Issues in the Provision of Medical Genetics Services in Malaysia (2019)	Family Health Development Division (BPKK), Ministry of Health Malaysia (MOH)
8.	The Malaysian Code of Responsible Conduct in Research (2020)	Academy of Sciences Malaysia, Ministry of Science, Technology and Innovation (MOSTI)
9.	Malaysian Code of Practice for The Care and Use of Animals for Scientific Purposes (2020)	Department of Veterinary Services, Ministry of Agriculture and Food Security (KPKM)
10.	NIH Guidelines for Conducting Research in MOH (2021)	National Institutes of Health (NIH), Ministry of Health Malaysia (MOH)
11.	National Assisted Reproductive Technology (ART) Policy (2021)	Family Health Development Division (BPKK), Ministry of Health Malaysia (MOH)
12.	Guidelines for Stem Cell and Cell-Based Research and Therapy (2024)	Clinical Research Centre, Ministry of Health Malaysia (MOH)

Table 3.1: Acts and Guidelines Related to the Biotechnology Ethics in Malaysia

Note: This list includes, but is not limited to, the guidelines mentioned. Other relevant acts, guidelines or documents may also be referred to as necessary.

3.6 Challenges in Biotechnology Ethics Governance in Malaysia

Although the governance structure for biotechnology ethics in Malaysia has been established through various existing policies, institutions and regulations, its implementation continues to face several challenges. Identifying these challenges are crucial to enable phased and systematic improvements, as well as to support the effectiveness of this guideline within the local context. The key challenges identified are illustrated in **Figure 3.5.**

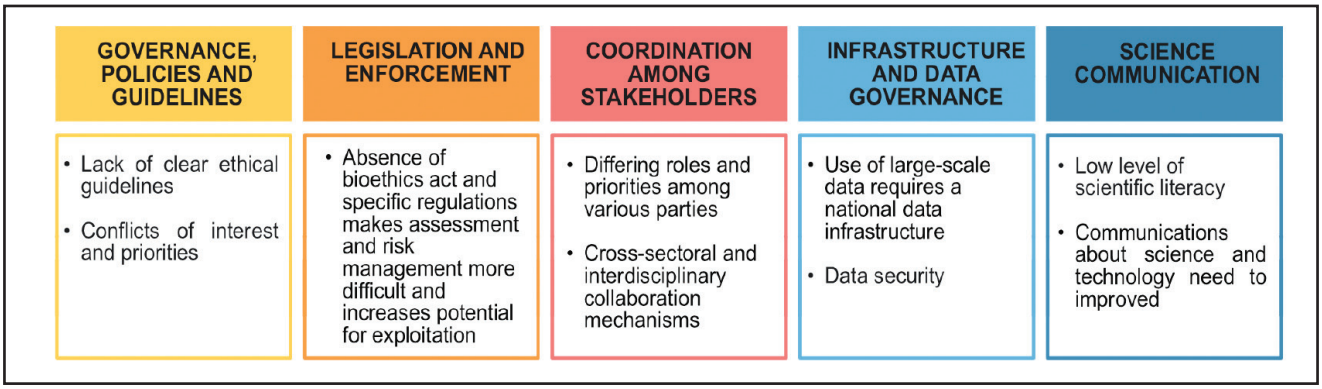


Figure 3.5: Challenges in Biotechnology Ethics Governance in Malaysia

These challenges highlight the need for a more systematic implementation plan and monitoring mechanism, as outlined in the following section. In addition, there is a need for inclusive and responsive governance to address the advancement of emerging biotechnologies such as AI in biotechnology and issues related to genetic data ownership. At the same time, the participation of the general society, religious communities and non-governmental organisations (NGOs) in governance mechanisms can also be strengthened to ensure more comprehensive policy acceptance.

3.7 Governance Structure for Implementation of Guidelines

Figure 3.6 illustrates the governance structure for the implementation of the Biotechnology Ethics Guidelines in Malaysia, designed to ensure effective and continuous execution.

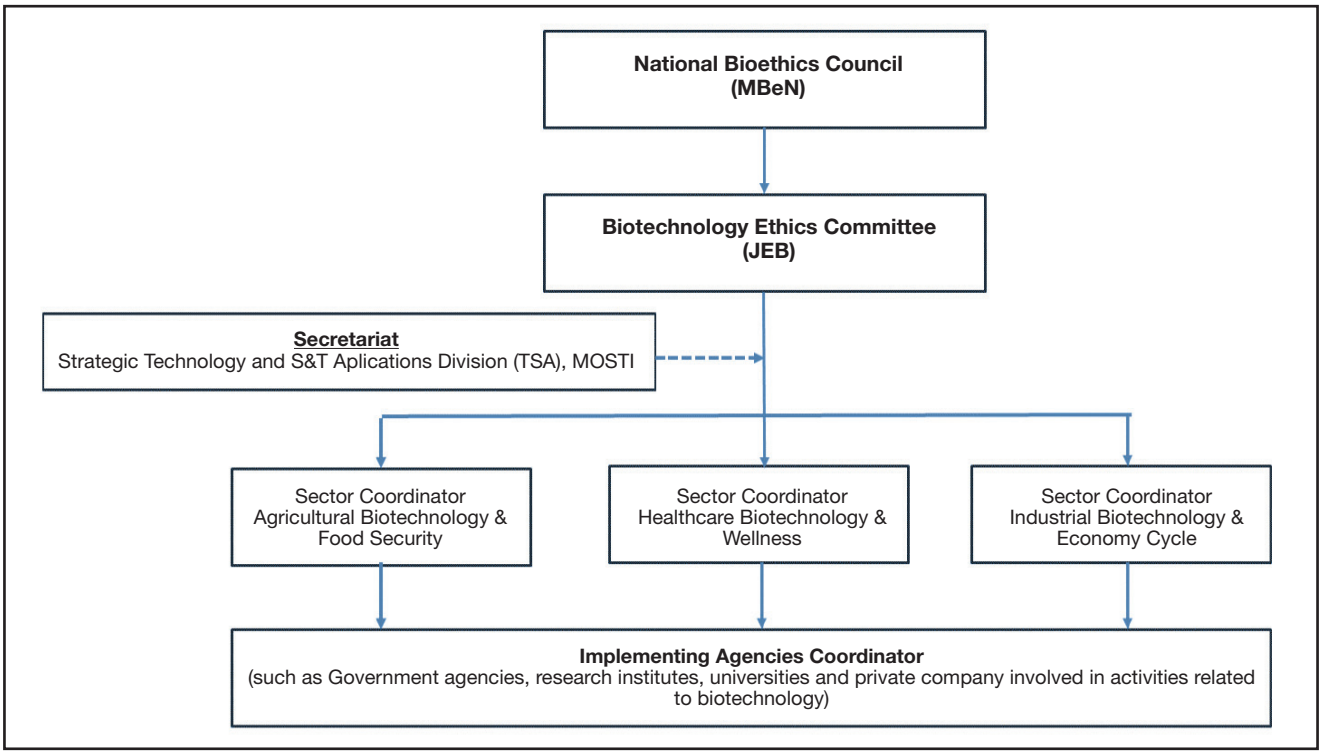


Figure 3.6: Governance Structure for Implementation of the Guidelines

Note: This governance structure is of a recommendatory nature and subject to adjustments in accordance with official mandates, capacities of organisational implementing bodies and decisions of the National Bioethics Council (MBeN).

3.8 Communication and Implementation of Guidelines Plan

Table 3.2 outlines the communication and implementation plan designed to support the strategic and effective execution of this guideline.

Matter	Activities	Responsible Party
Organisation Coordinator	i. Coordinate the establishment or expansion of the mandate of the Institutional Review Board (IRB) to include biotechnology-related issues at the organisational level. ii. Develop internal Standard Operating Procedures (SOPs) for the implementation of biotechnology ethics, including ethical risk assessment, informed consent and benefit-risk analysis, based on the framework provided by the Biotechnology Ethics Committee (JEB). iii. Coordinate the implementation of the guidelines at the organisational level. iv. Submit implementation and best practices reports to the sector coordinator. v. Ensure the integration of ethical compliance clauses in the organisation's procurement, licensing and commercial collaboration processes.	Implementing organisation
Sector Coordinator	i. Coordinate organisational coordinators within their respective sectors. ii. Report on sectoral implementation. iii. Organise sectoral engagement sessions. iv. Serve as the main liaison with the JEB on sectoral implementation issues and challenges.	Core ministry for each biotechnology sector
Cross-Sector Coordinator	i. Conduct regular meetings between the JEB and sector coordinators. ii. Publicise regular communication channels such as directories and official emails. iii. Submit implementation and best practices reports to the National Bioethics Council (MBeN) and relevant parties for review and dissemination of best practices across sectors. iv. Organise cross-sector engagement sessions to address issues and review implementation progress.	JEB
Communication Materials	i. Develop materials such as infographics, quick reference guides and frequently asked questions (FAQs).	JEB
Training and Capacity Building	i. Organise regular workshops and training sessions for stakeholders, including researchers, technology developers, and entrepreneurs. ii. Develop structured training modules, including online courses (Massive Open Online Courses, MOOC) and ethics certification programmes.	JEB

Matter	Activities	Responsible Party
Horizon Scanning	i. Identify emerging technologies and related ethical issues and propose improvements to existing guidelines or practices.	JEB (report submitted to the MBeN)
Ethical Impact Report	i. Prepare ethical impact assessment reports for new, sensitive or high-risk technologies such as the CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats). ii. The reports shall be used to review existing guidelines.	JEB (report submitted to the MBeN)
Digital Support Platform	i. Develop an official digital platform to provide access to the guidelines, communication materials, directories, inquiries and sharing of best practices.	JEB as content and technical coordinator

Table 3.2: Communication and Implementation Plan

Note: This plan may be improved from time to time based on feedback, engagements and evaluations of implementation effectiveness.

3.9 Monitoring and Reporting Mechanisms

Monitoring and reporting on the implementation of the guideline are essential components to ensure the continuous application of ethical principles, identify implementation gaps and support the periodic review as well as improvement of the guideline. This monitoring mechanism involves the roles of various parties from the implementing organisation level, sector coordinators, to the National Bioethics Council (MBeN). Recommended types of reporting include self-audit, voluntary reporting or documentation of good practices that can be adapted according to the organisation's capabilities and context.

Reports endorsed by the National Bioethics Council (MBeN) will be shared with the parties involved in the implementation of the guideline for the purpose of continuous improvement and coordination, as illustrated in **Figure 3.7**.

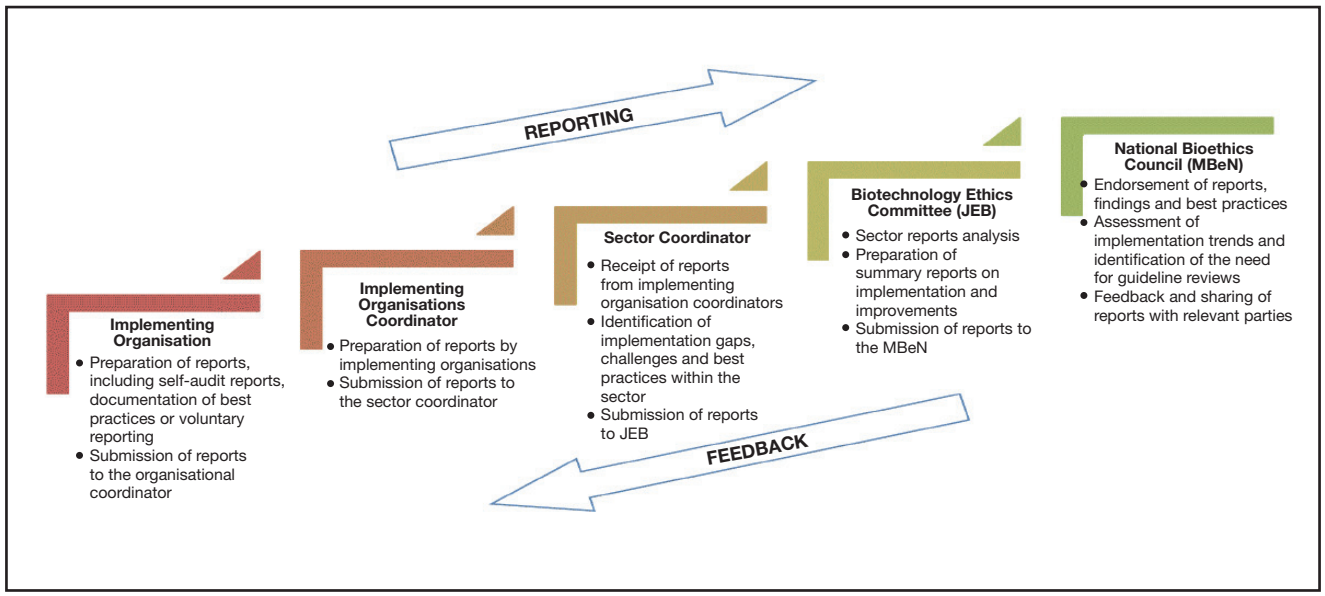


Figure 3.7: Monitoring and Reporting Mechanisms

CHAPTER 4

BIOTECHNOLOGY ETHICS IN AGRICULTURE AND FOOD SECURITY

CHAPTER 4
BIOTECHNOLOGY ETHICS IN AGRICULTURE AND FOOD SECURITY

4.1 Introduction

Biotechnology was first introduced into Malaysia's agricultural sector through research initiatives such as tissue culture and the recovery of local plant species. The Malaysian Agricultural Research and Development Institute (MARDI) was among the earliest institutions to play a crucial role in introducing biotechnology to this sector. Over time, the nation's agricultural sector expanded rapidly with the establishment of research institutions, the formulation of related policies and the adoption of modern technologies. The launch of the National Biotechnology Policy 2.0 (NBP 2.0) further strengthened the government's commitment to enhancing agricultural productivity and quality through biotechnology. Various biotechnological applications have since been developed and implemented in Malaysia's agricultural sector, covering crops, livestock and aquaculture. Some of these applications are illustrated in **Figure 4.1** and **Figure 4.2**.

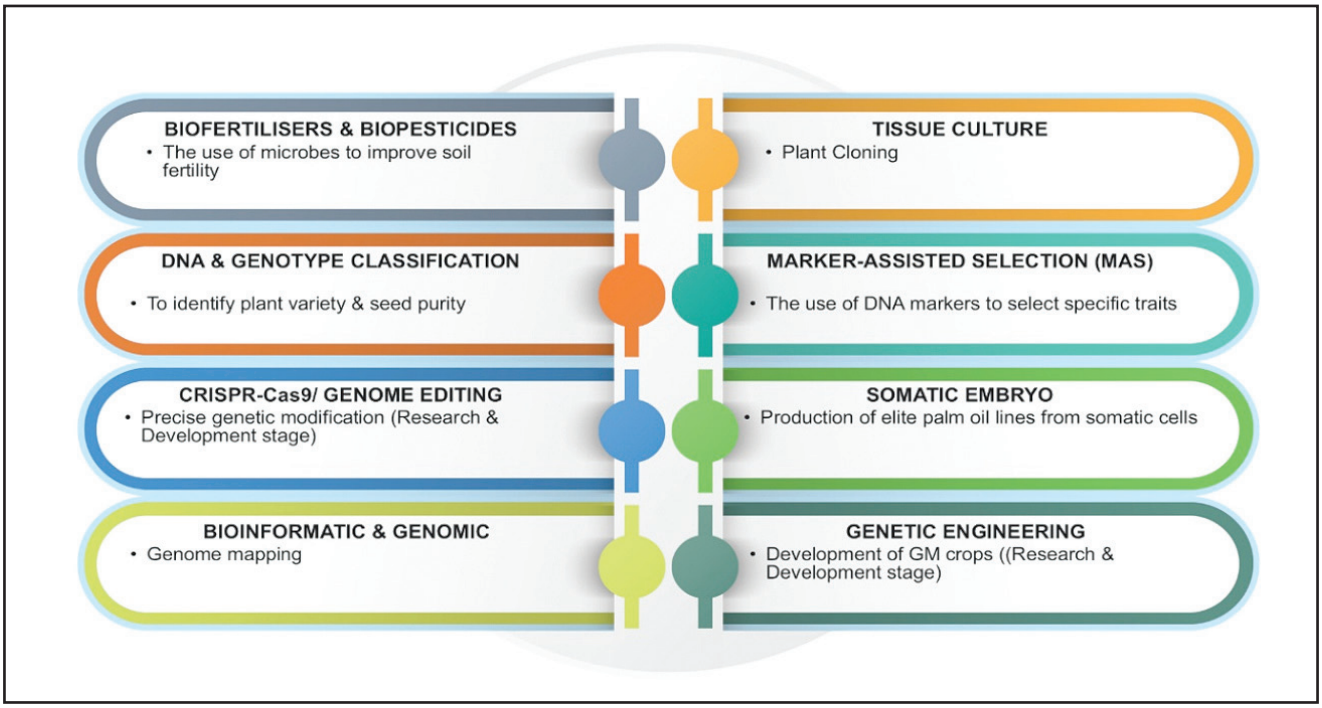


Figure 4.1: Biotechnology in the Crops Sector in Malaysia

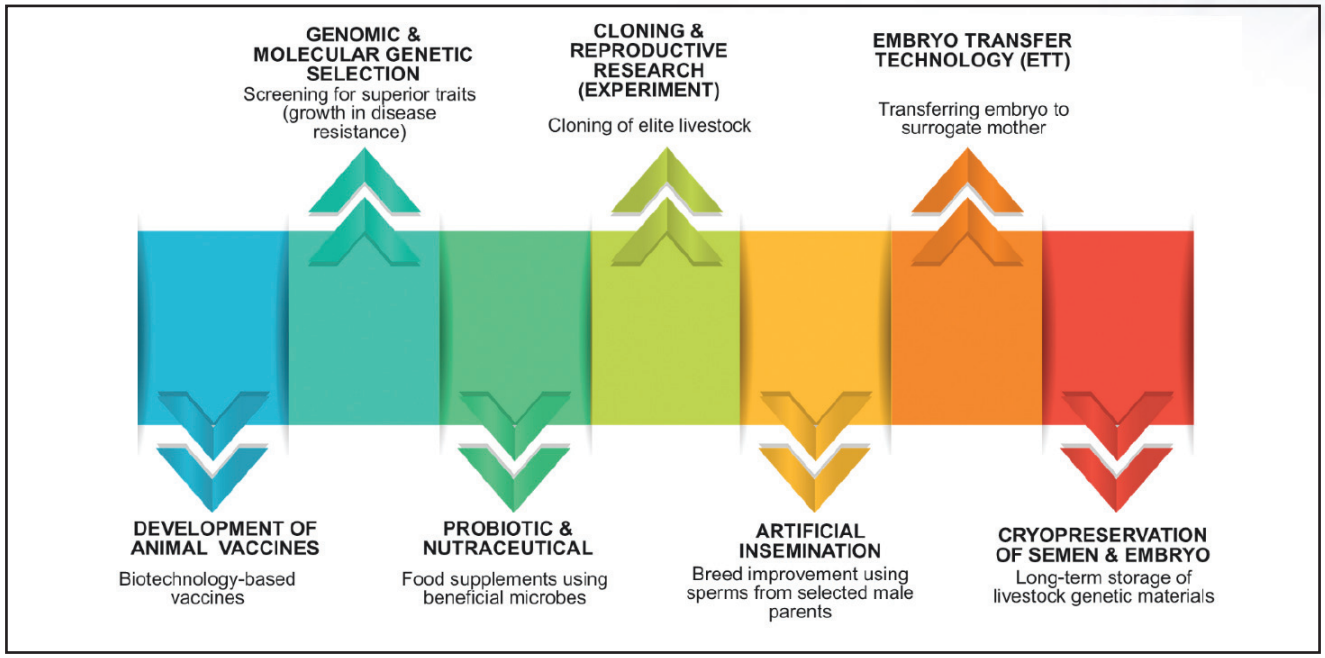


Figure 4.2: Biotechnology in the Livestock Sector in Malaysia

In line with the current technological advancements, biotechnology in the agricultural sector has also evolved through the integration of the Fourth Industrial Revolution (4IR) technologies such as Artificial Intelligence (AI), Big Data Analytics, the Internet of Things (IoT), blockchain and automation together with molecular biotechnology platforms such as gene editing, RNA interference (RNAi) and synthetic biology. The convergence of these technologies enables the implementation of smart agriculture, innovative diagnostics, innovation in biomanufacturing and transparent tracking systems. However, the emergence and application of these technologies also give rise to several ethical issues, as illustrated in **Figure 4.3**.

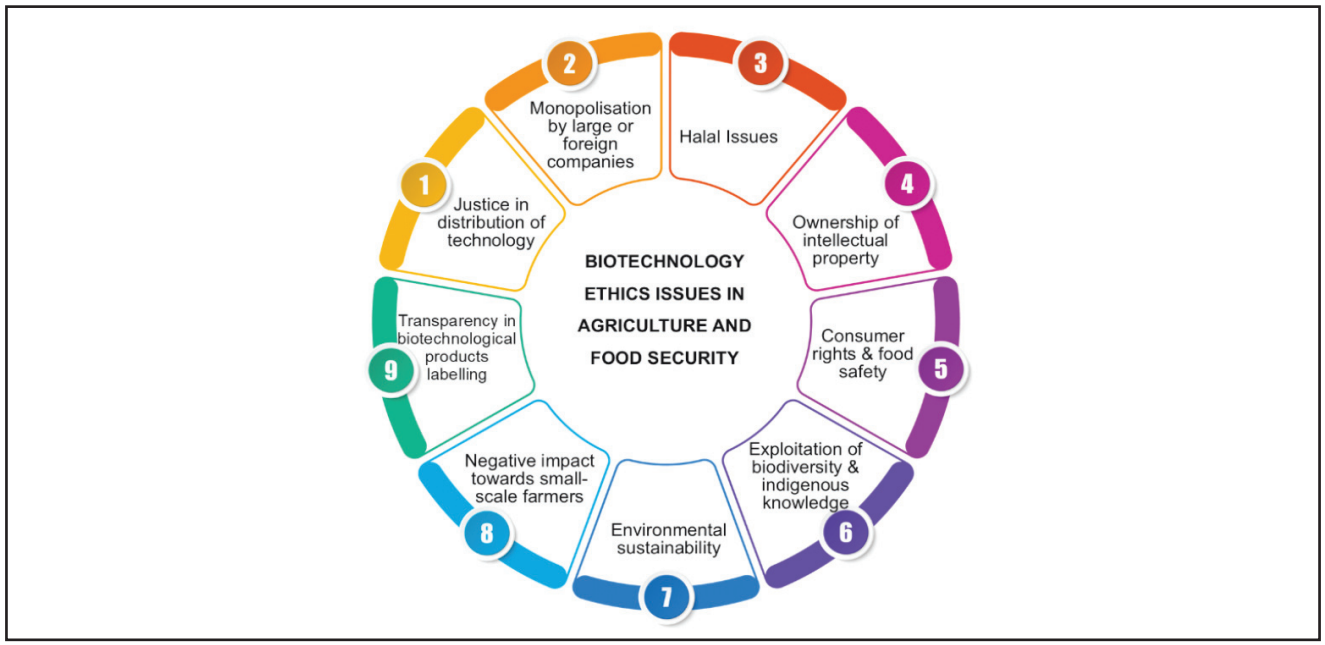


Figure 4.3: Biotechnology Ethics in Agriculture and Food Security Issues

4.2 Definition of Terms

Table 4.1 lists selected terms related to agricultural biotechnology and food security that are used in this chapter.

Term	Definition
Agricultural Biotechnology	The use of biology-based science and technology to modernise crop and livestock production through techniques such as tissue culture and gene editing.
Food Security	A condition in which all individuals have physical, social and economic access to sufficient, safe and nutritious food for an active and healthy life.
Gene Editing	A biotechnological method that enables specific changes to be made to an organism's DNA, such as through the CRISPR technology, to produce desired traits.
RNA interference (RNAi)	A biological process in which the RNA molecules inhibit gene expression, typically by causing the destruction of specific messenger RNA (mRNA) molecules.
Synthetic Biology	An engineering approach in biology that designs and constructs new biological components, systems or organisms that do not exist naturally.
Molecular-Based Breeding	A method of selecting and breeding plants or animals using the DNA markers or genetic information to identify desired genetic traits. This technology accelerates and improves the accuracy of conventional breeding without directly altering the organism's genetic structure.
Cultured Meat	Cultured meat or artificial meat is meat produced using cell culture technology rather than being obtained directly from animals.
Smart Agriculture	A technology-based agricultural approach that utilises sensors, artificial intelligence (AI) and big data analytics to enable more efficient and precise monitoring and management of crops and livestock, thereby supporting and optimising the application of biotechnology in the agricultural sector.
Biosafety	Control measures implemented to prevent or manage exposure and unintentional release of hazardous biological agents, including modified organisms, with the aim of protecting human, animal, plant health, the environment and biodiversity.

Table 4.1: Definition of Terms related to Biotechnology in Agriculture and Food Security

4.3 Scope of Application

The scope of application of this guideline covers research, development, production and commercialisation activities related to biotechnology in the agricultural and food security sectors in Malaysia. The scope includes the use of biotechnologies such as gene editing, RNA interference (RNAi), cell culture and synthetic biology in the production of plant-based foods, livestock and animal feed. It also encompasses applications of the Fourth Industrial Revolution (4IR) technologies that are directly related to the application of biotechnology, including smart agriculture and bioproduct tracking systems.

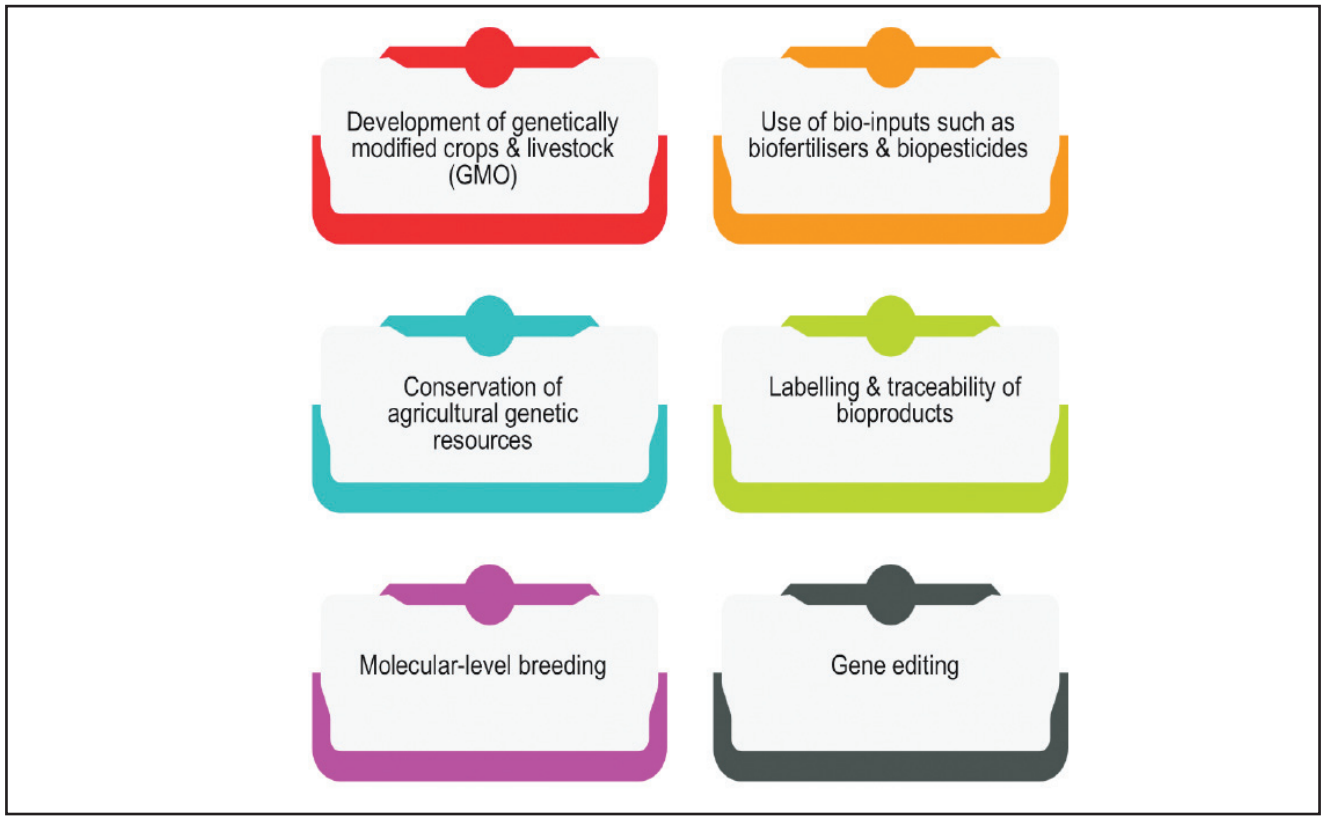


Figure 4.4: Application Scope of the Biotechnology Guidelines in Agriculture and Food Security

These guidelines may be referred to by all stakeholders, whether individuals or organisations, including researchers, policymakers, industry players, agricultural entrepreneurs, as well as educational and training institutions directly involved in the development and application of biotechnology in agriculture and food security.

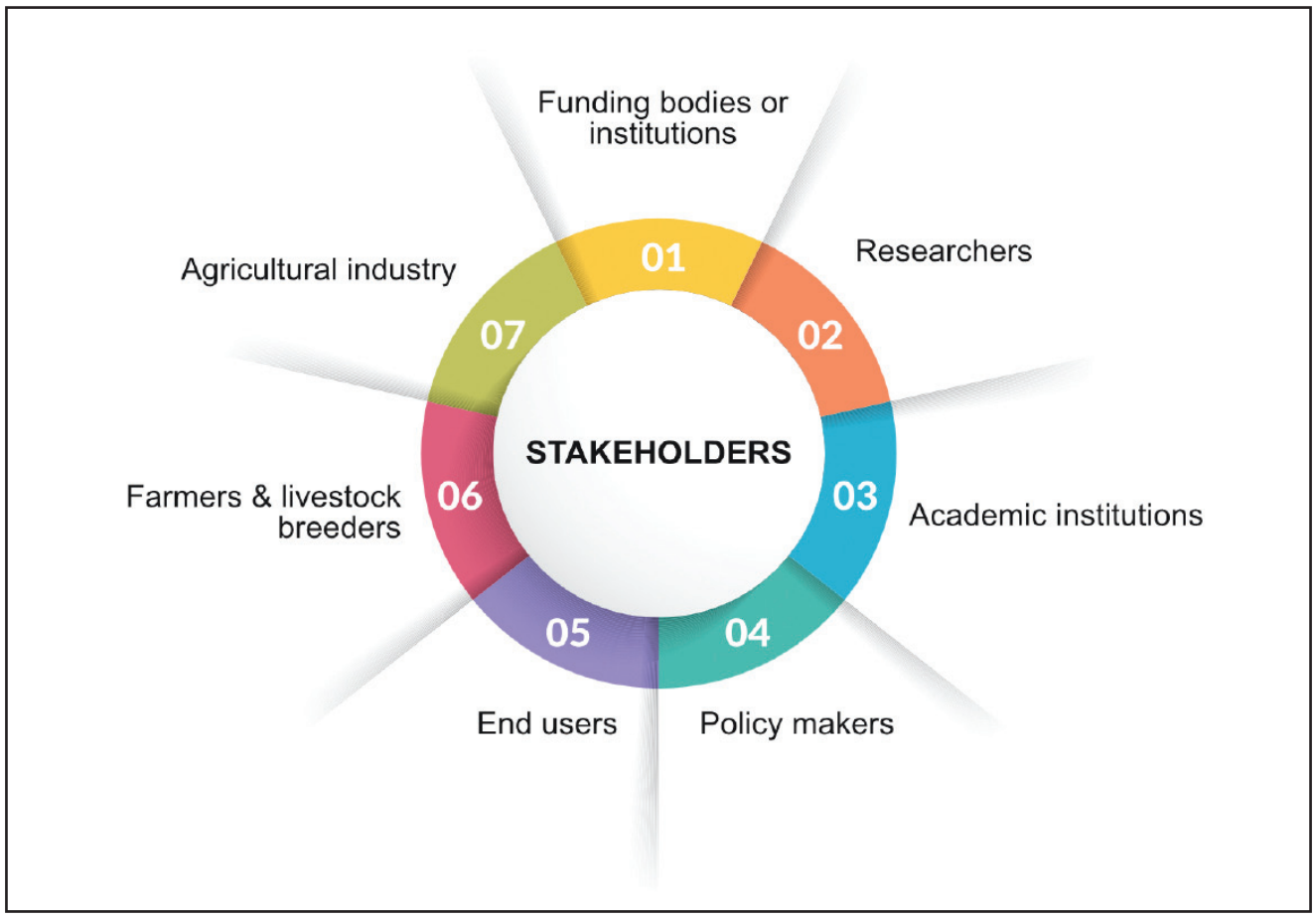


Figure 4.5: Stakeholders in Biotechnology Ethics in Agriculture and Food Security

4.4 Principles of Ethics

Table 4.2 outlines the principles of biotechnology ethics in agriculture and food security.

No.	Principle of Ethics	Explanation
1.	Respect for Autonomy	The autonomy of all parties involved, including local communities, must be respected. Every individual and community have the right to make decisions based on clear, transparent and understandable information, particularly regarding the implementation of biotechnology that directly affects them.
2.	Beneficence	Applications of biotechnology should provide clear benefits to farmers, consumers and the environment, including improving agricultural yield, nutritional value and supporting long-term food security and sustainability.
3.	Non-Maleficence	Risks to humans, animals, plants and the environment must be minimised. This includes conducting risk assessments and implementing risk management measures, as well as ensuring compliance with biosafety standards in the use of modified organisms or other biotechnological agents.
4.	Justice	The benefits and burdens of biotechnology must be distributed fairly, without marginalising small-scale farmers, vulnerable groups or minority communities. All stakeholders should be given the opportunity to participate in decision-making processes and the implementation of the technology.
5.	Transparency and Accountability	All parties involved in the development and implementation of biotechnology must carry out their responsibilities transparently and be accountable. This includes providing accurate information and ensuring product traceability in the production chain.
6.	Respect for Religion, Culture and Local Values	The development and application of biotechnology must consider the religious and cultural sensitivities of local communities, including aspects of halal compliance, preservation of local varieties, indigenous knowledge and community acceptance.
7.	Sustainability	The development and application of biotechnology must support the preservation of ecosystems, the conservation of biodiversity and the sustainable use of natural resources without causing harm to the environment in the long term.

Table 4.2: Principles of Biotechnology Ethics in Agriculture and Food Security

4.5 Reference Instruments

Reference instruments for the use of biotechnology in the agriculture and food security sectors are listed in **Table 4.3**.

No.	Act/Guideline
1.	Food Act 1983 [Act 281]
2.	New Plant Varieties Protection Act 2004 [Act 634]
3.	Biosafety Act 2007 [Act 678]
4.	Animal Welfare Act 2015 [Act 772]
5.	National Biotechnology Policy 2.0 (NBP 2.0) (2022–2030)
6.	National Science, Technology and Innovation Policy (NSTIP) (2021–2030)
7.	National Agri-Food Policy (NAFP 2.0) (2021–2030)

Table 4.3: Reference Instruments for Biotechnology Ethics in Agriculture and Food Security

Note: This list includes, but is not limited to, the instruments specified. Other relevant acts, regulations, guidelines or documents may also be referred to as needed.

4.6 Guideline Application Scenarios

The following scenarios are intended to illustrate several applications of biotechnology in agriculture and food security, as well as to aid understanding of the application of ethical principles. They may be referred to alongside the ethical checklist and recommended practices.

Technology	Scenarios
Genetically modified rice	A research institution in Malaysia is developing a genetically modified rice variety using the CRISPR technology to enhance resistance to diseases and environmental stresses such as floods and drought. This technology involves modifying the plant's DNA sequence without involving the transfer of genes from other species. The initiative is expected to increase yield and reduce dependence on chemical inputs. However, the use of this technology raises ethical considerations related to the transparency of information for consumers, equity in access to the technology and the involvement of stakeholders in its development and implementation processes.
Cultured meat	Cultured meat refers to meat produced through cellular agriculture, which is the process of growing animal cells in a laboratory environment using a bioreactor and appropriate culture media. This technology allows the production of muscle tissue that resembles meat without the need to slaughter animals. In Malaysia, there are efforts by the industry to develop this technology, including the production of laboratory-grown fish meat. However, it is still in the development phase and raises various questions regarding public acceptance, the adequacy of existing regulations and the implications for the environment and food culture.
Livestock feed	A start-up company is developing sustainable animal feed using agricultural waste such as pineapple pulp and corn stalks, which are fermented with the help of engineered microbes. These microbes have been genetically modified to improve fibre digestion and enzyme production. This initiative has the potential to reduce dependence on imported ingredients such as corn and soy. The project is also supported by research institutions but is still in the early stages of development and not yet subject to specific regulations governing the use of engineered microbes in the local animal feed supply chain. This initiative may raise ethical considerations regarding issues of safety, transparency and consumer acceptance.

Table 4.4: Application Scenarios for Biotechnology in Agriculture and Food Security

4.7 Fair and Unfair Practices

Table 4.5 lists some examples of fair and unfair practices in agriculture and food security biotechnology.

No.	Fair Practices	Unfair Practices
1.	Ensuring farmers and consumers are given sufficient information to make independent decisions.	Disregarding the need to obtain consent or consultation with the affected community.
2.	Conducting risk assessments prior to the use of biotechnology.	Implementing technology without conducting health or environmental risk assessments.
3.	Ensuring equitable access to technology across urban and rural communities.	Restricting technology access only to large-scale producers without providing support for small-scale farmers.
4.	Providing product information openly and reviewable by stakeholders.	Concealing information related to the technology or research findings from stakeholders.
5.	Promoting the use of technologies that minimise negative impacts on the ecosystem.	Using methods that threaten biodiversity or damage the environment.
6.	Documenting the technology development process in a responsible and auditable manner.	Avoiding responsibility for social impacts or scientific errors.
7.	Following biosafety protocols and ensuring animal welfare is upheld in research.	Disregarding laboratory safety guidelines or animal welfare during experiments.
8.	Considering local community perspectives and cultural contexts in project design and implementation.	Disregarding cultural and religious sensitivities in the selection of technologies or implementation approaches.
9.	Considering the sensitivities of the local culture, religion and community, including ensuring compliance with halal standards in ingredients, processes, packaging and supply chains.	Disregarding cultural and religious sensitivities and using questionable ingredients or processes without consulting an authorised halal certification body.

Table 4.5: Fair and Unfair Practices in Agriculture Biotechnology and Food Securit

4.8 Ethics Checklist

Table 4.6 contains sample questions for a checklist based on ethics principles in agriculture and food security biotechnology.

No.	Principle of Ethics	Guiding Questions
1.	Respect for Autonomy	a. Are the individuals or communities involved provided with clear and transparent information? b. Are they given the opportunity to make decisions independently and in an informed manner? c. Are food labelling requirements being complied with?
2.	Beneficence	a. Does this technology provide clear benefits to farmers, consumers or the environment? b. Does it contribute to food security or nutrition?
3.	Non-Maleficence	a. Have all potential risks to humans, animals, plants and the environment been identified and minimised? b. Are biosafety standards being complied with? c. Are food safety requirements being met?
4.	Justice	a. Are the benefits and burdens of the technology distributed fairly? b. Do small-scale farmers and vulnerable communities have access to this technology?
5.	Transparency and Accountability	a. Is information related to the process, risks and impacts of the technology shared openly and made accessible? b. Is the implementing parties prepared to be held accountable for its outcomes?

No.	Principle of Ethics	Guiding Questions
6.	Respect for Religion, Culture and Local Values	a. Are the cultural, religious, or belief sensitivities of the local community taken into consideration? b. Has an assessment been made on the suitability of the technology within the context of local values?
7.	Sustainability	a. Does this technology support the sustainable use of resources and avoid causing long-term negative impacts on the environment?

Table 4.6: Biotechnology Ethics in Agriculture and Food Security Checklist

CHAPTER 5

BIOTECHNOLOGY ETHICS IN HEALTHCARE AND WELLNESS

CHAPTER 5
BIOTECHNOLOGY ETHICS IN HEALTHCARE AND WELLNESS

5.1 Introduction

Biotechnology in healthcare and wellness is a vibrant field that combines molecular biology, genetics, and bioinformatics to provide innovative solutions within modern health systems. This technology has transformed approaches to disease diagnosis, treatment, and prevention, including the development of biopharmaceuticals, recombinant vaccines, and gene therapy. Advances in genomic profiling and molecular diagnostics have facilitated personalised treatments and precision medicine tailored to individual genetic profiles, while artificial intelligence (AI) enhances predictive capabilities, health data analysis, and clinical decision support. **Figure 5.1** highlights several applications of biotechnology in healthcare and wellness.

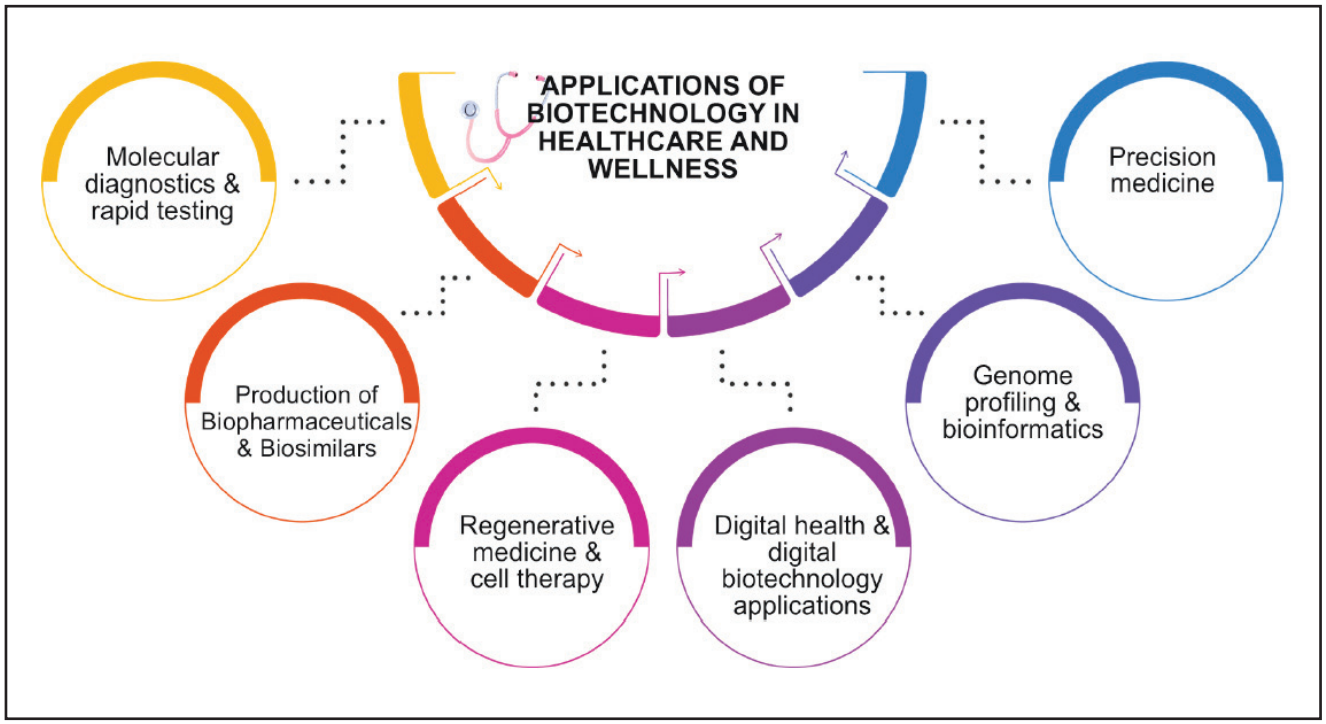


Figure 5.1: Applications of Biotechnology in Healthcare and Wellness

However, the increasingly advanced use of biotechnology applications in healthcare also raises important issues related to ethics, regulations and the cost of therapies. These include concerns over potential genetic manipulation, informed consent, safety and efficacy testing, misleading product information, privacy and data protection, accuracy and reliability of diagnostic sensors and biomarkers, intellectual property rights, unequal access, as well as issues related to religious and cultural values. **Figure 5.2** summarises the ethical issues associated with biotechnology in healthcare and wellness.

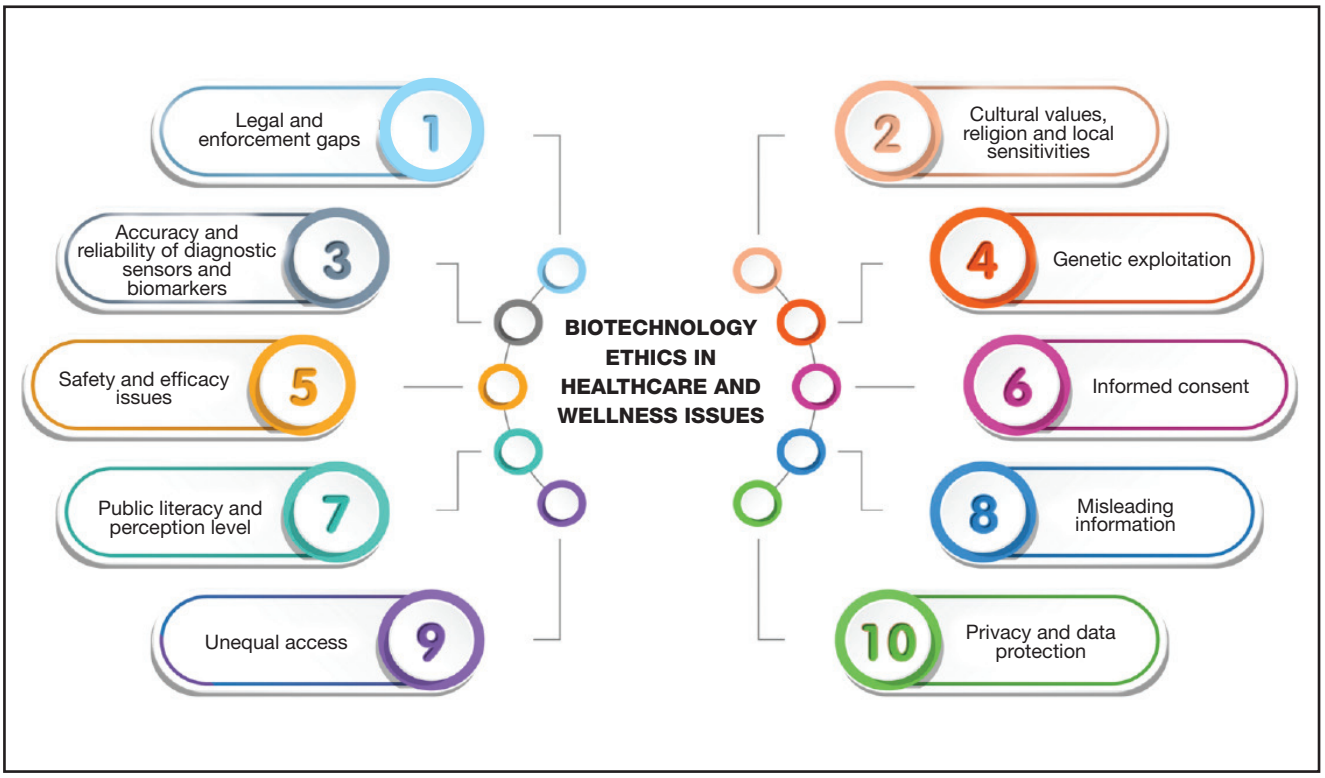


Figure 5.2: Biotechnology Ethics in Healthcare and Wellness Issues

5.2 Definition of Terms

Table 5.1 lists selected terms related to biotechnology in healthcare and wellness that are used in this chapter.

Terms	Definition
Healthcare Biotechnology	The use of principles and techniques of molecular biology, genetics and related technologies for the purposes of diagnosis, prevention, treatment of diseases as well as the development of health products such as medicines, vaccines and modern therapies.
Wellness	A holistic state achieved through the improvement of human quality of life resulting from the application of biotechnology in health, such as disease prevention, more effective treatments, health monitoring, and support for mental, physical and social well-being.
Informed Consent	The consent of a subject or individual to participate in a study or to receive an intervention based on sufficient information, including the benefits and risks associated with the intervention.
Recombinant Vaccine	A vaccine produced using the recombinant DNA technology, typically involving the insertion of viral or bacterial genes into a production system.
mRNA Vaccine	A vaccine that uses synthetic messenger RNA (mRNA) sequences to instruct the body's cells to produce specific proteins that trigger an immune response against a disease, without using live viruses.
Gene Therapy	A technique that uses genes to treat or prevent diseases.
CRISPR Technology (Clustered Regularly Interspaced Short Palindromic Repeats)	A gene-editing technology that enables precise modifications to DNA with high accuracy.
Precision Medicine	A modern approach to disease treatment and prevention that considers individual genetic variations, environmental factors and lifestyle differences.
Omics Technology	A group of technologies such as genomics, transcriptomics, proteomics, and metabolomics that are used to explore the functions, interactions and roles of biological molecules within an organism.
Biomarker	A biomarker refers to a subcategory within the broad field of medical indicators, representing objective measures of an individual's biological or medical condition, whether determined through biological samples (such as blood, urine or tissue) or clinical observation.

Terms	Definition
Artificial Intelligence	Artificial Intelligence (AI) refers to the capability of digital computers or computer-controlled robots to perform tasks that are typically associated with human intelligence.
Biosimilar	A biopharmaceutical product that is highly similar to an original biological product in terms of safety, efficacy and quality.
Smart Herbs	An integrative approach in the cultivation, processing and marketing of herbs that utilises modern technologies such as the Internet of Things (IoT), biotechnology, automation and data analytics to sustainably and competitively enhance the yield, quality and traceability of herbal products.

Table 5.1: Definition of Terms related to Biotechnology in Healthcare and Wellness

5.3 Scope of Application

This guideline can be applied in research, development, application, clinical practice, as well as the implementation of policy and regulation related to biotechnology in healthcare and wellness. The areas covered within this scope are illustrated in **Figure 5.3**.

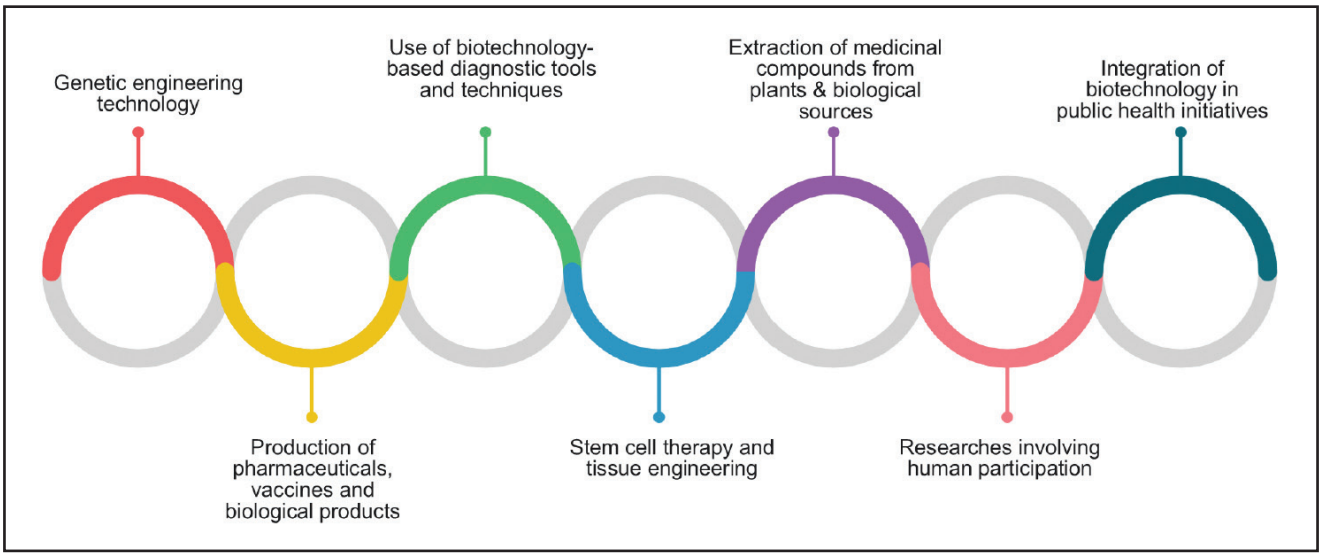


Figure 5.3: Scope of Application of Biotechnology in Healthcare and Wellness

This guideline may be adopted by all stakeholders, whether institutions or individuals, who are directly or indirectly involved in the field of biotechnology in healthcare, including researchers, healthcare professionals, related industries, regulatory authorities, patients and society, as illustrated in **Figure 5.4**.

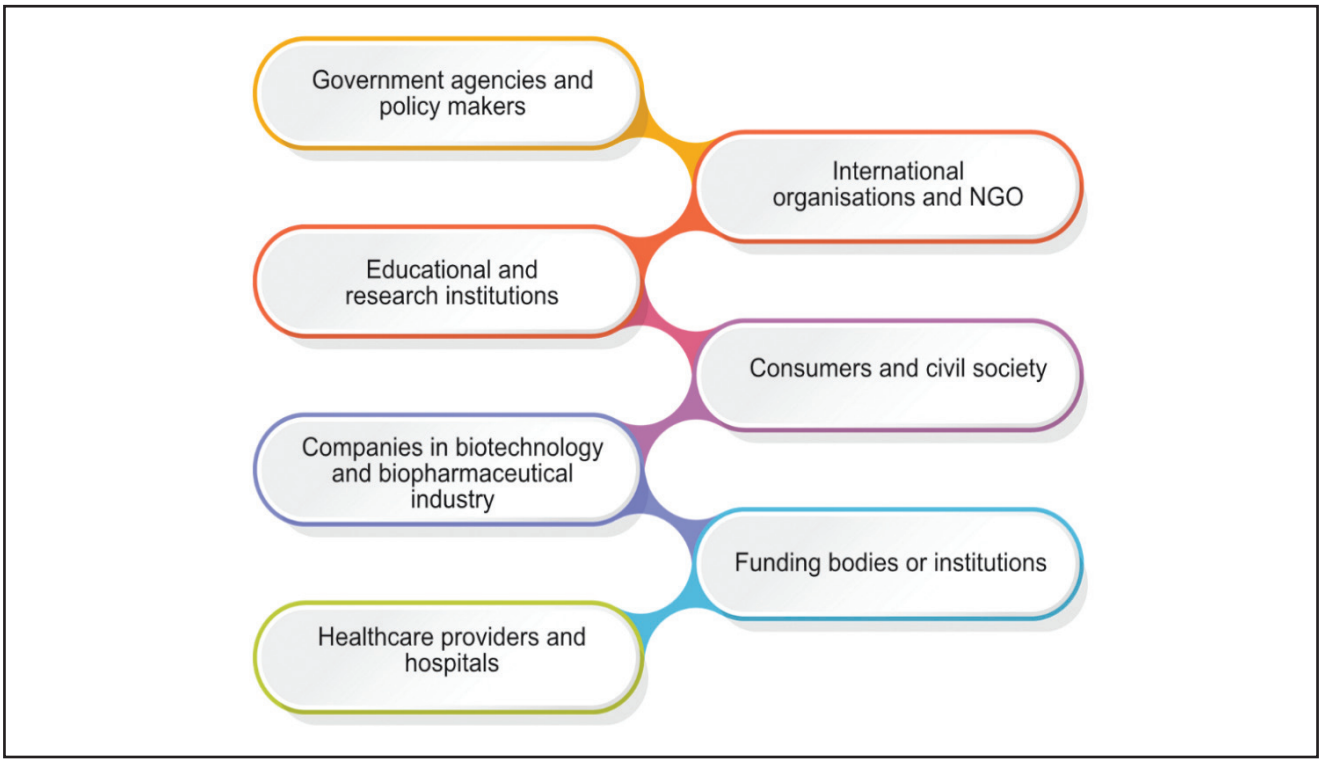


Figure 5.4: Stakeholders in Biotechnology Ethics in Healthcare and Wellness in Malaysia

5.4 Principles of Ethics

Table 5.2 outlines the principles of biotechnology ethics in healthcare and wellness.

No.	Principle of Ethics	Explanation
1.	Respect for Autonomy	Every individual has the right to make voluntary and fully informed decisions regarding their participation in biotechnology interventions or research.
2.	Respect for Human Dignity and Human Rights	The dignity and fundamental rights of every individual must be respected in all research, development, commercialisation and applications of biotechnology, including ensuring that there is no discrimination, exploitation or conduct that undermines human dignity.
3.	Beneficence	The well-being of individuals and communities shall be prioritised by ensuring that biotechnology is utilised to maximise benefits and enhance health standards.
4.	Non-Maleficence	Potential dangers or risks arising from the application of healthcare biotechnology shall be avoided or minimised.
5.	Justice	Access to biotechnology and the distribution of its benefits shall be ensured fairly and without discrimination.
6.	Privacy and Confidentiality	Personal and genetic information of individuals shall be protected from any disclosure or misuse without proper authorisation.
7.	Transparency and Accountability	All parties involved in biotechnology activities shall conduct their duties transparently, provide clear and accurate information, and be prepared to be held accountable for every decision and action.
8.	Respect for Religion, Culture and Local Values	Religious and cultural perspectives shall be taken into consideration in the development, research and application of healthcare biotechnology products.
9.	Prevention and Preparedness	Parties involved shall adopt a precautionary approach towards scientific uncertainty and be prepared to address potential risks arising from the use of biotechnology.
10.	Social Responsibility	Parties involved shall recognise their collective responsibility in addressing public health challenges and promote inclusive participation in decision-making processes.
11.	Sustainability	Long-term impacts on the environment, society and health shall be taken into account to ensure the well-being of future generations.

Table 5.2: Principles of Biotechnology Ethics in Healthcare and Wellness

5.5 Reference Instruments

Reference instruments regarding the biotechnology ethics in healthcare and wellness in Malaysia are listed in **Table 5.3**.

No.	Acts and Legislation
1.	Medical Act 1971 [Act 50]
2.	Patents Act 1983 [Act 291]
3.	Private Healthcare Facilities and Services Act 1998 [Act 586]
4.	Biosafety Act 2007 [Act 678]
5.	Personal Data Protection Act 2010 (PDPA) [Act 709]
6.	Medical Device Act 2012 [Act 737]
7.	National Science, Technology and Innovation Policy (NSTIP) 2021–2030
8.	National Biotechnology Policy 2.0 (NBP 2.0) 2022–2030
9.	Malaysian Guideline for Good Clinical Practice (Fourth Edition) (2018)

No.	Acts and Legislation
10.	Guidelines on Ethical Issues in the Provision of Medical Genetics Services in Malaysia (2019)
11.	Guideline For Herbal Medicine Research (2023)
12.	Guidelines on Stem Cell and Cell-Based Research and Therapy (2024)
13.	The National Guidelines on AI Governance and Ethics (2024)

Table 5.3: Reference Instruments for Biotechnology Ethics in Healthcare and Wellness

Note: This list includes, but is not limited to, the instruments specified. Other relevant acts, regulations, guidelines or documents may also be referred to as needed.

5.6 Guideline Application Scenarios

The following scenarios are intended to illustrate several applications of biotechnology in healthcare and wellness, as well as to aid understanding of the application of ethical principles. They may be referred to alongside the ethical checklist and recommended practices in the next subtopic.

Technology	Scenarios
Smart Herbal Products	A local start-up company is currently collaborating with a research institution to explore the potential of Malaysia's native herbs through emerging biotechnology approaches. The initial study involves genetic mapping of local plant species to identify those with therapeutic properties, followed by metabolomic analysis to detect natural compounds such as antioxidants, anti-aging agents or anti-inflammatory substances. The data obtained are then integrated with Artificial Intelligence (AI) algorithms to predict the most effective and safe combinations of active ingredients. The research outcomes are planned to be developed into functional food products, nutraceutical supplements and herbal cosmetics. While this development is seen as capable of enhancing the use of local biodiversity, it also raises various questions regarding resource ownership, knowledge transfer and the social responsibility of the industry toward local communities.
Locally Produced mRNA Vaccines	mRNA vaccine technology enables the rapid and flexible development of vaccines based on the genetic sequence of pathogens, with the potential to support precision medicine. However, it requires careful ethical consideration and good governance to ensure that it is developed and used responsibly, safely and in ways that are acceptable to society.
Gene Editing for Disease Treatment	Gene therapy technology is now being explored more extensively, particularly in the use of gene editing approaches to treat chronic and genetic diseases. Somatic gene therapy involves modifying genes within a patient's body cells to correct genetic defects or enhance cell function. This method has been used experimentally in several countries to treat conditions such as thalassemia, sickle cell anaemia and certain types of cancer. Gene-editing technologies like the CRISPR are applied to precisely insert, replace or remove sections of the DNA. Artificial Intelligence (AI) is increasingly used to identify optimal gene-editing sites, predict potential side effects and assess treatment safety. Among the ethical issues that arise are informed consent, long-term risks, genetic data privacy, equitable access to treatment and sensitivity to religious and cultural perspectives regarding genetic interventions.

Table 5.4: Application Scenarios for Biotechnology Guidelines in Healthcare and Wellness

5.7 Fair and Unfair Practices

Table 5.5 lists some examples of fair and unfair practices in healthcare and wellness biotechnology.

No.	Fair Practices	Unfair Practices
1.	Recognise the intrinsic value of every individual in all aspects of biotechnology research and application.	Disregarding human rights or undermining human dignity in biotechnology processes.
2.	Provide clear and comprehensive information to enable informed and evidence-based decision-making.	Involving individuals without consent or without providing sufficient information.
3.	Ensure maximum benefit to individuals and society.	Prioritising profit or experimentation over the welfare of participants.
4.	Reduce risks and take mitigation measures before implementation.	Ignoring potential side effects or risks to individuals or communities.
5.	Guarantee equitable access to the benefits of biotechnology.	Creating inequality based on socioeconomic status, ethnicity or other factors.
6.	Protect personal and genetic data from unauthorised disclosure.	Disclosing sensitive information without proper authorisation.
7.	Maintain transparency regarding research methods, objectives and outcomes.	Concealing conflicts of interest or withholding important information from participants or relevant parties.
8.	Conduct risk assessments and ensure continuous monitoring of biotechnology applications.	Neglecting scientific uncertainty or long-term risks.
9.	Consider the social and environmental impacts of biotechnology use.	Introducing technology without assessing its long-term impact on society or the environment.
10.	Ensure inclusive participation and fair benefit-sharing, especially with the public and vulnerable communities.	Marginalising vulnerable groups or imposing burdens on communities without consultation.
11.	Remain sensitive to cultural values and community beliefs in the development and use of technology.	Disregarding cultural and religious sensitivities in the implementation of biotechnology in healthcare and wellness.

Table 5.5: Fair and Unfair Practices in Healthcare Biotechnology and Wellness

5.8 Checklist for Ethics

Table 5.6 contains sample questions for a checklist based on ethics principles in healthcare and wellness biotechnology.

No.	Principles of Ethics	Guiding Questions
1.	Respect for Autonomy	a. Has informed consent been obtained voluntarily and fully understood by the participant or patient?
2.	Respect for Human Dignity and Human Rights	a. Are the rights and dignity of patients protected throughout the research or technology implementation process?
3.	Beneficence	a. Is the biotechnology intervention expected to benefit individuals or society?
4.	Non-Maleficence	a. Have all risks been identified, and have mitigation measures been prepared to prevent harm?
5.	Justice	a. Is access to the technology or treatment distributed fairly without discrimination?
6.	Privacy and Confidentiality	a. Are personal information and genetic data adequately protected?
7.	Transparency and Accountability	a. Is information related to the technology, risks and outcomes shared openly and honestly?
8.	Respect for Religion, Culture and Local Values	a. Are religion, culture and local values being considered in the design and implementation of the technology?
9.	Prevention and Preparedness	a. Has long-term risk assessment been conducted prior to the application of technology?
10.	Social Responsibility	a. Does the project or technology contribute to the collective well-being of society?
11.	Sustainability	a. Does the use of the technology consider long-term impacts on public health and the environment?

Table 5.6: Checklist for Biotechnology Ethics in Healthcare and Wellness

CHAPTER 6

BIOTECHNOLOGY ETHICS IN INDUSTRY AND CIRCULAR ECONOMY

CHAPTER 6
BIOTECHNOLOGY ETHICS IN INDUSTRY AND CIRCULAR ECONOMY

6.1 Introduction

Industrial biotechnology refers to the use of living organisms or enzymes to produce chemicals, biofuels, and other products sustainably from renewable resources. This technology plays a key role in reducing energy consumption, greenhouse gas emissions and industrial waste, while supporting the transition towards the bioeconomy. In Malaysia, the adoption of this technology has evolved from traditional processes such as fermentation, to modern approaches based on metabolic engineering and biocatalysis. Its applications span to multiple sectors, including manufacturing, energy, and waste management. **Figure 6.1** lists several applications of biotechnology in the industry and circular economy.

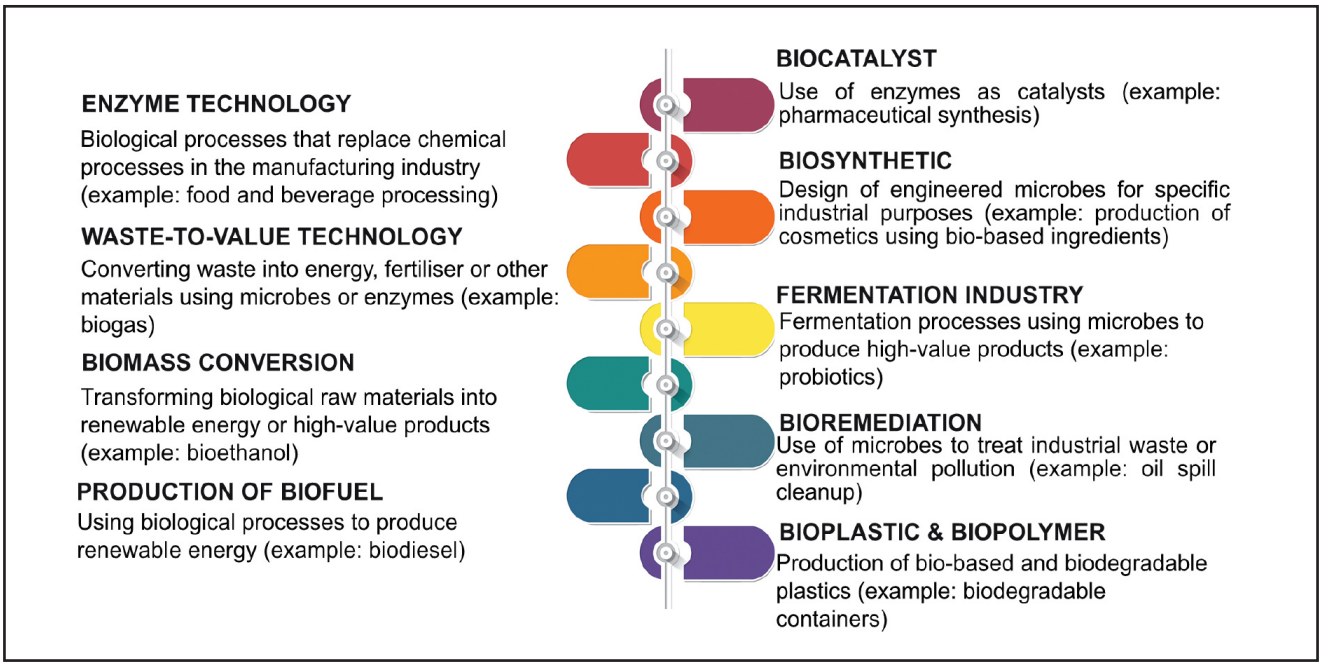


Figure 6.1: Applications of Biotechnology in the Industry and Circular Economy

Although industrial biotechnology offers various benefits, it also raises several significant ethical issues. Among them are environmental risks such as the release of genetically modified organisms (GMOs) into ecosystems, overexploitation of natural resources, the dual-use potential of biotechnology, which can bring both benefits and harm if misused, and the release of toxic substances that may pollute the environment and threaten human health.

In addition, there are concerns about social inequalities, such as the misappropriation of biological resources (biopiracy) and the domination of intellectual property rights, which hinder access to technology, especially for communities and developing countries. **Figure 6.2** summarises the ethical issues of biotechnology in the industry and circular economy.

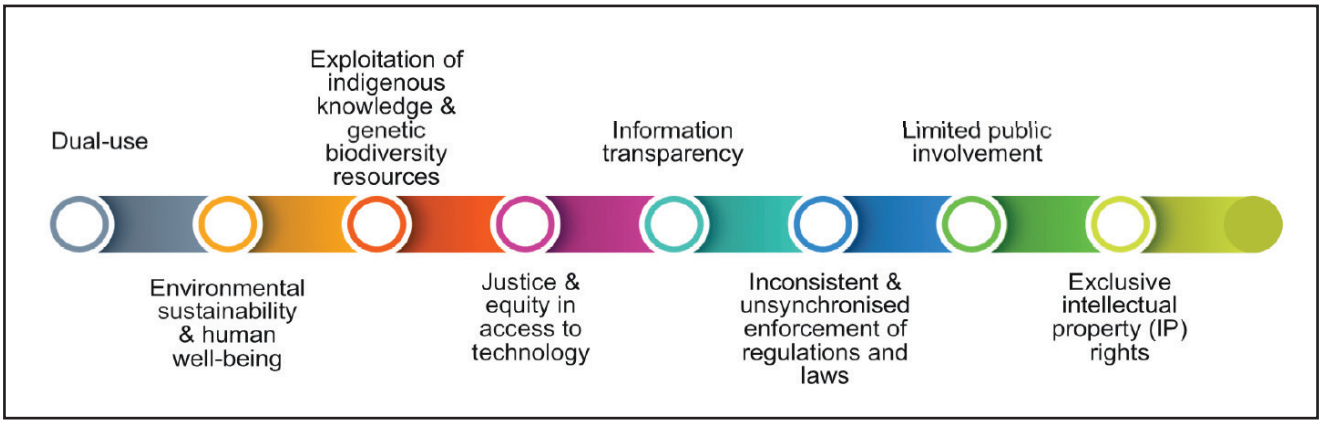


Figure 6.2: Biotechnology Ethics Issues in the Industry and Circular Economy

6.2 Definition of Terms

Table 6.1 lists selected terms related to biotechnology in the industry and circular economy that are used in this chapter.

Terms	Definition
Industrial Biotechnology	The application of modern biological technologies such as biocatalysts, genetic engineering and fermentation in industrial processes to produce products sustainably.
Circular Economy	An economic model that promotes reuse, recycling and regeneration of resources to reduce waste and maximise the value of raw materials.
Bioeconomy	Seen as knowledge-based production that utilises natural/biological resources along with biological processes and principles to enable the provision of profitable goods and services in an environmental-friendly manner.
Biocatalyst	The use of enzymes or microbes to accelerate chemical reactions in industrial production processes.
Industrial Fermentation	A biotechnological process that uses microorganisms under controlled conditions to produce substances such as ethanol, organic acids or enzymes for industrial use.
Genetically Modified Organism	An organism whose (which is) genetic material has been artificially modified for specific purposes such as increasing yield or production efficiency.
Misappropriation of biological resources (biopiracy)	The acquisition or use of genetic resources and traditional knowledge without authorisation or compensation to the original community.
Bioplastic	Bioplastic is a type of plastic material that is either bio-based, biodegradable or possesses both characteristics.
Bioenergy	Any form of renewable energy derived from biological raw materials or biomass, which exists in two types: traditional and contemporary.
Biofuel	A renewable energy source produced from biological origins such as microorganisms, plants or animals.
Enzyme Engineering	The modification of enzyme structures to improve their stability, efficiency or specificity in industrial processes.

Terms	Definition
Metabolic Engineering	Modification of the metabolic pathways of microorganisms to enhance the production of target compounds in industrial processes.
Bioremediation	The use of microorganisms or enzymes to naturally clean environmental pollution, such as contaminated soil, oil spills or toxic waste.
Dual-Use	The use of biotechnology or biotechnological knowledge that can be applied for beneficial purposes, such as product development, but also has the potential to be misused for harmful or unethical purposes.

Table 6.1: Definition of Biotechnology Terms in the Industry and Circular Economy

6.3 Scope of Application

The scope of application of the guidelines cover research, development, production and commercialisation activities under the field of Biotechnology in the Industry and Circular Economy, as outlined in **Figure 6.3**.

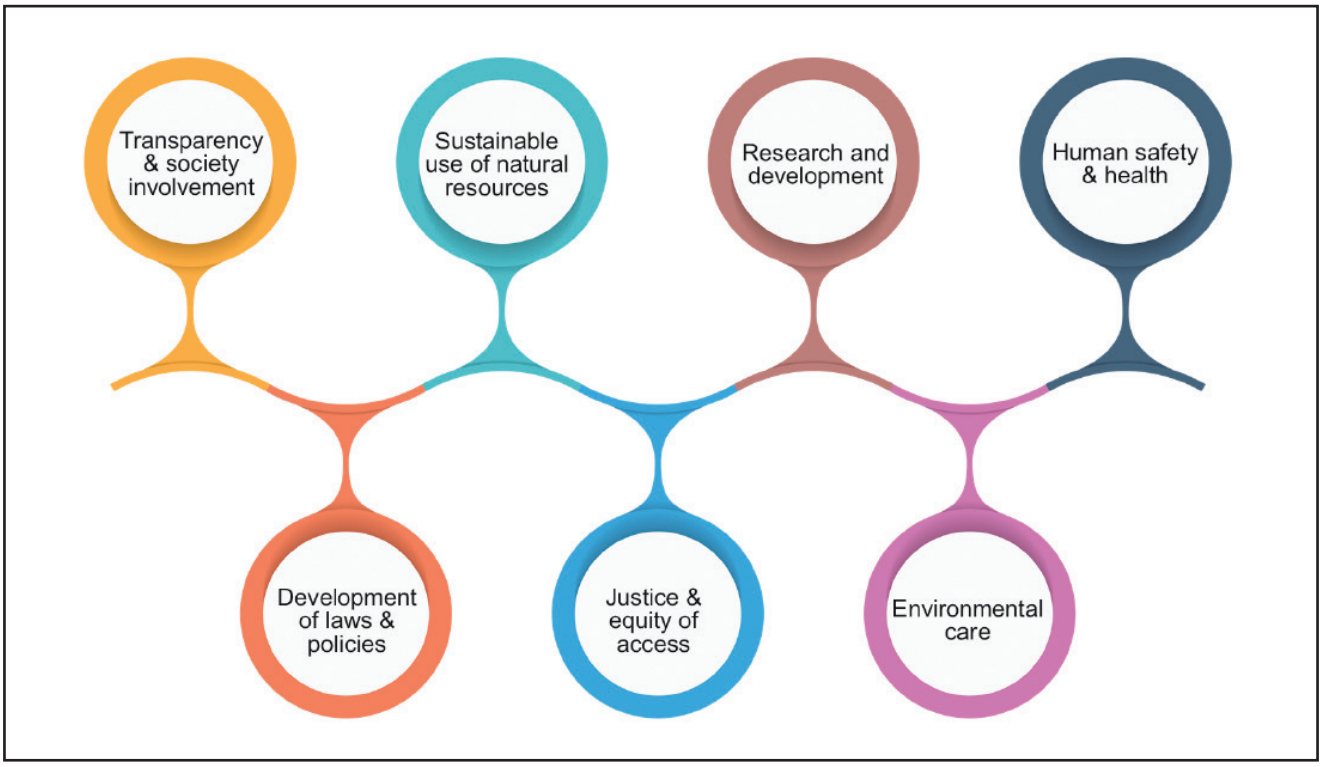


Figure 6.3: Scope of Application of the Biotechnology Ethical Guidelines in the Industry and Circular Economy

The main stakeholders for biotechnology ethics in the industry and circular economy are illustrated in **Figure 6.4**.

Figure 6.4: Stakeholders for Biotechnology Ethics in the Industry and Circular Economy

6.4 Principles of Ethics

Table 6.2 contains the principles of biotechnology ethics in the industry and circular economy.

No.	Principles of Ethics	Explanation
1.	Respect for Autonomy	The right of stakeholders to make independent and informed decisions regarding biotechnology in the industry and circular economy must be recognised.
2.	Beneficence	The right of stakeholders to make independent and well-informed decisions regarding biotechnology in the industry and circular economy must be respected and recognised.
3.	Non-Maleficence	Risks to humans, communities, and the environment arising from exposure to chemicals, GMOs or toxic by-products must be avoided.
4.	Justice	Equitable access to technology and economic benefits must be ensured, giving priority to the needs of vulnerable groups so they are not excluded from opportunities and advancements in biotechnology.
5.	Transparency and Accountability	Information related to products and production processes must be shared transparently, and all parties involved must be held accountable for the social, health and environmental implications.
6.	Prevention and Preparedness	Scientific uncertainties and biotechnology dual-use potential must be identified through early risk assessments prior to commercialisation, with ongoing monitoring, auditing and reporting implemented as needed.
7.	Safeguarding Biosovereignty	The rights of the nation and communities over biological resources and traditional knowledge must be recognised and protected, including their ability to control access, use and ownership of these resources.
8.	Benefit Sharing	Benefits derived from biotechnology research or products must be shared fairly with local communities and relevant parties in accordance with laws and local values.
9.	Sustainability	The use of renewable resources, green processing and circular economy practices must be promoted to ensure balance between development and environmental protection.
10.	Protection of Future Generations	Long-term impacts on the well-being and safety of future generations must be considered in every development and application of biotechnology.

Table 6.2: Principles of Ethics of Biotechnology in the Industry and Circular Economy

6.5 Reference Instruments

The reference instruments related to the ethics of industrial biotechnology and the circular economy in Malaysia are listed in **Table 6.3**.

No.	Acts/Policies/Guidelines
1.	Factories and Machinery Act 1967 [Act 139]
2.	Environmental Quality Act 1974 [Act 127]
3.	Food Act 1983 [Act 281]
4.	Biosafety Act 2007 [Act 678]
5.	Access to Biological Resources and Benefit Sharing Act 2017 [Act 795]
6.	National Intellectual Property Policy (2007)
7.	National Green Technology Policy (2010)
8.	National Science, Technology and Innovation Policy (NSTIP) (2021–2030)
9.	National Biotechnology Policy 2.0 (NBP 2.0) (2022–2030)
10.	Good Manufacturing Practice (GMP)
11.	Good Laboratory Practice (GLP)

Table 6.3: Reference Instruments for Biotechnology Ethics in the Industry and Circular Economy

Note: This list includes, but is not limited to, the instruments specified. Other relevant acts, regulations, guidelines or documents may also be referred to as needed.

6.6 Guidelines Application Scenarios

The following scenarios aim to illustrate several applications of biotechnology in the industry and circular economy, and to aid understanding of how principles of ethics are applied, as outlined in **Table 6.4**. These scenarios can be used in conjunction with the ethical practices and checklists provided in the subsequent subtopics.

Technology	Scenarios
Bioplastic	A local biotechnology company is conducting a project to develop environmental-friendly bioplastics using genetically modified microbes. These microbes were discovered through research in a forest reserve and later modified to produce specific biopolymers materials in large quantities. The resulting product is expected to replace petroleum-based plastics in the food packaging industry. The production process is carried out in a bio industrial plant with a closed control system, and the production waste is reportedly biodegradable. This project also involves collaboration between research institutions, private companies and international investors.
Bioremediation	A biotechnology project is being conducted by a local research institute in collaboration with the industry to identify natural microbes in Malaysian waters that have the potential to be used for bioremediation of oil and chemical pollution in coastal industrial areas. The microbes are collected through marine expeditions in several areas identified as strategic locations, including those near marine parks and protected marine zones. The collected samples are brought to the laboratory for isolation, cultivation and testing of their effectiveness in breaking down toxic pollutants. The project also explores the potential use of these microbes in bioenergy production and the development of high-value by-products. Although the project is viewed as a proactive step toward environmental conservation, the use of local biodiversity resources for commercial purposes continues to raise various policy-level discussions.
Microalgae-based Biofuel	A collaborative initiative between a coastal state government and an international biotechnology company is developing a microalgae-based biofuel farm in tropical shallow waters. The microalgae used have been genetically modified to enhance the efficiency of bio-oil production, which is then refined into renewable fuel. This process does not compete with food production and uses seawater, making it a more sustainable alternative compared to conventional biofuels. The project is viewed as an opportunity to drive the green economy, strengthen local technological capabilities and contribute to the nation's climate change goals. However, it also raises ethical concerns related to the involvement of affected communities, the safety of genetically modified microalgae and the potential impact on marine biodiversity.

Table 6.4: Scenarios of Guidelines Applications of Biotechnology in the Industry and Circular Economy

6.7 Fair and Unfair Practices

Several examples of fair and unfair practices of biotechnology in the industry and circular economy are presented in **Table 6.5**.

No.	Fair Practices	Unfair Practices
1.	Providing clear and comprehensive information to stakeholders and respect their independent decisions regarding the use or acceptance to the technology.	Forcing or influencing stakeholders to accept a technology without sufficient information or consent.
2.	Promoting the development of industrial biotechnology that benefits the environment and society, such as the production of eco-friendly products.	Prioritising profit alone without considering benefits to the community or the environment.
3.	Conducting risk assessments on potential harm to human health and the environment before implementing new technologies.	Neglecting safety assessments or releasing toxic substances into the environment without control.
4.	Ensuring equitable access to the outcomes and benefits of technology, including for rural communities and developing countries.	Focusing benefits on specific parties only or excluding marginalised groups from the benefits of technology.
5.	Implementing continuous monitoring and preparedness mechanisms for long-term risks.	Ignoring scientific uncertainty and potential risks to biodiversity or public safety.
6.	Considering the long-term impacts on natural resources, health and ecosystems for future generations.	Overexploiting resources or producing hazardous waste without considering long-term impacts.
7.	Prioritising environmental-friendly processes and products that utilise renewable materials.	Relying on non-sustainable raw materials and processes that pollute the environment.

No.	Fair Practices	Unfair Practices
8.	Reporting on information related to safety, environmental impact and manufacturing processes honestly.	Concealing important information from authorities or the society.
9.	Establishing fair collaboration with local communities, including benefit and knowledge sharing.	Exploiting community resources or knowledge without fair compensation or proper recognition.
10.	Respecting the rights of the nations and communities over their genetic and biological resources.	Obtaining genetic resources without permission or in violation of biological resource ownership regulations.

Table 6.5: Fair and Unfair Practices in the Industrial Biotechnology and Circular Economy

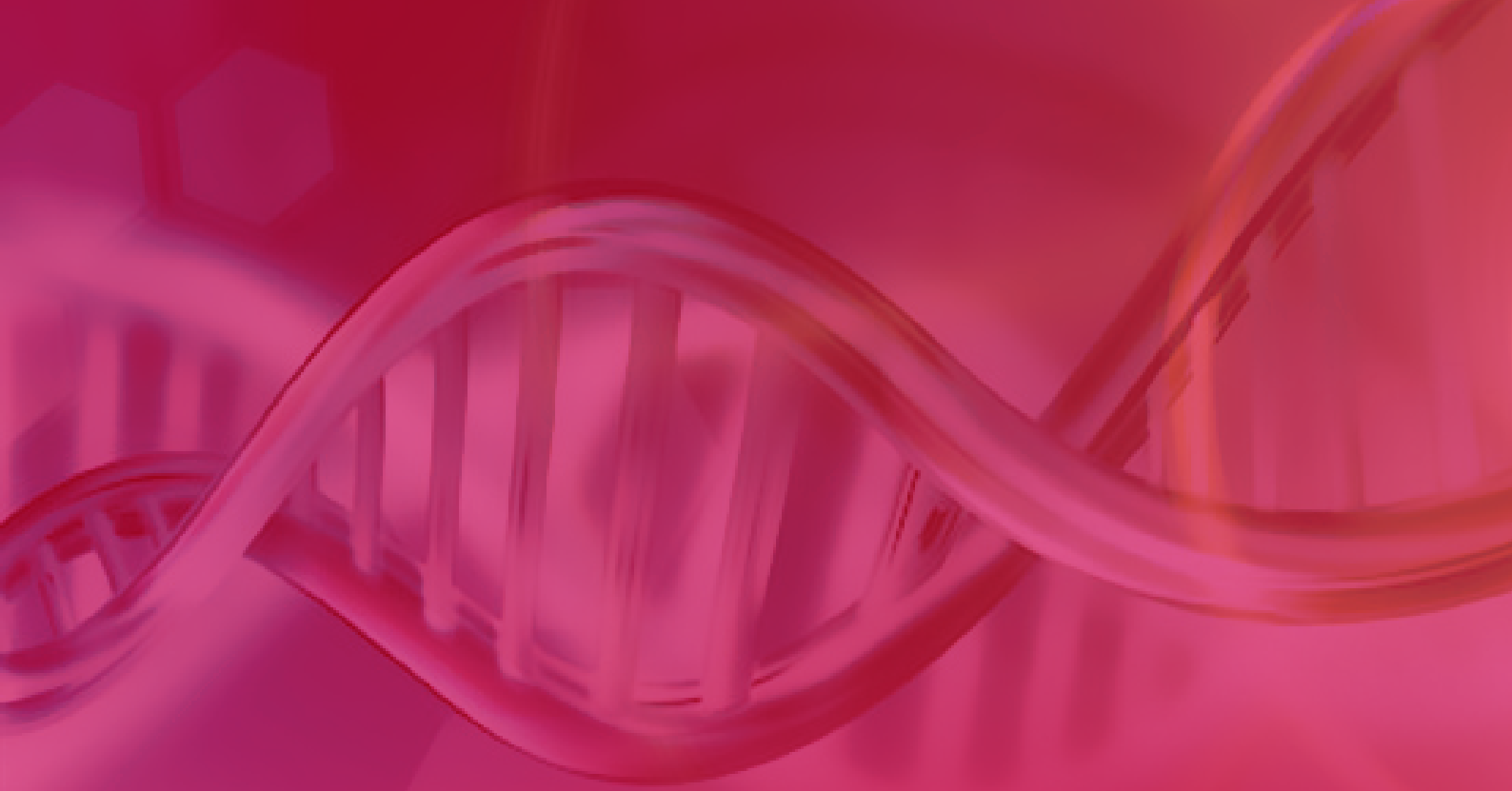
6.8 Checklist for Ethics

The checklist for Biotechnology Ethics in the Industry and the Circular Economy is provided in **Table 6.6**.

No.	Principles of Ethics	Guiding Questions
1.	Respect for Autonomy	a. Were stakeholders provided with clear and complete information before deciding?
2.	Beneficence	a. Does this project provide significant benefits to society or the environment?
3.	Non-Maleficence	a. Have the risks to humans and the environment been identified and mitigated?
4.	Justice	a. Are the benefits and risks distributed fairly without discrimination?
5.	Transparency and Accountability	a. Is project-related information disclosed transparently, and are the parties involved accountable for their decisions?
6.	Prevention and Preparedness	a. Has an early risk assessment been conducted to identify scientific uncertainties and potential dual-use issues? b. Are monitoring, auditing and reporting mechanisms implemented to ensure safe and sustainable use of the technology?

No.	Principles of Ethics	Guiding Questions
7.	Benefit Sharing	a. Are the benefits of the project shared fairly with all stakeholders, including local communities?
8.	Safeguarding Biosovereignty	a. Are the rights of the nation or communities over biological resources and traditional knowledge respected?
9.	Sustainability	a. Does the project contribute to the sustainable use of resources and avoid environmental harm?
10.	Protection of Future Generations	a. Have the long-term implications for future generations been considered?

Table 6.6: Checklist for Biotechnology Ethics in the Industry and Circular Economy



CHAPTER 7
CONCLUSION

CHAPTER 7
CONCLUSION

7.1 Summary

As biotechnology continues to advance across various sectors including agriculture, healthcare, industry and the environment, approaches to ethical issues must also be continuously updated to remain relevant, effective and sensitive to local background and needs.

This guideline outlines ethical principles and responsible practices in biotechnology, serving as a reference for various stakeholders. However, to ensure a more comprehensive and sustainable implementation and enforcement of ethics, policy support, involvement of various parties and alignment with local religious and cultural values are essential.

Therefore, several recommendations for improvements in the biotechnology ethics governance in Malaysia are proposed. This guideline also adapts universal ethical principles to local values and sensitivities and envisions a future of biotechnology ethics that is more integrated, responsive and grounded in social justice and sustainability.

7.2 Measures to Enhance Biotechnology Ethics in Malaysia

The following measures are recommended to enhance the implementation and effectiveness of biotechnology ethics governance in Malaysia:

a. Strengthening of Policies and Legislation

Improvements to existing policies and the formulation of specific laws related to bioethics and biotechnology should be expedited. Focus should be given to issues such as privacy and ownership of genetic data, as well as the management of access to genetic resources.

b. Development of National Data Infrastructure and Genetic Resource Repository

It is proposed that a national data repository be established, along with a committee to monitor access to sensitive data. The establishment of a national biodiversity database is also recommended to document and protect the country's natural resources, such as medicinal herbs in order to prevent external claims and exploitation of local resources.

c. Development of Ethical Guidelines for Digital Technology and Genetic Data

The growing use of artificial intelligence (AI) in diagnostics and genomics, big data applications and cloud computing within the health and biotechnology sectors has raised concerns related to data sovereignty, sharing and the cross-border protection of genomic data, which requires specific attention. Therefore, the development of specific ethical guidelines on these aspects is essential to ensure the protection of individual rights and the integrity of biotechnology research.

d. Establishment of Bioethics Emergency Advisory Unit

An ad hoc Bioethics Emergency Advisory Unit could be established to address unforeseen ethical issues in biotechnology. This unit would provide prompt and ethical guidance to authorities, policymakers and researchers. This unit could be placed under the National Security Council, with advisory input from the National Bioethics Council (MBeN).

e. Bioethics Education and Capacity Building

Bioethics education is recommended to be incorporated into formal curricula at schools and universities, particularly in life sciences and biotechnology programmes. Online courses (MOOCs) and certified training for ethics committee members should be made available and regularly updated. Investment in human resources, training facilities and funding is vital in building sustainable national capacity.

f. Enhancement of Public Understanding and Communication

Public understanding of bioethics and biotechnology issues remains limited. Therefore, effective communication strategies must be implemented. The government and industry are encouraged to disseminate information transparently, accessibly and in user-friendly formats through social media and high-impact public exhibitions.

7.3 The Importance of Religion, Culture and Local Values in Malaysia

This guideline recognises that religion, culture and local values are crucial elements in determining the acceptance and implementation of biotechnology in Malaysia. Therefore, every biotechnology application should be assessed not only based on universal bioethical principles but also in alignment with the values of the local community.

Considerations to such as religious perspectives, cultural beliefs and local norms including concepts like *maqasid shariah* (objectives of Islamic law), halal and social well-being should be taken into account in the research, development and application of biotechnology. This approach is essential to ensure the relevance and effectiveness of these guidelines within Malaysia's diverse societal context.

Malaysia is a nation rich in ethnic, religious and traditional diversity. Each community holds unique moral perspectives, particularly on issues related to health, life, the human body and emerging technologies. Hence, the development of inclusive biotechnology ethics must consider this uniqueness to ensure that ethical policies and guidelines are acceptable to all segments of society.

A culturally and religiously sensitive approach to biotechnology ethics also strengthens policy legitimacy, enhances public trust and prevents conflicts between scientific progress and belief systems. It further enables the adaptation of universal bioethical principles such as justice, autonomy and non-maleficence to Malaysian context.

7.4 Future Directions of Biotechnology Ethics in Malaysia

The rapid advancement of biotechnology necessitates a more dynamic, integrated and forward-looking approach to ethical governance. Malaysia must move beyond merely having guidelines towards developing a comprehensive national bioethics ecosystem that is robust and competitive at both regional and global levels. Several key strategies can be implemented as follows:

a. Development of National Bioethics Governance and Policy Model

A National Bioethics Governance Model, based on local cultural values and aligned with international standards such as the UNESCO and WHO, should be developed. This model must be translated into strong policies and regulations, as well as enforceable guidelines. This could strengthen stakeholder's confidence and enhance the credibility of Malaysia's biotechnology system.

b. Strengthening Ethical Capacity and Innovation Ecosystem

Investment should be increased in human capital development, specialist training, interdisciplinary research and bioethics support infrastructure. A dedicated fund should be established to support social impact studies, the development of responsive ethical frameworks and the implementation of continuous monitoring systems.

c. Integration of Digitalisation and Technological Innovation in Ethics Governance

The adoption of technologies such as artificial intelligence (AI) and blockchain can improve the efficiency of bioethics governance. Monitoring, reporting and evaluation systems can be enhanced through digital platforms that are transparent, integrated and accessible to various parties.

d. Research, Publication and Academic Promotion

Efforts to strengthen local bioethics discourse need to be implemented through increased academic publications, support for interdisciplinary research and publication of specialised (specific) journals. Bioethics sections can also be created in the existing local science journals.

e. Regional Cooperation and Science Diplomacy

Malaysia can play an active role in shaping the bioethics framework in the ASEAN region, including sharing best practices, creating joint declarations and strengthening its position as a regional bioethics reference centre. A role in international forums will position Malaysia within the global dialogue on contemporary bioethics issues.

Overall, this guideline acts as a crucial foundation in Malaysia's effort to foster an ethical, innovative, safe, and globally competitive biotechnology ecosystem. By implementing the outlined ethical principles and garnering ongoing support from various stakeholders, Malaysia can (has the potential to) develop a biotechnology landscape that respects local cultural and religious values, is socially and environmentally sustainable, and gains international respect. It is hoped that these guidelines will serve as the key reference in guiding the responsible development and utilisation of biotechnology for the well-being of society and the country's future.

REFERENCES

REFERENCES

Affendi, A. R., Yaakob, E., & Abd Halim, A. H. (2022). The roles of Halal Executive in Halal food industry. *Journal of Fatwa Management and Research*, 27(2-SE), 196–208.

al-Bar, M. A., & Chamsi-Pasha, H. (2015). *Contemporary bioethics: Islamic perspective*. Springer Open.

Assidi, M., Buhmeida, A., & Budowle, B. (2022). Medicine and health of 21st Century: Not just a high biotech-driven solution. *NPJ Genomic Medicine, 7*(1), 67.

Asveld, L., Osseweijer, P., & Posada, J. A. (2019). Societal and ethical issues in industrial biotechnology. *Advances in Biochemical Engineering/Biotechnology, 173*, 121–142.

Ayangbenro, A. S., & Babalola, O. O. (2017). A new strategy for heavy metal polluted environments: A review of microbial biosorbents. *International Journal of Environmental Research and Public Health, 14*(1), 94.

Baillie, L., Dyson, H., & Simpson, A. (2012). Dual use of biotechnology. In R. Chadwick (Ed.), *Encyclopedia of applied ethics* (2nd ed., pp. 876–883). Academic Press.

Beauchamp, T. L. (2016). Principlism in bioethics. In *Bioethical decision making and argumentation* (pp. 1–16). Springer.

Bekpayeva, Z. (2025). Corporate governance in agricultural holdings: Ensuring transparency and efficiency in management decisions. *Scientific Horizons, 28*(3), 133–145.

Benner, S., & Sismour, A. (2005). Synthetic biology. *Nature Reviews Genetics, 6*(7), 533–543.

Carus, M., & Dammer, L. (2018). The “circular bioeconomy”-Concepts, opportunities and limitations. *nova-Institut GmbH*.

Chamsi-Pasha, H., & al-Bar, M. A. (2013). Western and Islamic bioethics: How close is the gap? *Avicenna Journal of Medicine, 3*(1), 8–14.

Chen, C., & Reniers, G. (2020). Risk assessment of processes and products in industrial biotechnology. *Advances in Biochemical Engineering/Biotechnology, 173*, 255–279.

Chukwuneke, F., Umeora, O., Maduabuchi, J., & Egbunike, N. (2014). Global bioethics and culture in a pluralistic world: How does culture influence bioethics in Africa? A*nnals of Medical and Health Sciences Research, 4*(5), 672–675.

Clark, D. P., & Pazdernik, N. J. (2016). Protein engineering. In D. P. Clark & N. J. Pazdernik (Eds.), *Biotechnology* (2nd ed., pp. 365–392). Academic Cell.

Dai, X., & Shen, L. (2022). Advances and trends in omics technology development. *Frontiers in Medicine*, 9, 911861.

Dale, B. E. (2003). "Greening" the chemical industry: Research and development priorities for biobased industrial products. *Journal of Chemical Technology and Biotechnology, 78*(10), 1093–1103.

Danielson, N., McKay, S., Bloom, P., Dunn, J., Jakel, N., Bauer, T., Hannon, J., Jewett, M., & Shanks, B. (2020). Industrial biotechnology—An industry at an inflection point. *Industrial Biotechnology*, 16(6), 321–332.

De Mora, F. (2015). Biosimilar: What it is not. *British Journal of Clinical Pharmacology, 80*(5), 949–956.

Degerliyurt, K., Gunsolley, J. C., & Laskin, D. M. (2010). Informed consent: What do patients really want to know? *Journal of Oral and Maxillofacial Surgery, 68*(8), 1849–1852.

Frankena, W. K. (1973). *Ethics* (2nd ed.). Prentice-Hall.

Fuentes-Arderiu, X. (2013). What is a biomarker? It's time for a renewed definition. *Clinical Chemistry and Laboratory Medicine, 51*(9), 1689–1690.

Gjerris, M., Gamborg, C., & Röcklinsberg, H. (2016). Ethical aspects of insect production for food and feed. *Journal of Insects as Food and Feed, 2*(2), 101–110.

Guin, D., Thakran, S., Singh, P., Ramachandran, S., Hasija, Y., & Kukreti, R. (2021). Translational biotechnology: A transition from basic biology to evidence-based research. In Y. Hasija (Ed.), *Translational biotechnology: A journey from laboratory to clinics* (pp. 3–24). Academic Press.

Gupta, A., & Chaphalkar, S. R. (2016). Role of biotechnology in human health care. *Emergent Life Sciences Research, 2*, 67–72.

Hall, A., Sulaiman, V. R., Yoganand, B., & Clark, N. (2003). Post-harvest innovation systems in South Asia: Research as capacity development and its prospects for impact on the poor in developing countries. *Outlook on Agriculture, 32*(2), 97–104.

Harrison, M. (2008). Applying bioethical principles to human biomonitoring. *Environmental Health*, 7(Suppl 1), S8.

Henderson, L. M. (2005). Overview of marker vaccine and differential diagnostic test technology. *Biologicals, 33*(4), 203–209.

Herdt, R. W. (2006). Biotechnology in agriculture. *Annual Review of Environment and Resources, 31*(1), 265–295.

Hill, R., Moran, M., Cook, T., Jones, R. V., Sharkey, N., Sturgis, P., Calvert, J., Edgerton, D., Holm, S., Keshavarz-Moore, E., Stirling, A., & Tylecote, A. (2012). *Emerging biotechnologies: Technology, choice and the public good*. Nuffield Council on Bioethics.

Ibrahim, A. H. (2022). *Bioetika Islam: Pendekatan berasaskan Maqasid Syariah*. Penerbit Universiti Malaya.

International Bioethics Committee. (2021). *Report of the International Bioethics Committee (IBC) on the principle of protecting future generations.* UNESCO.

Iserson, K. V. (2022). Applying bioethics across cultures. *The Journal of Emergency Medicine, 62*(3), 413–421.

Koplin, J. J., Gyngell, C., & Savulescu, J. (2019). Germline gene editing and the precautionary principle. *Bioethics, 34*(1), 49–59.

Kuhse, H., & Singer, P. (2009). What is bioethics? A historical introduction. In H. Kuhse & P. Singer (Eds.), *A companion to bioethics* (pp. 1–11). Blackwell.

Kumar, B., & Verma, P. (2021). Biomass-based biorefineries: An important archetype towards a circular economy. *Fuel, 288*, 119622.

Lähteenmäki-Uutela, A., et al. (2021). Alternative proteins and EU food law. *Food Control, 130*, 108336.

Li, T., Yang, Y., Qi, H., et al. (2023). CRISPR/Cas9 therapeutics: Progress and prospects. *Signal Transduction and Targeted Therapy, 8*, 36.

Liu, C., Li, N., Niu, L., Li, X., Feng, J., & Liu, Z. (2025). Eco-friendly smart packaging film with high thermal stabilities, antibacterial activities, and food freshness monitoring. *Food and Bioprocess Technology, 18*(2), 1549–1562.

Ma, Q. P. (2021). Biotechnology: Recent developments, emerging trends, and implications for business. In A. Hooke (Ed.), *Technological breakthroughs and future business opportunities in education, health, and outer space* (pp. 112–132). IGI Global.

Madhavan, M., & Mustafa, S. (2023). Systems biology–The transformative approach to integrate sciences across disciplines: Systems biology: Integrating biological sciences. *Physical Sciences Reviews, 8*(9), 2523–2545.

Malod-Dognin, N., Petschnigg, J., & Pržulj, N. (2018). Precision medicine-A promising, yet challenging road lies ahead. *Current Opinion in Systems Biology*, 7, 1–7.

Mandal, J., Ponnambath, D. K., & Parija, S. C. (2017). Bioethics: A brief review. *Tropical Parasitology, 7*(1), 5–7.

Meijboom, F. L., & Stafleu, F. R. (2016). Farming ethics in practice: From freedom to professional moral autonomy for farmers. *Agriculture and Human Values, 33*(3), 403–414.

Méjécase, C., Malka, S., Guan, Z., Slater, A., Arno, G., & Moosajee, M. (2020). Practical guide to genetic screening for inherited eye diseases. *Therapeutic Advances in Ophthalmology, 12*, 2515841420954592.

O'Malley, P., Rainford, J., & Thompson, A. (2009). Transparency during public health emergencies: From rhetoric to reality. *Bulletin of the World Health Organization, 87*(8), 614–618.

Opara, U. L. (2024). Prospects for agricultural, biosystems, and biological engineering education and research for knowledge-intensive, data-driven, climate-smart, and sustainable agriculture. In *Agricultural, biosystems, and biological engineering education* (pp. 560–568). CRC Press.

Pardi, N., Hogan, M., Porter, F., et al. (2018). mRNA vaccines-A new era in vaccinology. *Nature Reviews Drug Discovery, 17*, 261–279.

Park, S. S. (2018). The challenge to gene patents as feminist patent litigation. *Technology & Innovation, 19*(4), 659–670.

Prakash, D., Verma, S., Bhatia, R., & Tiwary, B. N. (2011). Risks and precautions of genetically modified organisms. *ISRN Biotechnology, 2011*, 1–13.

Pretty, J. (2008). Agricultural sustainability: Concepts, principles and evidence. *Philosophical Transactions of the Royal Society B: Biological Sciences, 363*(1491), 447–465.

Razavi, M. A., & Alebouyeh, A. (2021). Genetically modified foods and principle beneficence. *Ethical Reflections, 2*(1), 26–44.

Robinson, D. (2010). *Confronting biopiracy: Challenges, cases and international debates*. Routledge.

Rossino, G., Robescu, M., Licastro, E., Tedesco, C., Martello, I., Maffei, L., Vincenti, G., Bavaro, T., & Collina, S. (2022). Biocatalysis: A smart and green tool for the preparation of chiral drugs. *Chirality, 34*(11), 1403–1418.

Ryan, M. (2023). The social and ethical impacts of artificial intelligence in agriculture: Mapping the agricultural AI literature. *AI & Society, 38*, 2473–2485.

Soetaert, W., & Vandamme, E. (2006). The impact of industrial biotechnology. *Biotechnology Journal, 1*(7–8), 756–769.

Sugarman, J., Clark, A., Fishkin, J., Kato, K., McCormack, K., Munsie, M., Peluso, M., René, N., & Solomon, S. (2023). Critical considerations for public engagement in stem cell-related research. *Stem Cell Reports, 18*(2), 420–426.

Süntar, I., Çetinkaya, S., Haydaroğlu, Ü. S., & Habtemariam, S. (2021). Bioproduction process of natural products and biopharmaceuticals: Biotechnological aspects. *Biotechnology Advances, 50*, 107768.

Tait, J., Wield, D., Bruce, A., & Chataway, J. (2007). *Health biotechnology to 2030*. OECD International Futures Project on 'The Bioeconomy to 2030'.

Tang, W. L., & Zhao, H. (2009). Industrial biotechnology: Tools and applications. *Biotechnology Journal, 4*(12), 1725–1739.

Tarannum, S., Jalal, M. S., & Huda, M. N. (2024). HALALCheck: A multi-faceted approach for intelligent halal packaged food recognition and analysis. *IEEE Access*.

Thomas, T. A., & Reed, P. A. (2020). Ethics: A historical perspective. In K. Mazur & S. Berg (Eds.), *Ethical issues in pediatric hematology/oncology*. Springer.

UNESCO. (1997). *Records of the General Conference, 29th session, Paris, 21 October to 12 November 1997, v. 1: Resolutions*.

van der Burg, S., Giesbers, E., Bogaardt, M., Ouweltjes, W., & Lokhorst, K. (2024). Ethical aspects of AI robots for agri-food: A relational approach based on four case studies. AI & Society, 39, 541–555.

Wirth, T., Parker, N., & Ylä-Herttuala, S. (2013). History of gene therapy. *Gene, 525*(2), 162–169.

Xue, Y., Yu, H., & Qin, G. (2021). Towards good governance on dual-use biotechnology for global sustainable development. *Sustainability, 13*(24), 14056.

Yaashikaa, P. R., Kumar, P. S., & Varjani, S. (2022). Valorization of agro-industrial wastes for biorefinery process and circular bioeconomy: A critical review. *Bioresource Technology, 343*, 126126.

Yoo, Y. J., Feng, Y., Kim, Y. H., & Yagonia, C. F. J. (2017). *Fundamentals of enzyme engineering*. Springer.

Zahavi, D., & Weiner, L. (2020). Monoclonal antibodies in cancer therapy. *Antibodies, 9*(3), 34.

Zeb, A., Rana, I., Choi, H. I., Lee, C. H., Baek, S. W., Lim, C. W., Khan, N., Arif, S. T., Sahar, N. U., Alvi, A. M., Shah, F. A., Din, F. U., Bae, O. N., Park, J. S., & Kim, J. K. (2020). Potential and applications of nanocarriers for efficient delivery of biopharmaceuticals. *Pharmaceutics, 12*(12), 1184.

APPENDICES

APPENDICES

Appendix 1: List of Stakeholders in Biotechnology Ethics in Malaysia

No.	Category	List of Stakeholders
1.	Ministries and Government Agencies	i. Ministry of Science, Technology and Innovation ii. Ministry of Health of Malaysia iii. Ministry of Plantation and Commodities iv. Ministry of Agriculture and Food Security v. Ministry of Natural Resources and Environmental Sustainability vi. Ministry of Tourism, Arts and Culture Malaysia vii. Ministry of Higher Education viii. Department of Veterinary Services ix. Department of Biosafety x. Department of Agriculture xi. Department of Islamic Development Malaysia (JAKIM) xii. Educational Policy Planning and Research Division, Ministry of Education Malaysia xiii. Biodiversity and Forestry Management Division, Ministry of Natural Resources and Environmental Sustainability xiv. National Institutes of Biotechnology Malaysia (NIBM) xv. Malaysian Vaccine Development Project Management Office, MOSTI xvi. Malaysian Nuclear Agency xvii. Malaysian Research Accelerator for Technology & Innovation (MRANTI) xviii. National Institute of Health xix. Institute for Public Health xx. Sabah Biodiversity Centre xxi. Biotechnology and Nanotechnology Research Centre, MARDI xxii. Institute for Medical Research (IMR) xxiii. Institute For Health Systems Research (IHSR), National Institutes of Health (NIH), Ministry of Health Malaysia xxiv. Food Safety and Quality Division, Ministry of Health Malaysia xxv. Malaysian Palm Oil Board (MPOB) xxvi. Malaysian Institute of Integrity (IIM) xxvii. Northern Corridor Implementation Authority (NCIA) xxviii. East Coast Economic Region Development Council (ECERDC)

No.	Category	List of Stakeholders
2.	Higher Learning Institutions	Most universities in Malaysia, both public and private, have researchers and educators specialising in research ethics, bioethics and related laws. These include: i. Universiti Malaya (UM) ii. Universiti Kebangsaan Malaysia (UKM) iii. Universiti Sains Malaysia (USM) iv. Universiti Putra Malaysia (UPM) v. Universiti Teknologi MARA (UiTM) vi. Monash University Malaysia (MUM) vii. International Medical University (IMU)
3.	Industry Players	Industry players are key stakeholders as they are directly involved in researching and developing biotechnology products. Among the biotechnology industry players in Malaysia are: i. Kelantan Biotech Corporation ii. Malaysian Bioeconomy Development Corporation Sdn. Bhd. iii. Invest Selangor Berhad iv. Federation of Malaysian Manufacturers Malaysian Food Manufacturing Group (FMM MAFMAG) v. Melaka Biotechnology Corporation
4.	Professional and Regulatory Bodies	Professional and regulatory bodies include: i. Genetics Society of Malaysia ii. National Pharmaceutical Regulatory Agency iii. Medical Research Ethics (MREC), Ministry of Health Malaysia iv. Medical Device Authority (MDA) v. Malaysian Medical Council (MMC) vi. Malaysian Medical Association (MMA) vii. Malaysian Society for Molecular Biology and Biotechnology (MSMBB) viii. Malaysian Society for Microbiology ix. Malaysian Society for Stem Cell Research and Therapy
5.	Healthcare Providers	i. Public hospitals and medical centres ii. Private hospitals and medical centres iii. Clinical Ethics Committee (CEC)
6.	Religious and Community Institutions	These include: i. Institute of Islamic Understanding Malaysia (IKIM) ii. Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism (MCCBCHST) iii. Malaysian Dhammaduta Association iv. The Spritual Assembly of the Baha'is of Malaysia
7.	Non-Governmental Organisations (NGOs)	These include: i. Malaysian Rare Disorders Society ii. Federation of Malaysian Consumers Associations (FOMCA) iii. Clinical Ethics Malaysia (CEM)

Note: The list in this table is not exhaustive and may be improved or expanded from time to time.

Appendix 2: List of Taskforce Members for the Biotechnology Ethics Guidelines in Malaysia

No.	Name
1.	**Dr. Ami Fazlin binti Syed Mohamed** Director Institute for Medical Research (IMR) National Institutes of Health (NIH) Ministry of Health Malaysia (MOH)
2.	**Dr. Mohana Anita Anthonysamy** Principal Assistant Director Evaluation and Research Section Department of Biosafety (JBK) Ministry of Natural Resources and Environmental Sustainability (NRES)
3.	**Dr. Shazwan bin Abd Shukor** Senior Research Officer Agro-Nanotechnology Programme Biotechnology and Nanotechnology Research Centre Malaysian Agricultural Research and Development Institute (MARDI) Ministry of Agriculture and Food Security (KPKM)
4.	**Dr. Shaikh Mohd Saifuddeen bin Shaikh Mohd Salleh** Director of Research Research Management Unit (RMU) Institute of Islamic Understanding Malaysia (IKIM)
5.	**Mrs Ernie Muneerah binti Mohd Adhan** Research Officer, Veterinary Research Division Department of Veterinary Services (DVS) Ministry of Agriculture and Food Security (MAFS)
6.	**Prof. Datuk Wira Dr. Raha binti Abdul Rahim** Chief Executive Officer National Institutes of Biotechnology Malaysia (NIBM)
7.	**Prof. Dato' Dr. Abu Bakar bin Abdul Majeed** Dean Faculty of Pharmacy Universiti Teknologi Mara (UiTM)
8.	**Assoc. Prof. Dr. Nor Azwady bin Abd Aziz** Dean Faculty of Science Universiti Putra Malaysia (UPM)

No.	Name
9.	**Prof. Dr. D Ravichandran K Dhakshinamoorthy** Professor Programme of Strategy and International Relations Research Centre for History, Politics & International Affairs (SPHEA) Faculty of Social Sciences and Humanities Universiti Kebangsaan Malaysia (UKM)
10.	**Assoc. Prof. Dr. Aimi Nadia binti Mohd Yusof** Medical Lecturer and Head of Department Department of Medical Ethics & Law (MELD) Faculty of Medicine Universiti Teknologi Mara (UiTM)
11.	**Dr. Lim Joo Kiong** Council Member & Chairperson of Ethics Committee Malaysian Medical Council (MMC)
12.	**Assoc. Prof. Dr. Mark Tan Kiak Min** Chairperson of Ethics Committee Malaysian Medical Association (MMA) Associate Professor of Medical Ethics Jeffrey Cheah School of Medicine & Health Sciences Monash University Malaysia
13.	**Dr. Tan Hui Siu** Head of Ethics Support Ampang Hospital (SEHA) Co-Chairperson, Clinical Ethics Committee (CEC), Ampang Hospital
14.	**Archbishop Julian Leow Beng Kim** Vice President Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism (MCCBCHST)
15.	**Dr. Nurain binti Mohd Noor** Chairperson Medical Research & Ethics Committee (MREC) Ministry of Health Malaysia (MOH) Head of Department Clinical Research Centre Hospital Putrajaya

No.	Secretariat
1.	**Datuk Seri Hj. Hasnol Zam Zam bin Hj. Ahmad** Secretary-General Ministry of Science, Technology and Innovation (MOSTI)
2.	**Datuk Ts. Dr. Mohd Nor Azman bin Hassan** Deputy Secretary-General (Technology Development) Ministry of Science, Technology and Innovation (MOSTI)
3.	**Ms. Aidawati binti Misdar** Undersecretary Strategic Technology and S&T Application Division (TSA) Ministry of Science, Technology and Innovation (MOSTI)
4.	**Ts. Dr. Radin Zulhazmi bin Radin Abdul Halim** Undersecretary II Strategic Technology and S&T Application Division (TSA) Ministry of Science, Technology and Innovation (MOSTI)
5.	**Ms. Siti Zuhaini binti Abd Samah** Principal Assistant Secretary Strategic Technology and S&T Application Division (TSA) Ministry of Science, Technology and Innovation (MOSTI)
6.	**Ms. Nurul Hasniza binti Kamaruddin** Senior Assistant Secretary Strategic Technology and S&T Application Division (TSA) Ministry of Science, Technology and Innovation (MOSTI)
7.	**Miss Nur Adilla binti Che Rosmi** MySTEP Personnel Strategic Technology and S&T Application Division (TSA) Ministry of Science, Technology and Innovation (MOSTI)

Appendix 3: List of Participants of the Engagement Session for the Development of Biotechnology Ethics Guidelines in Malaysia

Date : 18 June 2025 (Wednesday)
Location : Banquet Hall,
Persatuan Alumni Universiti Malaya Clubhouse,
Kuala Lumpur

Group 1

Moderator : Dr. Mohammad Firdaus Abdul Aziz
Rapporteur : 1. Mr. Iqbal Hakim Abd Razak
2. Mr. Wellester Anak Alvis

No.	Name	Organisation
1.	Dr. Kumitaa Theva Das	Advanced Medical and Dental Institute, Universiti Sains Malaysia
2.	Dr. Le Cheng Foh	School of Biosciences, Faculty of Science, University of Nottingham Malaysia Campus
3.	Prof. Dr. Lionel In Lian Aun	UCSI University
4.	Dr. Zainah Adam	Malaysia Nuclear Agency
5.	Assoc. Prof. Dr. Nazlina Ibrahim	Faculty of Science and Technology, Universiti Kebangsaan Malaysia
6.	Ts. Dr. Saiful Effendi Syafruddin	UKM Medical Molecular Biology Institute (UMBI)
7.	Dr. Nur Kusaira Khairul Ikram	Biotechnology Programme, Institute of Biological Sciences, Universiti Malaya
8.	Prof. Datuk Wira Dr. Raha Abdul Rahim	National Institutes of Biotechnology Malaysia (NIBM)
9.	Assoc. Prof. Dr. Syahida Ahmad	Faculty of Biotechnology and Biomolecular Sciences, Universiti Putra Malaysia
10.	Assoc. Prof. Dr. Sharon Kaur Gurmukh Singh	Southeast Asian Bioethics Network, Universiti Malaya
11.	Assoc. Prof. Dr. Wong Chiew Yen	International Medical University (IMU) University
12.	Dato' Prof. Dr. Noor Inayah Binti Ya'akub	International College University of MAIWP

Group 2

Moderator : Dr. Abdul Halim Ibrahim
Rapporteur : 1. Dr. Fatin Nur Majdina Nordin
2. Miss Elliyyan Mizati Mohd Ismail

No.	Name	Organisation
1.	Assoc. Prof. Dr. Aimi Nadia Mohd Yusof	Department of Medical Ethics and Law, Universiti Teknologi MARA
2.	Dr. Amnah binti Azahar	Department of Medical Ethics and Law, Universiti Teknologi MARA
3.	Dr. Asmah Ismail	Faculty of Educational Studies, Universiti Putra Malaysia
4.	Dr. Astrid Sinarti Hassan	Department of Medical Ethics and Law, Universiti Teknologi MARA
5.	Dr. Kuek Chee Ying	Faculty of Law, Universiti Malaya
6.	Prof. Dr. Lee Ping Chin	Biotechnology Research Institute, Universiti Malaysia Sabah
7.	Mr. Mohd A'imullah bin Azmi	IIUM Research Ethics Committee, International Islamic University Malaysia (IIUM)
8.	Prof. Dr. Nasser Muhammad Amjad	IIUM Research Ethics Committee (IREC)
9.	Ms. Natrah Farhana binti Abd Rahman	Sabah Biodiversity Centre
10.	Assoc. Prof. Dr. Sarina Sulong	Human Genome Centre, School of Medical Sciences, Universiti Sains Malaysia (USM)
11.	Dr. Shazwan Abd Shukor	Biotechnology and Nanotechnology Research Centre, MARDI
12.	Ts. Dr. Mohd Ibrahim Shapiai@ Abd. Razak	Centre for Artificial Intelligence and Robotics (CAIRO) Universiti Teknologi Malaysia
13.	Prof. Dr. Abd Rahman Milan	Genetics Society of Malaysia
14.	Miss Siti Nahdatul Isnaini Said Hussin	Agro-Biotechnology Institute, National Institutes of Biotechnology Malaysia (ABI-NIBM)

Group 3

Moderator : Dr. Suzana Ariff Azizan
Rapporteur : Miss Kumararoobini Poobalan

No.	Name	Organisation
1.	Dr. Yuslina binti Mat Yusoff	Institute for Medical Research (IMR)
2.	Mr. Fathullah Iqbal Ab Rahim	Institute For Health Systems Research (IHSR), National Institutes of Health (NIH), MOH
3.	Ms Melanie Hassim	National Pharmaceutical Regulatory Agency
4.	Mr. Mohd Zawawi bin Mohamad	Malaysian Vaccine Development Project Management Office, MOSTI
5.	Ms. Norazlina Noordin	Malaysia Nuclear Agency
6.	Ms. Norfarah Syaqirah binti Lasri	Sabah Biodiversity Centre
7.	Dr. Rohana binti Abu Bakar	Department of Veterinary Services
8.	Mr. Mohd Firdaus bin Md Kamal	Biomass and Biofuel Division, Ministry of Plantation and Commodities
9.	Dr. Siti Hafizah binti Zulkiply	Institute for Public Health
10.	Ms. Siti Norafizan binti Jalaluddin	Educational Policy Planning and Research Division, Ministry of Education Malaysia
11.	Dr. Sri Devi Sukumaran	National Institutes of Health
12.	Ms. Zurinawati Zainal Abidin	East Coast Economic Region Development Council (ECERDC)
13.	Miss Teoh En Wan	Ministry of Agriculture and Food Security
14.	Dr. Nurain binti Mohd Noor	Medical Research and Ethic Committee (MREC), Ministry of Health Malaysia
15.	Dr. Khairul Naim bin Adham	Biodiversity and Forestry Management Division, Ministry of Natural Resources and Environmental Sustainability (NRES)
16.	Mr. Mohamed Anas bin Mohd Akdi	Ministry of Natural Resources and Environmental Sustainability (NRES)

Group 4

Moderator : Dr. Noor Munirah Isa
Rapporteur : Miss Siti Nurliyana Shaikh Mohd Salleh

No.	Name	Organisation
1.	Ms. Nur Syafura binti Ariffin	Medical Device Agency (MDA)
2.	Dr. Khasnur Abd Malek	Research Ethics Committee (JEP), UiTM
3.	Dr. Lim Joo Kiong	Malaysian Medical Council (MMC)
4.	Assoc. Prof. Dr. Mark Tan Kiak Min	(i) Ethics Committee, Malaysian Medical Association (MMA) (ii) Jeffrey Cheah School of Medicine, Monash University Malaysia
5.	Prof. Dr. Nik Sherina Haidi binti Hanafi	Universiti Malaya Medical Centre-Medical Research Ethics Committee (UMMC-MREC)
6.	Assoc. Prof. Ts. Dr. Noor Faizul Hadry bin Nordin	International Islamic University Malaysia (IIUM)
7.	Ms Nor Farah Dina binti Paddy	Department of Biosafety, NRES
8.	Dr. Quek Kia Fatt	Sunway Medical Centre
9.	Ms. Siow I Rene	Department of Agriculture
10.	Dr. Tan Hui Siu	Ministry of Health
11.	Dr. Taqwa binti Zabidi	Department of Islamic Development Malaysia (JAKIM)
12.	Dr. Mah Kar Yee	Medical Research and Ethic Committee (MREC), Ministry of Health, Malaysia
13.	Mr. Jayappragas Muthuveeroo	Ministry of Tourism, Arts and Culture, Malaysia
14.	Mr. Muhammad Winal Zikril	Ministry of Higher Education, Malaysia
15.	Ms. Nur Syaza Mohamad Robani	Medical Device Agency (MDA)

Group 5

Moderator : Prof. Dr. Rofina Yasmin Othman
Rapporteur : 1. Miss Nurulain Natasha Muhammad Aris Fadzilah
2. Miss Nur Amirah binti Mohamed Nasir

No.	Name	Organisation
1.	Ms. Krisna Veni Balakrishnan	Subang Jaya Medical Centre (SJMC)
2.	Mr. Muhamad Rizal bin Mohd Merican	Northern Corridor Implementation Authority
3.	Mr. Mohd Afzanizan Arif	Kelantan Biotech Corporation
4.	Ms. Nora Mohamed	Malaysian Bioeconomy Development Corporation Sdn Bhd
5.	Ms. Nur Khaliesah Abdol Alim	Invest Selangor Berhad
6.	Mr. Ong Chun Hung	Malaysian Research Accelerator for Technology and Innovation (MRANTI)
7.	Dr. Benjamin Lau Yii Chung	Malaysian Palm Oil Board (MPOB)
8.	Ms. Renuga Prabhakaran	Federation of Malaysian Manufacturers (FMM)
9.	Assoc. Prof. Dr. Michelle Teo Yee Mun	Malaysian Society for Molecular Biology and Biotechnology (MSMBB)
10.	Dr. Tan Sik Loo	Malaysian Society for Stem Cell Research and Therapy
11.	Ms. Tee Mei Ghee	Melaka Biotechnology Corporation
12.	Ms. Zainal Azman bin Abu Kasim	Northern Corridor Implementation Authority (NCIA)

Group 6

Moderator : Dr. Mohd Salim Mohamed
Rapporteur : 1. Dr. Maisarah Hasbullah
2. Miss Nur Lisa Mohd Yusoff

No.	Name	Organisation
1.	Dr. Ahmad Firdhaus bin Arham	School of Liberal Studies, Universiti Kebangsaan Malaysia (CITRA-UKM)
2.	Ms. Cathryn Anila	Bahá'í International Community
3.	Mr. Chang Lee Wei	Universiti Malaya (Centre for Civilisational Dialogue)
4.	Assoc. Prof. Dr. Charanjit Kaur	Universiti Tunku Abdul Rahman (UTAR)
5.	Ms. Chia Ee Vy	Sunway Medical Centre
6.	Dato' Prof. Dr. Christopher Boey Chiong Meng	International Medical University (IMU)
7.	Dr. Faathirah binti Jamaluddin	Malaysian Institute of Integrity (IIM)
8.	Ms. Mariammah Subramaniam	Bahá'i Community of Malaysia
9.	Ms. Nadiah Hanim Abdul Latif	Malaysian Rare Disorders Society
10.	Ms. Nur Asyikin binti Aminuddin	Federation of Malaysian Consumers Associations (FOMCA)
11.	Dr. Muhammad Husni bin Mohd Amin	Institute of Islamic Understanding Malaysia
12.	Ms. Suzana binti Md Samsudi	Institute of Islamic Understanding Malaysia
13.	Mr. Thai Ming Yeow	Malaysian Dhammaduta Association
14.	Dr. Mahaletchumy Arujanan	Malaysian Biotechnology Information Centre
15.	Ms. Priyadarshini Subramaniam	Sunway Medical Centre

Appendix 4: List of Participants of the Validation Session for the Development of Biotechnology Ethics Guidelines in Malaysia

Date : 11 July 2025 (Friday)
Platform : online

Group 1

No.	Name	Organisation
1.	Dr. Kumitaa Theva Das	Advanced Medical and Dental Institute, Universiti Sains Malaysia
2.	Dr. Le Cheng Foh	School of Biosciences, Faculty of Science, University of Nottingham Malaysia Campus
3.	Prof. Dr. Lionel In Lian Aun	UCSI University
4.	Assoc. Prof. Dr. Nazlina Ibrahim	Faculty of Science and Technology, Universiti Kebangsaan Malaysia
5.	Ts. Dr. Saiful Effendi Syafruddin	UKM Medical Molecular Biology Institute (UMBI)
6.	Assoc. Prof. Dr. Syahida Ahmad	Faculty of Biotechnology and Biomolecular Sciences, Universiti Putra Malaysia
7.	Assoc. Prof. D.r Wong Chiew Yen	IMU University
8.	Dr. Amnah binti Azahar	Department of Medical Ethics and Law, Universiti Teknologi MARA
9.	Mr. Mohd A'imullah bin Azmi	IIUM Research Ethics Committee, IIUM
10.	Ms. Natrah Farhana binti Abd Rahman	Sabah Biodiversity Centre
11.	Dr. Shazwan Abd Shukor	Biotechnology and Nanotechnology Research Centre, MARDI
12.	Ts. Dr. Mohd Ibrahim Shapiai@ Abd. Razak	Centre for Artificial Intelligence and Robotics (CAIRO) Universiti Teknologi Malaysia
13.	Prof. Dr. Abd Rahman Milan	Genetics Society of Malaysia
14.	Dr. Phang Kean Chang (absent)	Medical Research Ethics Unit, Universiti Malaya Medical Centre Senior Research Fellow, Global Health Bioethics Network
15.	Dr. Rogayah Sekeli	Principal Research Officer Q14, Biotechnology and Nanotechnology Research Centre, MARDI
16.	Assoc. Prof. Dr. Norhasnida Zawawi	Head of Laboratory, Faculty of Food Science and Technology, Universiti Putra Malaysia
17.	Ts. Dr. Zarani Mat Taher	Advanced Membrane Technology Research Centre, Universiti Teknologi Malaysia
18.	Mr. Muhd Hanis	UiTM

Group 2:

No.	Name	Organisation
1.	Mr. Fathullah Iqbal Ab Rahim	Institute For Health Systems Research (IHSR), National Institutes of Health (NIH), MOH
2.	Ms. Norazlina Noordin	Malaysia Nuclear Agency
3.	Ms. Norfarah Syaqirah binti Lasri	Sabah Biodiversity Centre
4.	Ms. Natrah Farhana Abd Rahman	Sabah Biodiversity Centre
5.	Mr. Mohd Firdaus bin Md Kamal	Biomass and Biofuel Division, Ministry of Plantation and Commodities
6.	Dr. Siti Hafizah binti Zulkiply	Institute for Public Health
7.	Ms. Siti Norafizan binti Jalaluddin	Educational Policy Planning and Research Division, Ministry of Education, Malaysia
8.	Dr. Sri Devi Sukumaran	Institute for Health Management (IHM), National Institutes of Health
9.	Miss Teoh En Wan	Ministry of Agriculture and Food Security
10.	Dr. Khasnur Abd Malek	Research Ethics Committee (JEP), UiTM
11.	Dr. Alex Phang	UMMC MREC
12.	Assoc. Prof. Ts. Dr. Noor Faizul Hadry Bin Nordin	International Islamic University Malaysia
13.	Mr. Edwin Tan	Sunway Medical Centre
14.	Dr. Taqwa binti Zabidi	Department of Islamic Development Malaysia
15.	Dr. Mah Kar Yee	NIH (MREC)
16.	Mr. Jayappragas Muthuveeroo	Ministry of Tourism, Arts and Culture
17.	Ms. Nur Syaza Mohamad Robani	Medical Device Authority (MDA)
18.	Ms. Muhaida Mohammad	Department of Agriculture
19.	Dr. Syamsiah Abdul Ghani	Department of Veterinary Services
20.	Dr. Ifrah Harun	Ministry of Agriculture and Food Security
21.	Dr. Samsulida Abd Rahman	SIRIM Berhad
22.	Dr. Chai Ting Lee	Forest Research Institute Malaysia (FRIM)

Group 3:

No.	Name	Organisation
1.	Ms. Krisna Veni Balakrishnan	Subang Jaya Medical Centre (SJMC)
2.	Mr. Mohd Afzanizan Arif	Kelantan Biotech Corporation
3.	Mr. Ong Chun Hung	Malaysian Research Accelerator for Technology and Innovation (MRANTI)
4.	Dr. Benjamin Lau Yii Chung	Malaysian Palm Oil Board (MPOB)
5.	Assoc. Prof. Dr. Michelle Teo Yee Mun	Malaysian Society for Molecular Biology and Biotechnology (MSMBB)
6.	Dr. Tan Sik Loo (absent)	Malaysian Society for Stem Cell Research and Therapy
7.	Ms. Tee Mei Ghee	Melaka Biotechnology Corporation
8.	Mr. Zainal Azman bin Abu Kasim	Northern Corridor Implementation Authority (NCIA)
9.	Ms. Ruzanna Zainal	Halvec Laboratories Sdn Bhd
10.	Ms. Amy Ahmad	Malaysian Bioeconomy Development Corporation Sdn Bhd

Group 4:

No.	Name	Organisation
1.	Dr. Ahmad Firdhaus bin Arham	School of Liberal Studies, Universiti Kebangsaan Malaysia (CITRA-UKM)
2.	Ms. Cathryn Anila	Bahá'í International Community
3.	Assoc. Prof. Dr. Charanjit Kaur	Universiti Tunku Abdul Rahman (UTAR)
4.	Dr. Faathirah binti Jamaluddin	Malaysian Institute of Integrity (IIM)
5.	Ms. Mariammah Subramaniam	Bahá'i Community of Malaysia
6.	Ms. Nadiah Hanim Abdul Latif	Malaysian Rare Disorders Society
7.	Ms. Suzana binti Md Samsudi	Institute of Islamic Understanding Malaysia (IKIM)
8.	Mr. Thai Ming Yeow	Malaysian Dhammaduta Association
9.	Ms. Priyadarshini Subramaniam	Sunway Medical Centre, Research Ethics Centre
10.	Ms. Allida Muhammad Said	Malaysian Rare Disorders Society

Appendix 5: List of Consultants for the Development of Biotechnology Ethics Guidelines in Malaysia

1. Prof. Emeritus Datuk Dr. Azizan Baharuddin, Universiti Malaya (UM) (Project leader)
2. Dr. Noor Munirah Isa, UM (Assistant project leader)
3. Prof. Dr. Rofina Yasmin Othman, UM
4. Dr. Nurzatil Sharleeza Mat Jalaluddin, UM
5. Dr. Mohd Salim Mohamed, UM
6. Dr. Abdul Halim Ibrahim, UM
7. Dr. Suzana Ariff Azizan, UM
8. Dr. Mohammad Firdaus Abdul Aziz, UM
9. Dr. Angelina Patrick Olesen, UM
10. Ms. Nurmadihah Takhor, UM

KEMENTERIAN SAINS,
TEKNOLOGI DAN INOVASI
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION

Strategic Technology and S&T Application Division (TSA)
Ministry of Science, Technology and Innovation (MOSTI)
Level 3, Block C4, Complex C
Federal Government Administrative Centre
62662, Federal Territory of Putrajaya, Malaysia
Tel.: 603 – 8000 8000
E-mail: enquiry@mosti.gov.my
URL: http://www.mosti.gov.my

@mosti @mosti @MyMOSTI onemosti

ISBN 978-967-2741-26-8