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COMPARISON OF WORLDWIDE REGULATIONS AND GUIDELINES ON THE ETHICS OF MODERN BIOTECHNOLOGY

(*Perbandingan Peraturan dan Garis Panduan Mengenai Etika Bioteknologi Moden di Seluruh Dunia*)

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ABSTRACT

Modern biotechnology is one of the advanced technologies that promises many benefits for human life. However, the aggressive development in modern biotechnology has raised many issues including the effects on human health, and the impact on the environment. The ethical issues of 'playing God' on the part of scientists, and monopoly by industries have led to a great deal of controversy. The objective of this study was to analyse and compare the regulatory documents related to modern biotechnology ethics including national codes, regulations, and guidelines that have been approved and implemented globally. This study adopted a qualitative approach by carrying out content analysis of secondary documents. The results from the comparative study were discussed to determine the scope

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and comprehensiveness of the content of existing regulatory ethics documents for modern biotechnology. This study found that globally there were only seven different ethics documents related to modern biotechnology. Two documents were specific guidelines on modern biotechnology, four documents were guidelines on biomedical research, and one document focused on universal bioethics principles. One document was established as an Act while another document leveraged the associated existing gene technology legislation for effective implementation purposes. All the documents had coverage of ethical principles as the basis for decision-making on the part of modern biotechnology practitioners. There were some similarities and differences in the seven documents with respect to ethical principles, the names of sections, and the implementation procedures. Given that Malaysia still lacks ethical guidelines relating to modern biotechnology, the finding of this study is important as a reference point for policymakers in developing a comprehensive guideline.

Keywords: Modern biotechnology; ethical principles; ethical guideline; Malaysia.

ABSTRAK

Bioteknologi moden merupakan salah satu teknologi canggih yang menjanjikan pelbagai faedah kepada kehidupan manusia. Walau bagaimanapun, perkembangan bioteknologi moden yang agresif telah menimbulkan banyak isu termasuk kesan ke atas kesihatan manusia, dan kesan kepada alam sekitar. Isu etika dalam bioteknologi moden seperti 'tindakan seolah-olah Tuhan' dalam kalangan saintis, dan isu monopoli oleh pihak industri telah menimbulkan banyak kontroversi. Objektif kajian ini adalah untuk menganalisis dokumen garis panduan berkaitan etika dalam bioteknologi moden termasuklah kod, peraturan dan garis panduan yang telah diluluskan dan dilaksanakan pada peringkat global. Kajian ini menggunakan pendekatan kualitatif dengan menjalankan analisis kandungan dokumen sekunder. Hasil daripada kajian perbandingan telah dibincangkan untuk menentukan skop dan kecukupan kandungan dokumen garis panduan etika dalam bioteknologi moden sedia ada. Kajian ini mendapati bahawa hanya terdapat tujuh dokumen berkaitan dengan etika bioteknologi moden secara global. Dua dokumen adalah garis panduan khusus mengenai bioteknologi moden, empat dokumen adalah garis panduan mengenai penyelidikan bioperubatan, dan satu dokumen memberi tumpuan kepada bioetika sejagat. Satu dokumen telah diwartakan sebagai Akta manakala satu lagi dokumen perlu dibaca bersama perundangan teknologi gen sedia ada bagi memudahkan pelaksanaan. Semua dokumen mempunyai liputan prinsip etika sebagai asas untuk membuat keputusan bagi pihak pengamal bioteknologi moden. Terdapat beberapa persamaan dan perbezaan dalam tujuh dokumen berkenaan

seperti prinsip etika, nama bahagian dan prosedur pelaksanaan. Memandangkan Malaysia masih tiada garis panduan etika berkaitan bioteknologi moden, dapatan kajian ini penting sebagai titik rujukan penggubal dasar dalam membangunkan garis panduan yang komprehensif.

***Kata Kunci**: bioteknologi moden; prinsip etika; garis panduan etika; Malaysia.*

INTRODUCTION

Since it was introduced in the 1970s, modern biotechnology is considered to be a fast-evolving technology. It is a technology which is widely acclaimed in terms of improving lives in the agricultural, healthcare and industrial sectors. With the continuous growth of the world population and limited land area, modern biotechnology is the potential solution to addressing food and energy security (Sinebo & Maredia 2016). Modern biotechnology is defined by the Cartagena Protocol on Biosafety (2000) (CBD 2000) as the application of:

1. *In vitro* nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or
2. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.

Although modern biotechnology is perceived as being beneficial to society, there are concerns about its potential risks to human health and the environment (Hasim et al. 2020; Bawa & Anilakumar 2013; Prakash et al., 2011). The majority of biosafety assessments focused on safety, with only a few countries including socioeconomic impacts in their legislation (Falck-Zepada & Zambrano 2011). Biosafety assessment is deemed to be insufficient for regulating GM products because it is solely based on scientific criteria determined by scientists, and ignores the concerns of other stakeholders such as the public, farmers, owners of intellectual property rights, and others (Smyth & Phillips 2014). The regulation of modern biotechnology applications and products must accommodate both scientific assessment and socioeconomic considerations for it to be comprehensive in scope and to create a good regulatory system (Hasim 2019). However, the methodologies for assessing these two aspects will differ.

According to Amin et al. (2014), the successful adoption of GM products is influenced by societal perceptions, understanding, and the acceptance of modern biotechnology. In Malaysia, empirical evidence indicates that consumer perceptions

of the benefits and risks of GM foods are shaped by knowledge about such foods and their characteristics (Hassan et al. 2016). Modern biotechnology is a controversial topic because although it benefits both manufacturers and consumers, it also poses some potential risks to the environment and human health (Zhang et al. 2016; Hasim et al. 2019). This creates a moral quandary, and the ethics related to modern biotechnology are hotly debated all over the world (CHEMIC 2012). Modern biotechnology is linked to the ethical issue of "Playing God", which refers to humans attempting to dominate and create by producing something new, notably genetic engineering innovations, that are considered to be beyond the scope of nature (Clingerman & O'Brien 2014). Therefore, it is imperative that government regulators, scientists and industries adhere to ethical standards to ensure that the public will have the confidence to support the growth of modern biotechnology and its products (Hasim et al. 2019).

Zhang et al. (2016) also discussed the potential risks of genetically modified foodstuffs to human health and the environment. Potential health risks include the unintended production of allergens and toxins, as well as unwanted genetic changes such as pleiotropic effects during gene expression and potential interference with existing genes in targeted organisms (Zhang et al. 2016; Bawa & Anilakumar 2013; Hasim et al. 2019). The ethical implications with regard to socioeconomic effects are also debated, for example, the issues of multinational company dominance, patent issues, and patent technology that affect farmers because they rely on multinational companies (Idris et al. 2021). A number of scientists are concerned about the impact of modern biotechnology products on biological diversity. Bennet and colleagues (2013) reported the death of a Monarch butterfly after eating GM maize dust, potentially leading to the extinction of the species. This biological impact is also linked to the possibility of food chain disruption (Zhang et al. 2016). Insect resistance genes are incorporated into plants to create GM crops that are resistant to insects. This technology has the potential to alter pest species and create new predators (Bring & Anilakumar 2013; Hasim et al. 2019).

The majority of existing bioethical guidelines and regulations, such as the Nuremberg Code, the Declaration of Helsinki, and the International Ethical Guidelines for Biomedical Research involving Human Subjects, were developed to govern medical research. Biomedical research is concerned with the development of new medical techniques and drugs to treat infectious diseases and other diseases for public health systems. As a result, there is a plethora of national and international legislation, regulations, and guidelines on biomedical research ethics. It is important to distinguish between ethical guidelines for biomedical research and those for modern biotechnology research. The ethical guidelines for biomedical research focus on the relationship between doctors and patients, as well as specific subjects

of research interest (Masic, Hodzic & Mulic 2014). While the guidelines on modern biotechnology are directed towards applying bioethical principles and mitigating the risks associated with modern biotechnology applications and its products, there are only a few countries that already have ethical guidelines on modern biotechnology. These include Australia (3), South Korea (1), Singapore (1), South Africa (1) and UNESCO (1).

Malaysia still lacks a specific law or set of regulations governing the ethics of modern biotechnology. The Biosafety Act 2007, which focuses on scientific risk assessment, governs modern biotechnology applications and products in Malaysia (Hasim et al. 2019). In the 2009 Act and the Biosafety (Approval and Notifications) Regulations 2010, there is a non-mandatory provision that mentions the need to address socioeconomic aspects (Hamim & Idris 2007; Hasim 2022). However, the regulations' provisions on the protection of bioethical issues as part of socioeconomic considerations are rather ambiguous (Idris et al. 2013). The Act did not define the scope or types of bioethical issues (Idris et al. 2013; Hamin & Idris, 2011). Malaysia faces numerous challenges with regard to bioethics issues due to the lack of a legal entity regulating bioethics. To manage ethical issues relating to genetically modified organisms (GMOs), a framework for socioeconomic assessment that includes ethical considerations should be established (Hasim et al. 2021; Idris 2013).

In 2020, the Academy of Sciences Malaysia established 'The Malaysian Code of Responsible Conduct in Research' as a voluntary ethics guideline for research. However, this code of conduct is quite general for all research and not specific to modern biotechnology. Thus, this study did not include this code of conduct for analysis. There is a need to develop specific ethical guidelines or regulations for modern biotechnology in Malaysia in order to address ethical and socioeconomic issues (Amin 2009; Idris et al. 2021). A modern biotechnology ethics guideline must be developed in order to improve scientists', students', and citizens' ability to judge what is morally wrong and right in this particular technology (Abdul Majeed 2002). Moreover, biosafety evaluations should include ethical and socioeconomic considerations (Falck-Zepada & Zambrano 2011; Amin 2009; Hasim 2022). Prior to developing new ethical guidelines, the appropriate contents must be addressed. It is critical to define the scope clearly, whether inclusion is mandatory or voluntary, whether to broaden the scope to include ethical and religious considerations, to develop standard operating procedures in the method of assessment, and to have a standard timing of when the assessment will be done, whether in the lab, at the pilot or the commercial stage. It is also important to consider potential drawbacks such as increased compliance costs resulting from biosafety regulations and potential delays in the development of innovations (Idris et al. 2021; Falck-Zepada & Zambrano

2011; Zepeda et al. 2010). The goal of this paper is to review and compare the scope and content of the relevant and available regulations and guidelines on the ethics of modern biotechnology published by selected countries around the world. This study is important, particularly for Malaysian researchers and regulatory bodies interested in developing ethical guidelines for modern biotechnology in Malaysia.

METHODOLOGY

This study was conducted using the content analysis of secondary documents which helped the researchers to interpret the context of the materials used in this study (Mayring 2014). Content analysis is a research method used to systematically analyse and interpret the content of various forms of communication, such as text, audio, video, images, and more. It involves examining the content of these materials to identify patterns, themes, trends, and other meaningful insights (Kleinheksel et al. 2020). In this study, a comprehensive search of the available online data sources for regulations and guidelines relating to the ethics of modern biotechnology was undertaken using direct access to the relevant websites of various selected authority agencies. Seven documents from four countries, including three documents from Australia and one from UNESCO which cover the ethics of modern biotechnology, were retrieved. The four producing countries were Singapore, South Korea, Australia and South Africa. The focus of this study was on the contents or scope of the documents.

The approach used in this study was to compare the selected documents. Each of these documents was examined, categorised and then compared, to determine the similarity in terms of scope, format, contents and chapters. A limitation of this study was that it was based on documentation only available online. Consequently, the documents may be outdated and unrepresentative since they were from the selected institutions only.

RESULTS

This study presented the various regulations and guidelines that were available online and could be accessed by the public. Different guidelines adopted various approaches in governing modern biotechnology. Although the guidelines listed below (Table 1) are more than a decade old, they are still relevant and being used in those countries. Furthermore, the Australian Government's National Framework of Ethical Principles in Gene Technology is the latest version after it was updated in 2012. According to OECD (2010) in 'The Development of New Regulations', there is no need to update and develop new guidelines, regulations or Acts as

long as the purpose and the implementation are secured. In addition, guidelines and regulations may not be updated for several reasons, including bureaucratic hurdles, resource constraints, resistance to change, and differing priorities. As can be seen in Table 1, South Korea has enacted the Bioethics and Safety Act, of 2008, which was among the most recent of the seven documents studied on the ethics of modern biotechnology. In addition, Singapore and South Africa used the term 'Guidelines' in their respective documents, Ethical Guidelines for Gene Therapy, 2001, and General Ethical Guidelines for Biotechnology. The Australian government is the most proactive country and has issued three documents: i) The National Framework of Ethical Principles in Gene Technology (2012); ii) The Statement of Ethical Principles for Biotechnology in Victoria (2006); and iii) The Queensland Biotechnology Code of Ethics (2006). On the other hand, in an effort to govern bioethical issues in life sciences, UNESCO published the UNESCO Universal Declaration on Bioethics and Human Rights in 2005. Table 1 shows details of the various ethical guidelines discussed in this study.

TABLE 1 Details of Ethical Guidelines Worldwide

Country	Title of Guideline	Year	Authority
Singapore	Ethical Guidelines for Gene Therapy	2001	National Medical Ethics Committee, Singapore
UNESCO	The UNESCO Universal Declaration on Bioethics and Human Rights	2005	UNESCO.
Victoria, Australia	Statement of Ethical Principles for Biotechnology in Victoria, 2006	2006	Department of Health Services, Melbourne, Australia
Queensland, Australia	Queensland Biotechnology Code of Ethics	2006	Department of State Government, Queensland, Australia
South Africa	General Ethical Guidelines for Biotechnology Research	2008	Health Professions Council of South Africa
South Korea	Bioethics and Safety Act	2008	Ministry of Health, Welfare & Family Affairs, South Korea
Australia	National Framework of Ethical Principles in Gene Technology	2012	Department of Health and Ageing, Australia.

Singapore's ethical guidelines entitled "Ethical Guidelines for Gene Technology" were developed by the National Medical Ethics Committee. The guidelines focuses on gene technology in the context of medical practice, and the doctor-patient relationship (NMEC 2001). The guidelines are intended to help clinicians and doctor-researchers make ethical decisions about gene technology. The guidelines are divided into thirteen chapters (Table 2).

In addition, the UNESCO Universal Declaration on Bioethics and Human Rights is the only bioethics guiding document at the international level, published in 2005. The Declaration addresses ethical issues concerning medicines, life sciences, and related technologies as they apply to humans, taking into account the social, legal, and environmental implications (UNESCO 2005). The document provides universal principles and procedures for countries or organizations when it comes to developing their bioethics frameworks. However, it should be noted that the adoption of this declaration by countries worldwide is voluntary. The declaration is divided into thirty-one chapters, of which fifteen are dedicated to various ethical principles (Table 2).

The Statement of Ethical Principles for Biotechnology in Victoria is a guideline for individuals involved in biotechnology developments in the state of Victoria and relates to research into commercial products in agriculture, the environment, and health (DHSM 2006). The Statement is divided into eight chapters, each of which contains eight ethical principles to guide the understanding and application of the principles (Table 2). The Australian government has also established the Queensland Biotechnology Code of Ethics. This is an ethical framework that covers all major sectors of industry, including health and medical applications, agriculture, food and food manufacturing, together with industrial processes and the environment (DSGQ 2006). The Code of Ethics is divided into eight chapters, each of which contains six ethical principles (Table 2). The Code of Ethics applies to all Queensland biotechnology organizations, while other organizations that are not classified as such are encouraged to comply with the Code by signing a Statement of Intent (the template for which is included in the Code) to demonstrate their commitment to ethical practice. The Code requires Queensland biotechnology organizations to adhere to the Code and not violate any applicable laws. Failure to comply with these laws may result in a biotechnology organization being prosecuted by the Commonwealth or another government agency (DSGQ, 2006).

The General Ethical Guidelines for Biotechnology Research is a set of South African ethical guidelines published in 2008 as national guidelines for addressing ethical issues concerning biotechnology research in South Africa (HPCSA 2008). The Guidelines present six guiding principles for any biotechnology research conducted in South Africa (Table 2). The Guidelines contain 14 sections including specific content on waste disposal management, prohibitions on the development of biological weapons, intellectual property rights, and commercialization (HPCSA 2008).

The Bioethics and Safety Act is a South Korean law that governs biotechnology developments involving human embryos, cells, and genes, as well as general research involving human subjects (MoHWFA 2008). The Act is divided into fifty-five sections that covered embryo production and research, genetic testing, genetic information protection and use, gene therapy, supervision, supplementary rules, a penal clause, and the establishment of National and Institutional Bioethics Committees. Because the Act is legally binding, scientists and researchers are required to comply. For any violation of the Act, the authorities have the power to levy fines, revoke licenses, close facilities, and impose jail sentences. This Act applies to embryo-producing medical institutions, embryo research institutions, genetic testing institutions, gene banks, and gene therapy institutions (MoHWFA 2008).

Lastly, the National Framework of Ethical Principles in Gene Technology 2012 is the latest set of Australian ethical guidelines to provide a national reference point for ethical conduct in gene technology as it relates to human health, the environment, genetically modified organisms, and products (DHAA 2012). The framework is a set of principles that Australian scientists and researchers must follow at all times when working with gene technology and GMOs. To guide scientists and inform the public, the National Framework 2012 presents ten key ethical principles relating to gene technology, specifically GMOs. These principles have been developed to help shape policies and actions related to gene technology. The Framework also described the role of the Gene Technology Ethics and Community Consultative Committee, which created the National Framework, in advising the Regulator on ethical issues related to gene technology (DHAA 2012).

In general, most of the documents studied covered similar topics in order to emphasize important information. Table 2 summarises the comparison of the content sections of each document. Although all documents discussed have the same goal of promoting ethics in modern biotechnology, the terminology used to designate the content sections differs. Table 2 also displays the availability of each document's contents section. Furthermore, the number of content sections and ethical principles differ, which resulted in a different total number for each document. The South Korean document has the most content sections (55 sections) because the 'Bioethics and Safety Act' combines ethics and safety into a single document. The least adopted content sections, according to Table 2, relate to supervision, supplementary rules, additional provisions, acknowledgement, and statement of intent, which are only included in one document.

TABLE 2 Comparison of worldwide regulations and guidelines on the ethics of biotechnology

Content sections	Singapore	UNESCO	Victoria, Australia	Queensland, Australia	South Africa	South Korea*	Australia
Number of Contents / Chapters	13	31	8	8	14	55	12
Forward / Preamble	/	/	/	/	/		
Summary	/						/
Aims & Objectives / Purpose		/				/	/
Scope	/	/				/	
Definition			/		/		
Audiences / Organisations Covered by the Code				/			/
Ethical Principles	/	/	/	/	/		/
Number of Principles		15	8	6	6		10
Interpretation / Applications of the Principles / Implementation of the Guideline	/	/	/	/	/	/	/
Legislative				/		/	
Mandatory Status				/		/	
Ethics Committees	/	/			/	/	/
Breaches of Conduct Clause / Penal Clause				/		/	
Supervision						/	
Supplementary Rules						/	
Additional Provisions						/	
Appendix				/			/
Statement of Intent				/			
References	/						/
Acknowledgement			/				
Acronyms / Glossary etc.			/	/		/	/

**Note:* The South Korean document is "Bioethics and Safety Act" not a guideline. Thus, the document highlights the content section of the Act.

Table 3 shows the ethical principles stated in the various ethical guidelines. Only five guidelines contain sections on Ethical Principles, with at least six or more ethical principles. The UNESCO document contains the greatest number of ethical principles at fifteen, followed by Australia with ten, Victoria with eight, and South Africa and Queensland with six each. Four of the five guidelines examined have mentioned integrity, respect for persons, and justice as their ethical principles. Three guidelines have adopted protection for animals and protection for the environment as their principles, while only the UNESCO document has mentioned respect for cultural diversity and pluralism. All five guidelines stated that their specific ethical principles are to align with their home country-specific requirements.

TABLE 3 Ethical principles stated in the Ethical Guidelines

Ethical Principles	UNESCO	Victoria, Australia	Queensland, Australia	South Africa	Australia
1	Human Dignity and Human Rights	Respect for persons	Integrity	Integrity	Acting with integrity
2	Benefit and Harm	Respect for animals	Beneficence and non-maleficence	Autonomy / respect for persons	Avoiding conflict of interest
3	Autonomy and Individual Responsibility	Respect for the natural environment	Respect for persons	Beneficence	Maintaining records of scientific data
4	Consent	Respect for the public good	Respect for the law and system of government	Non-maleficence	Caring for the environment and sustainability
5	Persons without the capacity to consent	Benefit and harm	Justice	Justice / fairness	Avoiding harm to humans and animals
6	Respect for human vulnerability and personal integrity	Justice and equity	Care and protection of animals	Ethical duties	Assessing long-term impacts
7	Privacy and Confidentiality	Probity			Sharing knowledge and benefits

continue...

...continued

8	Equality, Justice and Equity	Accountability		Promoting benevolent purposes
9	Non-Discrimination and non-stigmatisation			Ensuring transparency
10	Respect for cultural diversity and pluralism			Considering responsibility beyond national borders
11	Solidarity and cooperation			
12	Social responsibility and Health			
13	Sharing of benefits			
14	Protecting future generations			
15	Protection of the environment, the biosphere and biodiversity			

DISCUSSION

Different countries and documents have adopted different approaches in their ethical documents. The findings of this study showed variation in the existing ethical documentation with regards to the guidelines content and the key ethical principles adopted.

An important issue that should be addressed is the definition of modern biotechnology. The Cartagena Protocol limits modern biotechnology to genetic modification. Queensland made the effort to align its code of ethics for biotechnology with the Gene Technology Act 2001 and therefore covered GMOs as well as current medical technologies such as genetic testing, gene therapy, cloning, biotechnology-based medicines, bioremediation and xenotransplantation. However,

this document, although mandatory is only limited to organizations receiving funds or assistance from the Queensland state government. Other regulations/ guidelines have their own versions, mostly including the latest technology in the medical sector such as genetic testing, stem cells, and cloning. The UNESCO Declaration covers a broader scope including the ethical issues of life sciences, medicine and related technologies. However, there is a serious need to come up with a standardised definition worldwide.

It is worrying to note that only four countries have made an effort to develop regulations/guidelines specifically dealing with the ethics of modern biotechnology. Australia is the most proactive, with three sets of guidelines at the state level. However, these come up short in terms of becoming legislation, with Queensland only imposing a mandatory application to all biotechnology organizations receiving Queensland's State Government funding or assistance. The legal system related to the environment in Queensland is dynamic due to its strong advocacy for sustainable development. This is much in line with the central epitome of its parent country, as well as being influenced by the international environmental policy and legal system (McGrath 2011).

South Korea is the most advanced country in terms of regulating the ethics of modern biotechnology. It is the only country in the world with a legally binding document on bioethics, including biotechnology, and it is also the most comprehensive, with nine chapters and 55 Articles. According to Yoon and colleagues (2010), the passage of this Act was due to the controversial biotechnology progress that had taken place in South Korea, as well as a supportive government. However, the Korean Bioethics and Biosafety Act focuses once again on medical technologies: human cloning, embryo production and research, genetic testing, genetic information protection and use, and gene therapy (Clay 2013). These applications do not cover modern biotechnology as laid out under the Cartagena Protocol. There is no mention of the involvement of genetic modification in those applications. According to Yoon and colleagues (2010), the Korean Biotechnology Ethics Act is still limited in terms of its scope and efficacy. The findings are not surprising, as the focus worldwide has been on scientific risk assessment. However, the fact that some countries have been far ahead in addressing the ethical aspects of modern biotechnology by developing dedicated regulations or guidelines should be applauded. At the same time, it should be noted that other countries have separate guidelines for different applications of medical technologies.

It is interesting to note that the key elements covered in these guidelines are the ethical principles as shown in Table 3. According to Di Mattia (2008), ethical principles are part of a normative theory that justifies or defends moral rules and/

or moral judgments and are not based on subjective perspectives. In modern biotechnology practice, ethical principles are general judgments that serve as the foundation for the many specific ethical prescriptions and evaluations of gene modification or related activities. Bioethicists believe that developing complete ethical principles that are in line with local societal values is one of the first steps toward resolving ethical issues (Hasim et al. 2020). The ethical principles pioneered by Beauchamp and Childress (1994) in bioethics, namely i) beneficence, ii) non-maleficence, iii) justice, and iv) respect for autonomy, have become the foundation of these studied guidelines. The ethical principles stated in the guidelines (Table 3) will serve as a reference for modern biotechnology practitioners seeking to be responsible and ethical in their work. Although two documents - Singapore's Ethical Guidelines for Gene Therapy and South Korea's Bioethics and Safety Act - do not explicitly state ethical principles, they do discuss ethical rights indirectly. Thus, countries that want to develop ethical guidelines for modern biotechnology should be proactive by identifying ethical principles that are consistent and inclusive with their values.

CONCLUSION

The limited number of modern biotechnology ethics-related regulations worldwide is not surprising, as the focus worldwide has been on scientific risk assessment. However, it should be applauded that some countries are well ahead in addressing the ethical aspects of modern biotechnology by developing dedicated regulations or guidelines, notably South Korea and the State of Queensland in Australia. Although there are differences between the various regulations and guidelines on the ethics of modern biotechnology, the aim of such guidelines is the same, that is to ensure that the ethical issues of respective applications are addressed.

Policymakers who consider establishing ethical guidelines for modern biotechnology in support of their decision-making processes, need to address key issues related to the inclusion of socio-economic consideration assessment. Another key challenge is to decide whether or not to implement guidelines as a mandatory or voluntary application. If mandatory, the guidelines have to be developed as an Act or Regulation that is legally binding, such as is the case with South Korea's Bioethics and Safety Acts. Another option with regard to guidelines being made mandatory is to leverage the relevant existing legislation in the particular country for permitting prosecution should a biotechnology organization fail to comply in such a way as has been examined in the "Queensland Biotechnology Code of Ethics".

It is recommended that policymakers, particularly in developing countries such as Malaysia, should develop a coherent ethical framework for modern biotechnology.

A balance between the development of modern biotechnology and ethical and socio-economic considerations is the key to the successful implementation of modern biotechnology. A comprehensive set of regulations that acknowledges the importance of socio-economic issues including the ethical, religious and cultural conditions of the country under consideration would enhance the transparency and accountability of the decision-making process with regard to new modern biotechnology product adoption, which in turn would further boost public confidence in the scientists, companies and government agencies, and lead to a better acceptance of new biotechnology products. It is hoped that this article has given insight to researchers and regulatory bodies to develop a comprehensive and inclusive ethical guideline for modern biotechnology in Malaysia.

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