

**NOBLE VALUES PRINCIPLE AND INDICATORS AS ETHICAL GUIDING
PRINCIPLES FOR MODERN BIOTECHNOLOGY IN MALAYSIA**

(Prinsip Nilai-nilai Murni dan Indikator Sebagai Prinsip Etika Panduan bagi
Bioteknologi Moden di Malaysia)

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ABSTRACT

Malaysia enacted the Biosafety Act 2007 and its regulations, the Biosafety (Approval and Notifications) Regulations 2010 to ensure the biosafety of modern biotechnology in Malaysia. However, the current Act and regulations do not fully consider the ethical issues arising in modern biotechnology. Besides the four well-established principles proposed by the well-known bioethicists, Beauchamp and Childress, there are other important principles which should be taken into account. In Islam, every human is a trustee (Khalifs), whose role is to take responsibility for the protection of God's creation and execute good values for a great civilization. The objectives of this study are to review the principle of the noble values of modern biotechnology, and develop practical indicators for this principle. The study was conducted using a descriptive literature review and Focus Group Discussions (FGD) among stakeholders. It was found that the noble values principle consists of four sub-principles, which are: 1) integrity; 2) accountability; 3) transparency and; 4) objectivity and disinterestedness.

The indicators for this principle referred to two suggestions from the stakeholders, which were 1) each of the sub-principles should have its indicators, or 2) to use one line of a self-declaration from modern biotechnology practitioners as the indicator to ensure the noble values principles have been incorporated.

Keywords: Modern biotechnology; ethical principles; noble values principle; indicators; Islam

ABSTRAK

Malaysia telah menggubal Akta Biokeselamatan 2007 dan peraturannya, iaitu Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010, untuk memastikan biokeselamatan pada bioteknologi moden di Malaysia terjaga. Undang-undang dan peraturan semasa dilihat tidak mempertimbangkan sepenuhnya masalah etika yang timbul dalam bioteknologi moden. Selain empat prinsip utama yang diusulkan oleh ahli bioetika terkenal, Beauchamp dan Childress, terdapat prinsip penting lain yang harus diambil kira. Dalam Islam, setiap manusia adalah pemegang amanah (Khalifah) yang berperanan memikul tanggungjawab untuk melindungi ciptaan Tuhan dan melaksanakan nilai-nilai baik bagi sebuah peradaban yang hebat. Objektif kajian ini adalah untuk mengkaji prinsip nilai murni dalam bioteknologi moden dan membangunkan indikator yang praktikal bagi prinsip ini. Kajian ini dilakukan dengan menggunakan tinjauan literatur deskriptif dan perbincangan kumpulan fokus (FGD) dalam kalangan pihak berkepentingan. Hasil mendapati bahawa prinsip nilai murni terdiri daripada empat sub-prinsip iaitu 1) integriti; 2) akauntabiliti; 3) ketelusan dan 4) objektiviti dan tidak-berkepentingan (disinterestedness). Indikator bagi prinsip ini, merujuk kepada dua cadangan daripada pihak berkepentingan iaitu 1) setiap sub-prinsip harus mempunyai indikator tersendiri, dan 2) satu ayat perakuan dari pengamal bioteknologi moden dijadikan sebagai indikator, bagi memastikan prinsip-prinsip nilai-nilai murni diguna pakai.

Kata kunci: Bioteknologi moden; Prinsip etika; Prinsip nilai murni; Indikator; Islam

INTRODUCTION

Since the advanced techniques and tools which are currently being used in modern biotechnology are continually being developed and explored for commercialization, modern biotechnology is concluded to be a potential technology (Rzymiski & Królczyk 2016). By definition, “modern biotechnology” means the application of (1) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles; or (2) the fusion of

cells beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding selection (Malaysia 2007). Modern biotechnology and products are concerned with advancing research, and by introducing political and social discussions about their use, advantages, threats, security, and constraints (Rzymiski & Królczyk 2016). There are many controversies related to modern biotechnology development. In Malaysia, these have been debated, and the National Biosafety Board (NBB) has approved various types of modern biotechnology products for the Malaysian market (Hasim et al. 2019; Amin et al. 2013). The main issues that have been highlighted are the ethical issues associated with modern biotechnology and its products, such as their long-term impact on human health and safety, their impact on the environment and biological diversity, and socio-economic implications (Hasim et al. 2019). The Malaysian government indicated its commitment to the development of the biotechnology industry by launching the National Biotechnology Policy in 2005 (Biotechcorp 2010). Presently, in 2020, this policy is in its third phase, targeted to develop global business by rebranding Malaysia as a global biotechnology hub. The biosafety of modern biotechnology in Malaysia is regulated by the Biosafety Act 2007 and its regulations, Biosafety (Approval and Notifications) Regulations 2010. Despite the Malaysian government's concern about modern biotechnology as shown by the enactment of the Biosafety Act 2007, there is a failure to properly consider any ethical issues, although there are provisions in terms of socio-economic considerations (Idris et al. 2013).

Although modern biotechnology proposes the development of promising products and services, this concurrently leads to several new uncertainties and insecurities linked to bioethical concerns (Idris et al. 2013). In order to judge between right and wrong actions, Western countries have developed Western ethics as a philosophical science to explore human reason and experience (Chamsi-Pasha & Albar 2013). For example, in approaching biomedical ethics, two American bioethicists, Beauchamp and Childress, developed four main ethical principles, which are nowadays widely used as the main reference point in the bioethics field. The four main ethical principles are: 1) respect for autonomy; 2) non-maleficent; 3) beneficence and 4) justice. All four ethical principles also prevail in the various frameworks, offer broad consideration of bioethical issues, and are not limited to medicine only (UKCEN Clinical Ethics Network 2011). There are some countries which have developed ethical principles, guidelines and codes with regard to modern biotechnology, which have highlighted the ethical principles suggested by Beauchamp and Childress as the core principles. Examples of ethical guidelines issued by Western countries are the *Toward a Coherent Ethics Framework for Biotechnology in Canada* (1999) and the *National Framework of Ethics in Gene Technology* 2012. UNESCO also published a *Universal Declaration on Bioethics and Human Rights* in 2005 to address related ethical issues in modern biotechnology.

Other than the four ethical principles proposed by Beauchamp and Childress in 1994, Western guidelines have emphasized the use of the noble values principle as an important principle to complement the four existing ethical principles found in modern biotechnology. A recent study conducted by Hasim et al. (2019) stated that the stakeholders in modern biotechnology in Malaysia agreed to improve the ethical principles by Beauchamp and Childress in the Malaysian context. The main suggestion by the stakeholders was to include that the noble values principle consists of four sub-principles: 1) integrity; 2) accountability; 3) transparency; and 4) objectivity and disinterestedness as one of the main ethical principles in the field of modern biotechnology (Hasim et al. 2019). All of these sub-principles are widely-used in the ethical guidelines with regard to modern biotechnology issued by Western countries, along with the ethical principles proposed by Beauchamp and Childress. Moreover, the noble values principle consists of common principles used in all fields of research and industrial settings to ensure that the research is conducted responsibly and ethically. In order to establish the noble values principle as a practical and applicable principle, some indicators of the sub-principles should also be explored.

The indicators are crucial when it comes to managing, tracking and evaluating information in different circumstances (Diaz-Chavez 2014). In recent years, the importance of indicators for assessing sustainability performance in various schemes of implementation of standards has become an obligation to be carried out (Diaz-Chavez 2014). Islam is constitutionally the official religion of Malaysia, which significantly encourages its followers to practice noble and good values. In Islam, every human is appointed as a trustee (caliph), who's responsible for protecting and preserving all of God's creations on earth (Hasim et al. 2020). The implementation of noble values is one of the responsibilities of a trustee (Sulaiman 2016). According to Sulaiman (2016), the biggest challenge to civilization and modern science is moral responsibility. The weakening of morals or values held by humans may lead to the fall and decline of civilization. In this study, the authors believe the proposed clarification of the noble values principle and indicators for modern biotechnology is important as a proactive step to uplift the civilization in Malaysia.

METHODOLOGY

This study was conducted using a descriptive literature review and a Focus Group Discussion (FGD) involving the following stakeholders: A) bioethicists and NGO representatives (n=8), B) regulators (n=5), C) researchers and industry representatives (n=5), and D) religious scholars and socio-economic experts (n=8) as shown in Table 1. The FGDs were conducted from April to August 2019 at Hotel Puri Pujangga, UKM.

The participants were selected based on the appropriateness of their background (position, rank, years of experience) to the characteristics of this study. This sampling method is also intended to maximise diversity in this study. The discussions were recorded and transcribed verbatim. The transcribed data was analysed by thematic analysis.

TABLE 1. Profile of Stakeholders

Group	Position
A	1. Senior lecturer (Biosafety's Law), Faculty of Laws, UiTM
	2. Senior lecturer (Ethics in Bio medical), Faculty of Science, UM.
	3. Senior lecturer (food safety, Halal, Policy and labeling) and Head of Department of Science and Technology, UM.
	4. High council of Malaysian Plant Protection Society, UPM
	5. Senior lecturer (Bioethics), Faculty of Medical, Perdana University
	6. High council of Persatuan Saintis Islam Malaysia (PERINTIS)
	7. High council of Federation of Malaysian Consumer Associations (FOMCA)
	8. High council of Persatuan Pengguna Islam Malaysia (PPIM)
B	1. Deputy director of the Department of Biosecurity Assessment and Research Section (NRE)
	2. Senior officer of Institute for Medical Research (IMR)
	3. Senior officer of Mardi
	4. Director of Department of Veterinary Officer (DVS)
	5. Senior officer of STRIDE
C	1. Senior officer of Bio Economy Corporation
	2. Senior officer of One Biotech
	3. Researcher at the Malaysian Genome Institute
	4. Director of Agro-Biotechnology Institute
	5. Senior lecturer (Biotechnology), Faculty of Science and Technology, UKM
D	1. Director of Maqasid al-Syariah Department, JAKIM
	2. Consultant of Young Buddhist Association Malaysia
	3. Senior officer of INHART, UIA
	4. Consultant of Young Buddhist Association Malaysia
	5. Advisor of Hindu Associations, UKM
	6. Priest of KL Church
	7. Advisor to Christian Associations UKM
	8. Senior lecturer (Socio-economic), LESTARI, UKM

RESULTS AND DISCUSSIONS

The results of this study show the description of the principle of noble values and the sub-principles derived from the literature review, which the stakeholders agreed to be used in the Malaysian context. Through the interpretation of these principles and sub-principles, the stakeholders proposed the appropriate indicators as follows.

Noble Values Principle and Sub-Principles Description

The Noble Values Principle refers to the concept that emphasizes the practice of noble values on the part of researchers, producers and all the parties involved in modern biotechnology, who must comply with all the values of the sub-principles below:

Sub-principle 1: Integrity is to act rightly and deal with things honestly and truthfully. It involves being fair and authoritative with others (National Framework of Ethics in Gene Technology 2012).

Sub-principle 2: Accountability refers to the need for individuals, groups or institutions involved in modern biotechnology to be fully responsible for the actions, considerations, purposes and consequences of action taken (Toward a Coherent Ethics Framework for Biotechnology Research in Canada 1999).

Sub-principle 3: Transparency means conducting matters related to modern biotechnology in a manner that ensures transparency and public scrutiny, and a process that allows consultation with those in the community with a direct or potential interest (Queensland Biotechnology Code of Ethics 2006).

Sub-principle 4: Objectivity and disinterestedness is a feature of claims, methods and scientific outcomes that cannot be influenced by community tendencies or personal gain (Reiss & Sprenger 2017). The principle of disinterestedness demands that the work of scientists remains unaffected by the actions of any stakeholders. It prevents scientists from pursuing science for the benefit of certain parties (Leisinger 2000).

Indicators for the Noble Values Principle

All the experts strongly agreed to use the noble values principle as a complement to the four principles suggested by Beauchamp and Childress. Both group A (bioethicists and NGOs representatives) and B (Regulators) agreed to use the 'The Malaysian Code of Responsible Conduct in Research' published by the National Science Council (2017), as the main indicator for this principle. The indicators are as follows:

Integrity a) Research must be conducted with adherence to its established aims, objectives and methodology, by executing relevant and proper analysis (National Science Council 2017); b) Ensure an honest and truthful expression of the findings and potential applications, avoiding deception or deviation; c) Ensure that the research is reliable by conducting it diligently, with thorough care and attention so that it is reproducible, replicable and verifiable (National Science Council 2017).

Accountability a) Ensure responsibility for the research subjects including humans, animals, inanimate or environmental aspects, all of which are vital to minimize risks, disturbances or harm, thus assuring the safety, wellbeing, dignity of, and respect for the research subjects (National Science Council 2017).

Transparency a) Have honest communication about modern biotechnology and products with the scientific and general community (National Science Council 2017); b) Colleagues should be able to verify data if necessary or required.

Objectivity and disinterestedness a) Research must be evidence-based and avoid overstated, unfounded and unjustifiable demands (National Science Council 2017); b) The analysis and interpretation of data must be undertaken scientifically, transparently and verifiably, in accordance with scientific reasoning and sound methodology; and c) Funders, ideological or political groups, or financial interests must not cause any conflict of interest (National Science Council 2017).

Interestingly, in the other FGD sessions conducted for the experts from group C (researchers and industrial representatives) and group D (religious scholars and socio-economic expert), it was believed the indicators for this principle and sub-principles should be carried out practically by the practitioners. The experts (groups C and D) suggested the need for an annex to the self-declaration document from practitioners who participate in modern biotechnology as an indicator of this principle. An example of such a self-declaration is suggested as follows:

'I hereby declare that I am conducting research and production of modern biotechnology and products with objectivity, integrity, accountability and transparency.'

Although the Malaysian government has emphasized the significance of ethics in organizations, these indicators of ethical principles will be voluntarily conducted by modern practitioners of biotechnology. Such self-declaration is assumed to be more practical and effective in terms of encouraging practitioners to be responsible in their practice compared to 'The Malaysian Code of Responsible Conduct in Research'. Dekhili and Achabou (2014) pointed out that such a self-declaration or 'promise' by producers or stakeholders tends to be well-accepted and trusted, especially on the part of customers. Therefore, there is no problem with simplifying the indicators to a self-declaration by stakeholders.

CONCLUSION

This study has contributed to the development of the literature on the establishment of a framework in the form of a set of ethical principles as one of the solutions to guide researchers and industries involved in modern biotechnology towards an ethical way of working in Malaysia. The study of noble values in modern biotechnology is important,

and is a proactive action towards a dignifying civilization. To protect Malaysia from any severe negative impacts of modern biotechnology, the research and development, innovation and commercialization of modern biotechnology must hold to such a set of ethical principles, including: 1) Respect for autonomy; 2) Non-maleficence; 3) Beneficence; 4) Justice (as proposed by Beauchamp and Childress), and 5) the Noble Values principle as discussed in this study. As for the indicators for the Noble Values principle, they may be conducted by 1) referring to “The Malaysian Code of Responsible Conduct in Research” or 2) summarized in a well-written document of self-declaration on the part of the stakeholders with regard to the matter of ethics. A future study is recommended to take this suggestion of principles and indicators for validation or a pilot study involving modern biotechnology stakeholders in Malaysia.

ACKNOWLEDGEMENT

The authors wish to thank the Ministry of Education (FRGS/2/2017/SSI12/UKM/01/1) and Universiti Kebangsaan Malaysia (DCP-2017-005/4) for supporting this project.

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