

**JAWATANKUASA PEMBAHARUAN UNDANG-UNDANG MALAYSIA  
BAHAGIAN HAL EHWAL UNDANG-UNDANG  
JABATAN PERDANA MENTERI**

**THE APPLICABILITY OF THE BIOSAFETY ACT 2007 IN ADDRESSING  
BIOETHICAL ISSUES RELATING TO GENETICALLY MODIFIED ORGANISMS  
(GMOs)**



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**NOVEMBER 2011**

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# **1. Acknowledgements**

This research is made possible with the funding of the Jawatankuasa Pembaharuan Undang-Undang Malaysia (JPUUM) granted by the Prime Minister's Department. We are eternally grateful to Allah SWT for His blessings and for this funding. We are greatly indebted to the Research Management Institute (RMI) of UiTM for their endless support and assistance in ensuring the completion of this report. We also wish to thank the Faculty of Law for their support and encouragement for a conducive research culture within the Faculty.

We wish to thank all those respondents from the National Biosafety Board (NBB), the Department of Biosafety, the Genetic Modification Advisory Committee (GMAC) and the TWN who have freely and kindly provided us the valuable time, effort and information, all of who must remain anonymous, but without whom, the research would not have been possible.

We are thankful to all our families and friends for their eternal support, without whom the research would not be completed in time. As the head of the project, I am truly obliged to the constant support and motivation of my beloved husband, Mohd Yazid Sharif, my beloved children, Yasmin Raihana, Erfan Syameer and Iman Natasha, without whom, the research would not have been meaningful achievement. My special thanks to my nieces cum research assistants, Aina Amirah, Syahidatul Atiqah and Aliah Madihah for their help with the collection and analysis of the data. Many thanks to my dear friends, Rafizah and Ani Munirah who have encouraged, support and help me in completing this research successfully. Finally, I also owe my gratitude to my dear researchers, Prof Madya Dr Zaiton Hamin and Professor Dr. Abu Bakar b Abdul Majeed for their great involvement and contribution throughout the process of this research.

### **3. Report**

#### **3.1 Proposed Executive Summary**

In recent years, biotechnology has resulted in the development of a number of genetically modified organisms (GMOs). However, the introduction of GMOs has led to wide debate on bioethical concerns. Such issues involved freedom of choice, ethics of interfering with nature, Islamic views on GM crops and ethical considerations of distributive justice as well as the effects of transgenic pollution to the environment (Latifah, 2010). Bioethical issue in biotechnology is an important aspect in the research stage, development stage and also the commercialization stage (Ida, 2009). The literature suggests that bioethics consideration should be included in the legal framework as the current legal regulations addressing GMOs are considerably varied less effective in discussing bioethical issues of the subject (Daniel Sperling, 2010). In Malaysia, there is no specific law on bioethics, except the Biosafety Act 2007. The law addresses all Living Modified Organisms (LMOs) with the objectives of protecting human, plant and animal health, the environment and biological diversity, and where there are threats of irreversible damage, lack of full scientific evidence may not be used as a reason not to take action to prevent such damage; and to provide for matters connected therewith. The law also recognizes the inclusion of the bioethical issues as part of the socio economic consideration under section 35. However, this law is rather vague on the bioethical issue.

This project proposes to examine the applicability of the Biosafety Act 2007 in addressing bioethical issues relating to GMOs in Malaysia. Apart from that, this research also seeks to propose recommendations for the amendment to the Biosafety Act 2007 for express provision to protect bioethical issues relating to GMOs in Malaysia. Based on a qualitative research method, this project employs a case study research design in order to propose to examine the applicability of the Biosafety Act 2007 in addressing bioethical issues relating to GMOs in Malaysia.

The outcome of this project is to create a legal mechanism in order to improve the current legal framework in dealing with bioethical issues in GMOs. It is hoped that the findings of this research could assist the industry in guiding them with best practices for themselves and the policy makers in formulating and implementing the relevant regulations and policies on bioethical issues relating to GMOs.

### 3.3 Introduction

Modern biotechnology, particularly the use of recombinant-DNA techniques, has allowed the introduction of novel or altered traits genes into other organisms, known as genetically modified organisms (GMOs)<sup>1</sup>. These organisms are generated for its significant advantages, including enhanced agricultural productions with a desired characteristic.<sup>2</sup> Worldwide, the development of this biotechnology application has generated a number of human health, environment, economic and social concerns on the safety of the technology over its immediate and long term effects.<sup>3</sup> Many of these concerns have legal, policy and ethical aspects to the extent that they are addressed by national and global policies and regulations. One of the concerns is bioethical issues associated with biotechnology, which arises in all biotechnological stages embracing from the research, development as well as at the commercialization stage.<sup>4</sup> Therefore, to ensure that those organisms are safe, it is essential for the biosafety regulatory system to review and approve each product for safety before it could be released into the environment or ingested by human.<sup>5</sup>

This biosafety regulatory system should include not only the scientific procedures and principles, but may also consider several socio-economic issues.<sup>6</sup> Article 26 of the Cartagena Protocol on Biosafety ("Biosafety Protocol") provides that socio-economic considerations can be a part of any decisions at the national level. In Malaysia, this biosafety decision-making process is undertaken by the National Biosafety Board ("the Board") as laid down in section 5(1) of the Biosafety Act 2007 ("the 2007 Act")<sup>7</sup>. In performing this function, section 35 of the 2007 Act states that the Board may consider socio-economic considerations which includes bioethical issues in their decision-making process.<sup>8</sup>

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<sup>1</sup> Brent, P., et al, 'Regulation of Genetically Modified Foods In Australia And New Zealand', Published by Elsevier Science Ltd - Food Control 14 (2003) 409–416 at [www.sciencedirect.com](http://www.sciencedirect.com) accessed on 22/08/2011

<sup>2</sup> Zarrilli, S., "International Trade in GMO and GM Products: National and Multilateral Legal Framework", U.N. Doc. UNCTAD/ITCD/TAB/30, U.N. Sales No. E.04.II.D.41 (2005)

<sup>3</sup> Latifah et al, 'Factors influencing Malaysian public attitudes to agro-biotechnology', *Public Understanding of Science Online First*, published on June 8, 2010 at [pus.sagepub.com](http://pus.sagepub.com) downloaded from [pus.sagepub.com](http://pus.sagepub.com) at Universiti Teknologi Mara (UiTM) on June 18, 2011 at p 1–16

<sup>4</sup> Ida Madiha Abdul Ghani Azmi, "The Gap between the Legal and Regulatory Framework of Health and Medical Biotech Research and Development in Malaysia in Malaysia and the Need of the R & D Institute in Malaysia." *Journal of International Biotechnology Law* (2009) Volume 6, Number 3.

<sup>5</sup> Jaffe, G, 'Regulating transgenic crops: a comparative analysis of different regulatory processes', *Transgenic Research* 13: 5–19, Kluwer Academic Publishers. Printed in the [springerlink.com](http://www.springerlink.com) 2004 at <http://www.springerlink.com/content/h502371126727304/> at p 5-15

<sup>6</sup> Husby, J, Sustainability, social and ethical considerations in regulations, in Terje Traavik and Lim Li Ching (eds.), *Biosafety First*, Third World Network & GenØk, Norway, 2009 at p 555-567.

<sup>7</sup> 39 ILM 1027 (2000)

<sup>8</sup> Act 678

Section 35 of the Biosafety Act 2007 and regulation 25(c) of the Biosafety (Notification & Approval) Regulations 2010.