Advancements in Genetic Engineering
ISSN: 2169-0111

Idris, Adv Genet Eng 2013, 2:2
DOI: 10.4172/2169-0111.1000111

Research Article Open Access

Integrating Bioethical Concerns into Biosafety Law for Genetic Modification Technologies in Malaysia

Siti Hafsyah Idris*

Faculty of Law, Universiti Teknologi MARA, Malaysia

Abstract

In considering the use of modern biotechnologies, specifically genetically modified organisms (GMOs), the Malaysian government recognizes the significant potential benefits as well as uncertainties, risks and doubts of this emerging technology. Though great benefits of this technology could help meet future needs, yet, this technology is often accompanied by public debate over its potential risks, which includes bioethical issues. In mitigating these risks in a sustainable manner, biosafety framework is required in order to protect human, plant and animal health, the environment and biodiversity.

One of the means to manage the risks is through rule of justice based on law as a decisive technology solution. The government passed the Biosafety Act in 2007 to serve as an "umbrella act" which include the setting up of the National Biosafety Board as well as legal and institutional provisions tailored to comply with the Cartagena Protocol on Biosafety, with the objective to regulate the import, export, deliberate release, contained use and marketing of GMO-related products in order to protect human, plant and animal health, the environment and biodiversity.

The question is how does this law addressing bioethical issues and how effective the law in addressing this issue? The purpose of this paper is to analyse the extent to which this Biosafety Act 2007 and its regulations may be effectively integrating bioethical issues relating to GM crops in realizing its objectives. The article specifically focuses on bioethical issues provisions of GMOs under the Act and its regulations. This paper adopts a qualitative research methodology of library- based method which includes a doctrinal analysis of legislation and law. The paper concludes that bioethical consideration is essential for the effectiveness of the biosafety regulatory frameworks and in promoting sustainable development.

Keywords: Modern biotechnology; GM crops; Biosafety law; Bioethics

Introduction

The United States Supreme Court's decision in Bowman vs. Monsanto [1], implies that farmers are legally has no right to save seeds from patented genetically modified (GM) crops one season, and plant them the next season [2]. This left many farmers unable to find high-quality non-GM seed [2]. Patents actually restrict innovation, as researchers can no longer freely use patented plants in breeding experimentation [2]. Today, GM companies control nearly three-quarters of sales.

This concentration has led to higher prices and shrinking choice for consumers [2]. GM crops also affect biodiversity in ways that gene transfers through cross pollination resulting in hybridization with related species because many plant species can be found both as a crop and as a weed [3]. Public [4] also expressed their concerns that humans do not have the absolute right to modify living things and called for the need for proper and appropriate labelling of modern biotechnology products. They were also concerned about the associated risks to human health and the possibility of market monopoly by giant companies and developed countries.

The ethics and safety of biotechnology have been debated since scientists first began to investigate the new technology in the early 1970s [5]. The concern expressed about the safety of biotechnology research led to a moratorium of GM crops in certain states in Australia, in India and some European Union countries.

In Malaysia, consistent with the Cartagena Protocol under Article 26 which states, socio-economic considerations should be taken into account in implementing the national biosafety law, section 35 of the Biosafety Act 2007 clearly state that decisions by the Minister or the Board in GMO's application may be based on socio-economic considerations [6]. This consideration focuses on 3 elements i.e. economic impacts, social and cultural issues and ethical considerations [6].

The question is how does this law addressing bioethical issues and to what extend does the law is adequate in addressing this issue. Hence, the first part of this paper explains the salient features of the Biosafety Act 2007 and its implementation, specifically on bioethical issues. Whilst the second part examines the adequacy of the Biosafety Act 2007 in addressing bioethical issues relating to GM crops, focusing at the decision making process phase. The last part that concludes this paper contends that bioethical consideration is essential for the effectiveness of the biosafety regulatory frameworks.

Journey to Biosafety Act 2007

Malaysia is located in Southeast Asia with two distinct regions, namely Peninsular west Malaysia and East Malaysia. It has a population of approximately 29 million [7] with one of the best economic records in Asia, by GDP growth was 5.1% in 2012 and projected at 5.0% in 2013 [8].

***Corresponding author:** Siti Hafsyah Idris, Faculty of Law, Universiti Teknologi MARA, Malaysia, E-mail: yasmin_yazid99@yahoo.com

Received July 29, 2013; **Accepted** August 12, 2013; **Published** August 19, 2013

Citation: Idris SH (2013) Integrating Bioethical Concerns into Biosafety Law for Genetic Modification Technologies in Malaysia. Adv Genet Eng 2: 111. doi:10.4172/2169-0111.1000111

Home to the world's oldest rainforest, Malaysia is indeed blessed with an abundance of biodiversity and natural resources, with an estimated 15,000 flowering plants species and 185,000 animal species [9]. As such, she is recognized as one of 12 mega-biodiverse countries of the world. This status could set the agenda in the areas of biotechnology and sustainable development in a way that would benefit and provide additional opportunities for economic growth [7].

Malaysia, nevertheless, also places a priority on conserving its rich natural heritage for the benefit of present and future generations. With such rich biodiversity housed in diverse habitats, it is imperative that biotechnology products advance safely from the laboratory to field tests and are released to the environment without adverse impact on its biodiversity and the environment [10]. As far as Malaysia is concerned, the niche area of biotechnology is primarily agricultural biotechnology, apart from healthcare biotechnology and industrial biotechnology, focusing on GM technology [10].

The Third National Agriculture Policy (NAP3) for 1998-2010 highlights the importance of human resource development in order to "generate highly skilled and innovative manpower in new and emerging sciences such as food, genetic engineering and biotechnology" [10]. In the National Agri Food Policy for 2011-2020, genetic modification (GM) technology is recognized as one of the mechanisms to ensure food security in a sustainable industry [11].

As for today, no GM crops are yet to be approved for planting. Most GM activities are still at the research and development stage and no plant varieties have been presented for commercialization for local planting with imported GM crops are under their ways here [12]. It is reported that, Malaysia imports about 3 million tons of corn and 500,000 tons of soybeans annually [13]. A large portion of this is genetically engineered (GE) grain [6].

In view of the above fact, as one of the mega-diverse countries in the world and a member of the Convention on Biological Diversity (CBD), Malaysia has acknowledged the importance of its biodiversity guided by the 1998 National Biodiversity Policy [14]. The policy calls for the sustainable utilization of the national biological resources among others through biotechnology and the need to establish a legal framework on biosafety. At this juncture, in 2005, the National Biotechnology Policy was formulated to use biotechnology as a mechanism for spurring Malaysia's economic growth, enhancing the wealth as well as the prosperity of the country sustainably. Recognizing the importance of modern biotechnology and its potential associated risks, Malaysia, as a member of the Cartagena Protocol on Biosafety (Biosafety Protocol), a specific law on biosafety of the genetically modified organisms (GMOs) commonly known as the Biosafety Act was passed in 2007.

The Biosafety Act was passed by the Malaysian Parliament on July 11, 2007. The approval of the Act can be seen as a positive and promising beginning for Malaysia to take proactive approaches towards protecting human health and the environment from the possible adverse effects of the products of modern biotechnology as well as fulfilling Malaysia's obligation under the Cartagena Protocol [15].

Correspondingly, on 1st of December 2009 the 2007 Act was enforced effectual, two years after it was passed by the Malaysian Parliament. This was followed by development of appropriate forms for application for release and notification for research works. As provided under the 2007 Act, and the understanding with stakeholders, the Biosafety [16] (Approval and Notifications) Regulations 2010 was formulated and enforced effective on 1st of November 2010. The Act, Regulations, Application Forms and Institutional Biosafety Committee Guidelines form the key elements of the biosafety legal framework in Malaysia [6].

Consistent with the above framework, the Board, was formed in March 2010 to function as a regulatory body for making decision pertaining to the release, importation, exportation and contained use of any LMOs derived from modern biotechnology. The Chairman of the Board is the Secretary General of the Ministry of the Natural Resources and Environment (the NRE) and its members comprise representatives from six other relevant ministries and four other persons with knowledge and experience in disciplines or matters relevant to the 2007 Act.

Soon after that, in May 2010 the Genetic Modification Advisory Committee (GMAC), consisting of experts from various science-based and other relevant disciplines working with the Government agencies, research institutes, private sectors and Non-Governmental Organisations (NGOs) to provide scientific, technical and other relevant advice to the Board. The status of the GMAC as the scientific advisor to the Board is backed up by legal and regulatory powers in the 2007 Act.

The implementation of the 2007 Act is delegated to the Department of Biosafety, which was formed in May 2010, under the NRE. The Department also acts as a one stop centre for all activities relating to biosafety in Malaysia in addition to fulfilling its core functions that is becoming secretariat to the Board, GMAC and committees or subcommittees established under the Board and GMAC [6].

The first decisions on LMOs based on the 2007 Act with proper processes and an appropriate procedure in place was in 2010. As of July 2013, the Board had made decisions on fourteen applications on approval for release [17]. These include GMOs for food, feed and processing and for contain used [18]. This indicates that the Malaysian government is pledging for biosafety in promoting modern biotechnology [18].

Salient Features of the 2007 Act

The objective of this 2007 Act is to regulate the release, importation, exportation and contained use of living modified organisms (LMOs)[1], and the release of products of such organisms, with the objectives of protecting

man, 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 [19]. In summary, the Act aims to strike a balance between creating an enabling environment in order to gain the maximum benefit from modern biotechnology and at the same time minimizing risks to the environment and health based on precautionary approach [20].

It should be noted that the 2007 Act uses the term Living Modified Organism (LMOs) instead of the term GMOs. Section 3 has provided the following definition for (LMO): living modified organism means any living organism that possesses a novel combination of genetic material obtained through the use of modern bio-technology.

Apart from LMOs, section 3 also provides that the definition of 'living organism' is taken to mean; any biological entity capable

[1]Malaysia uses LMOs instead of GMOs. However, Malaysia has made a declaration in the Convention of Biodiversity 1994 that the former term gives meaning to the latter.

of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

These two definitions of LMOs and living organisms under section 3 of the 2007 Act have been derived from the same definition of terms under Article 3 of the Cartagena Protocol. Hence, the 2007 Act and the Cartagena Protocol are sharing a common definition of LMO and living organism [21].

Scope of the Act

The 2007 Act states under section 2, it regulates all modern biotechnology but limited to: (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles; or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

As mentioned above, the 2007 Act covers all LMOs and its products in all stages of research and development (R&D). Products of LMOs means any product derived from a living modified organism or part of a living modified organism (a) If the product contains detectable recombinant deoxyribonucleic acid (DNA); or (b) Where the profile, characteristic or properties of the product is or are no longer equivalent to its conventional counterpart irrespective of the presence of the recombinant deoxyribonucleic acid (DNA).

There are two regulatory processes under the 2007 Act stipulates under Part III and Part IV. Part III deals with release activities and importation of LMOs which requires approval; while Part IV necessitates notification from the Board for contained use and exportation of LMOs. Pertaining to Part III of the Act on the release activities, it includes research and development (R&D) purpose in all field experiments; placing in the market; offer as gift, prize or free item; disposal and remediation purpose as mentioned in section 11. It can be viewed that there are two separate areas of LMOs with different requirements whereby Part III requires the prior approval whereas Part IV only requires notification on specific activities of LMOs (Figure 1).

Bioethical Consideration

Compliance with Article 26 of the Cartagena Protocol of the requirement on socioeconomic considerations should be taken into account in implementing the national biosafety law, section 35 of the 2007 Act implies that this consideration may be taken into account in the Board's decision making process.

As more clarity was requested on these terms, section 25 of the Biosafety (Approval and Notification) Regulations 2010 extends socio-economic considerations includes the changes in the existing social and economic patterns and means of livelihood of the communities and the effects of the religion, social, cultural and ethical values of communities arising from the use or release of the LMOs or its products.

Interpretation

Based from the above provisions, section 35 does explicitly emphasize on ethical issues for socio economic considerations. These particular provisions, however, do not comprehensively explain the precise requirements of such consideration. Despite these two provisions, the new legal framework is rather vague on the definition of bioethical issues, as they did not explicitly clarify this definition.

Not only the definition is problematic, the scope is also vague. Similarly, section 35 and regulation 25(b) are silent as to the scope and types of bioethical issues relating to modern biotechnology. Having said that, the law is vague on the extent to which this ethical issue can be integrated in the regulatory process. Could the law really intent to protect the environment and health as well as the rights of the public is yet to be determined as is has not been tested so far in the court.

Decision-making process

In relation to the extent to which the Board could consider socio economic consideration in its decision-making process is also unclear. Section 35 and regulation 25(b) state that the Board or Minister may take into account socio economic consideration in his decision making. The word "may" in these provisions give an indication that it is the discretionary power of the Board or the Minister whether or not to take socio economic consideration into account in assessing any GM application. The question remains at what level will this consideration be taken into account and whether or not the Genetic Modification Advisory Committee (GMAC) will dispense with this consideration in processing any GM application. Consequently, the Board acting on recommendation of the Genetic Modification Advisory Committee (hereinafter 'the GMAC') would normally based their decision purely on scientific and not ethical ones. This is inconsistent with the 2007 Act and in some ways does not promote the objectives of the protectionist principles of this law.

In relation to the biotechnology companies and GM researchers, at the research stage, development stage and commercialization stage, regard to the bioethical issues have never been their priority [22]. In all these processes, scientific consideration has been their primary consideration. This is evident in the approval of the releasing GM male mosquitoes into the wild in Bentong, Pahang and Alor Gajah, Melaka by the Board. The Board admitted that in reviewing the application, bioethical issues has never been a priority as GM mosquitoes does not concern on religious sensitivity [15].

Public participation

The 2007 Act clearly point to a need for public participation. Section 14 provides an opportunity to the public to participate in the decision making process of the Board. However, these opportunities

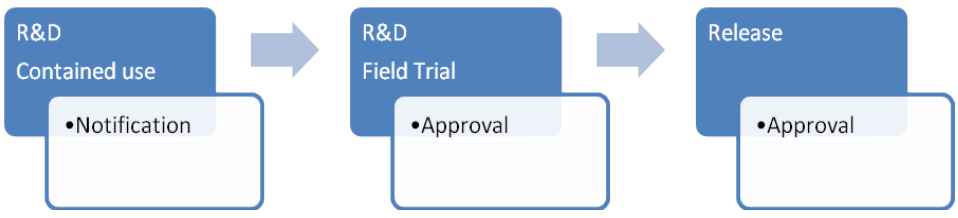

Figure 1: The summary of the regulatory process is shown below.

are subjected to the discretion of the Director-General of Biosafety and business confidentiality under section 59. The said Act is also silent on how to conduct public consultation or how to factor the results of the consultation into the decision-making process. It is apparent that under the 2007 Act, public involvement needs more transparency.

Same goes to section 60 of the Act, which mandates for public disclosure. There is, however a limitation in this provision, if the information contains business confidentiality as defined by section 59 and upon the discretion of the Director General of Biosafety, then the information cannot be publicized. This section also does not clearly define the word "in such manner as the Board thinks fit." This "manner" could be interpreted at best, in order to preserve the commercial interest, if sought by the applicant.

Section 14 provides an opportunity to the public to participate in the decision making process of the Board, while section 60 requires public disclosure on the GM application. However, these opportunities are subjected to the discretion of the Director-General of Biosafety and business confidentiality under section 59. The said Act is also silent on how to conduct public consultation or how to factor the results of the consultation into the decision-making process. It is apparent that under the 2007 Act, public involvement is also rather vague and it lack transparency.

In Point of Fact As of August 2013, the Board has approved fourteen applications for release approval which includes two field trial, ten for food, feed and processing and two for product of LMOs.

Limited-mark-release-recapture of *Aedes aegypti* (L.) wild type and OX513A(My1) strains: In the year 2010, the Board has made a controversial step of releasing the genetically modified (GM) mosquitoes (OX513A) into the wild (in Bentong and Alor Gajah) as part of an experiment to test their survival in natural conditions. This male GM mosquitoes has been approved to be released for a field trial to the Institute of Medical Research (IMR). The Board made this decision after its Genetic Modifications Advisory Committee (GMAC) has analysed the risk factors for the experiment [23].

The recommendation of GMAC to the Board was for an approval with terms and conditions. This approval permits the release of male GM Yellow Fever mosquitoes, *Aedes aegypti* OX513A(My1) strain and male non-GM *Aedes aegypti* mosquitoes (wild type) to conduct a field trial entitled "Limited Mark-Release-Recapture (MRR)" of *Aedes aegypti* wild type and OX513A(My1) [6].

The issue was opened for public consultation from 5th August to 4th September 2010. In reviewing the application, the Board received valuable feedbacks through public consultation. The first release was conducted in January 2011 at an uninhabited site in Bentong. However, numerous bodies including the NGOs have raised concerns on this GM mosquito release. This might be due to the fact that the information was only posted at the Biosafety Department website and published twice in a small section of two main local newspapers [24].

In light of these limited publicity, access to this information was also limited to the public at large. What was most amazing about the whole scenario was the fact that the local communities in Bentong and Alor Gajah were not part of the mandatory consultations before the approval was made by the Board. Local communities in the release sites should have been consulted with the highest standards of prior informed consent when it comes to obtaining their consensus and approval. Such lack of information suggests the lack of transparency, which has attracted considerable criticisms from the consumer association, the environmentalists and the public. For instance, the Consumer Association of Penang (CAP) is concerned about the safety of the residents within the area due to the lack of scientific consensus of the safety of GM insects and the numerous uncertainties involved in genetic engineering, which eventually will result in the difficulty in assessing their risks. Risk assessment process should have been made more obvious in this case by listing down all the potential hazards and its evaluations of their likelihood, their consequences and the estimated overall risks.

Confined field evaluation of delayed ripening transgenic Eksotika papaya: In May 2013, the Board granted approval with terms and conditions to an application from Malaysian Agricultural Research and Development Institute (MARDI) to conduct confined field evaluation of delayed ripening transgenic Eksotika papaya [25]. The purpose of the confined field trial is to evaluate the delayed fruit ripening characteristic of the transgenic papaya transformed with antisense ACC Oxidase 2 gene in a confined environment under a nethouse structure [25].

The recommendation of the Genetic Modification Advisory Committee (GMAC) to the Board was in accordance with the provisions of sections 16(3) and 16(4) of the 2007 Act. The recommendation was based on GMAC thorough evaluation which determined that the confined field trial does not endanger biological diversity or human, animal and plant health. Proper risk management strategies are to be followed as stipulated through the terms and conditions imposed [25].

The Board took into account statements from Department of Agriculture as the relevant department when making their decision on the application. A public consultation for this application was conducted for a month and comments were received from related NGOs regarding the integrity of the nethouse structure, risk of gene flow, mechanism for conferring the delayed ripening trait and risk of using marker gene nptII and ACC oxidase gene. These comments were reviewed by the GMAC and it was found that all the issues raised have been considered and taken into account in the risk assessment [25].

The fact that the approval was made in accordance with proper adherence to the law is not a guarantee the decision is free from risks. The approval of this GM crops could eventually lead to bioethical issues on fundamental right of farmers and consumers- right to farm conventional papaya crops and right of the consumers to choose non GM papaya.

Conclusion

In short, while Malaysia has identified biotechnology and agriculture as key economic drivers, the law on biosafety is still immaturity and yet to be put on trial in the court. Given the high speed growth of the modern biotechnology which employs genetic engineering, it is unbearable for the biosafety law to outpace the growth. Hence, bioethical issues should be addressed in the decision making process as a guideline in making approval. Informal advisory group under the Board to give advice on request and on a case by case basis is necessary to assist highlighting this issue. The role and functions of National Bioethics Council should be expanded to provide advice, resolve and manage bioethical issues in GMOs issues. The law should clearly spell out the scope and the role of ethical issues in its provisions as to avoid vagueness. The development of a simple framework for socioeconomic analysis which includes ethical consideration based on experiences in other areas and jurisdictions should be established to mitigate any challenges in this emerging technology.

Acknowledgment

The author extends her heartfelt appreciation to her supervisors Prof. Emeritus Dr. Shad Saleem Faruqi and Prof. Dr. Abu Bakar b. Abdul Majeed for their valuable input and comments in finalizing the paper.

References

1. Bowman v, Monsanto CO (2013) Certiorari To The United States Court Of Appeals For The Federal Circuit No. 11–796. United States Supreme Court, USA.
2. The Battle for Biodiversity: Monsanto and Farmers Clash.
3. Shaik Mohd NA, Hussain SM, Wan IA, Wan Talaat (2009) Religious and Bioethical Considerations on Genetic Modification Technology. The International Journal of Interdisciplinary Social Sciences 4: 6.
4. Latifah Amin, et al. (2011) Ethical Perception of Modern Biotechnology. African Journal Of Biotechnology. 10: 58 Pp. 12435-12447.
5. Foong P (2011) Human Embryonic Stem Cell (HESC) Research in Malaysia: Multi-faith Perspectives. Asian Bioethics Review 3: 182-206.
6. Letchumanan R, Johnny A (2012) Socio-economic Aspects in Decision-Making in the Context of the Biosafety Protocol: Malaysia's Experience and Case Studies. Asian Biotechnology and Development Review 14: 19.
7. Malaysia Demographics Profile 2013.
8. The World Bank, Accessed June 20, 2013.
9. Douglas Uggah Embas (2012) The Launching of The Biological Diversity Clearing House Mechanism (CHM Portal), Ministry of Natural Resources And Environment (NRE).
10. Environmental Agreements: Capacity Building and Implementation Project (MEA Project), Malaysia.
11. Jaganath IB (2012) GM Technology for Ensuring Food Security, Health and Environmental Sustainability. 24 September 2012, MARDI, Serdang.
12. Malaysian Biotechnology Information Centre (MACIC) 2011.
13. Ministry of Natural Resources and the Environment (NRE), Biodiversity in Malaysia, Multilateral Environmental Agreements: Capacity Building and Implementation Project (MEA Project), Malaysia.
14. Ministry of Natural Resources and the Environment (1998) National Policy on Biological Diversity.
15. Mohana A (2011) Elements of Bioethics in the Implementation of the Biosafety Act 2007, in the Seminar Perspektif Pelbagai Agama Budaya Mengenai Isu-isu Bioetik Terpilih Di Malaysia 22-23 Februari 2011 University Malaya.
16. Malaysian Biosafety Clearing House, Department of Biosafety, Ministry of Natural Resources & Environment.
17. Approved Events by the Government, Department of Biosafety. Malaysia
18. Amin L, Ahmad J, Jahi JM, Nor AR, Osman M, et al. (2010) Factors Influencing Malaysian Public Attitudes to Agro-Biotechnology. Public Underst Sci 20: 674-689.
19. Preamble Biosafety Act 2007.
20. The Hansard for the Dewan Rakyat meeting (2007).
21. Shahrizal Mohd Zin (2008) A Legal Study Of The Importance Of Food Labelling Of Genetically Modified Organisms (GMOs) In Developed Jurisdictions With Special Reference To Malaysia.
22. Respondents 2, 3, and 4 from semi structured interview.
23. Press Statement, by Ministry of Natural Resources & Environment (2010) National Biosafety Board Issues First Certificate of Approval for Field Trial of GM Mosquitoes.
24. Anonymous (2010) GM Mosquitoes-Government is Liable, Article of Consumer Association of Penang (CAP).
25. National Biosafety Board Decision. An Application For Approval For Confined Field Evaluation Of Delayed Ripening Transgenic Eksotika Papaya.