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ARTICLES

Biosafety Act 2007: Does It Really Protect Bioethical Issues Relating To GMOS

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Abstract Despite the (serious) global concerns about the safety and genetic stability of genetically modified organisms, the Malaysian National Biosafety Board (NBB) has recently approved the field testing for genetically modified (GM) male mosquitoes. With this development, bioethical issues, which in some respect could adversely impinge on the social, economic and environmental aspects of the society, have surfaced, and these concerns must be addressed by the authorities concerned. In reviewing this application, the National Biosafety Board has followed the requirements of the Biosafety Act 2007, which was created to strike a balance between promoting biotechnology and at the same time protecting against its potential environmental and human health risks in Malaysia. However, the 2007 Act fails to adequately take into account any bioethical issues in spite of the inclusion of a provision on socio-economic consideration. As part of an ongoing doctoral research project, and by way of an instrumental critique of the 2007 Act, the present paper attempts to address the role and function of the Malaysia biosafety legal framework in governing bioethical concerns relating to Genetically Modified Organisms (GMOs) within the current biotechnology background in Malaysia. Additionally, the paper suggests that the ambiguity of the provisions contained within the 2007 Act in governing such concerns, representing wider societal

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interests and welfare, in some ways might defeat the balancing role that this act was originally intended to fulfil.

Keywords Bioethical concern · Biotechnology · GMOs · Biosafety · Legal framework

Introduction

In the last few decades, biotechnology has been rapidly expanding to become a major global industry (Adcock 2007). Currently, the most widely explored area is modern biotechnology, which involves genetic modification by the genetic engineering (GE) of organisms in order to obtain certain desired traits (Claire 1998). This development offers the potential for novel products and services, but at the same time also generates new uncertainties and insecurities, including bioethical concerns. Numerous articles from the scientific literature are debating the potential risks arising from the introduction of Genetically Modified Organisms (GMOs) in the biotechnology industry, and this has led to a wide debate over bioethical concerns, affecting social, economic, legal environmental spheres as well as biosafety issues.[1] One of the recent debates has transpired in Malaysia. Following the decision of the National Biosafety Board (NBB) to approve the field release of GE Mosquitoes, concern are arousing about possible unintended effects on public health and the environment, because once these insects are released, they cannot be recalled (NRE 2010a, b, c, d).

Technology has been used for thousands of years by human beings in efforts to make their lives easier and better. Nevertheless, based on ethical principles, this technology must be utilized sustainably with ethical conscious (Macer 2007a). These concerns include environmental ethics such as the effects of GM organisms on non-target organisms, insect resistance in crops, gene flow, and the loss of diversity. There is also a general worry about the issue of interfering with nature, where every modification process itself disrupts natural processes within biological entities. Medical ethics is also a concern especially on public and animal health (Third World Network 2010). Moreover, experiences with GM seeds and crops in India have indicated that poor farmers did not benefit from GM technology, since they were often not allowed to trade or save GM seeds from one harvest to the next. This issue indicates a concern on individual's rights to modern biotechnology (Pray et al. 2006). Apart from bioethical issues per se, the procedural to implement this concern is also an issue. For example, the lack of public participation in the decision-making processes of the decision-makers in any GMOs' application is a concern that needs to be addressed. Such participation is important in order to

[1] The ethical principle of non-maleficence, or do no harm, would make public reasonably cautious about premature use of a technology when the risks are not understood. Recently some have advocated a total precautionary principle for genetic engineering, which would mean that no technology with more than 0 % risk should ever be attempted. However, to totally ban this technology, would means we hinder development and economy of the country. So what is needed is to strike a balance between biotechnology and bioethical consideration.

ensure that the public is aware and able to participate in a process that may have serious implication on their lives.[2] As such, it is submitted that bioethical issues pertaining to biotechnology have a wide range of applications during the research stage, development stage, and also the commercialization stage.

While bioethics regarding the subject of biotechnology concerns the arguments of balancing the benefits and risks of biotechnology to society (Macer 1998), biosafety describes the approaches to handling the perceived risks of GMOs released into the environment, such as their possible adverse effects on biodiversity or human health. This includes guidelines or legally binding instruments at the national and international level (Kaditi 2009). The Cartagena Protocol on Biosafety (hereinafter "the Protocol"), which is the main international legally binding instrument to regulate international movement of living modified organisms (LMOs), defines "biosafety" as the need to protect human health and the environment from the possible *adverse effects* of the products of modern biotechnology (NRE 2008). This Protocol bases biosafety on the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage (BCH 2009), which means that no technology with any known risk should be attempted. Since no human action can be guaranteed to have zero risk, in practice, these principles are used to assess the authorized safety of modern technology and are central to any public health program (Macer 2007b).

Modern Biotechnology in Malaysia

The commitment of the Malaysian Government towards the development of the biotechnology industry in Malaysia was reflected in the launching of the National Biotechnology Policy in 2005 (Biotechcorp 2010).[3] This Policy is currently entering its second phase in 2011, aimed at developing science and technology to businesses involving natural resources. Biotechnology was also identified as one of five core technologies that can accelerate Malaysia's transformation into an industrialized

[2] The public should have the freedom of information. Article 10 of the Federal Constitution (Freedom of Speech, Assembly and Association) does not mention anything about freedom of information, but under Article 19 of the Universal Declaration of Human Rights (UDHR) 1948,(http://www.un.org/Overview/rights.html) states that "Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers." According to Section 4(4) of the Suhakam Act-Act 597, the UDHR is applicable to Malaysia as long as it does not contravene the Federal Constitution. It is submitted that freedom to information does not contravene the Federal Constitution. In fact, it may be argued that for freedom of expression (as stated in Article 10 of the Federal Constitution) to be truly practiced, then freedom of information is a necessary element. Therefore, Article 19 of UDHR should applicable in Malaysia.

[3] The National Biotechnology Policy aims to develop biotechnology to become a new economic engine for Malaysia which eill enhancing the nation's prosperity and well-being. The Policy addresses vital aspects of biotechnology development such as the priority areas, legal, safety, financial and others issues. The policy spells out nine thrusts, which include transforming and enhancing the value creation of the agricultural sector through biotechnology. See Biotechcorp homepage. (2010) http://www.biotechcorp.com.my/Pages/NationalBiotechnologyPolicy.aspx?AudienceId=1. Accessed on 16 Nov 2009.

country by 2020. Currently, there are a number of ongoing research projects on modern biotechnology particularly involving GMOs,[4] with one approved for GM mosquitoes in 2010 for field trial, seven approved GMOs for Food, Feed, and Processing (FFP) and one product of LMOs (NRE 2010c). Thus, bioethical issues arise about this biotechnology development. There are two main arguments that revolve around this bioethical issue, the first one relates to the GM technology itself, and the second to the issue of intellectual properties rights (IPRs) (Nijar 2007).

At present, Malaysia does not have any specific law on bioethics relating to biotechnology, but this issue is regulated under the biosafety legal frameworks. Biosafety of modern biotechnology in Malaysia is governed by the Biosafety Act 2007 (hereinafter "the 2007 Act") and its regulations, Biosafety (Approval and Notifications) Regulations 2010 (hereinafter "the 2010 Regulation"). Apart from biosafety, however, the provisions of the Biosafety Act 2007 are rather vague on other bioethical issues in Malaysia. The Act 2007, which was gazetted in 2007, was developed to regulate all Living Modified Organisms (LMOs) with the purpose of striking a balance between biotechnology developments on the one hand and biosafety of LMOs on the other. The scope of the 2007 Act addresses all Living Modified Organisms (LMOs) (see footnote 4) including their products. The purpose of this 2007 Act is to regulate all GMOs with the objective to protect human and animal health and the environment. Similar to the Protocol, in which Malaysia is a party, this law adopts precautionary principles, which also recognize the need to protect socio-economic considerations as well.[5] The main focus of this paper is to look into the adequacy of the 2007 Act in protecting bioethical issues of GMOs in Malaysia.

Biosafety Act 2007: Reality Check

The Biosafety Act 2007 has been developed in Malaysia to fulfill its obligation on biosafety as under the Cartagena Protocol, which Malaysia has been party to since December 2003. The Protocol is the primary international instrument dealing with the regulation of LMOs. This Protocol grew out of the Convention on Biological Diversity (hereinafter "CBD"), which mandated the development of biosafety protocols on its provisions. The Protocol focuses on regulating LMOs released into the environment via planting and field trials, which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human and animal health.

One of the global bioethical issues is the concern on the impact of biotechnology on environmental sustainability and biodiversity. This has led to environmental biosafety policies at the global level under the "Precautionary Principle" approach to ensure the safe use of biotechnology. The principle demands the provisions to predict the consequences of technology, and where the biotechnology application

[4] 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.

[5] See Preamble, Biosafety Act 2007.

raises threats to human health or the environment, precautionary measures should be taken, even if some cause and effect relationships are not fully scientifically established. The Protocol does not refer to bioethics as grounds for the approval process for GMOs (Nijar 2007); nor does it mention it in any risk assessment. Some literatures suggest that the precautionary approach adopted by the Protocol could allow considerations of bioethics as it deals with sustainable use and minimizing risks (Macer 2005; Nijar 2007). However, how far these views are accurate is questionable. This is because the application of this principle has not been tested yet, as to what extent this principle can play a role in protecting bioethics with regards to biosafety issues.

In Malaysia, the Act 2007 recognizes the adoption of this Precautionary Principle, (see foot note 5) but similar to the position in the CPB, the stance of this approach is uncertain. The precautionary approach might go well with an ethical analysis as a literature suggests that an ethical analysis is closely linked with the understanding of how the technology may affect the well-being of humans, animals, and the natural environment. This includes the response to long-term consequences, certainty of zero risk, the role of decision-makers, and the rights of those affected parties (GenØk 2012). Based on the recent decision of the National Biosafety Board (NBB) in the GM's mosquitoes, precautionary measures relating to bioethical concerns were taken into account in their decision (NRE 2010a, b, c, d). Nevertheless, it is dubious whether the above-mentioned ethical analysis is truly implemented in making biosafety decision. This is due to the fact that the report states that the application was approved based on the GMAC's scientific assessment. This obviously shows that the precautionary approach is not the ultimate consideration in making decisions on the application of GMOs in Malaysia. This will eventually defeat the objective of the Biosafety Act 2007, which was to ensure the safe use of modern biotechnology.

The Protocol does have a provision on socio-economic considerations under Article 26. This consideration may be taken into account when making decisions relating to the application of GMOs. However, this provision is silent on the matter of bioethical concerns and whether they should be part of this consideration. The explanatory to the Protocol mentions that the value of biological diversity to indigenous and local communities could be part of socio-economic considerations under Art. 26 (Mackenzie et al. 2003). If this was truly the intention of this provision, the Protocol seems to have adopted bioethical concerns under its socio-economic considerations scope. As for Malaysia, despite the provision on socio-economic considerations under section 35 of the Act and regulation 25(b) of the 2010 Regulation, the new legal framework is rather vague on the protection of bioethical issues, as the scope and definition of ethics is not explicitly clarified anywhere in the 2007 Act nor in the 2010 Regulations. Section 35 does not comprehensively explain the precise requirements of socio-economic consideration. Although under the new regulation 25(b) of the 2010 Regulations, ethical issues are part of this socio-economic consideration, however, the regulation does not specifically define the meaning and scope of "ethics" relating to modern biotechnology. Thus, the definition of "ethics" in the 2007 Act and the 2010

Regulations remains questionable. Due to this vagueness it is uncertain as to the type of ethical issues that should be regulated under the said Act.

Even the fact that ethical issues have been included under the scope of socio-economic considerations in section 35, in the Biosafety Regulations, this does not clearly explain whether ethical issues are part of the consideration when assessing GM. This is because, in section 35 of the 2007 Act and regulation 25(b) of the Biosafety Regulation, the Board or Minister may take into account socio-economic considerations in their decision making. This provision is contrary to section 15 as all applications for approval of GM usage will be assessed by the NBB based on scientific evidence. The question remains as to what level will this consideration be taken into account and will it be disregarded at all by the Genetic Modification Advisory Committee (GMAC) when processing the GM application. The word *"may"* under section 35 and regulation 25(b) gives an indication of the Board's or Minister's discretionary power whether or not to take socio-economic considerations into account when assessing any GM application. Due to this lack of clarity on the process of incorporating socio-economic considerations in actual decision-making, it is unclear when socio-economic considerations are required, what information should be used for the analysis, how that analysis should be done, and by whom.

Bioethical issues are a pertinent matter under the 2007 Act as this law generally aims to protect human and animal health as well as the environment. Scientific assessment alone should not be a measure to determine the release of GMOs. However, this issue is problematic under the 2007 Act. This is because in considering the application of GM under section 15 of the Act, the National Biosafety Board will act on the recommendation of the Genetic Modification Advisory Committee (GMAC) on whether to approve or reject the application. Such recommendations are usually based purely on scientific assessments.[6] Thus, in making its decision, the Board would merely take scientific considerations and not ethical ones into account. This is inconsistent with the 2007 Act and in some ways does not promote the objectives of the protectionist principles of this law. It is recommended that ethical considerations should be taken into account as a priority over scientific evidence in the decision making of the National Biosafety Board. Both considerations, scientific and ethical, should be assessed collectively in any application affecting the GM technology. These issues remained unresolved despite the recent enforcement of the Act and creation of the Biosafety Regulations under it.

While the 2007 Act lacks provisions on the types and scope of bioethics, experiences in other countries such as the European Union (EU) have shown that they have incorporated ethical considerations into their socio economic considerations provisions in their national biosafety laws (Falck-Zepeda 2009). Norway, for example, has specifically created provisions on bioethics in their biosafety laws, in which GM assessment must be based on scientific evidence as well as ethical considerations (Traavik 2007). Even though the Norwegian law does not specifically define the scope of bioethics, nevertheless the law is clear on its stance

[6] See Section 15, Biosafety Act 2007 (Act 678).

on bioethics. These are some lessons that Malaysia could emulate in creating a clearly defined scope of ethical issues in the 2007 Act in order to avoid uncertainty.

Apart from the issue on the scope of bioethics, the procedural to implement bioethical issues is also problematic under the Act. It is apparent that in the 2007 Act, the involvement of the public in GM assessments is also rather vague. The importance of public participation is emphasized in in Section 14(c) and section 60 of the Biosafety Act 2007 The Board is mandated to consult the public in the decision-making process regarding GMOs and to make the results of such decisions available to the public. As such, whilst section 14(c) of the 2007 Act provides an opportunity to the public to participate in the decision-making of the Board, section 60 requires the Board to make a public disclosure on any GM application, in such a manner as it thinks fit. However, these opportunities are limited because under section 14(c) and section 60(1), 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. Furthermore, section 60 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. It is clear that this 2007 Act has failed in some ways by relegating this power to a mere discretionary exercise. Apparently, not only is there a sanctioned discretion pertaining to accessing information by the public and the controlled manner relating to its release, there is also a lack of desire at all for the Board to be transparent during pre-decision-making.

In the most recent and controversial step of releasing 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, the Malaysian National Biosafety Board has approved the male GM mosquitoes to be released for a field trial to the Institute of Medical Research (IMR). The National Biosafety Board made its decision after its Genetic Modifications Advisory Committee (GMAC) had analyzed the risk factors of the experiment. The issue was opened for public consultation from 5 August to 4 September 2010. The said Board claimed that in reviewing the application, they received valuable feedback through the public consultation (NRE 2010a, b, c, d). The first release was conducted in January 2011 in an uninhabited area in Bentong. However, until now, many have raised concerns on this GM mosquitoes release project. This might be due to the fact that the information was only posted on the Biosafety Department[7] website and published twice in a small section of weekly local newspapers. Therefore, access to this information was limited to large parts of the public. Without doubt the 2007 Act contains provisions that grant to the public formal rights of participation. However, it remains uncertain as to the extent to which the views of the public are being fed into the decision-making process itself. Furthermore, on a more general level, questions may be raised as to the efficacy of public engagement in technical and scientific issues. The 2007 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

[7] Department of Biosafety is under the purview of the Ministry of Natural Resources and Environment (NRE).

apparent that under the 2007 Act, public involvement is also rather vague and that such exercise lacks not only transparency but also a clear mechanism of such participation. Hence, despite the requirement on the public participation under the 2007 Act, section 60 is rather vague due to these limitations.

As biotechnology deals with people's lives, the law needs to give them sufficient understanding of the matter, including the potential benefits and hazards and the freedom to make the right choices and informed decisions. If the public are allowed to be involved, they could help address bioethical issues at an early stage. Such views could be an essential part in assessing GM applications. This could lead to a greater transparency of the potential risks involved in the technology. Macer rightly affirm that it is an ethical principle of autonomy that all research participants should give informed consent before receiving any intervention that has a reasonable risk of causing harm. Thus, in the case of GM mosquitoes, Macer suggests that researchers to provide information to potential participants (in this case- the local community). This can be done through disseminating information about the project and obtaining the consent of any person potentially affected by the release of transgenic insects, regardless of whether national guidelines mandate these procedures (Macer 2007b).

The Act does not specifically include any express provisions on informed decisions before any introduction of GMOs. Nonetheless, the NBB can impose a requirement of informed decisions in the terms and conditions of the approval before any GMOs field release (NRE 2010a, b, c, d). However, since this requirement is only stated in the approval letter, then the legal effect of such requirement is disputed. A question remains about how to implement this informed consent? Who are those affected parties? Whose consent should be obtained? Who should consult the parties involved? How are conflicts of interest to be overcome? In the recent case of GM mosquitoes, it is mandatory for the applicant through a public forum to obtain prior consensus and approval from the inhabitants in the release sites (NRE 2010a, b, c, d), but issues stir up, (1) on the parties who's giving the consultation whether there is conflict of interest or who are the best parties to consult with, and (2) the date of the real consultation was made whether the consultation was made before or only after the decision of granting the approval (for a field trial to release genetically modified (GM) male mosquitoes) by the NBB (TWN 2010). 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[8] before the approval was made by the Board. Local communities in the release sites should be consulted with the highest standards of prior informed consent when it comes to obtaining consensus and approval. Such lack of information suggests a lack of transparency, which has attracted considerable criticism from consumer associations, environmentalists, and the general public. For instance, the Consumer Association of Penang (CAP) is concerned about the safety

[8] One of the conditions of the approval, which has to be fulfilled before the start of the field releases, is that of public notification and consensus. The terms and conditions for the certificate of approval state that: "It is mandatory that the applicant through a public forum obtains prior consensus and approval for the inhabitants in the release sites regarding the proposed MRR [mark-release-recapture] field trial". See Ministry of Natural Resources & Environment (NRE). (2010a). Convention on Biological Diversity. Malaysia Biosafety Clearing House. http://www.biosafety.nre.gov.my. Accessed on 12 December 2011.

of the residents within the area due to the lack of scientific consensus on the safety of GM insects and the numerous uncertainties involved in genetic engineering, which eventually will result in the difficulty of assessing their risks (CAP 2010). For that reason, a provision on informed decisions and its mechanisms should be clearly defined in the 2007 Act as to avoid any denial of informed consent choice.

Based on the above scenario, the risk assessment process should have been more transparent by listing all the potential hazards and the evaluations of their likely consequences and estimated overall risk (Wallace 2011). This is because, not only will the approval process for the GM mosquitoes set a precedent for all future field trials and releases of genetically modified organisms in the country, it has far reaching implications for other GM crops, food, feed, and processing in the future. A Supreme Court of the United States decision on *Monsanto Co. v. Geertson Seed Farms* (Syllabus Monsanto Co. et al. 2010) to ban the planting of genetically modified alfalfa until the USDA's Animal and Plant Inspection Services ("APHIS") had fully analyzed the impacts of these crops on the environment, farmers, and the public in an Environmental Impact Statement ("EIS") is a good precedent to be referred to in this GM mosquitoes issue.

It is suggested that the inclusion of bioethical concerns is significant in all stages of the assessment and the regulation of GMOs. This consists of the national policy discussions, development, implementation, and the review of biosafety policies and regulations for the evaluation of risk assessments, specific applications and monitoring processes. As a part of a move towards a more democratic state, the decision-maker should encourage the public to participate in any decision-making process as part of bioethical procedural that could affect their lives and destiny. This would be in line with the Malaysian international trade relations and many internal factors including environmental, human and animal health, cultural and socio-economic ones as well as the country strategic positioning towards biotechnology. Therefore, it is submitted that the lack of bioethical certainty in the Act and the force of public's role in the biosafety decision-making process is a concern that must be urgently addressed by the relevant authorities. Such protection is important in order to ensure that the biosafety practice is a balancing process between promoting the development of biotechnology as well as protecting the environment and human also animal health.

Conclusions

Notwithstanding the existence of the 2007 Act governing GMOs in Malaysia, based on the discussion above, the law is rather vague in protecting bioethical issues. In view of that, this would, in some ways, defeat the intended objectives of the 2007 Act. Nevertheless, the 2007 Act is without doubt a significant piece of legislation in governing biosafety practices and the biotechnology industry. Its future role could be enhanced if it could play a balancing role between promoting the development of the biotechnology industry as well as ensuring environmental and public health safety at large.

In the eyes of the biotechnology industry, the inclusion of bioethical considerations in the Act 2007 could be an obstacle, as in some cases such considerations may delay or even block the release of potentially valuable products. However, these considerations should be balanced with the biotechnology development in order to ensure the objectives of the 2007 Act can be attained. In this respect, the considerations need to be transparent, well defined and understood by all actors and stakeholders in the biotechnology industry. The 2007 Act must properly accommodate the safety issues posed by GMOs and, in so doing, restore public confidence through bioethical consideration.

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