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Bioethical Issues on Genetically Modified Organisms (GMOs) In Malaysia: Biting Into the Legal Protection under the Biosafety Act 2007

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Abstract— **Of late, a growing number of ongoing researches on Genetically Modified Organisms (GMOs) in Malaysia were the consequences of the rapid advancement in the biotechnology industry. One such example is the genetically modified (GM) male mosquitoes and its field testing in two different regional areas, which has far reaching implications for not only for societal health and the environment but also for law. With this development, bioethical issues, which, in some respect could adversely impinge on the social, economic and environmental aspects of the society have emerged, which must be addressed by the authorities concerned. Despite the inclusion of a provision on socio-economic consideration in the Biosafety Act 2007 that has been created to govern the biotechnology industry in Malaysia, it lacks the force in protecting bioethical issues. Drawn from an ongoing doctoral research, the paper attempts to address the legal protection afforded by the 2007 Act and its most recently created regulation to bioethical concerns relating to GMOs within the current biotechnology terrain in Malaysia. Also, the paper suggests that the ambiguity of the provisions in the 2007 Act in protecting such concerns representing wider societal interests and welfare, would in some ways, vanquish the protectionist principles the 2007 Act intended to uphold and the balancing role that the 2007 Act was intended to play.**

Keywords- Bioethics, Biotechnology, GMOs, Biosafety, Legal Protection.

I. INTRODUCTION

Biotechnology has become the major industry in the world in the last few decades with rapid advancements (Mike, 2007). However, the introduction of Genetically Modified Organisms (GMOs) has led to a wider debate on bioethical concerns affecting social, economic and environmental spheres. These include the effects on non-target organisms, insect resistance crops, gene flow and the loss of diversity as well as the issue on interfering with nature in which the modification process itself is disrupting the natural process of biological entities. Ethics in biotechnology also includes the general subject of what should and should not be done in using recombinant DNA techniques in medical practice or in preparing pharmaceutical, food and agricultural products (Abu Bakar, 2002). Apart from that, experiences in India have indicated that poor farmers were not be helped by GM technology when they are not allowed to trade or save GM seeds from one harvest to the next (Carl, 2006). Although there is no biological evidence that genetically modified organisms in GM crops are detrimental as compared to non-GM crops, the cultivation and commercialisation of such crops have been criticized in the absence of any science-based protocols to assess the risks (Tomiko, 2009). This shows that the vast advances in life sciences and our multicultural and pluralistic modern societies create numerous bioethical problems requiring some stringent regulation (Tuija, 2004). As such, it is correctly argued that a guideline on "genethics" must be formulated in order to improve the scientists', students' and the citizens' abilities to make judgment about what is morally wrong and right in this particular technology (Abu Bakar, 2002).

Despite these risks and uncertainties, the development of the biotechnology industry in Malaysia is continually and consistently been driven by the Malaysian Government. Such commitment towards this development is reflected by the launching of the National Biotechnology Policy in 2005. The policy is to act as a catalyst for the development of biotechnology in Malaysia and at the same time to ensure the safety and risks of its development (Najib, 2005), in which the above-mentioned bioethical issues have surfaced. Currently, the part of bioethics that is most developed in Malaysia is that which relates to biosafety which is governed by the Biosafety Act 2007 (hereinafter 'the 2007 Act'). This Act is under the auspice of the Ministry of Natural Resources and Environment (NRE). However, strangely the biotechnology industry is under the supervision of the Ministry of Science, Technology and Innovation (MOSTI). As for the agriculture industry, the relevant ministry is the Ministry of Agriculture, while the Ministry of Health is responsible for medical practices and food products. The fact that different ministries are involved in governing issues in biotechnology has led to not only the lack of coordination between them but also possible overlapping functions in implementing the 2007 Act and its regulation.

Apart from this, however, the provisions of the 2007 Act is rather vague on other bioethical issues. The 2007 Act which was gazetted in 2007, generally provides for biosafety and addresses all Living Modified Organisms (LMOs). It is interesting to note that Malaysia uses the term LMOs rather than GMOs and Malaysia has made a declaration in the Convention of Biodiversity 1994 that the former term gives meaning to the latter. The 2007 Act is envisaged to strike a rather difficult balance between the creation of a sustainable biosafety on the one hand and the protection of socio-economic considerations of LMOs on the other.

This paper basically focuses on the legal protection provided by the new legal framework comprising of the 2007 Act and its most recent regulation in addressing

bioethical issues in GMOs in Malaysia. It will examine the question as to the adequacy of the biosafety legal framework in protecting bioethical issues and the broad powers of the National Biosafety Board (NBB) or the Minister in making its decisions relating to socio-economic considerations. Also, the issues relating to the application process of GM, in particular, the usual lack of public participation and consultation will be examined suggesting that in dealing with biotechnology with its attendant risks and hazards, inclusion of the local community and the public is imperative and should never be ignored.

II. THE LEGAL PROTECTION

The biosafety aspect of the 2007 Act generally aims at protecting public health and the environment. Also, it envisages to promote and/or to enable consumer choice and in fostering useful research by adopting a precautionary approach. In order to achieve these objectives, bioethical concerns should be part of the Act so as to assist decision-makers formulate more informed policy decisions and to improve stakeholders' abilities to make judgment about what is morally wrong and right in this technology. It is rightly contended that it is rather difficult to set a standard of ethics in biotechnology, what is more to prove a case based on these considerations. However, in order to legislate on bioethics, the term must be clearly defined as to avoid uncertainty (Ida, 2009).

Despite the provision on socio-economic consideration under section 35 of the Act and regulation 25(b) of the Biosafety (Approval and Notification) Regulations 2010 (hereinafter '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 the 2010 Regulations. Section 35, does not comprehensively explains the precise requirements on socio-economic consideration. Although under the new regulation 25(b) of the 2010 Regulations, ethical issues is 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.

While the 2007 Act lacks provision on the types and scope of bioethics, the Cartagena Protocol of Biosafety, which is an international instrument that governs biosafety issue relating to GMOs, requires its party to have their own national biosafety framework and Malaysia is a party to this protocol. Under Article 26, the said Protocol seems to have adopted ethical concerns in its socio-economic considerations provision. Experiences in other countries such as the European Union (EU) have also shown that they have incorporated ethical considerations in their socio economic consideration provisions in their national biosafety laws (Celine, 2007). Korea (Jose, 2007) and Norway (Jan, 2007) too, have specifically created provision on bioethics in their biosafety laws, in which GM assessment must be based on scientific evidence as well as ethical considerations. These are some lessons that Malaysia could emulate in creating a clear meaning and scope of ethical issues in the 2007 Act so as to avoid uncertainty.

Bioethical issue is a pertinent issue under the 2007 Act as this law generally aims at protecting human and animal health as well as the environment. Scientific assessment solely should not be a measure to assess the release of GM. However, this issue is problematic under the 2007 Act. Despite the fact that ethical issue has been included under the scope of socio-economic consideration in section 35, the 2010 Regulations does not clearly explain whether or not bioethical issues is part of the consideration in assessing GM. This is because, in section 35 of the 2007 Act and regulation 25(b) of the 2010 Regulation, the Board or Minister *may* take into account socio-economic consideration in his decision making. The word "*may*" under section 35 and regulation 25(b) gives 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.

In addition, this provision seems contrary to section 15 of 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 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. It is recommended that ethical consideration should be taken into account together with any 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 2010 Regulations under it.

As biotechnology is affecting people's lives, it is vital that the law provide them with sufficient understanding of the matter, including the potential benefits and hazards as well as the freedom to make the right choices. This is consistent with the requirement of the Cartagena Protocol and also the 2007 Act itself that Prior Informed Consent must be applied before any introduction of the GMOs (Ruth , 2003). If the public is allowed to be involved, they could help address bioethical issues at an early stage. Such public views should be an essential part in assessing any GM application. This could in some measures lead to a greater transparency of the potential risks involved in this particular technology. Open conversation and transparent decision-making processes are critical to the foundations of any liberal democratic society. Indeed, it is a truism that everyone must be involved in the debate and they must be allowed to state their opinions about GM no matter what

their opinion happens to be, or their level of acquaintance with the science and technology happens to be (Gary, 2010). In view of this, public participation should be clearly defined in the 2007 Act, including the mechanism of such participation. However, it is apparent that the 2007 Act is silent on the involvement of the general public in any GM assessment. Section 14(c) provides an opportunity to the public to participate in the decision making of the Board. However, this opportunity is limited if the information contains business confidentiality under section 59. Furthermore, it is also unclear as to whether the public could raise any bioethical concerns in their involvement in public participation under section 14(c) since there is no clear definition of public participation in the said Act.

In the most recent and controversial step of releasing genetically modified (GM) male mosquitoes (OX513A) into the wild (in Bentong, Pahang and Alor Gajah, Melaka) 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 purpose of this experiment is to combat dengue epidemic in Malaysia. The Board made its decision after its Genetic Modifications Advisory Committee (GMAC) had analysed the risk factors for 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 public consultation and responses from other countries. According to the press statement, the majority of the inputs supported the field trials and only one third of them raised objections (NRE, 2010). Even though feedback was obtained, transparency and meaningful public participation were lacking due to insufficient publicity and the short timeline of public consultation. Besides, it is unclear as to what was the feedback received from the public. Based on the comments and letters in the media, it seems that the public were not fully aware of the GM mosquito release.

What is most amazing about the whole scenario is the fact that the local communities in Bentong and Alor Gajah were not part of the mandatory consultations (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) before the approval was made by the Board. For the purpose of ethical conduct of research trial, informed consent is important to be obtained before the release of the research trial (Macer, 2005). Therefore, in this case, local communities in the release sites should be consulted with the highest standards of prior informed consent when it comes to obtaining the consensus and approval.

Such lack of information to the local communities and to the general public and the lack of consultation with the affected communities suggest the lack of transparency in the GM application procedures. It is not surprising that such glaring oversight have attracted considerable criticisms from consumer association, environmentalists and the public at large. 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 (CAP, 2010).

Given that the risk assessment and regulatory experience for GM insects worldwide is still immature and the World Health Organization (WHO) guidelines on the matter is yet to be established, the recent release of the GM mosquitoes in Malaysia is rather valiant, if not too hasty (CAP, 2010). Risk assessment process should have been more transparent by listing down all the potential hazards and its evaluations of their likelihood, consequences and estimated overall risk (Helen, 2011). A Supreme Court of the United States decision in *Monsanto Co. v. Geertson Seed Farms (June 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. This is because, not only will the approval process for the GM mosquitoes set a precedent for all future field trials and release of genetically modified organisms in the country, it has far reaching implications for other GM crops, food, feed and processing in the future. Experience from the Cayman Island on the open release of GM mosquitoes cannot be set as a benchmark as that country is not covered by the Cartagena Protocol being a non-signatory to that protocol. As such, their process of approval did not include public consultation or consent procedure (Helen, 2011). Therefore, it is submitted that the lack of public participation in the decision making process of the National Biosafety Board in any application on GMOs is a concern that must be urgently addressed by the relevant authority. Such participation is important in order to ensure that the public is aware of and participate in this process that may have serious implications on their lives.

In the context of freedom of information on the release of GM mosquitoes, Article 10 of the Malaysian Federal Constitution (Freedom of Speech, Assembly and Association) is silent about the freedom of information. However, Article 19 of the Universal Declaration of Human Rights (UDHR) 1948 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, 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 the freedom of information is a necessary element. Therefore, in this respect, Article 19 of UDHR should be applicable in Malaysia.

Experience in Brazil on public participation suggests a much different legal landscape than that of Malaysia. Access to information is repeatedly mentioned in the Brazilian Biosafety Law. For instance, paragraph 10 of Chapter III states that representatives from the scientific community, the

public sector and civil society can be invited to attend Brazil's National Technical Committee on Biosafety (CTNBio) meetings. In addition, in Article 14 of the same law, any proceedings with regard to GMOs will be published in the Federal Gazette to provide easy access to the public. In Article 15, public hearings will be carried out with the participation of civil society as conducted by CTNBio. Furthermore, parties involved in commercial clearance cases can request for a public hearing to provide proof of their relevant interests which must be in line with the provisions of the law. It is submitted that, it is crucial that Malaysia should have similar provisions, which would include transparency and effective public participation under the 2007 Act. In the long run, such an approach would serve Malaysia in good stead in governing the biotechnology industry as well as protecting the wider interests of the society.

Recently, the Ministry of Science, Technology and Innovation (MOSTI) has already set up the National Bioethics Council (NBC) to provide an arena in which stakeholders with widely differing moral views to discuss, interact and negotiate about controversial matters relating to bioethical issues in various aspects including biotechnology. Despite the setting up of a relevant committee for bioethical issues that invites the public to participate in giving constructive criticism, such participation and discussion have yet to reach all levels and sections of the community. It is correctly contended that despite considerable research in several advanced countries on public perceptions of and attitudes to modern biotechnology, limited effort has been in Malaysia that is geared towards developing a structural model of public attitudes to modern biotechnology (Latifah, 2010). Thus, even though the council has link to the government in an official advisory capacity, but if the council is to be implemented effectively and regarded as legitimate, the society as a whole should be included in the construction of the proposal and represented on the council, which in turn, should have the benefit of specialist advice when that is needed.

Bioethical issue is pertinent in the biosafety legal framework in Malaysia. Litigation in bioethical controversies is a poor method of resolution because "judicial decisions, once made, become precedent and thus have normative effect on the actions and conduct of citizens other than those before the court in the present controversy (Schaller, 2008). Due to this the uncertainty of the scope and the role of bioethics need to be clearly spelled out in the legal framework. If bioethical issue is not regulated in the legal framework, it can lead to endless litigation suit.

III. CONCLUSION

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

Despite the existence of the 2007 Act and 2010 Regulations governing GMOs in Malaysia, it is evident that the Act and 2010 Regulations lack clear provisions for the protection of bioethical issues and socio-economic implications of risks and hazards arising from biotechnology. Apparently this would suggest the ambiguity of the provisions in the 2007 Act and 2010 Regulations in protecting bioethical concerns representing wider societal interests and welfare, would in some ways, overwhelm the protectionist principles of the 2007 Act intended to uphold. In spite of its flaws, the 2007 Act is without doubt a significant piece of legislation in governing biosafety practices and the biotechnology industry. Against the current social, political and economic terrain in Malaysia, it remains to be seen if the 2007 Act in its current form would be adequate enough in protecting bioethical issues. Its future role could be enhanced if it could play a balancing role between promoting the development of the biotechnology industry and business interests as well as ensuring public safety, health and interests at large.

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