Liability and Redress of Trans-Boundary Movement of Genetically Modified Organisms and the Biosafety Law in Malaysia

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Abstract

Biosafety refers to the efforts taken in ensuring the safety of the application of biotechnology, which necessitates for proactive steps to be taken to "reduce and eliminate the potential risks resulting from biotechnology and its products". Modern biotechnology has enabled scientists to genetically and biochemically modify plants, animals as well as microorganisms. In the effort to increase crop production for the purpose of securing global food supply, the application of biotechnology in the agricultural sector must be carried out in a safe and sustainable manner. The recognition of the potential risks to human health and the environment must not be discounted and countries looking towards the application of biotechnology must ensure its safe application. The need for further regulations on biosafety was discussed in 1992, when the Convention on Biological Diversity (CBD) was adopted. Article 19(3) of the Convention requires its members to consider the need for a protocol on "the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity." This consequently led to the Cartagena Protocol on Biosafety (CPB**),** which primarily regulates the trans-boundary movement of living modified organisms (LMOs) or alternatively known as genetically modified organisms (GMOs). In Malaysia, the Biosafety Act 2007 (BSA) was passed to regulate the release, importation, exportation and contained use of GMOs in order to protect inter alia human, plant and animal health as well as the environment and biological diversity. This paper highlights the issues pertaining to liability and redress, which provides for the legal obligation to compensate the damage especially to the environment accruing from the trans-boundary movement of the GMOs, as well as the position of the present Malaysian biosafety law.

Keywords: LMOs, Biosafety, Trans-boundary movement, Liability and redress

1. Introduction

The advancement in biotechnology has brought the realm of possibilities very uncomfortably close, some say, to the realm of the probabilities (Shaik & Wan Izatul 2009). Biotechnology is an essential part of modern life and the most prominent development in biotechnology since the early 1970s is the creation of transgenic crops, which are genetically modified organisms (GMOs) or living modified organism (LMOs). Main traits of GM plants are herbicide tolerant and insecticide properties, which guarantees better yield. Since the early 1970s, modern biotechnology has enabled scientists to genetically and biochemically modify plants, animals and microorganisms. Today scientists are able to identify specific genes associated with desirable traits in one organism, and transfer those genes across species boundaries into another organism. Commodities containing genetically modified ingredients, as well GMOs, such as agricultural seeds, play an increasingly important role in the food and pharmaceutical industries. Despite some consumer concerns, the global distribution and quantity of GM crops and the global distribution of GMOs has increased rapidly over the last decade. In the effort to increase crop production, the application of biotechnology in the agricultural sector must be carried out in a safe and sustainable manner. The recognition of its potential risks to human health and the environment must not be taken lightly and countries looking towards the application of biotechnology must ensure its safe application.

The effort in ensuring the safety of the application of biotechnology is known as "biosafety" (Hill and Sendashonga 2006), which basically refers to the need to protect human health and the environment from any adverse effect of biotechnology and its products. Biosafety necessitates proactive steps to be taken to "*reduce and eliminate the potential risks resulting from biotechnology and its products*". The regulatory framework in

biosafety legislations specifically target the safety of human health and the environment in the event LMOs are being released into the environment. According to Qureshi (2000),

> "*Biosafety is an all encompassing reference to safety measures relating to potential or actual adverse effects on the conservation and sustainable use of biological diversity, including risks to human health, arising as a consequence of the application of the modern science of biotechnology*".

The need for further regulations on biosafety was discussed in 1992, when the Convention on Biological Diversity (CBD) was adopted [Article 19(3)], which consequently led to the Cartagena Protocol on Biosafety (the Protocol**),** which primarily regulates the trans-boundary movement of LMOs. Article 1 of the Protocol states its objectives as to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risk to human health, and specifically focusing on trans-boundary movements.

Although Article 4 defines the scope of the Protocol to the trans-boundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the actual scope can only be understood by looking at Article 5 and 6 which exclude the requirements of advance informed agreement procedure in respect of LMOs which are pharmaceuticals for humans, LMOs in transit and LMOs for contained use.

Essentially, the Protocol outlines the rights and obligations of Parties in respect of trans-boundary movement, transit, handling and use of LMOs in a manner to avoid any adverse effects on conservation and sustainable use of biological diversity including risk to human health. The Protocol calls for the enactment of legislation and the formulation of policy and administrative measures to ensure biosafety consistent with the objectives of the Protocol. In this respect domestic legislation on biosafety needs to deal with the matters provided in the Protocol, namely:

(i) Risk Assessment standards and procedures (Article 15)
(ii) Risk Management standards and procedures (Article 16)
(iii) Prior Informed Agreement standards and procedures (Article 7)
(iv) Standards for contained use (Article 6)
(v) Procedures of import of LMOs for direct use as food (Article 11)
(vi) Handling, Transportation, Purchasing and Identification (Parties to take necessary measures - including but not necessarily limited to legislative measure) of LMOs (Article 18)
(vii) Prevention and Punishment for illegal trans-boundary movement (Article 25)

It must be noted that the Protocol deals with LMOs and not their products and Parties are encouraged under Article 2(5) to take cognizance of available expertise, instrument and work undertaken in international forums with competence in the area of risk to human health. The design of any domestic biosafety law, to be consistent with the Protocol must surely take into account of both the above matters. More importantly, the Protocol allows the formulation of standards or the taking of actions that are more protective of the conservation and sustainable use of biological diversity than that demanded under the Protocol, provided that, they are consistent with the objective and provisions of this protocol and Party's other obligations under international law [Article 2(4)]. Paragraph 5 of Article 2 use the term 'encouraged', thus implying a non mandatory requirement but in the light of the spirit of the Protocol and the CBD, the paragraph must be deemed to be a strong ethical exhortation bordering virtually on the mandatory. It would tantamount to lack of good faith to ignore it. Similarly, paragraph 4 of Article 2 does not grant the right to arbitrarily set a more stringent standard of biosafety than those prescribed in the Protocol. Parties desiring to set these more protective measures must ensure that they do not conflict with the Party's other obligations under international law and the Protocol (Safrin 2002).

While the main thrust of the Protocol appears consistently focused on conservation and sustainable use of biological diversity and risks to human health, socio economic considerations may also be taken into account when considering the impact of living modified organism on the conservation and sustainable use of such resources, especially with respect to the value of biological diversity to indigenous and local communities (Article 26).

2. Liability and Redress of Trans-Boundary Movement of LMOs

Despite the observance of the safety procedures of the Protocol or domestic regulatory requirements of the country of import, damage arising from trans-boundary movement of LMOs may still occur. Liability issues grow as a result of economic loss or damage due to the adventitious presence of GM crops in other differentiated production systems (Zapeda 2006). In such an event, liability and redress provisions become an integral part of the Protocol, almost a condition for its effective observance. Hence Article 27 provides:

> *The Conference of the Parties serving as the meeting of the Parties to the Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from trans-boundary movements of*

living modified organisms, analyzing and taking into account of the ongoing processes in international law on these matter and shall endeavor to complete the process within four years.

At the first meeting of the Conference of the Parties serving as meeting of the Parties to the Protocol (COP-MOP), an Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress was established to carry out the mandate under Article 27. Since then several meetings had taken place and in May 2008 the COP-MOP 4 considered the final report of the Working Committee (UNEP 2009).

The contents of the Final Report are encouraging as they point towards a real likelihood of consensus in the near future negotiations. Of great significance are matters dealing with State responsibility, both primary and residual, scope of liability and redress rules and procedures, definition of damage and operators, standards of liability and computation and definition of damage, extended local standi, compensation scheme and the pivotal role of domestic law in giving effect to the rules and procedures of L&R once finally accepted by the members at the COP-MOP. A liability and redress regime provides a way of dealing with scientific uncertainty by giving rights to injured parties to charge those responsible for causing harm and imposing an obligation on others to limit risks, mitigate losses and provides redress (Kameri-Mbote 2004).

3. State Responsibility: Primary and Residual

The Final Report of the Open-Ended Ad Hoc Committee in both its operational text and the preamble categorically states that the rules and procedures shall not and would not affect the rights and obligations of States under the rules of general international law with respect to the responsibility of State for internationally wrongful acts. It is interesting to note that the question of what constitutes 'internationally wrongful act' is not a simple straight forward matter. The International Law Commission's Articles on State Responsibility define international wrongful act as conduct not in conformity with an international obligation and attributable to a State and for which the State should be responsible. Thus, State responsibility covers both the internationally wrongful acts of a State or of private actors whose acts can be attributed to that particular State, which generally means a State agency, or non-State agency acting under the direction, control and instructions of that state or which carry on aspects of governmental authority. This rule of attribution operates even retroactively by making a State responsible for prior conduct by private parties if the States "acknowledges and adopts the conduct as its own" (Bodansky & Crook 2002). It has been pointed out that in most cases this responsibility arises as a result of primary rules – to prevent or limit particular types of private conduct (Christenson 1991). Though in discussion leading to the Final Report of the Working Committee, many countries opposed the inclusion of primary state responsibility, the idea of residual state responsibility appeared less objectionable. This principle of state residual responsibility entails the obligation of a state to assume liability to pay when an operator of that state who is liable to pay compensation for damages for harm arising from the trans-boundary movement of LMOs becomes unable to meet the full sum claimed. The state to which the operator belong is liable to meet the difference.

While the mechanism of state residual responsibility serves a useful propose of ensuring that the claimant will be appropriately and fully compensated, the rational of making the state residually liable for the act of a private actor (the operator) without any determinants of attribution may be questionable. As pointed out by Boyle, sovereign states are less involved in the production and transport of LMOs although they have some power to control the industry (Boyle 2005). Moreover, the inclusion of residual state liability may result in 'hesitation for state to ratify this regime' (Kohm 2008).

4. Scope of L & R Rules and Procedures

The Final report offers four operational texts to deal with the scope of the L & R rules and procedures. Operational Text 3 appears to be the most comprehensive in that it proposes that the rules and procedures will apply to "shipments, transit, handling and use of living modified organism, provided that these activities find their origin in a trans-boundary movements". The text continues to provide that these rules and procedures will apply to both intentional as well as unintentional trans-boundary movement of LMOs and also to the trans-boundary movement of goods in contravention of domestic measures to implement the Protocol. The text emphasizes that with respect to intentional trans-boundary movements, the rules apply to damage resulting from any authorized use of the LMOs that is where the LMOs are intended for direct use as food and feed or for processing, for contained use or for intentional introduction into the environment including the use in violation of the authorization.

5. Standards of Liability

Perhaps among the most debated issues in the preparation of the L&R rules and procedures for trans-boundary movements of LMOs is the question of the most appropriate standard of liability. Some countries advocate the adoption of strict liability standards, including Malaysia while others proposed a fault-based standard of liability. The COP-MOP 4 Decision BS-IV/12 provides three options for standards of liability: strict liability, mitigated strict liability and fault-based liability.

The general trend in other international treaties and convention appears to favour strict liability regime for trans-boundary harm to the environment. According to Boyle, "the choice of strict, or in exceptional cases absolute, liability is an invariable feature of all international liability conventions" (Boyle 2005). Be that as it may, unlike other strict liability imposing Protocols, the Ad Hoc Working Group does not provide a cap on

amount of damages that a party is liable for although domestic law may provide for financial limits for strict liability but it shall not be less than (2) drawing rights (COP-MOP 4).

Another option considered by the Working Group is mitigated strict liability, that is the switching of fault-based liability to strict liability in cases where risk assessment has identified a LMOs as ultra-hazardous and/or acts or omissions in violation of national law have occurred or violation of the written conditions of any approval has occurred (Text 7, COP-MOP 4 Decision BS-IV/12). Of course the other option considered is fault-based liability regime which requires proof of intentional, reckless or negligent conduct on the part of the defendant. Both strict liability and fault based liability proposals channel liability to the person proven to have caused the damage.

6. The Malaysian Biosafety Law

Biotechnology in Malaysia is a gold mine. As a mega bio-diverse country, Malaysia has enormous potential for 'bio-wealth' creation through biotechnology. Under the National Agriculture Policy 3 (NAP3) for 1998-2010 as well as the Biotech Policy introduced in April 2005, biotechnology has been identified as one of the new sources of the nation's growth. Setting the Scene is through the reflection of the National Biosafety Framework through the Malaysian Premier's statement on 24 January 2005 in Paris as follows,

> *"The international community has recognised the potential hazards and risks of genetic engineering. The principle of precaution underpins the Cartagena Protocol on Biosafety as well as its parent convention, the CBD.*"

7. Biosafety Act 2007

Malaysia's ratification of the Cartagena Protocol mandated the performance of several obligations, one of which was the enactment of domestic law along the lines of the Protocol to deal with the safety aspect of transfer, handling and use of LMOs. Malaysia accordingly enacted the Biosafety Act 2007. Reactions to the Act had been mixed. There are those who view the Act as being too lenient, almost 'throwing precaution to the wind' (Kwan 2007), while others blame the Act for being too prohibited and not business friendly. In most legislation dealing with standards of safety, it is quite common that views tend to oscillate between two extremes. Be that as it may, for the non-partisan bystanders but very much concerned with the issue of safety of LMOs a detailed discussion of several important provisions of the Act can be useful.

The Act is divided into 7 parts. Part I deals with Preliminary matters such as the name by which it is to be cited, date of coming into force and the usual interpretation provisions. Part II deals with the establishment, composition and powers and functions of the National Advisory Board, the Genetic Modification Advisory Committee and other committees and sub-committees. The office of a Director General of Biosafety and the power of the Minister to give directions to the Board and the Advisory Committee are provided under this Part. Part III deals with the difficult question of approval for release and import. Basically this Part embraces the spirit of the AIA regime of the Protocol but not in its entirety. There are significant divergences. Part IV is dedicated to notification for export, contained use and importation of living modified organism for contained use activities. The risk assessment, risk management and emergency response plan are covered in Part V while Part VI deals with enforcement and Part VII, as in most legislation contains miscellaneous provisions.

The three fundamental parts of the Act are Part III, IV and V as they form 'substantive interpretation' of biosafety measures as mandated by the Protocol and as cautioned by the Precautionary Principle.

8. Part III – Release Activity and Importation.

Section II of Part III of the Act declares that this Part shall apply to release activities and import activities involving living modified organisms. 'Release activity' is defined to mean "any intentional introduction of living modified organisms or products of such organisms into the environment through activities or for the purposes specified in the second schedule". The Advanced Informed Agreement procedures of Part III therefore apply to all LMOs intended for direct introduction into the environment, including products of such LMOs. Apparently, this provisions appears to conflict with Article 7(1) and (2) of the Protocol which excludes the AIA procedures regarding first trans-boundary movement of LMOs for intentional introduction into the environment of the importing state where the LMOs are intended for direct use as food or feed, or for processing although the Minister may exempt these LMOs from any or all provisions of this Act (section 68).

It may be argued that these apparently stricter measures can be justified by the words of Article 2(4) of the Protocol, which in essence recognize the right of a Party to take a more protective action in respect of the conservation and sustainable use of biological diversity than that called for in the Protocol "*so long as such action is consistent with the objective of the Protocol and that Party's other obligations under international law*." Clearly, Malaysia's stricter measures in Part III can only be justified in the context of these measures being consistent with the Protocol and Malaysia's other international obligations.

9. Precautionary Principle

The 'precautionary principle', which underlines the Cartagena Protocol, appears to similarly characterize the essence of the Act, though its presence in the Act takes various levels of observance. Precaution has always played an essential role in regulating environmental risks (Shaik and Wan Izatul 2009). As a factor influencing decision about anything uncertain, precaution is the deeply ingrained cultural inclination towards being safe

rather than sorry. As a principle guiding the difficult decision choices in environmental matters, the principle finds its origin in the 1970s in the former West Germany in the concept of 'vorsorge' or foresight which later developed into the vorsorgeprinzip (or the precautionary principle) and which became the underlying justification for the new West German vigorous policies to tackle environmental issues such as acid rain, global warming and the North Sea Pollution (Jordan and O'Riordan 1998). The impact of this principle in environmental regulation and management has been remarkable and it made its most significant appearance in the Rio Declarations in 1992.

What does this principle exactly mean? At its core lies the intuitively simple idea that decision makers should act in advance of scientific certainty to protect the environment from incurring harm. There is in fact no single universally accepted statement of the principle and both proponents and opponents are inclined to move towards two opposing extremes i.e. prohibitive action and reactionary action (Kriebel 2001).The prohibitive action claims justification on the rationale that lack of scientific certainty as to the threats to the environment shall not hinder them from prohibiting a particular action while the reactionary action believes that no action should be prevented unless there is scientific certainty as to its threats to the environment.

Even the two famous formulations of the Principle, namely the Rio Declaration and the Wingspread Statement appear to differ in critical aspects. Marchant (2003) points out that the Rio Declaration aims at environmental degradation while the Wingspread Statement is wider to include harm to human health. More importantly, the Rio Declaration is phrased as a guiding principle while Wingspread appears to impose an obligation to act. The lack of definitive formulation of the Principle has led to inconsistent application of the Principle even to the point that it can become a tool for inaction or arbitrary action. Bodansky argues that the Principle should not require a technology proponent to prove that its products has zero risks (Bodansky 1994), but this is exactly what can happen when the parameters of the Principle are not fully formulated. Such inconsistency is also clearly evident in Malaysian Biosafety Act 2007.

It is now evident that Part III of the Act carries the precautionary principle to its most extreme interpretation by requiring the AIA procedure for importation of LMOs intended for direct use as food, feed or processing when indeed such procedure is exempted for such products under the Protocol, which is itself a collective solemnization of the Precautionary Principle by the Parties, including Malaysia. However, while maintaining what seemingly is a more stringent application of the PP, the decision norm in the entire regime of import and export regulation under the Act appears to be a derogation of the PP of the Protocol; compare the PP in the Act and the same principle in the Protocol:

> Section 35 of the Act
>
> *"The Board or Minister shall not be prevented from taking a decision, as appropriate, under Part III or IV, where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of living modified organisms or products of such organisms on human, plant and animal helath, the environment and biological diversity and may also take into account socio-economic considerations."*
>
> Under the Protocol, Article 10(6).
>
> *"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of the biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects."*

Comparing the two statements of PP above, several significant divergences become apparent: Firstly, the PP statement of the Act makes no mention of 'sustainable use' which is the very essence of biological diversity. Secondly, the Protocol statement allows a Party to either prohibit importation of LMOs (risk avoidance) or permit importation subject to appropriate measures being taken to minimize risks (risk management). Hence, a Party may oscillate between the two extremes of absolute prohibition of import or conditional permission of import, either of the two decisions to be subject to the "overriding aim" of "avoiding or minimizing such potential adverse effects". The PP under Act, however, does not mention this 'overriding aim' and a decision to allow importation (if considered appropriate) can be made purely on "socio economic considerations". It is, therefore, not surprising, and it is not entirely wrong for Kwan (2007) to claim that the Act "has thrown precaution to the wind". However, a closer examination of the PP under the Act may well suggest a plausible contrary. The Board or Minister may decide to prohibit import of LMOs or the product thereof if such importation may adversely affect the socio economic activities and interests in Malaysia, but this is only a plausibility not a possibility given the fact that the 'overriding aim' is absent.

It must be appreciated that the text of the PP in most, if not all, environmental related agreements and Protocols are worded in cautionary, albeit, prohibitive terms. As aptly commented by Bratspies (2002), *"…the uncertainty relates not to the possibility of harm but to the degree and care needed to prevent the harm.*"

10. Conclusion

Malaysia has amply shown her commitment towards environmental issue and the conservation of biological resources both through effective domestic legislative, administrative and policy measures as well as active involvement in and speedy ratification of international agreements and protocols on environmental biodiversity and safe and sustainable use of resources. However, despite this positive attitude towards sustainable use of resources, there are many policy and legislative aspects of safe and sustainable use of resources that require urgent revisit, especially having in mind Malaysia's obligation to comply with international protocols.

The present Biosafety Act 2007 cannot be faulted for appearing more stringent than the Cartagena Protocol of Biosafety, because this divergence is permitted by the Protocol itself. Nonetheless, Malaysia needs to be wary of claims that the Act contradicts the spirit of the Protocol and may even be anti-trade in nature, or at the very last, a disguised non-tariff barrier.

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