Journal of Agriculture and Environmental Sciences
June 2014, Vol. 3, No. 2, pp. 97-116
ISSN: 2334-2404 (Print), 2334-2412 (Online)
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Published by American Research Institute for Policy Development

Impact of Transboundary Movement of Gmos: Is the Malaysian Biosafety Act 2007 Sufficient to Sustainably Protect the Environment?

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Abstract

Biotechnology could be the answer to many of the modern world's problems including food scarcity as well as environmental degradation and diseases. While proponents of biotechnology promote the huge benefits of the application of biotechnology in the various fields, the critics put forth controversial legislative, environmental and healthissues. Thus, a workable and effective biosafety law should be in place to facilitate the introduction and development of biotechnological application especially in the field of agriculture. The Biosafety Act 2007 was enacted pursuant to Malaysia's international commitment on the preservation of biodiversity under the Convention of Biological Diversity and the Cartagena Protocol on Biosafety. Although the main objective of this biosafety legislation is in the regulation of the release, importation, exportation and contained use of living modified organisms and the release of products of such organisms, it is found to contain only provisions on criminal liability in the event of its contravention without providing any room for civil or private liability available to aggrieved parties. The civil liability regime extended compensatory claim to include damage to the environment apart from maintaining personal and proprietory claims. This paper comparatively looks into the possibility of revising this loophole by comparatively looking into three existing civil liability regimes available for environmental damage in the United States, Norway and Australia along with the LuganoConvention that dealsspecifically with civil liability. This paper concludes with the suggestion for a reform the existing BSA 2007to include civil liability to ensure sustainable environmental, as well as human, protection from the effect of biotechnology.

Keywords: LMOs, Biosafety, Sustainable Environmental Protection, Civil Liability

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Introduction

The benefits of the application of biotechnology are tremendous. Biotechnology can be seen as an answer to the various food and health problems faced by mankind. The proponents of biotechnology promote the huge benefits of the application of biotechnology in the various fields while the critics put forth controversial issues such as legislative, environmental and health. Therefore, the application of biotechnology in these fields, especially in the field of agriculture, does have its benefits and risks.

The adverse effects in the application of biotechnology, either in medicine, pharmaceutical or agriculture, can be divided into three categories namely environmental and health, legislative issues, and social and economic issues. The main theme of this thesis is on legislative issues particularly on the issue of liability and redress for damage resulting from transboundary movement of Genetically Modified Organisms (GMOs) or more commonly used term of Living Modified Organisms (LMOs).

The legislative framework in dealing with biotechnology from the legal perspective is commonly known as "biosafety". Biosafety is defined as "a range of measures, policies and procedures for minimizing potential risks that biotechnology may pose to the environment and human health" (UNEP, undated). Since there is rapid development in the field of biotechnology, the issue of biosafety becomes ever more pressing. Biosafety is supposed to prescribe the necessary stepsto protect consumers in terms of food safety as well as to protect the environment.

Materials and Methods

This study is a qualitative study carried out via content analysis on the data collected from the domestic primary source namely the Malaysian Biosafety Act 2007 and for the purpose of conducting a comparative study, legislationsfrom three foreign countries were also examined, namely:-

- 1. The United States of America
- 2. Norway
- 3. Australia

Apart from these legislations, other primary data studied are the international conventions namely the Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, commonly referred to as "the Lugano Convention", the Convention of Biological Diversity as well as the Catagena Protocol on Biosafety and its sister protocol of Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

The legal tool used for analysis is the Rule of Statutory Interpretation, which is the same tool used by the judges: once the Parliament has passed a statute, the duty to interpret such legislation thus lies with the judges. The role of a judge in interpreting statutes is twofold i.e. he has to firstly, ascertain the meaning of the statutory provision and secondly, accommodate that particular statute to existing body of law [the common law and statute law], which eventually become a precedent. To facilitate the interpretation of these statutes, the Interpretation Acts, which contains definitions for commonly used words and terms, have been passed. In addition to these Acts, the courts have to resort to some other techniques of interpretation, which have been evolved over the years. The rules are as follows: -

- (i) The Literal Rule: Under this dominant rule, the word or phrase in question is given its literal or ordinary grammatical meaning.
- (ii) The Golden Rule: This rule involves the actual modification of the language in a statute with the purpose to overcome the absurdity appears due to the defect in such Act.
- (iii) The Mischief Rule: If the word or phrases of the statute, in the light of the whole statute, are not plain and unambiguous, the court will look at the "mischief" that was intended by the legislature to remedy it.
- (iv) The Purpose Rule: Under this rule, the court will look into the overall intention of the legislature from reading the statute as a whole.

The Need for Biosafety Laws

New technologies require new legislative approach. Just because the new technology is perceived to contain inherent dangers does not mean that it is to be completely avoided. The precautionary principle indicates that the lack of scientific evidence does not preclude a particular country from taking a stand not to grant permission of the application of a particular technology.

The country intending to apply a new technology would need to weigh the benefits and risks in the application of such technology. The risk assessment and risk management procedures would have to be developed to avoid or minimise adverse effects to the environment and human health in the application of biotechnology in the field of agriculture.

It has been provided under Article 19(3) of the United Nation Convention of Biological Diversity (CBD) that the Parties shall consider the need for a protocol setting out appropriate procedures, includingadvance informed agreement, in the field of the safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. Pursuant to this requirement, the Conference of Parties to the CBD has reached an agreement on the need to have a protocol to deal with the safe transfer, handling and use of any living modified organism that may have adverse effect on the conservation and sustainable use of biodiversity. The agreement on the need for a protocol resulted in the birth of the Cartagena Protocol on Biosafety (CPB). CPB was adopted on 29 January 2000 and entered into force on 11 September 2003.

A workable and effective biosafety law would have to be enacted in order to facilitate the introduction and development of biotechnological application in the field of agriculture. It is common knowledge that the development of science most commonly surpasses the development of legislation. By the time a legislation is complete i.e. it has gone through the legal process of being promulgated as law, it could be obsolete and cannot be applied to a particular technology, in this case, biotechnology. Therefore, the stakeholders of the biotechnology industry, namelythe legislators, the scientists and the public at large, would have to be consulted in the framing of legislative framework in respect of biotechnology.

Due to the adoption of the precautionary principle in environmental decision making by the various countries, especially the developing countries, the legislative approach in the area of biosafety should reflect the careful and cautious stand taken by these countries. This stand is more needed for countries that are categorised as mega-diverse countries. Since Malaysia is one of the mega-diverse countries, her biosafety legislative framework should reflect this stand. However, by adopting the precautionary principle and a cautious biosafety legislative framework does not necessarily mean that Malaysia should not participate in biotechnology industry.

The economic gains to be derived from biotechnology industry would be beneficial for the country's national income. More income would mean that more economic activities could be carried out for the benefit of the public.

Currently, Malaysia is among the leadingAsiancountries actively participating in the agricultural biotechnology industry. The purpose of Malaysia's active participation is to enable Malaysia to produce more agricultural products to meet the national demand for food (Kamariah, 2012). The current food production in Malaysia is not sufficient to meet the demand for food by the Malaysian consumers. Therefore, Malaysia is turning to biotechnology to increase the production of basic crops to meet the domestic demand so that the expenditure on importing those crops could be reduced. With this in mind, the Malaysian Government has developed the National Policy on Biotechnology. Under this policy, the Malaysian Government has explicitly recognised the importance of biotechnology and its potential in creating wealth and economic growth (MOSTI, undated).

To date, Malaysia remains an importer of products derived from LMOs. Nevertheless, since the Malaysian Government has made a declaration to make biotechnology a new economic engine for Malaysia, enhancing the nation's prosperity and well-being (MOSTI, undated), this will soon change. Malaysia will eventually become a producer of products and crops containing LMOs. When the time comes, the role of Malaysia will transform from being an importer of GM products and crops to a producer of these products and crops containing LMOs. Obviously, there is some legal consequences when the transformation of Malaysia from an importer to producer or exporter of GM products and crops and therefore, Malaysia's legislative framework in respect of LMOs would have to reflect that position. Otherwise, without proper and sufficient legislative framework and protection, it would open to various legal claims from other countries and also private individuals.

Furthermore, the participants and players in the biotechnology industry would need to appreciate and understand the legal responsibilities in dealing with this new technology. New technology would require new legislative framework. The players in agricultural biotechnology, especially the farmers, would have to be educated on their legal responsibilities in the act of planting GM crops. New agricultural methods such as the requirement to have a buffer zone surrounding the agricultural plots which is planted with GM crops would have to be made known to these farmers.

Similarly, the Malaysian law on biosafety should not be too relax nor too rigid: the farmers would be open to various legal claims resulting from damage caused by possible contamination from GM cropsif it is too relax. On the other hand, the development of agricultural biotechnologywould be impededif it is too rigid: rigid laws would hinder the farmers from planting GM crops for fear of contravening the biosafety laws.

Biosafety law is important so that any products produced using GMOs can be accepted with ease globally. The biosafety laws on biotechnology research, confined field tests, open-field tests and eventually commercial planting of crops derived from LMOs would have to reflect the declared policy of the Malaysian Government on the development of biotechnology as an engine of economic growth. According to Teng(2008), a further requirement on the biosafety law is on Malaysia's international commitment on the preservation of biodiversity. He also views the National Biotechnology Policy of Malaysia as strong where agriculture is given the highest priority and institutional capacity for R&D in universities and government agencies is of the highest standard.

The Malaysian Biosafety Act 2007

Being an active party in the negotiations and discussions in drafting of the CPB, Malaysia signed and subsequently ratified the protocol instrument on 24th May 2000 (CBD, undated). The implication of this ratification is that Malaysia has made it an obligation on herself to have a regulatory framework in respect of biosafety laws in relation to the application of GMOs. The act of ratificationhas caused Malaysia to be legally bound by the terms of CBD and CPB. The Biosafety Bill 2006, whichwas drawn up to meet these obligations, was read in the House of Representatives for the second and third reading at the House of Representatives. The premise for the introduction of the Biosafety Bill was for the protection of the environment and human health and to complement the biotechnology industry in the country.

The Biosafety Bill was presented by the former Minister for the Natural Resources and Environment Ministry with the main purpose was the establishment of National Biosafety Board. The function of the board is to regulate the release, importation, exportation and contained use of LMOs and the release of products of such organisms as incorporated in the preambleto the bill. The Biosafety Bill obtained the Royal Assent on 29th August 2007 and was gazetted on 30th August 2007.

The overarching objective of the Biosafety Act 2007 (BSA 2007) is to protect the environment and the biodiversity of Malaysia from destruction as a result of the release, importation, exportation and contained use of LMOs, and the release of products of such organisms. It has also been presented that lack of scientific knowledge or proof shall not be a cause for not taking pro-active steps in preventing the impending damage resulting from the release, importation, exportation and contained use of LMOs and also to make the necessary legislative provisions in relation thereof. Indirectly, the application of the precautionary principle is proposed in theBSA 2007. Among the concerns raised in the release, importation, exportation and contained use of LMOs were related to socio-economic and religious considerations. It has been presented that the application of LMOs in Malaysia be conducted in a responsible manner so as not to cause severe harm and damage to human health and the environment. Apart from that, the BSA 2007 can also be utilised to detect use of LMOs that contravene religious observations such as the use of non-halal genes that are imported into Malaysia.

The BSA 2007 is supposed to be an enabling law, ensuing from Malaysia's international obligations under both CBD and CPB, to regulate the release, importation, exportation and contained use of LMOs and the release of products of such organisms. This legislation is also needed to ensure the safety aspect of such products are maintained and safeguarded before such products are released into the environment. Although Malaysia is currentlynot producing GM products for commercial purpose whereresearch and application of LMOs is used in the production of plants such as papaya, palm oil and orchids, it is felt that with a proper biosafety framework, the products produced in Malaysia using LMOs can be marketed globallywith ease. Hence, researchers, entrepreneurs and industry players will have to conform with the legislative and regulatory requirements of the BSA 2007.

The BSA 2007 contains seven parts and three schedules and 71 sections. Preliminary matters are contained in Part I which includes, inter alia, the title of the Act and the interpretation section.

Part II (Section 4-10) is entitled "National Biosafety Board" and deals, inter alia, with the establishment of the National Biosafety Board, the functions of the National Biosafety Board the establishment of the Genetic Modification Advisory Committee the appointment of Director General and other officers of the board, the delegation of the functions of the National Biosafety Board and the powers of the Minister in giving directions.

Part III deals with the approval for release and import of LMOs. The need for approval for release and import of LMOs is dealt with from sections 11 to 20. The requirement for notification for export, contained use and import for contained use of LMOs is dealt with in Part IV from sections 21 to 35. Part V deals with risk assessment and risk management reports and emergency response plan while enforcement is dealt with in Part VI.

Part VII deals with miscellaneous matters relating to release, import and export of LMOs. Schedule I deals with provisions relating to the National Biosafety Board. Schedule II deals with the release activities of LMOs while Schedule III deals with the persons who are eligible to be appointed as enforcement officers in accordance with the provision of section 38 of the Biosafety Act 2007.

Criminal Sanctions in the Biosafety Act 2007

As has been stated earlier, the main objective of the Biosafety Act 2007 is in the regulation of the release, importation, exportation and contained use of LMOs, and the release of products of such organisms. Hence, the main part of this Act contains provisions that impose criminal sanctions for acts done in contravention to the said provisions. Those who contravene these provisions face a fine, imprisonment or both. The sections that provide for criminal sanctions in the Biosafety Act 2007 are:

- Section 12 Requirement of Approval;
- 2. Section 16 Approval for release and import;
- 3. Section 18 Review of approval upon obtaining new information;
- 4. Section 19 Circumstances where Board may make further order on approval;
- 5. Section 22 Requirement for notification;
- 6. Section 26 Specific measures to be taken in contained use;
- 7. Section 30 Board to make appropriate order on notification;
- 8. Section 31 Board may require additional information;

- 9. Section 32 Review of notification upon obtaining new information;
- 10. Section 33 Circumstances where Board may make further order on notification;
- 11. Section 36 Risk assessment and risk management reports;
- 12. Section 37 Emergency response plan;
- 13. Section 40 Search by warrant;
- 14. Section 48 Obstruction of enforcement officers:
- 15. Section 50 Power to require production of things related to offence;
- 16. Section 52 Power of Board to require information on living modified organisms or products of such organisms;
- 17. Section 53 Power to take sample;
- 18. Section 59 Confidential business information;
- 19. Section 66 Power to compound;
- 20. Section 67 Falsification, concealment and destruction of document; and
- 21. Section 69 Power to make regulations.

It must be reiterated that the provisions under the BSA 2007 only provides for the penalty for its contravention. It, however, fails to consider the possible compensatory claim by individuals who have suffered damage resulting from transboundary movements of GMOs. For example, Section 12(1) provides that no person shall undertake any release activity or any importation of LMOs, or both without the prior approval of the National BiosafetyBoard. The penalty for the infringement of this section can be found in Section 12(2), which provides that anyindividual who contravenes subsection (1) commits an offence and shallbe liableto a fine not exceeding RM250,000or to imprisonment for a term not exceeding five years or to both. It is also provided that in the case of a continuing offence, the offender shall be subject to a further fine not exceeding RM10,000for each day during which the offence continues after conviction. Offender who is a body corporate shall be liable to a fine not exceeding RM500,000 and in the case of a continuing offenceafter conviction, to a further fine not exceeding RM25,000 for each day.

From the above provision, it is clear that the provision only covers the fault of the "offender" indicating that only criminal liability attached to the wrong committed by the offender. Section 12(1) of the BSA 2007 covers instances where the LMOs that have been imported without the prior approval of the National Biosafety Board. By reading the wordings of the provision, it can be safely assumed that the offender has already imported the LMOs and the LMOs are already on Malaysian soil.

This leads to another question – "what would happen if the LMOs escape and caused damage to the surrounding area where the GMOs are kept?".It would seem that such individuals would have to resort to the common law of torts to obtain compensation for the greivances suffered by him perhaps under the rule of Rylands v Fletcher.

Civil Liability as an Option for Environmental Damage

According to Rodgers (2003), despite the benefits that could be derived from the application of biotechnology, products developed through the process of biotechnology continue to be doubted by the public. There is potential liability for economic and environmental loss arising from dispute resulting from the damage caused by products containing LMOs. Disputes resulting in damage arising from the application of LMOs (or products containing LMOs) are the potential liability problems arising from the introduction ofherbicide and pesticide resistant GM crops. In the United States, there have been instances of civil suits taken in relation to the use of LMOs or GM products such as Re Star Link Corn Products Liability Litigation, Marvin Kramer et. al. v Aventis Crop Science USA Holding Inc. et. al. (2002) 212 F.Supp.2d 828 (US District Court N.D. Illinois), Monsanto v Schmeiser (2001) 12 C.P.R. (4th) (F.C.T.D.), R v Secretary of State for the Environment ex parte Watson [1999] Env. L.R. 310 CA and Hoffman, LB Hoffman Farms Inc. & Beaudoin v Monsanto Canada & Aventis Crop Science Canada Holding Inc. 2002 Sask.Q.B. no 67.

It is important to note that almost all countries in this world have some form of civil liability claims by private persons against damage caused by another person or organisation (Sheridan, 1996). Civil liability rules can be found either in common law or statutes. Rules in relation to attaching responsibility for harm to the environment resulting from riskyactivities are quite underdeveloped (Mason, 2002). There are a dearth of legal provisions in relation to state and non-state responsibility for damage to the environment. Iwama (1992) and Sandvik&Suikkari (1997) have suggested that the deficiency in allocating responsibility is in the area of financial accountability in determining the liability of a tortfeasor.

Most international treaties in relation to environmental damage prescribe state responsibility for damage to the environment but these treaties lack the mechanism how it should be addressed (Mason, 1992).

In the case of acrashed USSRsatellite on the Canadian soil, Canada won the claim for the clean-up of radioactive debris on the ground of state liability obligations under the 1972 Convention on International Liability for Damage Caused by Space Objects. While it is convenient to get the state involved in the issue of establishing liability, the current trend is now shifting from state responsibility to liability on private actors or corporations. The reason being thatnot all activities are solely governed by the state, who merely facilitates the carrying on of an activity. The shift of economic activities which are carried out by state-own corporations to economic activities which are performed by private owned corporations is the current trend.

Most government desire close co-operation between the government and the private sector, which is also the trend in Malaysia as reflected in the Government Transformation Policy blueprint. Private sector is expected to assume more roles and responsibilities in economic activities. Thus the shift towards civil liability. The same sentiment has been reflected in the stand taken by the International Law Commission when it states that in instances of liability, the preference is moving from state liability to private or civil liability (Boyle, 1997 and Rao, 1998). According to Mason (1992), this move from state responsibility to liability attached to private actors would be the "preferred vehicle for rule development" in the area of environmental damage. The main focus of civil liability regime is in the field of financial accountability of operators of hazardous or dangerous activities which is in line with the international obligation of a country. Under the civil liability rules, an aggrieved party can claim compensations against the other person. The civil liability regime extended compensatory claim to include damage to the environment apart from maintaining personal and proprietory claims (Mason, 1992).

The civil liability regime can be in the form of legislations or in common law. The problems of not having a civil liability regime in the form of legislation and by merely relying on the common law can be seen in the Australian case of Tame v New South Wales (2002) 191 ALR 449 where McHugh J was sceptical on the effectiveness of the common law of negligence in the following words,

"...Given the undemanding nature of the current foreseeability standard, an affirmative answer to the question whetherdamage was reasonably foreseeable is usually a near certainty.

And a plaintiff usually has little trouble in showing that the risk was reasonably preventable and receiving an affirmative answer to the second question. This is especially so since Lord Reid said that a reasonable person would only neglect a very small risk of injury if there was 'some valid reason' for disregarding it, a proposition that effectively puts the onus on the defendant to show why the risk could not have been avoided. Once these two questions are answered favourably to the plaintiff, there is a slide – virtually automatic -- into a finding of negligence. Sometimes, courts do not even ask the decisive question in a negligence case: did the defendant's failure to eliminate this risk show a want of reasonable care for the safety of the plaintiff? They overlook that it does not follow that the failure to eliminate a risk that was reasonably foreseeable and preventable is not necessarily negligence."

The judgment of McHugh J above has the effect of questioning the effectiveness of the law of negligence, in particular the process of reasonableness according to the perception of the reasonable man. He quoted Lord Reid by stating the obvious that the common law ought never to produce a wholly unreasonable result. A similar sentiment can also be found in the judgment of Kirby J in Graham Barclay Oysters Pty Ltd v Ryan (2002) 211 CLR 540when he obiterred that:

"One day this court may express a universal principle to be applied in determining such cases. Even if a settled principle cannot be fashioned, it would certainly be desirable for the Court to identify a universal methodology or approach, to guide the countless judges, legal practitioners, litigants, insurance companies and ordinary citizens in resolving contested issues about the existence or absence of a duty of care, the breach of which will give rise to a cause of action enforceable under the common law tort of negligence"

Based on the decisions of the above cases, it is clear that the common law of negligence has produced a wholly unreasonable result. Needless to say, the cases stated above deals with the normal activities in life. However, when dealing with new technologies, such as biotechnology, the courts ought to be more thorough in coming to a conclusion. Thus, if the law of negligence will produce "unreasonable result", then it is the appropriate time to introduce the civil liability regime in the form of a legislation in dealing with litigation involving new technologies such as biotechnology where effect on the environment and human health may not be as prompt as in normal cases of negligence such as road accidents.

Two clear models of civil liability regimesin environmental pollution namely are marine oil pollution and environmental damage resulting from nuclear outbreaks. Mason further suggests that the oil pollution liability regime deserves a study due to the inclusion of "private law remedies for transboundary damage" by quoting the incident of The "Torrey Canyon" which was shipwrecked off the western coast of Cornwall, England in March 1967. It was a massive environmental disaster where 120,000 tonnes of oil was spilled into the ocean, which subsequently jolted the Inter-Governmental Maritime Consultative Organization (IMO) to review the state systems of civil liability for oil pollution damage. This led to a compromise at the International Convention on Civil Liability for Oil Pollution Damage (CLC) which was held in Brussels in 1969 where a liability regime was adopted in which the liability for oil pollution damage was strictly placed on the registered ship-owner from which the oil escaped or is discharged (IMO, undated). The CLC covers pollution damage resulting from spills of persistent oils suffered in the territory (including the territorial sea) of a State Party to the Convention.

The reason by placing strict liability was to facilitate prompt and equitable compensation payments to victims for damage resulting from oil-spills. The liability regime for oil-spills is not, however, tilted only towards the victims. In an effort to alleviate the burden placed on the registered ship-owners, an insurance liability scheme was introduced. Under the insurance liability scheme, ships which had a cargo of oil which is more than 2,000 tonnes had to subscribe to this insurance liability scheme (Mason, 1992).

The CLC was subsequently replaced by the 1992 Protocol which had also widened the scope of the CLC to cover pollution damage caused in the exclusive economic zone (EEZ) or equivalent area of a State Party (IMO, undated). The Protocol covers environmental damage compensation is limited to costs incurred for reasonable measures to reinstate the contaminated environment and also allows expenses incurred for preventive measures to be recovered even when no spill of oil occurs if there is grave and imminent threat of pollution damage. Under the 1992 Protocol, a shipowner cannot limit liability if it is proved that the pollution damage resulted from the shipowner's personal act or omission, committed with the intent to cause such damage, or recklessly and with knowledge that such damage would probably result.

Even though the solution as provided under the CLC is not a one size fits all solution, it, nevertheless, provides a basis for some kind of civil liability regime that can provide pointers for establishing the same for the biotechnology industry. It should be obligatory on producers of products or seeds derived from the application of GMOs to ensure that their products are not dangerous for use on human health and the environment.

As far as nuclear energy is concerned, the OECD's Nuclear Energy Agency and the International Atomic Energy Agency (IAEA) have drawn up two instruments, namely the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy and the 1963 Vienna Convention on Civil Liability for Nuclear Damage where the jurisdiction and procedure for claims of damage resulting from nuclear energy is left to the national legal systems (Lee, 2000). In the UK for instance, the Nuclear Installations Act 1965 was enacted to deal with civil responsibility of the nuclear industry.

Existing Civil Liability Regimes

The Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, commonly referred to as "the Lugano Convention", dealing specifically with civil liability. The aim and object of the Lugano Conventionis to ensure adequate compensation for damage resulting from activities dangerous to the environment and also provides for means of prevention and reinstatement (Article 1). Article 2 provides a detailed definition of a dangerous activity that includes:

- (a) The production, handling, storage, use or discharge of one or more dangerous substances or any operation of a similar nature dealing with such substances;
- (b) The production, culturing, handling, storage, use, destruction, disposal, release or any other operation dealing with one or more:
- (i) GMOs which as a result of the properties of the organism, the genetic modification and the conditions under which the operation is exercised, pose a significant risk for man, the environment or property;
- (ii) micro-organisms which as a result of their properties and the conditions under which the operation is exercised pose a significant risk for man, the environment or property, such as those micro-organisms which are pathogenic or which produce toxins;

(c) The operation of an installation or site for the incineration, treatment, handling or recycling of waste, such as those installations or sites specified in Annex II, provided that the quantities involved pose a significant risk for man, the environment or property;

(d) The operation of a site for the permanent deposit of waste.

Clause (b) clearly classifies the production, culturing, handling, storage, use, destruction, disposal, release and related activities in relation to GMOs as a dangerous activity. Therefore, it is important for a country that intends to deal with GMOs and products derived from GMOs to have some kind of liability regime to protect persons or organizations that have suffered losses or damage resulting from dealing and transboundary movements of GMOs.

Countries such as the United States, Norway and Australia have also enacted civil liability statutes to cover damage resulting from activities carried out by the tort-feasor by which the act or omission have caused damage to the aggrieved person. The liability rules adopted in these civil liability laws are combination of strict liability rules and fault-based liability rules. The civil liability law in the United States is the Comprehensive Environmental Response, Compensation and Liability Act 1980 (CERCLA or more popularly known as Superfund). The purpose of CERCLA is to clean up uncontrolled releases of specified hazardous substances. Under the American CERCLA, the Environmental Protection Agency (EPA) is given the power to force parties responsible to clean environmental contamination or to reimburse the Superfund for response or remediation costs incurred by EPA. The EPA is also empowered to require agricultural establishments and other agribusinesses to conduct response actions to address actual or threatened releases of CERCLA hazardous substances (EPA, undated).

In Norway, an example of a civil liability statute is Act 29 November 1996 No. 72 relating to petroleum activities. Under the statute, the establishment of liability for damage resulting from petroleum activities can be found in Chapter 7 (**Liability for pollution damage**), which has seven sections dealing with liability for pollution damage. Section 7-3clearly outlines the liability of the tort-feasor that "...the licensee is liable for pollution damage without regard to fault". This section places strict liability rule on damage resulting from oil pollution.

The liability of the tort-feasor is clearly outlined in this section and in such a situation, the duty of the court is simplified with the prior attachment of the liability in response to the damage done.

The various states in Australia have enacted their respective civil liability legislations. Examples of civil laws in the various states of Australia are the Queensland Civil Liability Act 2003, the New South Wales Civil Liability Act 2002, the Tasmanian Civil Liability Act 2002 and the Western Australia Civil Liability Act 2002. Under the Queensland Civil Liability Act 2003, Section 9(1) provides that a person does not breach a duty to take precautions against a risk of harm unless the risk was foreseeable, the risk was not insignificant, and in the circumstances a reasonable person in the position of the person would have taken the precautions. Section 9(2) further provides that in deciding whether a reasonable person would have taken precautions against a risk of harm, the court has to consider the following factors:-

- 1. The probability that the harm would occur if care were not taken;
- 2. The likely seriousness of the harm; thirdly the burden of taking precautions to avoid the risk of harm; and
- 3. The social utility of the activity that creates the risk of harm". In addition to that, the court must also consider other relevant things if necessary.

It must be noted that in this Queensland Civil Liability Act 2003, it is clearly provided that the courts must interpret and follow strictly the wordings of the statute in attaching liability for a tort-feasor. In such a circumstance, the court need not look at the common law principles in its attempt to attach liability to a tort-feasor.

It must also be noted that under the federal Australian law, there are various civil and criminal penalties that can be imposed upon those who contravene the Environmental Protection and Biodiversity Conservation Act (EPBCA) 1999. An instance can be found in Section 15B EPBCA which provides for civil penalty involving the imposition of 5,000 penalty units for individual and 50,000 penalty units for body corporate. Lying in the same vein is the imposition of criminal penalty under Section 15C(13) involving the imposition of imprisonment for breach of the relevant sections of the EPBCA. Again, it must also be noted that there are also provisions in the EPBCAthat impose strict liability for contravention of the Act where Section 15C(10A) clearly provides that to invoke strict liability, reference has to be made to Section 6.1 of the Australian Criminal Code.

Is civil liability regime an option for Malaysia in cases of damage resulting from transboundary movements of GMOs?

From the above discussion, it is clear that the BSA 2007 lacks the avenue for private individuals to claim for damages resulting from transboundary movements of LMOs. Section 12(2)only covers the fault of the "offender" indicating that only criminal liability attached to the wrong committed by the offender.

It must be noted that there is no avenue in the BSA 2007 for a private individual that has been affected by the LMOs should they escape. It can be argued that the individual can resort to common law to make a claim against the party that has illegally brought in the LMOs. However, looking at the nature of LMOs, it would be difficult for the plaintiff to succeed in his claim against the defendant. The manifestation of any adverse effect from the GMOs would be long. The plaintiff would have an uphill task of proving the causation to prove damage. Therefore, a civil liability regime for liability and redress for damage resulting from transboundary movements of GMOs should be enacted. The provisions on civil liability should be developed and incorporated in the current Biosafety Act 2007 to provide an avenue to private individuals that have been affected by the LMOs brought in by the importers, either legally or illegally. There should also be an extended limitation period in order to establish the existence of the LMOs. This limitation period should be long enough based on scientific arguments so as not to cause injustice to the producers, transporter, importer and exporters.

Thus, to realise this, it is important for Malaysia to look into the civil liability statutes in the United States, Norway and Australia. It would be extremely important and a great contribution to the nation if civil liability clauses are to be included in the Malaysian BSA 2007 to deal with the civil claims in respect of damage suffered by an individual resulting from the transboundary movements of GMOs. From the examples of the three statutes given above, Malaysia could learn on how to deal with attaching liability for an aggrieved party in cases of damage resulting from instances of carrying out a dangerous activity. Reforms to the existing BSA 2007 is necessary to adapt to the changing needs especially even after the Lugano Convention has acknowledgedthe carrying out of activities involving GMOs as a dangerous activity.

However, it must also be noted that unlike activities such as oil pollution or nuclear outbreak where the impact is quite instantaneous and the damage is almost immediate resulting from the mishap, the danger from GMOs would not manifest itself until several years after the activity has been carried out.

While damage from oil pollution and nuclear outbreaks is clearly visible to the naked eye and the sufferings are clearly identifiable, the adverse effects from GMOs would not be as clear. Nonetheless, this dilemma has now been answered by the provision of Article 4 to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, where it is provided that a causal link shall be established between the damage and the LMOs in question in accordance with domestic law. Thus, it is the duty of the respective Contracting Parties to establish a nexus between the damage and the particular LMO. This process has to be done in accordance with the domestic law on causation. It would seem that Article 4 to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress is a regression from the initial intention of the international community to develop a standard liability and redress regime. The effect of Article 4 to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress is that the Contracting Parties would be given a free hand to determine the rules on causation in establishing liability for damage resulting from transboundary movement of GMOs.

Therefore, it would be wise for Malaysia to incorporate the rules on liability and redress in its domestic biosafety law namely the BSA 2007 by taking pointers from the civil liability legislations in the United States, Norway and Australia.

Conclusion

The absence of biosafety laws exposes countries to regulatory gaps (Obonyo et. al., 2011), thus the importance of having a biosafety legislative framework. The development of products using LMOs is basically meant for commercialisation and obviously, such products would be transported either domestically or internationally, which would eventually involvetransboundary movement of such products. There is likelihood that such products could contaminate the area in which they are being transported. In such a case, the aggrieved party would want to recover damages from the party who has caused the damage.

Hence, the existing biosafety law would have to include provisionsthat deal with damage resulting from transboundary movement of products containing LMOs.

Since Malaysia has shown interests to develop and commercialise products derived from LMOs, it would be imperative to have a biosafety legislative framework that provide for civil claims for damage, to the environment or human, resulting from transboundary movement of GMOs.

By looking into its counterparts in the United States, Norway and Australia that have already provided for civil liability for damage resulting from activities dangerous to the environment as well as the Laguna Convention, Malaysia should take necessary steps to reform the existing BSA 2007. The Malaysian legislative framework on biotechnology should also clearly reflect its declared intention to be a producer of products containing LMOs to assist the biotechnology industry in Malaysia to proceed with no or little impediment.

Acknowledgement

Malaysian Ministry of Higher Education

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