# Malaysia Biosafety Act 2007 and Cartagena Protocol on Biosafety: A Critical Comparative Analysis

**Kok-Gan Chan[1]***

[1] Division of Genetics and Molecular Biology, Institute of Biological Sciences, Faculty of Science, University of Malaya, 50603 Kuala Lumpur, Malaysia

*Corresponding author: kokgan@um.edu.my

**Abstract:** Advancement of modern biotechnology has wide impact on various industries. Modern biotechnology in the past has gone unregulated but the responsible use of biotechnology is the main focus worldwide. The most important living modified organisms (LMOs) regulatory framework is the Cartagena Protocol on Biosafety. This Protocol provides guidelines for the national legal framework. This paper aimed to perform comparative studies on Malaysia *Biosafety Act 2007* and the Cartagena Protocol on Biosafety. The results show that while certain clauses in the Protocol are highly similar, and some proviso in the *Biosafety Act 2007* are broader in scope, and conversely, certain clauses of the Protocol are well reflected in the *Biosafety Act 2007*. It is submitted that in overall perspective, *Biosafety Act 2007* is consistent with the Protocol. It is concluded that Malaysia biosafety regulation system satisfies this international requirement. However, with regards to enforcement of this Act, it remains unanswered, as no precedent has been reported. Interestingly, non-compliance of some proviso in the *Biosafety Act 2007* will result in criminal penalty, and its impacts on the research and development in the biotechnology industry, commercial investment from abroad and domestic markets, and international trading of LMOs as food and feed, remain to be seen.

Keywords: Biosafety Law, genetic modified organisms, living modified organisms (LMOs), Cartagena Protocol, Convention on Biological Diversity, modern biotechnology, risk assessments, risk management

## Qualification for Authorship

***KG Chan is Associate Professor at the Institute of Biological Sciences (Division of Genetics and Molecular Biology), Faculty of Science, University of Malaya, 50603 Kuala Lumpur,

Malaysia. He has both advanced degrees in molecular biology and laws. He is expert in LMOs biosafety on the Risk Assessment and Risk Management. The author may be contacted at kokgan@um.edu.my, Tel. +603-79677748; Fax: +603-79677727.

## 1. Introduction

Ever since the discovery of DNA double helix structure [1] which paves the way of modern biotechnology, this leads the direction for the creation of living modified organisms (LMOhereinafter) involving bacteria, plants, and animals [2]. With the availability of some essential enzymes *viz* restriction enzymes, ligase, fragments of DNA from any organisms can be 'cut' (restricted) and 'joined' (ligated) to create what is commonly known as recombinant DNA. This recombinant DNA can then be introduced into the recipient (host), hence creating Genetic Modified Organisms (GMOhereinafter).

In the last few decades, DNA recombinant technology has shown great potential in biomedical, agriculture, food production, and system biology [3-6]. DNA recombinant may be regarded as another wave of post-modern industrial revolution. It allows molecular biologists to create many GMO, from the routine to somewhat controversial. Modern biotechnology that relies on DNA recombinant technology has indeed raised some concern in relations to the GMO itself, the side effects of this technology on both human and environment well-being as a whole[7-10].

On one hand, modern biotechnology is of great potential, but in order to protect human and environment from possible adverse effects of this technology, there is a need for checks and balances. Consequently, the Convention on Biological Diversity (CBD hereinafter) has entered into force on 29 December 1993, and after several years of negotiations, the Cartagena Protocol on Biosafety [11] (CPB hereinafter) to the CBD was adopted in Montreal on 29 January 2000 at an extraordinary meeting of the Conference of the Parties. This Protocol is to address *inter alia*, biosafety issue. CPB formed the very basis of an international regulatory framework that allows application of modern biotechnology and yet keeping its adverse effects at a minimal level through proviso in this Protocol.

Malaysia, being a member of the CBD, as required by the CPB ([11], Art. 2, p. 1) hence fulfilled its obligation to implement legal and administrative measures on biosafety by enacting

the *Biosafety Act 2007* [12] (2007 Act hereinafter) which came into force at the end of 2009. The paper primary aim is to critically compare between 2007 Act and CPB.

The 2007 Act is reflecting the CPB since the terms and definitions used are similar in meaning[1], and some are verbatim for e.g. 'living modified organisms'[2], 'living organisms'[3], 'modern biotechnology'[4], which is an important concept in both the 2007 Act and the CPB. It is interesting to note that an important molecular biology technique called RNA interference that is used mainly for gene silencing, seems to be out of the scope of both the 2007 Act and the CPB, it remains to be seen how both of the provisoes will apply on the use of RNA as 'modern biotechnology'

## 2. Overview

This paper will focus mainly on Parts III, IV and V of the 2007 Act which broadly satisfies the objective as stipulated in Article 1[5] of the CPB.

To provide a brief overview, the 2007 Act can be divided into eight parts, *viz:*

Part I –mainly concerns nomenclature and definitions used in the 2007 Act
Part II –concerns establishment of the National Biosafety Board
Part III – apply to release activities and import activities involving LMOs
Part IV – apply on the export, contained use and import for contained use activity
Part V – apply on the risk assessment and risk management reports and emergency response plan
Part VI – concerns mainly on the enforcement and its enforcement personnel
Part VII – concerns miscellaneous issues such as confidential business information, labelling and public disclosure.

It is submitted that Part III of the 2007 Act which apply to release and import activities involving LMOs, which is in essence in line with the proviso stipulated in Article 7 of the CPB[6]. Article 7 stipulated the need of regulation on import of LMO for release activity[7] into the environment of the import country[8].

With reference to Article 6 [11] concerning the advance informed agreement procedure shall not apply to the transboundary movement of LMOs destined for contained use which is duly reflected in section 11(2)[12][9] but note that even for contained use of LMOs, one shall

satisfy the requirement of notification to the National Biosafety Board, as stipulated in section 21 [12] regardless it is for importation or exportation[10]. Incompliance of the 2007 Act is a criminal offence for individual on the requirement of import and deliberate release into the environment ([12], *s12(2)(a)*[11]). The 2007 Act distinguishes the punishment on a natural person and legal person such as company that contravene the requirement on import and release activity on LMO.

According to the 'identification test' as illustrated in *Tesco Supermarkets Ltd v Nattrass* [13][12] and applying Lord Denning's judgment in *Bolton (Engineering) Co. v. Graham* [14], it is submitted that the company directors or high-level managers could be liable for infringing in *s12(2)* punishable by imprisonment but *s12(2)(b)* [13]specifically removes the imprisonment penalty for corporate body:

*'where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction'* ([12], *s12(2)(b)*)

By virtue of *s12(2)(b)*, this will avoid the complication of corporate criminal liability under *s12(2)(a) 16(7)(a), 18(6)(a), 19(5)(a), 22(2)(a), 26(2)(a), 31(2)(a), 32(4)(a), 33(3)(a), 36(4)(a), 37(2)(a), 40(4), 67(a) and 69(3)(a)*.

Although *s12(2)(a)* removes the complicated needs to held a legal entity such as company to be criminally liable, it is arguable, however, by imposing a criminal penalty of imprisonment on individual violating 2007 Act, it remains to be seen the effect of these clauses whether it will discourage the economic activity involving import and release of LMO. On the other hand, it remains to be seen that the somewhat arguable small amount of five hundred thousand ringgit fine on corporate that contravenes this section, could prevent the breach of *s12(2)(b)*.

Similarly, contravening the requirement ([12], *s22(2)*)[14]) on notification to the National Biosafety Board (NBD), shall be a criminal offence, and the penalty clauses are similar to those of *s12(2)(b)*. The 2007 Act clearly defines three types of activities that require notification to

NBD, *viz*. (a) exportation of LMOs ([12], *s22(1)(a)*); (b) contained use involving LMOs ([12], *s22(1)(b)*); (c) importation of LMOs for purposes of undertaking a contained use activity ([12], *s22(1)(c)*). Taken together, Article 8[15] of CPB is depicted in *s22(1)*, notably in sub-section (a) and (c) of the 2007 Act. Again, breach of this section whereby the penalty varies between a natural person and a legal person, is similar to those stated aforesaid[16].

Article 8, Para 2 [11] provides that the party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter. The burden of providing the notification and all relevant is placed on the party of export, which is reflected in *s23(1)* [12] stipulates 'that any person who intends to export LMOs shall comply with the requirements of the importing country on the importation of LMOs…'.

## 3. Risk Assessment and Risk Management

Under the Article 15, Para 1 [11], risk assessments should be science-based, and in accordance with *Annex III* of the Protocol by taking into account recognized risk assessment techniques. Such risk assessments and other available scientific evidence in order to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health. In contrast to this article, *s36(1)(a)* [12]stipulates that the risk assessment and risk management reports shall be in a form prescribed by the Minister and shall contain an assessment of the risk and adverse effect that such LMOs and products of such organisms will have or are likely to have on the human, plant and animal health, the environment and biological diversity. Note that *s36(1)(a)* is silence on the issue of risk assessment whether it should be science-based. In *s6(5)* [12], it is expressly stated that all member of the Genetic Modification Advisory Committee (GMAC) shall consist of experts from various science-based and other relevant disciplines. Mischief interpretation of *s6(5)* together with Article 15 showed that albeit the 2007 Act is silent on the issue of science-based risk assessment, but through the inception of science-based committee (i.e. GMAC), it is submitted that risk assessment is still science-based.

### 3.1 Risk Assessment

The concept of risk assessments is well defined in Article 15, Para 1 [11] where risk assessment undertaken 'shall be carried out in a scientifically sound manner, in accordance with *Annex III* and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 [11] and other available scientific evidence in order to identify and evaluate the possible *adverse effects of LMOs* on the *conservation and sustainable use of biological diversity, taking also into account risks to human health*'. The corresponding clauses for risk assessment are found in *s36* [12]. For example, *s36(1)(a)* provides that 'an assessment of the risk and adverse effect that such LMOs and products of such organisms will have or are likely to have on the *human, plant and animal health, the environment and biological diversity*'; and *s36(1)(b)* provides that 'the proposed measures that shall be undertaken to prevent, reduce or control the *risks and adverse effect* that such *LMOs and products* of such organisms will have or are likely to have on human, plant and animal health, the environment and biological diversity'.

It is clear that Article 15, Para 1 placed emphasis on the scientific approach of risk assessment which is not expressly stated in the corresponding *s36(1)(a)* and *s36(1)(b)*. The CBD has engaged the *Ad hoc Technical Expert Group* (AHTEG) to draft the 'road map' for the parties of the Convention, whereby this 'road map' shall serve as guidelines for risk assessment as stipulated in *Annex III*. But the 2007 Act has made it clear that such risk assessment shall also include the consideration of plant and animal health, which appears to be more expansive on the possible effects on the use of LMOs. It is worth to note that while the Article 15 concerns about the adverse effects of LMOs only, but again, the 2007 Act extends to cover the LMOs and products of such organisms, which is in agreement with the *Annex III* of the Protocol. It is argued that some products remain to be LMO itself and hence are still capable of replication, and therefore products of the LMO warrants risk assessment. The opposite view on exclusion of risk assessment on products of LMO or "and product thereof" is because it is out of the scope of the Protocol and therefore there is no mandate on this requirement.

### 3.2 Risk Management

Article 16 [11] deals with measures whereby parties to the Convention should take at the national level on risk management[17]. But for the *s36(2)* [12] is stipulates the requirement of 'minimum risk management measures'[18]albeit the risk management is not clearly explained. On the contrary, Article 16 clearly defines 'risk assessment shall be imposed to the extent necessary to prevent adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import'. Article 16, Para 3 [11] goes on stating that 'each party shall take appropriate measures to prevent unintentional transboundary movements of LMOs, including such measures as requiring a risk assessment to be carried out prior to the first release of a LMO'. Again, similar clause is not found in the 2007 Act. It is strongly advised that this clearly defined risk management can be used in addition to, *inter alia*, 'minimum risk management measures'. Failure to comply with *s36* [19] can be a criminal offense, and the penalty clauses are similar to those of *s12(2)(b)*.[20]

Article 16, Para 5(a) concerns LMOs or specific traits of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and (b) taking appropriate measures regarding the treatment of such LMOs or specific traits. Proviso of Article 16, Para 5(a) is indeed very similar to the scope of *s37(1)* [12]which provide detail on the safety measures and procedures for the protection of human, plant and animal health, the environment and biological diversity against harm or damage caused directly or indirectly by LMOs or products of such organisms; and all necessary measures to be taken in the event of an emergency. However, contravening *s37(1)* i.e. who fails to take the necessary measures in an emergency according to what has been approved by NBD, may be liable for criminal prosecution[21].

Under the Article 17 [11], any unintentional transboundary movement of a LMO under its jurisdiction shall take appropriate measures to notify[22] affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. No such clause corresponding to Article 17 is seen in the 2007 Act. But being a party to the Convention, Malaysia is obliged to notify the

affected States, take appropriate risk management, emergency measures and notify the relevant international organizations.

**4. Handling, Transport, Packaging and Identification**

With regards to handling, transport, packaging and identification of LMOs that are subject to intentional transboundary movement must be handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards within the scope stipulated in Article 18, Para 2 [11][23] stipulates that LMOs as intended for direct use as food or feed, or for processing[24]; destined for contained use[25]and intended for intentional introduction into the environment[26]must clearly identify the LMOs but these clauses are not found in the 2007 Act.

Accordingly, in *s61* [12], which I quote '*all LMOs, items containing LMOs and products of such organisms shall be clearly identified and labelled in a manner to be prescribed and the requirements for such identification and labelling shall be in addition to any other written law*'. As the Malaysia Food Act 1983 [15] has been recently been amended[27] requiring the need of labelling of LMOs, *s61* should be sufficient to cover the labelling of LMOs that used as food. It seems that no labelling is required when labelling of LMOs is needed when it is used as feed (*cf* Article 18).

**5. Socio-economic Considerations**

Although the risk assessment and risk management of LMOs is solely based on precautionary principle, science-based and balanced approach *per se* as manifested by the CPB, but it is also expressly stated that social-economic concern can be taken into consideration and research and information exchange with indigenous and local communities on LMOs ([11], Art. 26)[28]. The major feature of the 2007 Act, although just a section by itself, embodied the view of, by the virtue *s35* [12],

'The Board or Minister... *may also take into account socio-economic considerations* …'

This provision is highly desirable considering the fact that Malaysia is a multi-racial, multi-faith and multi-cultural society. However, *s35* has suffered similar problems with Article 26 [11] i.e. socio-economic is not defined in the Protocol. What amount to socio-economic considerations in Malaysia under *s35*, is therefore remains a question of law for the court to interpret.

In contrast to the Article 26 which 'may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities'[29]. It is worthy to note that *s35* however, has shown improvement in drafting 'where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of LMOs or products of such organisms on human, plant and animal health, the environment and biological diversity and may also take into account socio-economic considerations'[30]. This seems to allow the 2007 Act to deal with potential adverse effects of LMO *or its products* on *human, plant and animal health* and biological diversity as well. This is in sharp contrast to the Article 26 which seems to limit consideration of socio-economic directly linked to an impact on biodiversity only. It is submitted that *s35* is a much desirable version on socio-economic consideration on biosafety.

Social-economic impact is of paramount relevance in this context and *s35* is therefore appropriate. This articulates the proviso of the 2007 Act are those concerning availability of remedies through administrative and judicial proceedings and the inclusion of socio-economic, cultural, and ethical considerations. Similar approach can also be found in *National Biosafety Framework Project (NBFP) of the Philippines* [16][31]. In contrast to this, Australian's approach is adopting a comprehensive, science-based, case-by-case analysis process [17][32].

**6. Public Interest in Biosafety Regulatory Process**

Public disclosure and involvement are the key for consumer trust and confidence in LMOs. It is therefore important for public to engage actively in the process of biosafety regulatory process. In Article 23 [11], which states '*The Parties shall ... consult the public in the decision-making process regarding LMOs and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21*'[33]. The 2007 Act has taken into account the public involvement as *s14(c)* [12] which subject to *s59* [12], shall for purposes of public disclosure, invite public participation, in such manner as may be determined by the Director General, for their views on the application. Note that the NBD is required by law to consider, *inter alia*, public opinion prior to granting approval for release and import of LMOs[34]. Also, *s60(1)* [12] provides that '*the public may have access to such information relating to any application for approval, approval granted or notification, which has not been granted confidentiality under* s59(2)*) in such manner as the Board thinks fit*'. But the 2007 Act provides little guidance as to how to conduct public consultation and incorporation of public opinion into the biosafety decision making process. Without such proper guidance, it is foreseeable inefficient and meaningless public engagement involved in a complicated biotechnology application for biosafety consideration. The right of confidentiality of the applicant is balanced by the right of public disclosure as stipulated in *s59*[35]. Failure to comply with this, may result in imprisonment under *s59(5)*[36].

## 7. Conclusion

The results of this study show that while certain clauses and proviso in the Protocol are highly similar, and some proviso in the 2007 Act are broader in scope, and conversely, certain clauses of the Protocol are well reflected in the 2007 Act . It is submitted that in overall perspective, 2007 Act is consistent with the CPB. It is believed that while no biotechnological activity notably genetic modification is absolutely risk-free, and safety is a matter of relative concept rather than an absolute principle, but nonetheless, it is arguable that with the Act enacted, Malaysia will be more equipped with national regulatory and legal framework to monitor its biosafety and issues. However, with regards to enforcement of this Act that involve

personnel from a spectrum of expertise and ministries, it remains unanswered how this Act can be effective to protect biological diversity in this natural resources-rich country. Interestingly, non compliance of come proviso in the 2007 Act will result in criminal penalty, and its impact on the research and development in biotechnology industry, commercial investment from abroad and domestic markets, and international trading of LMOs as food and feed, particularly, remain to be seen.

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**Conflicts of Interest**

The author declares no conflict of interest.

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[1] 'contained use' means any operation including research and development, production or manufacturing operation involving living modified organisms, or storage of living modified organisms, undertaken within a facility, installation or other physical structure such that it prevents the contact and impact of the living modified organisms on the external environment ([12], p. 1, *s3)*, *cf* 'contained use' means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment ([11], Art. 3, para (b)).

[2] 'living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology ([12], p. 1, *s3*)and [11], Art. 3, para (g)).

[3] 'living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids ([12], p. 1, *s3* and [11], Art. 3, para (h)).

[4] 'modern biotechnology' means the application of -
(a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles; or
(b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection ([12], p. 1, *s3*)and [11], Art. 3, para (i)).

[5] In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements ([11], Art. 1).

[6] Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import ([11], Art. 7, para 1).

[7] Section 11(1) [12] expressly stated the need of approval for import and release activity of LMO.

[8] Article 7, Para 2[11], and *s11(2)*[12] excludes regulation of contained use of LMO.

[9] Notwithstanding sub-s (1), this Part shall not apply to the importation of living modified organisms intended for purposes of undertaking a contained use activity ([12], *s11(2)*).

[10] Part IV shall apply to the exportation and contained use activities involving living modified organisms and importation of living modified organisms for purposes of undertaking a contained use activity ([12], *s21*).

[11] Where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction ([12], *s12(2)(a)*).

[12] *'I must start by considering the nature of the personality which by a fiction the law attributes to a corporation. A living person has a mind which can have knowledge or intention or be negligent and he has hands to carry out his*

*intentions. A corporation has none of these: it must act through living persons, though not always one or the same person. Then the person who acts is not speaking or acting for the company. He is acting as the company and his mind which directs his acts is the mind of the company. There is no question of the company being vicariously liable. He is not acting as a servant, representative, agent or delegate. He is an embodiment of the company or, one could say, he hears and speaks through the persona of the company, within his appropriate sphere, and his mind is the mind of the company. If it is a guilty mind then that guilt is the guilt of the company.'* as per Lord Reid [13].

[13] *Section 12(b)* [12] stipulates where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

[14] *Section 22(2)(a)* [12] where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
*Section 22(2)(b)* [12] where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.
Taken *s21* and s*22* together, it is arguable that these clauses may cause jeopardy to the economic activities involving LMO, which also highlight the need for checks and balances on biosafety protection and economic activity e.g. foreign direct investment.

[15] The information required in notifications under Article 8 is given in *Annex I* of the Cartagena Protocol, where *Annex I* also applies to Articles 10 and 13. It is believed that the Malaysian authority will draft the Biosafety Regulation in a similar manner as stipulated in *Annex I*.

[16] *Sections 12(a) and 12(2)(b)* [12] , see note 11 and 13 above.

[17] Article 16, Para 1 [11]: The Parties shall, taking into account Article 8(g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

[18] Notwithstanding any risk assessment and risk management reports submitted by an approved person, the approved person shall comply with the minimum risk management measures as may be determined by the Board, after consultation with the Advisory Committee ([12], *s36(2)*).

[19] Any approved person who contravenes *s36(3)* [12] commits an offence and shall, on conviction, be liable-(a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
(b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

[20] See note 13 above.

[21] *Section 37(2)* [12] : Any approved person who fails to take the necessary measures in an emergency according to the emergency response plan commits an offence and shall, on conviction, be liable-
(a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
(b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

[22] Any notification arising from Para 1 above, should include:
(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;
(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;
(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;
(d) Any other relevant information; and
(e) A point of contact for further information. ([11], art. 17, para 3)

[23] In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards. ([11], Art. 18, para 1)

[24] Must 'clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment' ([11], Art. 18, para 2(a)).

[25] Must 'clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned' ([11], Art. 18, para 2(b)).

[26] Must 'clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter' ([11], Art. 18, para 2(c)).

[27] *Food (Amendment No. 2) Regulations 2010*. Amendment was made to Regulations 2, 11 and 17. In Food (Amendment) Regulations 2010, *s3A* requires approval for sale of food obtained through modern biotechnology. *Sections 4* and *5* require that the origin of food and food ingredients obtained from modern biotechnology must be stated as "*gene derived from (common name of such animal)*, "*gene derived from (origin)* and if such food is displayed for retail sale other than in a package, any such information shall be displayed on or in connection with the display of the food.

[28]The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities ([11], Art. 26, para 1)

[29] See note 28 above.

[30] See note 28 above.

[31] *Section 5.4,* Paras 2 and 3, [16] states that '…NCBP shall issue guidelines relating to the conduct of social, economic, ethical, cultural and other assessments, as appropriate, particularly prior to decisions to commercialize products of modern biotechnology…these assessments shall be conducted separately from risk assessment and in a transparent, participatory and rigorous manner.'

[32] *Sections 48-67* [17] set up a clear process that the Gene Technology Regulator must follow in preparing a risk assessment and risk management plan and in making a decision about whether or not to issue a license.

[33] Article 23, Para 2 [11].

[34] After having considered the recommendations of the Advisory Committee, the comments of the relevant department or agency referred to in Para 14(b), the views of members of the public, if any, referred to in Para 14(c), and any additional information, particulars or documents furnished pursuant to a request under sub-section (1), the Board may grant the application by issuing a certificate of approval or refuse the application. ([12], *s16(3)*).

[35] *Section 59(2)* [12] *:* The Director General may grant confidentiality based on the criteria in sub-section (3) and where confidentiality is granted such information shall not be made public. Under sub-section 3, the Director General shall consider the claim for confidentiality according to the following criteria:
(a) that the information is not known generally among, or readily accessible to, any person within the circle that normally deals with the kind of information sought to be made confidential;
(b) that the information has commercial value because it is secret; and
(c) that reasonable steps have been taken to keep the information secret.
Sub-section 4 provides that except for the purposes of this Act or for the purposes of any civil or criminal proceedings under any written law or where otherwise authorized by the Director General, as the case may be-
(a) no member of the Board or Advisory Committee, or any of its committees or subcommittees, as the case may be;
(b) no person attending any meeting of the Board or Advisory Committee, or any of its committees or subcommittees, as the case may be; or
(c) the Director General and any officer appointed
whether during his tenure of office or during his employment or thereafter, shall disclose any information obtained by him in the course of his duties for which confidentially has been granted under sub-section (3).

[36] *Section 59(5)* [12] *:* Any person who contravenes *s59(4)* commits an offence and shall, on conviction, be liable to a fine not exceeding ten thousand ringgit to or imprisonment for a term not exceeding one month or to both.