THE LEGAL REGULATION OF BIOSAFETY RISK: A COMPARATIVE LEGAL STUDY BETWEEN MALAYSIA AND SINGAPORE

Noor Dzuhaidah binti Osman

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ABSTRACT

The Cartagena Protocol on Biosafety to the Convention of Biological Diversity, that was adopted on the 29th January, 2000 and became into force on 11th September 2003, is the most important global agreement on biosafety that governs the transboundary movement of living modified organisms for the protection of human health and environment . Malaysia and Singapore were among the countries participated during the Protocol negotiations. In the end, Malaysia signed the Protocol on 24th May, 2000 and ratified it on 2nd December, 2003. However, Singapore ended up not being a party to it. This study analyses the different stances taken by both countries towards the Protocol, in the domestic biosafety laws implementations. This study, in summary, is a comparative legal study with the Singapore legal and institutional framework of biosafety laws.

This thesis examines Malaysian compliance towards the Cartagena Protocol on Biosafety by analysing the current domestic legal and institutions' compliance with the Protocol requirements. The regulatory theory is used as the theoretical framework to investigate the relevancy and application of the various regulatory strategies which were the norms in the environmental protection, from the traditional command and control approach to the new governance such as smart regulation, reflexive and meta-regulation, licence model also civil and self-regulation, within the biosafety regulations both in Malaysia and Singapore.

Even though Singapore chose not to be a party of the Cartagena Protocol on Biosafety, the Protocol is used as a global model of biosafety governance as it outlines the most crucial issues of biosafety. Towards the end of the comparative study, the similarities and differences of legal and institutional biosafety laws in both countries are highlighted, with a view to suggest recommendations for improvement of Malaysian future biosafety governance.

The findings of the thesis revealed that Malaysia, like other developing countries, is protective of its biosafety laws, in order to balance the needs to generate income from the modern biotechnology research, development and commercialisation, and protecting its rich biodiversity. Singaporean biosafety and biosecurity laws, on the other hand, are more open and liberal, with less legal restrictions thus enabling Singapore becoming top 5 world producers of modern biotechnological products.

The study concludes that, as there are differences with Singaporean biosafety laws, the harmonisation of biosafety laws of both countries, being neighbours and main trading partners, are crucial, and the harmonisation of the biosafety laws of the Association of the South East Asian Nations (ASEAN) is desirable.

DEDICATION

To my husband, mother, parents-in-laws, five (5) children and nine (9) siblings.

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I pray for your success too, and may all of you be granted success in your future endeavours by God. My warm prayers also go to all people who have made prayers for my success in my PhD journey.

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LIST OF ABBREVIATIONS AND ACRONYMS

A*STAR	Agency for Science, Technology and Research
ABSA	International American Biosafety Association
ACRE	Advisory Committee on the Release to the Environment
AFC	Approved Facility Certifiers
AG	Attorney's General Chambers
AIA	Advanced Informed Agreement
APBA	Asia Pacific Biosafety Association
ASEAN	Association of Southeast Asian Nations
ASOES	SEAS Senior Officials on Environment
ATP	Approved Training Providers
AVA	Agri-Food and Veterinary Authority of Singapore
BA	Biological Agents
BAC	Bioethics Advisory Council
BAS	Biorisk Association of Singapore
BATA	Biological Agents and Toxins Act
BCH	Biosafety Clearing House
BSL	Biosafety Level
BWC	Biological Weapons Convention
CAP	Consumer Association of Penang
CASE	Consumer Association of Singapore
CBD	Convention on Biological Diversity
CDD	Communicable Diseases Division
COP-MOP	Conference of Parties at meetings for the Parties to the Protocol
COST	ASEAS Committee on Science and Technology
CPB	Cartagena Protocol on Biosafety
CWC	Chemical Weapons Convention
DOB	Department of Biosafety
EDB	Economic Development Board

EU	European Union
FAO	Food and Agriculture Organization
GATT	General Agreement on Tariffs and Trade
GDP	Growth Domestic Product
GE	Genetic Engineering
GEF	Global Environment Facility
GLC	Government-linked Company
GMAC	Genetic Modification Advisory Committee
GMO	Genetically Modified Organism
IKIM	Institute of Islamic Understanding Malaysia
IMCB	Institute of Molecular and Cell Biology
ISAA	Service for the Acquisition of Agri-biotech Applications SE Asia Center
ISNAR	International Service for National Agricultural Research
IUCN	International Union for Conservation of Nature
JAKIM	Department of Islamic Advancement of Malaysia
LMOs-FFP	LMOs intended for direct use as food or feed, or processing
LMO	Living modified organism
MABIC	Malaysian Biotechnology Information Centre
MARDI	Malaysian Agricultural Research and Development Institute
MEWR	Ministry of the Environment and Water Resources
MOH	Ministry of Health
MOM	Ministry of Manpower
MOSTE	Ministry of Science, Technology, and the Environment
NA	National Authority
NBB	National Biosafety Board
NBC	National Biosafety Committee
NBP	National Biotechnology Policy
NEA	National Environmental Agency
NIE	National Institute of Education
NGO	Non-governmental organisation

NParks	National Parks Board
NTU	Nanyang Technological University
NUS	National University of Singapore
OECD	Organisation for Economic Cooperation and Development
PPIM	Muslim Consumers' Association
SARS	Severe acute respiratory syndrome
SEA	South East Asia
SOM-AMAF	Senior Officials Meeting - ASEAN Ministers on Agriculture and Forestry
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
TLL	Temasek Life Sciences Laboratory
TWC	Technical Working Committees
TWN	Third World Network
UN	United Nations
UNDP	United Nations Development Programme
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organization
UPM	Universiti Pertanian Malaysia
USDA	United States Department of Agriculture
USFDA	United States Food and Drug Administration
WHO	World Health Organisation
WTO	World Trade Organisation

TABLE OF AUTHORITIES

STATUTES AND STATUTORY INSTRUMENTS

Birds Act 1965 (Chapter 7) (Original Enactment: Ordinance 3 of 1965)
Constitution of the Republic of Singapore

Infectious Disease Act 1976 (Chapter 137) (Original Enactment: Act 21 of 1976)

Singapore Supreme Court Of Judicature Act (Chapter 322)

Strategic Goods (Control) Act Chapter 300) (Original Enactment: Act 40 of 2002)

Supreme Court Of Judicature Act (Chapter 322)

International

Australia Gene Technology Act 2001 (Act No. 169 of 2000 as amended)

Australia Gene Technology Regulation 2001

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. *Official journal of the European Union* L043 40: 0001-0006.

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing council Directive 90/220/EEC—Commission declaration. *Official Journal of the European Union* L106 40: 0001-0039.

The Norwegian Ministry of Environment (1993) The Act relating to the production and use of genetically modified organisms (Gene Technology Act), Act No. 38 of 2 April 1993

United States Food and Drug Administration 1992

INTERNATIONAL TREATIES

Cartagena Protocol on Biosafety (adopted 29 January 2000, entered into force 11 September 2003) 2226 U.N.T.S. 208

Convention on Biological Diversity (CBD) (adopted 5 June 1992, entered into force 29 December 1993) 2226 U.N.T.S. 20

Rio Declaration on Environment and Development (adopted 13 June 1992) UN Doc. A/CONF.151/26 (vol. I)

The General Agreement on Tariffs and Trade (GATT) 1994 (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 187

The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress (adopted 15 October 2010 entered into force 5 March 2018) UNEP/CBD/BS/COP-MOP/5/17

The Technical Barriers to Trade (TBT) Agreement (adopted 15 April 1994, entered into force 1 January 1995) 1868 U.N.T.S. 120

WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (adopted 15 April 1994, entered into force 1 January 1995) 1867 U.N.T.S. 493

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Council of Civil Service Unions v Minister for the Civil Service [1985] AC 374

EC-Measures Affecting the Approval and Marketing of Biotech Products, Panel Report WT/DS291/R, WT/DS292/R, WT/DS293/R, 29 Sept 2006 (Biotech).

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PART I: INTRODUCTORY CHAPTER

1. Introduction and background on biosafety

The biosafety awareness on modern biotechnology came to prominence during the negotiations of the Convention on Biological Diversity (CBD) before it was signed on 5th June 1992 at the United Nations Conference on Environment and Development (UNCED).

CBD acts as a general treaty on biodiversity[1] with the objective as follows:

> *…the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.*[2]

It was during the CBD negotiations that the majority of the countries (except for the United States) demanded that CBD not only to be a convention of conservation but also include social and economic aspects of biodiversity as well as biotechnology.

The United States of America, one of the most exporting countries of LMOs, was concerned about the development, management, safe use and release of genetically modified organisms, and about the protection of

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[1] Laurence Boisson De Chazournes, "Convention on Biological Diversity and Its Protocol on Biosafety" (2009) United Nations Audiovisual Library of International Law.
[2] Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993) 2226 U.N.T.S. 20 (CBD) art 1.

intellectual property rights (IPRs), and also opposed the prior informed consent of exporting biotechnology or its products.[3]

The developing countries, on the other side, opposed any new convention if biotechnology was not included since the raw materials of genetic resources are within their territories and favoured national rather than international rights over biological resources.[4]

Thus Article 19 of CBD reflected the agreement on biotechnology that '…the Contracting Parties shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities.' The developing countries that provide the genetic resources for research were particularly affected. Article 19(3) states that the countries shall consider a Protocol for '…safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity'. The countries by natural or legal persons are to provide use, safety regulations and information on the potential adverse impacts for the handling of such organisms.[5] The CBD later led the development of negotiations of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as Cartagena Protocol on Biosafety).

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[3] De Chazournes (n1)2.
[4] ibid.
[5] Convention on Biological Diversity, art 19(4).

The controversies of modern biotechnology products and process, as well as the unknown risk such as contamination with the wild species, social, ethical, environmental and health issues, were raised by the public, environmental and non-governmental organisations as well as by developing countries during the CBD negotiations.

According to Cartagena Protocol on Biosafety, the term 'biosafety' is used to describe the efforts in reducing and eliminating potential risk such as producing newer toxins and allergens, resulting from biotechnology and its products.[6] Cartagena Protocol on Biosafety was negotiated by various countries to protect the potentially harmful effects of modern biotechnology products that affect human health and the environment.[7]

The word 'biotechnology' comes from the usage of science and technology in biology is said to be coined by Karoly Ereky, a Hungarian agricultural engineer. Biotechnology is defined in CBD[8] as '…any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.' Biotechnology has been practised for decades and includes plant breeding techniques that improve survival and produce better quality crops also fermentation process even from the ancient Egypt time such as the making of cheese, salami, beer, yoghurt and wine-making process.

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[6] Convention on Biological Diversity (CBD), 'Frequently Asked Questions (FAQs) on the Cartagena Protocol' (2012)<https://bch.cbd.int/protocol/cpb_faq.shtml#faq2> accessed 13 December 2013.
[7] art 1.
[8] art 2.

The relationship between different branches of science is essential to understand the underlying evolution of biology to various biology fields namely, botany, microbiology and zoology, and then to biotechnology due to the usage of technology in biology, which later led to an awareness of the importance of bioethics.

The relationship is illustrated as follows:[9]

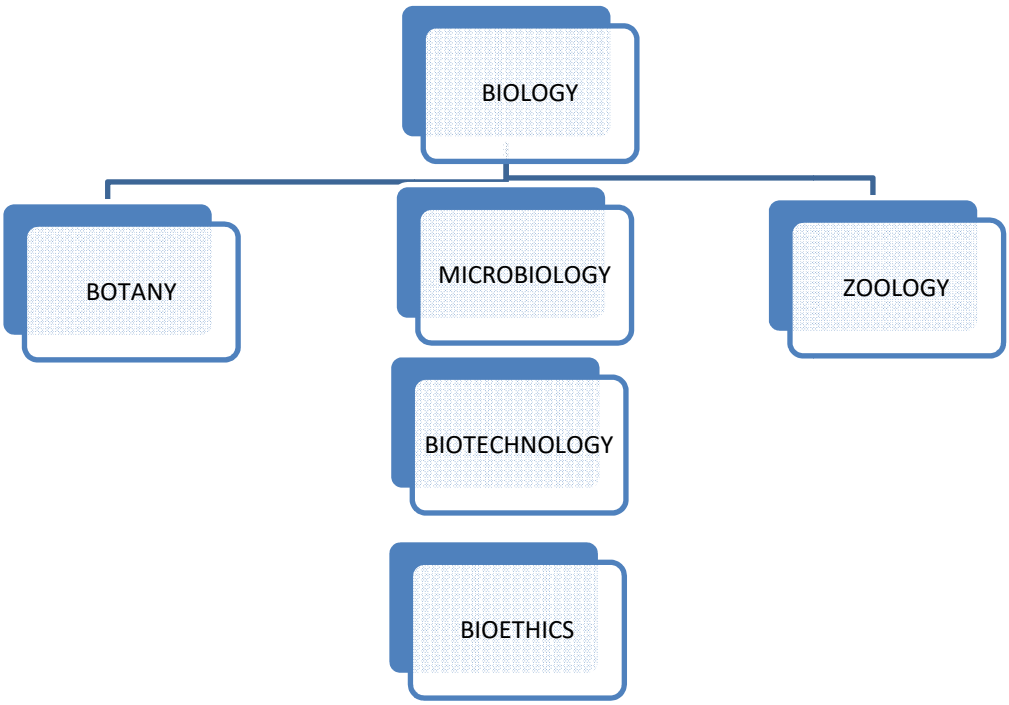

Figure 1: Evolution of different branches of science and their relationship

[9] M.K. Sateesh, *Bioethics and biosafety* (IK International Pvt Ltd 2008) 2.

The difference between biotechnology and modern biotechnology is of great significance. Interestingly, biotechnology has evolved from traditional biotechnology to modern biotechnology, i.e. from the early 'developments' in food production such as fermentation of cheese and curd to the discovery of DNA as genetic material and role of DNA in the genetic transfer information.[10] After the end of the Second World War, using this technological advancements DNA knowledge and techniques, scientists are now able to transfer the foreign DNA into another host and were even able to monitor the transfer of a foreign DNA into the next generation.[11]

Modern biotechnology can be illustrated as below[12] to differentiate it from other types of biotechnology.

[10] Verma Ashish Swarup and others, 'Biotechnology in the Realm of History' (2011) 3(3) J Pharm Bioallied Sci 321.
[11] ibid.
[12] Ketill Berger/IAASTD and Arendal/UNEP/GRID, 'Biotechnology and modern biotechnology defined' <http://www.grida.no/graphicslib/detail/biotechnology-and-modern-biotechnology-defined_b9d8> accessed 1 May 2015.

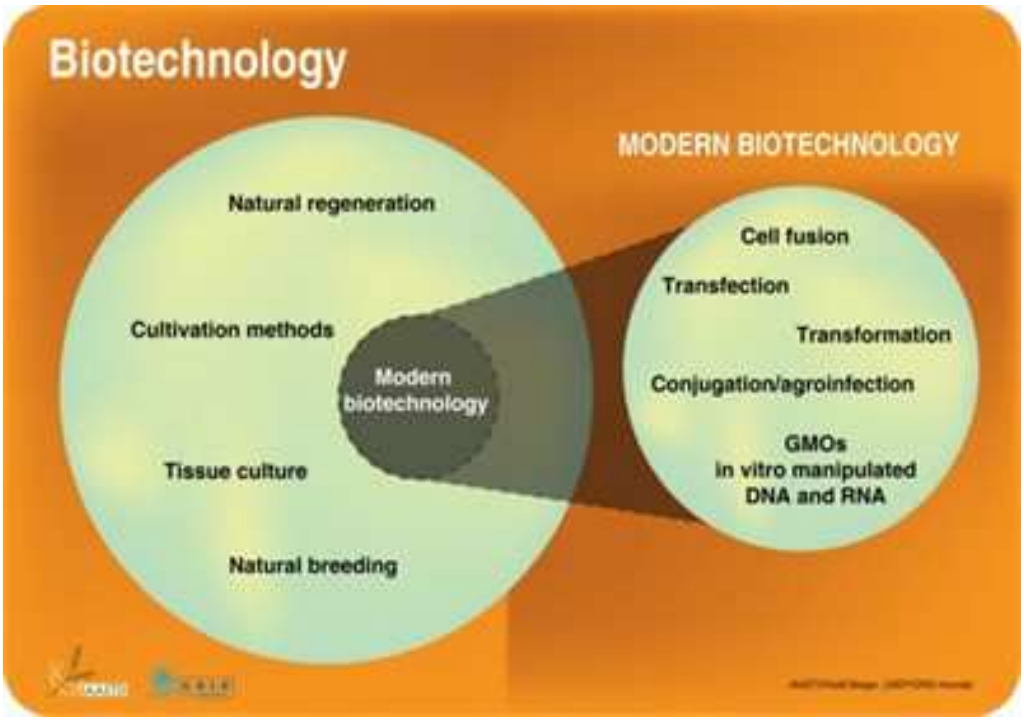

Figure 2: Modern biotechnology

Modern biotechnology is defined in Article 3(i) of the Cartagena Protocol on Biosafety as the application of:

a. *In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of 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.*

Modern biotechnology differs from traditional biotechnology, even though both involve alteration of the genetic organisms, summarised as follows:[13]

i) traditional biotechnology usually involves same species but genetic engineering (from modern biotechnology) can move between entirely unrelated genes;
ii) for the pace of change, traditional biotechnology work within years whereas for genetic engineering gene transfer can be made within weeks;
iii) traditional biotechnology relatively involved small number of species whereas genetic engineering is far more ambitious as it can create micro-organisms, plants and animals that can make human products such as insulin, even capable of changing the makeup of a human.

Despite the future potential benefits gained from modern biotechnology, there are mixed expert and public perceptions.

The Food and Agriculture Organization of the United Nations (FAO) Panel of Eminent Expert on Ethics in Food and Agriculture[14] held its meeting session from 26th to 28th September 2000 addressing three issues on

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[13] Straughan R and Reiss MJ, *Ethics, Morality and Crop Biotechnology* (ICI Seeds Fernhearst, Surrey, UK 1992) 5.
[14] The State of Food and Agriculture 2001, Food and Agriculture Organisation of the United Nations, Rome 2001.

biotechnology including genetically modified organisms (GMO). The result of the meeting on GMOs is summarised as follows:

i) risks, uncertainties and doubts on the use of genetically modified organisms (GMOs) are acknowledged;
ii) potential benefits and problems of GMOs are recognised;
iii) conditions to realise the potential of GMOs and to avoid the risks of GMOs.

At this juncture, the benefits of modern biotechnology are acknowledged, as well as the risks and uncertainties. The benefits and risks of modern biotechnology will be elaborated in the next discussion. Law is identified as one of the enabling mediums in realising the potential and avoiding the risks of GMOs.[15]

Whenever issues of modern biotechnology arise, the usual debate will be either the products or process of modern biotechnology that is more important. The process of 'genetic engineering' however has become the primary controversy of modern biotechnology perhaps because the risks of process or techniques of genetic engineering or products of LMOS and GMOs have been exaggerated or could not be understood by the public as it changes God’s creation.

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[15] Glowka L and Christy LC, *Law and Modern Biotechnology: Selected Issues of Relevance to Food And Agriculture* (Food & Agriculture Org. 2003) 1.

The products of modern biotechnology are mainly either living modified organisms (LMOs) or genetically modified organisms (GMOs) such as GM corn, potato, tomato, rice, drugs, human insulin and many others. This product comes with benefits resulted from the used of modern biotechnology namely increased micronutrients levels and removal of food allergens. However, there is also a potential risk to human health and the environment since it can produce newer toxins and allergens. The risk is going to be elaborated further below.

Genetic engineering as one of the processes in modern biotechnology is defined as the direct modification of an organism's genetic material (genome) directly bypass the conventional breeding method which produces novel genetic combinations that would never occur in nature.[16] Genetic engineering is controversial mainly because the genetic modification or genetic engineering physically changes the original DNA of the plants, animals and humans. Thus this process is heavily criticised as 'playing God'[17] as it alters the source thus raises issues of consent, ethics and bioethics as those techniques will physically change the original features of those products to different traits perhaps better than before.

[16] *Hutchinson Encyclopaedia of Science* (2nd edition).
[17] Young Tomme R, *Genetically Modified Organisms and Biosafety: A Background Paper for Decision-Makers and Others to Assist in Consideration of GMO Issues* (IUCN 2004)10.

2. Living Modified Organisms (LMO) or Genetically Modified Organisms (GMO)

LMO or GMO are commonly used terms to describe products of modern biotechnology and yet are conceptually difficult to be defined with precision. The words LMO or GMO have been used interchangeably to mean the same.[18] According to science, there is no such thing as Genetically Modified Organisms (GMO) as it genetic modification refers more to process rather than a final product.[19] GMO has long been widely embraced to shorthand that refers to the products of genetic manipulation. Thus to accurately scientifically define GMO or LMO have been challenging to regulators.

As for Cartagena Protocol on Biosafety, European Union (EU) Directive 2001/18/EC[20] and the Norwegian Gene Technology Act 1993[21], the terms LMOs and GMOs have three different definitions but the same legal interpretation.[22]

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[18] 'Cartagena Protocol' <http://bs.biosafetyclearinghouse.net/cartagenaprotocol.shtml> accessed 28 August 2015.
[19]Genetic Literacy Project. 'GMO FAQ' (2016) <https://gmo.geneticliteracyproject.org/FAQ/what-are-gmos/> accessed 28 June 2015.
[20] Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Union, L 106, 17.4.2001.
[21] The Norwegian Ministry of Environment (1993) The Act relating to the production and use of genetically modified organisms (Gene Technology Act), Act No. 38 of 2 April 1993.
[22]Jane Husby, 'Definitions of GMO/LMO and modern biotechnology' in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007).

LMO is the term used in Cartagena Protocol on Biosafety is defined in Article 3(g) as '…any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. GMOs include both LMOs (living organisms) and organisms, which are not capable of growing, i.e. are dead.[23]

The linkage between 'living modified organism', 'living organism' and 'modern biotechnology' is illustrated as follows:

> Cartagena Protocol; Article 3, Use of Terms
> *g) 'Living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;*
> *h) 'Living organism' means any biological entity capable of transferring or*
> *replicating genetic material, including sterile organisms, viruses and viroids;*
> *i) 'Modern biotechnology' means the application of:*
>
> a. *In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of 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;*

GMO is the term used by EU Directive and the GMO definition in the EU directive 2001/18/EC was not altered during the amendment of the old directive 90/220/EC. The term GMO is illustrated as follows:

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[23] ibid.

EU Directive 2001/18/EC, Article 2
Article 2, Definitions
1) 'Organism' means any biological entity capable of replication or of transferring genetic material;
2) 'Genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination

The term LMO in Cartagena Protocol on Biosafety has been accepted by the EU member countries and interpreted this definition to be in line with the definition of GMO in their directive 90/220/EC.[24]

Norway was also in agreement with the definition of LMO according to the Cartagena Protocol on Biosafety but formulated a different definition of the Protocol and the EU Directive. Norway like EU used the term GMO.

The Norwegian Gene Technology Act; Section 2, Technical area of application of the Act.

The Act applies to the production and use of genetically modified organisms. The Act also applies to the production of cloned vertebrates and crustaceans. The provisions of the Act relating to genetically modified organisms also apply to substances and products that consist of or contain modified organisms. Unless the genetically modified organisms are used as parent organisms, the Act does not apply to the production with the aid of cell technology of:

a) Genetically modified plant cells when the same result can be obtained using traditional methods of cultivation, or

[24] Article 2(2) Definitions; 'GMO means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.'

b) Animal cells in culture where the cell material has been obtained from different individuals of the same species and where the cells could have been produced by natural reproduction, and the use of such plant or animal cells.

If the purpose is not to produce cloned individuals, then the act does not apply to the cloning of genes, cells or tissue. The Act does not apply to the production of non genetically modified cloned animals that can occur naturally as a result of natural biological processes.

SECTION 4, DEFINITIONS

In this Act the following terms mean:

a) Microorganisms: any cellular or non-cellular microbiological entity that is able to reproduce or transfer genetic material;
b) Genetically modified organisms: microorganisms, plants and animals in which the genetic material has been altered by means of gene or cell technology;

From the above three (3) all include an introduction and/or injection of nucleic acids (or heritable material, DNA/RNA) into viruses, microorganisms, plants, and animals.[25] The central requisite of 'alteration', 'modification' or 'recombination' of genetic material is included in the definitions. The standard interpretation is the introduction of any DNA/RNA into cells or organisms through the different molecular gene technologies and methodologies in use, or to be developed.[26]

Food and Agriculture Organisation of the United Nations (FAO) defined GMO as '…GMOs and products thereof are produced through

[25]Husby (n22).
[26] ibid.

techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.[27]

The World Health Organisation (WHO) adopted the similar GMO definition by FAO[28] without amendment.

It is interesting to note here that Malaysian Biosafety Act 2007 uses the term 'living modified organisms' as compared to 'genetically modified organisms'. Section 3 of the Malaysian Biosafety Act 2007[29] in the interpretation section defines 'living modified organisms' as '…any living organisms that have the novel combination of the genetic material obtained through the modern biotechnology process'.

This definition is similar to LMO definition in the Cartagena Protocol on Biosafety. The definition of LMO in the Protocol is instructive on this point.[30] The products from LMOs, which are not living, and which are therefore not covered by the scope of the Protocol, for example, oil produced from genetically modified (GM) canola or meat from GM animals.[31]

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[27] FAO/WHO, 'The Codex Alimentarius Commission And The FAO/WHO Food Standards Programme, Guidelines For The Production, Processing, Marketing and Labelling of Organically Produced Foods' (2017) <http://www.fao.org/docrep/005/y2772e/y2772e04.htm#fn5> accessed 20 November 2015.
[28] WHO, 'Frequently asked questions on genetically modified foods' <http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/> accessed 28 July 2015.
[29] Act 678.
[30] Lim Li Lin, 'Cartagena Protocol on Biosafety' in Traavik, Terje and Lim Li Ching (eds), *Biosafety First* (Tapir Academic Publishers 2007)4.
[31] ibid 5.

Thus, it can be seen here that for the EU Directive, Norway Technology Act, WHO and FAO use the term GMO. On the other hand, Cartagena Protocol on Biosafety and Malaysia Biosafety Act 2007 used the term LMO. Even though the terms LMO and GMO might scientifically mean different, they are interpreted as similar. In short many countries use the terms 'LMO' and 'GMO' interchangeably, and consider that the terms refer to the same thing.[32] This thesis will use the term LMO and GMO interchangeably as by interpretation they have the same meaning.

3. Historical link between food safety issues and the earlier GMO regulation in 1990s

Some cases of food safety issues have links with the historical controversies on GMOs in the European Union, is of relevance here. It started back in 1990 in the United Kingdom (UK) and Europe, as there were series of food safety consumption issues such as mad cow disease[33], horse meat scandal[34] and much more thus making people more wary about their food intake or sources.

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[32] ibid.
[33] Burgiel SW, 'The Cartagena Protocol On Biosafety: Taking the Steps from Negotiation to Implementation' (2002) 11(1) Review of European, Comparative & International Environmental Law 53.
[34] Premanandh, J,'Horse meat scandal–A wake-up call for regulatory authorities' (2013) Food control, *34*(2), 568-569.

It started with the mad cow disease during the late 1997 and foot and mouth diseases[35] that made Europeans ban beef from the UK. Later the horse meat scandal in Europe[36] in 2013 that made people lost faith in the food safety issues in Europe and in a way contribute to people turning to organic food which used less pesticide for health purposes.

At the international level, there were some alleged issues or GM BT corn Starlink from the United States (US) that is certified not fit for human consumption as it contained some GM corn.[37]

The peak of the GM products controversy was the case in WTO that is *EC-Measures Affecting the Approval and Marketing of Biotech Products.*[38] In the EC Biotech case, the complainants the United States, Canada and Argentina brought the claim in the WTO against the European Communities stating that there was general EC moratorium on approval of agricultural biotechnology products. The WTO findings were that the EC applied a general de facto moratorium on biotech products approval and inconsistent with its obligations under the WTO trade agreements.[39]

There were anti-GMO campaigns worlwide, propagated by non-governmental organisations (NGOs) also environmental groups; the most

[35] Burgiel (n33).
[36] McEvoy JD, 'Emerging Food Safety Issues: An EU Perspective' (2016) 8(5-6) Drug Testing and Analysis 511.
[37] Bucchini L and Goldman LR, 'Starlink Corn: A Risk Analysis' (2002) 110(1) Environ Health Perspect 5.
[38] Panel Report WT/DS291/R, WT/DS292/R, WT/DS293/R, 29 Sept 2006 (Biotech).
[39] Young MA, 'The WTO's Use of Relevant Rules of International Law: An Analysis of the Biotech Case' (2007) 56(4) The International and Comparative Law Quarterly 907.

known is the anti-Monsanto campaign in approximately 400 cities[40] that fundamentally affect the world's population belief towards GMO.

During the Convention of Biological Diversity in 1993, there were voices raised mainly by developing countries that led to the negotiations of Cartagena Protocol on Biosafety. The developing countries had the fear that the United States (US) and the like countries will be dumping GMOs on the developing countries. Thus there were raising the need for biosafety to be regulated for fear of human health and environment.

4. Biotechnology law or biosafety law

The earlier regulation in this area was known as biotechnology law or rather modern biotechnology law and regulation. However, later years especially during the negotiations of the Convention on Biological Diversity (CBD) in 1992, various countries raised concerns and controversies on the effect of modern biotechnology on the safety of human health and the environment. Thus the regulation now is focused on biosafety regulation. The biosecurity laws are not covered in this thesis, but will be reviewed in the discussion on Singapore only, as it has both biosafety and biosecurity laws inter-related regarding regulatory or institutional framework.

Biotechnology regulation broadly covers every aspect of biotechnology that needs to be regulated that is comprehensive that will include inter alia

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[40] 'World Stands Up Against Monsanto: Over 400 Cities Protest GMOs' RT News (25 May 2015 24 May 2015 2015) News.

intellectual property, biopiracy and bioethical issues. On the other hand, biosafety regulation only regulates the biosafety issues and concerns of the modern biotechnology and its products. Biosafety regulation in particular reference to Cartagena Protocol on Biosafety only covers the transboundary movement of genetically modified organisms (GMOs) or living modified organisms (LMO) also environmental biosafety as other biosafety aspects of LMO or GMO are covered by other laws, regulations and agreements.

5. Definition of biosafety

Biosafety, while not clearly defined in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity but stated in the introduction as the Objective, it is referred to as a concept that refers to the need to protect the human health and environment from the adverse effects of modern biotechnological products. However, that concept is precise and general in explaining the term 'biosafety' as biosafety can cover extensive areas of application. The biosafety definition is said to be very general as there is no 'best' approach to biosafety analysis.[41] Biosafety can be defined as the regulatory systems and risk analysis process that is designed to perform proper risk assessments, mitigation and communication of GM products to ensure their safe use.[42]

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[41]McLean MA and others, 'A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation' (International Service for National Agricultural Research (ISNAR) 2002) 1.

[42]José B. Falck-Zepeda, 'Socio-economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake?' (2009) Vol 12 (1) The Journal of Agrobiotechnology and Management and Economics 90. Available on the World Wide Web: http://www.agbioforum.org.

Biosafety regulation is not comprehensive, as Codex Alimentarius internationally govern the food safety of GM products (hereinafter referred to as Codex) while environmental biosafety by Cartagena Protocol on Biosafety. The scope for environmental biosafety regulation according to the Cartagena Protocol on Biosafety is only limited to LMO or GMO.

6. Benefits and risks of modern biotechnology and LMOs

It is imperative to state here that the discussion in this thesis will be limited to modern biotechnology products in general and specifically LMO and GMO and not covers genetic engineering as a whole. The Cartagena Protocol on Biosafety focuses on the regulation of modern biotechnology and its products, i.e. GMO or LMO and not specifically on genetic engineering.[43] There are some benefits and risks of modern biotechnology products in general and LMO in specific which will be discussed in turn. Thus it is vital to summarise the benefits of the modern biotechnology products.

The benefits of modern biotechnology and its products

The benefits of modern biotechnology, in general, cannot be denied as mainly they are claimed to increase world food production as compared to the conventional agricultural method that takes longer to be cultivated and grown. They can be summarised as follows[44] (the list is not exhaustive):

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[43] Preamble.
[44] Ratledge C and Kristiansen B, *Basic Biotechnology* (Cambridge University Press 2006) 5.

1) GM plants that are insect resistance[45] and herbicide tolerance[46]

   These GM plants' traits will have huge impacts on the agriculture community regardless whether they have big or small plantations. As infection of the plants due to insects is known, therefore if the plant is insect resistance, less herbicide will be used.

2) GM plants contain better traits of food[47] that can feed the growing population in the world.[48]

   The better traits of GM crops, in turn, will produce better food that can feed the world. A consumer will perhaps be happier to consume a delayed-ripening tomato, papaya that can last longer compared to those that will quickly rot.

3) GM plants have increased micronutrients levels,[49] removal of food allergens[50] and productions of vaccines.[51]

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[45] Schuler TH and others, 'Insect-Resistant Transgenic Plants' (1998) 16(4) Trends Biotechnol 168.
[46] Shah DM and others, 'Engineering Herbicide Tolerance in Transgenic Plants' (1986) 233(4762) Science 478.
[47] Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (Nuffield Council on Bioethics , May 1999) 30.
[48] Conway G and Toenniessen G, 'Feeding The World in the Twenty-First Century' (1999) 402 Nature C55.
[49] Bouis HE, Chassy BM and Ochanda JO, '2. Genetically Modified Food Crops and Their Contribution to Human Nutrition and Food Quality' (2003) 14(5) Trends Food Sci Technol 191.
[50] Eliot M. Herman, 'Genetically Modified Soybeans and Food Allergies, Journal of Experimental Botany' Volume 54, Issue 386, 1 May 2003, 1317–1319.

4) Genetic modification that extends beyond foodstuffs for example cotton has been modified to resist essential pests such as boll weevil.[5253]Fuel for electricity generation could be based on GM plants rather than fossil fuels.[54] These are crucial scientific breakthrough from modern biotechnology that could improve on human living rather than depend on the natural resources from the biodiversity. Therefore in this regard, the modern biotechnology should be commended.

The scientific risks of modern biotechnology and its products

On the other hand, despite the known benefits, there are some products of genetically modified organisms as a result of modern biotechnology is also said to pose higher risks in the following ways:[55]

a) genetically modified organisms (GMOs) can adapt and multiply in the ecosystem compared to native flora[56]
b) GMO can transfer genes[57] related to virulence[5859] or pathogenesis[6061] into native microbial[6263] flora

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[51] Nuffield Council on Bioethics (n47)2.

[52] ibid 3.
[53] The boll weevil is a beetle which feeds on cotton buds and flowers.
[54] Bouis(n49)3.
[55] M.K. Sateesh, *Bioethics and biosafety* (IK International Pvt Ltd 2008)10.
[56] Prakash D and others, 'Risks and Precautions of Genetically Modified Organisms' (2011) ISRN Ecology.
[57] ibid.
[58] 'The degree of pathogenicity of a microorganism as indicated by case fatality rates and/or its ability to invade the tissues of the host,'
[59] *Dictionary of Medicine, Nursing, and Allied Health* (Seventh Edition,2003)

c) GMO can produce newer toxins[6465] and allergens[66]

d) GMO can transfer the new traits to the related microbes[67]

As a consequence, these organisms create situations which are unpredictable, unexplained, uncontrolled and unmanageable. However, this is not always accurate as it can happen to unmodified organisms as well.[68]

Biosafety is regulated due to the facts that there are biosafety risks and concerns. The biosafety risk is said to be more scientific as it involves the process from technology application. However, the risks and concerns that are non-scientific will be discussed alongside as they might affect the biosafety regulation as well.

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[60] 'The development of morbid conditions or of disease; more specifically the cellular events and reactions and other pathologic mechanisms occurring in the development of disease'.
[61] *Dictionary of Medicine, Nursing, and Allied Health* (Seventh Edition,2003)
[62] 'Relating to a microbe or to microbes (A unicellular or small multicellular organism including bacteria, protozoa, some algae and fungi, viruses, and some worms, esp. those that are injurious to other organisms'.
[63] *Medical Dictionary* (2009).
[64] 'A noxious or poisonous substance that is formed or elaborated either as an integral part of the cell or tissue (endotoxin), as an extracellular product (exotoxin), or as a combination of the two, during the metabolism and growth of certain microorganisms and some higher plant and animal species'
[65]*Dictionary of Medicine, Nursing, and Allied Health* (7th Edition,2003)
[66] Bawa A and Anilakumar K, 'Genetically modified foods: safety, risks and public concerns—a review' (2013) 50(6) Journal of food science and technology 1035.
[67]M.K. Sateesh, *Bioethics and biosafety* (IK International Pvt Ltd 2008).
[68] ibid.

7. Precautionary principle

Another problem with modern biotechnology also associated with biosafety risk of scientific knowledge is that there are still some grey areas and uncertainty in science. Thus in this area precautionary principle as stated in Cartagena Protocol on Biosafety is being reaffirmed as stated by Principle 15 of Rio Declaration on Environment and Development.[69] Principle 15 states that to protect the environment, precautionary principle shall be used by states according to their capabilities. When there are threats of severe irreversible damage, lack of full scientific certainty shall not be reasons to postpone taking cost-effective measures to prevent environmental degradation.

There are some issues related to precautionary principle in biosafety application. One of the problems with precautionary principle is the standard of scientific knowledge. For developing countries with less science capacity, facilities and human resources how do they be up to the standard like other developed countries? However, Rio Declaration explicitly provides for the difference in capabilities of states, thus perhaps limiting claims of non-compliance against developing countries when dealing with uncertain areas of science.

The problem with precautionary principle will be discussed in more detail in Chapter 2 when criticisms on Cartagena Protocol on Biosafety are discussed.

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[69] Cartagena Protocol on Biosafety: Preamble.

8. Potential adverse effects of modern biotechnology on socio-economics

The discussion of the socio-economic considerations which is part of Cartagena Protocol on Biosafety can be broad likewise complicated and convoluted.These issues are called the 'fourth criterion'[70] as they are 'non-scientific' issues and concerns advocated by some groups and seen as inadequate measures but yet becoming part of the decision making process. It is to be seen how these socio-economic considerations will be placed in the regulation and taken into consideration by the regulators in the decision-making process.

The potential adverse effects of modern biotechnology especially LMOs /GMOs are limited within the scope of Cartagena Protocol on Biosafety thus only related to the environmental and human health aspect of biosafety. These socioeconomic issues seem to be in line with the socio-economic considerations suggested by the Explanatory Guide.[71] According to the International Union for Conservation of Nature (IUCN), not all socio-economic considerations may be taken into consideration but limited only to those LMOs affecting the biodiversity. Article 26 of the Cartagena Protocol on Biosafety is said to identify some particular socio-economic considerations that are expected to be taken into account namely the '…especially about the

[70] Ratledge (n44),14.
[71] Mackenzie R and others, *An explanatory guide to the Cartagena Protocol on Biosafety* (IUCN Publications Services Unit 2003)163.

value of biological diversity to indigenous and local communities'. The Explanatory Guide[72] suggested to include '…the ability of indigenous and local communities to make use of the biological diversity upon which their community's survival and traditional livelihood depends'.[73]

The socio-economic considerations can be further elaborated and summarised as follows:

a) the continued availability and biodiversity range in the areas inhabited or used by indigenous or local communities;
b) the erosion of genetic and other natural resources, previously available to
   indigenous or local communities in their territories; or
c) the loss of cultural traditions, traditional knowledge, and practices in a particular indigenous or local community as a result of the loss of biodiversity in their areas.[74]

The discussion of socio-economic considerations in this thesis is limited to these three (3) broad issues listed as follows:

a) Socio economic consideration
b) Moral and ethical issues
c) Cultural and religious issues

[72]ibid.
[73]ibid 164.
[74]ibid.

a) Socio-economic considerations on modern biotechnology

Definition of socio-economics

The term 'socio-economic' seems to be used very broadly as to include social and economic factors.[75] Such considerations are important in part because they are related to values that many countries have already officially acknowledged as being relevant and vital in international or domestic law.[76] Taking them into account in biosafety decisions is therefore consistent with such values and law.[77]

Legal recognition of socio economic considerations in Cartagena Protocol on Biosafety

The primary convention on biosafety the Cartagena Protocol on Biosafety legally recognised socio-economic considerations as it is stated in Article 26 of the Protocol. According to Article 26 of Cartagena Protocol on Biosafety on socio-economic considerations:

> 1. *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*

[75] Armin Spök, *Assessing Socio-economic Impacts of GMOs: Issues to Consider for Policy Development*; Final Report (Bundesministerium für Gesundheit, Sekt. II, 2010).
[76] ibid.
[77] ibid.

diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. *The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.*

However, the definition of ‘socio-economic’ is nowhere defined in the Cartagena Protocol on Biosafety. The only important socio-economic consideration issue that is stated in Article 26 is the impact of the living modified organisms (LMOs) on the ‘conservation and sustainable use of biodiversity especially about the value of biodiversity to indigenous and local communities’. Moreover, it is mentioned in the next part of the Protocol that the Parties are expected to collaborate on research and information exchange on such issues of socio-economic. The socio-economic considerations leaves a room for broad interpretation.

Biosafety risk assessment procedures are now an established prerequisite for transboundary movements of GM materials, also for research, developments and release of LMO into the environment. Although Cartagena Protocol on Biosafety focused on the potential effects and harms of the GMO on the environment as it is the scope of the Convention on Biological Diversity, the Protocol allows the possibility of including of other considerations such as food safety and socio-economic considerations. Furthermore, it is true that Cartagena Protocol on Biosafety is not the only guidance document about risk assessment of GMO, as other treaties and agreements exist, such as Codex Alimentarius. However, Cartagena Protocol

on Biosafety due to the negotiations between parties has indeed broadened the narrower environmental scope of the Protocol.[78] Jaffe[79] however argues that Cartagena Protocol on Biosafety limits its scope to factors affecting biodiversity.

An analysis of the socio-economic considerations according to the Cartagena Protocol on Biosafety

Article 26 of the Protocol does not detail out on how this socio-economic considerations is to be taken into account, but it must be consistent with their international obligations such as World Trade Organisation (WTO) as it might create trade barriers.[80] However, the broad language of Article 26(1) enables the states to take socio-economic considerations into account during:

i) a decision on import under the Protocol or
ii) under its domestic measures implementing the Protocol

Thus parties may take relevant socio-economic considerations when implementing some provisions according to the Protocol[81] and also in

[78] José B. Falck-Zepeda, 'Socio-economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake?' (2009) Vol 12 (1) The Journal of Agrobiotechnology and Management and Economics 90.
[79] Gregory Jaffe, 'Implementing the Cartagena Biosafety Protocol Through National Biosafety Regulatory Systems: An Analysis Of Key Unresolved Issues' Journal of Public Affairs (2005) 5.34 299.
[80] Mackenzie R and others, *An explanatory guide to the Cartagena Protocol on Biosafety* (IUCN Publications Services Unit 2003)164.
[81] ibid 165.

accordance to its domestic measures in implementing the Protocol to protect the impact of the LMOs on its biodiversity.

The pros and cons of including socio-economic considerations in the biosafety decision-making process

The inclusion of the broader socio-economic considerations into GMO biosafety analysis decision-making process is controversial. Zepeda[82] highlights that there are two opposing views on the issue of inclusion of socio-economic considerations in the biosafety risk assessment.

The most important opinion against the inclusion of socio-economics in the biosafety decision-making process is that it will serve as a 'blanket justification' to reject GM technologies without a clear statement or reason. In this regard, socio-economic considerations may follow the regulatory development pathway in which some countries used the precautionary principle that allows them not to make a regulatory decision and/or as pre-emptive measures to reject GM technologies. Paarlberg (2008)[83] presents similar arguments in this line of thought. The view states that the inclusion of socio-economic view states that a broad, undefined socio-economic consideration will be disruption to technology development and transfer.

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[82] José B. Falck-Zepeda, 'Socio-economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake?' (2009) Vol 12 (1) The Journal of Agrobiotechnology and Management and Economics 90.
[83] Paarlberg R, *Starved For Science: How Biotechnology Is Being Kept Out Of Africa* (Harvard University Press 2009).

On the other hand, socio-economic consideration is important to protect the negative impact of GM products towards local and indigenous people. This view includes not just the scientific risk assessment but also broader socio-economic considerations including ethical, philosophical and religious concerns and by doing so this position potentially aligned itself to the precautionary principle.

This thesis is in line with the second view especially about the Malaysian context which will be discussed in the next Chapter 3, i.e. to what extent socio-economic considerations should be included in the Malaysian biosafety law and what issues are relevant to be included. In essence, for the inclusion of socio-economic considerations to be successful and fruitful into the biosafety and biotechnology decision-making process it is useful to characterise the so-called functional biosafety system by Jaffe[84] which are transparent, well defined, protective and understood by all actors and stakeholders. These biosafety regulation aims should serve as a general guide for inclusion of the socio-economics in Malaysia biosafety decision-making.

Isaac[85] criticises the different 'trajectories' of the United States and the European Union in aligning themselves well to scientific and social approaches to regulatory paradigms. According to him, the fundamental difference between scientific and social rationalities is the fundamental role of

[84] Mackenzie (n 71).
[85] Grant Isaac, 'Agricultural Biotechnology and Transatlantic Trade: Regulatory Barriers to GM Crops' (2002) CABI.

science and technology has to offer to the society. It will be discussed in more detail in Chapter 2. Chapter 2 starts with a general discussion of the relationship between law and science and technology which is of relevance here in discussing how countries differ in their biosafety risk assessment.

In realising socio-economic considerations into biosafety, the decision-making process is to identify what are the socio-economic issues at stake and why there is the need for these issues to be taken into account. Then after agreeing on the relevant issues, next questions will be how are they to be realised, how to implement them and at what point of decision-making are they relevant. These are general issues when socio-economic considerations are to be broadly included in the biosafety decision-making process.

b) Moral and ethical perspectives on biosafety risks from modern biotechnology application

Moral issues

This moral issue is another controversial issue as the technology used in modern biotechnology, especially genetic engineering and the genetically modified products. The issues of moral, ethical and cultural are closely related and have connections in which case to some community, religions shape their belief. However to those who have no belief in religion, moral is their perception and judgment of good and evil or perhaps the current socially accepted norms.

Social norms serve as foundations of social order, helping to ensure that people will act in ways considered pro-social by their society, for example from taking care of their children to paying their taxes.[86] While in the law and technology regulation context, social norms might not play an important role, because layman is clueless on the modern biotechnological scientific process, only to depend on the information supplied by the science community.

The moral is the concept of right or wrong. While there have been many debates as to whether there is any relationship between law and morality[87], this thesis is not going to discuss this issue in detail. There are some underlying moral issues regarding genetically modified organisms and the genetic engineering mainly: Are humans allowed to intervene the God's creations?

While these issues are controversial and debatable and different religions might have slightly different views on these issues, these questions might not be relatively easy to answer. However, the general view based on religions is that humans are not allowed to change God's creation. However, if the change for instance through science and technology is for human good then the process and product is morally acceptable. Therefore religions might permit it to be done perhaps subject to some limitations. Thus this fundamental issue will then lead to this issue: If we humans create better

[86] Etzioni, Amitai, 'Social Norms: Internalization, Persuasion, and History' (2000) 34 Law & Society Review 157.
[87] Hart HLA, 'Positivism and the Separation of law and Morals' (1958) 71 H.L.R. 593.

creations than the original creation of genetic engineering. Are we better than God Himself then? This issue is somewhat thought-provoking but should be borne in mind, morally at least.

While it is claimed that scientific intervention especially the robust technology as in modern biotechnology contradicts with moral belief to change God's original creation sometimes the intervention leads to better life, better crops, it then made humans tolerate with that intervention and accept it. Therefore the Genetic Engineering (GE) technology and Genetically Modified (GM) products should be equally accepted as conventional goods provided they do not go beyond certain accepted ethical principles.

Ethical issues in modern biotechnology

Ethics is defined as the system of moral principles.[88] Ethics is the way how people make decisions and lead their lives usually derived from religious belief, philosophies and cultures.

While natural science attempts to tackle the scientific issues systematically, ethical dilemmas are not usually dealt with in a systematic framework[89] and regarded as 'too vague'. While the ethical argument is regarded as vague, the discussion on ethical issues on genetically modified

[88]'Ethics guide' <http://www.bbc.co.uk/ethics/introduction/intro_1.shtml> accessed 15 April 2015..

[89] Macer D, 'Ethical, Legal and Social Issues Of Genetically Modified Disease Vectors in Public Health. Social, Economic and Behavioural Research. Special Topics No. 1' (2014) 9 World Health Organization/TDR. Available online at: <http://www.who.int/tdr/publications/tdr-research-publications/seb_topic1/en> accessed 26 July 2015.

organisms is valid and sound in principle. The peer-reviewed paper by Macer[90] is of relevance here even though it relates to genetic engineering in public health. Genetic engineering process is part of producing genetically modified organisms that discuss primarily the same core ethical issues. In the author's opinion , the paper brilliantly laid down fundamental basic ethical principles in GM-related issues with the idea of resolving ethical dilemmas.

There are some essential ethical principles in modern biotechnology which can be summarised as follows:

a) animal rights concerns
b) consent issues
c) access to information and benefit
d) autonomy, ethics of technology choices and knowledge development
e) intellectual property rights and technology transfer
f) the inducement to participation
g) environmental ethics

a) Animal rights[91] concerns

In modern biotechnology, animals are commonly subjected to clinical trials for research and development before successful commercialisation.

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[90]Macer DR, 'Biotechnology and Bioethics: What Is Ethical Biotechnology?' (1995) in D. Brauer (ed) *Modern Biotechnology: Legal, Economic and Social Dimensions, Biotechnology*, Volume 12. (Weinheim, Germany: VCH, 1995)115-154.

[91] ibid.

The practice is justified due to the facts that animals' lack of ability to sense pain for example insects.[92] However, the painless argument is said to neglect the animals' interest[93] and rights even to defend themselves through research and development which are meant for human good mostly.

b) Consent issues

The consent issues are especially relevant in GMOs; from trial participants, the society on possible environmental risks and on cessation of trials. For instance, in the case of release of some GM vectors nearby their living area, some people in the society might be unable to express their objections due to their lack of literacy, knowledge and information and social status. Thus their consent may be abused. The privacy of the data also obtained through trials for immunisation for example especially involving children without the parents' consent will also be questionable.[94]

In that case should every individual be asked for consent if it involved specific locality or should a referendum be good enough? The establishment of the Ethics Committee in that matter that takes the public view into account for instance during the release of some GM mosquitoes to improve the existing environment and local diseases is essential.

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[92] Singer P, *Animal Liberation* (London,Jonathan Cape 1976) (as cited in ibid).
[93] Macer D,'Uncertainties About 'Painless' Animals', *Bioethics*, 1989, 3:226-235 (as cited in Macer (n89).
[94] Macer (n 90) 17.

It was also suggested that broad ecological understanding of the impact, beyond public health, should be carried out.[95] This idea should be welcomed especially for countries with abundant biodiversity for sustainability.

c) Access to information and benefit

The public access to information by illiterate people as to the information and benefits of modern biotechnology is another crucial issue. The benefits of modern biotechnology should not be limited based on geographical also regardless of wealth. Alternatively, else people with political power, for instance, might reject any release of GM vectors in their locality leaving others with no choice but to accept the trial at their area. Thus, the sharing of the benefits from modern biotechnology with the locality is justified as part of compensatory justice.[96]

d) Autonomy,[97] ethics of technology choices and knowledge development.[98]

Individuals have autonomy in deciding what is good or bad depending on what they believe. Consumers of GMOs or LMOs should decide for themselves whether to consume the GM products or not. In assisting them to choose, thus it is only ethical for them to be informed for instance for the

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[95] ibid 18.
[96] Macer (n 90)20.
[97] Silverman E, 'The 5 Most Pressing Ethical Issues In Biotech Medicine' (2004) 1(6) Biotechnol Healthc 41.
[98] Macer (n 90) 20.

LMOs to be labelled. This right should also be recognised and translated in the form of implementation of GMO labelling.

In most countries nowadays it seems that on technology choices, the paternalistic interventions were taken on behalf of citizens. Thus the government is taking the lead to accept or reject the technology on behalf of the people. Governments rightfully should offer the people the chance to use new technology[99] if it is for the betterment for instance in agriculture and food production under the ethical principle of beneficence.[100]

However, civil rights movements have empowered people to take these decisions themselves. In modern biotechnology, biosafety regulation at the international level, the public participation seems to be part of the practice, i.e. to include public in the biosafety decision-making process. However to what extent their voices are effective is again questionable.

e) Intellectual property rights (IPR) and technology transfer

On the moral rights in agriculture, the GM seeds' monopoly by some biotechnology conglomerates[101] will enable those producers to potentially gain enormous profits that will stir issues of concerns to the developing countries that initially possessed the traditional variety of those. These are issues of concern in the future GM plant. It is hoped that win-win cooperation

[99] Macer (n90) 3.
[100] ibid.
[101] ibid.

between the countries and producers will benefit humankind as a whole. Thus a better trait of plant and more food is produced for people, and the people that have the traditional knowledge of the plant should be given compensation or royalty such as technology transfer that benefits all. For example the basmati rice that is very well known in India and Pakistan. Future GM basmati rice seed producer should share the IPR and the technology transfer with the people of India and Pakistan.

f) The inducement to participation

It is ethically believed that the actual or future benefits also financial gains from modern biotechnology should not be an incentive to participation.[102] However, the possibility of reimbursement for an individual's time, inconvenience and expenses (if any), should be counted even if there is a general distribution of benefits to the community. It is argued that limiting the financial return to only some tribal leaders or chief in the community for community consent is not in line with solidarity thus considered as a bribe. Therefore, for the community in return should obtain inter alia healthcare infrastructure, vaccines, tests, drugs, treatments, or other humanitarian efforts.

g) Environmental ethics.[103]

As humans live, dependant and utilise on the environment such as the plants, animals and microorganisms, the environment is therefore justified to

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[102] HUGO Ethics Committee, *Statement on Benefit Sharing*, April 2000.
[103] Macer, 'Uncertainties About 'Painless' Animals' (n91) 5.

be protected. The environment has its value as from the religious point of view, God as the owner creates the world with values. Humans are to make use of the environment to preserve its sustainability.

Bioethics

Bioethics, which was coined by Van Rensselaer Potter in 1971 at the University of Wisconsin[104] is the study of ethical aspects of the biology, medical research and practice.[105] In the context of biosafety, bioethics had been institutionalised leading the Bioethics Council to be established and advising various ethical issues in modern biotechnology.

Bioethics is defined as the broad terrain of the moral problems of the life sciences, ordinarily taken to encompass medicine, biology and some essential aspects of the environmental, population and social sciences. The traditional domain of medical ethics would be included within this array, accompanied now by many other topics and problems.[106] Therefore bioethics is the more specific, relevant and direct moral issues associated with life science, especially modern biotechnology.

Bioethics can be viewed as descriptive, prescriptive and interactive bioethics.[107] Descriptive bioethics is how people view their life, moral interactions and responsibilities with living organisms in their life. Prescriptive

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[104] Reich WT, 'The Word" Bioethics": Its Birth and The Legacies of Those Who Shaped It' (1994) 4(4) Kennedy Inst Ethics J 319.
[105] Bobyrov V. M. , *Bases of Bioethics And Biosafety: Study Guide for Study of Higher Med,* Нова Книга 24.
[106] *Encyclopedia of Bioethics.*
[107] Macer (n 90) 4.

bioethics is informing people what is ethically good or bad and vital principles involved in decision-making process. Interactive bioethics is debate and discussion between people, groups and communities about descriptive and prescriptive bioethics.

There are some fundamental theories of ethics namely consequence, actions and motives.[108] The consequential arguments apply to assess the ethics of biotechnology applications whether they contribute to well-being or not by looking at the outcome. The action-based ethics looks at the morality of the act itself without looking at the consequences. The motive-based theories judged the ethics by looking at the motive of the action for instance whether it was done with good intentions or not.

The underlying ethical principle that is vital in modern biotechnology is that it should not harm the human health and the environment, regardless of the good motive and benefit it offers. The harm could be done to the animals, humans, plants, environment and public. Also, by looking at the fundamental theories of ethics, they might conflict among themselves for example in the application of modern biotechnology field, for instance, using genetic engineering that involves cross gene between animals and plants with the good motive of producing better traits of plants. Therefore the bioethics is to weigh the benefits and disadvantages of advising on genetic engineering process or genetically modified food. Thus careful decision-making should be made.[109]

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[108]Macer (n 90) 5.
[109] O'Mathúna DP, 'Bioethics and biotechnology' (2007) 53(1-3) Cytotechnology 113.

The establishment of bioethics has been in practice in the developed countries, whereas in developing countries bioethics might range to almost unheard of due to lack of information, knowledge and expertise, to development and education process. In developing countries, it is only in recent years references were made to Bioethics Council in matters concerning sciences as it is quite commonplace for them to adopt and adapt the practice from the developed countries. However, it is interesting to see the development of bioethics in protecting humans, animals, biodiversity from excessive manipulations by human themselves.

c) Cultural and religious issues in modern biotechnology

To some communities, culture is closely associated with religious belief as it is the religions that shape their cultural perspective regarding habits, rituals and beliefs. The cultural and religious perspectives must be taken into account not just to acknowledge the religions that humans profess but perhaps a more significant issue of the acceptance and marketing or business prospect of the GM products. In the case of GMOs, the religious and ethical concerns will be the most controversial issues in the countries where religions remain a robust societal force.[110] For example on the

[110] Daño EC, 'Potential Socio-Economic, Cultural and Ethical Impacts Of GMOS: Prospects for Socio-Economic Impact Assessment' in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007).

acceptability of the GM products, the concept of 'halal'[111] or 'haram'[112] sets the tone for debate in Muslim societies.[113]

It is essential to see how much cultural and religious issues shape the agricultural landscape of a region and the legality of these measures to be examined in a later chapter.

Although cultural perspectives have been largely ignored for the sake of development, modernisation, urbanisation and so, cultural issues can interestingly be seen in the case of taro plant in Hawaii. Taro[114] according to the Hawaiian people is a belief as the incarnation of their ancestors. To modify the genetics of Hawaiian taro is to alter that which is divine therefore sparked resistance towards GM taro in Hawaii.[115]

In the bigger context of religion, there are some known features of dietary requirement worldwide. For example, the Buddhists who are vegan and vegetarian do not consume animals at all. Hindus do not consume beef as cows are regarded as their Gods whereas Muslims are prohibited from

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[111] Permissible, Lawful, Halal Food Authority (HFA), 'Definition of halal' (2016) <http://halalfoodauthority.com/definition-of-halal> accessed 20 January 2015.
[112] Unlawful, forbidden, can be found in Al Quran (Al Maidah 5:3).
[113] Yasmin Hanani Mohd Safian, 'Islam and Biotechnology: With Special Reference to Genetically Modified Foods Science & Religion: Global Perspective' (June 2005) 4.
[114] 'A tropical Asian plant of the arum family which has edible starchy corms and edible fleshy leaves, especially a variety with a large central corm grown as a staple in the Pacific.'
[115] Alexandra Coe, 'Considering Religious and Cultural Aspects of Food and Agriculture when Seeking to Introduce or Develop GMOs' The Journal of Agrobiotechnology Management and Economics, Volume 17 Number 3 Article 5.

consuming pork and liquor as those are banned according to the Al Quran.[116] Therefore these social values issues are vital to be addressed especially when the target marketing areas such as the Muslim Middle East countries whereby the issue of labelling plays a vital role. The biosafety aspect of the GM products is not an issue here but more on the choice of the consumers in either consuming or not the GM products that might contain pork, liquor, beef even allergens like nuts, gluten that would not be accepted by the consumer due to allergies, cultural and religious belief. The religious issue would be a legitimate concern on labelling of GM product with similar concern on the conventional food. If these concerns are neglected, the producers themselves will be losing potential customers. Thus it is of great importance apart from food safety issue to take into account of these cultural and religious concerns which could reasonably be achieved by a proper labelling that enables the consumer to be educated about the products and then to make choices whether to consume or not. It is submitted that it is also ethically wrong not to provide the necessary, relevant content of the GM products by labelling due to cultural and religious concerns although there are some countries do not make labelling a requirement in importing these GM products.

Labelling is good enough to address the cultural and religious concerns on the content of the GM products. However as to the issues of the process of GE technology that might have controversial issues, perhaps other measures should be taken to address this concern. Apart from 'halal'

[116] Noble Book that is believed and followed by the Muslims transpired to Prophet Muhammad by Allah s.w.t.

issues in Islam for food consumption the objectives of the Shari'ah,[117] the issues are discussed in much broader scope which is the benefits of protection and preservation of the religion, life, of intellect, of progeny, of property, and of the environment.[118]

On the other hand still in the context of food interestingly enough, under Jewish dietary laws (called Kashrut), safety and healthiness of food are not necessarily an overriding factor when determining if something is 'kosher'.[119][120]

Any consequences of those risks and concerns if they become a reality will cause irreversible damage to the human and environment as a whole. Therefore there is an essential need for this area of modern biotechnology in general and biosafety in specific to be adequately regulated.

In this thesis, the issues on whether this 'fourth criterion' will have any place in the rules and regulation of biosafety and to what extent they will influence the decision-making process will be discussed. These issues are essential to understanding the factors that influence rules and regulation in the countries specifically Malaysia in this thesis.

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[117] Islamic Law.
[118] Abu-Sway M, 'Towards an Islamic jurisprudence of the environment (Fiqh al-Bi'ah fil-Islam)' (1998) 15.
[119] (of food, or premises in which food is sold, cooked, or eaten) satisfying the requirements of Jewish law.
[120] Alexandra Coe (n115).

9. Biosafety risk regulation: risk assessment and socio-economic issues

In summary, the principal objections towards the genetically modified products of modern biotechnology are based on three reasons, which are as follows:

1) possible harm to human health
2) possible damage to the environment
3) uneasiness of the state of GM products and technology as being unnatural

Risks can be defined as the possibility that something unpleasant or unwelcome will happen.[121] However, it is important to note here that these are only risks that can be foreseen to happen or not happened yet. On the issue of regulation, biosafety is very much a risk regulation type which will be discussed in the next Chapter 2 on regulatory theory.

It seems that risks identified as above are managed by risk assessment and management. Thus the question is whether that assessment solved the scientific biosafety issues especially in the areas of scientific uncertainty. Another concern is the 'non-scientific' issues such as the socio economic that includes mainly ethics, moral, religious and cultural issues as to how these issues should be managed within the biosafety decision-making process.

[121] 'Risk' <https://en.oxforddictionaries.com/definition/risk> accessed 25 December 2015.

Thus some suggested that there is the need for 'socio-economic assessment' to be introduced in the biosafety risk assessment. Prima facie the inclusion of the so-called 'socio-economic assessment' will look daunting as it perhaps adds cost to the existing risk assessment and management. However, perhaps as a start, these socio-economic risks should be part of the biosafety decision-making process. For instance, to be raised and included in the risk assessment themselves. Thus the justification and explanation for the socio-economic issues should be made clear to all parties concerned. As stated above some even suggested the socio-economic impact assessment (SEIA) to add further to the bureaucracy process.[122]

10. The importance of public participation in biosafety regulation

Biosafety stakeholders

Another critical issue in biosafety decision-making is to identify the stakeholders involved in biosafety governance as it will have an impact on them. Thus it is not an easy task for the decision-makers in considering not just the scientific risk assessment also the socio-economic issues, simultaneously taking the various stakeholders into account.

There are many stakeholders of the GM products ranging from the biotechnology-related industries, scientists, regulators, government,

[122] Stabinsky, D, 'Bringing Social Analysis into a Multilateral Environmental Agreement: Social Impact Assessment and the Biosafety Protocol' (2000) The Journal of Environment & Development, 9(3), 260–283

enforcers, farmers, religious bodies, a non-governmental organisation (NGO), environmental and consumer groups and public as they are consumer themselves. The public as the ultimate consumer of the LMOs products is one of the main stakeholder in biosafety. Thus the public awareness and participation in the biosafety decision-making process are crucial.

Public perception of LMOS

Public perception of GMOs or LMOs will be discussed in detail in the Malaysian context as there are some secondary data on public perception on LMOs. Apart from the modern biotechnology products benefits such as storage qualities and transportation, there are no apparent benefits to the consumers.[123] Also due to the propaganda mainly from the environmental groups, the consumers who have not much trust in science, and because of ethical, cultural, and religious beliefs will continuously not consuming them. Therefore public confidence must be restored, and they must be educated. Unless the GM products have clear benefits such as extra vitamins as compared to the conventional food, this should persuade them to consume LMOS or GMOs.

[123]Nuffield Council on Bioethics, 'Genetically Modified Crops: The Ethical and Social Issues' (Nuffield Council on Bioethics , May 1999) <http://nuffieldbioethics.org/project/gm-crops/#sthash.jyZ2v9WQ.dpuf> accessed 7 August 2015.

Therefore, controversies, propagations either by the public or some environmental groups will not help until the full understanding of how the science work alongside with effective biosafety regulation to protect human health and environment is achieved.

Public participation and biosafety

In this thesis, it is identified that there are some critical issues about public and LMOS namely as follows:

a) What is the role of the public in biosafety decision making process?
b) What is the justification for public involvement in the biosafety decision making?
c) How to go about institutionalising public participation in biosafety?
d) How compelling so far is the public involvement in biosafety?
e) What needs to be done to improve public participation in biosafety?

Public participation in decision-making have been long known but not been much widely practised. Recently smart regulation practices such as the views from civil rights groups have been taken into consideration by the regulators. The public participation has been part of the democratic process[124] in decision-making either in developed and developing countries. Issues of public participation in biosafety decision-making have been very much academically discussed.

[124] The Co-Intelligence Institute. 'Principles of Public Participation' <http://www.co-intelligence.org/CIPol_publicparticipation.html> accessed 25 December 2016.

The justification for the public participation is very much centred on the ethical issues,[125] as the need to respect consumer and public rights of choice to decide whether to consume or not to consume LMOs due to their ethical, cultural and religious beliefs. The fact that the decision directly affects their lives justifies it. Apart from these issues as discussed above, bioethics issues such as consent to participation, the principle of beneficence and technology choices are also part of the considerations.[126]

An essential part of the justification for public involvement in biosafety is the legitimacy and acceptance of the public of the rules, regulations and the law. The law in essence for it to be accepted it must be accepted by the people or else it faces rejection not being obeyed or followed. Legitimacy is not a significant issue provided that it goes through the right legal procedure. However next are issues of acceptance of the biosafety law which is of concern.

Thus public participation is included as part of the biosafety decision-making process, and that effort is justified and it is said to 'democratise biotechnology'.[127] However the issues then move on to what extent public participation is being entrenched into the biosafety decision-making process, and how is it practised. Then the issue moves on to what extent public can efficiently contribute to the decision-making process taking into account their knowledge and information of the biosafety issues at hand. The issue of

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[125] The Steering Committee, in TDR, on Strategic Social, Economic and Behavioural (SEB) Research (as cited in Macer (n89).
[126] Macer (n90).

[127] Dominic Glover, *Public participation in national biotechnology policy and biosafety regulation* (IDS Working Paper 198, August 2003).

awareness of the public and biosafety education to the public will again to be discussed in the suggestions and recommendations part.

11. Aims, objectives and research questions

Aims

1) to identify the existing legal and institutional arrangements of biosafety regulation at the international and national level
2) to conceptualise the existing biosafety rules and regulation with the regulatory risk theories
3) to analyse the Malaysian legal and institutional framework of biosafety
4) to analyse Malaysian compliance towards Cartagena Protocol on Biosafety
5) to compare the legal and institutional framework on biosafety between Malaysia and Singapore
6) to suggest recommendations for the improvement of biosafety regulation in Malaysia

Objectives

1) to analyse the biosafety risk regulations at the national or international level
2) to analyse the legal basis for the decision-making process during the importing of living modified organisms (LMOs) at the international level and the Malaysian context
3) to analyse the current scientific and non-scientific issues in biosafety regulation such as socio-economic, ethical, moral, cultural, religious also taking into account of local conditions in regulating biosafety

4) to analyse the issues of compliance and harmonization especially about current national regulations on biosafety and relevant international agreements on biosafety
5) to examine the best strategy in regulating biosafety with the aims of conserving the biodiversity and protecting human health

Research questions

1) What are the current legal and institutional regulations on biosafety at the national and international level?
2) What are the current conflicts on the relationship between law and biosafety on pertinent issues that need to be regulated?
3) How do we regulate the biosafety risks and concerns?
4) What should be the primary role of law and science in biosafety?
5) How do the different kinds of biosafety risks regulate?
6) Whether the legal basis of decision-making in importing LMOs is justified either at the international or national level?
7) What are the best regulatory strategies for protecting human health and the environment taking into account the nature of biosafety risk involved?

12. Research methodology and sources

Like other legal research, this legal study applies the doctrinal legal method whereby primary and secondary sources are being used. The sources are from the books and website available to fulfil the research aims, objectives and answering the research questions. The relevant statutes, regulations, case laws, international agreements such as conventions and its supplementary also textbooks, documents of countries reports, decisions, policies, journal articles, encyclopedia, dictionary and other types of materials are being studied in order to analyse the implementation of Cartagena Protocol on Biosafety and Malaysia compliance with the Protocol. This study

also analyses how Singapore legal and institutional frameworks deal with the critical issues in biosafety.

13. Organisation of the thesis

This thesis is structured in six (6) chapters as follows. The present chapter is the Introductory Chapter on the critical terms of biosafety, modern biotechnology, living modified organisms (LMOs), also benefits and risks relating to them. This chapter is a contextual framework of the thesis. Chapter 1 outlines the justifications for a comparative law study between Malaysia and Singapore. Chapter 2 focuses on the theoretical framework of biosafety legal regulation namely the regulatory theory especially the command and control approach also the smart regulation. The critical issues contained in the Cartagena Protocol on Biosafety with strengths and criticisms also are being discussed. Next, the discussion on the Malaysian legal and institutional framework on biosafety is divided into Chapter 3 and Chapter 4 respectively although both chapters are inter-related. Chapter 3 and 4 are analysed as part of Malaysian compliance with Cartagena Protocol on Biosafety. Chapter 5 is the discussion on the Singapore biosafety legal and institutional framework. Finally, Chapter 6 is the analysis for both Malaysia and Singapore and recommendations chapter for Malaysia biosafety laws.

14. Limitations of the thesis

Since the discussion parameter of regulation of biosafety can be quite extensive, the area of discussion in this thesis will be limited to environmental biosafety according to Cartagena Protocol on Biosafety. In this thesis, there will be no discussion of issues of conflict between World Trade Organisation

(WTO) and Cartagena Protocol on Biosafety but only relevant discussions on what both conventions require in GM food regulation.

There will not be so much discussion as to the effectiveness of rules, regulations and institutions as this is doctrinal research also a comprehensive analysis of Key Protocol issues of biosafety in Malaysia. Thus the scope of discussion is different. The vital biosafety issues of Cartagena Protocol on Biosafety in relation to Singapore are being used as guidelines for discussion, not as compliance as Singapore is not a party to it.

LMO and GMO are the terms being introduced and used interchangeably even though there are issues on the difference between both, but this thesis uses both especially in the Malaysian context as the law states GMO to mean LMO as well.

The thesis, in essence, discusses how the law regulates biosafety by looking at the rules and regulations in compliance with the critical biosafety issues. It also covers the discussion of the institutional framework that is being practised in Malaysia and Singapore based on the regulatory theory.

So far there has been little discussion or the analysis of the various national and international regulations and the best regulatory strategy that suits the need for biosafety risk regulation in Malaysia and Singapore, the extent to which Malaysia complies with the Cartagena Protocol on Biosafety and Singapore legal and institutional biosafety framework in relation to international biosafety standard. In making the analysis, the local conditions will be taken into account such as the issues of ethical, socioeconomic, cultural and religious considerations. The local circumstances is another crucial issue that will be analysed to what extent national sovereignty is acknowledged under this Cartagena Protocol on Biosafety. These are among the main aims of this study.

Although at the very outset it is stated that among the aims of biosafety is to protect human health and environment. However, it is not within this thesis to discuss in the great length of the effectiveness of biosafety law as to what extent the rules and regulations in protecting human health and the environment.

15. Conclusion

In conclusion, this chapter gives the basic definitions and background of biosafety, biotechnology, modern biotechnology and controversial issues related to it, to understand the real biosafety risks either scientific risks or socio-economic issues. The background of the GMOs or LMOs needs to be understood first before laying out the acceptable rules and regulations also an institutional framework for biosafety governance. The biosafety issues in Europe and the United States significantly influenced other countries as those are the primary worldwide events that shaped the food safety, GMOs, modern biotechnology later biosafety rules and regulation internationally. The next Chapter 2 will look in more detail of regulatory theory and further the background of the Cartagena Protocol on Biosafety.

Cartagena Protocol on Biosafety covered mostly environmental biosafety. The Cartagena Protocol on Biosafety regulated the transboundary movement of LMOs and introduced some procedures namely Advanced Informed Procedure (AIA), Living Modified for Food, Feed, Processing (LM-FPP) and Notifications.

However, as it is a comparative legal study between Malaysia and Singapore biosafety law, it is important to present the justifications for comparison in the next Chapter 1.

PART II

A COMPARATIVE LEGAL STUDY BETWEEN MALAYSIA AND SINGAPORE LEGAL AND INSTITUTIONAL BIOSAFETY FRAMEWORKS

CHAPTER 1: JUSTIFICATION FOR A COMPARATIVE LEGAL STUDY BETWEEN MALAYSIA AND SINGAPORE

1. Introduction

The thesis is a comparative functional legal study on Malaysia and Singapore biosafety regulations and institutions. It is interesting to compare Malaysia, a party to Cartagena Protocol on Biosafety, with Singapore, a non-party to the said Protocol. Therefore, the justifications for comparing the two countries are essentially explained.

It is important to examine as to how the Protocol's decision criteria of scientific risk assessment, precautionary principle, socio-economic considerations and other crucial biosafety issues are interpreted or institutionalised in both Malaysia and Singapore context. Although in the Singapore context some of these criteria are not directly relevant to them as they are not a party to the Protocol, it is an essential study, specifically in the context of vital global biosafety issues and future biosafety laws harmonisation at the South East Asian region.

Singapore was one of the negotiating countries during the Cartagena Protocol on Biosafety negotiations. Singapore then took a different stance and not being parties to Cartagena Protocol on Biosafety, presumably at the very outset due to their perception of biosafety and biosecurity concepts, approach and also their national and economic aspirations.

2. Justifications for comparisons between Malaysia and Singapore

The general difficulties of comparative law approach are known such as conceptual and methodological difficulties, is also occurring in comparing Malaysia and Singapore in this thesis. The central fact is that Malaysia is a party to Cartagena Protocol on Biosafety whereas Singapore is not a party, in the South East Asia region (together with Brunei). It is an interesting comparison to analyse as to the differences of the stance taken by both countries even though being in the same South East Asia region, Association of Southeast Asian Nations (ASEAN) as member also regional biosafety cooperation known as Asia Pacific Biosafety (APB).

Malaysia and Singapore were formerly part of the same country named Malaysia, also previously part of the British colonial past. Both are members of the Commonwealth of Nations. Thus in this regard, it is understood that they shared the same legal history. Thus there are similarities between them on the legal and political structure. The comparison is useful even though at present Malaysia, an emerging economy, is ambitiously struggling to be a developed country by the year 2020 as opposed to Singapore, a developed economy. The comparison is also beneficial as both are neighbouring ASEAN countries thus harmonisation between both countries biosafety laws are crucial.

Malaysia, being a party to the Protocol, is bound to comply with the requirements of the Cartagena Protocol on Biosafety. Thus, it raises issues of harmonisation of regional biosafety laws with the neighbouring countries of South East Asian, especially with Singapore and Brunei (being non-parties to the said Cartagena Protocol). As of today Malaysia has no formal bilateral agreements with Singapore on biosafety and biosecurity. Both countries maintain strategic multilateral dialogue on biosecurity together with United

States and Indonesia.[128] Among the general topics discussed were the national priorities for mitigating biosecurity threats; approaches to biological risk assessment; biosafety and biosecurity at national laboratories; and the growing threat of terrorism and its corresponding implications for both regional and international security.

Conceptual and methodological difficulties in comparative law

The case studies in these two countries are not a mere comparison of similarities and differences, but an analytical and critical view on Malaysia's and Singapore's approaches to biosafety decision-making process. Biosafety is a vital issue that affects human health and the environment also future generation and becoming a critical global issue, especially on the emerging new biotechnology innovations and inventions. Thus any different stance taken by the Malaysian government might affect its neighbour, Singapore. Consequently, it might lead to Malaysia's different actions on biosafety export, import or ban on specific LMOs and GMOs. The different stand might affect Malaysia's relation to trade agreements such as WTO or biodiversity agreements, either lateral, bilateral or multilateral agreements.

While the typical pitfalls of conceptual and methodological problems in the comparative legal study between countries are known, this study also

[128] Strategic Multilateral Dialogue on Biosecurity UPMC Centre for Health Security, Report on the second dialogue session held between the United States, Singapore, Malaysia, and Indonesia, January 2016, can be found online at <http://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2016/Multilateral%20Report_FINAL.pdf> accessed on 19th October 2018.

experiences the same difficulties. The conceptual problems[129] in comparative law may range from the different concepts, definition, interpretation, terminology, scope and coverage of issues of law that need to be investigated as countries have different sources of laws namely primary and secondary. The fact that the binding nature of those legal sources might affect the practice by the countries differently is an aspect that could not merely be neglected as it may have different legal implications.

For example, the term biosafety in Malaysia, a party to Cartagena Protocol on Biosafety, mainly covers the domestic use and export of LMO and GMO. However, the term biosafety in Singapore encompasses more extensive coverage to include regulation of lab biosafety, biosecurity and bioterrorism as well. Moreover, Singapore distinguishes between biosafety and biosecurity, the former dealing with LMOs whereas the latter with biological agents (BA) and toxins.

The methodological problems also arise in the comparative legal study. While the methodology is defined as the scientific study of these methods,[130] the methodology in comparative law is not easy to define. Perhaps the functional approach of the analysis of the legal and institutional biosafety of both countries will again pose problems as they might cover broader aspect beyond biosafety than the names suggested. However, the comparative law approach in relation to this thesis tends to reflect the reality

[129] Zweigert K, 'Methodological Problems in Comparative Law' (1972) 7(4) Israel Law Review 465.
[130] Samuel G, *An Introduction to Comparative Law Theory and Method* (Bloomsbury Publishing 2014)2.

in the words of Zweigert [131] '…comparative law and its very merit rest on the fact that it brings legal thinking back to reality, to the actualities of law.'

The comparative legal study between Malaysia and Singapore is prima facie justified as there are similarities between them on the basis of legal history, political structure, legal sources and judicial review aspects. This will validate the comparison as there is no striking difference between Malaysia and Singapore. This will be discussed in the next discussion in this chapter.

The agriculture-related business, population and geographical proximity of both countries are the paramount issues of discussion that determine the directions of biosafety regulations.

3. Comparison between Malaysia and Singapore Biosafety Law

Background facts of Malaysia and Singapore

As Singapore and Malaysia historical link could not be separated, the same with economic as both are main trading partners apart from being neighbouring countries. There are some issues of points of similarities and differences to be discussed in both countries namely:

a) Country's economic aspiration
b) Population, cultural/ local issues

[131] Zweigert (n 129) 466.

c) Public perception of GM goods
d) Research and development
e) Current state of food importer or exporter

Country's economic aspiration in biotechnology

Agricultural products are mainly the target for modern biotechnological innovations and commercialisation. Thus the agricultural-related business generates income for many countries especially those with large lands. In light of that, Malaysia aspires biotechnology is one of the five strategic technologies expected to accelerate Malaysia's transformation into a highly industrialised nation by 2020 due to its rich in natural resources. Therefore the policies, Malaysian Development Plan and Annual Budget were allocated to fulfil its aspiration. As of 2017 Malaysia's Growth Domestic Product (GDP) stands at USD$314.5 billion.[132] In 2018, for the first three quarters, Malaysia's GDP moderated to 4.7 per cent with a value of RM907.2 billion (roughly around USD$217.74 billion) at constant prices and RM1, 055.2 billion (roughly USD $253.25 billion) at current prices.[133]

Singapore is an industrialised city-state with little natural resources. Singapore's vision is to develop as a regional Biomedical Science Hub. In

[132] 'GDP (current US$) Singapore, Malaysia' (2018) < https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?end=2017&locations=MY-SG&start=1960&view=chart>accessed 20 November 2018
[133] Department of Statistics Malaysia Portal. 'Malaysia's Economy Q3 2018', <https://www.dosm.gov.my/v1/index.php?r=column/cthemeByCat&cat=100&bul_id=NUtDV2RPTktsZXRjMlcxWXpHS0RYZz09&menu_id=TE5CRUZCblh4ZTZMODZIbmk2aWRRQT09>accessed 20 November 2018

2017 Singapore's GDP stands at USD323.907 billion.[134] Singapore basically follows US model in biosafety, emerged as one of the top 10 global in biotechnology innovations.[135] Scientific American ranked countries' biotechnology innovations based on these criteria namely; intellectual property (IP) protection, intensity, enterprise support, education workforce and foundations. Overall, Singapore is ranked second after the United States.[136] In terms of enterprise support whether the country is "business friendly", Singapore is ranked second after the United States, and ranked first for education workforce as the more educated the workforce, the better the score. Before going into further discussion on Malaysia and Singapore biotechnological business, the population aspects of both countries need to be understood.

Population, cultural/local issues

Both countries, Malaysia and Singapore are multi-ethnic, multi-religious and multi-cultural. The major ethnics in both countries are comprised of Malay, Chinese and Indian. The only difference is the composition of those races. Malaysia's majority population is Malay whereas Singapore majority ethnic is Chinese. Islam is Malaysia's official religion. Thus apart from Malays Muslims, there are other races such as Chinese and Indians and the native of Sabah and Sarawak who are Muslims as well. As

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[134] ibid.
[135] 'Healthcare Economist.'Top Countries for Biotechnology Innovation' < https://www.healthcare-economist.com/2009/06/08/top-countries-for-biotechnology-innovation/>accessed on 20 November 2018
[136] ibid.

for Chinese they can be either Buddhist, Christians or Muslims. The same is for the Indians. As for Singaporeans, Buddhism/Taoism is the majority religion (44.2%), next is Christianity (18.8%), no religion(18.5%), Islam (14%) and others (5.7%).[137]

As most majority Malays are Muslims in Malaysia, thus they observe the strict dietary requirement which will be elaborated further in Chapter 3. The same applies with the majority Buddhist/Taoist in Singapore, with mostly vegetarian dietary requirement. The race composition is explained as it marks a great significance culturally or religiously in food consumption and dietary requirement. The general ruling on dietary restrictions have been summarised in the previous Introductory Chapter.

Thus the issues concerning GMOs are importation of food, halal certification, seed for plantation agriculture, and the need to certify exports.

Malaysian and Singaporean public perceptions of GM products

In Malaysia, the private sector and the consumer groups have shown some interest as either advocates or opponents. There are oppositions from Consumer's Association of Penang (CAP) and Third World Network (TWN). Genetically modified food is a sensitive issue as in other countries when

[137] Department of Statistics, Singapore. <https://www.singstat.gov.sg/-/media/files/visualising_data/infographics/ghs/highlights-of-ghs2015.pdf>accessed on 20 November 2018

there is awareness as there are some religious beliefs and sentiments associated with GM goods.

Labelling of GM while there is a provision on it, by section 61 of the Biosafety Act 2007, the enforcement of the mandatory or voluntary labelling is still ongoing. The word ‘shall’ in Biosafety Act 2007 while denotes mandatory labelling of GM products, however, the enforcement is still at the discussion level. There is labelling regulation[138] in the Malaysia Food Regulation that states LMOs food must be labelled. However, the clarity of this labelling is still a continuing issue.[139]

While Malaysians are generally being cautious in GM food consumption due to their awareness, the Singaporean public perception is 50% open to GM and some negative sentiments but no report of any organised campaign.[140] There is no labelling provision at the moment on GM products only Biohazard labelling on products that contain BA and toxins on transportation and conveyance transporting using public roads.[141]

While both countries are geographically proximate to each other, there might be influences on the issues of religious, dietary, cultural and public perception towards the GM products.

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[138]Malaysia Food Regulations 1985 reg 11(3A), 11(6) and 11(7).
[139]Zainol ZA, Nordin R and Akpoviri FI, 'Mandatory labelling of genetically modified (GM) foods' (2015) 15(2) International Environmental Agreements: Politics, Law and Economics 199.
[140]Bhumiratana S, *Report on Biosafety Policy Options and Capacity Building Related to Genetically Modified Organisms in the Food Processing Industry of ASEAN* (UNIDO 2002)18.
[141]Singapore Biological Agents And Toxins Act 2005 (Chapter 24A) s5,6,7.

Research and development

In Malaysia, there are active ongoing research activities in developing varieties both plant and tree crops using gene technology such as palm oil and rubber as those agricultural commodities are Malaysia most export. However, the most promising GM crops to be commercially released into the market are GM rice[142] and shorter-ripening palm.[143]

In realising this research and development, there are some government agencies involved namely Malaysian Agricultural Research and Development Institute (MARDI) and the Agricultural University of Malaysia (UPM). These two bodies are government agencies involved in detection techniques for LMOs. MARDI is also responsible for field trials of LMOs.

The Malaysian government has spent $US26 million to build three institutes in the new BioValley Malaysia, a massive complex that is part of a plan to attract $US10 billion in biotechnology investment within a decade.[144]

In Singapore, the Institute of Molecular Agro-biology in Singapore, undertakes research activity on the development of plant varieties for resistance to disease, to produce pharmaceutical products and to obtain

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[142] Amin L and others, 'Public Perception of the Ethical Aspects of Golden Rice in Malaysia' (2011) 2(3) International Journal of Science in Society 15.
[143]Cuong NL, 'UNU-IAS Working Paper No. 122' (2004)5 can be found online at <http://archive.unu.edu/hq/library/Collection/PDF_files/IAS/IAS-WP122.pdf>.
[144] 'Preventing Accidental Disease Outbreaks: Biosafety in East Asia', APSNet Policy Forum, September 07, 2006, <http://nautilus.org/apsnet/0631a-enemark-html/>.

higher yields. It is more likely that Singapore will use such transgenic varieties for farming.

Singapore invested heavily in biotechnology research and hoped to become the “World Class Life Science Hub”. The research is focussed not so much on the end product but mostly to generate intellectual property. Moreover, in 2001 Singapore started on a 15-year, $US8.2 billion project to make Singapore a high-technology hub with a strong emphasis on biotechnology’. The plan comprises the $US500 million BioPolis complex.[145] This venture of interest and investment in biotechnology are mainly due to infectious disease challenges, economic interests, and security concerns about biological weapons.[146]

In Singapore, the field trials are undertaken in collaboration with researchers from China and New Zealand. However, research on sensitive issues such as human cloning or stem cell engineering may require approval from the National Bioethics Advisory Panel. It seems here Singaporean are taking the sensitive ethical issues into great consideration especially dealing with experiments on humans[147] while being liberal on other types of biotechnology research.

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[145] ‘The Biotechnology Promise: Capacity-Building for Participation of Developing Countries in the Bioeconomy,’ (New York: United Nations, 2004), 38, 40, L.T.
[146] Hickok and R.M. Salerno, ‘Time to Wake up to Bioterror Threat,’ Straits Times, 26 January 2004).
[147] Research involving Human Subjects: Guidelines for Institutional Review Board by BAC.

Singapore played a leading role in the adoption of ASEAN guidelines on risk assessment and the harmonisation of risk assessment in ASEAN. Singapore is taking the lead being the headquarter of Asia Pacific Biosafety. This raise issues of what is Singapore's ambition in the Asia Pacific Region on biosafety and biosecurity. It is argued that due to Singapore's signing into WTO trade-related agreements, that accounts for the development of biosafety regulation in Singapore. This will be further discussed in Chapter 5.

Current state of food importer or exporter

Malaysia is a major food importer and, mainly through being the world's major supplier of palm oil, also a food exporter. Therefore Malaysia aspires to develop its biotechnology to produce better food not just for local consumption also to be exported. Another area for potential modern biotechnology research and commercialisation are rice and rubber.

On the other hand, Singapore is a food importing country. The GMO policy seems to be more liberal towards GM food and food products with no labelling requirement. However, for LMO that relates to agriculture, Genetic Modification Advsory Committee (GMAC) function is to analyse the risk assessment as to effects on the human health and environment. It seems here Singapore performs a risk assessment on LMO agriculture products, guided by Singapore GMAC Guidelines.

There is minimal control on GM in Singapore. Singapore develops a framework to promote biosafety culture namely as follows:

a) transparent and follows internationally-recognised standards
b) comprehensive but not prescriptive
c) balanced between safety and research freedom

Singapore follows the steps of other developed countries such as the United States and Britain, that separated laws on biosafety and biosecurity.[148] Singapore defines biosafety and biosecurity. Biosafety is based on principles and techniques that protect workers from exposure. Biosecurity is based on security measures designed to reduce the risk of loss, theft or diversion.[149] Therefore the biosafety laws in Singapore are very much on Biological Agents and Toxins Act 2005 whereas the regulation of GM products or LMOs is by GMAC Guidelines.

Malaysia and Singapore Legal History

Apart from the fact that they are close neighbouring countries with the same interests in the modern biotechnological products, also population/ cultural attachments, there are strong historical, economic and political ties. The most significant similarities between Malaysia and Singapore are the fact that both have the same colonial experience, i.e. the British colonialism from the period 1819 starting in Singapore until both countries independence in 1957 for 138 years.

By looking at the past histories of both countries, it is vital to explain on the current conditions that provide the background of similar political, legal similarities and issues on judicial review that is connected with biosafety

[148] Chang Ai-Lien, 'Biosafety Laws To Instil Research Confidence' <http://www.gmac.gov.sg/News/2005/2005_04_12_B.html> accessed on 11th November 2015.
[149] Koh Peng Keng, 'Singapore's Perspectives s Perspectives on Biosafety & Biosecurity' <http://www.biosecurity.sandia.gov/ibtr/subpages/pastConf/20032005/redi/koh-peng-keng.pdf> accessed on 11th November 2015.

decision making process. Malaysia and Singapore have been the same country since 1963 when Malaysia was formed as among Peninsular Malaysia which consists of thirteen (13) states also consists of Sabah and Sarawak and three (3) Federal Territories (Kuala Lumpur, Putrajaya and Labuan). However, due to some political dispute between both countries, Singapore left Malaysia in 1965 and became a different country.

Malaysia and Singapore political and legal similarities

Both countries Malaysia and Singapore have resemblances in their political and legal structure. This is because they were from the same country (Malaysia) and both share the same, British colonial past, which greatly influenced the legal and political administration of both countries.

Malaysia political structure

Executive

Malaysia practices the British style democracy constitutional monarchy. The Yang Dipertuan Agong (King of Malaysia) is similar to the Queen/ King of England. The executive of Malaysia is made up of the Prime Minister and his cabinet ministers whom he appointed at the advice of the Yang Dipertuan Agong. They run the day-to-day administration of the country as they are elected from the General Election held every 5 years at the Federal level and known as Members of Parliament.

Judiciary

The head of the judiciary is the Lord President who is the head of all judges in Malaysia and Sabah and Sarawak. There is also the Attorney General who is the head of the government prosecution service known as the

Attorney General Chambers which is an essential branch of the government service.

Legislative

Malaysia is also very much influenced by the British model Parliament whereby law is made by the Parliament but subject to the Constitutional Supremacy, not as Parliamentary supremacy as in the United Kingdom.[150]

Today, this country, Malaysia is governed by a Federal Government. The Federal matters are under the Ninth Schedule[151] of the Federal Constitution such as finance, defence, education and other vital issues. The Federal Constitution is the supreme written law of the land. The Federal Government is ruled by the Prime Minister and his cabinet ministers, whereas the State Government administered the state matters[152] such as on water, land and Islamic law.

Each state has their leaders namely the Chief Ministers, Sultan and Tuan Yang Dipertua. The State Governments have their Chief Minister and States Excos. For states that have no Sultan/ Malay Ruler such as Pulau Pinang, Melaka, Sabah and Sarawak they have their Tuan Yang Dipertua instead. For Sabah and Sarawak, they are unique in the sense that they have more autonomy in their state matters as they have their own Chief Ministers

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[150] Parliament UK, 'Parliamentary sovereignty' (2017) <https://www.parliament.uk/about/how/role/sovereignty/> accessed on 20 June 2017.
[151] Malaysian Federal Constitution Ninth Schedule List I.
[152] ibid Ninth Schedule List II.

and cabinet ministers, state election and their exclusive power over their immigration matters.[153]

The head of the country is the Yang Dipertuan Agong, the monarchy. The head of the executive is the Prime Minister, and head of the judiciary is the Lord President. The Yang Dipertuan Agong is the Head of Islam and for states that have no Sultan or Malay ruler. This political and administration illustration is essential not for the narrative of it but to show the changing of the old structure of Malaya to newborn Malaysia in 1963. There are some issues such as land matter, the natural biodiversity, Islamic Law in a particular state is not directly governed by the Federal Government but by the relevant State Government. The issues of biodiversity (especially Sabah and Sarawak) and Islamic Law jurisdiction the matters for the State Government rather than the Federal Government, cause complications in enforcement.

Malaysia legal sources

The highest source of Malaysian law is the Federal Constitution.[154] Article 4 of the Federal Constitution states that any law that is against the Federal Constitution is void and invalid. The laws in Malaysia mainly enacted by Act of Parliament. The statute is legislated by Parliament through the elected House of Representative (Dewan Rakyat) and appointed House of Senate (Dewan Negara) and obtained the approval of the Yang Dipertuan Agong (The King).

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[153]ibid art 95 E.
[154]ibid art 4.

From these Acts of Parliament, there are delegated legislation whereby certain public institutions are established that gives the power to some institutions and to make regulations, and decisions. Biosafety Act 2007[155] is the enabling Act that gives the Ministry of Natural Resources and Environment to make biosafety-related laws on the movement of LMOs and LMOs inside and outside the country but simultaneously in relation to other related government agencies.

Singapore political and legal structure

Singapore is a Republic that has the Prime Minister and the President. The Yang Dipertuan Negara is the Head of Government. The Prime Minister is the head of Cabinet Minister. The President also plays roles in the Singapore government. Thus the administrative structure which is slightly different from Malaysia due to the different type of democracy adopted as a Republic. The Singapore judiciary departed from Malaysia judiciary but greatly influenced by Malaysia and British system, and legislative is very much British model Parliament. Singapore highest form of law is the Constitution of the Republic of Singapore.[156]The Singapore Constitution is the Supreme law.[157] Thus like Malaysia, Singapore upholds constitutional supremacy.

[155] Act 678.
[156] Original Enactment: S 1/63.
[157] Constitution of the Republic of Singapore art 4.

British Common Law in Malaysia and Singapore

One crucial aspect of the British Common Law is the Doctrine of Judicial Precedent or the doctrine of *stare decisis*, i.e. to stand by its previous decided cases, primarily by the higher court in Malaysia the High Court, Court of Appeal and the Federal Court. Judges in Malaysian courts were trained in Britain previously even the lawyers. Therefore, the British laws greatly influenced the Malaysian laws. The English laws are cited and argued in courts, but the application of English law is of persuasive authority not of binding authority.

The same is true for Singapore courts. Singapore Section 3 of the Application of the English Law[158][159] preserves the application of the common law and equity. Section 3(2) states that common law may be modified to suit Singapore circumstances. Singapore Section 5[160] states that no English enactment shall be part of Singapore law save by the Act. Section 4(1)[161] the Key provision states that the English enactments specified in First Schedule or made applicable by any written law should continue in force in Singapore.[162]

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[158] Chap 7A.
[159] came into force on 12 November 1993.
[160] ibid.
[161] ibid.
[162] Tan K, *The Singapore Legal System* (NUS Press 1999) 240.

Judicial review in Malaysia and Singapore

Judicial review is the application to seek the court declaration that the administrative decision is ultra vires due to the arguments that are beyond its power, illegal, irrational and unfair. It is a very much concept followed the English law. According to the English law, judicial review is the check of balance among the three central organs of the government namely the executive, judiciary and legislative. Judicial review is the act of challenging the administrative act of the government in a court of justice who has the locus standi to bring the case in court. It is believed that every organ of the government should be separate and independent in line with the doctrine separation of power by Montesquieu[163] to prevent abuse of power.

Every organ of the government is entrusted with defined roles and responsibility namely for the executive to run the administration of the country, the judiciary to be the upholder of justice and legislative to make laws. When any of them used power than what they are supposed to hold, therefore their acts are up to challenge in court. In English law, the judicial review can be summarised due to these grounds[164] namely (a) illegality;
(b) fairness; and (c) irrationality and proportionality.

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[163] De Secondat C and De Montesquieu B, The Spirit of Laws (Translated by T. Nugent). Chicago: *Encyclopaedia Britannica*.
[164] Council of Civil Service Unions v Minister for the Civil Service [1985] AC 374, per Lord Diplock.

Judicial review in Malaysia

Although the origin of judicial of judicial review is from English law, it is used sparingly in Malaysia and Singapore. In fact, in Malaysia, judicial review has been used as against the Federal Government, State Government, and local authorities although not as much back in Britain.

In Malaysia judicial review is not an appeal but an application for judicial review requires leave of court by virtue of Order 53 rule 1(1) of the Rules of the Court 2012.[165]Order 53 states that '…the Order shall govern all applications seeking the relief specified in paragraph 1 of the Schedule to the Courts of Judicature Act 1964 and for the purposes therein specified and subject to the provisions of Chapter VIII of Part 2 of the Specific Relief Act 1950 [Act 137].'[166]

Paragraph 1 of the Schedule to the Courts of Judicature Act 1964 explains;

> *Power to issue to any person or authority directions, orders or writs, including writs of the nature of habeas corpus, mandamus, prohibition, quo warranto and certiorari, or any others, for the enforcement of the rights conferred by Part II of the Constitution, or any of them, or for any purpose.*

In the biosafety rules and regulation, there are provisions for the appeal against the decision of the biosafety decision makers as provided in

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[165]Previously known as Rules of the High Court 1980.
[166]'Enforcement of Public Duties.'

Malaysian Biosafety Act 2007.[167] Thus any unsuccessful appeal might give the applicants to challenge the Ministry's decision through judicial review. However to what extent the court will hear biosafety appeals is doubtful. For example, if the National Biosafety Board has decided due to the advice was given by Genetic Modification Advisory Committee (GMAC), scientific risk assessment and relevant public consultation, it is tricky to see the Malaysian courts' willingness to interfere with the decision.

Judicial review in Singapore

In Singapore, judicial review has been used but subjected to restrictions. Order 53 of the Rules of the Court[168] application for a mandatory order, prohibiting order, quashing order, or declaration is to be obtained with leave of the court. The court in granting the relief must be satisfied that '…the applicant has a cause of action that would have entitled the applicant to any appropriate relief if the relevant relief had been claimed in a separate action, the Court may, also, grant the applicant the relevant relief.'[169]

Thus the same legal issue might occur in Singapore. If any applicant is aggrieved by the decision of Ministry of Health, for instance, the concern arises as to what extent the Singapore court would entertain the judicial review application.

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[167] s34.
[168] Singapore Supreme Court Of Judicature Act (Chapter 322, Section 80).
[169] Order 53 r7(1).

4. Malaysia and Singapore negotiations in relation to Cartagena Protocol on Biosafety

Both countries' stances in relation to Cartagena Protocol on Biosafety is an interesting heated discussion and comparison as this lies the heart of the discussion. There are considerable differences on this issue. However, reasons have yet to be found out as to the different stances towards Cartagena Protocol on Biosafety 2000 by both countries.

In this issue, Malaysia is a party to the said Cartagena Protocol on Biosafety whereas Singapore is not. Therefore this comparison is unique and interesting to understand as to why both countries adopt different stances and approaches towards the Protocol. Perhaps the latter part of this thesis will answer this question.

The justifications above are in line with the idea of '…comparative law as its concepts identify the demands that a particular slice of life poses for the law where the social and economic conditions are similar and provide a realistic context within which to compare and contrast the various solutions, however much they may differ technically or substantially.'[170] Therefore the comparison between Malaysia and Singapore is justified as both countries have almost the same legal, political, social but with different economic conditions.

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[170] Zweigert K, 1911-, *Introduction to Comparative Law* (2nd rev. ed.. edn, Oxford : Clarendon Press 1992) 44.

It is argued that the critical Protocol issues provide the benchmark of discussion in the comparison between Malaysia and Singapore. This is because the Cartagena Protocol on Biosafety Protocol highlights the most critical and accepted issues in biosafety at the international level. Thus this thesis studies on how Malaysia and Singapore deal with those crucial biosafety issues. This thesis analyses Malaysian compliance with the Cartagena Protocol on Biosafety. This thesis also examines Singaporean implementation and institutionalisation of the most crucial issues on biosafety/ biosecurity. Harmonisation of biosafety laws between these countries as part of the South East Asia region is crucial in preparing for future disputes resolutions.

Cartagena Protocol on Biosafety and World Trade Organisation (WTO) agreements

The countries involved in these international trade and biodiversity agreements perhaps shape the biosafety rules and regulations. As Malaysia is a party to Cartagena Protocol on Biosafety, thus the rules and regulations on biosafety contain all the vital biosafety issues as mentioned above.

Since Singapore is not a party to the Protocol but a party to the various related WTO biosafety, trade and biodiversity agreements, such as The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), The Technical Barriers to Trade (TBT) Agreement and The General Agreement on Tariffs and Trade (GATT). Thus

the biosafety rules and regulation seem to work well with trade and protection of human health but perhaps not biodiversity protection.[171]

Their involvement also reflects country's agricultural trade priorities[172] or countries' trade priorities in general. Thus this explains the different approaches taken by both countries about genetically modified, genetically engineered, living modified organisms, biological agents and the like.

It is argued due to these differences there will be some conflicting issues between Malaysia and Singapore. One issue is the risk assessment as to which party bears the cost. Under the SPS Agreement, it is the importing country that eventually bears the cost of the risk assessment, while under the Cartagena Protocol on Biosafety the exporting party might be required to finance the assessment.

Another issue is on documentation with regard to labelling as part of the Cartagena Protocol on Biosafety. Thus these issues might need to be considered by both countries in future GM dealings. Perhaps this should be resolved by the ASEAN cooperation in GM Guidelines and Asia Pacific Biosafety whereby both countries are members. Thus in light of this opinion, harmonisation of biosafety laws between Malaysia and Singapore is essential.

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[171] Charnovitz S, 'A New WTO Paradigm for Trade and the Environment' (2007) 11 SYBIL 15.
[172] Gupta A and Falkner R, 'The influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa' (2006) 6(4) Global Environmental Politics 1.

5. Conclusion

From this justification chapter, it is hoped that by the end of the study, the analysis of similarities or differences between Malaysia and Singapore biosafety approaches will be better understood. The comparison is essential in understanding the background that shaped the biosafety governance. The type of regulatory approach taken by the Singapore biosafety decision-maker will be analysed and what Malaysia could learn lessons about that issue. It is also interesting to analyse to what extent non-scientific issues such as ethical, religious and socio-economic considerations will be taken into consideration by Singapore biosafety decision makers in comparison to Malaysia.

Cartagena Protocol on Biosafety is seen by many countries especially Europe and developing countries as a model of good biosafety governance even though there are many criticisms towards it. Cartagena Protocol on Biosafety outlines the most critical aspect of biosafety governance that is being negotiated among various countries. It seems to validate the aims of protecting human health and the environment. It can be seen from the various Key Protocol issues that are being signed, agreed and implemented by many countries.

Singapore has played a leading role in the adoption of ASEAN guidelines on risk assessment and the harmonisation of risk assessment in

ASEAN[173] also in the Asia Pacific Biosafety association. Thus this should serve as medium or forum for future reconciliation rather than confrontation should any issues of biosafety conflicts arise between Malaysia and Singapore.

The next Chapter 2 will discuss the regulatory theory of biosafety regulation. This provides the basic understanding of biosafety regulation as a risk regulation. It further discusses on the relevant regulatory strategies in implementing biosafety. Next, there will be a discussion on Cartagena Protocol on Biosafety that provides a framework for biosafety regulation. This provides a model of biosafety legal and institutional framework as it summarises the vital issues in biosafety.

[173]Bhumiratana S (n140)18.

CHAPTER 2 THE LEGAL REGULATION OF BIOSAFETY RISKS AND THE CARTAGENA PROTOCOL ON BIOSAFETY

1. Introduction

The previous Chapter 1 discussed on the justifications of a comparative legal study between Malaysia and Singapore on biosafety legal and their respective institutional frameworks.

This chapter discusses two important aspects of this thesis namely;

i) the biosafety risk regulation; and
ii) the Cartagena Protocol on Biosafety

The regulatory theory provides the underlying theoretical framework on the biosafety risk regulation. It provides an understanding of the risk regulation theories and strategies. This chapter also analyses the Cartagena Protocol on Biosafety, the leading international agreement in biosafety risk regulation. This is because Malaysia is a party to that Protocol even though Singapore is not. The Cartagena Protocol on Biosafety is said to be a model national biosafety framework that outlines the most essential biosafety issues, is used to as a parameter of discussion between Malaysia and Singapore. It is important to understand the background the Protocol, key biosafety issues, strengths and criticisms.

This chapter provides the theoretical framework to analyse the biosafety risk regulation in Malaysia and Singapore in later Chapters 3,4 and 5.The discussion is important as it provides the discussion of the Cartagena Protocol on Biosafety.

2. The legal regulation of biosafety risk

In the previous Introductory Chapter, biosafety risks and concerns were outlined. This chapter examines the biosafety as a 'type' of risk regulation.

Definition of regulation

There is no universal standard definition of regulation due to its various perspectives and contexts. A commonly accepted definition of regulation is a specific set of commands[174] issued by the government.[175]

When discussing the topic of regulation, it is usually associated with another field such as the economy, finance, law, or politics, thus making it a diverse and complex field. Regulation is seen as a necessity in a civilised society, and every aspect must be in order.

Regulation issues have created topical debates and prompted numerous activities by international organisations. The criticisms and issues were very prominent during the financial crisis in the years between 2007 and 2009.[176]

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[174]Selznick P, 'Focusing Organizational Research on Regulation' Regulatory Policy and the Social Sciences (1985)1 363.
[175]Baldwin R, Cave M and Lodge M, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press on Demand 2012) 2.
[176] ibid.

Over time, the regulation strategy has changed from the traditional command and control approach to new governance such as responsive regulation, smart regulation, meta-regulation, self-regulation and so on. These essential strategies will be defined, and their applicability to biosafety regulation will be analysed.

As Baldwin[177] stated, the field of regulation has come to maturity in an intellectual and practical sense as almost every aspect of life has been 'regulated'. Hence, regulation has been the subject of study across various disciplines. However, biosafety-specific regulation is still in the developing stage, as attempts are made to integrate it with the existing theories of regulation.

The existence of regulation comes with its pros and cons. The supporter of regulation sees it as a technocratic device, as there is potential to exert rational control over significant economic and social activities, whereas the sceptic of regulation will see it as nothing more than bureaucratic red tape, a hurdle to economic growth.[178]For instance Cartagena Protocol on Biosafety is seen as red tape to the Miami and Compromise Groups, and put hurdles in front of the free movement of LMOs worldwide. The Protocol may restrict modern biotechnology growth, research and development, and also the billion-dollar industries associated with it. While both sides have the truth, this thesis focuses on the advantages of the regulation of biosafety.

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[177]ibid 2.
[178] ibid 1.

Regulation in the United Kingdom (UK)

The changing trend in regulation is a global phenomenon such as in the UK especially on the modern biotechnology. In the UK, the financial crisis and the emergence of new technologies and GM products related to mad cow[179] disease have changed the frontiers of existing regulatory regimes.

As Malaysia was previously part of the British colonial history, it is essential to observe the scenario in the UK for better understanding of the changing of regulatory strategy from a command and control approach to new governance. Regulation changes also occurred in other countries since the UK influenced their perspectives on regulation. The changes occurred mainly because of financial and economic conditions that affected the global financial market. This globalisation of regulation change reinforced and encouraged international agreements and conventions, especially on environmental issues.

There are various issues in UK regulation in the millennial era such as the appropriateness of regulatory strategies and structures, and also the significant public concern. The prominent issues in the UK relate to the governance of regulatory bodies.

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[179] Andorno, R, 'The precautionary principle: a new legal standard for a technological age' (2004) Journal of International Biotechnology Law 1.1 14

Another relevant issue is the emergence of new technologies and producers. In the UK, consumers became critical of food production after a chain of food safety scandals such as mad cow disease contamination.[180]

In the areas of GM food and new communication technologies, a raft of new control challenges exists. There is a growing appetite to explore the potential of non-traditional methods and strategies of regulation such as meta-regulation and self-regulation. In addition to these responsive regulation-type methods, smart regulation and problem-centred regulation theories are being explored. These aim for better regulation in general and the same diversification of the methods of regulation is also expected for other types of technology. These will be explored in the next discussion of strategies of regulation.

However, it is useful to remember that the focus here is mainly on biosafety regulation in Malaysia and Singapore.As both countries were previously British colonial past as explained in Chapter 1, it is argued that the trend of regulation in the UK affected Malaysia especially on the food safety controversy and modern biotechnology also biosafety issues.

Regulation in Malaysia

Malaysia experienced the same changes in regulation due to globalisation and its involvement in the international treaties. As nothing much has been written on the changes in regulation and on strategies in

[180] ibid.

regulatory theories in the Malaysian context, this thesis will lead the way in the discussion of regulatory changes in biosafety.

Malaysia, like Britain, is a democratic monarchy and implements its laws based on Acts passed in Parliament. Apart from statutes, there are delegated legislation derived from government bodies and agencies. From the early establishment of Malaysia in 1963, and perhaps during British occupation in Malaya until Independence in 1957, it was traditionally a command and control approach to regulation. However, from 1963 when Malaysia was formed, treaties that were signed and ratified by Malaysia were also adopted into Malaysian domestic law. The changes can be seen in the case of biosafety legislation in Malaysia that emanates from the Cartagena Protocol on Biosafety.

In environmental treaties and biosafety legislation specifically, Malaysia has adopted other strategies for regulation apart from the traditional command and control such as responsive regulation and smart regulation. These strategies in biosafety regulation are to be determined and will be analysed later in Chapter 3 and 4.

Biosafety regulation is mainly for the protection of human health and the environment to address any biosafety risks and concerns. Thus it is essential to understand the relationship between biosafety and the law that shapes the biosafety legal and institutional frameworks.

3. The relationship between biosafety and the law

The regulatory perspective provides the theoretical framework of this thesis to investigate biosafety regulation in order to understand how biosafety risk is shaped and strategies to improve its governance. Therefore it is

important first and foremost to understand the essential relationship between biosafety, the science, and the law.

Science and the law

Biosafety issues pertaining to modern biotechnology come under the regulation of science. It is essential to appreciate the relationship between science and the law. Peel[181] explained the role of science is to assess health, safety and environment. Science, therefore, becomes an essential component in risk regulation. Previously, science and expertise had less power, but it is now becoming acknowledged and more widely accepted.

The issue now is should science be the only or primary component of the decision making process? It is argued that prima facie science alone is rarely sufficient basis for credible and legitimate risk decision making under international law as it implicates various debatable issues. International law and institutions are becoming a legitimate source of risk governance rather than science. The Hormones case is an example of the application of scientific evidence and risk assessment as required by Sanitary and Phytosanitary Measures (SPS)-WTO at the international level in the late 1990s. Thus science later appears to be an instrument in legitimising the decision-making for risk assessment.

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[181] Jacqueline Peel, 'Science And Risk Regulation In International Law', vol 72 (Cambridge University Press 2010) vii.

The scientific risk assessment in biosafety has been used widely in conjunction with the Cartagena Protocol on Biosafety. While it provides a valid instrument for assessing biosafety risk, specifically LMOs, there are debates on the inclusion of non-scientific issues such as socio-economic factors, or social science issues.

In recent years, and distinct from bioscience, social science has gained prominence in the regulatory decision-making process. This can be traced back to much of the social science literature by the influential and debatable Weiss,[182] from which social science research governs the decision-making process by providing an educated, informed climate in which rational decisions can be made.

In the field of biosafety regulation, the socio-economic benefit is seen as an extension of a socially scientific study that examines how the society is progressed because of their local economy. The fact that the socio-economic outcome has become part of the biosafety decision-making process should be welcomed as this view reflects the writer's view as well. Socio-economic benefits, sometimes known as non-scientific benefits (or non-safety[183]), are distinctly different to the scientific benefits in the biosafety context.

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[182] Weiss CH and Bucuvalas MJ, *Social Science Research And Decision-Making* (Columbia University Press 1980).
[183] Marcoux J, Gomez OCC and Létourneau L, 'The Inclusion of Nonsafety Criteria within the Regulatory Framework of Agricultural Biotechnology: Exploring Factors that Are Likely to Influence Policy Transfer' (2013) 30(6) Review of Policy Research 657.

It is argued that science as the sole perspective in biosafety governance is controversial. There are valid reasons for socio-economic considerations to be taken into account, and these have been proven since they have been incorporated into the Cartagena Protocol on Biosafety. However, unlike science (the risk assessment of LMOs) the socio-economic perspective, despite being included in the Cartagena Protocol on Biosafety, lacks a reliable assessment method. Even though the Socio-Economic Impact Assessment (SEIA) method has been suggested, its future is uncertain.

It is argued that the critical problem in relation to science in biosafety regulation is the uncertainty of science. Therefore the precautionary principle should be applied in the Cartagena Protocol on Biosafety in cases of uncertainty in science. This raises questions about the adequacy of science as the primary instrument in biosafety regulation. Hence the issue arises - should the rationales for governance in this field (biosafety) be based purely on scientific logic? It is argued here that this should not be the case but should be supported by socio economic considerations and other issues specific to a country's circumstances.

Technology and the law

The next discussion now moves on to the relationship between technology and the law. Technological progress in information technology, biotechnology, nanotechnologies and the like are moving forward at a fast rate compared to previous decades. This progress is a landmark of human achievement, and a country with advanced technologies is considered to be a prosperous nation, as many improvements can be done and achieved with useful technology.

Nevertheless, the problem with rapid technological progress is that the law cannot cope with the regulation of the technology industry. Modern biotechnological products are commonly imported and exported across boundaries. A contaminated LMO exported from the United States may be imported by Japan for instance. It is then either the national legal system of Japan that prosecutes or the international law can prosecute. Joint international agreements, laws and conventions that legitimise prosecutions such as of non-compliance or contamination are crucial and need to be established.

Laws seem to become rigid over time and formalities before recognition and enforcement of any laws will take some time. The emergence of new forms of technology will usually be a disadvantage to a developing country as it does not have the capacity building or local expertise to deal with the advanced technology. Hence, legal expertise on that particular kind of technology will also be lacking. In a more complex technologies, the legal experts need to have the knowledge of that technology or be able to consult with the relevant expert in that field of technology before the regulation is enacted. This challenge is not just unique to a developing country but also the most advanced nations.[184]

The primary challenge is the adaptation of the legal systems to the ever-changing realities and needs that arise with the progress of science and

[184]Newell P and Glover D, 'Business and Biotechnology: Regulation and the Politics of Influence' (2003) 8.

technology.[185] When adapting becomes problematic, what approach should then be used? These are some of the issues of technology and the relevant law.

It is interesting that Francioni (2006)[186] highlights that, unlike domestic law, international law is unable to respond to the challenge of rapid technological progress due to institutional mechanisms such as the majority vote[187] restricting the timely enactment of any legislation. The challenge of technology regulation is not just at the national level but at the international level as well.

It is argued that technologies pose risks that need to be regulated. The biosafety risks as part of modern biotechnology have been discussed in the Introductory Chapter. The issue is then how to regulate the technologies thus the regulatory strategy is of paramount importance.

Modern biotechnology and the law

Perhaps the most controversial issue is the relationship between modern biotechnology and the law. The problems in regulating the modern biotechnology process of genetic engineering and the genetically modified organisms (GMOs) and its products, such as living modified organisms

[185] ibid.
[186] Francioni F, 'International Law for Biotechnology: Basic Principles' (2006).
[187] ibid 5.

(LMOs) range from scientific, socio-economic, ethical, religious and cultural issues.

The law and modern biotechnology have a strained relationship. The law may be seen as unsuitable in controlling scientific advances as opposed to specific behaviours. For instance, the strictly process-based legislation is criticised as it should be more related to the resulting product rather than process. For example, new legislation on genome editing could define plants produced by novel genome editing techniques and could replace old legislation so that it stays abreast of scientific progress.[188] On the other hand, if the scientific progress is for human good, it should be accepted by the public. In accepting these scientific and technological advancements, there must be some scientifically assessed, ethical, and permissible standards developed, especially in the areas of scientific uncertainty.

Modern biotechnology products affect almost everybody within a country as they may consume the products daily thus exerting personal choices based on their belief. However, modern biotechnology issues are more than issues of consumer choices but more significant issues of effects to the biodiversity. Nowadays, everybody has access to food that is either locally produced or imported from other countries, i.e. transboundary. Modern biotechnology, which is generally for the benefit of humankind, raises public outcries such as in the cases of the Hormones case, and the Starlink.

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[188] Sprink T and others, 'Regulatory hurdles for genome editing: process-vs. product-based approaches in different regulatory contexts' (2016) 35(7) Plant Cell Rep 1493.

LMOs corn leads to specific issues of biosafety risks, and these concerns have been discussed in the previous Introductory Chapter.

Broad principles are needed to provide a foundation for legal action in response to such contemporary bioethical dilemmas[189][190] such as in the area of LMOs. The different stages of social, scientific developments and economic interests of countries facing biological dilemmas should result in solutions that are ethically sound but also nationally advantageous. Additionally, the force of globalism that is at work in scientific developments together with a diversity of cultures and national interests brings a divergence of ethical principles.

Thus in order for modern biotechnology to be better regulated, the various aspects apart from science should be taken into consideration.

Biosafety and the law

Another controversial issue that will be faced by many countries lies in biosafety law. Although biosafety covers general issues of the safety of modern biotechnological products, the Protocol restricts biosafety to living modified organisms (LMOs), or more accurately the environmental view of biosafety. Biosafety should prevent any adverse effects of modern

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[189] The foreword by The Hon Justice Michael Kirby AC CMG
[190] in Hocking BA (ed), *The nexus of law and biology: New ethical challenges* (Routledge 2016)xi.

biotechnological products, but the issue is becoming more complex as the Protocol adopts a dual-faceted scientific and non-scientific approach.

There are issues of biosafety and compliance with the Cartagena Protocol on Biosafety. The interaction of various cultures, national interests, and ethical principles of different countries may raise questions and issues. Such issues may not affect non-ratifying countries since they are not answerable to the Cartagena Protocol on Biosafety. The issue of harmonisation between the Cartagena Protocol on Biosafety and a nation state's diversity is one issue to be examined in this study.

The complexity of acquiring effective legal responses to biotechnology issues when international cooperation is essential is acknowledged.[191]The factors that stand in the way in such as dialectical,[192] economic, and religious factors and cultural impediments[193] are also shaping the regulation.

The universal problem facing scientific advancement and new technologies is that regulation does not seem to be effective. This might explain why some groups differed in their opinions on regulating biodiversity and biosafety during the Cartagena Protocol on Biosafety. Some groups preferred internationally accepted WTO procedures rather than the formal Protocol. This can be seen from their modern biotechnology research,

[191] Baldwin(n 175).
[192] relating to the logical discussion of ideas and opinions.
[193]Baldwin (n 175) xii.

development, the rate of LMOs commercialisation, expertise and exposure on LMOs advancement.

There was enormous public and private campaigning by Green Peace[194] and various environmental groups[195] involving many countries on the importation and acceptance of genetically modified products at the international level. The issue was finally addressed by the Cartagena Protocol on Biosafety.

Biosafety is governed at a national and international level since it addresses cross boundaries issues of LMOs. This governance seems to be an efficient mechanism for control. The problem with the Protocol adopted internationally by 170 countries is that there are some divisional groups like the Miami group and the Compromise Group that did not sign the said Protocol. It raises the question on the effectiveness of this so-called global measure that does not legally bind every country. However, good national biosafety laws, whether they comply with the Cartagena Protocol on Biosafety or not, should provide reasonable solutions to the common biosafety issues.

The various scientific issues of modern biotechnology present biosafety problems and risks. Questions arise as to how biosafety risks are

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[194] Burgiel SW, 'Non state actors and the Cartagena Protocol on Biosafety', in Betsill, MM and Corell, E in NGO diplomacy: The influence of nongovernmental organizations in international environmental negotiations (MIT 2008) 67-100

[195] ibid.

regulated? Since the Cartagena Protocol is the principal international agreement that regulates biosafety, there are scientific risk assessments and risk management procedures that need to be fulfilled. All signatory countries importing and exporting biotechnological products have to comply with Advance Information Agreements (AIA) and other relevant procedures that occur before accepting the genetically modified goods.

Another controversial issue contested by various countries during the negotiations of the Cartagena Protocol on Biosafety was the socio-economic issue that while not scientific, was of relevance. Arguably the term 'biosafety' issue does not include socio-economic or 'non-safety' issues. Nonetheless, it is argued in this thesis that the key drivers in biosafety regulation should outline not only the scientific issues but also the other 'non-scientific', 'non-safety' or socio-economic issues.

One interesting issue that is difficult to assess adequately is the limitation period of legal cases that can be brought into litigation concerning genetically modified products. Adverse effects of genetically modified organisms products may take a long time to be seen and in some cases might exceed the limitation period of 20 years even though the damage has been suffered. Therefore the ordinary limitation period of 20 years in civil claims should not prevail in genetically modified cases.[196] Rodges[197] seen this is a unique relationship between law and biology.

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[196]Rodgers C, 'Environmental Risk, Environmental Liability and the Regulation of Biotechnology: Mediating Law and Biology?' (2009) in Hocking BA (n190) 103.
[197] ibid.

Thus it is then important to determine what should be the role of law in biosafety.

The role of law in biosafety

Having seen the role of science as explained above, it is then crucial to elaborate on the role of regulation in biosafety. Before proceeding further, there might be issues that there exists a dichotomy between science and law as different modes of regulation. Some might argue the real issue is how to utilise expert scientific information (which might not be neutral) within regulatory policy formation especially risk.

It is argued that there are many viewpoints on these issues. One of them is the issue of legitimacy as between science and regulation. Thus for science to be accepted as part of regulation, it must be a precise science with evidence as that will legitimise it. For instance, for risk regulation, a risk assessment and management should be an acceptable mode of evidence. Another point is that regarding scientific opinion from a scientific expert, people tend to believe expert rather than a non-expert. Thus it is argued that regulation should be utilised in balancing between these various perspectives. The modern view of relationship between science and policy[198] claims that science informs policy by producing objective, valid and reliable

[198]Funtowicz S and Strand R, 'Models of Science and Policy' (2007) in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007).

knowledge. This then leads to a second step, i.e. to sort out diverse values and preferences.

Regulation serves the purpose of controlling business run by public departments, private companies, governmental bodies, and other stakeholders. The law plays a vital role in social control. In biosafety control, the law must consider that there are uncertain biological risks in genetically modified products that are consumed by the public. The law, through its mechanisms of regulation and institution, represents the legitimate medium of social control. Science manages biosafety in the form of risk assessment tools which are essential for safeguarding human life and the environment.

The law on biosafety exists in the form of regulations, Acts of Parliament, statutory directions, and guidelines and these have usually emanated from government policy. The policy will also describe the country's capacity to govern biosafety concerns. The fundamental issue arises of why there is a need to legitimatise. Whom do we trust more? Do we trust the scientists or lawmakers? Are these two players representing various stakeholder interests in the public sector, the business or agriculture communities, the religious and economist sectors, or any others?

It can be argued that there is good science and bad science even though all science aims to be for the benefit of humankind. Modern biotechnology is an enormous business sector that involves gigantic corporations. These corporations both private and government-owned are worth billions of dollars in business that extends worldwide. Scientists do not work alone in their work, with the research and development providing the government and private companies with commercial power and business interests. Scientists may have their motives in their work, such as making a name for themselves in the industry, fame, reputation, and also the company's reputation. This raises the issue of whether science is it purely

benefits humankind? Alternatively, are there hidden agendas that are well disguised? These considerations are some of the underlying issues that we need to think about when addressing public concern about whether we trust the scientist or the lawmakers.

The lawmakers form part of Parliament in most countries and are a group of democratically elected people. They can be from political, legal and non-legal specialists or scientist backgrounds. The lawmakers make laws that are often introduced by an executive who might have political motives. The executive may aspire to be a political champion, grow the business of the government and the public as a whole, or just to obtain a legitimate source of income for the people.

When a law is passed, the executive will be the decision maker for the government and be advised by scientists and experts. In some countries, some ethics committees will advise on ethical issues. If something goes wrong, the court of law will act as an adjudicator to interpret the law after listening to expert evidence by the scientist, government and other relevant parties. This raises the legal issue of locus standi amongst other issues, i.e. the public raised objections to the court on the successful applications of some LMOs being imported or released into the environment. This issue will be explored further in the next chapters 3 and 4 within the local Malaysian context.

A court will usually rely on scientific evidence from the scientist since the court will not have the expertise to decide on the safety or non-safety of biotechnological products. This was highlighted in the UK case of *R v Secretary of State of the Environment ex parte Watson.*[199] This case is significant because it illustrates the court's reluctance to reject the risk assessment of the regulator. In this case, the applicant Watson was an organic farmer producing vegetables including sweet corn. He was worried about the trial planting of LMOs maize on the adjoining farm as it might cross-pollinate with his organic corn and he could lose his accreditation and status as an organic farmer. Due to the LMOs threat, Watson moved his maize plants a further 2km away and asked the respondents not to start on the LMO trial. The respondents sought advice from the Advisory Committee on the Release to the Environment (ACRE) who replied that the probability of cross-pollination was zero. The respondents replied that they would neither vary nor revoke the consent, so Watson later challenged this response by way of a judicial review.

The UK Court found that LMOs even though ACRE report fell short of an adequate risk assessment as requested by the environmental groups, to the Court would not go against the report. The ACRE guaranteed that there would be no risk of cross-pollination. The court, however, struck a balance however between competing interests in questions also provides a reasonably confident assessment that realistically no more than minimal risk. Thus the respondent decision is not irrational.

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[199] R v Secretary of State for the Environment ex p Watson [1998] EGCS 122.

This decision shows the Court's reluctance to reject the risk assessment even though it fell short of a full risk assessment. It shows the court's willingness to accept a scientific risk report that is deemed to be adequately balancing competing interests and is based on grounded reasoning. However, it is yet to be seen how Court will respond to socio-economic arguments in the future for LMOs agriculture and product trials.

In the area of biosafety, what are the scientific and non-scientific risks and areas of concern from the public? In this area, the risks and concerns of the regulators may not be the same as those of the general public. Some of these have been discussed previously will be illustrated further. In short, there are some biosafety risks and concerns that a regulator has the mandate to regulate. On the other hand, there are valid socio-economic concerns held by the public and other stakeholders, but the extent to which it is incorporated into the decision-making process is unclear.

Therefore, the primary challenge in a democratic, socially representative society is to provide a medium within the different decision-making processes that deal with general public concerns. This challenge has seen a change or variation from the traditional command and control approach of regulation towards smarter regulation and other regulatory options. These will be discussed in detail later.

The functions of regulation in biosafety

The essential functions of the regulation of biosafety can be summarised accordingly:[200]

i) to protect human health
ii) to protect the environment
iii) to promote or enable consumer choice
iv) to foster useful research

It is suggested that society can manage GMOs in three different ways, namely by:[201]

a) a precautionary principle that bans activities and technologies that generate risks
b) a command and control approach by field testing and a regulatory approval process
c) a market approach by instituting compulsory insurance

While the first two ways are common and institutionalised in the national biosafety laws through the Cartagena Protocol on Biosafety; the third approach will perhaps be practised in the future as LMOs regulation comes to maturity and public acceptance of LMO is more positive than before.

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[200]Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (Nuffield Council on Bioethics , May 1999).
[201] McManis CR, *Biodiversity and the Law:" Intellectual Property, Biotechnology and Traditional Knowledge"* (Routledge 2012) 131.

Why are biosafety issues controversial?

Biosafety is thought to be one of the most controversial issues due to the following facts:

i) there are many stakeholders involved in biosafety regulation - scientists, the public, decision and lawmakers, government bodies, and the business and agricultural communities
ii) the consumption of genetically modified (GM) products involves a public who has different religious, ethical, and cultural beliefs and there is resistance by the public
iii) the roles of non-governmental organisations and influential environmental groups dominate the public perception delivered through prime media and social media
iv) the consumption of GM products may involve daily consumption of this food consumption, and will likely involve everybody, and also impact future generations.

Due to its controversial nature, all attempts in regulating biosafety will have to adhere to some sound principles. It is acknowledged that the State is not left with an easy task in performing its role as the protector of biodiversity within the public and business domains. A nation's progress must be in line with other developing and developed countries. Its regulation development needs to proceed with caution as it needs acceptance (both inward facing the countries' people and outward facing the international obligations), legitimation and not resistance. If anything were to go wrong, the decision-maker would be blamed, and the irreversible nature of the damage would not be recoverable or fiscally compensated.

4. Biosafety as risk regulation

Having discussed the relationship between law and biosafety, it is then essential to examine biosafety regulation from a risk regulation perspective. Biosafety is a form a regulation of risk. Risk plays a significant and an important role in regulatory process.[202]

Biosafety regulation adopted risk assessment and risk management tools for GM products. Risk assessment and management tools seem efficient and convincing; however, their use seems technocratic and has raised a lot of controversial points from the public, consumers, environmentalists and ethicists.

The core concepts in regulating risks will be explored in an attempt to understand risk regulation in biosafety. The terms risk and biosafety risk elicit questions around their definitions, certainties, and types of risks.

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[202] Julia Black, *The Role of Risk in Regulatory Processes*, Chapter 14 in The Oxford Handbook of Regulation, Practice (Oxford University Press on Demand 2010).

Thus there are two essential definitions of risk to be highlighted which are summarised as follows:

a) Beck's definition of risk

'Risk' is defined by influential German sociologist, Beck, as part of an age that we are living in.[203] Biosafety regulation regulates a type of risk. Biosafety risks are the result of the advancement of modern biotechnology and its activities, and LMOs specifically.

Risks are not a matter of fate but are a result of human decisions and actions. Beck defined 'advanced modernity' as requiring specific expertise to identify and recognise global risks. These risks are evaluated by experts through scientific methods, but this increases the level of insecurity. The tools for coping with modern risks are limited since their applications are likely to have transboundary and possibly global implications. The same is also true in biosafety regulation of LMOs which are transboundary.

Beck argues that contemporary society's attempts to anticipate risks are futile since those risks cannot be calculated. It is widely known that risk assessments underestimate real threats. The risk assessment is criticised as being a methodology that legitimises an individual's exposure to incalculable risks. It is suggested that other tools be used hand in hand with risk assessments to address all possible risks that could be involved.

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[203] Beck U, 'Risk Society: Towards A New Modernity', Vol 17 (Sage 1992).

b) Knightian's definition of risk

Knight's[204] opinion contrasts risk with uncertainty. He defines risk as the probability of a particular event (or hazard) occurring and the consequential severity of the impact of that event.[205] Whereas risk can be quantified, uncertainty is impossible to measure. Regulation is therefore viewed as the control of risk. Risk regulation is mainly concerned with the Knightian management of risk and uncertainty.

Risk and expert analysis

The problem with risk is that either view of risks from Beck or Knight, both depends on expert analysis of probabilities. Baldwin's[206] fundamental work on risk regulation is important in understanding of risk regulation in general and biosafety risk specifically. Risk regulation and awareness of literature on risk control add a new dimension of our understanding of regulation. Essentially, this leads to understanding perceptions of regulatory priorities, construction and development of regulatory agendas and legitimation.

We live in an era in which there is a growing distrust towards experts and authorities[207] which has partly motivated a move towards the 'regulatory

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[204]Knight FH, *Risk, Uncertainty and Profit* (Courier Corporation 2012).
[205]ibid 83.
[206] Baldwin (n175) ch 6.
[207]Wynne B, Benton T And Redclift M, *Scientific Knowledge And The Global Environment* (Routledge 1994).

State'.[208] Risk regulations pose problems for the regulators and implementation. A new era of debates on how to regulate risks like mad cow disease and the safety of GM foods demonstrate these risk regulations problems. It follows that the precautionary principle in the Cartagena Protocol on Biosafety[209] should be applied as it is justified in such instances.

Technologies are a constructed by society, and social choices have to be made to deal with the natural risks.[210] This has many implications for society. In biosafety regulation, society should be part of the decision-making process in dealing with biosafety risks. Thus, labelling of LMOs is justified partly due to social choice.

Beck states that risk is the anticipation of catastrophe. The literature on risk management focuses on the causes of disasters and failures. Failures can be attributed to social causes, for example, intentional acts of obstructions and unintentional acts. Some scenarios can occur in biosafety regulation. While intentional acts of transboundary movement of LMOs are regulated, unintentional LMOs are also regulated according to the Cartagena Protocol on Biosafety.

Risk regulation is seen as an organisational dimension of risk control. This organisation provides procedures for decision-making which is the norm in biosafety. In addition to risk assessment, there is also risk management.

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[208]Baldwin (n 175175) 84.
[209]Preamble.
[210]Baldwin (n 175175) 85.

Risk management, or risk control, is part of the risk quantification process whereby individuals or organisation dealing with hazards in their work have procedures on how to go about dealing with issues if they arise. These processes provide individuals and organisations with rational boundaries and outline well-documented biases in decision-making.

Below are some vital features in regulating risks:

a) defining and assessing risks
b) regulatory challenges in regulating risks
c) approaches and solutions for risk regulation

Regulatory responses to risk in biosafety

Some theories raise issues about regulatory responses to risk and how the regulation can be justified or validated. A technical approach to risk will emphasise leaving risk regulation to experts and establishing regulatory priorities from technical evaluations. The economic-cost benefit approach to biosafety risk was suggested[211] but has never been realised, possibly as it might lead to unnecessary bureaucratic measures.

On the other hand, the firm belief that risks are socially constructed[212] might suggest that regulatory priorities and policies cannot be left to the

[211] Fransen L and others, *Integrating Socio-Economic Considerations into Biosafety Decisions* (Washington, DC: World Resources Institute (2005).
[212] Dake K, 'Myths of nature: Culture and the social construction of risk' (1992) 48(4) J Soc Iss 21.

objective evaluations of experts but should emerge from a democratically valid process of debate and consultation.[213]The psychological-public tolerance approach could be used to explain why, despite the many risks of LMOs, the public in the United States are more tolerant and receptive of LMOs compared to the European Union. Perhaps it is because the benefits of GMOs outweigh the risks and so LMOs are treated like conventional food. While the cultural theories approach has no measurement of risk; it is a theory that could take the disguise of socio-economic concern and thus influence biosafety risk regulation.

A final challenge is the level of democratic acceptability of regulations and the appropriate degree of participation in risk management decisions. It is challenging in itself to balance expert opinion with unfounded public opinion.

Expertise is expensive and comes as an advantage to the wealthy and developed nations. Even though some groups of consumers may mistrust expert advice, ethicists, or environmentalists due to their negative perceptions of GM products and GE technology, expert advice is needed to identify the type of risk and to regulate accordingly. In short, knowledge and expertise are also challenges in risk regulation.

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[213] Baldwin (n17575) 93.

Breyer's model of risk

Breyer[214] discussed the expertise rationale and stated that small but significant health risks are plagued by three serious problems. The problems are:

i) tunnel vision (over-regulation that does more harm than good)
ii) random agenda selection (regulation that focusses more on public attention than a rational appraisal of the risks) and
iii) inconsistency (agencies use different methods to calculate effects of regulations). -

The basis of these problems creates a 'vicious cycle' that eradicates trust in regulatory institutions and inhibits rational regulations. These are listed below:

a) public perceptions[215] that 'differ radically from the consensus of experts in the field' and do not 'reflect rational sets of priorities'
b) congressional actions and reactions involving detailed statutory directions on the risk that are later proven inappropriate
c) uncertainties in the technical process due to lack of knowledge, data and predictive power that hamper the regulation process

Breyer proposed that a 'depoliticised regulatory process might produce better results' if divided into two groups. The first would be a group

[214] Breyer S, *Breaking the vicious circle: Toward effective risk regulation* (Harvard University Press 2009).
[215] ibid 33.

of civil servants with experience in health and environmental agencies, Congress, and the Office of Management and Budget.

The second would be a small centralised administrative group of civil servants that produce a coherent risk programme with rational priorities for regulation. This second group would have jurisdiction over various agencies, with a degree of insulation to withstand political pressures. Their prestige, authority, and expertise would make their decisions more legitimate.

One criticism of this type of group is that they may consider public perception and desires less than other priorities. Breyer's approach fits a command and control model. The command and control approach will be elaborated further below.

Shrader-Frechette's model of risk

Shrader-Frechette,[216] on the other hand, offers a risk-cost-benefit analysis (RCBA) and adds scientific proceduralism using three mechanisms.

These are as follows:

a) ethical weighting that designates a public role in deciding, rather than an RCBA

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[216] Shrader-Frechette KS, *Risk and rationality: Philosophical foundations for populist reforms* (Univ of California Press 1991).

b) alternative risk analysis and evaluation that allows the public, not the experts, a more significant role in determining risk choices
c) weighted expert opinions

This Shrader-Frechette model offers a more appealing system to public involvement with more ethical issues being taken into account. In biosafety regulation, however, the implementation of an RCBA seems fundamentally complicated and adds bureaucratic burden to the decision-making process. The Shrader-Frechette model reflects the new governance approach.

The proposed ‘depoliticised regulatory process’ institutional structure by Breyer seems to be the basis of most national biosafety institutions such as Malaysia, with a few modifications. The National Biosafety Board of Malaysia consists of representatives from various government departments. However the regulatory strategy in biosafety seems to have some elements of new governance Shrader-Frechette as well such as the public participation, risk assessment, weighted expert opinion and ethical weighting. This seems a combination with modification and adoption of both approaches.

The process of regulating risk needs a pluralistic approach from any analytical perspective in real practice. Such an approach will ensure more vital issues are being taken into account so that a valid and improved risk regulation process is created.

For future risk regulation, it is essential to highlight Posner's[217] suggestions that specific catastrophic risks need anticipative solutions since the impact of those risks would lead to the eradication of humankind. This is despite the low probability of an occurrence of any such events. In biosafety regulation, the risk might occur for instance if there is contamination of LMOs with substances that are not fit for human consumption. The contamination might occur despite the existence of rules and regulations and compliance standards.

Article 17 of the Cartagena Protocol on Biosafety attempts to address this issue and provides for unintentional transboundary movements and emergency measures. Posner[218] calls for a fundamental transformation in (legal) education, with a stronger emphasis on science and the ability of legal and political systems to deal with risks. However, the non-science aspects (or socio-economic considerations) should not be neglected either since it is argued that science should not be the sole contributor in the biosafety decision-making process.

At this point, it can be argued that biosafety regulation and national laws that comply with the Cartagena Protocol on Biosafety, primarily address scientific risks rather than socio-economic concerns. The scientific risks have a unique system of risk assessment and management whereas there is no such organised system for the latter. Socio-economic considerations are

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[217] Posner RA, *Catastrophe: Risk and Response* (Oxford University Press 2004).
[218] ibid.

being mentioned as part of decision-making processes but, in some countries, are only briefly reported.

Biosafety regulation aims

Thus this will ultimately leave biotechnology law with the following aims, according to Scott:[219]

a) to impose bans, for example, on human cloning and genetically modified crops
b) to permit activities only within its agreed limits, for example, controls over the use of genetic testing results by insurance companies
c) to permit activities only with a licence
d) to permit marketing only subject to certain conditions such as labelling of genetically modified products

5. Important biosafety regulatory strategies

There are various regulatory strategies according to Baldwin,[220] that best accommodate various objectives. However, it can be deduced in this thesis, as abovementioned in line with Breyer and Shrader-Frechette's that two main strategies that are relevant in biosafety regulation namely

[219] Scott C, 'Rethinking Regulatory Governance For The Age Of Biotechnology' (2007) Chapter 2 19.
[220] Baldwin (n175).

command and control and new governance or non-state regulation respectively.

The new governance or non-state regulation can be summarised as follows namely:

i) meta-regulation
ii) self-regulation
iii) responsive regulation
iv) smart regulation

a) Command and control

Command and control regulation involves influencing actions by imposing standards backed by criminal sanctions.[221] Command and control enforce positive actions and prohibits specific actions while laying down the terms and conditions for those actions. This is the most traditionally popular regulatory strategy and constitutes the norms, rules, and regulations that are enforced by legal institutions and backed up by criminal and civil liabilities. An executive or advisory committee on biosafety such as a biosafety board, or ethics or genetic modification committee is usually given the mandate by the government or by law to regulate or advises on this jurisdiction. The law usually creates the biosafety institution which is backed up by fine and punishment for non-compliance with the law. This is considered a common practice for national biosafety laws.

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[221]ibid 106.

While command and control constitutes the primary strategy for biosafety regulation, their main strength behind is the force of the law. Certain minimum standards of acceptable behaviour are set along with unacceptable behaviours, and this strategy is seen as highly protective of the public as it imposes penalties that are enforced by authorities. Considering that the interests of human health and environment are at stake, command and control is perhaps the most justified strategy for the biosafety sector. The difficulties with command and control are its inflexibility, its expensive administration, enforcement and compliance, and the fact that it can inhibit desirable behaviour. The command and control approach to biosafety is sometimes known as a 'strictly process-based legislation'. In other words, it creates regulatory hurdles, that are either process or product based, and is criticised by the scientists in the industry as being a hindrance to progress and research freedom.[222] The labelling requirements and the bureaucracy in biosafety are said to add costs to biotechnology producers.[223]

b) New governance

In recent years, the traditional command and control strategy has been eroding despite its relevance and legal force. This is because there are many areas of regulation such as technology, biodiversity, economy, and financial that are regulated at global conventions and later ratified and signed

[222] Sprink T and Others, 'Regulatory Hurdles for Genome Editing: Process-Vs. Product-Based Approaches in Different Regulatory Contexts' (2016) 35(7) Plant Cell Rep 1493.
[223] Huffman WE and others, 'Should The United States Initiate A Mandatory Labelling Policy for Genetically Modified Foods' (6th International Consortium on Agricultural Biotechnology Research (ICABR) Meetings, Ravello, Italy 2002) 3.

by different countries. These conventions were later implemented by countries at a national level. Even though the basis of regulation is still the command and control approach, since the law is enacted by Acts of Parliament, the approach to these laws has varied. For example, biosafety laws from the Cartagena Protocol on Biosafety have some strategies that are not command and control regulations.

Besides state rule, regulations can also be carried out by a variety of other organisations such as self-regulatory, or non-state, bodies. Examples of these include professional bodies, trade associations, public interest groups, business partners, consumers and other associations.[224] These non-state organisations are still supervised by the state through different mechanisms. These mechanisms are listed below:

i) meta-regulation
ii) self-regulation
iii) responsive regulation
iv) smart regulation

i) Meta-regulation

Meta-regulation refers to processes in which a regulatory authority oversees a control or risk management system. The authority does not carry out the regulation directly[225] but it 'steers rather than rows'.[226]Meta-regulation

[224]Baldwin (n175) 137.
[225] ibid 147.

is a process of 'regulating the regulators, whether they are public agencies, private corporate self regulators or third party gatekeepers'.[227] The 'institutional meta-regulation' is 'the regulation of one institution by another'.[228] Through meta-regulation, 'each layer [of regulation] regulates the regulation of each other in various combinations of horizontal and vertical influence'.[229]

For general biosafety regulation, the ministry responsible within the government for biosafety requires the applicant to complete a risk assessment and risk management plan.[230]The applicants are responsible for carrying out the risk assessment and risk management, and the National Biosafety Board monitors all LMOs activities. This strategy of biosafety regulation will be discussed further in a Malaysian context in Chapter 3 and 4.

ii) Self-regulation

Self-regulation takes place when a group of companies or individuals has power and control over its members and their behaviour. Self-regulation '…rel[ies] substantially on the goodwill and cooperation of individual firms for

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[226] Osborne D, 'Reinventing Government' (1993) Public Productivity & Management Review 349 (as cited in Baldwin (n175)
[227] Parker, C. *The Open Corporation: Effective Self Regulation and Democracy*, (Cambridge University Press 2002) 15.
[228] Parker & Braithwaite J, (2004) 'Conclusion' in C. Parker, C. Scott, N. Lacey, & J. Braithwaite (eds.), *Regulating Law*, New York: Oxford University Press, 283.
[229] ibid 6.
[230] Malaysia Biosafety Act 2007 s36.

their compliance'.[231] Self-regulation is the process of '…standard setting bodies…operate independently of, and parallel to, government regulation' and with respect to which, 'government yields none of its own authority to set and implement standards'.[232]

This type of regulation can be seen in some professions such as barristers and solicitors, accountants, professional sports, advertising, insurance and the British press. This type of regulation may exist in other countries. However, in the case of biotechnology and biosafety, this regulation does not exist except in regional and national biotechnology and biosafety associations. These associations do not have any regulatory force and only represent society's interests, as well as implement the policies, rules and regulations of their countries. Such associations are more of a forum for regional interactions that can promote cooperation for biotechnology and its safety. Self-regulation alone is apparently not appropriate in the context of biosafety as the human health and environment are at stake. Furthermore the biotechnology companies are tied to the rules and regulations imposed by the regulator. In this sense, there is little room for self-regulation.

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[231] Sinclair D, 'Self Regulation Versus Command and Control? Beyond False Dichotomies' (1997) Law & Policy, 19:534.
[232] Freeman J,'Private Parties, Public Functions and the New Administrative Law' (2000) Administrative Law Review, 52: 831.

iii) Responsive regulation

Responsive regulation, according to Ayres and Braithwaite,[233] is a strategy in which compliance is more likely because a regulatory agency operates an enforcement pyramid.

This enforcement pyramid is illustrated below:

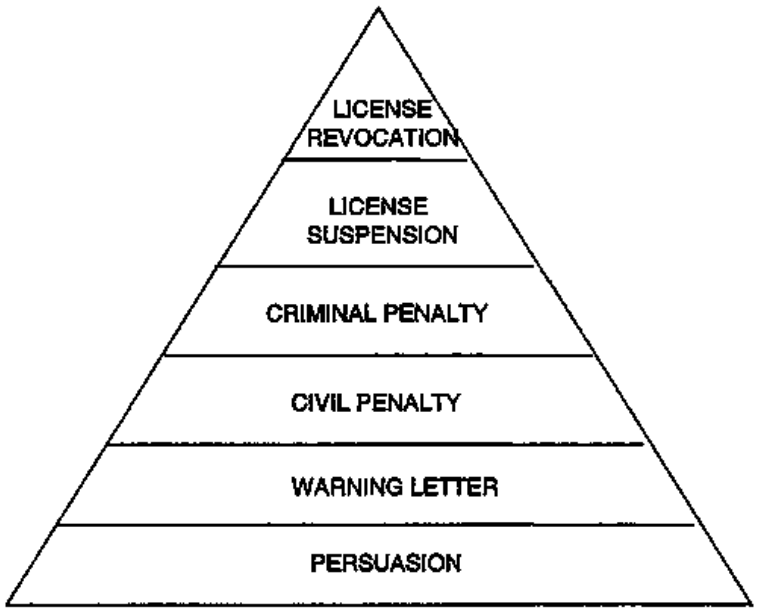

Figure 3: The enforcement pyramid

According to this strategy, regulation always starts at the base of the pyramid. However, this pyramid contains sanctions aimed at single regulations. This responsive regulation-type pyramid, while hugely influential worldwide, is not without criticism. One main criticism is that step by step

[233] Ayres I and Braithwaite J, *Responsive regulation: Transcending the deregulation debate* (Oxford University Press on Demand 1994) ch 4.

implementation of the pyramid may not be appropriate.[234]In the context of biosafety regulation enforcement, there is no pyramid step by step progression as it seems unsuitable. Perhaps it is more suitable in environmental regulation.

iv) Smart regulation

The advocates of smart regulation (Neil Gunningham, Peter Grabosky and Darren Sinclair[235]) build further upon 'responsive regulation'. The main difference is that this type of strategy considers a broader range of regulatory players than responsive regulation. Responsive regulation is concerned with the interaction between two parties, the State and businesses. Smart regulation can also be comprised of a group of quasi-legislators such as public interest groups, professional bodies and industry associations.[236]

[234]Baldwin R and Black J, 'Really Responsive Regulation' (2008) 71(1) The Modern Law Review 59.
[235]Gunningham N, Grabosky P and Sinclair D, 'Smart regulation' in (1998) *Regulatory Theory* 133.
[236]Baldwin (n 17575) 266.

The pyramid of smart regulation can be explained as follows:

GOVERNMENT AS REGULATOR	**BUSINESS AS SELF REGULATOR**	**THIRD PARTIES (PUBLIC INTEREST GROUPS ETC.)**
DISQUALIFICATIONS	DISQUALIFICATION	DISMISSAL
PENAL SANCTIONS	SANCTIONS	DISCIPLINE
NOTICES	WARNINGS	PROMOTIONS
WARNINGS	GUIDANCE	REVIEWS
PERSUASION	EDUCATION	INCENTIVES
EDUCATION	ADVICE	TRAINING SUPERVISION
ADVICE	-	ADVICE

Table 1: The pyramid of smart regulation

According to the above table of smart regulation, it has three sides and uses some different instruments that implemented by three different parties. The pyramid 'conceives of escalation to higher levels of coerciveness not only within a single instrument but also across several instruments'.[237]

In relation to biosafety regulation, the government as the regulatory player can use all of the instruments depending on the type or nature of the transaction with various parties, either the businesses or interested third

[237]ibid 399-400.

parties. If the business is the regulator, it is unclear how they go about regulating themselves in biosafety and this is discussed in the Malaysian context in the next Chapter 3 and 4. As for third parties as regulators, for instance the public, or other environmental groups, this will also be examined in the Malaysian context in the next chapter.

Whilst these smart regulation-type strategies are ideally to be implemented in the hope of yielding better regulation, it is perhaps not always the case. Smart regulation looks to expressly co-opt third-party regulators such as other institutions rather than the ministry and government. This is going to be explored in more detail in Chapter 4.

One reason is because of the brevity and gravity of the interests to be protected i.e. human health and the environment. Another is that the nature of issues to be may not always be amenable to smart regulation and the government may be a better regulator. The regulation of new technology is not easy due to its complexity and the various stakeholders involved and the controversial issues that are raised. From the main regulatory strategies outlined above, it seems that not all main regulatory strategies are appropriate to fulfil the biosafety regulations' aims and purposes.

The appropriate and relevant strategies in biosafety regulation are summarised as follows:

a) command and control
b) new governance through:
    i) meta-regulation and
    ii) smart regulation

Gunningham's theories on regulatory framework on biotechnology seem a better biosafety framework apart from the traditional command and control.

6. Gunningham's main regulatory framework on biotechnology

This thesis tries to import the frameworks of biotechnology regulation to the frameworks of biosafety regulation with some adjustments so that they comply with the Key Protocol issues in the Cartagena Protocol on Biosafety. The regulation of biosafety frameworks involves a more specific area in modern biotechnology that regulates the transboundary movement of LMOs and its products. The Protocol mainly outlines the vital biosafety issues to be complied with but not on the suitable regulatory strategies. This will be up to the countries' capacity building and regulatory strategies.

At this juncture, the real cross-cutting issues in this thesis are how the different/ same regulatory strategies are able to address the various biosafety issues? It is hoped that there will be a clue to this pertinent question in biosafety regulation at the end of this thesis.

This biosafety regulatory framework is based on Gunningham's framework of biotechnology regulation. The starting point for regulation on biosafety should be based on Gunningham's article[238] as it underpins the

[238]Gunningham N, 'Regulating Biotechnology: Lessons from Environmental Policy' (2007) in Somsen, H, *The Regulatory Challenge Of Biotechnology: Human Genetics, Food And Patents* (Edward Elgar 2007) 9.

Cartagena Protocol on Biosafety and the Convention of Biodiversity that applied the environmental precautionary principle.

Gunningham listed four main frameworks of biotechnology regulation. These are: smart regulation, meta-regulation, civil regulation and licence model. These are essential frameworks for analysis of biosafety regulation. These frameworks will be used for a detailed analysis of biosafety governance in Malaysia and Singapore.

Even though Gunningham uses the term 'biotechnology regulation', it is of relevance because by definition biosafety is the regulation from the harmful effects of modern biotechnology and its products, especially LMOs, on human health and the environment. Biosafety law specifically focus on an aspect of biotechnology regulation namely the transboundary movement of LMOs.

Gunningham explains the reason for the phenomenon of 'regulatory reconfiguration' such as state control. He also considers various stakeholders' interests in regulation inter alia public awareness, and the use of science and technology, for example satellite imaging, by the environmental groups that put pressure on governments. This 'regulatory reconfiguration' that shapes the landscape for regulation is essential to comprehend the way the law and regulations change in many countries from traditionally command and control strategies to new governance.

Gunningham's four (4) main regulatory frameworks on biotechnology are explained as follows:

a) Smart regulation and regulatory pluralism

Traditionally, regulation is regarded as a two-part process between the government and the business or company, the government being the regulator and the business being the regulatee. In reality, empirical data shows that there is a number of forms in which regulation can occur, better known as 'regulatory pluralism', and involve numerous players in the decision making process[239] and the different mechanisms of informal social control[240] often prove more important than the formal ones.

The insights from empirical data have led some policy-makers to examine how public agencies can enable institutions and resources outside of the public sector to further policy objectives in specific situations. The role of the government in this regard changes from 'rowing the boat to steering' it[241] and it regulates from a distance by acting as facilitators of self- and co-regulation[242] rather than regulating directly.

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[239]Gunningham 'Smart regulation' (n235) 133.
[240]ibid 134.
[241] Osborne D and Gaebler T, *'Reinventing Government: How The Entrepreneurial Spirit is Transforming Government'* (1992) Reading Mass.Adison Wesley Public Comp.
[242] Grabosky PN, 'Using Non-Governmental Resources to Foster Regulatory Compliance' (1995) 8(4) Governance 527.

Smart regulation as a biosafety regulatory strategy

It is undoubtedly true for biosafety regulation; regulatory pluralism is also seen as an important element in the regulatory framework. In regulatory pluralism, environmental policy-making involves governments harnessing the capacities of markets, civil society and other institutions to accomplish its policy goals more effectively, with greater social acceptance and at less cost to the State.[243] Gunningham's method is excellent in emphasising the parties of smart regulation that interact with the policy instruments. Thus, careful regulatory design on smart regulation is needed to ensure that the regulations are mutually reinforcing rather than repetitive or, even worse, conflicting.[244]

Gunningham and Grabosky's[245] impressive study of the application of smart regulation shows considerable effects in environmental regulation but is problematic in biotechnology and biosafety. This discussion will summarise their work. The design principles of smart regulation are restricted in their application to biotechnology[246] and consequently biosafety as well. This is due to two aspects – namely, the instruments used in smart regulation, and the broad range of stakeholders/actors in biosafety.

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[243] Gunningham N and Sinclair D, 'Regulatory Pluralism: Designing Policy Mixes for Environmental Protection' (1999) 21(1) Law & Policy 49.
[244] Gunningham N, Sinclair D and Grabosky P, *Smart Regulation: Designing Environmental Policy* (Clarendon 1998) ch 6.
[245] ibid.
[246] ibid.

The smart regulation policy instruments have limited application. For example, they might include information and education, volunteering, self and co-regulation, market-based instruments and direct regulation. However, many of these instruments have little or no role to play. An increase in education and information may not necessarily influence the regulatee i.e. business sectors like biotechnology companies.

The self-regulation instrument may not be credible given that businesses usually try to maximise profits and rapidly commercialise their products. These aims have to be balanced with public concern over the harmful effect of the modern biotechnology products.

Similarly, market-based instruments may not influence the market or even consumer behaviour. It is then up to the government regulation to use instruments such as mandatory pre-market risk assessments and approval processes, to establish and monitor safety standards, and set liability rules for failure to comply with legal standards. The government might also use informational regulation such as labelling and co-regulation.

Smart regulation advocates the involvement of a broad range of stakeholders from either the government (regulator), from businesses (regulatee) or other third parties. The limitations in such a broad range include the extent to which it is practicable for all parties to be involved even though public participation has an influencing role for greater transparency in

the decision-making process. The same can be implied for scientists' involvement in providing expert scientific advice.

Apart from these stakeholders, there is limited scope for surrogate regulators[247] such as financial institutions, markets, and industry associations in the smart regulation system. The efficacy of the surrogate regulators' role and involvement in future biosafety regulation is questionable. This is not so much from a compliance point of view to the Cartagena Protocol on Biosafety, but from a country's economic perspective.

It is important to note here that while the role of the NGOs is crucial and should be recognised, the position essentially has a counteractive force. It is true that if the State confined itself to 'steering not rowing' then the fundamental pillars of effective biotechnology regulation (risk assessment, mandatory pre-market approval, established safety standards etc.) would be undermined. This is the important aspect of biosafety regulation issues. The regulator is to balance among the various essential biosafety issues matching it with the right regulatory strategies.

It was recommended that in the smart regulation approach, instruments should be sequentially utilised by first introducing less interventionist measures and sending a clear message that more draconian measures will be introduced for non-compliance. In the area of biotechnology

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[247] Gunningham N, Phillipson M and Grabosky P, 'Harnessing Third Parties as Surrogate Regulators: Achieving Environmental Outcomes by Alternative Means' (1999) 8(4) Business Strategy and the Environment 211.

and biosafety where irreversible damage occurs to both human health and the environment from the harmful effects of modern biotechnology, this smart regulation policy failure could lead to catastrophic consequences.

It is difficult in the smart regulation approach to biotechnology to accommodate all the stakeholders (public, financial institutions, markets, non-governmental organisations and so on). Whilst biosafety regulation is not meant to accommodate every single stakeholder's conflicting interests and aims, it is important that biosafety regulation is accepted by them. It would be detrimental to have resistance to the regulation and even worse to be seen by stakeholders as protective, discriminatory or neglectful to some but not others.

Another issue is whether smart regulators can capitalize for win-win situation is without problem. Biotechnology companies have argued that GM products are not materially different from conventional food and that they produce cost-effective means of feeding the poor and solving world poverty.

Some principles of smart regulation resonate strongly with biotechnology regulation, for example, the considerable scope for empowering civil society to act as surrogate regulators, and the informational regulation in the form of product labelling. However product labelling creates an issue in itself because there are disagreements amongst some countries which mean it is not applied uniformly worldwide. Hence smart regulation offers limited insights into biotechnology and biosafety regulation.

Finally, a more general concern with smart regulation in the biotechnology and biosafety area is its normative approach. The advantage to it is the 'good' public policy and objectives that are set to deliver the goals effectively, efficiently and politically acceptable.[248] The disadvantage is that it is only possible through some common agreement on all the preferred policy objectives.

The problem inherent with biotechnology is that the policy agenda is shaped by political agendas and the focus is lost on the policy objectives. One side to this problem is that individuals are diametrically opposed on fundamental issues. For example, in biotechnology regulation, the moderate views on policy goals are: 1) to ensure the safety of products for humans and on the environment and engendering public trust; 2) no unnecessary burdens that prevent transgenic products being realised. Whilst the first objective is agreeable, the second objective is rejected by NGOs.

In biotechnology for instance, at the international WTO and WHO level, GM food is treated no differently than conventional food. The United States and the European Union have different approaches and divergent views on biosafety regulation. This is largely based on different political constituencies and the influence of different institutional environments rather than on rational policy choices.

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[248] Gunningham (n175).

b) Reflexive and meta-regulation

The literature on reflexive law[249] recognises that the capacity of the regulatory State to deal with increasingly complex social issues has declined dramatically. The traditional command and control approach (a form of material law)[250] is said to be unresponsive to the demands of an enterprise and unable to generate sufficient knowledge to function efficiently. In other words, society's complex needs have outgrown the legal system's possibilities to deal with these needs in a manner that is permissible within the constraints of the law.[251] For example, in the case of the Three Mile Island nuclear accident and quasi-meltdown, the operators were simply following the rules. There was no capacity for strategic thinking in this case. Eventually, it was decided that the events that unfolded were not covered by a rule, and the operators had no capacity to read the situation and respond appropriately.[252]

Reflexive regulation, in contrast, uses indirect means to achieve broad social goals. It also has a much greater capacity to come to terms with interestingly complex social arrangements. Reflexive regulation is procedure-oriented rather than directly focused on a prescribed goal, and

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[249] Teubner G, 'Substantive and reflexive elements in modern law' (1983) Law Soc Rev 239.
[250] Form of law having broad goals and using specific direct means to achieve the goals.
[251] Koch, C., and K. Nielsen, (1996) 'Working Environment Regulation: How Reflexive-How Political? A Scandinavian Case' (Lyngby, Denmark: Working Paper, Technical University of Denmark, June 1996) (as cited in Ayres(n 249).
[252] Three Mile Island case see Rees JV, *Hostages of each other: The Transformation Of Nuclear Safety Since Three Mile Island* (University of Chicago Press 2009).

seeks to design self-regulating social systems by establishing norms for organisational structure and for procedures.[253]

This strategy can also be viewed as a form of 'meta-risk management' whereby governments, rather than regulating directly, oversee the risk management of individual enterprises. A reflexive environmental law for instance is 'a legal theory and a practical approach to regulation that seeks to encourage self-reflective and self-critical processes within social institutions concerning the effects' on the environment.[254]

This approach has some issues when it comes to regulating biotechnology, and these are outlined as follows:

a) Biotechnology is a complex problem that does not lend itself to prescriptive regulation.[255] It is rightly pointed out by Gunningham that regulatory systems are slow to evolve and adapt. Governments also often react to technological change in the private sector rather than driving change. There are some known practical difficulties in biosafety regulation such as tracking cross-border trade in GMO, and enforcing biosafety regulations at farm level. These difficulties present

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[253] Fiorino DJ, 'Rethinking Environmental Regulation: Perspectives on Law And Governance' (1999) 23 Harv.Envtl.L.Rev. 447.
[254] Eric W. Orts, ` A Reflexive Model of Environmental Regulation',
Business Ethics Quarterly, Vol. 5, No. 4, The Environment (Oct., 1995) 779
[255]Gunningham N, 'Regulating Biotechnology: Lessons from Environmental Policy' (2007) in Somsen, H, *The Regulatory Challenge Of Biotechnology: Human Genetics, Food And Patents* (Edward Elgar 2007).

technical, logistical and administrative challenges to even the most developed countries.[256]

b) There is a substantial imbalance of knowledge between government and the biotechnology industry. The independent risk assessment on the information supplied by the companies and risk management. The industry is far more capable of identifying the risks at ground level, and of managing them, than the regulators. It is on the basis of this fact that some opinions are that the regulation of biotechnology should be left to the industry.

Newell and Glover[257] rightly described biotechnology companies as the 'street level bureaucrats' of biotechnology that are expected to implement biosafety regulation determined by the government. They are the front line producers and distributors of the technology and are in a position to provide insights and use their experience to design the regulatory system. The fact that the companies have the in-house scientific expertise and capital makes them potentially excellent key advisers and also powerful political players.

However, the industry actions will only be effective, if given incentives to manage the risks and only if this risk management is closely scrutinised by government and the threat of more direct intervention is

[256]Newell P and Glover D, *Business and biotechnology: Regulation And The Politics Of Influence* (2003) 8.
[257] ibid 9.

imminent if it fails in its actions. Thus, independent risk assessments on the risk management information supplied by the industry and its companies are needed. It seems that there is little choice but to take this path.

Parker[258] states that corporate self-regulation has a public, social, and legal responsibility. The corporate self-regulation area is accountable to public debate and public dialogue.

Another issue is that the gap between the meta-regulation framework and the reality may be so large it is unattainable in biotechnology and it might appear more attractive on paper rather than in reality.

For example, the industry corporate may not view non-compliance in the same regard as the regulators but as an aspect of risk management. Regulators may view non-compliance as failure. When shareholders are looking to maximise their returns, and protect their investments, corporate stakeholders may prioritise minimising the loss of reputation rather than ensuring compliance when economic benefits are considered.

Baldwin[259] is correct in stating that it is not possible to 'stimulate corporate self-regulation' or to produce coherence and harmony between corporate and social needs and that it may rather be a case of 'confusion and

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[258]Parker C, *The Open Corporation: Effective Self-Regulation And Democracy* (Cambridge University Press 2002) 246.
[259] (n175).

conflict'. Parker's[260] view in the case of biotechnology is the sort of permeability may not be practicable given.

There are also concerns that permeability and deliberation will lead to regimes of 'high cost, high friction management that are characterised by delays, obfuscations, smokescreens, indecisiveness, confusion and inaction.[261]

Here, meta-regulation is indeed a viable regulatory option, however its credibility is still questionable or that it may be another variant of self-regulation. Would meta regulation regain public trust in its government's management of biotechnology safety? In Europe, public trust is said to be at low ebb especially after the food safety scandal illustrated in the Introductory Chapter.

b) Civil regulation

Civil regulation is where organisations in society,[262] such as NGOs, set the standards for business behaviour. Civil regulation, according to Murphy and Bendall,[263] is established by organisations such as NGOs and enterprises either choose to follow the standards or not. The arguments supporting civil regulation include: a lack of State resources; and political

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[260] Parker C, *The Open Corporation: Effective Self-Regulation And Democracy* (Cambridge University Press 2002) 246.
[261]Baldwin R, 'The New Punitive Regulation' (2004) 67(3) The Modern Law Review 351.
[262] Diamond LJ, 'Toward Democratic Consolidation' (1994) 5(3) Journal of democracy 4.
[263]*Murphy*, D. and J. *Bendall* (*1998*), '*Editorial*', *Greener Management* International, 24,8.

incapability to reach businesses outside national territories. The goals of civil regulation are to fill in the gap left by the State and to compensate for the 'deficit of democratic governance that we face as a result of economic globalisation'.[264]

Under civil regulation, there are numerous methods society can influence corporations, consumers and markets, often bypassing the State and rejecting political lobbying. In biotechnology, this may be seen by direct action against large reputation-sensitive companies, such as boycotting products that are environmentally harmful, or market campaigning against high-visibility branded retailers. There may also be information campaigns, political discourses, lobbying retailers such as McDonalds to reduce demand for GM food, influencing inter-government forums for stricter trade regulations. Civil regulation may occur in the form of watchdogs and monitoring, or by litigation.[265]For example, March Against Monsanto is an example of civil society opposition to GM food and products that advocated for mandatory labelling of GM products.

Governments are gradually providing for more involvement of communities, environmental groups and the public which should be applauded especially as this in line with the Cartagena Protocol on Biosafety. This may be due to particular pressure from outside, or due to the

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[264] Bendell J, 'Civil regulation: A New Form Of Democratic Governance For The Global Economy' (2000) 201 In Terms For Endearment: Business, NGOs and Sustainable Development 239.
[265] Prakash A and Kollman KL, 'Biopolitics in the EU and the US: A Race to the Bottom or Convergence to the Top?' (2003) 47(4) Int Stud Q 637.

government recognising the limits of State regulation. Many NGOs are of the view that governments are influenced by the multinational biotechnology companies. Hence the norms of the precautionary principle, transparency and sustainability should be globally accepted.

It is argued that civil regulation is essentially a form of voluntarism by way of corporate social responsibility (CSR).Thus civil regulation alone is essentially self-regulation thus not suitable for adaptation. This is further supported by the facts that in some countries, the state and business community will exert their power and influence over the public. Thus civil regulation seems unsuitable strategy of regulation.

On the flip side, the problem with civil regulation is that society cannot stand as the sole gatekeeper that produces countervailing forces. For instance, lobbying, boycotts and remedial actions create opposition in biosafety regulation. Hence it lies the importance of meta regulatory strategies such as pre-market approval and risk assessments with government oversight.

c) Licence model

As there is not any real development of the new governance approaches in biosafety, thus this would fit with the licence model for discussion.

The licence model developed by Gunningham, Kagan and Thornton (2003)[266] endeavours to explain why large business enterprises behave the way they do towards the environment, and considers the normative and policy implications of these behaviours.

Thus it views business enterprises as motivated and constrained by the three types of licences which are:

i) a regulatory licence
ii) a social licence
iii) an economic licence

These three licence examples are monitored and enforced by the stakeholders who generate them. Thus in the context of biotechnology, this model gives a useful insights of the interaction between these three different licence types.

In biosafety regulation, the environmental group may use social licence to shame and adversely publicise GM goods. This group may also use economic licence through consumer boycotting of GM products or 'Frankenstein' food.

The impacts from each and every licence may be different. For example, the social activist may be given regulatory licence by having access to information such as the level of public participation in the biosafety

[266] Gunningham N, Kagan RA and Thornton D, *Shades of Green: Business, Regulation, and Environment* (Stanford University Press 2003).

decision-making process. As a result, companies that fail to respond to social licence or economic licence face the risk of products being rejected by consumers. The NGOs in the biosafety area must subject their expert claims to public scrutiny that challenges their risk-based and scientific-based decision-making processes. Hence, important aspects in biosafety such as precautionary principle, sustainability and transparency are being introduced.[267]

Regulatory licence plays an important role in curbing the food safety risks and environmental risks in biotechnology. Companies will have to perform to the minimum standard and in doing so the economic licence is undermined. Failure to obtain a regulatory licence could cause companies to exploit technology that is free from constraints but that ignores ethical and social issues. The companies' interests would be seen as largely economic. However, the extent to which regulatory licence plays such a role depends on the political strengths of the key stakeholders. The idea of involving wider parties in procurement formulation is important for knowledge and legitimacy to provide the space for the socio-economic and cultural factors to be taken in the regulatory field. To what extent this licence model could play a role would be analysed later in the Malaysian context in Chapter 3 and 4.

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[267]Newell P and Glover D, *Business And Biotechnology: Regulation And The Politics Of Influence* (2003).

An analysis of the biosafety regulatory strategies

From the above analysis it can be seen that there are two main strategies in biosafety regulation namely the command and control approach and new governance. The four regulatory frameworks by Gunningham above have their own advantages to offer biosafety regulation. Smart regulation and regulatory pluralism have a plethora of instruments that enable the regulatory State to steer rather than row and harness the capacity of second and third parties to fill the gaps left by the State. Meta-regulation will be reliable and effective if regulatory structures exist that strengthen the capability of individual institutions and enterprises for internal reflection and control. Under civil regulation, the civil institutions will be empowered if the state provide mechanisms and make corporations more accountable. Lastly, the licence model framework is viable if mechanisms are devised that reinforce the various strands and interactions of the social and economic licences.

Gunningham rightly viewed each framework has having something to offer and making different contributions in accordance with the nature and context of different policy issues. Gunningham, in his conclusion, stressed the importance and relevance of direct state regulation in environmental policy, biotechnology and hence biosafety policy.

The command and control still play important roles in biosafety regulation in many countries. Scott[268] criticises the use of old and new regulatory instruments that highlight weaknesses which focus narrowly on the conduct of government departments and agencies. On the deployment of law sets normative standards or incentivises compliance with such standards, which Scott also sees as weaknesses. The new governance beyond command and control offers variety of mechanisms of regulatory for effective implementation. Scott rethinks the biotechnology governance from a different perspective that focuses on the process of monitoring and mechanisms of behavioural modification.

It is submitted that while the strategy is argued either should be command or control or new governance, it is very much dependant on the countries' biosafety capacity building. In most countries where the role of the state is central to biosafety regulation, it is hoped that in future there should be more involvement of more stakeholders effectively in the decision-making process. The idea of involving wider parties is important for knowledge and legitimacy in particular to provide a medium for the socio-economic and cultural factors as abovementioned.

Top-down and bottom-up approaches in biosafety policy implementation

Another issue posed by regulation is whether a top-down or bottom-up approach should be taken, as both have their own benefits and implications.

[268] Scott C (n219).

From the institutional viewpoint, the strengths and weakness of those institutions and ways to improve will be analysed. Although an institutional framework is typically regarded as adding to bureaucracy, it is more important to strengthen those institutions to reflect both the expert and layperson's key views.

A top-down approach involves the policy–makers as the central actors,[269] also known as an autocratic leadership approach whereby the upper management make decisions to improve policy.[270]The bottom-up approach involves local stakeholders participating in the decision-making of strategies and priorities for their local area.[271]

In biosafety, legal and institutional frameworks are predominantly seen as top-down approaches. This is due to the fact that the government as the regulator and enforcer makes decision such as accepting or refusing LMOs. Decisions/sanctions are imposed on the applicants/wrongdoers. It is interesting that, in the biosafety decision-making process, the government's consideration of public views is in line with the Cartagena Protocol on Biosafety. The extent to which the public views affect decisions, however, is not overtly stated.

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[269]Cerna L, 'The Nature Of Policy Change And Implementation: A Review Of Different Theoretical Approaches' (2013) Organisation For Economic Cooperation And Development (OECD) Report 18 Citing Matland, R. (1995), 'Synthesising The Implementation Literature: The Ambiguity-Conflict Model Of Policy 9 as cited i implementation', Journal of Public Administration Research and Theory 5(2): 145.
[270]Carol Deeb, 'Top-Down Approach to Policy Decisions' (2017) <http://smallbusiness.chron.com/topdown-approach-policy-decisions-35494.html> accessed on 20 January 2017.
[271]European LEADER Association for Rural Development, 'The Bottom Up Approach' <http://www.elard.eu/en_GB/the-bottom-up-approach> accessed on 20 January 2017.

7. Fundamental pillars of effective biosafety regulation

Having discussed on the relevant biosafety regulatory strategies, the discussion moves on the principles of good biosafety regulation. There are some important foundations to biosafety regulation, which are the following: risk assessment, mandatory pre-market approval, and established safety standard. Whilst this thesis does not intend to discuss the effectiveness of biosafety regulation in Malaysia (Chapter 3 and 4) in detail, these pillars will be examined in order to improve the existing biosafety system not just for compliance with the Cartagena Protocol on Biosafety but also for capacity building.

What is good biosafety regulation?

According to Baldwin,[272] there are five (5) key tests that denote good regulation, namely:

a) support by legislative authority
b) accountability
c) fair, accessible and open
d) sufficient expertise
e) efficient

A good biosafety regulation should contain all those characteristics. Throughout this thesis, references to Malaysian biosafety rules and

[272] Baldwin (n 17575) 26.

regulations will be made as to ascertain the adequacy of those laws, and ways to improve those laws will be suggested. However it is noted here this is a doctrinal research whereby perhaps some characteristics could not be sufficiently, adequately assessed, only on the surface as it based on primary and secondary sources only. However a future research on those important issues is desirable.

It is further submitted that a good biosafety regulation should ideally covers all intended risks including the scientific and non-scientific risks (socio-economic considerations namely ethical and religious beliefs, and cultural factors). The rationales have been discussed in the Introductory Chapter. The present issue is that the scope of socio-economic considerations needs to be broadened (Article 26 of the Cartagena Protocol on Biosafety).

A formal method of assessment of risk has not been prescribed; hence socio-economic groups have proposed the socio-economic impact assessment (SEIA). A sound biosafety regulation should not just be technocratic (taking expert opinion into consideration) but should also have a layperson's view for public acceptance of LMOs, rules, and regulations. The justification for democratic public participation is a vital element in smart regulation. National biosafety regulation should be transparent, predictable, efficient and effective[273] whether it is comprehensive or not.

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[273]Gregory Jaffe, 'Implementing the Cartagena Biosafety Protocol Through National Biosafety Regulatory Systems: An Analysis Of Key Unresolved Issues' Journal of Public Affairs (2005).

National biosafety laws and regulatory strategies

The rules and regulations of biosafety, for most countries, focus on the transboundary movement, handling, transit, contained use and release of genetically modified organisms into the environment. Some countries implement comprehensive biosafety laws, whereas others have partially comprehensive or minimal laws. The degree of regulation depends on various factors such as countries' priorities, capacity building, biodiversity policies and so on. Regulations are further strengthened by the relevant biosafety institution that establishes the biosafety laws.

The framework of biosafety regulation in compliance with Cartagena Protocol on Biosafety has an element of 'regulatory pluralism' as it uses various strategies. The main strategy is command and control as the government is taking the central role in regulating the import, export and contained use of genetically modified products with the aims of protecting the human health and environment. This approach is criticised as a hindrance to the growth of science and technology as it adds more to the regulatory costs.[274] Another important strategy is of the new governance as it takes into account the public's opinions and concerns. This is directed under Article 23 of the Cartagena Protocol on Biosafety that stipulated public awareness and participation.

However, the way in which the regulatory framework shapes the law is by including the various stakeholders of genetically modified products,

[274]M.K. Sateesh, *Bioethics and biosafety* (IK International Pvt Ltd 2008).

namely the regulator, the public and the business community. It is not an easy task to fulfil the expectations of these stakeholders, therefore an examination of the very basic nature of regulations and law in society seems to be a good starting point of analysis for biosafety regulation.

It is interesting to note here that Gunningham acknowledges that the political, social, economic and scientific contexts in which biotechnology and environmental regulation must operate are very different. Biotechnology regulation must take into account several factors such as high scientific uncertainty, high risks, an imbalance in knowledge and power between the State and the private sector, and the lack of public trust. These are among the core issues of biotechnology regulation to that need to be analysed for the protection of human health and the environment.

8. Cartagena Protocol on Biosafety

Biosafety regulation at the international and national levels

While the relevant regulatory theory and strategies on biosafety have been much discussed above, it is then important to move to the discussion on the biosafety regulation in practice i.e. the Cartagena Protocol on Biosafety as the internationally signed agreement on biosafety.

Due to globalisation and international concern about environmental issues and economic co-operation, it is a growing trend that international agreements be ratified by signatory parties at international conventions. It is

true that in the field of biotechnology, the diverse and multicultural nature of the international community hinders a consensus on a core set of ethical values and interests.[275] This was the case in biosafety regulation and in the Cartagena Protocol on Biosafety, and reflected various countries' stance and ethical values. These will be discussed more in Chapter 3 within the Malaysian context.

As mentioned earlier, the common aims of ensuring effective regulation and governance of biosafety are found in many countries, and biosafety is regulated through national laws and recognising international agreements such as the Cartagena Protocol on Biosafety. Biosafety regulations are either comprehensive or not comprehensive as they may overlap with other laws such as biodiversity, biosecurity and regulations of various agencies and ministries which aim to protect human health and the environment.

At a national level and in reference to the issues of transboundary handling, movement, transit of LMOs, and contained use of genetically modified products, the main Biosafety Act will take the lead in ensuring compliance with the Cartagena Protocol on Biosafety. This will occur in most countries that ratified the Protocol, and the power to enforce biosafety laws will usually lie with the Ministry of Environment.

There is a full range of frameworks and tools used for ensuring the effective regulation of biosafety. Countries that ratified the Cartagena

[275]Francioni F, *International Law For Biotechnology: Basic Principles* (2006) 5.

Protocol will legislate their own biosafety Acts in compliance with the Protocol and through the statutes and regulations that permit the establishment of national laws and institutional biosafety measures.

LMOs have been regulated at international agreements in various WTO instruments. The Cartagena Protocol on Biosafety is the main international agreement that regulates any transboundary movement of LMOs which is an environmental aspect of biosafety governance. Other areas of biosafety regulation are either ruled by lab protocol and procedures, and biosecurity measures for highly contagious biological agents.

The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety can be seen as the realisation of biosafety risk regulation at the national and international level. It should be highly praised as an international environmental biosafety agreement that has attempted to balance the benefits of modern biotechnology products (mainly LMOs and their rapid development, utilising simultaneous biodiversity) with protecting human health and the environment.

The Cartagena Protocol on Biosafety to the Convention of Biological Diversity is an international instrument that achieves agreement on biosafety regulations to regulate the transboundary movements of living modified organisms (LMOs) that are the result of modern biotechnology. It was adopted on the 29th January 2000 as a supplement to the Convention on Biological Diversity (CBD) and came into force on 11th September 2003.

Previously, biosafety concerns arose during the CBD that highlighted the need to regulate LMOs pursuant to Article 19 of the CBD. Article 19(1) of the CBD emphasised the importance of the Contracting Party especially the developing countries to prepare legislative, administrative or policy measures

and to provide for the effective participation in biotechnological research activities. More importantly, Article 19(3) states the need for a protocol to set out the appropriate procedure, including a specific, detailed informed agreement, for the safe transfer, handling and use of any living modified organisms from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.

Thus the Cartagena Protocol on Biosafety fulfilled the CBD by providing procedures for the transboundary movement of LMOs and called these the Advanced Informed Agreements (AIA).[276] This included the LMOs intended for feed, food, or processing (LMOs-FPP)[277] and the AIAs defined the practical requirements for handling, transportation, packaging and identification of LMOs that undergo transboundary movement.[278] This Protocol upgraded the procedures from a standard procedure for transboundary movement of LMOs to a Protocol or system of rules to be followed by the signing countries. It established the first step in acceptable international standard practice and the procedures in handling LMOs. [279]

The Protocol also established the Biosafety Clearing-House[280] in order for countries to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms.[281] The Cartagena Protocol on Biosafety also reaffirms in its preamble the

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[276] Cartagena Protocol on Biosafety art 7.
[277] ibid art 11.
[278] ibid art 18.
[279] Jaffe (n 7979) 309.
[280] Cartagena Protocol on Biosafety art 20.
[281] ibid art 20(1)(a).

precautionary principle that is contained in Principle 15 of the Rio Declaration on Environment and Development. Principle 15 states that for the protection of the environment, each State is to apply the precautionary principle according to its capabilities in the case of threats of serious or irreversible damage, and, where there is a lack of full scientific certainty, this shall not prevent them from taking cost effective measures to prevent environmental degradation.

Historical background of the Cartagena Protocol on Biosafety

It is interesting and useful for the brief history[282] of the Cartagena Protocol on Biosafety to be summarised here, as later, certain issues on biosafety in the Malaysian and Singapore context need to be understood. During the negotiations of the CBD, the majority view called for the negotiation of a biosafety protocol as contained in UNEP's Panel IV Report (UNEP 1993), and a minority group rejected the Protocol. This group consisted of the United States and representatives from the Organisation for Economic Cooperation and Development (OECD). The United Nations Environment Programme (UNEP) then promoted the UNEP International Guidelines for Safety in Biotechnology in order to stifle the majority call for a biosafety protocol. However, this was soon discovered by developing countries and environmental NGOs, and they called for the UNEP Panel IV

[282] Egziabher TBG, 'The Cartagena Protocol On Biosafety: History, Content And Implementation From A Developing Country Perspective' (2007) in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007).

Report to start negotiations on the Protocol.[283] The negotiating countries were divided during the Conference of Parties at meetings for the Parties to the Protocol (COP-MOP)[284] but they later accepted the need to negotiate a biosafety protocol due to the risks and effects of LMOs from modern biotechnology. However, once biosafety protocol negotiations had started, they were divided on whether socio-economic considerations and liability and redress issues should be included in the biosafety protocol. In the end, the controversial protocol issues were resolved and that led to the establishment of the Cartagena Protocol on Biosafety despite with delays from original plans for sign-off in Cartagena in 2000.

Key Protocol Issues

It is relevant to note here that there are some key issues for compliance[285] with the Protocol and these issues need to be integrated into the national laws of the ratifying signatory members. Specifically:

a) handling, transport, packaging and identification[286]
b) liability and redress[287]
c) public awareness and participation[288]
d) risk assessment[289] and risk management[290]

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[283] ibid 2.
[284] Cartagena Protocol on Biosafety art 34.
[285] ibid.
[286] ibid art 18.
[287] ibid art 27.
[288] ibid art 23.
[289] ibid art 15.

e) socio economic consideration[291]

f) risk and precautionary principle

The key protocol issues mentioned above are significant as they affect the rules and regulations of the nation State and the way it responds to the Biosafety Protocol. The discussion will also assess whether the relevant Malaysian rules and regulations effectively deal with those biosafety issues.

a) Handling, transport, packaging and identification (Article 18)

This biosafety measure requires products that contain LMOs for food, feed or processing (LMOs-FPP),[292] LMOs in contained use,[293] and those released into the environment,[294] to be clearly identified. This then raises the issue of the labelling of LMO products not just during shipment to the destined countries but also when they reach the consumers in the form of the final products. There is the issue of the cost of labelling to the industry. This issue will be examined further in the next chapter in a Malaysian context and will deal with consumer choices, preferences and beliefs.

However questions arise as to whether effective labelling is a consumer-choice issue and has emerged at the expense of the benefits

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[290] ibid art 16.
[291] ibid art 26.
[292] ibid art 18(2)(a).
[293] ibid art 18(2)(b).
[294] ibid art 18(2)(c).

gained from LMOs products. This is closely associated with public awareness issues.

Another issue is the halal labelling of LMOs and is a cross-over on issues of public awareness, ethics, religion and socio-economic consideration. It could be argued that these issues have no relevance to biosafety. It also raises the question as to whether labelling provides a solution for consumer choice, ethical, and religious belief issues. There may be a more serious sustainability development issue.

In reflecting the addressing of these issues is labelling the answer to solve these problems? This perhaps depends on the precise problem that needs to be addressed. This is especially relevant in the Malaysian context with regard to the halal labelling and LMOs. The question arises - is Halal a purely biosafety issue? Or can it be considered a part of the socio-economic considerations? These issues are going to be discussed in more detail in the next chapter 3 in the Malaysian context.

b) Liability and redress (Article 27)

The COP-MOP will adopt appropriate international rules and procedures for liability and redress for damages resulting from transboundary movements of living modified organisms, and this process should be completed within four years. This is another issue voiced by developing countries like Malaysia and in furtherance to that in its decision BS-V/11 the COP-MOP adopted the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress. The Supplementary Protocol provides international rules and procedures on liability and redress for damage to biodiversity resulting from LMOs.

c) Public awareness and participation (Article 23)

In the previous Introductory Chapter, the theories and justifications of public participation were discussed. The Cartagena Protocol on Biosafety requires the signatories of the Protocol to facilitate public awareness and to consult the public in the decision-making process since it affects them directly. Article 23(3) states that each party must inform the public through the Biosafety Clearing-House. The issues remain on how to go about consulting the public and the effectiveness of public participation in the biosafety decision-making process.

d) Risk assessment (Article 15) and risk management (Article 16)

There are tools both for risk assessment and risk management. These align the World Trade Organisation's (WTO) agreements that include the Sanitary and Phytosanitary Measures Agreement (SPS Agreement), The Agreements on Technical Barriers to Trade (TBT Agreements), Agreements on Trade Related Aspects of Intellectual Property Rights (TRIPS), and General Agreements on Tariff and Trade (GATT) with Cartagena Protocol on Biosafety .Risk assessment and risk management are the two main tools used when assessing importation and exportation of LMOs. The implementation of these tools is different even though they are part and parcel of the same process.

The risk assessment part is the scientific assessment that a country makes when deciding on the importation of goods. Risk management utilises non-scientific tools to assess other factors in relation to the same issue. A discussion, however, on the TBT Agreements, SPS Agreements, TRIPS and GATT is beyond the scope of this thesis as the sole focus of this study is on the Cartagena Protocol on Biosafety. These agreements are to illustrate that there are a variety of models used in the global risk regulatory system. Risk

assessment, according to the Cartagena Protocol on Biosafety, should be carried out in a scientifically sound manner[295] and be based on a minimum provision of information under the notification procedure.[296] Other available scientific evidence should also serve to identify and evaluate the possible adverse effects of LMOs on biodiversity and the risks to human health. This risk assessment must be done by the Party of Import and may require the exporter to carry it out.[297]

The risk management process[298] requires all parties to establish and maintain appropriate mechanisms, measures and strategies in order to regulate, manage and control risks identified in the assessment of the use, handling and transboundary movement of LMOs. Thus, risk management even though part of the same risk procedure, is classified as a 'non-scientific' tool.

Professor Beck[299] is of the view that risk assessment underestimates the real threats and relies on methodologies that legitimise individuals' exposure to incalculable risks. Whilst that may be true, the label 'risk' suggests only probabilities of those risks as opposed to real danger. In this regard, the adoption of the precautionary principle in the Cartagena Protocol on Biosafety is justified.

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[295] ibid Annex III.
[296] ibid art 8.
[297] ibid art 15(2).
[298] ibid art 16(1).
[299] Beck U, 'Living In The World Risk Society: A Hobhouse Memorial Public Lecture given on Wednesday 15 February 2006 at the London School of Economics' (2006) 35(3) Economy and society 329-45.

e) Socio-economic considerations (Article 26)

This is one of the most controversial issues in the Protocol as it originally outlined the scope of socio-economic considerations arising from the impact of LMOs. This includes the conservation and sustainable use of biological diversity, especially on the value of biological diversity to indigenous and local communities. However, despite its confined scope, there were various suggestions on socio-economic considerations from countries' multi-ethnic and multicultural beliefs that attempted to broaden this scope.

f) Risk and the precautionary principle

Precautionary principle, mentioned in the preamble of the Protocol, reaffirms Principle 15 of the Rio Declaration on Environment and Development. This is in relation to the uncertainty in science that leads to the precautionary principle being applied.

The precautionary principle was not favoured by WTO and its related trade agreements and there was resistance from the Miami Groups.[300] Despite this opposition, the Principle was enforced for the protection of human health and the environment due to the modern biotechnology risks. Whilst the focus of biosafety regulation is on the risks of modern

[300]Egziabher TBG, 'The Cartagena Protocol On Biosafety: History, Content And Implementation From A Developing Country Perspective' (2007) in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007)7.

biotechnology, it is important that the specific (biosafety or LMO) risks are identified and the methods for regulating those risks. Thus, risk assessment and management plans are good tools for covering the scientific aspects and managing the identified risks. In an era of growing information, research and development on modern biotechnology, there are still uncertain risks in science, thus the precautionary principle is rightly adopted by the Cartagena Protocol on Biosafety.

Criticisms of the Cartagena Protocol on Biosafety

The ground-breaking Cartagena Protocol on Biosafety was signed and agreed through various negotiations among various countries who signed the Convention on Biological Diversity (CBD). The negotiation process was lengthy and there were many issues that were not agreed upon by countries that later re-grouped themselves. These groups became the Miami Groups,[301] Like-Minded Group of Developing Countries,[302] European Union, Compromise Group,[303] Central and Eastern European Group and others. During the negotiations, the Miami Groups, Like-minded Group of Developing Countries and European Union played more active roles whereas Central and Eastern European Group remained rather quiet.[304]The main issues which divided opinions were the inclusion of socio-economic consideration,

[301] Canada, Australia, Argentina, Uruguay, Chile, and the United States of America
[302] The developing countries, with the exception of Mexico, Argentina, Chile and Uruguay
[303] Mexico joined with Japan, Switzerland, Norway, and New Zealand
[304]Egziabher TBG, 'The Cartagena Protocol On Biosafety: History, Content And Implementation From A Developing Country Perspective' (2007) in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007.

liability and redress, products of LMO, the precautionary principle, the scope of the Protocol, and packaging and labelling. In the end, the content and scope of the Protocol concluded with a compromise between the various groups' interests and opinions. However, the compromise also led to some countries who had re-grouped not signing the Protocol despite the lengthy negotiations. Uruguay from the Miami Group ended up signing and ratifying the Protocol.

Australia's move was timely in enacting the Gene Technology Act 2001 which specifically regulates gene transfer technology. At the international level though, and with criticism from the Miami groups namely United States of America and its allies, Australia they refused to sign the Cartagena Protocol on Biosafety. Australia appears to be more open to the acceptance and growing business of biotechnology products.

However if other related WTO agreements on LMOs, modern biotechnology and biosafety are taken into account, there would be much more debate on issues that are not relevant are here. The difference might be about the openness of a country in accepting or not accepting genetically modified products. This may be due to local conditions that need to be taken into account and that will be discussed later in the Malaysian context.

The Cartagena Protocol on Biosafety not only provides a minimum[305] set of rules and procedures, it also attempts to deliver global harmonisation of biosafety regulation. The Protocol provides a good model for biosafety regulation. It is more than an acceptable and common practice for the transboundary movement of LMOs; it was a negotiated Protocol that had the effect of becoming a legally-binding and comprehensive international treaty.[306] It is evident that the Cartagena Protocol on Biosafety is the primary force behind the establishment of a national biosafety framework for many countries. It provides a common and coordinated approach to address the potential risks of LMOs and balances the various competing goals like environmental protection, modern biotechnology utilisation, trade, national sovereignty and the relationship with other international treaties.[307]

Strengths of the Protocol

It is important to acknowledge the strengths of the Protocol, as discussed by Jaffe,[308] which can be summarised as follows:

a) The proportionate risk-based reviews

Cohen[309] rightly stated that a good regulatory system looks at each application individually and assesses the potential risks to human

[305]Gregory Jaffe, 'Implementing the Cartagena Biosafety Protocol Through National Biosafety Regulatory Systems: An Analysis Of Key Unresolved Issues' Journal of Public Affairs (2005) (n79) 299.
[306]ibid.
[307]ibid.
[308] ibid.

health and the environment based on a scientific risk-based analysis. Each application must meet the relevant safety standards which can be seen in the procedures of the Protocol. For LMO release into the environment which carries a relatively higher risk, the Advanced Informed Agreement (AIA) requires a risk assessment, a risk management plan, and consent by the importing party. For LMOs that are used for FPP and that carry a significantly lower risk, an AIA is not needed but parties are allowed to make decisions based on the safety decision of the exporting country or may conduct their own risk assessments. For LMOs in contained use such as in labs with lesser risks, there are no required safety procedures. Article 7 exempts certain LMOs that have no adverse effects from AIAs.

b) Clear and understandable procedures

The AIA procedures[310] laid down in Article 7 to Article 10 of the Protocol are clearly explained for LMOs released into the environment, and clearly state what type of notification is required by the Party of Import.[311] Article 10[312] also states the procedure expected and the timeframe for risk assessment for the Party of Import. For LMFPP,[313] the same procedure is applicable for the parties concerned. The Protocol also states that an AIA does not apply to transit and

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[309] Cohen JI, 'Harnessing Biotechnology For The Poor: Challenges Ahead For Capacity, Safety And Public Investment' (2001) 2(2) Journal of Human Development 239.
[310] Cartagena Protocol on Biosafety art 7.
[311] ibid art 8.
[312] Decision Procedure.
[313] ibid art 11.

contained use.[314]For any new scientific information, review of decision,[315] is laid down the procedure, rights and timeframe for the Parties of Import and Export are also laid down. Thus, the Exporting Party will know the type of information that they need to supply and the consequences, rights and obligations of the Importing Party, and the public will be informed on how such decisions are reached.

c) Risk assessment information and analysis

Annex I requires the information of the intended LMOs for notification which are detail in nature as to its origin and taxonomic status. Annex II requires the same information for LMFPP. A risk assessment is provided in Annex III which should serve as a general guide for countries to make their own more detailed risk assessments. Risk assessment essentially sets out the general principles, methodology and points to consider. These analyses are detailed in nature for risk assessment, so as to suit the requirements of the local conditions and the nature of biodiversity.

Unsettled aspects of the Protocol

Despite these strengths, there are some important issues that remain controversial and unresolved by the Protocol and these could be taken into

[314] ibid art 6.
[315] ibid art 12.

consideration by individual countries in their national biosafety laws. They are listed below:

a) Legal Safety standards

Whilst the Cartagena Protocol on Biosafety's Article 7 provides AIAs for release into the environment, the Protocol lacks an essential safety standard for decisions on approvals permitting release. Such a standard is not prescribed anywhere in the Protocol. This may lead to countries applying different safety standards.

Below are some good examples of safety standards:

1) EU Regulation 258/97 states that genetically modified food must not '…*present a danger to the consumer...*'[316]

2) United States Food and Drug Administration 1992 for GM food states that food additives have '…*a reasonable certainty of no harm*…'

3) US FDA 1992 states that for biotech crops a different standard is applied to ensure that it is 'substantially equivalent ' to their conventional counterpart.

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[316]European Parliament. 1997. Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. *Official journal of the European Union* L043 40: 0001-0006.

Whilst it is up to the national government or sovereign State to apply safety standards, their obligations towards other international agreements should be considered. These might include not being overly trade-restrictive, not based on scientific assessment, or being over-reliant on socio-economic considerations.

b) Socio-economic considerations

As previously mentioned, Article 26 of the Cartagena Protocol on Biosafety literally states that countries may take socio-economic factors into consideration when assessing the LMOs impact on biodiversity, and especially the value of biodiversity to the local and indigenous people. It is again at each country's discretion as to the degree of influence that socioeconomic factors will have in the decision-making process.

The definition of socio-economic considerations is also questionable as some groups believe that its scope is limited to Article 26.[317] This view means that it can only include the value of biodiversity to the local and indigenous people.

Conversely, there are other stakeholders who believe that socio-economic considerations may be broader and may include:

> *'... impacts on farmers' incomes and welfare, cultural practices, community wellbeing, traditional crops and varieties, domestic science and technology, rural employment, trade and competition, the role of*

[317] Ruth (n 71) 163.

transnational corporations, indigenous peoples, food security, ethics and religion, consumer benefits, and ideas about agriculture, technology, and society…'[318].

However, the most important thing is that any inclusion of socio-economic considerations must align with a country's obligations to other international agreements,[319] such as WTO agreements for example. Countries should consider incorporating broader socio-economic factors that could be addressed through other means such as voluntary processes by research and institutions, and rules and regulations.[320] It is agreed that when countries do use socio-economic considerations, it is vital how, when, and which factors to be used[321] to show transparency and the efficiency of those considerations. Fransen[322] even presented examples on how socio-economic considerations should be analysed for interested countries.

Whilst the US and Canada did not take socio-economic factors into account for their risk assessment framework, Argentina requires market analyses as a third part to the approval process, and can deny approval if the risks or products can affect the economy of the country.[323] The next Chapter

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[318] Garforth, 2004, *Socio-Economic Considerations in Biosafety Decision-Making: An International Sustainable Development Law Perspective (as cited in* La Vina A and Fransen L, 'Integrating socio-economic considerations into biosafety decisions: The challenge for Asia' (2004) International Development Research Center (IDRC): Ottawa, Canada).
[319] Cartagena Protocol on Biosafety art 26(1).
[320] Fransen L and others, *Integrating Socio-Economic Considerations into Biosafety Decisions* (Washington, DC: World Resources Institute 2005).
[321] ibid.
[322] ibid.
[323] Burachik M, Traynor PL. 2002. *Analysis of a national biosafety system: regulatory policies and procedures in Argentina*. ISNAR Country Report (as cited in Jaffe (n79).

3 will examine how Malaysia takes socio-economic considerations into account.

Scientific and socio-economic issues

The question is often what are the real issues that we are trying to regulate? The public are concerned about the goods and products that they consume and they neither understand nor believe science.

Biosafety regulations address both issues, namely the scientific risk and the public concern. This is explained by the position of the Cartagena Protocol and the Malaysian National Biosafety Act 2007. In these, the first and foremost issues to be tackled are: the scientific biosafety issue of any irreversible damage or harm which is the adverse effect of modern biotechnology products (this is the transboundary issue that led to the establishment of the Cartagena Protocol); and, the vital public perception issue as consumers that affect the production, perception and consumption of genetically modified products. The public perceptions may exist due to the consumer's own awareness, or propagation of some known environmental groups such as Green Peace, that give the impression that genetically modified goods are bad from an ethical viewpoint.

The public concern that should be reflected in biosafety regulations was defined in Article 23 of the Cartagena Protocol on Biosafety. This Article introduced public participation and awareness on biosafety, so that the public has a say in what they are consuming. In compliance with the Protocol, the countries that are party to the Protocol need to adopt public awareness and participation strategy into their local regulations.. The discussion will examine in more in depth to what extent the public say actually has any power in biosafety.

The relationship between science and risk regulation, at the national and international level, stimulates an interesting discussion on the Biosafety Protocol, particularly as to how much reliance is put on science as opposed to the non-scientific methods of regulation. One issue highlighted by Peel [324] is the role of science that is viewed by governments in international risk regulation. The capability of science to identify the global risks and provide a basis for developing acceptable solutions is not without its flaws. This task places substantial demands on science and scientific experts, and these expectations will not be met in the case of scientific uncertainties and inherent normative aspects of risk regulation.

This scientific reliance, in my view, will cause problems for developing countries as they generally do not have the necessary local scientific experts and need to rely on foreign scientific experts. However, Peel later recognised two views on the science and non-scientific roles. From one viewpoint, science-based tools like risk assessments play an important role in curbing the excessive political debate on risk issues, they enable systemisation and they make the processes of risk decision-making transparent.

From the other viewpoint, there are 'technical and normative frailties'[325]that affect scientific risk assessments and these require non-scientific inputs, such as public views, in order to improve both their credibility

[324]Peel J, *Science and risk regulation in international law*, vol 72 (Cambridge University Press 2010) 3.
[325] ibid 387.

and broader social acceptance and are the basis for global risk decision-making.

Due to the nature of scientific uncertainty, it is unacceptable for scientific uncertainty to be prioritised without giving due and equal recognition to the social values or 'socio-economic' issues. There are assessment mechanisms for the scientific concerns in accordance with the Cartagena Protocol on Biosafety but there is very little scope for social values issues. It is contended that social issues are more obvious, predictable and bound to happen either immediately or gradually compared to scientific uncertainties which can be more worrisome. For example, GM products contain beef which cannot be consumed by Hindus and, if not labelled, the consumers consume the beef unknowingly. Public outcry would occur if the truth was somehow later discovered, and consequently the public would totally distrust GM products. This issue is foreseeable and predictable and actions should be taken to prevent such failures. Thus, social values should have the same significance as scientific concerns.

In summary, both science and law need to be recognised and legitimised to be accepted by decision-makers and the public as the end users of genetically modified products. For science to be accepted, the scientific assessment tools and the GM experts must be fully equipped, however this is beyond the scope of this thesis. With regard to the law, it is within the scope of this thesis to analyse how far, and in what ways the law

can be used to regulate biosafety, at the national and international level, and acceptable approaches to regulating it.

c) Public participation[326]

Article 27 of the Protocol provides for the promotion and facilitation of public awareness and participation. The issue is how public participation is included and implemented in regulatory decision-making.

In recent years, it is true that public participation has been a central element in the legal regulation of science and technology.[327] This could be related to the earlier argument on the acceptance of biosafety regulation by the public. The rationale for increased public participation is that it is critical for establishing an effective regulatory framework and this can be traced back to the Rio Declaration on the Environment and Development, the Aarhus Convention, and the Cartagena Protocol on Biosafety.[328] Furthermore, public participation is important in the overall national biosafety framework as well as in individual applications.[329]

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[326] Jaffe G (n79)299.

[327] A.Bora, and H. Hausendorf, Democratic Transgressions of Law: Governing Technology through Public Participation, (2010)(Brill Publication, Netherland)1-20 (as cited in Idris SH, Majeed ABA and Hamin Z, 'Public engagement in biosafety decision-making process: Appraising the law in Malaysia' (ICIMTR 2012 - 2012 International Conference on Innovation, Management and Technology Research 2012) 373)

[328] Lim Li Ching, 'Public participation in biosafety issues' (2007) in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007)555.

[329] ibid.

Whilst little guidance is provided by the Cartagena Protocol on Biosafety on how to implement public participation, the practice of some countries could be imported to other countries. Public participation can take many forms such as opportunities to provide comment, information on the rules, regulations or applications, or even providing written testimony at public hearings.[330]

For instance, the EU Directive 2001/18 specifies that all applications will be made publicly available and the public will have 30 days to comment.[331] In the USA and Australia, the public is informed through government publications when a policy or product application is available for review and a specific amount of time is given to send relevant comments to the decision makers.[332] However, this process might only be effective if the public are given information and ample time to comprehend the issues before providing feedback, or it would be rendered ineffective. This will be examined in the Malaysian context in the next chapter 3. Therefore, there needs to be transparency of information for the public in the government procedures and decision-making. The relevant public should include small farmer groups with

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[330] McLean MA and others, A conceptual framework for implementing biosafety: linking policy, capacity, and regulation (International service for national agricultural research (ISNAR) 2002) 10.

[331] Jaffe (n79) citing European Parliament. 2001. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms
and repealing council Directive 90/220/EEC—Commission declaration. *Official Journal of the European Union* L106 40: 0001-0039.

[332] World Bank,'Regulation of genetically engineered plants and foods: country specific examples'(2003)in *Biosafety Regulation: A Review of International Approaches, Report No. 26028.* World Bank Agriculture and Rural Development Department.

different opinions as they should be equally equipped with the relevant knowledge and tools to actively participate.[333]

There is another issue on how these public participations are being factored into the decision-making process. This relates to how the information and comment on the legal safety of certain LMOs are taken into account, and whether countries are limited to scientific and risk assessments only. Another medium of public participation is evident when expert scientific opinions are sought about a product or government policy such as consultation with experts from science advisory committees. However these consultations are treated as advice not requirements in government decision-making.[334] The public participation issue is a difficult and complicated one and the implementation is thus left to individual countries to determine.

Cartagena Protocol on Biosafety: Important Articles in the Protocol for implementation

According to the Cartagena Protocol on Biosafety, there are 40 important articles for the countries that ratified and signed the Protocol. However, there are only 26 Articles that need to comply with other provisions are either definition or explanation sections.

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[333] Ching LL, 'Public participation in biosafety issues' in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007).
[334] Gregory Jaffe, 'Implementing the Cartagena Biosafety Protocol Through National Biosafety Regulatory Systems: An Analysis Of Key Unresolved Issues' Journal of Public Affairs (2005).

The relevant articles are summarised as follows:

ARTICLE	DESCRIPTION
2	General provisions
5	Pharmaceutical
6	Transit and contained use
7	Application of the Advance Informed Agreement (AIA) Procedure
8	Notification
9	Acknowledgement of Receipt of Notification
10	Decision Procedure
11	Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, Or For Processing (LMOs-FFP)
12	Review of Decisions
13	Simplified Procedure
14	Bilateral, Regional and Multilateral Agreements and Arrangements
15	Risk Assessment
16	Risk Management
17	Unintentional Transboundary Movements and Emergency Measures
18	Handling, Transport, Packaging and Identification
19	Competent National Authorities and National Focal Points
20	Information Sharing and the Biosafety Clearing-House
21	Confidential Information
22	Capacity-Building
23	Public Awareness and Participation
24	Non-Parties

25	Illegal Transboundary Movements
26	Socio-Economic Considerations
27	Liability and Redress
28	Financial Mechanism and Resources
33	Monitoring and Reporting

Table 2: Relevant Articles in Cartagena Protocol on Biosafety for implementation

Thus these 26 articles need to be complied with by the parties as required by the Cartagena Protocol on Biosafety. The parties then need to report back to The Secretariat of the Protocol, to what extent did they indeed comply in accordance with the reporting format.

The important implementation measures that are required can be summarised as follows:

i) the necessary legal, administrative and other measures for the implementation of the Protocol (Article 2)
ii) the details of the regulation of pharmaceutical LMOs (Article 5)
iii) the implementation of transit and contained use of LMOs (Article 6)
iv) the relevant law(s) / regulations / administrative measures for the operation of the AIA for the transboundary movement for intentional introduction of LMOS into the environment, also measures in case of lack of scientific certainty (Article 7,8,9 and 10)
v) the specific law(s) or regulation(s) for decision-making regarding domestic use, including placing on the market, of LMOs-FFP, also measures for lack of scientific certainty (Article 11)
vi) a mechanism for the review and change of a decision regarding an intentional transboundary movement of LMOs (Article 12)

vii) a system for the application of the simplified procedure regarding an intentional transboundary movement of LMOs (Article 13)

viii) any bilateral, regional and multilateral agreements and arrangements entered by countries (Article 14)

ix) a national framework for conducting risk assessments and management prior to taking decisions regarding LMOs, infrastructure and the use "Guidance on Risk Assessment of LMOs" (Article 15 and 16)

x) the appropriate measures to prevent unintentional transboundary movements of LMOs (Article 17)

xi) the measures to require that LMOs that are subject to transboundary movement are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards (Article 18)

xii) a competent national authority and a mechanism for the coordination of their actions prior to taking decisions regarding LMOs (Article 19)

xiii) the status of the mandatory information provided by countries to the Biosafety Clearing House (BCH) (Article 20)

xiv) the procedures to protect confidential information received under the Protocol (Article 21)

xv) reliable funding for building capacity for the effective implementation of the Protocol also identification areas of improvement (Article 22)

xvi) a strategy or put in place legislation for promoting and facilitating public awareness, education and participation concerning the safe transfer, handling and use of LMOs (Article 23)

xvii) any bilateral, regional, or multilateral agreement with non-Parties regarding transboundary movements of LMOs (Article 24)

xviii) domestic measures aimed at preventing and/or penalizing transboundary movements of LMOs carried out in contravention of its domestic measures to implement this Protocol (Article 25)

xix) specific approaches or requirements that facilitate how socio-economic considerations should be taken into account in LMO decision making (Article 26)

xx) liability and redress (Article 27)

xxi) funding mobilised beyond the regular national budgetary allocation(Article 28)

xxii) monitoring and/or an enforcement system for the implementation of the Cartagena Protocol on Biosafety(Article 33)

Compliance to the Cartagena Protocol on Biosafety: An effective framework?

The Cartagena Protocol on Biosafety Protocol is said to provide the minimum requirement for the establishment of a national biosafety framework[335] for all countries that signed and ratified the Protocol. Jaffe[336] is correct in questioning whether compliance to this Protocol will result in a transparent, predictable, efficient and effective national biosafety framework. Or will it provide national biosafety systems that are harmonious with each other? Furthermore, does the Protocol answer the key questions surrounding the national biosafety regulation? Whilst these issues are not easy to answer,

[335]ibid.
[336] ibid.

it is then important to unveil the essence of these issues so that they can guide biosafety governance.

Environmental governance in regulating biosafety complexity

Another important issue with the Cartagena Protocol on Biosafety is that this Protocol covers environmental aspect of biosafety but not other types of biosafety. Perhaps a more comprehensive biosafety regulation that stands on its own combined with biosecurity might provide better governance of modern biotechnology and its products. Additionally, environmental governance from the Protocol in regulating biosafety, and LMOs specifically should be broadened in the future to govern human health as well.

9. Conclusion

In conclusion, it is hoped that this chapter provides a useful insight into regulatory theory of the biosafety risk regulation. These theories will be discussed in further detail during the discussion of Malaysian biosafety law in Chapter 3 and 4 also when comparing to Singapore biosafety law (Chapter 5). The Cartagena Protocol on Biosafety is seen as the realisation of the scientific and social risks, next Chapter 3 will examine Malaysian compliance towards this Protocol. Even though Singapore is not a signatory country to the said Protocol, the vital biosafety issues outlined will be the used as the parameters of discussion.

There are some common problems of modern biotechnology in the developing countries, such as capacity building from the legal and institutional aspects. Different countries' interests and national priorities reflect their biosafety regulations. It is hoped that a comparative law study between Malaysia and Singapore biosafety regulation will provide useful

insights and lessons for both countries. The Malaysian legal aspect of implementation of biosafety law will be examined in the next Chapter 3.

CHAPTER 3:
A CRITICAL ANALYSIS OF MALAYSIAN POLICIES AND LEGAL FRAMEWORK ON BIOSAFETY

1. Introduction

The regulatory theory in Chapter 2 provides the underlying understanding of biosafety regulation, also analyses the vital issues of compliance with Cartagena Protocol on Biosafety. This Chapter 3 essentially addresses the critical legal aspects of biosafety implementation in Malaysia in compliance with the Protocol. Chapter 4 later complements this Chapter as it addresses the institutional aspects of biosafety regulation in Malaysia. Both Chapter 3 and 4 are connected with each other as the legal and institutional aspects are essential features for an efficient biosafety framework.

Since Malaysia is still in the phase of building and empowering its biosafety framework, there are many issues on the implementation of its laws and regulations. The purpose of this chapter is to review the Malaysian existing laws and regulations and analyse the framework for implementing biosafety. This chapter also critically analyses the crucial biosafety issues notably risk assessment and management, precautionary principle, public awareness and participation, socio-economic considerations, labelling, liability and redress of the living modified organisms (LMO).

The study is organised to analyse the compatibility of the existing Malaysian biosafety framework with Cartagena Protocol on Biosafety, with suggestions and recommendations for future improvement in the following conclusion in Chapter 6. This chapter examines to what extent Malaysia applies the fundamental Articles contained in the Cartagena Protocol on Biosafety, towards complying and strengthening its national biosafety laws and institutions. The Protocol provides a basic framework of implementation

to the ratifying and signing countries, which outlines the essential features in biosafety regulation. Before engaging in a more in-depth analysis of compliance, the background of Malaysia national policies that led to biosafety implementation will be examined.

2. Background on Malaysia's development of biosafety policy

Malaysia's development in biosafety policy and laws is closely associated with its national aspiration and priorities that shaped its national policies on biodiversity, environment, biotechnology and biosafety. The Malaysian's interest in biotechnology started from Vision 2020[337] led to the formulation of the National Biological Diversity Policy 1998.

Vision 2020

Vision 2020[338] is a Malaysian ideal introduced by the fourth most famous and aspirational Prime Minister of Malaysia, Tun Mahathir Mohamad to lead Malaysia to be a developed country by the year 2020. Vision 2020 was announced during the tabling of the Sixth Malaysia Plan in 1991.

[337] Tun Mahathir Mohamad, 'Malaysian: The Way Forward (Vision 2020)' (1991) <http://unpan1.un.org/intradoc/groups/public/documents/apcity/unpan003223.pdf> accessed on 25 December 2015.
[338] In Malay translated as Wawasan 2020.

The introduction to Vision 2020 can be read as follows:

`By the year 2020, Malaysia can be a united nation, with a confident Malaysian society, infused by strong moral and ethical values, living in a society that is democratic, liberal and tolerant, caring, economically just and equitable, progressive and prosperous, and in full possession of an economy that is competitive, dynamic, robust and resilient.'

There are nine challenges towards achieving Vision 2020 which are outlined as follows:

Challenge 1: Establishing a united Malaysian nation made up of one Bangsa Malaysia (Malaysian Race).
Challenge 2: Creating a psychologically liberated, secure and developed Malaysian society.
Challenge 3: Fostering and developing a mature democratic society.
Challenge 4: Establishing a fully moral and ethical society.
Challenge 5: Establishing a matured liberal and tolerant society.
Challenge 6: Establishing a scientific and progressive society.
Challenge 7: Establishing a fully caring society.
Challenge 8: Ensuring an economically just society, in which there is a fair and equitable distribution of the wealth of the nation.
Challenge 9: Establishing a prosperous society with an economy that is fully competitive, dynamic, robust and resilient.

Figure 4: Nine challenges towards achieving Vision 2020

From the above Vision 2020, Challenge 4 is establishing an entirely moral and ethical society reflects Malaysian awareness on these issues also identified as an essential element towards a developed nation. Challenge 6 is establishing a scientific and progressive society shows the aggressive Malaysian venture into biotechnology. One of the engines of growth for the economy is the use of science and technology and the local natural resources for further utilisation of biotechnology development and products.

Malaysia is rich in biodiversity and thus seeks to fully utilise its natural resources using modern biotechnology thus generates income for the country. Malaysia is one of the world's largest producers of palm oil[339] (2nd), and rubber[340] (4th) as Malaysia gains most revenue from agricultural products.[341]

Figure 5: Global share of natural rubber production: in percent[342]

[339] IUF UITA IUL, 'Background Document An overview of the palm oil sector: countries and companies' (Global Palm Oil Conference Bogota, Colombia 12-13 March, 2015) 9.
[340] Daniel Workman, 'Natural Rubber Exports by Country' (2016) <http://www.worldstopexports.com/natural-rubber-exports-country/> accessed on 4 February 2016.
[341] Malaysia External Trade Development Corporation, 'Top 10 Major Export Products, 2015' (2016) <http://www.matrade.gov.my/en/malaysia-exporters-section/33-trade-statistics/3816-top-10-major-export-products-2015> accessed on 31 December 2015.
[342] Yukako Ono, 'Seven countries allying to halt rubber price slide' <https://asia.nikkei.com/Politics-Economy/International-Relations/Seven-countries-allying-to-halt-rubber-price-slide> accessed on 20 January 2017.

Therefore inventions and innovations in modern biotechnology innovations in both agricultural products mainly will generate more revenue for the country. Malaysia is undertaking research and development to cultivate better genes and quality of rubber[343] and palm oil fruits.[344]

Malaysia is one of the world's mega bio-diverse countries as Malaysia ranked the 12th in the world, according to the National Biodiversity Index, which is based on estimates of country richness and endemism in four terrestrial vertebrate classes and vascular plants.[345] Malaysia has a mega-biodiversity that offers much potential for economic growth. Malaysia then is making steps to venture the need to fully utilise the available natural resources to realise its Vision 2020.

Malaysia earlier ratified the Convention on Biological Diversity on 22nd September 2009[346][347] due to the biodiversity threats. Threats to biodiversity in Malaysia include threats to ecosystems and species, such as land development, pollution, poaching and collection, encroachment, climate change and invasive alien species. The primary drivers of these threats consist of economic growth, increased demand for food, agricultural

[343] USDA Foreign Agricultural Service, *Malaysia:GE Rubber tress* (Global Agriculture Information Network (GAIN) MY5001, 2015) 1.

[344] Singh R and others (2013), 'Oil Palm Genome Sequence Reveals Divergence Of Interfertile Species In Old And New Worlds' (2013) Nature 500: 335-339.

[345] Convention on Biological Diversity (CBD), 'Malaysia - Country Profile: Biodiversity Facts ' (2016). <https://www.cbd.int/countries/profile/default.shtml?country=my#facts> accessed on 30 December 2015.

[346]Convention on Biological Diversity (CBD). 'List of Parties' (2018) <https://www.cbd.int/information/parties.shtm> accessed on 29 December 2017.

[347]ibid.

products, goods and services, exotic wild meat, traditional and herbal remedies, wild animals for pets and wild ornamental plants. Therefore as part of the compliance towards Convention on Biological Diversity, Malaysia then formulated National Biological Diversity Policy 1998.

National Biological Diversity Policy 1998

The vision of the National Biological Diversity Policy 1998 is to transform Malaysia into a world centre of excellence in conservation, research and utilisation of tropical biological diversity by the year 2020. This policy is in line with the Vision 2020. The policy is to conserve Malaysia's biological diversity and to ensure that its components are utilised sustainably for the continued progress and socio-economic development of the nation.

The objectives of the policy are as follows:

(i)	To optimise economic benefits from sustainable utilisation of the components of biological diversity;
(ii)	To ensure long-term food security for the nation;
(iii)	To maintain and improve environmental stability for proper functioning of ecological systems;
(iv)	To ensure preservation of the unique biological heritage of the nation for the benefit of present and future generations;
(v)	To enhance scientific and technological knowledge, and educational, social, cultural and aesthetic values of biological diversity;
(vi)	To emphasize biosafety considerations in the development and application of biotechnology.

Figure 6: Objectives of the National Biological Diversity Policy 1998

From the above list of objectives, it can be seen that objective (vi) of biosafety should be considered in the utilisation of biodiversity in the development of biotechnology.

In relation to the thesis topic, objectives (v) and (vi) to enhance scientific and technological knowledge, educational, social, cultural and aesthetic values of biodiversity and the consideration of biosafety considerations in the development and application of biotechnology are of relevance here. As much of the Malaysian biodiversity needs scientific investigation, research and development primarily in genetics, biotechnology, pharmaceuticals, agriculture and fisheries could be fully explored.

As for biosafety risk is acknowledged however the creation, transportation, handling and release of genetically modified organisms (GMOs) carry specific environmental, safety and health risks that are still inadequately understood. Starting from this policy, Malaysia has realised the biosafety risk and has therefore made biosafety concerns a high priority. In the development of biotechnology, especially genetic engineering, there must be a corresponding development of an adequate regulatory framework for biosafety. This is the earlier development of biosafety concern in Malaysia.

As part of the strategies for effective management of biological diversity management, Malaysia develops policies, regulations, laws and capacity building on biosafety. Malaysia introduced measures for the incorporation of biosafety principles and concerns, especially about genetic engineering, and the importation, creation and release of genetically modified organisms.

National Biotechnology Policy 2005 (NBP)

Malaysia then formulated the National Biotechnology Policy 2005 to complement the biotechnology development. The Malaysian Government recognised biotechnology as one of the key strategic drivers to propel the country's social and economic development in pursuit of the status of a developed nation which aims to turn the biotechnology sector into one of the

key economic drivers in the nation, contributing 5% of the nation's GDP by 2020.

The Government launched the National Biotechnology Policy (NBP) in 2005 to further develop three economic sectors namely agriculture, healthcare and industrial manufacturing, as well as to support the growth of an enabling eco-system throughout the scientific, academic and business communities in the country. Bioeconomy Corporation (previously known as Biotechnology Corporation[348]) was created as the lead agency responsible for the coordinated implementation of the NBP.[349]

The NBP is envisioned to be executed in three phases:

1) Phase I for Capacity Building (2005-2010)
2) Phase II on Science to Business (2011-2015) and
3) Phase III to Develop Global Business (2016-2020)

Figure 7: National Biotechnology Policy 2005 phases

[348]Bioeconomy Corporation, 'About us' <http://www.bioeconomycorporation.my/corporate-profile/about-bioeconomycorporation/> accessed on 1 December 2016.
[349] Malaysian Biotechnology Corporation, 'National Biotechnology Policy' <http://www.biotechcorp.com.my/national-biotech-policy/> accessed on 20 October 2015.

These are the critical national development goals for implementation of the NBP over the three phases.

1) Capacity Building: Phase I, 2005-2010

Establishment of the Malaysian Biotechnology Corporation, Advisory and Implementation Councils

Development of knowledge workers and job supply

Development of legal and Intellectual Property (IP) framework

Building of Malaysian branding within the biotechnology industry

2) Science to Business: Phase II, 2011-2015

Development of local expertise

Development of new products

Technology acquisition and develop capability in technology licensing

Intensified investment promotion and branding

Global Presence

3) Phase III, 2016-2020

Consolidation of strengths and capabilities

Strengthen technology and innovation licensing

Further develop expertise

Promote global Malaysian companies

Figure 8: National Biotechnology Policy 2005 Phases of Implementation

The NBP spells out nine key thrusts that underpin these aspirations, namely:

1) Agriculture Biotechnology Development
2) Healthcare Biotechnology Development
3) Industrial Biotechnology Development
4) R&D and Technology Acquisition
5) Human Capital Development
6) Financial Infrastructure Development
7) Legislative and Regulatory Framework Development
8) Strategic Positioning
9) Government Commitment

Figure 9: Nine thrusts of National Biotechnology Policy 2005

Thus from the none key thrusts above, apart from the private local or foreign companies, research universities and government agencies that implemented research and development on biotechnology, the government of Malaysia also invested heavily through its government-linked companies (GLC) such as Bioeconomy Corporation.[350]

Strategies for implementing the National Biotechnology Policy 2005 (NBP)

There are some essential strategies and activities done on implementing the NBP[351] inter alia:

a) Bio Nexus status
b) Bio Nexus partner
c) Bio Economy roadmap
d) National Biomass Strategy
e) Malaysia Bio-Industry Organization (MBIO)
f) Year of Science and National Innovation Movement 2012
g) National Bioethics Council of Malaysia

Figure 10: Strategies and Activities of National Biotechnology Policy 2005

As can be seen from Figure 10 above, the establishment of National Bioethics Council of Malaysia is part of the strategy and actions of the government about biotechnology business which is timely and in line with

[350] Bioeconomy Corporation, 'About Bioeconomy Corporation' (2017) <http://www.bioeconomycorporation.my/corporate-profile/about-bioeconomycorporation/> accessed on 30 December 2017.
[351] Malaysian Biotechnology Information Centre, 'Strategies' (2016) <http://www.bic.org.my/biotech-in-malaysia/strategies> accessed on 20 October 2015.

biosafety considerations. However to what extent the National Bioethics Council's involvement in the biosafety decision-making process is yet to be examined in the next Chapter 4.

Malaysia's signing in Cartagena Protocol on Biosafety 2000

Cartagena Protocol on Biosafety 2000 as mentioned in the Introductory Chapter is the supplementary agreement to the Convention on Biological Diversity which aims to ensure the safe handling, transport and use of living modified organisms (LMO) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.[352]

Malaysia was one of the parties during the negotiations, that later led to the signing of Cartagena Protocol on Biosafety 2000.After several stages of negotiations together with other mostly developing countries, Malaysia then signed and ratified the Protocol. A year after ratifying the Protocol, Malaysia became the host for the First Meeting of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD).[353] This meeting served as the Meeting of the Parties (MOP) to the Cartagena Protocol on Biosafety (COP/MOP-1).During that COP/MOP-1, Malaysia was only commencing the Projects on Implementation of National Biosafety

[352] United Nation Environment Programme (UNEP), 'The Cartagena Protocol on Biosafety' (2016) <https://bch.cbd.int/protocol> accessed on 1 February 2015.
[353] Ismail R, Mamat I and Anuar M, 'Malaysiya's Response to International Biodi-Versity Policies of the United Nations: An Analysis of Cartagena Protocol on Biosafety Between 2000 and 2010' (2013) 7(4 April-June 2013) J Environ Res Develop 1419.

Frameworks managed by United Nations Development Programme (UNDP).[354] It was during this occasion the Ministry of Science, Technology and Environment, under the leadership of Dato' (now Tan Sri) Law Hieng Ding, acted as the critical referral institution in the negotiation process. Essentially, Malaysia made a significant reform in managing its biosafety issues by enacting the Biosafety Act 2007 and later Biosafety (Approval and Notification) Regulations 2010.

This is the Malaysia historical background towards biosafety which is essential to understand Malaysia journey and progress in biotechnology innovation and movement towards biosafety framework.

In summary, as biosafety is also closely associated with biodiversity coupled with a lot of controversial issues associated with LMO that have irreversible effects on the environment (which have been elaborated in the Introductory Chapter), Malaysia then signed the Cartagena Protocol on Biosafety. As part of the capacity building to encourage biosafety in Malaysia, it has been given an incentive under Global Environment Facility (GEF) funding[355] to fund biosafety activities in 2002 for three years. The total cost of $5.2 million projects was being allocated to Malaysia for capacity building activities are summarised as follows:

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[354] Convention on Biological Diversity (CBD), 'UNEP/CBD/BS/COP-MOP/1/INF/19: GEF Support for Capacity-Building' (2012) <https://www.cbd.int/doc/meetings/bs/mop-01/information/mop-01-inf-19-en.pdf> accessed on 30 December 2017.

[355] United Nations Development Program in co-ordination with UNEP and UNIDO implemented by Malaysia Ministry of Science, Technology and the Environment (MoSTE).

i) risk assessment scientific and technical level
ii) implement necessary activities for risk management
iii) evaluate and strengthen legal and regulatory biosafety framework
iv) development of a structure for exchange information
v) public awareness and participation programmes

Thus it can be seen that the GEF Funding is closely related with Chapter 4 whereby the institutional aspect of biosafety implementation being funded and trained by GEF funding such as the LMO detection lab for the Chemistry Department and legal expert to be trained on biosafety laws.

Being a signatory to Cartagena Protocol on Biosafety, Malaysia has several obligations to comply with the Protocol. However, like other countries, Malaysia faced many challenges to conform to the Protocol such as building capacity, finances, public awareness and participation and many others.

In September 2001, the Ministry of Science, Technology, and the Environment (MoSTE) organised a public consultation on the proposed National Biosafety Bill. The participants were from non-governmental organisations (NGOs), government, agro-industry, scientific and academic communities and were invited to voice their views about the draft bill before it was sent to Parliament. It is rare in the Malaysian process of legislation to hold such public consultations with the scheme of the proposed law made available to the public in advance to allow for comments. It is recognition of

the importance of public consultation in the field of biosafety and shows the commitment of the Government in viewing the public as essential stakeholders in the field of biosafety.[356]

3. Malaysia compliance of the Cartagena Protocol on Biosafety

Biosafety in Malaysia, like most other countries, is implemented and enforced as part of environmental issues. Malaysia takes a role to balance protection of its rich biodiversity and developing biotechnology for commercialisation to generate economic growth.

Malaysia is a party to the Cartagena Protocol on Biosafety 2000 as it is signed on 24th May 2000 and ratified on 3rd September 2003.[357][358] The Protocol later came into force on 2nd December 2003. Being a party to the Protocol and as part of its compliance, Malaysia then enacted national Biosafety Act 2007[359] which was in force on 1st December 2009.

A supplementary Protocol then reinforced the Cartagena Protocol on Biosafety is known as the Nagoya - Kuala Lumpur Supplementary Protocol

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[356] Ministry of Science, Technology and the Environment Malaysia, Malaysia: Capacity-building for Implementation of National Biosafety Framework (Project Brief PIMS 2182, 2013) 6.
[357] Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety Ratification List* (Cartagena Protocol on Biosafety , 2018) 1
[358] Cartagena Protocol on Biosafety, 'Parties to the Protocol and signature and ratification of the Supplementary Protocol' (2017) <http://bch.cbd.int/protocol/parties/> accessed on 29 December 2017.
[359] Act 678.

on Liability and Redress.[360] The Supplementary Protocol specifies response measures to be taken in the event of damage to biodiversity resulting from LMO.[361] Malaysia is not a party yet to this Supplementary Protocol even though has started the process of signing since 2011.Malaysia is still in the process of providing a detailed assessment of the biosafety law and identifies gaps in liability and redress to formulate the most practical approach to formulating the best approach.[362]

Decision-making procedure
Fourth National Report to the Convention on Biological Diversity, 2009
First Regular National Report on the Implementation of the Cartagena Protocol on Biosafety, 2007
Interim National Report on Implementation of the Cartagena Protocol on Biosafety, 2005
Third National Report to the Convention on Biological Diversity, 2005
Second National Report to the Convention on Biological Diversity, 2005
Report on Implementation of Global Taxonomy Initiatives (GTI) Work Programme, 2004

Table 3: Decision-making procedure used by Malaysian government from 2000-2010[363]

[360] Signed in Nagoya, Japan, on 16th October 2010.
[361] United Nation Environment, 'The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety' (2017) <https://bch.cbd.int/protocol/supplementary/> accessed on 2 February 2017.
[362] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia, 'Third National Report on the implementation of the Cartagena Protocol on Biosafety' (2017) <https://bch.cbd.int/database/record.shtml?documentid=109107> accessed on 20 January 2017.
[363] Ismail R, Mamat I and Anuar M, 'Malaysiya's Response to International Biodi-Versity Policies of the United Nations: An Analysis of Cartagena Protocol on Biosafety Between 2000 and 2010' (2013) 7(4 April-June 2013) J Environ Res Develop 1419.

Malaysia's status of compliance with Cartagena Protocol on Biosafety can be seen from the Biosafety Clearing House website.[364] From this link, the essential documents in relation to compliance towards Cartagena Protocol on Biosafety can be seen and summarised as follows:

a) Roster of the biosafety experts
b) Capacity building needs
c) Competent national authority
d) Country's decision
e) Law, regulation and guidelines
f) National database and focal points
g) News
h) Risk assessment
i) Reports on the implementation of the Protocol

The Biosafety Clearing-House detailed the relevant questions that countries need to answer to ensure compliance towards every article contained in the Cartagena Protocol on Biosafety (CPB). Thus from here, it can be analysed whether countries complied fully with the Protocol or not. As one of the countries that signed and ratified the CPB, Malaysia has produced its compliance report to CPB. Malaysia has made the widespread efforts at its domestic level and submitted various reports.

[364]Convention on Biological Diversity (CBD), 'Biosafety Clearing House: Country Profile; Malaysia' (2017) <https://bch.cbd.int/about/countryprofile.shtml?country=my> accessed on 20 January 2015.

Type of report
Interim National Report 2005
First National Report 2007
Second National Report 2011
Third National Report 2015

Table 4: Compliance report by Malaysian government on the Implementation of the Cartagena Protocol on Biosafety from 2005-2015

4. Malaysian conceptual framework for implementing biosafety

Having discussed the Malaysian background before signing the Cartagena Protocol on Biosafety, it is then vital to address the Malaysian conceptual framework in implementing biosafety.

The International Service for National Agricultural Research (ISNAR) report by McClean MA et al.[365] convened an expert consultation with ISNAR in July 2001 was initially to assist developing countries that ratified and signed Cartagena Protocol on Biosafety.This Report is comprehensive and essential in analysing the framework of the Malaysian biosafety law even though it does not intend to provide a standard roadmap to be followed by all parties. The ISNAR Report intends to complement the UNEP/GEF Global Project on the Development of National Biosafety Frameworks (Briggs 2001)

[365]McLean MA and others, 'A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation' (International Service for National Agricultural Research (ISNAR 2002).

by providing guidance on the design and implementation of regulatory frameworks and related capacity-building initiatives. The Report linking with the policy, capacity and regulation, as part of the analysis on the developing country consultation project.

This thesis attempts to analyse the current development Malaysian situation by ISNAR Report framework for a better understanding of biosafety implementation from the legal and institutional aspects.

According to ISNAR Report, there are five (5) essential elements for implementation of biosafety regulations which will be elaborated and discussed as follows:

1. Element 1:National policy
2. Element 2:National inventory and evaluation
3. Element 3:Scientific Knowledge, Skills and Capacity Base
4. Element 4:Development of Regulations
5. Element 5:Implementation of Regulations

Figure 11: Elements for Implementation of Biosafety Regulations

Element 1: Malaysia National Policies on Biosafety

The ISNAR report rightly opines that the national policy that relates to biosafety in most countries should ideally be closely associated with food, agriculture, environment and sustainable development. However, the more critical issue is perhaps to what extent the enforcement of the Malaysian biosafety regulation efficiently associated with those essential elements abovementioned and integrated with public health.

From the discussion of the above Malaysian national policies namely National Biological Diversity Policy 1998, National Biotechnology Policy 2005 and Vision 2020 show that there are links between biodiversity, biotechnology thus biosafety development. In Malaysia, biodiversity and environmental issues are under the purview of Ministry of Natural Resources and Environment (NRE). The formulation of National Biological Diversity Policy 1998 is impressive as it includes sustainable development of utilisation of natural resources. The policy also stressed and recognised the importance of biosafety in the biotechnology development. This is in line with compliance towards Convention of Biological Diversity.

The National Biotechnology Policy 2005 is also consistent with Vision 2020 transforms the Malaysian aspiration to generate economic growth through biotechnology consequently as one of the strategies led to the establishment of National Bioethics Council. The involvement of this National Bioethics Council in biosafety decision-making process will be discussed in the next chapter 4. It is agreed that the importance of a national biosafety strategy cannot be overstated as it provides a set of principles to guide subsequent development and implementation of a biosafety system and regulations.[366]

Biosafety policy articulates a national approach to biosafety regulation and the goals and objectives of the regulatory framework, and it may provide direction on many of the fundamental issues and public policy choices that must be considered during the development of regulations. Mclean et.al in

[366] ibid 3.

that ISNAR report also stressed that regardless whether the biosafety policy is developed before or after the biosafety regulations the importance of different goals such as economic and regional development, and environmental protection may be integrated and communicated as a single national vision.

It is submitted that Malaysia perhaps still lacks the general national biosafety policy that should be comprehensive to include not just lab biosafety,[367] environmental biosafety but also more advanced biosafety issues associated with biosecurity and bioterrorism. Perhaps this is because biosafety in Malaysia is inter-related with other ministries, for instance, public health issues that are under the purview of Ministry of Health, food safety under other agencies, biodiversity under Ministry of Natural Resources (NRE), etc. However, a comprehensive biosafety policy that integrates with food, agriculture, environment, sustainable development and health is hoped to be formulated in the future. This should be done to consistency and effectiveness of governmental actions through various agencies on biosafety, biotechnology and environment that would benefit the public, regulator and business as a whole.

Element 2: National Inventory and Evaluation

The inventory and evaluation of national priorities, agricultural policies, existing regulatory regimes, and national scientific and technical means are prerequisite to the development and implementation of biosafety-related

[367] Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline 2015.

policies and regulations. This is due to the fact that resources and regulatory infrastructures, the national appraisal provides a mean to identify and characterise available resources and regulatory infrastructures, assess their adequacy for supporting a biosafety system, and identify gaps where capacities need to be strengthened. The national scientific and technical means information is provided by the GEF Funding Report[368] lists down the detail of the lab scientific officers, training, workshop, GMOs lab and related activities to LMO capacity building in Malaysia. In short Ministry of Science, Technology and the Environment Malaysia have all the necessary detail on the building capacity of the national scientific and technical means.

The inventory of biosafety should include:

a) existing regulatory structures and legislation pertaining to the import and export of agriculture commodities, environmental protection, animal and human health safety, and biotechnology;
b) existing mechanisms for the development of public policy, legislation, and regulations;
c) existing human, financial, and scientific infrastructure;
d) the current status of biotechnology research and development, including programs for the safe use and handling of LMOs;
e) existing mechanisms for regional cooperation and regulatory harmonization; existing capacity building programs;
f) the role of civil society in processes for policy and regulatory development; and
g) administrative and enforcement capacity.

Figure 12: National Biosafety Inventory

[368] Ministry of Science, Technology and the Environment Malaysia, *Malaysia: Capacity-building for Implementation of National Biosafety Framework* (Project Brief PIMS 2182, 2013) 1.

As previously mentioned, a country rarely reviews all of these items before actually managing/regulating LMO. More commonly, and perhaps more practically, countries evaluate their national capacities on a stepwise basis, as dictated by domestic needs: the capability to manage LMO in contained facilities, followed by confined small- and large-scale field trials, and finally, the unconfined release of an LMO. This part especially on (c), (d) and (g) while it is of not much detail in this thesis due to its limitations. This will be of interest for future research for Malaysia strengthening of its biosafety system as a whole.

Element 3: Scientific Knowledge, Skills and Capacity Base

Again this element in the Malaysian context has realised the importance of incorporating biosafety modules in the tertiary and secondary school curriculum.[369] However, to date, there is no significant progress on the biosafety education in Malaysia. This is among the issues that should be in the suggestions and recommendations chapter whereby scope and quality of competency in the disciplines of biological science; expertise in information acquisition, communications, and management; and experience in critical thinking, analysis, and decision making are deemed essential thus calls for improvement.

[369] Question 160 of Second Regular National Report on the Implementation of the Cartagena Protocol on Biosafety submitted on 30/09/2011.

There are two key decision points and related policies namely:

a) Coordinating scientific expertise

This aspect stressed the importance of the national scientific expertise and knowledge on risk assessment, management and regulation such as for biotechnology product evaluation. If local expertise is inadequate, they should get the sub-regional, regional, and international cooperation in performing risk assessments, on outside experts, and on the international academic community.

b) Locating the science evaluation function

This is related to the institutional biosafety framework whereby some countries rely on expert advisory committees, while others have relied primarily on scientists and professionals working within government agencies. There are also independent advisory committees.

Thus it is crucial to observe the consequences highlighted by Mclean that a thin, weak, or limited knowledge and skills base tends to produce regulations that are highly protective, at the expense of innovation, poorly defined or inconsistent, comparatively rigid, and narrowly interpreted. On the other hand, a deep and broad knowledge, skills, and capacity base will foster more latitude in regulatory development and more flexibility in regulatory implementation.

Therefore, it is undeniably true that the scientific knowledge, skills and capacity base need to be strengthened in Malaysia for the future of biosafety in Malaysia.

Malaysia faces several challenges in implementing the National Policy Biosafety Development, especially in the field of enforcement of environmental legislation. There is also a need to improve the scientific knowledge base. At the base of these two challenges lies the need for more trained personnel in the field of biodiversity and biotechnology.[370]

a) Systemic level

The proposed legal framework for biosafety is broad and not sufficiently well detailed to be completely operational. However, the legislation has evolved to be a general act, under which details for implementation will be mostly captured in the regulations, to allow MoSTE more flexibility should the need to adapt to changing needs arise.

b) Institutional level

At present, there is insufficient institutional capacity, in research capabilities as well as management systems.

c) Individual level

MoSTE and other government agencies remain ill-equipped to successfully implement the Biosafety Bill (before Biosafety Act 2007 was

[370] Ministry of Science, Technology and the Environment Malaysia, *Malaysia: Capacity-building for Implementation of National Biosafety Framework* (Project Brief PIMS 2182, 2013) 8 can be found online at <http://mkak.moh.gov.my/download/Biosafety_Policy_and_Guideline_2015.pdf.>

enacted) as there are insufficient capacities, regarding numbers and skills, in risk assessment and risk management, administrative systems, enforcement and legal implementation.

Element 4: Development of Regulations

There are some critical elements in the development of biosafety regulations which are listed as follows:

(1) the legislative framework

The biosafety framework can be either voluntary or mandatory. Voluntary biosafety guidelines so far have no proven evidence of compromising with environmental safety. Flexibility to adapt to new information of biosafety is another advantage. However, lack of public confidence may exist as there is no enforcement and monitoring from the government to ensure company's compliance and redress for suspected negligence.

Mandatory framework, on the other hand, lead countries to either to;

i. develop new acts to address the LMO regulations either product or process specifically,
ii. regulate the LMO under the auspices of the existing laws, rules and regulations and ministerial or presidential decrees

The former leads to flexibility thus new technological advances can also be captured without significant regulatory amendment besides instilling public confidence on biosafety importance by the regulator. However, legislation process will take a long time so does regulation of LMO in perpetuity. For instance, some LMO might have a safe history for a long time

thus LMO with this element will still be singled out for exceptional regulatory oversight.

In light of this discussion, it is important to highlight here that regarding biosafety framework, Malaysia imposed mandatory biosafety legislation, i.e. the Biosafety Act 2007. The detailed discussion on Biosafety Act 2007 is at section 3.5 below. While there are pros and cons of having national biosafety law, Malaysia chose to have a national biosafety law. This move is part of the effort to comply with Cartagena Protocol on Biosafety. However, there are other areas of law related to biosafety namely food regulation, environment, agriculture and health. These laws are regulated by different Acts within their scope of jurisdictions that bind one another. Malaysia before enacted its national Biosafety Act 2007 has its national biosafety guidelines as a soft approach in biosafety.

(2) regulatory “triggers.”

This is a process versus product regulation which is not going to be discussed in detail here as the Malaysian biosafety law opted to have its very own process and product biosafety regulation. Even though Malaysia might be criticised as covering broader scope than Cartagena Protocol on Biosafety, this is justified as covering as what is required by the Protocol, i.e.

and the products thereof[371] i.e. Malaysia is covering the products of the modern biotechnology as well.

(3) transparency and public involvement in the policy-making and regulatory decision making processes

These cross-cutting issues are going to be discussed in the next section. In particular, the regulatory decision-making process as it closely related with institutional biosafety framework will be discussed in the next chapter 4.

(4) approaches to risk assessment and risk management.

The approaches are closely associated with current scientific capacity and knowledge base. These building capacities are regarded as key to identifying hazards and assessing their impacts and likelihood. As for approaches to risk assessment and management, it is a reasonable international consensus that risk assessments should focus on scientific consideration of the evidence or potential for adverse impact. This consensus is reflected in Article 15 of the Protocol, which asserts: 'Risk assessments undertaken under this Protocol shall be carried out in a scientifically sound manner [...].'Annex III to the Protocol provides further details on risk assessment principles and a suggested methodology.

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[371]Ministry of Natural Resources and Environment Malaysia, 'The Biosafety Act of Malaysia: Dispelling the Myths' <http://www.nre.gov.my/Malay/Pusat-Media/Penerbitan/Dispelling%20the%20Myths.pdf> 31.

Thus a separate discussion of the scientific risk assessment and regulatory decision-making processes is advisable. This tiered-approach is to avoid political interference or impinge on existing international trade agreements. However again this should be subject to adequate transparency, openness, and objectivity to the successful implementation of such an approach. Malaysia is applying a two-tier biosafety decision-making process whereby the National Biosafety Board is making the approval based on the risk assessment and management assessed by Genetic Modification Advisory Committee (GMAC). Thus this move should be seen as reducing the political interference but slightly depending expert opinion based on risk assessment and management.

Another issue is the inclusion of the socio-economic considerations which is going to be discussed shortly as to how to include it in the biosafety decision-making process.

It was argued however that it does not appear feasible, nor advisable, to include broader ethical and social considerations (excluding economic consequences) into the process for individual product approvals. These important considerations are best dealt with by establishing ethics committees or other expert bodies responsible for providing governments with policy advice on ethical, legal, or social issues related to the adoption of new technologies. The exploration of ethical issues can serve both to develop a public consensus on the acceptability of various technologies and to guide the evolution of a policy framework for regulation. It seems that no systematic approach integrates both scientific and socio-economic consideration. However, Malaysia like most countries depends on the risk assessment and management while including the socio-economic considerations in the risk assessment consideration.

It is the most important to harmonize with the existing risk assessment criteria and standards that have achieved international acceptance in either practice or principle like the various World Trade Organisation (WTO) agreements such as Technical Barriers to Trade (TBT), General Agreement On Tariffs And Trade (GATT), Sanitary and phytosanitary measures (SPSS) also the World Health Organisation (WHO) food standard of Codex Alimentarius , Food and Agriculture Organization (FAO) of the United Nations. However, a detailed discussion of this harmonisation with the WTO agreements is outside the coverage of this thesis.

Element 5: Implementation of Regulations

The critical issues in the implementation of biosafety regulation are the establishment of appropriate risk assessment, risk management, and risk communication mechanisms while managing within existing financial, technical, and human resource constraints.[372]

Traynor[373] listed down four elements that allow biosafety implementation namely as follows:

a) regulation that defines the structure of the biosafety system
b) knowledgeable and well-trained human resources
c) the review process is up-to-date scientific information

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[372]McLean MA and others, *A conceptual framework for implementing biosafety: linking policy, capacity, and regulation* (International service for national agricultural research (ISNAR) 2002 citing Cohen JI, 'Harnessing biotechnology for the poor: challenges ahead for capacity, safety and public investment' (2001) 2(2) Journal of Human Development 239.
[373] ibid citing Traynor PL, 'Biosafety managment: key to the environmentally responsible use of biotechnology' (1999) Biotechnology in Agriculture Series (Netherlands).

d) feedback mechanisms to review the system

a) Harmonisation of the risk assessment, management at the sub regional, regional and international

Harmonisation success can be attributed to these factors namely:

a) agreed shared values and objectives
b) similar interests and concerns, economic and other benefits
c) overcome differences and disputes
d) cooperate against other interests
e) simplified procedures

Harmonisation is said to occur on three fronts – which are an authority, risk analysis, and administration. Harmonisation of authority from sub regional, regional and international are difficult due to the diversity of laws and regulations. Thus Cartagena Protocol on Biosafety is an example of a more reasonable model biosafety laws that list out the critical issues of biosafety that need to be incorporated in the parties biosafety law. This is done with a view that it is also harmonised with regional and international obligations and objectives.

Harmonisation in risk analysis can be divided into two namely:

a) conceptual framework and
b) technical.

The former refers to the agreement on general principles of risk assessment such as food safety standard and environmental risk assessment. The latter refers to an agreement on methodologies, information requirements, or criteria for determining unacceptable risks. This perhaps

would pose issues on countries that are lacking scientific human resources capacities and updated knowledge, such as Malaysia.

Harmonisation of administration refers to the implementation of norms, rules, and standards. However, in this regard, the Biosafety Clearing House for parties is a suitable mechanism for sharing of information on scientific, technical, environmental, and legal information relating to the risk assessment and transboundary movement of LMO.

b) Transparency of decision-making and public participation

As biosafety is said to involve controversial issues, transparency in decision-making is a pre-requisite to gain the trusts of the stakeholders. The public engagement as part of the decision-making process before regulatory or policy-making contributes to the degree of transparency. The process and criteria for risk assessment and risk management should be widely published to gain trusts of the developers, stakeholders, and the public thus biosafety system to be both credible and predictable. At the Malaysian national biosafety level, this transparency aim is perhaps to be achieved in the future which seems to be in line with the aspiration of the Cartagena Protocol on Biosafety. It is argued that while there is publication of the report from the National Biosafety Board and GMAC, there is no detail on the response from the public. Thus in this regard, the transparency topic is undermined.

c) Monitoring and compliance

At the international level, few countries implement systematic monitoring of post-market (post-approval) monitoring. Biosafety Clearing House (BCH) provides informative mechanisms of LMO transboundary movement. The practical, technical, and economic limitations to monitoring of LMO remains

to ensure that national and international rules and regulations are respected. In this post-market monitoring, Malaysia did not have a mechanism to address liability and redress at the national level yet.[374]

5. A critical analysis of the legal framework on biosafety law in Malaysia

An analysis of the existing legal framework on biosafety in Malaysia cannot be completed in isolation with the other laws related to biodiversity and biotechnology. Therefore the existing relevant laws, rules and regulations in Malaysia biosafety law from 2000 to 2015 is summarised as follows:[375]

Local policy/rule and regulation
The Biosafety Act 2007 (Act 678)
Guidelines of Institutional Biosafety Committee (IBC): Use of Living Modified Organism and Related Material, 2007
National Biotechnology Policy, 2005
Protection of New Plant Variety Act, 2004
National Policy on the Environment, 2002
Sabah Biodiversity Enactment, 2000
Chapter 22, 9th Malaysia Plan, (2006-2010)
Chapter 19, 8th Malaysia Plan, (2001-2005)

Table 5: Local policy/rule and regulation adopted at domestic level in Malaysia between 2000-2010

[374] Third National Report on the implementation of the Cartagena Protocol on Biosafety can be found at <https://bch.cbd.int/database/record.shtml?documentid=109107>accessed on 1 February 2017.
[375] ibid.

Biosafety (Approval and Notification) Regulations 2010
Food Regulation 1985 (amended 2010) by Ministry of Health

Table 6: Local policy/rule and regulation adopted at domestic level in Malaysia between 2010-2015

The primary acts and regulations related to biosafety are as follows:

a) Biosafety Act 2007
b) Biosafety (Approval and Notification) Regulations 2010

a) Biosafety Act 2007 (Act 678)

Malaysia as part of the compliance towards Cartagena Protocol on Biosafety passed its national biosafety law, the Biosafety Act 2007. The Act was passed by Parliament on 11th July 2007 and received the Royal Assent on 29th August 2007. It came into effect on 1st December 2009.[376] The Act is with the aims to regulate the release, importation and contained use of living modified organisms (LMO) and the products of such organisms.

Biosafety Act 2007 is divided into seven main parts namely as follows:

[376] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia, User's Guide to the Biosafety Act and Regulations (Department of Biosafety, Ministry of Natural Resources and Environment Malaysia 2012) 6.

a) Part I: Preliminary
b) Part II: National Biosafety Board
c) Part III: Approval for release and import
d) Part IV: Notification for export, contained use and import for contained use
e) Part V: Risk assessment and risk management report and emergency response plan
f) Part VI: Enforcement
g) Part VII: Miscellaneous

Malaysian Biosafety Act 2007 is perhaps even more detailed as compared to Cartagena Protocol on Biosafety 2000. This is because in the long title of the Act it regulates not just the living modified organisms (LMO) but also the products of such organisms, i.e. the genetically modified (GM) products such the GM corn, soy, flower and many others. The Biosafety Act 2007 is to be read together with any other written law relating to import and export, human, plant and animal health, the environment and biological diversity and in addition to and not in derogation of such written laws.[377]

Thus from different Parts in the Biosafety Act 2007, there are different procedures applied for Approval for release and import (Part III) and Notification for export, contained use and import for contained use (Part IV).

Section 4 of the Biosafety Act 2007 established the National Biosafety Board (NBB), whereas Section 6 established the Genetic Modification

[377] Biosafety Act 2007 [Act678] s2.

Advisory Committee (GMAC). NBB acts like a biosafety regulatory board[378] while GMAC is an advisory committee that gives scientific, technical and other relevant advice to the Minister of Natural Resources and Environment (NRE) and NBB.[379]

b) Biosafety (Approval and Notification) Regulations 2010

Biosafety Act 2007 established the National Biosafety Board.[380] The Minister[381] of Natural Resources and the Environment then upon consultation with the National Biosafety Board (NBB) has made this regulation.[382] This Regulations 2010 came into operation on 1st November 2010. The Regulation gives the NBB to direct the Institutional Biosafety Committee (IBC) to be established to any organisation that undertakes modern biotechnology research and development. This regulation primarily detailed out the process and procedure for approval for any release activity and importation of living modified organisms.

Criticism of Biosafety Act 2007

While Biosafety Act 2007 was enacted that in line with Malaysia National Biodiversity Policy and National Biotechnology Policy, this Act is not free from criticism. This Biosafety Act 2007 is part of Malaysia compliance towards Cartagena Protocol on Biosafety.

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[378] ibid s5.
[379] ibid s6(1).
[380] ibid s4.
[381] ibid s3.
[382] By the power conferred by Biosafety Act 2007 s69(a), (b), (c), (g), (h) and (l).

However, there are some issues and criticisms related to Biosafety Act 2007, as follows:

Risk assessment and risk management of the GMOs

The risk assessment done by Genetic Modification Advisory Committee (GMAC) is an issue in relation to Biosafety Act 2007. Risk assessment and management is provided for in Section 36 of the Biosafety Act 2007. It contains only the core provisions, details of the risk assessment and management procedures are to be developed by the Department of Biosafety, Ministry of Natural Resources and Environment (NRE).

It is stated that the risk assessment and management report shall contain:

a) an assessment of the risk and adverse effect of the LMO and products; and
b) the proposed measures to prevent the risks and the adverse effect of such LMO and products that are likely to have to human, plant and animal health, the environment and the biological diversity.[383]

[383]Biosafety Act 2007 s36(1)(a) and (b).

The issue of criticism here is that the relevant provision in the risk assessment is very brief, with no mention of the actual procedures taken.[384] This is true despite the fact that the risk assessment is one of the primary foci of the Act.[385] The Biosafety Act 2007 also establishes emergency response plan that shall provide safety measures and procedures for the protection of human, plant and animal health, the environment and biological diversity against harm caused by LMO and the products of LMO.

The Act is elementary with only a brief provision on risk assessment, and it is found to be science-based.[386] It is criticised as there is no specific coverage on the socio-economic and ethical aspects as well as the precautionary approach.[387]The risk assessment of the LMO is mainly focused on the protection of human health and the environment.

Two concepts have to be incorporated into the regulatory frameworks governing GMOs namely as follows:

a) substantial equivalence, which is used to assess risks posed to human health[388]
b) Familiarity, which is used in environmental risk assessment.[389]

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[384] Amin L and others, 'Risk assessment of genetically modified organisms (GMOs)' (30 September, 2011) 10(58) African Journal of Biotechnology 12422.
[385] ibid.
[386]Chan K, 'Malaysia Biosafety Act 2007 and Cartagena Protocol on Biosafety: A critical comparative analysis' (2016) 5.
[387] Amin L and others, 'Risk assessment of genetically modified organisms (GMOs)' (30 September, 2011) 10(58) African Journal of Biotechnology 12422.
[388] OECD-Organisation of Economical and Development (1993a). Safety evaluation of foods derived by modern biotechnology, concepts and principles, France (as cited in ibid).

The underlying concept of the substantial equivalence is the requirement that any safety assessment should show that a genetically modified variety is as safe as its traditional counterparts, through a consideration of both intended and unintended effects.[390] The primary comparing newly developed products or techniques to existing ones has long been applied in various fields, including agriculture, and science, and technology.[391]

Global guidelines for risk analysis and risk assessment of GMOs have been developed by the Codex Alimentarius Commission (CAC) in several documents. One of those documents, “The Principles Document”, advocates that a new GM food product should be assessed for its safety by comparing it with food that has an established history of safe consumption, to identify potential hazards requiring further considerations. As noted earlier on, this view is typically referred to as the “concept of substantial equivalence”. This document also stresses that risk managers should take into account uncertainties identified in the risk assessment and implement appropriate

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[389]OECD-Organisation of Economical and Development (1993b). Safety considerations for Biotechnology: Scale-up of crop plants, France (as cited in ibid).

[390] Food and Agriculture Organization of the United Nations and World Health Organization, Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology: Topic 1: The Concept of Substantial Equivalence, its Historical Development and Current Use (FAO/WHO Biotech 00/03, 2000) 1 (as cited in ibid).

[391] Latifah Amin and others, 'Risk assessment of genetically modified organisms (GMOs)' (30 September, 2011) 10(58) African Journal of Biotechnology 12422 ibid citing Schauzu M. The concept of substantial equivalence in safety assessment of foods derived from genetically modified organisms.(2000) AgBiotechNet, 2: 1.

measures to manage them.[392] Therefore, various countries adopt their different approach to biosafety risk assessment and management.

As for risk management Section 36(1) states that the risk management shall be in a form prescribed by the Minister, and Section 36(2) of the Biosafety Act 2007 states the approved person shall comply with the minimum risk management measures as may be determined by the Board, after consultation with the Advisory Committee. Thus again the risk management is not detailed out in the Act 2007 but put together in the risk assessment form.

Analysis of risk assessment and management from Biosafety Clearing House website

However when an examination of the Malaysian GMAC report on Risk assessment and management,[393] it can be seen that despite having perhaps its form of safety assessment, GMAC also takes the Cartagena Protocol on Biosafety 2000, Risk assessment and Codex Guidelines on Risk Assessment on GMOs into consideration and also relevant scientific research by other countries as reported in the risk assessment report.

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[392] ibid citing Codex Alimentarius Commission 2003 (ALINORM 03/34A). Guideline for the conduct of food safety assessment of foods derived from recombinant DNA plants. Annex on the assessment of possible allergenicity, Rome, Italy. Codex Alimentarius Commission, Yokohama.

[393] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'Approval for Release For Field Trial | Food, Feed and Processing | Product of LMO' (2016) <http://www.biosafety.nre.gov.my/country_decision/app_plmo.shtml> accessed on 20 January 2016.

Since the Malaysian Biosafety Act 2007 and regulations follow the Australian Gene Technology Regulation (2001), it demonstrates some similarities with the regulations of the developed countries, such as those of the EU and the UK even though risk assessment and risk management are not detailed out in the Act. The procedures for actions to be taken in the release of GMOs can be seen in the forms supplied by the Department of Biosafety, NRE which is the government body that is responsible for management of the biosafety aspects of GMOs and GMO-related products, as well as all matters connected with the modern biotechnology process.[394]

There are two situations that should be concerned when dealing with risk assessment of GMOs.[395] The regulation of GMOs can be divided into two parts namely:

1) contained use and
2) deliberate environmental release (non-contained use).

The contained use is for research and development mainly in the laboratories and physically contained facilities whereas non-contained use is for release into the environment. Malaysian Biosafety Act 2007 contained both provisions, but as mentioned earlier the detail is left to the Department of Biosafety and NRE. The Act only laid down the procedures for approval for release and import, and notification for export and import and contained use

[394]Amin L and others, 'Risk assessment of genetically modified organisms (GMOs)' (30 September, 2011) 10(58) African Journal of Biotechnology 12422.
[395] ibid citing Sparrow PAC (2010). GM Risk assessment. Mol. Biotechnol. 44: 267-275

also the roles played by Department of Biosafety, Minister and Director General of NRE, National Biosafety Board and Genetic Modification Advisory Committee (GMAC).

It was observed that while the Cartagena Protocol on Biosafety 2000 does mention the subjects of risk assessment, its provisions on contained use are insufficient compared to the EC directives. The Protocol is more focused on the procedures for LMO intended for direct use as food or feed, or for processing. This is a sharp contrast from the Biosafety Act 2007 in which contained use is the primary point of concern.[396]

Apart from the risk assessment, other tests are essential methods of testing meant to identify and improve the quality as well as the safety of GMOs that are developed by renowned scientists. These tests include the nutritional assessment test, the allergenicity test, the toxicity test and the compositional studies that are well-known tests that GMOs have to go through to ensure that the safety of the products is acceptable and raise confidence to all consumers and members of the general public.[397]

Analysis of risk assessment and management from Malaysian compliance report

As Malaysia was at its infancy stage of the risk assessment and management after signing Cartagena Protocol on Biosafety before enacting

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[396]ibid.
[397]ibid.

its Biosafety Act 2007, the earlier two compliance Reports[398][399] did not show any significance Malaysian very own risk assessment and management system rather than relying on international standard and procedure as mentioned above.

It was during the later Report of Second National Report, Malaysia using its local experts has established Environmental Risk Assessment Guideline on GM Plant and Risk Assessment Manual on GM Microorganism. In the Third National Report apart from the Protocol other documents as mentioned above, Malaysia also referred Guidance on Risk Assessment of Living Modified Organisms (developed by the AHTEG on Risk Assessment and Risk Management[400]) when making their assessments of LMO mainly for food, feed and processing. Moreover, relevant biology documents produced by Organisation for Economic Co-operation and Development (OECD) are also being referred as well. A detailed discussion of the risk assessment and management will be too technical and scientific as outside the purview of this thesis.

However, apart from the lack of detail in Malaysian risk assessment of the LMO, the next issues are the precautionary principle, public awareness

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[398]Conservation and Environmental Management Division, Ministry of Natural Resources and Environment Malaysia., *Malaysia Interim National Report on Implementation of the Cartagena Protocol on Biosafety* (2005) 1.
[399]Conservation and Environmental Management Division, Ministry of Natural Resources and Environment Malaysia., *Malaysia First National Report on Implementation of the Cartagena Protocol on Biosafety* (2007) 1.
[400] According to Second National Report, two experts were appointed from Malaysia

and participation, socio-economic considerations and bioethics issues according to Biosafety Act 2007.

Precautionary principle

The precautionary principle was being reaffirmed in the preamble to the Cartagena Protocol on Biosafety 2000 as contained in Principle 15 of the Rio Declaration on Environment and Development[401] to ensure the safe use of biotechnology. Principle 15 of the Rio Declaration states that precautionary approach shall be applied widely to protect the environment. Where there are threats of severe or reversible damage, lack of full scientific certainty shall not be used as a reason to postpone cost-effective measures to prevent environmental degradation.

According to Article 10(1) of the Cartagena Protocol on Biosafety 2000 lack of scientific certainty due to insufficient scientific information and knowledge on the extent of the potential adverse effects of a LMO on the conservation and sustainable use of biological diversity to the Party of import, where human health risks are taken into account as well, shall not prevent the party from taking decision as appropriate with regard to the import, in order to avoid or minimise potential adverse effects.

The preamble to Biosafety Act 2007 contains the precautionary principle that reads:

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[401]United Nation Environment Programme (UNEP). 'The Cartagena Protocol on Biosafety' (2016) <https://bch.cbd.int/protocol> accessed on 1 February 2015.

'…with the objectives of protecting human, plant and animal health, the environment and biological diversity, and where there are threats of irreversible damage, lack of full scientific evidence may not be used as a reason not to take action to prevent such damage: and to provide for matter connected therewith.'

Section 35 of the Biosafety Act 2007 reads*;*

'The Board or Minister shall not be prevented from taking a decision , as appropriate, under Part III or Part 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 health, the environment and biological diversity and may also take into account socio-economic considerations.'

Section 35 is criticised as cannot be termed as precautionary.[402] However, a positive perception of Section 35 is that it encourages a decision-making process that takes account of the substantial social and economic cost to whose livelihood may be adversely affected by the intended precautionary principle.[403]These two provisions of the same Act are conflicting, the former (from the preamble) seems to accord with most formulations of the Precautionary principle whereas the latter[404]lacks the command approach as does not command the Board or the Minister to take

[402]Kwan C, 'Malaysia's Biosafety Bill-Throwing Precaution to the Wind?' [2007] 5 CLJ i 6 .
[403] Hussain&Wan, Shaik Mohd Noor Alam SM and Talaat IW, 'Precautionary Principle in the Malaysian Biosafety Law' (2009) 4(2) Journal of Sustainability Science and Management 146.
[404] Biosafety Act 2007 s35.

appropriate action to protect against adverse effects having regard to among others, socio-economic considerations.[405]

Section 35 may be perceived as an 'attempt' to balance between conservation of the environment and the livelihood of the indigenous and local communities who depend on the biological resources.[406]

Public awareness and participation

In the previous Chapter 2, these were the issues on public participation, namely:

a) the role of the public in biosafety decision making process
b) the justification for public involvement in biosafety
c) the institutionalisation of the public participation
d) the influence of the public involvement in biosafety
e) the improvements of public participation in biosafety

It is hoped that this Chapter 3 and 4 and the Conclusion chapter will be able to enlighten these issues.

Article 23(1)(a) of the Cartagena Protocol on Biosafety requires parties public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, also taking into account risks to

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[405] Hussain (n403) 155.
[406] ibid.

human health. Article 23(2) requires the parties to make a public consultation for the release of LMO except for confidential business information and such information to be published.

One of the criticisms is on the issue to what extent do the public participate in the biosafety decision-making process. It can be seen that in Section 14(c) of the Malaysian Biosafety Act 2007 states that the Director General (DG) shall for purposes of public disclosure invite public participation for application under Section 13 for the approval of any release activity, or any importation of living modified organisms. The word 'shall' denotes mandatory public participation. Section 60 of the Biosafety Act 2007 provides for public disclosure whereby 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 subsection 59(2)[407] in such manner as the Board thinks fit. It is rightly contended that his "manner" could be interpreted at best, to preserve the commercial interest, if sought by the applicant.[408]

The decision made under Part III[409] and IV[410] shall be made available to the public in such manner as the NBB thinks fit. Therefore the public

[407] Confidential Business Information (CBI)
[408] Idris SH, 'Integrating Bioethical Concerns into Biosafety Law for Genetic Modification Technologies in Malaysia' (2013)(2:2) Adv Genet Eng.
[409] Part III : Approval for release and import
[410] Part IV: Notification for export, contained use and import for contained use

opportunity to participate is limited if the information contains confidential business information.[411]

The Biosafety Act 2007 does not specify the types or categories of public participation, which will leave the issues to the broad discretion to the Department of Biosafety and its Director General, also the National Biosafety Board and the Minister of Natural Resources and Environment. The advertisement by the National Biosafety Board[412] on inviting public comments or opinions without specifying what types comment/ opinion will be taken into consideration. For instance, if the public has a science background will their opinions be taken into consideration as opposed to the more structured scientific GMAC Risk Assessment. If the public even has other opinions such as bioethical, religious or cultural views, to what extent that their views will be heard is also questionable.

The said Act is also silent on how to conduct public consultation or perhaps more importantly how to factor the results of the consultation into the decision-making process. Thus this needs more transparency. This is among the cross-cutting issues as discussed above.

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[411]Hamin APDZ and Idris SH, 'Bioethical Issues on Genetically Modified Organisms (GMOs) In Malaysia: Biting Into the Legal Protection under the Biosafety Act 2007' (2nd International Conference on Biotechnology and Food Science IPCBE IACSIT Press, Singapore 2011).

[412] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'JBK(S) 602-1/1/28 - MS8RF3 Oilseed Rape' (2016) <http://www.biosafety.nre.gov.my/regulatory_process/pub_ann_syngenta.shtml#annex22> accessed on 5 January 2016.

However, it is important to note here that public consultation is just practised in Part III application for approval but not for Part IV notification of LMO and GMO products. However, decisions for both approval and notification are published on Malaysia Biosafety Clearing House website[413][414].

The public is made known of the LMO activities through newspaper and the Malaysia Biosafety Clearing House website.[415] Guidelines on the public announcement are available and shall be borne by the applicant.

Therefore, next question is to what extent Malaysian public respond and participate in this biosafety decision-making process is yet to be analysed. It is not clear to why Malaysian did not comment on the approval application. This is perhaps due to a few reasons:

a) lack of knowledge or information on LMO or merely an ignorant attitude
b) lack of access to the application information since it was done through website and newspaper

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[413] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'Approval' (2016) <http://www.biosafety.nre.gov.my/regulatory_process/approval.shtml> accessed on 20 January 2016.
[414] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'Notification' (2016) <http://www.biosafety.nre.gov.my/regulatory_process/notification.shtml> accessed on 20 January 2016.
[415] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'Public consultation' (2016) <http://www.biosafety.nre.gov.my/regulatory_process/pub_ann_syngenta.shtml> accessed on 20 January 2016.

The public participation on LMO approval was asked by a Member of Parliament from Parit Sulung during a questioning time during Parliamentary Session as to what extent the Malaysian public participate towards it and what are the measures taken by the government to increase the Malaysian interest to participate. Dato Sri Dr Haji Wan Junaidi Tuanku Jaafar[416] answered that these issues even though important have few attendees and does not attract public interest to attend even efforts were made to implement public consultation.[417]

In short public participation can be through any of these ways namely:[418]

a) the advisory committee especially issues on social, ethical and also economic considerations whereby any member of the public should participate
b) public consultation for amendment of laws, regulations and guidelines
c) risk assessment process

It seems Malaysia has already practised all of the above only it is not clear as how much is the Malaysian public either a bioethics expert, religious

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[416] Deputy Minister of the Ministry of Home Affairs.
[417] Parliamentary House of Representative 13th Term First Meeting No.16,Thursday 31st March 2016 page 11 can be found at http://www.parlimen.gov.my/files/hindex/pdf/DR31032016.pdf#page=10&zoom=70&search=biokeselamatan
[418]McLean MA and others, 'A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation' (International Service for National Agricultural Research (ISNAR) 2002)10.

scholar, lawyer, scientists, non-governmental organisation or mere layman have participated in the biosafety process.

Analysis of Malaysian public participation from Biosafety Clearing House website

From the Malaysia Biosafety Clearing House website, the public can view the country's decision[419] starting from 2010 to 2015. It is important to note here that the Biosafety Act was enacted in 2007 and only came into force in 2009. In 2010, Malaysia, for the first time, made decisions on LMO based on a proper legal framework, processes and appropriate procedures in place.[420]

i) Approval for Release: For field trial

On the report of the approval for field trial from 2010 up to 2015 onwards it can be seen that there were comments received from Consumer's Association of Penang (CAP) and Third World Network (TWN) and also the public on some technical and scientific issues. However, it was mentioned that the GMAC had assessed those issues through the risk assessment. The details of the technical and scientific issues raised were not mentioned.

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[419] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'Approval for Release For Field Trial | Food, Feed and Processing | Product of LMO' (2016) <http://www.biosafety.nre.gov.my/country_decision/app_plmo.shtml> accessed on 20 January 2016.

[420] Letchumanan R and Andrew J, 'Socio-economic aspects in decision-making in the context of the biosafety protocol: Malaysia's experience and case studies' (2012) 14.3 Asian Biotechnol Dev Rev 22.

For better understanding of the reactions of the public and the non-governmental organisations (NGOs), the summary of the type of project and events is reproduced.

The summary of the report on those projects is as follows:

Date of decision	Project title	Applicant
5 October 2010	Limited-Mark-Release-Recapture of Aedes aegypti (L.) Wild-Type and OX513A(My1) Strains	Institute of Medical Research
29 May 2013	Confined Field Evaluation of Delayed Ripening Transgenic Eksotika Papaya	Malaysian Agricultural Research and Development Institute (MARDI)
28 July 2015	Release of Genetically Modified Rubber (*Hevea brasiliensis*) Trees for Confined Field Trial for Research and Development Purpose	Malaysian Rubber Board

Table 7: Malaysia's decision: Approval for release for field trial

From the table, it can be concluded that there were public inputs due to the severity and influence of the local socio-economic issues in Malaysia such as the GM mosquitoes release and rubber tree as the main agricultural export.

ii) Approval for Release: For food, feed and processing

Next is on approval for release for food, feed and processing it can be seen that in the earlier 2010 up to 2012 there were applications made, but no comments were received from the public. However, from 2013 up to 2015 onwards, there were comments received from Consumer's Association of Penang (CAP) and Third World Network (TWN) and also the public on some technical and scientific issues. However, it was only mentioned that the GMAC had assessed those issues through the risk assessment.

The summary of the report of the event is as follows:

Date acknowledged by NBB	Event	Applicant
25 May 2010	MON 4032 Roundup Ready™ Soybean MON 603 Roundup Ready™ Maize MON 810 YieldGard™ Maize against Corn-Borer MON 863 YieldGard® Rootworm Maize	Monsanto
28 March 2012	SYN-Bt11-1 - YieldGard™ Maize	Syngenta Crop Protection Sdn. Bhd.
	ACS-GM5-3 - Herbicide-tolerant Soybean (A2704-12)	Bayer Co. (Malaysia) Sdn. Bhd.
27 November 2012	MON 89788 Glyphosate-Tolerant Soybean (RoundupReady2Yield™)	Monsanto Malaysia Sdn Bhd

8 January 2013	T25 herbicide-tolerant corn (LibertyLink® corn)	Bayer Co. (Malaysia) Sdn. Bhd
	TC1507 insect-resistant and herbicide-tolerant corn	Du Pont Malaysia Sdn Bhd
2 October 2013	Imidazolinone-Tolerant CV127 Soybean	BASF Malaysia Sdn.Bhd.
11 February 2014	Glufosinate-tolerant A5547-127 LibertyLink® Soybean	Bayer Co. (Malaysia) Sdn Bhd
19 December 2014	Glyphosate and Isoxaflutole Tolerant FG72 Soybean	Bayer Co. (Malaysia) Sdn Bhd
30 April 2015	Lepidopteran-protected Corn MON89034 Corn Rootworm-Protected and Glyphosate-Tolerant Corn MON88017	Monsanto Malaysia Sdn Bhd
10 March 2016	Rootworm-resistant Event 5307 corn Rootworm-resistant MIR604 corn Lepidopteran-resistant MIR162 corN Glyphosate-tolerant GA21 corn Thermostable Event 3272 corn	Syngenta Crop Protection Sdn. Bhd.
23 June 2016	SYHT0H2 - Soy modified for tolerance to Mesotrione and Glufosinate	Syngenta Crop Protection Sdn. Bhd.

	DAS-59122-7 - Herculex™ RW Rootworm Protection maize	DuPont Malaysia Sdn. Bhd.
6 October 2016	MS8RF3 Oilseed Rape	Bayer Co. (Malaysia) Sdn Bhd
17 January 2017	GHB614 cotton	Bayer Co. (Malaysia) Sdn Bhd
30 March 2017	T304-40 cotton	Bayer Co. (Malaysia) Sdn Bhd
30 March 2017	LLCotton25 cotton	Bayer Co. (Malaysia) Sdn Bhd
30 March 2017	GHB119 cotton	Bayer Co. (Malaysia) Sdn Bhd
01 August 2017	305423 soybean	DuPont Malaysia Sdn. Bhd.
	305423 soybean	Dow AgroSciences (Malaysia) Sdn. Bhd.
	MZHG0JG corn	Syngenta Crop Protection Sdn. Bhd
19 October 2017	DAS-81419-2 soybean DAS-44406-6 soybean DAS-68416-4 soybean	Dow AgroSciences (Malaysia) Sdn. Bhd.

Table 8: Approval for Release: For food, feed and processing

From the above, it can be concluded that there were inputs from the public consultation on these type of LMO due to these reasons:

a) there were known benefits and risks of these soybean, cotton, corns (which were already explained in the previous Introductory Chapter)

b) there were also herbicide and tolerant characteristics which benefits and risks were worrying the public

This is arguably due to science publications of this LMO; the public is being educated on the risks and benefits thus they are raising the concerns for the regulator to take the necessary precautions. It can be seen from the reports that the government is taking the necessary steps in addressing the concerns such as labelling requirement, the authority to be informed of any spillage also the transportation required to be in secured and closed condition.

iii) Approval for Release: For Products of LMO

The earlier 2010 report was reasonably simple that it did not mention any public participation. The same goes for 2011 National Biosafety Board (NBB) report. However, this time the report was far more comprehensive than before. In 2012, there was public consultation on GM Carnation done, but no comments were received from the public. The same happened for 2014 report whereby there was again no comment received from the public. Interestingly enough in 2015, there were some feedbacks received from the public on some technical and scientific issues. However, it was mentioned that those issues had been assessed by the GMAC through the risk assessment. It seems that from the website only one (1) application for GM products is received each year since its establishment. Moreover, there was no such application in 2013.

The summary is as follows:

Date decision acknowledged by NBB	Product name	Applicant
25 May 2010	ISP type III HPLC 12 Glacein™	Unilever Malaysia

26 July 2011	MOUSTICIDE™ Wettable Powder (WP) and MOUSTICIDE™ Rice Husk (RH)	EntoGenex Industries Sdn. Bhd.
27 November 2012	Cut flowers of genetically modified carnation, *Dianthus caryophyllus* L.	Suntory Holdings Ltd.
29 April 2014	Single Cell Protein (SCP), Liquid Fertilizer and Solid Fertilizers	CJ Bio Malaysia Sdn Bhd
17 February 2015	TMOF_Yeast (to produce Mousticide RH & Mousticide WP) and Mousticide WP (for Release)	Entogenex Industries Sdn Bhd

Table 9: Approval for Release: For Products of LMO

However, it interesting to note here on the particular case of field trial on the GM mosquitoes in 2010[421] in Bentong and Alor Gajah, Malaysia. From the NBB report, it was mentioned that concerns raised by the public were

[421] National Biosafety Board, Application for Approval for Limited Mark-Release Recapture of Aedes Aegypti Wild Type and Aedes Aegypti Genetically Modified Mosquitoes Ox513a(My1) (, 5 October 2010) 1.

addressed and taken into consideration when making the decision. It is noted that residents from the field trial site were engaged in public awareness activities and information about the field trial was made available. Besides, socioeconomic consideration was included such as the number of deaths moreover the cost of medication due to dengue fever.

The first release was conducted in January 2011 at an uninhabited site in Bentong. However, concerns have been raised by numerous bodies of NGO as the announcements to the public were posted on Malaysian Biosafety Clearing House website and published twice in a small section of two leading local newspapers.[422] Not all the public especially those who were living nearby have limited access to the information on the website and the newspaper. The local communities in Bentong and Alor Gajah were not part of the mandatory consultations before the approval was made by the Board and this suggests lack of transparency of the NBB and attracted considerable criticisms from the consumer association, the environmentalists and the public.[423]

Despite these criticisms, in fact, there were efforts made by the Director-General of the Department of Biosafety whereby a survey carried out by the Department of Biosafety in 2011 with about 1500 target participants indicated that more than 50 percent supported the release of GM mosquitoes. Though it was a small survey, the result was useful to reflect

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[422] Idris SH, Majeed ABA and Hamin Z, 'Public engagement in biosafety decision-making process: Appraising the law in Malaysia' (ICIMTR 2012 - 2012 International Conference on Innovation, Management and Technology Research 2012) 375.
[423] ibid.

that people are not entirely against GM mosquitoes. This can be easily rationalised as those affected by death cases arising from Dengue would surely like the problems solved.[424]

On the other hand, it is important to note here the eagerness to accommodate for public participation must be balanced with the fact that socio-economic considerations in the decision making based on detailed analysis is indeed tricky, time-consuming and an expensive job. Parties have their sovereign right to decide what is appropriate to their society based on facts in hand.[425]

This is quite a debatable issue in Malaysia and needs to be rectified by learning what has been done by other countries to get public confidence especially in cases of release of LMO involving the local community.

Again the issue is to what extent a public dialogue even being held in the first place and how productive is the public dialogue and how useful is the public dialogue as the medium taking into account that the dialogues will range from concerns, worries and informed information on the effects of LMO and GM technologies. Another issue is how much issues of ethical, legal and social implications have been discussed in the Malaysian context of the biosafety either in general or in relation to specific GM or LMO products as discussed above.

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[424]Letchumanan R and Andrew J, 'Socio-economic aspects in decision-making in the context of the biosafety protocol: Malaysia's experience and case studies ' (2012) 14.3 Asian Biotechnol Dev Rev 26-29.
[425]ibid.

The right of confidentiality of the applicant is balanced by the right of public disclosure as stipulated in section 59 of the Biosafety Act 2007. Failure to comply with this may result in a fine not exceeding RM10, 000 or to imprisonment under section 59(5) for a term not exceeding one month or to both.

In the general discussion of ethical, legal and social implications of LMO much have been written by the academics as have been discussed previously, however there is still little discussion in the Malaysian context. While an academic should be increased to educate people awareness on biosafety; this should be balanced with the upcoming campaign against LMO, GM and GM technology which can hamper the growth of modern biotechnology research and development in Malaysia thus failing the Malaysian ambition to generate economic growth based on modern biotechnology products.

Analysis of public awareness and participation in Malaysian compliance report

From the recent Malaysian compliance report[426] towards Cartagena Protocol on Biosafety,[427] it is shown that Malaysia has established the

[426]Department of Biosafety, Ministry of Natural Resources and Environment Malaysia, 'Third National Report on the implementation of the Cartagena Protocol on Biosafety' (2017) <https://bch.cbd.int/database/record.shtml?documentid=109107> accessed on 20 January 2017.
[427] In response to Cartagena Protocol on Biosafety art 23.

mechanism for public consultation in the biosafety decision-making process.[428] For release activities, public consultation is mandatory as it is advertised in major local newspapers.[429] The summary of the results taken on LMO is published[430] in national websites such as Malaysia Biosafety Clearing House, newspaper, mailing lists and social media.[431] Malaysia has also made the efforts either offline or online to educate the public on LMO. The Department of Biosafety for instance published education kits, flyers, newsletter, posters and booklet in different languages for different target groups on issues of biosafety.[432]

While a lot could be done to address on the inadequacies of public awareness and participation, it is important to note here that a lot has been achieved since the Biosafety Act 2007. In the Report,[433] Malaysia did not even consult the public and made the biosafety information available to the public as there is no legal requirement to do so at that time. The establishment of Biosafety Act 2007 had changed that Malaysian public participation position.

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[428] ibid Question 165.
[429]Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'Third National Report on the implementation of the Cartagena Protocol on Biosafety' (2017) <https://bch.cbd.int/database/record.shtml?documentid=109107> accessed on 20 January 2017 Question 164.
[430] ibid Question 166.
[431] ibid Question 168.
[432] ibid Question 176.
[433] Conservation and Environmental Management Division, Ministry of Natural Resources and Environment Malaysia, *Malaysia First National Report on Implementation of the Cartagena Protocol on Biosafety* (, 2007) 1.

The absence of a domestic law makes the participation of the public very much limited before 2007.[434] As one of the members of GMAC during that time was a member of an NGO, it was said that in a way Malaysia took public participation into account. However, in those issues, it was admitted by Malaysia that it is not a total substitution for public participation.[435] The mass media at that time played a role in raising the Malaysian public awareness on biosafety issues which can be further enhanced with the participation of more stakeholders.[436]

The socio economic considerations, ethics, bioethics, religious and cultural

Socio-economic considerations

The socio-economic considerations as have been discussed in the earlier chapter was from Article 26 of the Cartagena Protocol on Biosafety 2000. Hence it raises the issues as to what extent Malaysian biosafety laws recognised the inclusion of cultural issues.

Socio-economic considerations is contained in Section 35 of the Biosafety Act 2007 whereby the Board or Minister may also take into account socio-economic considerations. However, the definition of socio-economic considerations is not mentioned anywhere in the Act.

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[434] Question 21 of the Interim National Report on Implementation of the Cartagena Protocol On Biosafety submitted on 26/10/2005
[435] ibid.
[436] ibid.

Nevertheless, in Biosafety (Approval and Notification) Regulations 2010 lays down general guideline on the socio-economic considerations. According to Regulation 25, the Minister or the Board *may* consider –

a) the changes in the existing social and economic patterns and means of livelihood of the communities that are likely to be affected by the introduction of the living modified organisms or products of such organisms;
b) the effects of the religion, social, cultural and ethical values of communities arising from the use or release of the living modified organisms or products of such organisms.

Therefore we can see here that there are two (2) significant aspects of socio-economic considerations that are taken into account namely:

a) social and economic patterns and means of livelihood of the communities
b) religion, social, cultural and ethical values of communities.

From the above discussion, it seems that the Biosafety (Approval and Notification) Regulations 2010 recognises the inclusion of religion and culture also ethical values of communities.

However, it seems that it further Guidelines are needed either by the National Bioethics Council and Department of Islamic Advancement of Malaysia (JAKIM) on the religion, social, cultural and ethical issues. The National Bioethics Council should, for instance, be represented by the views of other religions as well such as Christian, Buddhists, Hindus including the Bumiputeras (native tribes) of Sabah and Sarawak.

Although the Regulations 2010 has expended this consideration further, it seems it is still insufficient to create a framework of parameters for comprehensive socio-economic analysis. This provision could be of use later especially about the native of Sabah, Sarawak and the jungle which are inhabited by the ‘orang asli’ (aborigine in Malaysia) when products from the jungle that have commercial value but have to compete for the GM products. The same can happen to the small-scale farmer that produce domestic or export agriculture products in various parts of Malaysia. Therefore this socio-economic considerations has to be taken into consideration by the biosafety decision-maker.

As mentioned earlier, Malaysia is rich in biodiversity, and its economy is very much dependant on agriculture product mainly palm oil and rubber. Therefore any introduction of LMO and GMOs that are specifically related to products that are produced in Malaysia are subjected to rigorous biosafety decision-making process.

In Malaysia, socio-economic considerations may become very important if the plantation industry of the primary commodities like oil palm, rubber, cocoa and others migrate into LMO options of high productivity or high value-added products at some stage. The smallholders will then face problems of having to compete with plantations owners in selling their non-LMO products. However, such problems may be resolved based on current experiences in related sectors.[437]

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[437]Ramatha L and Andrew J, 'Socio-economic aspects in decision-making in the context of the biosafety protocol: Malaysia’s experience and case studies' (2012) 14(3) Asian Biotechnol Dev Rev 19.

Thus it raises the further issue in the future if the LMO affect the social and economic livelihood of the local and indigenous people; the option not to include socio-economic considerations will stir up problems. Thus the decision-makers will have to be more cautious as in that case as it might be injurious to the country's economy in the illustrated case mentioned above.

However in the case of importing of grains whereby Malaysia so far approved the importing of 6 types of grains. As these grains are not able to grow in Malaysia, the socio-economic considerations are said to be remote whereby they are only for food, feed and processing and is not to be used as planting material. As corn is grown in some parts of Malaysia, the growth of spilt GM grains during transportation may pose contamination though the probability is very low. These grains are subjected to Malaysian rules and regulation such as labelling, regular reports of spillage etc. As the country is still at the infancy level of modern biotechnology development, so far Malaysia has not come across any socio-economic situations in the conservation and sustainable use of biodiversity as highlighted by MacKenzie and others (2003).[438]

The most controversial perhaps on these socio-economic issues related to public participation was in the case of the release of GM-type Aedes mosquitoes in Pahang. In that case in the National Biosafety Board report it was stated that the consistently growing socio-economic problems

[438]See Mackenzie R and others, *An explanatory guide to the Cartagena Protocol on Biosafety* (IUCN Publications Services Unit 2003)163-165.

arising from the increasing death cases caused by dengue fever from Yellow Fever Mosquito (Aedes aegypti) in Malaysia and many parts of the world and the fact that country may partly own the intellectual property right of the innovations support the release of GM mosquitoes into the wild jungle in Pahang.[439]

It is interesting to note here that like the Cartagena Protocol on Biosafety, the Biosafety Act 2007 also used the term 'may' in considering socio-economic issues. Thus this show options available in socio-economic considerations as opposed to mandatory scientific risk assessment and management.

Ethics and bioethics issues

Ethics, as defined earlier in the Introductory Chapter, is the way how people make decisions and lead their lives usually derived from religious belief, philosophies and cultures.[440] Bioethics is the more specific, relevant and direct moral issues associated with life science, especially modern biotechnology.[441]

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[439] Ramatha L and Andrew J, 'Socio-economic aspects in decision-making in the context of the biosafety protocol: Malaysia's experience and case studies' (2012) 14(3) Asian Biotechnol Dev Rev 19.
[440] 'Ethics guide' <http://www.bbc.co.uk/ethics/introduction/intro_1.shtml> accessed on 15 April 2015.
[441] M.K. Sateesh, *Bioethics and biosafety* (IK International Pvt Ltd 2008).

Bioethics consideration is closely related with socio-economic considerations as it is one of the factors considered according to Regulation 25 of the Biosafety (Approval and Notification) Regulations 2010 as it touches on the religion, social, cultural and ethical values of communities as mentioned above. Bioethical concerns should be part of the Act to assist decision-making process to formulate more informed policy and to improve stakeholders' abilities to make a judgement about what is right and wrong with biotechnology.[442] The term bioethics must be defined to avoid uncertainty.[443] The term 'ethics' according to Biosafety Act 2007 is not defined by scope thus caused vagueness.[444] According to Malaysia Biosafety Act 2007 the National Biosafety Board after having considered the recommendations of Genetic Modification Advisory Committee (GMAC), the comments of the relevant department or agency referred to, views of a member of the public, the Board may approve release and import.[445] It seems here there is no room for bioethics consideration as the GMAC report is purely scientific. Thus this is inconsistent with the 2007 Act and in some ways do not promote the objectives of the protectionist principles of this law.[446]

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[442]Hamin APDZ and Idris SH, 'Bioethical Issues on Genetically Modified Organisms (GMOs) In Malaysia: Biting Into the Legal Protection under the Biosafety Act 2007' (2nd International Conference on Biotechnology and Food Science IPCBE IACSIT Press, Singapore 2011).
[443] Azmi IM, 'The Gap between the Legal and Regulatory Framework of Health and Medical Biotech Research and Development in Malaysia and the Needs of the R & D Institutes in Malaysia' (2009) 6(3) Journal of International Biotechnology Law 109.
[444]Hamin APDZ and Idris SH, 'Bioethical Issues on Genetically Modified Organisms (GMOs) In Malaysia: Biting Into the Legal Protection under the Biosafety Act 2007' (2nd International Conference on Biotechnology and Food Science IPCBE IACSIT Press, Singapore 2011).
[445] Biosafety Act 2007 s16.
[446]Azmi IM (n443)109.

Bioethics issues even still at the development stage in Malaysia gained prominence as mentioned in the earlier part of this chapter after the National Biotechnology Policy 2005 (NBP). The establishment of National Bioethics Council lays out government strategies and plans for the biotechnology industry. Later it is to be seen that bioethics apart from biotechnology industry ethical issues is also part of medical ethics concerns. The bioethics issue in biosafety decision-making process is yet perhaps other relevant advice[447] to be given to NBB other than scientific and technical issues.

However, if the relevant department or agency such as National Bioethics Council and Department of Islamic Advancement of Malaysia (JAKIM) referred to and the public gives bioethics input only then bioethics consideration will be taken into account. Nevertheless, it is also unclear whether the public could raise any bioethical concerns in their involvement in public participation under section 149 (c) as there is no precise definition of public participation in the said Act.[448]

Other countries such as the European Union,[449] Korea[450] and Norway[451] have provisions specifically include bioethics whereby GM

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[447] Biosafety Act 2007 s6(2).
[448] Hamin (n444).
[449] Celina Ramjoue, "The Transatlantic Rift In Genetically Modified Food Policy", 2007, Journal Of Agricultural And Environmental Ethics (2007) 20:431 (as cited in Hussain&Wan, Shaik Mohd Noor Alam SM and Talaat IW, 'Precautionary Principle in the Malaysian Biosafety Law' (2009) 4(2) Journal of Sustainability Science and Management 146).
[450] José B. Falck-Zepeda, 'Socio-economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake?' (2009) Vol 12 (1) The Journal of Agrobiotechnology and Management and Economics 90.

assessments must be based on scientific evidence as well as ethical consideration. For example in Norway even though the law does not explicitly define the scope of bioethics, nevertheless the law has a clear stance on ethics.[452]

The bioethical issue even though is relatively new in Malaysia is pertinent in the biosafety legal framework. If litigation ensues due to claims of actions against bioethical principles, this is going to be a weak method of resolution[453] because "judicial decisions, once made, become precedent and thus have a normative effect on the actions and conduct of citizens other than those before the court in the present controversy".[454] Thus, scope and role of bioethics need to be spelt out in the legal framework to prevent future litigation suit.[455]

Perhaps to the biotechnology industry, the inclusion of bioethical consideration will provide hurdles to the business as it might delay production of beneficial products. However, it is agreed that this consideration must be balanced with biotechnology development. It is rightly argued that the bioethical consideration must be transparent, well-defined and understood by all stakeholders and actors in the biotechnology industry. However, the writer

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[451]Idris SH, Wei Chang L and Baharuddin A, 'Biosafety Act 2007: Does It Really Protect Bioethical Issues Relating To GMOS' (2013)(S26.4) Journal of agricultural and environmental ethic 747-757
[452]ibid.
[453]ibid.
[454]Schaller BR, 'Understanding Bioethics and the Law' (2008) 65.
[455]Daño EC, 'Potential Socio-Economic, Cultural and Ethical Impacts Of GMOS: Prospects for Socio-Economic Impact Assessment' in Traavik, Terje and Lim Li Ching (eds), *Biosafety first. Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007).

further argues that the Biosafety Act 2007 must adequately accommodate safety issues raised by GMOs and in doing so restore public confidence through bioethical consideration.[456] Conversely, it is submitted that perhaps 'safety' issues is not the right word to use but 'perception of safety' to the public as safety can be scientifically proven. Therefore it is rightly contended that Biosafety Act 2007 in this respect the ambiguity of bioethical aspect in some ways might defeat its role which was initially intended to achieve.[457]

It should be agreed that approval in adherence to biosafety law does not mean that it is free from risks. GM approval worryingly could lead to further bioethical issues on rights of farmers to farm conventional food and consumers' right to choose non-GM products.[458] Therefore the issues of labelling of GM products are of importance in Malaysia for consumers should resolve that particular issue. Thus scientific and ethical consideration should be assessed collectively in any LMO application.[459]

Religious and cultural issues on LMO in Malaysia

Apart from the general bioethical issues discussed worldwide, the same issues apply to Malaysia. The composition of Malaysian ethnics has

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[456] ibid.
[457] Idris SH, 'Bioethical assessment in the biosafety decision making process on GM crops? Approval in Malaysia: An analysis of the Biosafety Act 2007' (International Conference on Genetic Engineering & Genetically Modified Organisms DoubleTree by Hilton, Raleigh, NC, USA August 12-13 2013).
[458] Idris SH, 'Integrating Bioethical Concerns into Biosafety Law for Genetic Modification Technologies in Malaysia' (2013)(2:2) Adv Genet Eng.
[459] Idris SH, Wei Chang L and Baharuddin A, 'Biosafety Act 2007: Does It Really Protect Bioethical Issues Relating To GMOS' (2013)(S26.4) Journal of agricultural and environmental ethic 747-757.

been elaborated in Chapter 1. While the Islamic law ruling only affects the Muslims, the Buddhists and Hindus, some who are vegetarians or vegans with the strict dietary requirement should be considered as well. Therefore the non-consumption of animal origins in their food will also be observed just as the Muslims non-consumption of pork and liquor also non-slaughtered animals. Furthermore, Malaysians are cautious and sensitive in food consumption related to religious, cultural and dietary requirement.

As the majority of the population in Malaysia are Muslims, therefore, bioethical issues in relation to genetically modified organisms are mainly related to the rulings in the Islamic law. However, the application and the enforcement of Islamic Law is not uniform throughout the country due to its unique Islamic legal history. Historically the states in Malaysia before Malaysia under various colonialisms were ruled by their Sultan (Islamic ruler) following Shafie Mazhab (Shafie School of thoughts). Islamic law in Malaysia after 1963 is under List II[460] i.e. the jurisdiction of the state rather than the federal government. Therefore, any Islamic rulings ('fatwa') of the Islamic scholar (Mufti or 'fatwa council') legally is only applicable to that particular state. The ruling of the National Fatwa Committee has no legal force to all Muslims in Malaysia only unless each state gazettes it. However as good practising Muslims, regardless the fatwa comes from the National Fatwa Committee or the State Fatwa Authority, they just need to follow their faith and conscience.

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[460] Malaysia's Federal Constitution Ninth Schedule List II: State List.

Apart from the local Malaysian fatwa, a Muslim also observes international fatwa discussed by international contemporary Muslim scholars and the old school scholars as the consumption of genetically modified products is a new issue, not a traditional issue affecting Muslim consumers. Therefore the Islamic ruling on this GM products is not directly based on the two main sources of Islamic law, i.e. the Quran and Al-Hadith (Prophet Muhammad's sayings), but more on the Islamic scholar opinions but still based on the Quran and Al-Hadith subject to some Islamic rulings and methodology and in-depth study.

According to the National Fatwa Committee,[461] they take note that the genetically modified goods are sources from 'halal' (permissible to consume) and 'non-halal' (non-permissible to consume) origins either from animals or plants that provide the required characteristics of food or medicine. On this issue, Islam takes the view that Muslim ummah (people) should consume toiyyibah (good) food that is halal, pure and not harmful to human spirit and mind and the production process should not be detrimental to human health and the environment. Thus the genetically modified products that are not permissible according to Islamic law, and the production process that will cause harm to human health and environment is not permissible. On the other hand, the use of halal livestock is permissible if it is slaughtered by the methods allowed under the Shari'ah (Islamic law). Therefore, the GM products that contain pork or alcohol will not be permissible to consume. The

[461] Jabatan Kemajuan Islam Malaysia (JAKIM), 'Eating Genetically Modified Food law (Genetic Modified Food)' (2016) <http://www.e-fatwa.gov.my/fatwa-kebangsaan/hukum-memakan-makanan-terubahsuai-genetik-genetic-modified-food> accessed on 21 January 2016.

same is the case if the product of cow or goat that is not slaughtered according to *Shari'ah* is not permissible to be consumed. The same happens if the process of GM will cause environmental damage or destroy human life. Thus this is also not permissible in Islam.

Thus we can see that the Islamic ruling on GM food towards the Muslims is quite strict as they concern on the effect of non-halal ingredients and non-permissible GM process. Apart from this ruling, JAKIM has the power to issue a certificate of 'halal' (permissible to consume) throughout Malaysia. Although there is no mandatory 'halal' labelling on all food products in Malaysia as it is a multiracial country, the companies knowing the majority of consumers in Malaysia are Muslims usually seeks for this 'halal' certificate even multinational companies such as McDonald, Pizza Hut, and KFC etc. This is obviously for business strategy and profit. For them to obtain the 'halal' certificate, they have to fulfil specific requirements such as the non-halal ingredients are not allowed, the slaughtering according to Islamic principles etc. Thus, apart from halal labelling that is usually observed by food producers, the GM labelling perhaps put a bit more burden on them. However, it is believed that regardless whether they like it or not, they have to abide or else they will lose their profitable chance of business.

If the LMO affects the religion, social, cultural and ethical values of communities thus it calls for the empowerment of the National Bioethics Council and other related institutions. Malaysia by the Federal Constitution (as the highest law of the land) is a religious state. The religious issues could

not just be ignored even in biosafety and related issues. As stated earlier, Malaysia is multiracial thus multi-religious and multicultural country. Hence, government must take racial and religious sensitiveness into account. Therefore, this step is regarded as 'highly desirable'[462] to include those sentiments.

It then provokes another issue, if Malaysia were to include socio-economic considerations such as cultural factors and broader issues than the Protocol, will it contradict Cartagena Protocol on Biosafety as being too protective of its national law. It is argued that consistent with Article 2(1) of the Cartagena Protocol on Biosafety that 'Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.' If the measures of the Malaysian government are to include cultural factor is a necessary measure, this should be justified. Article 2(2) also provides Malaysia shall ensure the manner of handling of LMO is to prevent or reduce the risks to biological diversity, also taking into account risks to human health, in the Malaysian context and unique to Malaysia. If it affects the Malaysian biodiversity and human health again, this could be another good reason for inclusion.

Article 2(4) of the CPB - that expressly allows countries to 'take action that is more protective … than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol

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[462] Chan K, 'Malaysia Biosafety Act 2007 and Cartagena Protocol on Biosafety: A critical comparative analysis' (2016) 9.

and is by that Party's obligations under international law'.[463] Thus it is rightly argued that the questions not be whether the law is broader whether it adequately protects the biodiversity and human health.[464] Section 35 however, states that in case of scientific uncertainty 'due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of LMO 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'. 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.[465] Thus this explains the other indirectly related to biosafety laws, regulations and guidelines which seem to integrate all these connecting essential elements in Malaysian biosafety regulations. Thus socio-economic considerations in Biosafety in Malaysia is of broader application and may be considered in case of scientific uncertainty.

Handling, Transport, Packaging and Identification of GM products

Malaysia is to handle, transport,[466] package and identify the LMO according to international standard and procedures as required by Article 18,

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[463]ibid.
[464]ibid 9-10.
[465]ibid 9.
[466] Malaysia has a Standard Operating Procedure for Transport of Biological Specimens in Malaysia for hospital lab.

but nothing similar is found in Biosafety Act 2007.[467] Due to the bioethical issues that are closely related to the consumers' belief, religious, cultural and perception, there were calls for mandatory labelling of GM products. In Malaysia there is provision for mandatory food labelling for GM product perhaps after several calls from non-governmental organisation[468] and consumer groups on the safety and effects of those LMO on human health, animals and environment. US government for instance when negotiating the Federal Trade Agreements (FTA) with Malaysia, opposed the measure, fearing that it would hinder US imports.[469]

While there are arguments for pro mandatory and voluntary labelling such the EU and the US respectively, Malaysia opted for mandatory labelling. The mandatory labelling is provided by section 61 of the Biosafety Act 2007 that states all LMO and GM products '…shall be identified and labelled in a manner to be prescribed' also in addition to any other written law. This will not just reflect consumers' choice also the consumers' right to know whatever they are consuming regardless of what their belief or stance on GM food consumption. This is strictly related to ethics towards the consumers. However, perhaps, more importantly, there are significant scientific uncertainties on the safety of those GM products.[470]

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[467] ibid 8.
[468] Third World Network (TWN). 'Malaysia's GMO Labelling Stance and US Pressure' (2016) <http://www.twn.my/title2/FTAs/info.service/fta.info.service103.htm> accessed on 10 January 2016.
[469] Zainol ZA, Nordin R and Akpoviri FI, 'Mandatory labelling of genetically modified (GM) foods' (2015) 15(2) International Environmental Agreements: Politics, Law and Economics 199.
[470] Consumers Association of Penang. 'Labeling of genetically engineered foods in Malaysia threatened by TPPA' (2016) <http://www.consumer.org.my/index.php/development/socio-

Malaysia is one of the 64 countries that provides for mandatory labelling of GM products.[471][472] However the mandatory labelling threshold higher than 3%.[473] The labelling requirement can be seen in Food Regulations 1985, amended in 2010 (Ministry of Health, MOH).[474]

a) Approval (regulation 3A)
b) Labelling [regulation 11(3A), 11(6), 11(7a-e)

These regulations were enforced in July 2014.

Regulation 11(3A) states that the origin of food and food ingredients obtained through modern biotechnology shall be stated as follows:'…gene derived from (common name of such animal). 'Thus this Regulation is of useful information for those who are Muslim, Hindus or vegetarian who is forbidden from consuming any relevant types of animals.

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economic/720-labeling-of-genetically-engineered-foods-in-malaysia-threatened-by-tppa> accessed on 23 January 2016.

[471] Jill Ettinger, 'GMO Labelling Laws Around The World:The 64 Countries That Do it' <http://www.organicauthority.com/foodie-buzz/gmo-labeling-laws-around-the-world-the-64-countries-that-do-it.html> accessed on 15 December 2015.

[472]Centre for Food Safety, 'Genetically Engineered Food Labeling Laws' <http://www.centerforfoodsafety.org/ge-map/> accessed on 15 December 2015.

[473] Gurmit Singh and June E Tan, 'What Malaysians Should Know About GMOs, and GMO Labelling in Malaysia' <http://www.mesym.com/discussions/what-malaysians-should-know-about-gmos-and-gmo-labelling-in-malaysia/> accessed on 31 October 2015.

[474] Andrew Morgan Tennant, 'Genetically Modified Food and Canning' (2012) <http://www.mfca.org.my/index.php?page=genetically_modified_food_and_canning> accessed on 20 January 2016.

Regulation 11(6) state that the origin of food and food ingredients obtained through modern biotechnology shall be stated as follows: '…gene derived from (origin)' also a statement indicating that the food may cause hypersensitivity;[475]also (5) listing out them as cereal, nut, fish, egg and milk. This is particularly useful to those who have allergies to that food.

Regulation 11(7) states that for food and food ingredients obtained through modern biotechnology shall be labelled as follows:

a. in the case of food and food ingredients are composed of or contains genetically modified organisms, the words "genetically modified (name of the ingredient)" shall appear on the label;
b. in the case of food and food ingredients are produced from, but does not contain genetically modified organisms, the words "produced from genetically modified (name of the ingredient)" shall appear on the label;

In short, the product needs to be labelled as contains 'Genetically Modification' and specifying the name of the ingredient for composed or contained also produced from.

Labelling is also related to precautionary principle whereby the consumer is taking precaution in choosing whether or not to consume the GM products.[476]Thus is agreed that the mandatory labelling requirement by Malaysia is justified.[477] Labelling perhaps argued as a non- scientific biosafety measure, however, should be justified due to respecting public

[475] Food Regulations 1985 Reg 11(6) (1)(ea).
[476] Zinatul Ashikin Zainol, and others 'Mandatory labelling of genetically modified (GM) foods' (2015) 15(2) International Environmental Agreements: Politics, Law and Economics 199.
[477] ibid.

choices exercises due to ethical, bioethics, religious and cultural views. This is done partly perhaps for public acceptance of the LMO. Again another issue is that labelling of LMO is only for food but not LMO for FPP.[478] Thus, whether Malaysian like it or not, or more precisely whether they realise it or not, they have already consumed them, since less than 3% GM ingredient does not need labelling also LMO for FPP.

Labelling also raises issues of compliance, monitoring and public education. The Malaysian public level of awareness it seems according to the previous study varied directly with the level of specialised education. Scientists, biologists, students, and others involved in the modern biotechnology field tended to be more acquainted with GM foods than other members of the society[479][480].

Liability and redress

Liability and redress is stated in Article 27 mentions that the Conference of Parties (COP) serves as Meeting of Parties (MOP) adopt a process of appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall

[478] Chan K, (2016) Malaysia Biosafety Act 2007 and Cartagena Protocol on Biosafety: A critical comparative analysis 8.
[479]Latifah Amin and others, 'Public attitude towards modern biotechnology' (2011a) African Journal of Biotechnology, 10(58), 12409.
[480] ibid.

endeavour to complete this process within four years. In its decision BS-V/11, the COP-MOP adopted The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety by providing international rules and procedures in the field of liability and redress relating to living modified organisms.[481]

In the event of damage, Parties shall require the appropriate operators to:

(a) Immediately inform the competent authority;
(b) Evaluate the damage; and
(c) Take appropriate response measures.[482]

Thus the competent authority shall:

(a) Identify the operator which has caused the damage;
(b) Evaluate the damage; and
(c) Determine which response measures should be taken by the operator.[483]

The parties in developing civil liability shall address inter alia

(a) Damage;
(b) Standard of liability, including strict or fault-based liability;
(c) Channeling of liability, where appropriate;

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[481]Cartagena Protocol on Biosafety art 2.
[482]ibid art 5(1).
[483]ibid art 5(2).

(d) Right to bring claims.[484]

However, to date, Malaysia has not yet regulated nor implemented the liability and redress provision as Malaysia has not signed and ratified The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety. In the standard of liability, Malaysia advocates adopting strict liability.[485]Strict liability may also be one way of operationalising the Precautionary Principle which governs the critical elements of the Cartagena Protocol on Biosafety.[486]

Other biosafety related laws, regulations and guidelines and indirectly related to biosafety

Apart from the primary biosafety laws and regulations namely the Biosafety Act 2007 and the Biosafety Regulation 2010, there are other biosafety and indirectly related laws, regulations and guidelines. As the names suggested, these regulations are the regulating of their respective areas which are shown as follows:

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[484]Cartagena Protocol on Biosafety art 12(3).
[485] Wan Izatul Asma WT, Norhayati MT and Mohd LH, 'Liability and Redress of Trans-Boundary Movement of Genetically Modified Organisms and the Biosafety Law in Malaysia' (2011) 4(4) Journal of Sustainable Development 112.
[486] see Nijar GS, 'Developing a liability and redress regime under the Cartagena Protocol on Biosafety' (2000).

i.	Protection of New Plant Varieties Act 2004 (PNPVA)
ii.	Guidelines of Institutional Biosafety Committee (IBC): Use of Living Modified Organism and Related Material, 2007
iii.	Guidelines for Contained Use Activity of Living Modified Organism
iv.	Exemption under S68 of Biosafety Act
v.	User's Guide to the Malaysian Biosafety Act and Regulations
vi.	Biosafety Guidelines: Confined Field Trial of Living Modified Plants in Malaysia
vii.	Biosafety Guidelines: Environmental Risk Assessment of Genetically Modified Plants in Malaysia
viii.	Biosafety Guidelines: Risk Assessment of Genetically Modified Microorganisms
ix.	Control of Drugs and Cosmetics Regulations 1984 (Amendment 2009)
x.	Animals Act 1953
xi.	Guidelines on Labelling Of Foods And Food Ingredients Obtained Through Modern Biotechnology (Regulations 11(3a), 11(6) And 11(7), Food Regulations 1985)
xii.	Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline 2015

Table 10: Malaysian Rules and Regulations on Biosafety

The Biosafety Act is the enabling Act that gives the power to make the later Biosafety Approval Regulation 2010. The latter derived its jurisdiction from the parent Biosafety Act 2007. The Acts and Regulation (either related or indirectly related to biosafety) are hard laws that have binding legal force. The Guidelines, on the other hand, are soft laws that are not legally binding only guidance on practices.[487] It is essential for LMO from research and development to product commercialisation to follow regulatory compliant practices.[488] This is pertinent to gain public confidence for the safety benefits of human health and the environment. Even though termed as 'Guidelines', these instruments are regulatory compliant practices whereby it detailed out an acceptable standard that should be followed in that field of practice.

[487] Biosafety Guidelines: Confined Field Trial of Living Modified Plants in Malaysia 7.
[488] ibid.

The Biosafety Guidelines: Environmental Risk Assessment of Genetically Modified Plants in Malaysia (ERA Guidelines) as mentioned above is essential for release into the environment for trial purpose. For contained use, however, is used as a framework which helps in the decision-making as to whether such an application should be approved or rejected.[489]

Some Guidance Note is to guide and support the Regulations. For instance Guidance on Classification is to guide for Control of Drugs and Cosmetics Regulations 1984 (Amendment 2009) and Guidelines on Labelling of Foods and Food Ingredients Obtained Through Modern Biotechnology is to support the Food Regulations 1985 for food labelling.

The indirect acts to biosafety laws, regulations and guidelines such as Animal Act 1953, Protection of New Plant Varieties Act 2004 (PNPVA), Control of Drugs and Cosmetics Regulations 1984 (Amendment 2009) for example, beside regulating the conventional animals, pharmaceutical products and new plants are regulating the jurisdiction respectively if they contain LMO as well. These laws are consistent with Section 2 of the national Biosafety Act 2007 that states that it is to be read together with other laws.

[489]Biosafety Guidelines: Environmental Risk Assessment of Genetically Modified Plants in Malaysia 12.

6. Conclusion

In conclusion, as matter compliance towards Cartagena Protocol on Biosafety Malaysia has enacted the relevant Biosafety Act 2007 and later formulated the Biosafety Regulations 2010 as the primary laws and regulations on biosafety. It can be concluded that overall perspective that Malaysia Biosafety Act 2007 is consistent with the Protocol.[490] Apart from these laws, there were other related or indirectly related to biosafety laws such as biodiversity, food safety, animals, etc. From the long title of the Biosafety Act 2007, it can be seen that the 'objectives of protecting human, plant and animal health, the environment and biological diversity.' Thus this could provide a basis for future amendments for a more comprehensive biosafety laws not just on environmental biosafety but other aspects of biosafety as stated above. The position of the Malaysian biosafety law as of today is that the laws on human, plant and animal health even though relates on LMO are on the existing Acts and Regulations respectively with amendments to include LMO as well.

The present research aims to examine the Malaysian background in signing Cartagena Protocol on Biosafety by analysing the relevant policies. This study also scrutinises the crucial elements of the biosafety conceptual framework. The primary goal of the current study is to analyse Malaysian legal framework in compliance towards the most critical Key Protocol issues. This study has found that Malaysia has complied with those Key Protocol

[490] Chan K, (2016) Malaysia Biosafety Act 2007 and Cartagena Protocol on Biosafety: A critical comparative analysis 10.

issues and the only issue is the breadth and depth of its laws. Thus critics that said Malaysia biosafety exceeds its minimum requirement as compared to Cartagena Protocol on Biosafety[491] are unjustified. At this juncture it can be safely concluded that the existing Malaysian current legal framework on biosafety laws lack cohesion and have a lot of rooms for improvement. There are still some key issues that need to be further developed for the future capacity building of biosafety law in Malaysia. This is the first study to compile the overall most crucial biosafety issues in Malaysia. Notwithstanding the relatively limited data sample, this work offers valuable insights into the existing biosafety legal framework. These findings suggest several courses of action for recommendations of future stronger biosafety law.

As this chapter focus on the legal framework, next chapter will discuss the institutional framework that implements the existing laws, regulations and guidelines. The next Chapter 4 will complement the analysis in Chapter 3 in line with the aim of the study to examine the vital institutional aspects of Malaysia's biosafety implementation for future improvements.

[491] Ministry of Natural Resources and Environment Malaysia, 'The Biosafety Act of Malaysia: Dispelling the Myths' <http://www.nre.gov.my/Malay/Pusat-Media/Penerbitan/Dispelling%20the%20Myths.pdf 31.>

CHAPTER 4
AN ANALYSIS OF THE MALAYSIAN INSTITUTIONAL FRAMEWORK FOR BIOSAFETY REGULATION

1. Introduction

The previous Chapter 3 analyses the Malaysian legal biosafety framework towards compliance to Cartagena Protocol on Biosafety. Countries that signed the Protocol applied various strategies for implementing its legal and institutional framework such as having an expert advisory committee, independent risk assessment committee, the inclusion of ethics committee and many more.

This chapter is focusing on the Malaysian approach on institutional biosafety framework to complement the legal framework with references to the existing rules and regulations as stated in Chapter 3. It is important to analyse the various biosafety institutions that are involved directly or indirectly and practically on the biosafety decision-making process. The chapter also tries to examine the Malaysia regulatory strategy in the biosafety decision-making process which enables to find loopholes in its implementation with a view to improve on its institutional structure. This chapter is closely related to Chapter 3 that provides the legal basis for the institutional biosafety framework in Malaysia.

2. Malaysian institutional framework to implement Cartagena Protocol on Biosafety

Malaysia's policy on biodiversity and biotechnology as part of the action plans had led Malaysia established a committee on biosafety that includes representatives from the environment, health and research fields, and keep abreast of developments in this field in the international arena.

Malaysia then apart from that, established enforcement unit on biosafety within an appropriate government department. Training programs in biosafety management and practice were developed.

Malaysia institutional framework on biosafety

In Malaysia the institutions responsible for land biodiversity issues and related to biosafety is illustrated in Table 11 below: [492]

Referral institution
Key referral agency
Ministry of Science, Technology and Environment (until 2004)
Ministry of Natural Resources and Environment (from 2004 onwards)
Subsidiary referral agency
Institute of Biodiversity
National Council for Biodiversity and Biotechnology
Genetic Modification Advisory Committee
Sabah Biodiversity Centre
Sabah Biodiversity Council
National Biosafety Board

Table 11: Referral institutions responsible for land biodiversity issues in Malaysia between 2000-2010

[492] Ismail R, Mamat I and Anuar M, 'Malaysiya's Response to International Biodi-Versity Policies of the United Nations: An Analysis of Cartagena Protocol on Biosafety Between 2000 and 2010' (2013) 7(4 April-June 2013) J Environ Res Develop 1419.

Department of Biosafety
National Biosafety Board
Genetic Modification Advisory Committee (GMAC)

Table 12: Leading institutions responsible for biosafety issues in Malaysia

Ministry of Natural Resources and Environment Malaysia
Malaysian Department of Biosafety
Department of Veterinary Services
National Pharmaceutical Control Bureau
Food Safety and Quality Division, Ministry of Health

Table 13: Competent national authority on biosafety[493]

The Malaysian institution on biosafety has been established to accommodate the biosafety laws, regulations and guidelines that were established dated from the national Biosafety Act 2007.

The Ministry of Science and Technology (MOSTE) was the earlier ministry that was involved in the drafting of Biosafety Act 2007. However, later it was the Ministry of Natural Resources (NRE) that took the lead in the biosafety decision making process after the Biosafety Act 2007 came into force.

The three (3) leading institutions in biosafety, namely as follows:

a) National Biosafety Board (NBB)

[493] Malaysia Competent National Authority ' (2016) <https://bch.cbd.int/database/results?searchid=691487> accessed on 25 January 2015.

b) Genetic Modification Advisory Committee (GMAC)

c) Department of Biosafety

The Malaysian institutional biosafety framework is illustrated as follows;

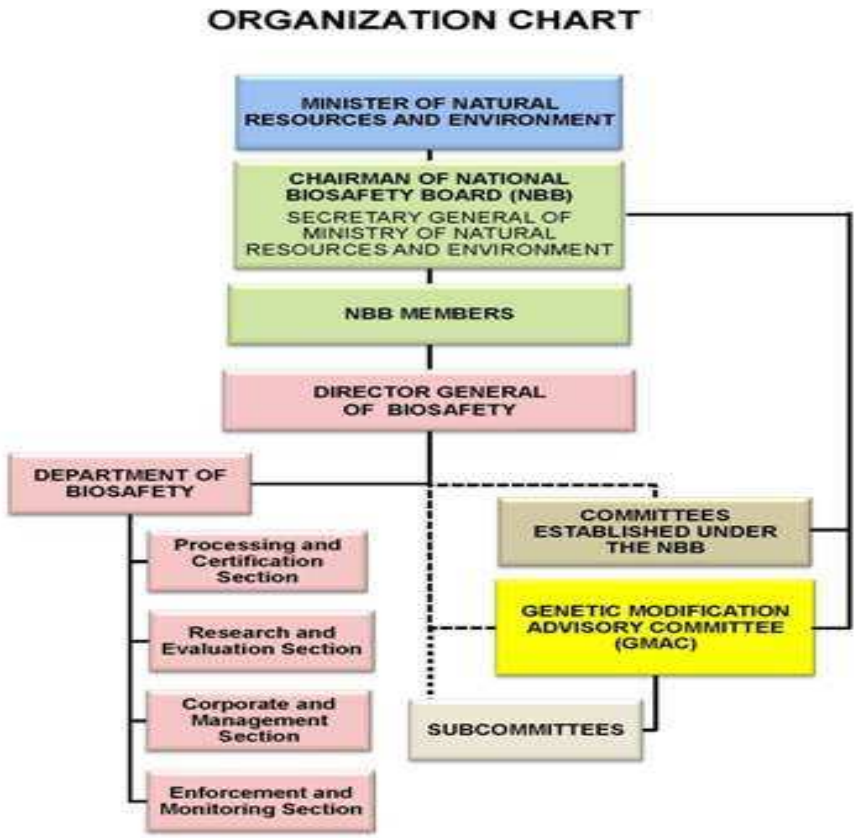

Figure 13: Malaysian institutional biosafety framework

From the biosafety organisation chart, it can be seen that Minister of Natural Resources and Environment (NRE)[494] is taking the lead in biosafety decision making starting from the approval for the import, export and release of the living modified organism (LMO) as acted upon by the National Biosafety Board (NBB). The Minister has the power to hear any appeals.[495]

Mclean's observation[496] reveals that some countries have implemented a system of expert advisory committees, while others have relied primarily on scientists and professionals working within government agencies. In the latter approach, the mandate for risk assessment may be vested within a single agency exclusively tasked with regulating products of biotechnology (e.g., a gene technology regulator) or it may be distributed between agencies by their existing responsibilities (e.g., departments of health, agriculture and/ or environment).

In general, independent advisory committees have more transparent accountability frameworks than government departments and agencies, where the range of expertise and academic credentials of risk assessors is rarely published. However, advisory bodies may suffer from the fact that committee members are part-time volunteers who cannot devote their full energies to risk assessments. An approach to LMO regulation whereby

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[494] Biosafety Act 2007 s3.
[495] ibid s34.
[496] McLean MA and others, 'A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation' (International Service for National Agricultural Research (ISNAR) 2002) 5.

product evaluations performed by competent scientists within a regulatory agency is supplemented by the results of the issue. A specific expert panel of consultations may combine the best of both approaches described above.

i) National Biosafety Board (NBB)

National Biosafety Board[497] is the main board that is responsible for accepting or rejecting the living modified organism either in the research or importing or exporting of the living modified organism in Malaysia. NBB was established on 15 March 2010 after the enforcement of Biosafety Act 2007. The secretariat for the National Biosafety Board is the Department of Biosafety[498] under the Ministry of Natural Resources (NRE).The Secretary-General of Ministry NRE is the Chairman of the NBB.[499]

The composition of the members of the NBB[500] requires a representative from the:

a) Ministry of Agriculture and Agro-based Industry;
b) Ministry of Health;
c) Ministry of Plantation Industry and Commodities
d) Ministry of Domestic Trade and Consumer Affairs;
e) Ministry of International Trade and Industry
f) Ministry of Science, Technology and Innovation;
g) and not more than four other persons who have the knowledge or experience or both in any of the disciplines or matters relevant to this Act.

Figure 14: Members of the National Biosafety Board (NBB)

[497] Biosafety Act 2007 s4.
[498] In Malay;Jabatan Biokeselamatan (JBK)
[499] Biosafety Act 2007 s4(2)(a).
[500] ibid s(4)(2)(a).

According to the existing organisation chart,[501] the four other persons were appointed from these bodies as of today namely as follows:

a) Sabah Biodiversity Centre
b) Sarawak Biodiversity Centre
c) University Malaya
d) Academy of Science Malaysia

These four other persons are presumably from the science discipline and have the relevant experience in biodiversity, also from the academic background.

[501]National Biosafety Board (NBB), 'National Biosafety Board (NBB)' (2017) <http://www.biosafety.nre.gov.my/about/nbb.shtml> accessed on 20 January 2017.

Functions of NBB:[502]

a) To decide on all applications and matters under Part III (Approval for Release and Import) and Part IV (Notification for export, contained use and import for contained use)
b) To monitor activities relating to LMOs and products of LMOs
c) To promote research, development, educational and training activities relating to biosafety
d) To establish mechanisms to facilitate the collection, storage and dissemination of data relating to living modified organisms and products of such organisms and biosafety
e) Where so directed by the Minister, to perform or provide for the performance of the obligations arising from agreements, conventions or treaties relating to biosafety to which Malaysia is a party where such agreements, conventions or treaties relate to the purposes of this Act

Figure 15: National Biosafety Board (NBB) and its functions

It was suggested that the roles and functions of NBB should be expanded to provide advice, resolve and manage bioethical issues in GMOs issues.[503] This will be only effective if NBB works together with National Bioethics Council by legalising that Bioethics Council in the biosafety institutional framework. That can be achieved by amendments to the existing laws or regulations by having a new regulations or guidelines on bioethics.

[502] Biosafety Act 2007 s5.
[503] Hamin APDZ and Idris SH, 'Bioethical Issues on Genetically Modified Organisms (GMOs) In Malaysia: Biting Into the Legal Protection under the Biosafety Act 2007' (2nd International Conference on Biotechnology and Food Science IPCBE IACSIT Press, Singapore 2011).

This should start by having a stance or national policy on bioethics in biosafety regulation.

ii) Genetic Modification Advisory Committee (GMAC)

The Genetic Modification Advisory Committee (GMAC)[504] is the body that advises the NBB on the scientific risk assessment performed on the living modified organisms before making the decision either to accept or to reject the LMOs. GMAC members[505] were appointed on 25th May 2010. GMAC is to provide scientific, technical and other relevant advice to the Minister or the National Biosafety Board (NBB).[506] Hence primarily the composition of the GMAC is consists of the experts various science-based and other relevant disciplines. As most members of the GMAC are from the science background thus the scientific risk assessment is being used in advising the NBB.

The Third World Network (TWN) as representatives from civil society are also included in the GMAC.[507] In 1996, the GMAC published the National Guidelines for the Release of GMOs into the environment, which was developed from existing principles and documents including the UNDP International Technical Guidelines on Safety in Biotechnology, 1996 and the

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[504] Biosafety Act 2007 s6.
[505] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia, 'Genetic Modification Advisory Committee (GMAC)' (2016) <http://www.biosafety.nre.gov.my/about/gmac.shtml> accessed on 20 November 2015.
[506] ibid.
[507] Ministry of Science, Technology and the Environment Malaysia, *Malaysia: Capacity-building for Implementation of National Biosafety Framework* (Project Brief PIMS 2182, 2013) 2.

UNIDO Voluntary Code of Conduct for Release of Organisms into the Environment 1991.[508]

MoSTE is making the budget to implement the hiring of personnel within their overall institutional framework. However, training will still be needed, particularly for risk assessment and risk management as mentioned earlier in Chapter 3.

It is also likely that under the previous proposed Biosafety Bill, the GMAC membership to include representatives of other ministries. While this will hopefully result in broader involvement, it also means that the need for capacity building will be increased at least for raising awareness among participating government officers.[509]

iii) Department of Biosafety (DOB)

From the organisation chart (Figure 13 above), it can be seen that DOB plays an essential role in the administration of biosafety in Malaysia. DOB was established on 24th May 2010.

[508] ibid.
[509] ibid 7.

The objective of DOB is to act as a One Stop Centre for all activities relating to biosafety.

a) To implement and enforce the Biosafety Act;
b) To be the secretariat and the operational arm of the National Biosafety Board (NBB);
c) To be the secretariat of the Genetic Modification Advisory Committee (GMAC) and committees/sub-committees established under the NBB and GMAC;
d) To monitor all activities relating to living modified organism (LMO) and products of such organism;
e) To provide a platform for consultation with various parties in order to formulate and update policies, laws and guidelines related to biosafety;
f) Coordinate and integrate the efforts taken by Federal Government agencies and State and Non-Government Organizations and the Modern Biotechnology Industries related to biosafety issues;
g) Build strategic partnerships with relevant agencies within and outside the country in the field of biosafety;
h) Establish mechanisms to facilitate the collection, storage and dissemination of data related to biosafety;
i) Help the Government to formulate the country's stand on the issues of biosafety at international forums; and
j) Increasing public awareness on biosafety.

Figure 16: Functions of the Department of Biosafety

Apart from these three (3) primary bodies, there are other essential bodies in biosafety which are discussed as follows;

a) Institutional Biosafety Committee (IBC)

The NBB may direct that any organisation that undertakes modern biotechnology research and development to establish an Institutional Biosafety Committee (IBC).

The purposes of the establishment of IBC are as follows:[510]

(a) to provide guidance for safe use of modern biotechnology; (b) to monitor activities dealing with modern biotechnology; (c) establishing and monitoring the implementation of policies and procedures for the purpose of handling living modified organisms; and (d) determining the classes of Biosafety Levels for contained use activity for the purpose of modern biotechnology research and development undertaken within a facility where the institutional biosafety committee is established

Figure 17: IBC purposes

[510] Biosafety (Approval and Notification) Regulations 2010 reg 5(1).

The IBC is required to, among others:[511]

- Periodically review research projects that are recommended for approval;
- Assess and monitor the facilities, procedures, practices, training and expertise of personnel involved in research;
- Assess and set containment levels and modify them as necessary;
- Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plans are sufficient;
- Adopt and implement emergency response plans covering accidental spills and personnel contamination, resulting from LMO/rDNA research;
- Review and report to the head of organisation and the NBB any significant problems with non-compliance of the Act or Regulations and any significant research-related accidents or illness;
- Recommend suspension of project approval or use of LMO/ rDNA materials where there is non-compliance or that the use or possession poses a threat to the health and safety of the community; and
- Routinely review the policies and procedures of the IBC and modify as necessary to ensure appropriate biosafety measures and compliance with the Act and Regulations[13]

Figure 18: IBC tasks

b) National Bioethics Council of Malaysia

National Bioethics Council of Malaysia was established on 9th July 2010 with its secretariat administered by the Ministry of Science, Technology and Innovation of Malaysia (MOSTI). The establishment of the National Bioethics Council is one of the strategies in implementing National

[511] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia, User's Guide to the Biosafety Act and Regulations (Department of Biosafety, Ministry of Natural Resources and Environment Malaysia) 20.

Biotechnology Policy 2005 as stated previously in Chapter 3. The National Bioethics Council plays a role as an advisory panel that discusses and resolves bioethical issues that may have an impact concerning the environment, social, health, culture, laws and religions and Malaysian society in general.[512]

Earlier a Socio-Economic Committee was suggested, but as socio-economic issues can be susceptible at times, and based on experiences in other areas such as environment, the National Biosafety Board decided to set up just an informal advisory group. This can be referred back to the incident of the release of GM mosquitoes that stirred up controversial issues of consent besides the impact on local people in the nearby release area namely Bentong in Pahang and Melaka.

Later National Bioethics Council (NBC) was established that opens a window for consultation by NBB thus complementing its effort. As this is a new set up, the working mechanism between the NBC and the NBB will have to be periodically reviewed to ensure effectiveness.[513]

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[512] Ministry of Science, Technology and Innovation, Malaysia. 'Terms of Reference' <http://www.bioetika.gov.my/index.php?option=com_content&view=article&id=3&Itemid=155> accessed on 20 November 2015.

[513] Ramatha Letchumanan and Johnny Andrew, 'Socio-Economic Aspects in Decision-Making in the Context of the Biosafety Protocol: Malaysia's Experience and Case Studies' , Vol 14.3 (2012)

Roles and Purposes of the Council

i. Provide direction towards awareness on bioethical issues to the researchers, educators, policymakers, and industries on the recent or novel and opinions or perspectives regarding the current practice in life sciences including health and medical sciences, biotechnology, genetics, biology and other related fields. ii. Advise and assist in mainstreaming bioethics among policymakers, researchers, industries, educators, practitioners and the public. iii. Disseminate information and nurture awareness as well as encourage bioethics in every aspect of life, promote dialogues and networking between stakeholders in issues of bioethics. iv. Establish a committee from time to time to execute the proposed and planned activities.

Figure 19: National Bioethics Council purposes

While it can be seen from the organisation chart the National Bioethics Committee is not being seen as part of the decision-maker, prima facie it is safely presumed that the ethical, bioethical issues do not play an influential role in the biosafety decision-making process in Malaysia. From their website, it can be seen that members of the National Bioethics Council have been publishing literature on creating bioethics awareness among Malaysians.[514] Even though the council and the government have links in an official advisory capacity, it can only be implemented efficiently if the society

[514] See http://www.bioetika.gov.my/index.php?option=com_content&view=article&id=15&Itemid=103

as a whole is included in the construction of the proposal and represented on the Council to have the benefit of specialist advice when that is needed.[515]

Other essential government departments in biosafety implementation and enforcement

i) Chemistry Department

The Chemistry Department provides scientific services (analysis, investigation, and consultation) to MoSTE as well as to other ministries. The GMO laboratory is one of the laboratories in the Environmental Health Division. The establishment of the GMO laboratory is to fulfil the needs arising from the proposed amendments to the Food Regulations 1985, which plan to make mandatory labelling of GMOs found in food.

The Chemistry Department will also hire two scientific officers and three assistant scientific officers to be competent to carry out risk assessment tests for LMOs. In future, MoSTE would like to set up a laboratory for NBB, but it realises that first, more capacity among local scientists has to be developed.

[515] Idris SH, Majeed ABA and Hamin Z, 'Public engagement in biosafety decision-making process: Appraising the law in Malaysia' (ICIMTR 2012 - 2012 International Conference on Innovation, Management and Technology Research 2012)17.

ii) The Malaysian Biotechnology Information Centre (MABIC)

MABIC was set up to fill the gap between information available from research institutions needs of the public for non-technical information about biotechnology and biosafety. It has three-year funding from the International Service for the Acquisition of Agri-biotech Applications (ISAAA). Its mission is to develop a biotechnology information centre that is recognised to be a resource based on sound science to the public and policymakers and by doing so, to support the government of Malaysia's efforts to develop biotechnology as a tool for national development. MABIC is also a country node of ISAAA's Global Knowledge Centre and depends on a scientific advisory committee that consists of local biotechnology scientists. One of their three advisors is also a member of GMAC. Activities of MABIC include the organisation of seminars to create public awareness on issues concerning biotechnology (an example being a public forum on "Assuring the safety of Biotechnologically-produced foods" in September 2001) and workshops on risk communication targeted at biotechnology researchers (November 2001), so they can present their research work in a more efficient way to the media and the public to enhance the understanding of biotechnology and GMOs in general.

iii) Bioeconomy Corporation

It was previously known as Malaysian Biotechnology Corporation was created as the lead agency responsible for the coordinated implementation of the NBP. It is also the leading development agency for the bio-based industry in Malaysia, under the purview of Ministry of Science, Technology, and Innovation (MOSTI). Bieconomy Corporation is owned by the Minister of Finance Incorporated & Federal Lands Commissioner (a government-linked company (GLC) and acts to identify value propositions in both R&D and

commerce and to support these ventures via financial assistance and developmental services.[516]

Various Islamic institutions

Various Islamic institutions are relevant in the Islamic discussion and jurisprudence on biosafety and bioethics issues. This is discussed as follows:

i) National Fatwa Council

The National Fatwa Council is comprised of all the Muftis (Head of Islamic Scholar) from every Malaysian state. Even though it is criticised as misnomer and non-existence,[517] it is a meeting of those muftis on the contemporary issues that relate to Muslims in Malaysia known as Conference (Muzakarah) of the Fatwa Committee National Council for Islamic Religious Affairs. They provide Islamic rulings based on Quran, Hadith and other Islamic jurisprudence. However, they have no legal force only significantly influence the Muslims in Malaysia. The Conference (Muzakarah) of the Fatwa Committee National Council for Islamic Religious Affairs gave the rulings on the consumption of LMO as previously discussed in Chapter 3.

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[516] Bioeconomy Corporation. 'About us' <http://www.bioeconomycorporation.my/corporate-profile/about-bioeconomycorporation/> accessed on 1 December 2016.
[517] Editors, 'Asyraf Wajdi: 'Majlis Fatwa Kebangsaan' tak wujud, tiada kuasa perundangan' (2017) <http://www.themalaymailonline.com/projekmmo/berita/article/asyraf-wajdi-majlis-fatwa-kebangsaan-tak-wujud-tiada-kuasa-perundangan#doPSLTTMPzEsH5vT.97> accessed on 20 January 2017.

ii) Department of Islamic Development Malaysia (JAKIM)

JAKIM is under the Prime Minister Department with the primary function is to be the central agency in the planning, management of Islamic Affairs and Muslim development. One of the functions is to assist in enacting and standardising the needed laws and regulations while evaluating and making it uniform for the implementation of the existing laws and administrative from time to time to settle the Muslim ummah (society) problems.[518] It is proposed that JAKIM is consulted as one of the parties during LMO approval but it is yet to be seen to be implemented.

iii) Institute of Islamic Understanding Malaysia (IKIM)

IKIM was established on 18th February 1992 under Companies Act 1965 with the aim to spread the actual Islamic teaching through various programmes and activities such as research, seminar, workshop, forum, consultancy, training and publication.[519] Among the functions is to implement comprehensive and integrated research on the role of Islam and Muslim to face the contemporary challenges of the changing world.

It is an interesting observation that it is a common practice that some members of IKIM (usually the Director or Deputy Director) are being

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[518] Jabatan Kemajuan Islam Malaysia (JAKIM), 'Fungsi JAKIM' (2017) <http://www.islam.gov.my/en/about-jakim/jakim-functions> accessed on 20 January 2017.
[519] Jabatan Kemajuan Islam Malaysia (JAKIM), 'Fungsi, Visi, Misi & Nilai' (2017) <http://www.ikim.gov.my/index.php/fungsi-visi-misi-nilai/> accessed on 20 January 2017.

appointed as members of the National Bioethics Council.[520] Thus it can be seen here that bioethics is considering Islamic point of view.

3. The biosafety decision-making process

The process of the decision-making in Malaysia can be summarised as in the chart below:

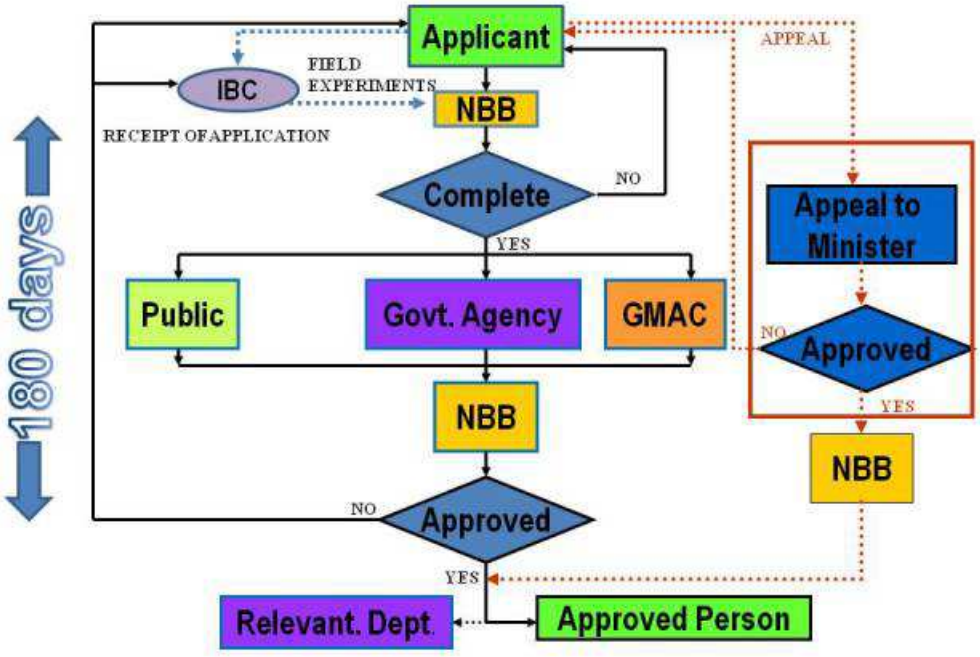

Figure 20: Biosafety decision-making process

[520] IKIM Media, 'Pelantikan Y. Bhg. Dr. Mohd Zaidi Bin Ismail Sebagai Timbalan Ketua Pengarah Institut Kefahaman Islam Malaysia (IKIM)' (2017) <tp://www.ikim.gov.my/new-wp/index.php/2015/10/02/pelantikan-y-bhg-dr-mohd-zaidi-bin-ismail-sebagai-timbalan-ketua-pengarah-institut-kefahaman-islam-malaysia-ikim-2/> accessed on 20 January 2017.

When a party wants to release, import or export the living modified organisms (LMOs), they have to obtain the approval from the NBB. If what they need is just the notification from the importing country, they can appeal to Minister against such decision.[521] Minister according to Biosafety Act 2007 is the minister charged with the responsibility for natural resources and environment.[522] In the current situation, it is the Minister of Natural Resources and Environment. The Minister has the power to confirm, reverse or vary the decision of the Board. The aggrieved party can request for a variation in the case of terms and conditions imposed on the certificate of approval. They could not request the NBB to review its decision. The NBB may review its decision upon obtaining new information or evidence on the LMOs or products of such LMOs. It can do so at any time. The considerations taken into account before the NBB makes a further order upon the review are when the NBB is satisfied that there is a risk posed to human, plant or animal health, the environment or biological diversity by the activity.[523]

The appeal is made to the Minister of Natural Resources and Environment, by:

1) giving notice to the Minister in writing of the intention to appeal within 30 working days from the date the decision was communicated, and

[521] Biosafety Act 2007 s34.
[522] ibid s3.
[523] ibid s18(2) and 32(2).

2) submitting to the Minister the grounds of appeal and other relevant documents within 30 working days after giving the above notice.[524]

Therefore, if the aggrieved party is again aggrieved by the decision by the Minister, can he proceed with judicial review? This is an issue not yet challenged and tested in court although it is legal, and it is their legal rights to do. Questions as to what extent court will interfere with the Minister's decision are still left open.

The working of the biosafety decision-making in Malaysia

i) The approval for release and import of LMOs

Malaysia in compliance with the Cartagena Protocol on Biosafety is bound to follow the AIA procedures also the notification procedures as prescribed by the Protocol.

When the Director General of Department of Biosafety (DG) receives the application for approval, making sure that the IBC has checked the application,[525] the DG then has to process the application and forward it to GMAC, relevant Government department or agency and initiates public consultation.

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[524] Biosafety (Approval and Notification) Regulations 2010 reg 20.
[525] ibid reg6(1).

a) GMAC

DG must refer to GMAC for its recommendations. GMAC has been set up to provide scientific, technical and other relevant advice to the Minister or the NBB. GMAC then assess the application to release, import of the LMOs will not affect the environmental, health and safety of people.

The application consists of risk assessment and management report by the applicant. GMAC then can further ask advice from experts including international experts to advice on the application. GMAC also can appoint subcommittee if they find it is necessary or expedient to do so.[526] Having gone through all these, GMAC then makes recommendations whether or not to approve the applications. If GMAC advises approval GMAC then can advise terms and conditions to NBB upon approval. From here it can be seen that NBB is not just working together with GMAC but also other experts and subcommittee to work with.

b) relevant Government department or agency

If the application involves the expertise of relevant government department or agency, DG then forwards the application to the relevant department or agency. For instance, if the LMOs is soybean, feedbacks from Ministry of Health, Department of

[526] Biosafety Act 2007 s7(1).

Chemistry, Department of Agriculture, Department of Fisheries, Department of Veterinary Services and Malaysian Quarantine and Inspection Services.[527]

c) public consultation

Simultaneously, the DG will then seek the public consultation for their view on the application. Public consultation in Malaysia is executed by adhering to the Guideline on Public Consultation Procedures. The Guideline was published in October 2014 as part of the National Policy on the Development and Implementation of Regulations provides the essential guiding principles in public consultation. According to the Guideline, there are two ways of consultation namely formal consultation and online public consultation. The Guidelines also provides the requirements to conduct public participation procedures. As there is no detail guideline on the public consultation on biosafety in Malaysia, it seems that in biosafety the Guideline on Public Consultation Procedures is followed.

In implementing public consultation on biosafety, the DG will practically advertise the application for public view in the newspaper and Malaysian Biosafety Clearing House website. Usually, the view is on the risks

[527] National Biosafety Board, *National Biosafety Board Decision Application for Approval for Import for Release of Products of Das-68416-4 Soybean for Supply or Offer to Supply for Sale or Placing In the Market* (National Biosafety Board JBK(S) 602-1/1/38, 2017) 1.

involved on how to manage the risks. In some cases, they will even ask the local people's view if the case is directly affected with them at the cost of the applicant. This happened in the case of the release of GM mosquito in Pahang (a state in Malaysia). For this to realise, the public even was given the necessary information exclusive of confidential business information (CBI).

Later, after GMAC recommendations, views of the relevant government department and the public will be submitted to NBB. NBB will then decides on the application.

NBB will then make the decisions either:

i. refuse to issue the certificate of approval; or
ii. approve the application by issuing the certificate of approval. In this case, it may impose terms and conditions for the approval.

To make a decision, the NBB must consider the following:

- recommendations of GMAC on the assessment of the application;
- comments of the relevant Government department or agency;
- views of members of the public, if any; and
- any additional information, particulars, documents (IPD) furnished.[528]

[528] Biosafety Act 2007 s16(3).

The NBB will decide within 180 working days from the date of issue of the acknowledgement of receipt of the application[529] and a further extension of 60 working days maximum if necessary.[530]

ii) Notification for Export, Contained Use and Import for Contained Use[531]

As the name suggests, this is another type of application involving the LMOs. This application is for notification for export, contained use and import for contained use. 'Contained use' is defined as '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'.[532]

Therefore these are activities that need notification namely:

a) export of LMO
b) contained use, i.e. any operation including research and development, a production involving LMOs that prevents the contact and impact on the external environment
c) import for contained use

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[529] Biosafety (Approval and Notification) Regulations 2010 reg 8(1).
[530] ibid reg 8(2).
[531] Biosafety Act 2007 Part IV.
[532] Biosafety Act 2007 s3.

It is important to note here that only activities involving LMOs are covered under this Biosafety Act 2007 and not the products of the LMOs.[533] Under this notification, any individual, an organisation or a legal entity such as a corporation can give the notification.

i. For contained use and importation for contained use, these are the information needed:
   a. Risk assessment;
   b. Risk management;
   c. Emergency response plan; and
   d. Other information such as description of the LMO and the facilities being used for the confined activities.

ii. For export, the following information must be supplied:
   a. The requirements of the importing country on the importation of LMO; and
   b. Evidence of such compliance.[534]

Once the notification has been prepared, the notification must be submitted directly to the DG or through the organisation's registered IBC for consideration, where the NBB has directed the establishment of the IBC. This will be only in cases of R&D involving LMOs.[535][536] In all other cases,

[533] ibid s21.
[534] Biosafety Act 2007 s23.
[535] Biosafety (Approval and Notification) Regulations 2010 reg 16(2)(b) read with reg 5(1).

including where there has been no direction for the establishment of an IBC, the notification is made to the DG.[537] For export of LMO the notification is made to the DG in Form F.[538]

The IBC must assess the activity in the notification and fill up the sections in Form E[539] relating to their details and specified information relating to its assessment. The notification is signed by the Chairperson of the IBC. The IBC must submit the completed form to the NBB together with the IBC Assessment Report form.[540] Once all the information required by the form has been completed, the notification may be forwarded to the NBB through the DG.

Then the DG will screen the notification and ensure that it has fulfilled all the requirements of the Acts and Regulations and in important cases will make sure the IBC has already assessed the notification. If the DG is satisfied that the notification meets the necessary requirements, the DG sends an acknowledgement of receipt to the person giving the notification.[541]

The main difference between the approval process (for direct release activity, as earlier discussed) and a notification process is that:

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[536] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia, *User's Guide to the Biosafety Act and Regulations* (http://www.biosafety.nre.gov.my/guideline.shtml edn,) Chap 6 .
[537] Biosafety (Approval and Notification) Regulations 2010 reg 16(2).
[538] Form F for export of LMOs.
[539] Form E for contained used activities involving LMOs and import for contained use activities.
[540] see Form E, p. 7, instruction under item 9. See also Guidelines for IBC, IBC/AP/10/ANEX2, p. 30.
[541] Biosafety Act 2007 s25 ; Biosafety (Approval and Notification) Regulations 2010 reg.18.

i. For the approval process – the activity can only start after the approval is given;
ii. For the notification process – the activity can start after the acknowledgement of receipt is given.

In both cases, the applicant becomes an “approved person”.[542]

The DG then refers the notification to GMAC and relevant Government department or agency as explained in the approval process above. The NBB then must consider the recommendations given by the GMAC[543] in making the decision. Although not explicitly provided in the Act, the NBB would have before it as well:

i. The comments of the relevant Government department or agency; and
ii. Any additional IPD furnished.

The NBB decision on this notification will necessarily be based primarily upon the evaluation by GMAC of the risk assessment report, the risk management plan, and emergency response plan; as well as the fulfilment of any other requirements under the Biosafety Act 2007 in Form E.

However, it can be seen here that during the notification process, there is no public consultation process as in the approval process.

[542] Biosafety (Approval and Notification) Regulations 2010 reg.10(3).
[543] Biosafety Act 2007 s30(3).

Presumably, the public does not need to know any research and development involving LMOs that is not being released into the environment as it does not affect them directly for the sake of the progress of science and biotechnology without much unnecessary hindrance from the public.

From this, it can be seen that the IBC plays a vital role in the decision-making process as making the first assessment of the approval application and notification.

4. An examination of the Malaysian institutional framework for biosafety

Scientific risk and management assessment

From the organisational chart of institutional biosafety framework and the flowchart of the biosafety decision-making, the risk assessment report greatly influenced NBB decision-making process apart from the initial risk assessment exercise by the IBC. Although inputs were gathered from other relevant departments and agencies, those reports were exclusively scientific as well leaving little room for socio-economic considerations even though it may be taken into account by NBB.

Another issue is the Risk Assessment and Management as mentioned above by Wynne[544] that risk assessments are, as a rule, presented as open

[544] Wynne B (2005),'Reflexing Complexity: Post Genomic Knowledge and Reductionist Returns in Public science.' Theor. Cult. Soc. 22(5): 67-94 (as cited in Latifah Amin and others. 'Risk assessment of genetically modified organisms (GMOs)' (30 September, 2011) 10(58) African Journal of Biotechnology 12418-12424)

scientific knowledge, but in practice, always framed in a way that supports social control and authority. This is also the case in Malaysia whereby the actual information that is given by the applicant is nowhere to be seen in the NBB and GMAC report, only the GMAC assessment report based on their scientific assessment of that risk assessment. If that information is contained in Confidential Business Information (CBI)[545] again, this issue could not be investigated further by an interested party, therefore, lack of transparency.

Public participation

It was mentioned earlier that public consultation is just practised in Part III application for approval but not for Part IV notification. This is perhaps as for the release of LMOs and products will directly affect the public, whereas Part IV is just for contained use thus the public does not need to know and aware what is being researched and developed at the biosafety labs.

In Malaysia, it can be seen that limited effort is geared towards developing a structural model of public attitudes to modern biotechnology.[546] Therefore the perhaps more structured form of representation from the local communities and indigenous people, other than from the academic, Islamic and scientific background as in those abovementioned institutions, is needed for the input from the society to reflect democratic voice.

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[545] Biosafety Act 2007 s59.
[546] Latifah Amin, and others, “Factors Influencing Malaysian Public Attitudes to Agro-Biotechnology”(2010) Journal of Public Understanding of Science 674.

Socio economic considerations

As mentioned above Regulation 25 provides for socio-economic considerations. From the country's decision in approving TMOF_Yeast to control the Aedes mosquito larvae, it is mentioned in the report by NBB that product is intended for use to control outbreaks of dengue fever, which is one of the critical health issues in Malaysia population, therefore it can be seen that social issues are being taken into consideration.[547] Again in the release of GM mosquitoes, socioeconomic consideration including the number of deaths and the cost of medication due to Dengue were included.[548] However, the methodology on how the NBB go about assessing the socio-economic considerations is not mentioned in the NBB reports. In assessing the socio-economic aspects of the biosafety decision making it is apparent that the institutions having consulted the relevant parties using the existing rules and regulations will ultimately make the decision what is the best for the communities especially when it is related to them directly based on the facts in hand. However, the decision may be reviewed when new and credible information is made available.[549]Therefore, the biosafety decision making is more likely authoritative in the end but making the public involvement as part of the decision-making process.

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[547] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'Approval for Release For Field Trial | Food, Feed and Processing | Product of LMO' (2016) <http://www.biosafety.nre.gov.my/country_decision/app_plmo.shtml> accessed on 20 January 2016.
[548] ibid.
[549] Ramatha Letchumanan and Johnny Andrew, 'Socio-Economic Aspects in Decision-Making in the Context of the Biosafety Protocol: Malaysia's Experience and Case Studies' , Vol 14.3 (2012) 23.

However, the biosafety institutions are open to new decisions if there is new evidence coming up in the future. The only element that is lacking perhaps is the transparency of the decision-making process to boost public confidence and acceptance of the LMOs and products. It is suggested that a comprehensive socio-economic analysis is needed especially for the biosafety decision-making process. However, this can only be realised with the necessary socio-economic experts.

It is important to mention here that Section 35 and Regulation 25(b) state that the Board or Minster may take into account socio-economic considerations in his decision-making. The usage of the word 'may' indicates that is the discretionary power of the Board or Minister whether or not to take socio-economic considerations into account in assessing the GM application. Another point is that the NBB will take recommendations from GMAC indicates that NBB will base their decision purely on scientific and not ethical ones.[550] Thus it is suggested that more involvement of experts other than from science background in GMAC.

Therefore it can be seen that there is lack of clarity on the process of incorporating socioeconomic considerations in actual decision-making. It seems that from NBB report, socio-economic issues are mentioned but it is unclear when it is needed, what information should be used for the analysis, how that analysis should be done and by whom.[551] In light of the importance

[550] Hamin (n 411)15.
[551]Idris SH, Wei Chang L and Baharuddin A, 'Biosafety Act 2007: Does It Really Protect Bioethical Issues Relating To GMOS' (2013)(S26.4) Journal of agricultural and environmental ethic 751.

of socio-economic consideration, a comprehensive framework for socio-economic considerations is needed to be included as part of the biosafety decision-making process.

Bioethics

Despite the establishment of the National Bioethics Council, the active and productive involvement of that Council in the biosafety decision-making process is somewhat questionable. At present, there is no specific law on bioethics relating to biotechnology[552] as it is regulated under Biosafety Act 2007.

Other than that it is suggested that the involvement of National Fatwa Council and JAKIM should either be part of the National Bioethics Council or among part of the relevant government department and agency to be consulted by the NBB to give feedback on Islamic ruling on that GM product. However, since the involvement of the National Bioethics Council is yet to be seen in the NBB report, perhaps political, consumers input or pressure should be channelled to the Minister of NRE to realise the involvement of these Islamic authorities. Alternatively, perhaps JAKIM should be consulted as part of the other relevant government agencies in issues of Islamic consumption of certain types of LMO.

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[552] ibid.

Dual-use technology issue

Another issue that has less concern in the Malaysian context is the dual-use technology issues that the concern that biotechnology instead of being used for peaceful means but hostile or military purposes. This issue is going to be discussed again in the Singaporean biosafety context in Chapter 5. It is interesting to note here that Malaysia has its own Laboratory Biosafety and Biosecurity Policy and Guideline.[553] The nation has three BSL-3 laboratories, which handle potentially deadly pathogens like anthrax and plague and no BSL-4 laboratories yet.[554] As BSL-4 labs are very expensive to build, there are concerns over the plans to construct a high-security biological research laboratory in Malaysia. There are some worries over possible proliferation of highly lethal disease materials as Pro Publica reported.[555] However it is submitted that to be at par with modern biotechnology with other countries, Malaysia plans to build BSL-4 lab should be seen as a good step in combating lethal viruses in the future, not just for the nation also the Asia Pacific region. It is hoped that the stringent guidelines by WHO lab and other well-developed countries BSL-4 plans should be adhered to curtail any misuse of bioterrorism in the future.

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[553] Ministry of Health Malaysia, *Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline* (First edn, National Public Health Laboratory 2015).
[554]Editors,'Planned Malaysian Biolab Raises Security Concerns' (2017) <http://www.nti.org/gsn/article/planned-malaysian-biolab-raises-security-concerns/> accessed on 10 March 2017.
[555] ibid.

Handling, transportation, packaging, identification

At present, there is a similar provision in handling, transportation[556] and packaging in the existing Malaysian laws and regulations. The provision on the identification of LMOS as in Regulation 11(3A), 11(6), 11(7a-e) Food Regulations 1985 as required and monitored by the Ministry of Health (MOH), a different ministry from the main biosafety Ministry of NRE. This is because food regulation and safety issues are under the purview of MOH.

Cross-cutting issues in decision making of biosafety

The government has been making progress on biosafety. This is mostly scientific and technical based.[557] It is crucial for the issue of transparency in the decision making process from the permission to import LMO, GMO to be addressed. This issue of transparency is vital in gaining public trust in the controversial GMO and LMO products.

In the issue of public consultation, these institutions namely NBB, GMAC, Department of Biosafety have been said to consult the public on various occasions. Apart from that, there were numbers of workshop and seminars held to raise the biosafety awareness and educate the public. Announcements were released to invite public opinions on two national newspapers (Malay and English) with two announcements in each

[556] Standard Operating Procedure for Transport of Biological Specimens In Malaysia
[557] Ministry of Science, Technology and the Environment Malaysia, *Malaysia: Capacity-building for Implementation of National Biosafety Framework* (Project Brief PIMS 2182, 2013)8.

newspaper. In that process, the public can upload information about the application to biosafety website. Then the input received for 30 days. The public's other concerns or issues raised were reviewed and given to Board to make decision.

There is a study on stakeholders' perception towards modern biotechnology and biosafety in Malaysia. The 47 respondents are from six stakeholder groups which are as follows:

a) Regulatory bodies/enforcement bodies/ policy makers (RB/EB/PM)
b) Research institutions & universities (RI&U)
c) NGOs, religious bodies & organic shops (NGO, RB&OS)
d) Industry players (IP)
e) Media & educators (M&E)
f) Consumers (CONS)

The findings showed that public awareness is low, but some initial work has been done thru the GEF project. Awareness level is reasonably good for regulatory bodies and research institutions group. However, awareness level has to be intensified in NGOs, industry players, media, educators and consumers group.

While the resources are available, we need local expert also overseas expert assistance. However, consultations referred to a various government department that has the expertise in their relevant field should be embraced

to encourage not just international but local expertise as well. Nevertheless, the presentation by Department of Biosafety under Ministry of Natural Resources[558] led to the conclusion that resources are not enough is seem to be the hindrance.

MoSTE plans to allocate an annual US$ 16,448 grant to each of the thirteen federated Malaysian States for biosafety public awareness programmes. Also, MoSTE will feed funds directly to an NGO to also carry out public awareness programmes. It will apportion US$5,263 per State per year for this purpose. However, it will also need to swiftly commence activities such as the production of education kits, flyers and posters for different target groups (consumers in general, school children etc.) as well as documentary films.

MoSTE plans to hold an awareness workshop in 2002 to familiarise stakeholders from government, research organisations, media and NGOs on main issues covered in the Cartagena Protocol.

Although MoSTE has stated that it will undertake the development of public awareness, it does not have the capability at hand to promote

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[558] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia. 'Status and initiatives in promoting public awareness, education and participation concerning LMOS in Malaysia ' (2013) <https://s3.amazonaws.com/bch.webfiles/8289/741d/fa4ef5c72d5f39af0ec23c42?AWSAccessKeyId=AKIAI7FAKFTLBEQGAW3Q&Expires=1480940174&response-content-disposition=inline;%20filename=%22malaysia.pdf%22&response-content-type=application/pdf&Signature=QDgbuQfy/QQnSb2HFSTKj6wwugM=> accessed on 12 May 2016.

awareness within policymakers and enforcement officers. At present, little provision has been made for activities targeted at raising awareness among members of the private sector.[559]

5. An analysis of the Malaysian regulatory strategy on biosafety

Command and control

From the structure, it can be safely concluded that the strategy of regulation in Malaysia is primarily still of command and control approach. The primary legislation is Biosafety Act 2007 sets out what is permitted and illegal under the Act. In discussing on the Malaysian strategy on biosafety regulation, perhaps there is some political situation that needs to be understood. Malaysia is a Federation of thirteen (13) states and Federal government whereby there are a Federal list and State list and concurrent list. The land issues, for instance, are state matters, agriculture, Islamic law, whereas biotechnology is in the Federal list.

The Federal list empowers the Federal government to manage essential issues of trade, commerce and industry (including imports and exports and the establishment of standards of quality of goods manufactured in or exported from the country), scientific and technical research and health. The Federal Government has the duty of general environmental protection and pollution control. The State governments have jurisdiction over forests

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[559] ibid.

and other natural resources. Concurrently, both Federal and State may legislate on the protection of wild animals, national parks and town and country planning. Biosafety is a federal issue, and the development of the national biosafety framework has been at the federal level.

National Biosafety Board (NBB)

From the above discussion, it can be seen that Malaysia practised a two-tier biosafety framework. The National Biosafety Board acts as the biosafety decision-maker but advised by GMAC as the expert biosafety committee mostly on scientific issues also other relevant government department and agencies. Additionally, for import and export and release of LMO into the environment, the public participation is required. Thus it adds another tier to the biosafety decision-making process. The Board is responsible to the Minister,[560] a government officers including politician, are making decisions on the part of the Malaysian public. Even though NBB is the biosafety decision-maker for LMO approval, any person aggrieved by the NBB'S decision will appeal towards the Minister[561] of Natural Resources and Environment (NRE). Thus it shows the ultimatum lies within the purview of the Minister of Natural Resources and Environment.

Presumably, the aggrieved party could bring the case to court under Judicial Review again if the outcome is not in their favour. It is assumed here that with the risk assessment report by GMAC also reports from the relevant

[560] Biosafety Act 2007 s4(5).
[561] ibid s20(1).

government department and agencies, as previously in the illustrated United Kingdom case of R v. Secretary of State of the Environment ex parte Watson [562] the court will pay more attention to those reports unless the plaintiff can prove that the LMO is safe in other countries elsewhere and no report of adverse effects to human health and environment. While again the reports of either risk assessment or socio economic considerations or other issues will play significant roles for the court to make the decision. Then hypothetically if the LMOs exporter dissatisfied with Malaysian court's decision, they will bring the case to WTO against Malaysia for trade restrictions. Malaysia then should be ready with its national biosafety laws justifications. It is suggested at this juncture that Malaysian biosafety laws should be harmonised with WTO and other international laws and agreements as well as the CPB. As the issue is outside the scope of this thesis, this could be an exciting future area of research.

The NBB is seen as having governmental and administrative power in biosafety decision-making process as board members are mostly representatives from various government departments. As biosafety is an essential pressing issue thus, it is justified that it is decided by ministries that are important and relevant.

Apart from the institutional setup, the Malaysian biosafety laws and regulations is mainly a direct state regulation. It practices a command and control approach whereby fines will be imposed RM250,000.00 for individual

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[562] R v Secretary of State for the Environment ex p Watson [1998] EGCS 122.

imprisonment for a term not exceeding five years or to both and fine RM500,000.00 for corporate for contravention of Section 36(4)(a) and (b) of the risk assessment and management requirement respectively.

As a breach of biosafety regulation could affect human health and the environment, thus the state regulation strategy enable the regulator to act directly for instance to control nuisance. For instance to act in emergency response plan as provided in Section 37 of the Biosafety Act 2007 and for the enforcement officers to act towards any persons or corporations that act in contravention of any of the provisions.[563]

Command and control impose positives acts and prohibits undesirable behaviour. Thus in compliance with the biosafety laws and regulations, the relevant person or corporations have to adhere to the approval procedures for release and import, notification for export, contained use and import for contained use, risk assessment and management requirement failures which could made them liable to civil and criminal and liabilities as mentioned above. It has the force of law either nationally or internationally. However, these measures as mentioned earlier could arguably be seen protective trade measures and anti-GM.

[563] Biosafety Act 2007 Part VI.

Genetic Modification Advisory Committee (GMAC)

The GMAC is perceived as an expert advisory committee. From the latest GMAC chart[564] it seems that most of the members are from the various science backgrounds. It is suggested that GMAC composition should include from social science background as well such as members of the National Bioethics Council, Department of Islamic Development Malaysia (JAKIM), Institut Kefahaman Islam Malaysia (IKIM), Third World Network (TWN), Consumer Association of Penang (CAP), Muslim Consumer Association of Malaysia (PPIM) and other relevant associations. This is apart from scientific risk assessment; the socio-economic considerations will be of importance especially for some LMOs such as for palm oil and rubber as discussed in the previous chapter.

The second layer lies with the advisory expert consultations and relevant expertise from the relevant government departments. This two-tier system seems prima facie reliable as it seems that NBB relied heavily on GMAC and government agencies that will provide mostly technical and scientific expertise. While acknowledging that there is public consultation involved, the pertinent issue at hand is to what extent the public views are sufficiently heard and taken into account into the decision-making process, as there are not much details on them on the Department of Biosafety website.

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[564] Department of Biosafety, Ministry of Natural Resources and Environment Malaysia, 'Genetic Modification Advisory Committee (GMAC)' (2016) <http://www.biosafety.nre.gov.my/about/gmac.shtml> accessed on 20 November 2015.

Thus there is a need for the advisory committee to have a public dialogue and addressing cross-cutting issues related to the ethical, legal, and social implications of biotechnology. While there is GMAC as an advisory committee in Malaysia to address crosscutting issues related to the ethical, legal and social implications of biotechnology, the impact of these issues being brought up seem insignificant. This is because from the Department of Biosafety website, issues of socio-economic considerations was mentioned but no details were provided in the report.

The Department of Biosafety (DOB)

The Department of Biosafety (DOB) that is from Ministry of Natural Resources and Environment that plays the prominent role as the secretariat for implementing biosafety is seen as administrative. It seems that the fact that DOB is from within NRE shows Malaysian commitments towards protecting its biodiversity and environment in developing biotechnology and biosafety. However, again lack of integration and coordination with other ministries that stand alone even on the same issues of biosafety such as MOSTE or MOH, unlike some countries is something to be looked for in the future. It is submitted that this perhaps could start with a comprehensive national biosafety policy.

Institutional Biosafety Committee (IBC)

The IBC plays a crucial administrative role within the organisations that use LMO. Thus the risk assessment and management are vital in

ensuring compliance towards the biosafety laws and regulations. Thus Malaysian and international standard Guidelines on LMO, risk assessment and management, environmental assessment, etc. should be adhered to by these IBC as a failure which can make them liable to an offence.[565] This is another feature of command and control approach.

Other relevant institutions

Other institutions such as National Bioethics Council, National Fatwa Council, Department of Islamic Development Malaysia (JAKIM), IKIM roles are very much raising the awareness and educating not just the public but the stakeholders in biosafety as well. It is not to be forgotten that they have more general and specialised (other than biosafety) roles and duties such as the former in advising on general ethics and bioethics, medical ethics issues, the latter is more on fatwa on contemporary Muslim issues, Islamic development, food consumption and spread the authentic Islamic teaching. Their roles in advising the GMAC or NBB is yet to be suggested and proposed in the future.

In strengthening its biosafety capacity building, as stated earlier Malaysia has established Bioeconomy Corporation and MABIC. Bioeconomy is a Malaysian Government-linked company (GLC) that support the business of biotechnology industry whereas the latter a non-profit organisation funded by Service for the Acquisition of Agri-biotech Applications South East Asia

[565] Biosafety (Approval and Notification) Regulation 2010 reg 5(3).

Center (ISAA). MABIC is a biotechnology and biosafety information centre that supports the dissemination of knowledge to the public.

New governance strategies

Apart from the command and control as the primary biosafety regulatory strategy, there are elements of new governance being practised in Malaysian biosafety.

Smart regulation and regulatory pluralism

Biosafety regulation contains the element of smart regulation and regulatory pluralism (as discussed at a great length previously in Chapter 2) as there are numerous actors and various strategies in the decision-making process. This can be seen from the two-tiered biosafety decision-making process in Malaysia whereby the NBB is making the decisions based on advice by GMAC, another relevant department and (also) public consultations especially for the release of LMOs into the environment. The actors are the government as the regulator, the business as self-regulator (theoretically) and the third parties such as public interest groups.

The instruments and range of actors of smart regulation might not seem suitable or no role to play in biosafety regulation. This is examined not just from the principal Biosafety Act 2007 and Regulations 2010 but other relevant Acts, Regulations and guidelines also the institutional framework. A significant feature of the Malaysian biosafety instrument is the government is imposing penal sanctions for non-compliance with the laws and regulations. Moreover, the regulator is to educate and advise the public on safe handling of LMO also the other biosafety related parties and decision-makers. This is an element of smart regulation. The issue is to what extent it is applicable when dealing with other stakeholders such as the biotechnology companies.

Other instruments such as disqualifications, notices, warnings, persuasion might not be applicable or even suitable due to the gravity of the biosafety consequences that can cause irreversible damage.

However it is argued that prima facie, the applicability of the regulatory strategy would depend on the Biosafety level (BSL) involved and also the type of use of LMOs such as for contained use in the labs. For lower level of BSL (Biosafety Level) such as BSL 1 and just for contained use, the various instruments such as warnings, notices, persuasion could be applied.

However, the law and biosafety institutions instruments to range from one extreme to another, i.e. from education or advice to penal sanctions and no suitable in-between instruments (warnings, notices). Perhaps for a lesser risk of biosafety activity for instance LMO, these standard instruments (warnings, notices) are applicable rather than straight to impose sanctions as this could be seen to restrict biotechnology research and development innovation. For example for IBC that did not comply with the documentation and record-keeping requirement as required[566] for release or import approval on terms and conditions imposed by NBB. This certificate should not be revoked straight away, but instead, warnings and notices should be imposed to make things rights. However, the standard biosafety procedures should not be compromised.

As for third parties as a biosafety actor, that can include the public, interested groups, for the instruments, only advice (participation and

[566] ibid reg 9(2)(d).

awareness) through education are seen as vital and applicable compared to other instruments. This is mostly due to the fact in capacity building of biosafety, the cost in empowering the regulator is a lot, and thus educating the third parties would involve more cost thus making it a secondary biosafety strategies.

Reflexive and meta-regulation

Reflexive regulation is procedure-oriented seeks to design self-regulating social systems by establishing norms of organisation and procedure.[567] This strategy can also be viewed as a form of 'meta-risk management' whereby government rather than regulating directly, manage the risk management of individual enterprises.

Meta-regulation, as explained in Chapter 2, is whereby regulatory authority oversees a control or risk management system rather than carries out regulation directly.[568] The main Ministry that has the power to appeal in approving LMO in Malaysia is the Ministry of Natural Resources and Environment. NBB with the Director of NRE as the head decides upon receiving a risk assessment and management report from GMAC. This is seen as a meta-regulation element as the main NBB who is composed of

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[567] Fiorino DJ, 'Rethinking Environmental Regulation: Perspectives on Law And Governance' (1999) 23 Harv.Envtl.L.Rev. 447 as cited in Gunningham N, 'Regulating Biotechnology: Lessons from Environmental Policy' (2007) in Somsen, H, *The Regulatory Challenge Of Biotechnology: Human Genetics, Food And Patents* (Edward Elgar 2007).
[568] Baldwin R, Cave M and Lodge M, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press on Demand 2012) 147.

government administrative officials basically, by delegating the power to GMAC to assess the risk assessment and management are steering rather than rowing.[569]

Thus NBB makes biosafety decision according to GMAC's advice. The applicant for LMO approval is to make the risk assessment and management to be assessed by GMAC. Thus for this risk assessment and management to be valid must be carefully scrutinised by the government also with the threat of intervention if it fails. Thus it will both beneficial to the industry and regulator if both work cooperatively.

Civil regulation

The fact that public and the non-governmental organisations (NGO) such as consumer and environmental groups are participating in biosafety should be commended. This can be seen earlier in the drafting of Biosafety Bill and later after Biosafety Act was enacted. This has been explained in the chapter before as public and NGO participation in LMO approval also the controversial case of release of GM mosquito in Bentong, Pahang and Melaka. However, from the earlier Biosafety Bill, it has been seen that perhaps the business community has pressurised the government in shaping the biosafety law.

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[569] Osborne D, 'Reinventing government' (1993) Public productivity & management Review 349(as cited in ibid).

However, in issues such as labelling of LMO, it seems that the public, academic and Third World Network have pressured the government in legalising the mandatory labelling requirement. Thus in short even though seems ineffective in some issues, civil regulation in Malaysia even though not as aggressive as abroad has played essential roles in Malaysia. However, in future, it is hoped that this public and civil regulation should be more systematic in its education and awareness rising thus could give useful and effective input on the biosafety decision-making process. This could be done in a more diplomatic manner rather than hostile to the democratic involvement of the public.

However, it is argued in light of the current Malaysia social, economic and political position; there will be lesser roles of civil regulation. The pressure and inputs from the public and non-governmental organisations will only be able to create awareness but not means for effective solutions either through mainstream media or social media.

Licence model

The licence model propounded Gunningham, Kagan and Thornton are examining corporate behaviours towards the environment. Thus perhaps in future, the licence model could be explained in examining the biotechnology corporate behaviour toward human health and the environment namely regulatory, social and economic licences.

The public and interested parties, for instance, may use the regulatory licence for the public to participate in the biosafety decision-making process to give inputs on the LMO approval. The environmental group with the economic licence may use social media, for instance, to disgrace the LMO products especially the controversial ones thus consumer will boycott those products. The companies that ignore the social licence, for instance, the

consumers' wary on the LMO products without adequately explaining of the safety of the LMO ingredients will face rejection of their products. Thus product labelling as a regulatory licence that is required by the biotechnology companies to follow is essential in this regard. However, it is argued these licences model will face the same future like civil regulation in light of the current Malaysian position. There is little practice of licence model in Malaysia. However, the involvement of broader parties will enable further space for the inclusion of socio-economic factors in the biosafety regulatory field.

Malaysian good biosafety governance

Based on this research, there are some aspects that Malaysia needs to pay attention to namely:

i. transparency of the regulatory process
ii. transparency (data)
iii. public information (application)
iv. use of external scientific expert
v. post-approval monitoring

However, Malaysia is found competent in these aspects namely:[570]

[570] Penalba LM And Others, *Biotechnology Product Development, Biosafety Regulation and Environmental Risk Assessment in the Philippines* (2006)(EEPSEA, IDRC Regional Office for Southeast and East Asia, Singapore, SG).

i. the use of existing legislation
ii. mandatory premarket approval
iii. established safety standards

6. Conclusion

In conclusion, Malaysia is gearing up its legal and institutional biosafety framework not just to comply with the Cartagena Protocol on Biosafety 2000 but to empower it to protect human health and the environment. Nevertheless, much needs to be improved to achieve its ambition to utilise its biological resources using modern biotechnology entirely. Modern biotechnology that is seen as a new engine of economic growth should be complemented with a useful, practical and transparent legal and institutional biosafety comprehensive framework. Lack of proper biosafety framework will undermine not just future issues of sustainable development of biological diversity but also the future transboundary movement of living modified organisms (LMOs) and genetically modified (GM) products between Malaysia and other countries. Apart from that being a party to Cartagena Protocol on Biosafety 2000, Malaysian government is answerable the Protocol and related parties also other international agreements such as the WTO agreements.

Beside the existing legal framework on biosafety, further compliance towards the Cartagena Protocol on Biosafety should be addressed such as the liability and redress aspect as previously discussed in Chapter 3. The law and regulations are arguably should not be measured according to its width but rather in depth to ensure essential issues are dealt with efficiently to avoid conflict with other international agreement. The institutional framework arguably should be broadened to include the relevant stakeholders for knowledge and legitimacy. This, in turn, will provide rooms for harmonisation.

This will lead to a further discussion of the Singapore biosafety laws to examine its existing aspects of implementation. The comparative legal study is important as justified in Chapter 1 in order to analyse the existing similarities or differences between both countries approaches in the Conclusion Chapter.

CHAPTER 5
AN ANALYSIS OF THE SINGAPORE BIOSAFETY LEGAL AND INSTITUTIONAL FRAMEWORK

1. Introduction

In this thesis, the Singapore biosafety law is analysed and compared with Malaysia on the essential aspects of legal and institutional implementation. This study is essential to examine Singapore as a non-party to Cartagena Biosafety Protocol on how they implement their biosafety framework.

The comparative approach between Malaysia and Singapore as discussed in Chapter 1 is academically justified as both are very close neighbouring ASEAN countries thus harmonisation of biosafety laws is necessary. It is also probable that Singapore's implementation of its biosafety and biosecurity laws is reflected due to its obligations towards the WTO namely the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Technical Barriers to Trade (TBT) Agreement and the General Agreement on Tariffs and Trade (GATT).

The study will examine and analyse Singapore's response to the Key Biosafety Protocol issues namely risk assessment and management, public participation, socio-economic considerations, precautionary principle, labelling, liability and redress, procedures for transboundary movement and many more. Even though Singapore is not a party to the said Protocol, the Key Protocol issue is being used as guidance for biosafety framework of comparison between both countries, Malaysia and Singapore and this is mentioned in the concluding chapter.

2. Singapore legal framework on biosafety law

First and foremost, it is essential to note here that, in the Singapore context, the laws and regulations explicitly distinguish between biosafety and biosecurity. Biosafety is based on principles and techniques that protect workers from exposure.[571] Biosecurity based on security measures designed to reduce the risk of loss, theft or diversion.[572] Biosafety is to ensure national biosafety and biosecurity are safeguarded, with minimum hindrance to the development and growth of bio-industries in Singapore.

So far Singapore has no specific umbrella legislation for transgenic organisms or products thereof, only guidelines. Therefore the regulation of GMOs and LMOs are not by Biological Agents and Toxins Act (BATA) 2005[573] only by Guidelines as mentioned below. Biological Agents and Toxins Act (BATA) 2006 primarily deals with biosecurity as Singapore separates laws for biosafety and biosecurity.

Since both laws in Singapore are inter-related, thus the discussion on Singapore will be on both biosafety and biosecurity. Although the paper intends to deal on biosafety mostly, the written biosecurity Act in Singapore is most relevant to the biosafety institutional arrangement since they are both

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[571] Koh Peng Keng, 'Singapore's Perspectives on Biosafety & Biosecurity' <http://www.biosecurity.sandia.gov/ibtr/subpages/pastConf/20032005/redi/koh-peng-keng.pdf> accessed on 11 November 2015.
[572] World Health Organization, *Biorisk management: Laboratory biosecurity guidance* (Geneva: World Health Organization 2006)6.
[573] GMAC Guidelines, 'Overview on GMAC Guidelines', < http://www.gmac.sg/Index_Guidelines_Overview_on_GMAC_Guidelines.html> accessed on 20th January 2014.

either for biosecurity or biosafety purposes. As for biosafety issues that are related to GMOs, they are regulated by Genetic Modification Advisory Committee (GMAC) Guidelines.

Singapore and national aspiration

Singapore is a developed country that is situated in the South East Asian region. As it is an industrialised city country, coupled with the fact that it is a small territory with very limited land and natural biodiversity also agricultural land for agriculture to less than 3% due to urbanisation in the late 1980s but aspired to be a 'global city'.[574]In the late 1990s, Singapore opened up to biotechnology in agriculture and genetically modified products with very limited areas available for field experiments.[575] Singapore then progressed further according to its resources' availability.

Singapore biosafety and biosecurity background

The controversy about the SARS incident in Singapore's labs has sparked the country's concern over the importance of biosafety and biosecurity measures. Thus the Singapore biosafety historical perspective is essential to appreciate Singapore's early involvement in the biosafety and biosecurity. This is to understand the rationale of the different legal and

[574] LePoer BL, *Area Handbook Series: Singapore: A Country Study* (Library of Congress Washington DC Federal Research Div, 1989) 83.
[575] ibid.

institutional approaches in biosafety and biosecurity adopted by Malaysia and Singapore.

Singapore's intensive involvement in the biosafety and biosecurity[576] can be traced back to the first event of the spread of Nipah virus in 1998 that infected bats and later pigs in Malaysia, its neighbouring country. Previously Singapore had in place Animals and Birds Act 1965[577] also, Infectious Disease Act 1976.[578] Later Singapore was taking precautions during the Anthrax letter events in the United States in 2000.

In 2001 Singapore aspired by Singapore's Economic Development Board's (EDB)[579] drive to develop biomedical industry an area that included the pharmaceutical biotechnology and medical technology sectors.[580] EDB has shifted new focus to these industries namely chemicals, electronics and engineering.[581]

Aspired by these aims and national priorities, Singapore then strengthened its national biosafety and biosecurity laws and regulation to

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[576] Ai Ee L, 'Singapore's response to biorisk events at home and abroad' (Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories The National Academies Press, Istanbul,Turkey 10-13 July 2011 2012) 73.
[577] (Chapter 7)(Original Enactment: Ordinance 3 of 1965).
[578] (Chapter 137) (Original Enactment: Act 21 of 1976).
[579]EDB Singapore, 'Economic Development Board' (2018) <https://www.edb.gov.sg/en/about-edb/who-we-are.html>accessed on 27 December 2017.
[580]EDB Singapore,'Pharmaceuticals and Biotechnology' (2018) <https://www.edb.gov.sg/en/our-industries/pharmaceuticals-and-biotechnology.html> accessed on 27 December 2017.
[581] EDB Singapore, 'The Nineties' (2016) <https://www.edb.gov.sg/content/edb/en/why-singapore/about-singapore/our-history/1990s.html> accessed on 20 October 2017.

attract potential researchers and future investors to Singapore. In 2002 Singapore enacted Strategic Goods (Control) Act.[582]

Severe acute respiratory syndrome (SARS) incident that occurred in 2003 is the Singapore's major event that shaped Singapore biosafety and biosecurity regulation. In 2003 Ministry of Health commissioned Biosafety Level 3 lab at the same time of SARS outbreak. During that event, the SARS lab acquired the infection.[583] That has led to the making of the Biological Agents and Toxins Act (BATA) 2005. There are some primary existing biosafety rules and regulations in places in Singapore namely BATA 2005 mainly for biosecurity and Genetic Modification Advisory Committee (GMAC) Guidelines for Research and Agriculture using Genetically Modified Organisms (GMOs).

Singapore's aspiration not so much on developing agrobiotechnology products due to its limited land and biodiversity but ambitiously growing to be biotechnology research and development hub notably on intellectual property and later to commercialise those modern biotechnology products.

In 2006 Genetic Modification Organisms (GMO) Guidelines was released followed by 2008 Guidelines on Animal Transport and Use in Clinical and Public Areas (IACUC). In 2009 during the Influenza A (H1N1)

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[582] (Chapter 300) (Original Enactment: Act 40 of 2002).
[583] Review Panel on New SARS Case and Biosafety, *Biosafety and SARS Incident in Singapore September 2003 Report* (, 2003) 1.

outbreak lab guidelines were issued and in 2009 Codes of Ethical Practice were issued.

Singapore's Biological Agents and Toxins Act (BATA)[584] 2005 came into force on 3 January 2006. In writing the legislation, recommendations were from the National Biosafety Committee (NBC), and its Technical Working Committee (TWC). TWC are represented by related government agencies, research institutions, hospitals and vital industry players were taken into considerations. The Ministry of Health (MOH) conducted public consultation for the draft BATA from 11 April 2005 to 14 May 2005. The Parliament approved Singapore's first-ever law on the use of biological agents (BA) and toxins on 18 October 2005[585].On the recommendation of the NBC, the MOH has adopted the Laboratory Biosafety Manual, 3rd edition (World Health Organization, 2004) as the national guidelines for biosafety to supplement the BATA 2005. The World Health Organization (WHO) has long recognised that biosafety and biosecurity are critical international issues.[586]

Singapore despite their lack of natural resources became the next research and development hub of genetically modified food. Singapore has an extensive lab collaboration and co-operation with other countries. This is the leading target of future exports from Singapore worldwide. Therefore

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[584] Chapter 24A.
[585] Legislative History of BATA 2005 can be found at <http://statutes.agc.gov.sg/aol/search/display/view.w3p;ident=40a79baa-78b5-4303-bb08-39399539d2f0;page=0;query=DocId%3A%226b6eae33-48b3-4aeb-bbbd-651b14629c01%22%20Status%3Ainforce%20Depth%3A0;rec=0#xv-.>
[586] Tun T, Sadler KE and Tam JP, 'Biological Agents and Toxins Act: Development and Enforcement of Biosafety and Biosecurity in Singapore' 39.

prima facie it is an assumption as to why is Singapore more liberal and acceptance towards the genetically modified goods compared to Malaysia with less strict regulations and laws to comply with other than for hazardous materials and high-risk lab-containment activities.

Singapore biosafety and biosecurity laws

These are the existing laws and regulations on the Singapore biosafety and biosecurity;

1) Biological Agents and Toxins Act (BATA) 2005 is the legislation to promote biosafety and enhance biosecurity
2) Singapore Guidelines on Release of Agriculture-Related Genetically Modified Organisms (GMOs) Genetic Modification Advisory Committee of Singapore August 1999 by Genetic Modification Advisory Committee (GMAC)
3) Singapore Biosafety Guidelines for Research On Genetically Modified Organisms (GMOs) 2006 by Genetic Modification Advisory Committee (GMAC)

The first two (2) guidelines regulate GMOs whereas BATA 2006 regulates biosafety, biosecurity and bioterrorism. These guidelines have been developed together with the Ministry of Health (MOH), the Agri-food and Veterinary Authority of Singapore (AVA), the National Environment Agency (NEA) and the Ministry of the Environment and Water Resources (MEWR). On the very outset, Singapore has lesser laws as it depends on guidelines as compared to Acts of Parliament in regulating LMOs or GMOs.

Biological Agents and Toxins Act (BATA) 2005 (Act 36)

BATA 2005 is an Act to prohibit or otherwise regulate the possession, use, import, transhipment, transfer and transportation of biological agents, inactivated biological agents and toxins, to provide for safe practices in the handling of such biological agents and toxins.[587] Its objectives include preventing acts of bioterrorism, establishing a robust national biosafety culture and facilitating emerging bioscience industry in Singapore. The critical objectives of the BATA 2005 are provisions of safety practices in the handling of BA and toxins and promotion of biosafety training.[588] The BATA is related to companies and institutions in biomedical and life sciences research working with biological agents and toxins listed in schedules.

There are some essential components in the BATA legislation which is summarised[589] as follows:

Biological agent and toxins lists

There are five (5) separate schedules with different degree of control based on risk assessment. Apart from that, there are 38 biological agents, and 5 toxins with biosecurity concerns identified to have potential to be weaponised. These agents require maximum controls. This is attached as Table 14.[590]

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[587] Biological Agents and Toxins Act (Chapter 24a) Long title.
[588] Tun T, Sadler KE and Tam JP, 'Biological Agents and Toxins Act: Development and Enforcement of Biosafety and Biosecurity in Singapore' 39.
[589] ibid.
[590] ibid 40.

Schedule Classification	Risk Group	Descriptions of Schedule	No. of BA	Facility Requirements
Schedule 1 (Part I)	3	(1) Potential to cause serious disease which is high risk to individual	56	BSL3 Certified (Uncertified facility can appeal)
Schedule 1 (Part II)	3	(1) Potential to cause serious disease which is high risk to individual (2) Potential to be weaponized	23	BSL3 Certified and Protected Place (Uncertified facility and protected place can appeal)
Schedule 2	4	(1) Can cause severe/lethal disease, high risk to individual and community (2) Potential to be weaponized	14	BSL3 Certified and Protected Place with Special Approval granted by the Director (Medical Services)
Schedule 3	2	(1) Can infect humans (2) Need special attention in large scale Production	3	Specified in the Approval by the Director (Medical Services)
Schedule 4	2	(1) Can infect humans	250+	Conditions of a Permit granted by the Director (Medical Services)
Schedule 5	-	(1) Microbial toxins with potential to be weaponized	5	Protected Place and Conditions of an Approval granted by the Director (Medical Services)

Table 14: Singapore Biological agents and toxins list

Five schedules in BATA with their descriptions, corresponding Risk Group, number of BA in each schedule and Facility Requirements.

From this table, it can be seen that Singapore has identified the types of biological agents and toxins and further identified the types of them that

are possible to be weaponised. Thus it can be concluded here that Singapore is preparing its legislation not just for biosafety but biosecurity and bioterrorism prevention as well. The types of lab facility are also identified with presumably the same standard Biosafety Level (BSL) level labs elsewhere and also identified certification and approval by Director of Medical Services.

The risk group classification of hazardous agents varies from country to country, even though there are global standard laboratory practices and many aspects of laboratory culture are shared throughout the world. This is due to '…geographic and climatic distribution of the micro-organisms, their reservoir and vectors, especially when an animal or plant pathogens are concerned.' [591]An agent classified into Risk Group 2 in one country may be classified as Risk Group 3 in another country.

Agent tracking system

There are:

Import control

All biological agents in the schedules from 1 to 5 require an import permit. This is provided for in Subdivisions 2 on Import and Transhipment[592]

[591] Belgian Biosafety Server, 'International classification schemes for micro-organisms based on their biological risks' (2017) <http://www.biosafety.be/RA/Class/ClassINT.html> accessed on 3 January 2018.
[592] Division 2 (First Schedule) to Division 6 (Inactivated) for biological agents.

for all the biological agents and Subdivision 3[593] for toxins.[594] The applications for import permits can be submitted online at Singapore Customs Tradenet System.[595] The TradeNet launched in 1989 is the world's first nationwide electronic data interchange system that enables traders to submit permit applications electronically to government bodies for processing. In 2006 TradeNet® processed over nine million permits, with over 90% processed in less than 10 minutes. The importer of the BA into Singapore must obtain approval, i.e. a valid permit to possess the BA. Even when engaging a courier service provider in applying for the import permit on behalf of the institution, the importer must verify that the correct permit has been obtained from the Ministry of Health (MOH).

There are no requirements for export of biological agents and toxins in BATA 2005 as it is controlled by the Strategic Goods (Control) Act 2002 administered by Singapore Customs. The said Act is '…to control the transfer and brokering of strategic goods, strategic goods technology, goods and technology capable of being used to develop, produce, operate, stockpile or acquire weapons capable of causing mass destruction, and missiles capable of delivering such weapons; and for purposes connected therewith.'[596]

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[593]on Import and Transhipment.
[594]Fifth Schedule for toxins.
[595] Singapore Customs, 'Features' (2008) <http://www.customs.gov.sg/~/media/cus/files/insync/issue02/features/features.html> accessed on 20 October 2017.
[596]Strategic Goods (Control) Act 2002 Long title.

Possession control

The law on possession controls of biological agents (BA) and toxins in Singapore according to BATA 2005 relate to biosecurity. However, BATA 2005 provided the institutional aspect of biosafety and biosecurity implementation in Singapore. Approval to possess BA and toxins are by Director of Medical Services of Ministry of Health, and the facility must be certified as a BSL facility that fulfils all the requirements. For genetically modified organisms (GMOs), approval must be sought from Genetic Modification Advisory Committee (GMAC) before an application for approval and permit to MOH is submitted.

Transfer control

These are the essential controls for the biological agents identified, starting from import, possession and transfer of those biological agents. There are clear and specific directions to notify MOH of the proposed transfer with notification requirement.

Transport requirements

Transport by postal mail or public transport is strictly prohibited. The packaging and labelling must follow the principles as stipulated by the International Air Transport Association (IATA) during the transportation. The drivers have to undergo training in the management of accidents involving biohazardous materials and affixed with biohazard labels.

Facility requirements

The facilities are certified by MOH approved certification bodies while the facilities must undergo annual re-certification. The inventory record must be maintained of scheduled Biological Agents (BA), and toxins and MOH must be notified of all labs-acquired infections and accidents involving them. The certified facility must be gazetted as a protected place. It is noted here that Singapore is also a party to the Biological Weapons Convention (BWC) which is linked to the UN Security Council Disarmament initiative.

Singapore Guidelines on the Release of Agriculture-Related GMOs (1999)

These Guidelines were developed to ensure safe import, release and use in Singapore of agriculture-related organisms obtained through genetic engineering.

They cover two main issues:

i) the assessment of risk to the environment and human health and
ii) the mechanism for approval of agriculture-related GM organisms in Singapore.

The term agriculture-related organism is used to indicate plants, animals, microorganisms and vaccines used in cultivation, farming, horticulture, husbandry and agronomy.

Thus from the Guidelines, the applicants need to comply the procedures for notification[597] to submit a proposal which GMAC will later approve according to the approval procedure.[598]

Anyone who intends to import agriculture-related GM organisms into Singapore is required to apply to GMAC, which then forwards it to the Subcommittee on the Release of Agriculture-Related GMOs. Each application is evaluated on a case-by-case basis and can either be fully approved or endorsed under specified conditions. The Guidelines deal with the food safety issue based on substantial equivalence[599] as the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner concerning safety.

Procedures for Approval are listed as follows:

i. The GMAC will then forward the proposal to the Sub-Committee who may either approve/reject the proposal or appoint the relevant agency or an expert panel to evaluate the proposal within 90 days.
ii. The panel of experts will then review and assess the risks associated with each stage of the release using the questionnaire and risk assessment criteria. The agency/expert panel will submit their recommendations to the Sub-Committee within 90 days. The

[597] Guidelines on the Release of Agriculture-Related GMOs (1999) s5.
[598] ibid s6.
[599] ibid s1.2.

GMAC will decide on the recommendations of the Sub-Committee within 60 days. The GMAC can request further information/ clarification from the Proponent if any need arise.

iii. The GMAC will decide on the release on a case-by-case basis. The GMAC will either:

a) endorse the release of the agriculture-related GMOs,
b) endorse the release of the agriculture-related GMOs under specified conditions,
c) require the Proponent to submit additional information which the GMC deems necessary to complete the assessment, followed by decision (i) or (ii).

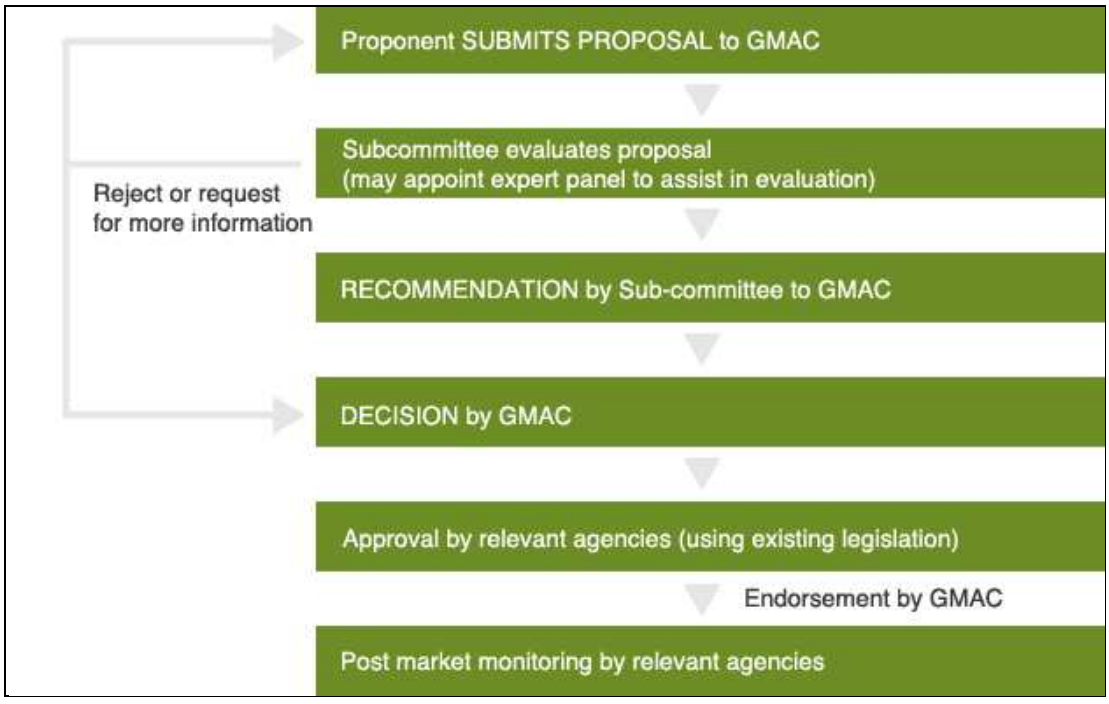

Figure 21: Flow Chart for Evaluation, Approval and Registration of Agriculture-Related Genetically Modified Organisms (GMOs).

Singapore Biosafety Guidelines for Research on GMOs (2006)

In 2006, after consultation with researchers, regulatory authorities and biosafety experts, the Singapore Genetic Modification Advisory Committee released the Singapore Biosafety Guidelines for Research on Genetically Modified Organisms (GMOs). The guidelines take into account international regulations and recommendations (mainly from Australia, USA, Europe, World Health Organization and United Nations Environment Programme)[600] and are not legally binding. These guidelines were designed to grant safe containment, handling and transport of GMOs intended for research purposes and moreover to keep track of the status of research on GMOs. If the GMOs are derived from biological agents and toxins are known for their danger to human health, the research work must comply with the Biological Agents and Toxins Act 2005.

The scope of the guidelines covers experiments that involve the construction and/ or propagation of all biological entities (cells, organisms, prions, viroids or viruses) which have been made by genetic manipulation and are of a novel genotype and which are unlikely to occur naturally or which could cause public health or environmental hazards.[601] The GMAC research guidelines differentiate experiments involving GMOs or derived products into three categories according to the level of risk, giving clear

[600] s1.1.
[601] s2.1.1.

indications on how to manage each situation, which is the responsible authority and how to apply them to adhere to the requirements.[602]

However for work with GMOs derived from biological agents and toxins known to be hazardous to human health are regulated, under the Biological Agents and Toxins Act 2005.[603] Large-scale production of GMOs derived from biological agents and toxins known to be hazardous to human health may be regulated under the Biological Agents and Toxins Act (2005).

Research proposals where the introduction into human subjects of nucleic acids (genetically manipulated or chemically synthesised), or genetically manipulated micro-organisms, or cells, is designed to stimulate an immune response to antigenic determinants of infectious agents, as in the case of a classical vaccine, should be submitted to the appropriate Bioethics Committees. If necessary, advice from GMAC could also be obtained.[604]

GMAC guidelines list down the regulatory agencies related to GMOs.[605] According to the GMAC Guidelines, the national agencies responsible for enacting the various aspects of GM technology and activities in Singapore are tabulated as below.

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[602] Adduci G, 'GM Crops and Biosafety in South-East Asia: Singapore as Case Study' in (2012)9.
[603] BATA 2005 s2(c)
[604] s2.1.5.
[605] s2.3.

Agencies	Roles
Agri-Food and Veterinary Authority of Singapore (AVA)	Regulation of laboratories dealing with GMO research, involving animal pathogens and plant pests
AVA, Ministry of Health (MOH) and National Environmental Agency (NEA)	Importation of organisms including GMOs
MOH	Certification or Inspection of Laboratories handling biological agents or toxins regulated under the BATA
Ministry of Manpower (MOM)	Regulation of Workplace Safety and Health

Table 15: National agencies legislating GM in Singapore

Section 3 of the Guidelines provides for a summary of procedures. Section 3.1 outlines the decision flowchart for assessment and notification of research work. Section 3.2 provides flow chart for the importation of GMOs for research.

GMAC also emphasises the institutions that deal with GMOs are required by GMAC to have Institutional Biosafety Committee. Section 6 of the Guidelines is on import, export and transport for GMOs and/or GMOs-derived materials.

Section 4 of the Guidelines list out the Category A, B, C that requires IBC, GMAC or nil approval at all according to the level of risks namely which is summarised as follows:

a) Category A – Experiments Requiring IBC Approval And GMAC Notification (Regulated Experiments with Significant Risks)
b) Category B – Experiments Requiring IBC Approval (Notifiable Experiments with Low Risks)

c) Category C – Experiments Exempt From The Guidelines (Experiments with Extremely Low Risks)

From these GMAC Guidelines, it can be summed up that they established and identified some essential institutional framework on biosafety namely the relevant government departments also involved the Institutional Biosafety Committee (IBC). GMAC involvement can be seen as advisory on GMOs on research and agriculture products. Apart from IBC and GMAC, the Principal Investigator (PI) is the person responsible inter alia to apply for an import permit, before commencing work for proposal and later to experiment. The Guidelines[606] list the roles and responsibilities of the institutions, IBC and PI.

[606] s5.

3. Singapore Institutional Framework on Biosafety Law

Ministry responsible

These are ministries that are competent national agencies which are entrusted with biosafety responsibilities in Singapore namely:

Agri-Food and Veterinary Authority of Singapore (AVA)
Ministry of Health (MOH)
Ministry of Manpower (MOM)
National Environmental Agency (NEA)

Table 16: Singapore competent national agencies

This is mentioned in the GMAC Guidelines as mentioned above.

Apart from these ministries, there is system In-place to facilitate the Administration of the BATA 2005. This is listed as follows:

Gazetting of facilities as protected place by the *Ministry of Home Affairs*
Vetting of personnel accessing protected facilities by the *Internal Security Department, MHA*
Involving *Singapore Civil Defense Force, MHA* in emergency response of Labs
Collaborating with other ministries & agencies (*esp. the Singapore Police Force, MHA*)on sensitive materials
Annual certification of BSL3facilities by *MOH-Approved Facility Certifiers*
Training of biosafety training courses by *MOH-Approved Training Providers*
On-line application for approval & permit using IT system *(MOH & Singapore Customs)*

Table 17[607]: System In-place to facilitate the Administration of the BATA

The leading authority on the topic is the Agri-Food and Veterinary Authority of Singapore (AVA) which is responsible for food, animals and pets as well as the agricultural and fisheries sectors. AVA regulates the import of plants, plant products, fertilisers of plant origin, insects or microorganisms of agricultural importance and cut flowers, to safeguard plant health and to prevent any introduction of exotic pests and diseases into the country. The central regulation for cultivation, import and export of plants and plant-derived products is the Control of Plants Act (1994). This Act covers the import and transhipment of fresh fruit and vegetable, control of plant cultivation (licences and use of pesticides), any issue related to prohibited plants, pest controls, licences and permits.[608] The Act does not cover GM plants as the importer

[607] Ai Ee L, 'Singapore's response to biorisk events at home and abroad' (Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories The National Academies Press, Istanbul,Turkey 10-13 July 2011 2012).
[608] ibid.

needs to get the recommendations from Genetic Modification Advisory Committee (GMAC) before importation.

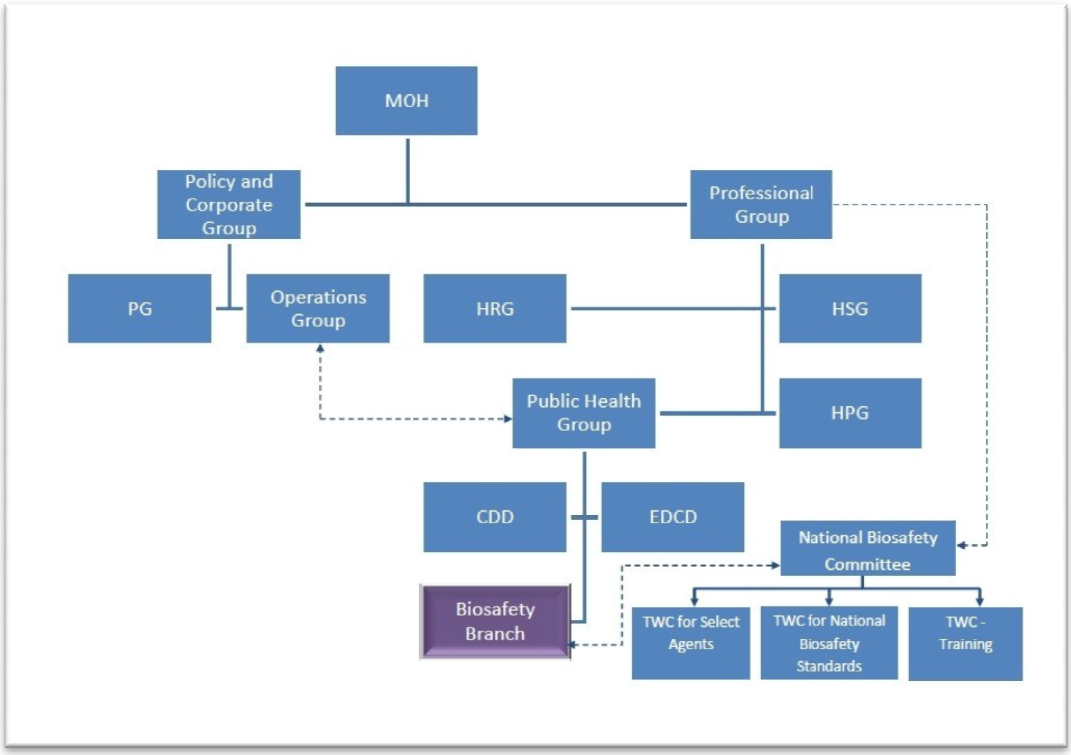

Figure 22: Singapore Biosafety Organizational Chart

In Singapore these are the leading institutions that deal with Biosafety namely;

Bioisafety Branch
National Biosafety Committee
Genetic Modification Advisory Committee
Institutional Biosafety Committee
Bioethics Advisory Committee

Table 18: Singapore main institutions in biosafety

Biosafety Branch

The Biosafety Branch was established in 2005 to cater for all biosafety matters in a sustainable and organised manner. The Biosafety Branch is to promote high standards of biosafety in the research and biomedical community, establish the framework and guidelines for biosafety training, promote links with the international biosafety community and prevent bioterrorism by controlling the use of high-risk biological agents. It is set up under the Operations Group as it works closely with the Communicable Diseases Division (CDD) and Preparedness & Response Division to facilitate implementation of containment measures in the event of laboratory accidents of public health significance.

The Biosafety Branch plays a vital role in administering the Biological Agents and Toxins Act 2005 (BATA 2005). The Biosafety Branch also acts as the secretariat for the National Biosafety Committee, and the three Technical Working Committees, namely, Select Agents List, Biosafety Training and Biosafety Standards.[609]

[609] Ministry of Health (MOH) Singapore,'Biosafety' (2nd September 2015) <https://www.moh.gov.sg/content/moh_web/biosafety.html> accessed on 11th November 2015.

Roles and functions of the Biosafety Branch can be summarised as follows to:

- Administer and enforce BATA
- Represent the Ministry of Health as the National Authority (NA) for Biological Agents and Toxins
- Promote biosafety awareness and nurture biosafety culture in Singapore
- Act as a resource and coordination centre for all biosafety and biosecurity issues in Singapore.
- Provide secretariat support for the National Biosafety Committee, including appointed technical committees.
- Develop policies, procedures and guidelines for biosafety emergencies and response.
- Keep abreast with the latest biosafety and biosecurity development, and to review and update existing policies to ensure policies are always kept in line with the emerging biosafety and biosecurity trends.

Figure 23: Roles and functions of the Biosafety Branch

The branch keeps lists of Approved Facility Certifiers (AFC) and Approved Training Providers (ATP), and also sets the topics for biosafety training and the checklists for facility certification and biosafety audit purpose. There is a dedicated webpage, and all relevant information is available online for the Biosafety Level 3 (BSL-3) facilities in Singapore.[610]

IT system of biosafety allows all users to perform activities such as registering the facility, applications for permits and approvals, notification of

[610] Ministry of Health (MOH) Singapore, 'About us' (2015) <https://www.moh.gov.sg/content/moh_web/biosafety/about-us.html> accessed on 10 January 2015.

transfers, receipt, inactivation and disposal, reporting of incident and inventory for biological agents, and many others.[611]

National Biosafety Committee

The formation of the multi-disciplinary National Biosafety Committee (NBC) is to implement the Biosafety Framework in March 2003. There are three (3) Technical Working Committees (TWCs) namely as follows:

i) TWC for Select Agents
ii) TWC National Biosafety Standards
iii) TWC Training

The Three Technical Working Committees (TWCs) appointed by the NBC with specific tasks to:

i) draw up and update the biological agent list
ii) formulate and update the biosafety standards
iii) define the training requirements

Genetic Modification Advisory Committee (GMAC)

Genetic Modification Advisory Committee (GMAC) was established under the Ministry of Trade and Industry in April 1999 with aims to administer

[611] ibid.

and advise on the research and development, production, use and handling of Genetically Modified Organisms (GMOs) in Singapore.

The Committee is currently chaired by Prof Paul Teng from the National Institute of Education (NIE). Twelve (12) agencies represent the GMAC members. Each member of GMAC is of different expertise to the committee, thereby enabling GMAC to make decisions based on holistic views of issues related to genetic modification.[612]

The GMAC Main Committee consists of:

i) GMAC Chairman
ii) Deputy Chairman

There are four (4) subcommittees namely:

i) Subcommittee on release
ii) Subcommittee on research
iii) Subcommittee on labelling
iv) Subcommittee on awareness

[612] Genetic Modification Advisory Committee (GMAC) Singapore, 'The GMAC Main Committee' (2015) <http://www.gmac.gov.sg/Index_The_Committee.html> accessed on 11 November 2015.

There are eight other members inclusive of one (1) Consumers Association of Singapore. The GMAC consists of representatives from national agencies listed as below:

• Agency for Science, Technology & Research (A*STAR)
• Agri-Food and Veterinary Authority of Singapore (AVA)
• Attorney General's Chambers (AG Chambers)
• Consumers Association of Singapore (CASE)
• Institute of Molecular and Cell Biology (IMCB)
• Ministry of Health (MOH)
• Ministry of Manpower (MOM)
• Nanyang Technological University (NTU)
• National Institute of Education (NIE)
• National Parks Board (NParks)
• National University of Singapore (NUS)
• Temasek Life Sciences Laboratory (TLL)

Table 19: GMAC representatives

The national agencies responsible for the various aspects of regulatory affairs on behalf of the GMAC are:[613]

Regulation of laboratories dealing with GMO research, involving animal pathogens and plant pests – AVA
Importation of organisms including GMOs – AVA, MOH and NEA(please also see section 6)
Certification of Safety and Health of workers – MOM
Research Laboratory Certification – MOM
Clinical Laboratory Certification – MOH

Table 20: National agencies responsible on behalf of GMAC

From the composition of GMAC, it seems that the stakeholders are well represented from the legal, relevant government departments and national agencies, consumer association, research institute, universities and parks authority. The only setback is in the environment department as perhaps Singapore is a city-state with not much biodiversity and limited land, Singapore perhaps will not involve in the massive scale of GM agriculture. Thus it will not have a significant impact on the environment and biodiversity.

[613] The Singapore Biosafety Guidelines for Research on Genetically Modified Organisms (GMOs) 2006.

The tasks and responsibilities of GMAC are listed as follows:

To advise and recommend for approval, or otherwise, the research and development, production, use and handling of GMOs
To monitor the control of release of GMOs into the environment
To review proposals related to the release of GMOs into the environment.GMAC may establish sub-committees of experts in specific areas to assess the risks involved
To provide advice on matters related to the release of GMOs
To inform the public, where deemed necessary, on planned release of GMOs
To establish mechanisms for exchange of information with overseas agencies and to facilitate the harmonisation of guidelines with regional and international authorities
To develop and approve biosafety guidelines for the research and development, production, use and handling of GMOs
To create public awareness on GMO and GMO-related issues

Table 21: Tasks and responsibilities of GMAC

Bioethics Advisory Committee Singapore (BAC)

Singapore Cabinet established BAC[614] in December 2016 with a task to address ethical, legal and social issues in biomedical research in

[614] Bioethics Advisory Committee Singapore, 'Bioethics Advisory Committee Singapore' (2016) <http://www.bioethics-singapore.org/> accessed on 11th November 2015.

Singapore. Singapore acknowledges bioethics as essential and integral to rapid progress in biomedical science and research to be based on high ethical and legal standard. To this aim, BAC gathers the relevant views and information from the local and international community to advise the Singapore government. However, BAC's view is not binding but only persuasive.

Institutional Biosafety Committee (IBC)

This Committee was appointed under the Biological Agents and Toxic Act 2005 (BATA). Its duties include to conduct risk assessments on the activity proposed by the applicant, evaluate the correlated risk management, advise the applicant on the best practice and code of conduct to carry out the proposed activity safely (including personnel training). Finally, IBC is to review and control the proposed activity every two years to make sure it is appropriately conducted. In the specific context of activities involving genetically modified organisms, the Committee is responsible for conducting inspections, monitoring the facilities and assessing the level of competence of the personnel involved in the work.[615]

[615] Adduci G, 'GM Crops and Biosafety in South-East Asia: Singapore as Case Study' in (2012) 8.

Other important biosafety institutions in Singapore: Institutional Biosafety Committees

National University of Singapore (2002)
Singapore General Hospital Animal Facility Biosafety Committee (2006)
SGH Institutional Biosafety Committee (IBC) (2007)

Table 22: Other important biosafety institutions in Singapore

According to Sing Health IBC (2010) there is overarching oversight of 9 national institutes using common structure, standard risk assessment template, expert panel that provide interagency liaison, compliance with BATA, secretarial assistance (annual reports, etc.).[616]

[616] Ai Ee L, 'Singapore's response to biorisk events at home and abroad' (Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories The National Academies Press, Istanbul,Turkey 10-13 July 2011 2012) 1.

Biorisk Association of Singapore (BAS)

The Biorisk Association of Singapore (BAS) was founded in 2010 by Dr Ai Ee Ling. BAS is a non-profit, multidisciplinary association promoting biosafety in Singapore with the aim of fostering the development and recognition of biorisk management as a profession, promoting safe management of biological materials, providing a vital platform for knowledge-sharing in biorisk management, facilitating collaboration within the local and international biorisk management groups/ associations, promoting education in biorisk management, and promoting applied biorisk research. BAS is affiliated with the American Biosafety Association (ABSA International) and the Asia-Pacific Biosafety Association (APBA). APBA offers biosafety training throughout the region, including principles and practices, biosafety management, and Certified Biosafety Coordinator for Singapore.[617]

4. Singapore Biosafety and Biosecurity Law

Singapore BATA 2005 is said to contain similar terms with the United States regulations; only it is stricter regarding non-compliance.[618]

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[617] Asia Pacific Biosafety Association, 'About A-PBA' (2016) <http://www.a-pba.org/about> accessed on 22 January 2016.
[618] Reynolds M. Salerno, Jennifer Gaudioso (ed), *Laboratory Biorisk Management: Biosafety and Biosecurity* (2015)4.

The non-compliance part of BATA 2005 Offences is summarised as follows:[619]

Use of BA or toxins for non-peaceful purpose	Life imprisonment and/or S$1 million
Possession of BA or toxins without approval	10-years imprisonment and/or S$100K
Large scale production of BA without approval	1 year imprisonment and/or S$10K
Importation/transshipment of BA or toxins without permit	½ year imprisonment and/or S$5K
Transportation of BA or toxins by mail/public transport	(Severity of punishment depends on degree of offence)
Failure to perform duties and obligations	

Table 23: BATA 2005 offences and punishments

Perhaps Singapore has learnt its lesson from the SARS incident in 2003 in Singapore lab also in Taiwan and China,[620] thus strengthen its laws empowerment. Singapore also realises the potential use of some biological agents as weapons of bioterrorism.[621] Thus there are some solutions to the

[619]Ai Ee L, 'Singapore's response to biorisk events at home and abroad' (Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories The National Academies Press, Istanbul,Turkey 10-13 July 2011 2012)1.
[620] Wen-Chao Wu, Li-Li Lee, Wei-Fong Chen, Shih-Yan Yang, Ho-Sheng Wu, Wen-Yi Shih, and Steve Hsu-Sung Kuo, 'Development of Laboratory Biosafety Management: The Taiwan Experience' (2007) Applied Biosafety, 12(1) pp. 18-25 © ABSA
[621]Koh Peng Keng, 'Singapore's Perspectives on Biosafety & Biosecurity' <http://www.biosecurity.sandia.gov/ibtr/subpages/pastConf/20032005/redi/koh-peng-keng.pdf> accessed on 11 November 2015.

biosafety and biosecurity issues by having the Singapore BATA 2005, whereby they developed a biosafety framework to promote biosafety culture which is transparent and follows internationally recognised standards. Singapore followed the international standard, as its biosafety lab procedure and guidelines are according to the WHO standard, and its BATA 2005 content is quite similar to the United States.

As the issue of transparency, it is yet to be examined. BATA 2005 is said to be comprehensive but not prescriptive. Another advantage of BATA 2005 is said to be balanced between safety and research freedom. While this is supposedly the ultimate best aims of biosafety culture, again this is not an easy issue to be analysed, however presumably all the best procedures are being implemented and followed, hopefully in future, there will be no more SARS acquired lab incident occurred again in Singapore labs. As to the issue of research freedom, again this is a complicated issue to be examined in detail only a fair view could be presented.

An excellent regulatory framework will strengthen Singapore's standing as a biomedical hub and help it to attract world-class researchers. Therefore there is the need for the laws to strike a balance between keeping research safe and being too restrictive. The requirements should not result in unnecessary cost increases, research being hampered, and scientists being discouraged from working to prevent disease outbreaks.

A fine up to $1 million Singapore dollars and life imprisonment for a deliberate attempt to use biological agents and toxins for biological warfare or any non-peaceful purpose. Such severe penalties for convicted offenders reflect Singapore's serious commitment to biosafety and biosecurity.[622] This is the general overview of the Singapore BATA 2005. It is submitted that this view is right in light of the seriousness of the offence also the severity of the nature of biosafety and biosecurity taking into account of the SARS incident that occurred previously in Singapore.

Singapore, GM products and Genetic Engineering (GE)

Singapore does not produce any GE agricultural plants or animals, and so far there is no GE field trial.[623] GE related activities in Singapore confined to laboratory research primarily related to pharmaceuticals. Animal biotechnology in Singapore is not significant. As for food labelling on GM, there is nothing yet as Singapore adopts the substantial equivalence Codex Alimentarius principle.

Issues of dual use of technologies

Another issue of importance is the dual-use issue of modern biotechnology. The dual-use issue is primarily the use of technology either for peaceful or military purposes. Dual use in the modern biotechnology means

[622] Tun T, Sadler KE and Tam JP, 'Biological Agents and Toxins Act: Development and Enforcement of Biosafety and Biosecurity in Singapore'.
[623]USA Foreign Agricultural Service, *Singapore Agricultural Biotechnology Annual 2015* (USDA GAIN Report SN5003, 2015) 3.

that apart from the good use of modern biotechnology or science in general for the betterment of peoples health and environment mainly, however, there is an evil tendency on the scientist part due to greed, fame, or money or for whatsoever reason. This led them to use the modern biotechnology or science for an evil purpose other than good, i.e. for instance military purpose or to create bioterrorism.

In the South Pacific Region, recent studies suggest that the dual-use issue has gained low awareness among the life scientists. Singapore is said to have a traditional emphasis on biosafety and a relatively low awareness on the dual issue.[624] Their concerns are mostly on the preservation of biodiversity and human health and maintaining agricultural security. One of the reasons suggested is due to the lack of academic courses on dual-use risks associated with certain types of biotechnological research.[625]

Singapore who has an advanced biotechnology industry aspired to become a biomedical hub in the Asia Pacific region, is said to have comprehensive biosafety legislation modelling the WHO biosafety guidelines having the research, handling and transport of GMOs.

It is rightly observed that the primary trend in the governance of dual-use technologies is done through the reinforcement of the international treaties such as CPB, BWC and Chemical Weapons Convention (CWC) via

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[624] Tucker JB, *Innovation, Dual Use, And Security: Managing The Risks Emerging Biological and Chemical Technologies* (MIT Press 2012)59.
[625] ibid.

domestic legislation that establishes biosafety and biosecurity at the national level. This is the current trend that has been followed by many countries worldwide and Malaysia for instance signed and ratified the Cartagena Protocol on Biosafety. Singapore although themselves involved in the Cartagena negotiations decided to join the like-minded group but set up their national biosafety legislation and not signing the Cartagena Protocol on Biosafety.

Another set of governance tool is the use of soft laws and informal measures that are not legally binding such as professional guidelines, codes of ethics, education and awareness rising. These soft measures are voluntary and lack of strict enforcement. It is aimed to create a culture of responsibility of dual-use research and to forestall strict government intervention.

However, due to the security risks of emerging technologies such as synthetics genomics, it is rightly submitted that it is sufficient to warrant a mixed-governance method. For example for both Malaysia and Singapore, there are biosafety acts that regulate the critical parts of research, handling and transport of LMOs. Apart from that the guidelines on LMOs research are soft laws, also code of ethics developed by bioethics councils also education and awareness rising by other biosafety related-bodies. It is opined that there should be a critical need for collaboration between government and non-governmental actors including scientific and industries, also the ability to strike up the balance between the top-down and bottom-up regulatory tools. The mixed governance strategies are said better to keep up with the changing phase of rapid evolution of technologies.

Singapore investment in modern biotechnology

It is a fact that Singapore has BSL-3 laboratories at Biopolis, at the time estimated at 16 laboratories. Several uncited accounts are reporting that the Singapore Defense Science Organization operates a BSL-4 facility. Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections, agents which cause severe to fatal disease in humans for which vaccines or other treatments are not available, such as Bolivian and Argentine hemorrhagic fevers, dengue fever, Marburg virus, Ebola virus, hantaviruses, Lassa fever, Crimean-Congo hemorrhagic fever, and other various hemorrhagic diseases.[626]

A 2009 WHO report, supported by other sources, indicates that Singapore operates a mobile BSL-4 autopsy suite.[627] The BSL-4 lab is very expensive to build.[628]

Singapore's negotiation in the Cartagena Protocol on Biosafety

Singapore had their share of involvement in the Cartagena Protocol on Biosafety starting from the earlier negotiations. Singapore perhaps due to

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[626] Bionity.com, 'Biosafety level' (2017) <http://www.bionity.com/en/encyclopedia/Biosafety_level.html> accessed on 20 February 2016.
[627] Chui P and others, 'Mobile Biosafety Level-4 Autopsy Facility—An Innovative Solution' (2007) 12(4) Applied Biosafety 238.
[628] ibid.

their economic aspirations and biosafety history were among the Compromise Group, and later did not sign and ratified the Cartagena Protocol. However, besides being a non-party Singapore developed their comprehensive biosafety and biosecurity system.

5. An Analysis of the Singapore Legal and Institutional Biosafety Framework

This analysis will be based on the Cartagena Protocol on Biosafety even though Singapore is not a party to the Protocol. This is arguable because the Key Protocol issues focus on the most crucial biosafety issues. However, the discussion will not be as detailed in Malaysian compliance but to what extent Singapore fulfils it. Singapore previously was part of the Protocol discussion and became the Compromise Group in the negotiations together with Switzerland and other countries.

Risk Assessment and Risk Management

This so-called scientific risk assessment and management can be seen from the application for the use of LMOs in Singapore as there are sets of questions and answers provided in the GMAC Guidelines that need to be answered by the applicants in their applications. The GMAC Guidelines on the Release of Agriculture-Related GMOs (1999) provide a common framework for the assessment of risks of agriculture-related GMOs to human health and the environment and the approval mechanisms for their release in Singapore. Thus the risk assessment also taking food safety issue into account as it adopts the substantial equivalence concept. This risk assessment is known as Appendix 1, and 2. As for Singapore Biosafety Guidelines for Research on GMOs (2006) only requires proposal form for assessment of genetic manipulation work.

For dealing with the human subject in research experiments, the Bioethics Advisory Council (BAC) and GMAC should be consulted.[629] However, there is a member of consumer association in GMAC perhaps giving a room for socio-economic other than the scientific input. Thus at this juncture, it can be safely be concluded that Singapore assessments risk of biosafety and biosecurity are technocratic, purely taking scientific risk assessment into accounts, leaving little room for socio-economic considerations possibly to its lack of biodiversity and Singaporean better perception towards LMOs as explained in Chapter 1.

Public Awareness and Participation

As for public awareness and participation, during the earlier tabling of Biological Agents and Toxins Bill, there were public consultations done, thus raised the awareness of what intended to be protected namely biosecurity and biosafety. By looking at GMAC websites, there are contests done on raising the awareness of the public on biosafety and biosecurity issues in Singapore.

On the biosecurity issues, apart from the earlier public consultation done during the BATA Bill, however, it seems that Singapore government either legislator or institutions applied the technocratic method whereby scientific risk assessment being used or those directly related with the LMOs.

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[629]Biosafety Guidelines for Research on GMOs (2006) 2.3.3

The public only can be informed of the outcome from biosafety website of the current news on Singapore biosecurity.[630]

On the research and agriculture that involves with GMOs, GMAC is responsible for informing the public, where deemed necessary, on planned releases of GMOs.[631] However, GMAC at the same time is to facilitate public education and create awareness on GM issues.[632] GMAC efforts on educating and raising Singaporeans awareness can be seen from GMAC website on various activities done by GMAC and the types of underlying knowledge that Singaporeans should know about GMOs.[633] This is because GMAC has its own Public Awareness subcommittee that bears the responsibility to disseminate information that is objective, factual and scientific so that members of the public can make educated, rational decisions on GM technology and its products.[634]

There is no legal requirement for the public to be consulted for LMOs and biologcal agents and toxins, through website or newspaper, only raising awareness and educate them. However, the public awareness has been

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[630] Ministry of Health (MOH) Singapore, 'News update' (2017) <https://www.moh.gov.sg/content/moh_web/biosafety/news.html> accessed on 15 March 2015.
[631] Genetic Modification Advisory Committee (GMAC) Singapore. 'News update' (2017) <https://www.gmac.sg/> accessed on 20 January 2017.
[632] ibid.
[633] Genetic Modification Advisory Committee (GMAC) Singapore, 'Education' (2017) <https://www.gmac.sg/Education/Index.html> accessed on 20 January 2017.
[634] Genetic Modification Advisory Committee (GMAC) Singapore, 'GMAC Subcommittee for public awareness' (2017) <https://www.gmac.sg/Index_Subcommittee_for_Public_Awareness.html> accessed on 20 January 2017.

instutionalised through GMAC Public Awareness subcommittee. As raising awareness is literally different from participation during the biosafety decision-making process, thus it is yet to be seen which medium effectively encourage the public participation.

Socio economic considerations

There is no direct mentioned on socio-economic considerations for GMOs. However, GMAC Agriculture Guidelines provides a common framework for (a) assessment of risks of agriculture-related GMOs to human health and the environment. However, it seems it is not so much of the equals to Cartagena Protocol on Biosafety which stressed the importance of GMOs effect on the biodiversity and the local and indigenous people. This is perhaps because Singapore has not much biodiversity, a city country and not an agriculture exporter country.

Precautionary principle

The concept of the precautionary principle is nowhere to be found either in the biosafety GMOs related Guidelines or on biosecurity. Thus this concept is not being approved and used in Singapore either for BA or toxins or GMOs products. This seems to be in line with the United States approach rather than EU stand on GMOs. Singapore seems to be more in line with the WTO trade-related agreements either on BA, toxins or GMOs. The GMAC Agriculture GMOS Guidelines address issues related to food safety based on the concept of substantial equivalence.

Handling, transportation, packaging and identification of GMOs

As for Singapore, as they learnt many lessons from the SARS acquired lab incident as in Taiwan and China, they developed their lab biosafety protocol also the model WHO lab biosafety Protocol.

As for handling, transportation, packaging and identification of GMOs, Singapore differentiates between biosafety and biosecurity issues, whereby biological agents and toxins are being listed according to biosafety level in accordance to Biological and Toxins Act (BATA) 2006. As for GM products for research and agricultural, it is by the GMAC Guidelines which are not compulsory but usually followed by the institutions that deal with GMOs. As for handling, transportation, packaging and identification of Biological Agents and Toxins, these are contained in the BATA 2006. While for handling, transportation, packaging and identification of GMOs, these are contained in the GMAC Guidelines on GMOs for Research or Agricultural purposes. It is important to note here that Singapore adopts a liberal attitude towards GMOs as they applied the substantial equivalence concepts towards GM food.

Information sharing

The information for biosafety in Singapore can be seen in Singapore Biosafety website that is maintained by Ministry of Health Singapore. The website seems user-friendly, as it looks easy to be used for those companies or individuals who want to apply for biological agents and toxins application.

For application related to GMOs, it is to be seen at the GMAC website. The current news of the types of biological agents, toxins and GMOs can be seen from those websites.

Another issue is that GMAC website also published the lists of GMOs being approved in Singapore, as this can be seen from the website.[635]

Liability and Redress

For liability and redress for BATA 2005 on biological agents and toxins, it can be seen clearly that the offender will suffer heavier punishments compared to the United States rules and regulation. For GMOs related offences, as the GMAC Guidelines are not legally binding, it seems GMOs are treated no different than conventional products. If the GMOs are either Biological Agents or Toxins, perhaps BATA 2005 will be applicable thus fall under that Act and offenders can be punished accordingly.[636]

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[635] see <http://www.ava.gov.sg/docs/default-source/tools-and-resources/resources-for-businesses/listofapprovedgmcropswebsitever2.pdf?sfvrsn=2>
[636] Singapore Biosafety Guidelines for GMO Research 2014 s2.3.1

Procedures for moving LMOs across border

There is an approval procedure like AIA procedure for LMOs that cross-border Singapore that is to be imported into Singapore for agriculture-related GMOs. These Guidelines are established to ensure the safe movement and use of agriculture-related GMOs in Singapore. There is monitoring procedure after approval. This can be seen from GMAC approval procedure flowchart. These Guidelines provide a common framework for (a) assessment of risks of agriculture-related GMOs to human health and the environment; and (b) approval mechanisms for their release in Singapore. From the GMAC Agriculture Guideline, it can be seen that Singapore is concerned with the effect of GMOs on the environment and the human health of Singaporean. This can be seen from the Risk Assessment questionnaires.

Also, it is a requirement that if LMO is part of the BA or toxins whereby they have to be labelled as Biohazard and follow the strict BATA 2005.

For export of GMOs from Singapore otherwise, they are up to the Singapore import and export Act perhaps Strategic Goods Act and other relevant rules and regulations, the relevant countries and international rules and regulations.

Advanced Informed Agreement (AIA)

From BATA 2005 there is no mention of AIA Procedure, however, from GMAC Guidelines, there is approval needed from GMAC for the release of agriculture-related GMOs. Thus this procedure as mentioned above look like an AIA procedure before importing of GMOs into Singapore. This risk assessment is done at this stage to be forwarded to GMAC for approval.

As for research on GMOs as it is within contained use in the research labs only notification is needed for GMAC, not approval. For research on GMOs, the IBC plays a critical role whereby the Principal Investigator and Biosafety Officer are to assess and report also notify the GMAC.

LMOs intended for direct use as food or feed, or processing (LMOS-FFP)

As Singapore treated food safety issues as substantial equivalence to conventional food, thus there is no strict requirement for FFP, as to labelling and such in other countries. Thus this is not a big issue. It is to be recalled the LMOS that contain in the FPP are excluded from all the rules contained in the Cartagena Protocol on Biosafety, thus no AIA requirement and such.

Contained used and transit

For contained use of GMOs, this is covered by GMAC Guidelines on LMOs research that IBC plays essential roles, only notification to GMAC. However, for the transit of GMOs, there is no specific mention of any specific procedure of that unless those GMOs contain BA or toxins that falls under BATA 2005 thus the rules and regulations are applicable with Biohazard sign. Thus the relevant local Singapore rules and regulations apply such as

customs and others. Besides, the party needs to apply for a transhipment permit for BA and toxins as provided by BATA 2005.[637]

Unintentional transboundary movements

For GMOs, there is no specific procedure for unintentional transboundary movements only there were questions that need to be answered and assessed by GMAC during the approval process according to the GMAC Agriculture Guidelines. This is further strengthened by the monitoring process by GMAC after approval. Thus this issue is addressed. As for BA and toxins or LMOs that contain them, this is strictly according to BATA 2005 that punishes the offenders for non-compliance.

Monitoring and Reporting

Singapore system of biosecurity as provided in BATA 2005 that lays down the going on of any incidents in the Biological Agents and toxins. The biosafety website also provides the forms to be completed mainly MOH to be notified of any incidents.[638] Apart from this BATA 2005 also specify the contact person to be notified if any incidents occur. BATA 2005 listed down various duties and obligations of the applicants in which failure to comply with reporting will make them liable to be punished under BATA 2005.

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[637] Ministry of Health (MOH) Singapore, 'Transhipment' (2015) <https://www.moh.gov.sg/content/moh_web/biosafety/common/transhipment.html> accessed on 30 March 2016.
[638] Ministry of Health (MOH) Singapore, 'Incident/activities report' (2015) <https://www.moh.gov.sg/content/moh_web/biosafety/common/notifications/incident---activities-report.html> accessed on 30 March 2016.

Roster of Experts

It seems that from Biosafety MOH and GMAC website, there is no exact information of the members of Biosafety Branch, only an organisational chart. The same for National Biosafety Committee there is no details of the members, only the relevant government agencies involved with biosafety. The contact person for BA and toxins is the Director of Health MOH. As for GMAC that deals with GMOs the members of the subcommittee are listed. Thus it seems in line with Cartagena Protocol on Biosafety that needs the roster of expert that relates GMOs not very much on BA and toxins (biosecurity) which seems outside Cartagena Protocol on Biosafety scope.

Biosafety Clearing House (BCH)

The Biosafety Clearing-House (BCH) is set up by the Cartagena Protocol on Biosafety to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol.[639] Since Singapore is not a party to Cartagena Protocol on Biosafety, thus they are not required to have the BCH. However, according to Biosafety under MOH website for BA and toxins, they had their systematic information and organised institutional contact point whereby it is user-friendly and easy to use. From the website, the steps and forms needed for different types of application and the Ministry or agency to be contacted are provided.

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[639] Convention on Biological Diversity (CBD), 'Welcome to the BCH Central Portal' (2017) <https://bch.cbd.int/> accessed on 20 March 2015.

On the dealing with LMO or GMO, as the Guidelines are not legally binding as such, the relevant GMAC Committees are listed thus making it easy for them to contact the relevant contact person. The information on the GMO approvals by GMAC are listed on the website.[640]

Thus in a way Singapore has their BCH for information of lists of LMOS approved in that country and the reports. However, the details of those applications are not available, unlike Malaysia.

6. Singapore regulatory strategy on biosafety

Command and control

From the above discussion, it is opined that the primary strategy is still the state regulation whereby the Ministry of Health is taking the lead role in governing the biosecurity and biosafety issues in Singapore with other ministries and government agencies and department. The command and control is the primary strategy as there are laws and guidelines that must be followed by the interested and relevant parties in biosafety and biosecurity or else they will be liable to sanctions and punishments.

The law imposed the fines ranging from $5000 to $1 million also imprisonment for non-compliance of the LMO and hazardous materials for handling, transport, packaging and identification. It is important to note here while Singapore is very strict in hazardous materials that trigger biosecurity

[640] see (n635).

issues. From BATA 2005, for handling of LMO that is other than higher BSL levels, Singapore is using soft laws such as the Guidelines rather than Act of Parliament. This measure is seen as embracing the biotechnology research and development and future commercialisation rather than hard laws all the way.

Smart regulation and regulatory pluralism

However, apart from the primary command and control approach, there are elements of smart regulation in Singapore biosafety governance. This can be seen from the institutional biosafety chart as shown above. The Biosafety Branch of the working biosafety committee for BATA 2005 is providing the secretariat for the National Biosafety Committee. It is also representing the Ministry of Health as the National Authority (NA) for biosafety in general. They are performing the biosafety administrator and enforcer roles in ensuring compliance towards BATA 2005. Whereas the GMAC is an advisor also approver of the LMO applications after the relevant IBC have performed their roles, duties and responsibilities of scientific risk assessment and management. Thus there is 'regulatory pluralism' as well in Singapore biosafety governance as there is more than one actor in the decision-making process. The National Biosafety Committee regulates biosafety and biosecurity in general whereas GMAC and IBC are in charge of LMO risk assessment and management for research and release. The government in Singapore (Ministry of Health in particular) biosafety governance is seen to take more steering rather than rowing role as it seems to delegate the task of biosafety and biosecurity to NBC and GMAC for issues in handling biohazardous materials and LMOs respectively.

The Singapore NBC as the regulator is practising instruments of smart regulation such as penal sanctions, education and advice. NBC roles in

educating and advising are by promoting biosafety awareness and nurture biosafety culture in Singapore through coordinating and monitoring training programmes in Singapore and the region also making recommendations to the Ministry of Environment for the revised Science guidelines for schools. Thus it can be seen that Singapore is making biosafety and biosecurity of paramount importance by introducing it at the early school level.

The business as the self-regulator can be liable for sanctions for non-compliance with BATA 2005 also other relevant laws and regulations. They are also given guidance on how to conduct their biosafety and biosecurity related-business by Singapore non-binding Guidelines which they are not bound to follow but usually followed as a matter of practice and custom. These strategies perhaps reduce business tense in following the standard strict procedures but ensure compliance as a matter of right business practice.

The role of third parties such as the consumer association in GMAC is embraced as a good practice of democratic involvement thus ensuring public voices is heard. Public education on GM has increased and as to the public and groups but there is no significant oppositions against GMO in Singapore.

Reflexive and meta-regulation

The reflexive regulation is the self-regulation procedure whereby Singapore biosafety governance also practices the established norms and procedure. This can be seen by IBC risk assessment and management that is monitored by GMAC for LMOs. The risk assessment and management is a form of meta-regulation seems a norm for countries biosafety governance.

Self-regulation

Biosafety self-regulation can be seen in IBC that mainly oversees its biosafety management but still tied to the BATA 2005 and GMAC approval for LMO also the Guidelines for GMOs and Agriculture. Singapore apart from being a member of Asia Pacific Biosafety like Malaysia is also hosting Singapore Biorisk Association. These bodies are self-regulated thus support and supplement the biosafety organisations and development in Singapore at the national and international level.

Civil regulation

Civil regulation in Singapore role is being formalised and institutionalised as the members of consumers association are part of GMAC for LMOS approval committee for research and release. Thus when voices of members of the public are being legalised in one of the most crucial biosafety institutions such as GMAC, thus public confidence could be restored thus enable more natural public acceptance of the LMO. It must be mentioned that Singapore aspiration is for the commercialisation of the biotechnology research and development. Thus public acceptance of the commercialised LMO products is vital not just in Singapore, but to the neighbouring countries such ASEAN and further abroad. Thus elements of transparency in LMO and biosafety can be seen here that could prove Singapore can go further with its biotechnology products. While this is seen as a good biosafety strategy, which is further enhanced by biosafety and biosecurity education that begins at the school level. These moves could bring Singapore to a further level that it intends with its billion dollars of biotechnology investment in biomedical research not just on the technology but human resources as well.

Licence model

Again the three main licences namely economic, social and regulatory licences are the three licences that could be used by the various actors in biosafety and biosecurity in Singapore. The business sector if they ignore the regulatory licence could risk their biotechnology investments and licences through the Guidelines were not binding. However, BATA 2005 enforcement is strict on hazardous materials. Thus the regulator either NBC, GMAC, MOH also should be very careful on the trust put to them by the interested groups and the public could tarnish if, for instance, the same incident of SARS occurs again in the future thus jeopardising their regulator's licence.

The public and interested parties could then resort to using social licence by joining international powerful vocal voice against LMO such as movements against Monsanto, Greenpeace and others. This is partly because Singapore is more open and liberal in accepting those international environmental, consumer organisations and non-governmental organisations.

7. Conclusion

In conclusion, Singapore biosafety and biosecurity law seems to be a comprehensive model although not based on Cartagena Protocol on Biosafety but very much the US and international model. Singapore paradigm on biosafety and biosecurity issues is more towards protecting human health rather than the environment. This is perhaps understandably due to the Singapore SARS events and the fact that Singapore is a city-country with not much rainforest unlike its neighbour, Malaysia. Thus the fact that Singapore treats hazardous substance of importance rather than LMOs alone shows Singapore's more liberal attitude in research, development and biomedical commercialisation towards LMO. This stand seems balance stance with Singapore BATA 2005 that deals with issues of biosecurity and GMAC to deal with LMOs approval in Singapore.

Apart from the above analysis, perhaps Singapore obligations towards WTO further explains Singapore framework on biosafety. Singapore is dependent on free and open international trade for its economic growth.[641] Singapore membership in GATT ensured vital access to international market. This is especially essential for the product commercialisation also intellectual property rights (IPR) of the modern biotechnological products where billions of money have been invested in research and development. The free and open international trade is vital for Singapore to market the biotechnology

[641] Singapore Government. 'Singapore accedes to the GATT' (2014) <http://eresources.nlb.gov.sg/history/events/c290cadb-54f9-45b1-bc95-7c25186e4a93> accessed on 30 December 2017 citing Hon on how S'pore fosters trade. (1973, September 14). *The Straits Times*, 24.

products and IPR. Thus this explains Singapore liberal attitude towards LMOs. As one of the GATT principles is to trade without discriminations, which explains Singapore's attitude of non-labelling of LMOs as it is equally as good as the conventional food.

Singapore also attempts to reduce TBTs as standards, regulations and conformity assessment procedures as considered as TBTs.[642] There is a commitment that in trading, parties should confer no less favourable than its jurisdiction. As Cartagena Protocol on Biosafety is often argued a disguise as a TBT, that explains Singapore stance not being party to it.

Another important of Singapore obligation towards WTO can be seen in Sanitary and Phytosanitary (SPS) whereby measures are used to protect human, animal or plant life or health by preventing the introduction of pests and diseases and to help ensure that food is safe for consumption.[643] Thus Singapore develops its biosecurity regulation, BATA 2005 to prevent biological agents and toxins. SPS measures require Party to favourably consider accepting the equivalence of each other's SPS measures thus no further measures need be applied. As Cartagena Protocol on Biosafety[644] requires identification of LMOs which is not required by SPS, thus there seem to be conflicts in future. In short, it is argued that Singapore prepares

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[642] International Enterprise Singapore, 'Technical Barriers to Trade' (2015) <https://www.iesingapore.gov.sg/Trade-From-Singapore/ASTEP/Technical-Barriers-to-Trade> accessed on 26 December 2017.
[643] International Enterprise Singapore, 'Sanitary & Phytosanitary (SPS) Measures' (2015) <https://www.iesingapore.gov.sg/Trade-From-Singapore/ASTEP/Technical-Barriers-to-Trade> accessed on 26 December 2017.
[644] Article 18.

its biosafety and biosecurity regulations and institutions in anticipation of its obligations with WTO.

This will lead to the conclusion chapter of comparison between Malaysia and Singapore, not just for understanding but for the betterment of the biosafety system in Malaysia and harmonisation at the South East Asia region.

CHAPTER 6
CONCLUSION AND RECOMMENDATIONS

The present research aims to examine the legal and institutional framework on Malaysia biosafety in compliance with Cartagena Protocol on Biosafety and a comparative legal study with Singapore biosafety laws. The analysis is based on the regulatory theory primarily the risk regulation as explained at length in Chapter 2. The various strategies of the biosafety regulation are examined to analyse and demonstrate the shift of trend in regulation from command and control approach to new governance.

There are some significant findings emerged from this study. It is found that there are many shortcomings of the existing biosafety legal and institutional framework in Malaysia (Chapter 3 and 4) when compared with Singapore (Chapter 5). The existing regulatory strategies of command and control, and the new governance such as smart regulation, civil regulation, reflexive and meta-regulation and licence model[645] were identified in Chapter 4 and Chapter 5 on Malaysia biosafety and Singapore respectively.

The Cartagena Protocol on Biosafety is used as a model biosafety framework in the thesis as it includes the most pressing biosafety issues worldwide thus provides the parameter of discussion. The thesis analyses towards the extent of Malaysia compliance with the Protocol in the legal and

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[645]Gunningham N, 'Regulating Biotechnology: Lessons from Environmental Policy' (2007) in Somsen, H, *The Regulatory Challenge Of Biotechnology: Human Genetics, Food And Patents* (Edward Elgar 2007).

institutional framework. As for a comparative legal study with Singapore, how the pertinent biosafety issues at hand are being implemented and institutionalised.

This study is important in future, for knowledge and legitimacy for possible wider stakeholders and for the possible inclusion of cultural and socio-economic factors apart from scientific risk assessment and management for better governance of biosafety.

This chapter is concluded with suggestions and recommendations to improve Malaysian biosafety law and institutions.

1. A Comparative Legal Analysis of the Malaysia and Singapore Biosafety based on the Regulatory Theory:

Command and control or new governance

From the discussion of Malaysian (Chapter 3 and 4) and Singaporean (Chapter 5) respective legal and institutional framework, it is submitted that both countries' biosafety regulations seem to practice mainly the command and control approach. However, there are elements of new governance approaches such as smart regulation, reflexive and meta-regulation, licence model as well as civil regulation in the biosafety regulation and implementation. This is to be elaborated further in the end of each country's discussion of the existing legal and institutional framework.

Malaysia

Before moving on to the biosafety regulatory strategy, the shortcomings of Malaysian existing legal and institutional biosafety are to be highlighted initially. The Biosafety Act 2007 is the primary Act that regulates

the movement of LMOs in Malaysia either for contained use or release in the environment. Biosafety Act 2007 also established the important biosafety institutions such as NBB also GMAC thus making the biosafety law comprehensive. The Biosafety Rules and Regulations 2010 established IBC requirement for LMOs related research and release and also detailed out the further biosafety regulations such as risk assessment and management. Additionally, Malaysia also formulated the Guidelines on Lab Biosafety Procedure[646] for lab biosafety. However, Malaysia does not have a comprehensive biosecurity laws like Singapore and the European countries[647] in controlling biological agents and toxins.

Malaysia Biosafety Act 2007 is also being criticised as being not fully compliant with the Cartagena Protocol on Biosafety as some Key Protocol Biosafety issues are not being adequately addressed such as labelling, public participation, socio-economic considerations, religious, bioethics and many others. These aspects of biosafety are to be elaborated further below. Thus despite having a 'comprehensive' biosafety law, there are many issues that need to be addressed by Malaysia either by strengthening the Act or further producing more regulations or Guidelines like Singapore.

Malaysia biosafety law is seen trying to accommodate and satisfy relevant stakeholders namely the existing government economic and political

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[646] Ministry of Health Malaysia, Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline (First edn, National Public Health Laboratory 2015).
[647] Anna Bielecka and Ali Akbar Mohammadi, 'State-of-the-art in biosafety and biosecurity in European countries' *Archivum immunologiae et therapiae experimentalis* vol. 62,3 (2014)169-78

also international relations, public, business community, consumer associations, non-governmental organisations (NGOs) also religious, international trade and environmental organisations. In order to strengthen the existing laws and regulations, the institutional role is to support them.

In Malaysia, the NRE is the main Ministry that gives the final approval but again GMAC Malaysia provides mostly the scientific advice. The National Biosafety Board is the most important institution that will approve or disapprove LMOs applications based on GMAC's advice and consultation with relevant government agencies and the public (where needed). The Biosafety Department acts like the Secretariat for the National Biosafety Board and ensures the implementation and enforcement of Biosafety Act 2007. Other than that Act, there is Biosafety Approval and Regulation 2010 which is a binding instrument, as part of the delegated legislation.

Another crucial aspect of biosafety implementation in Malaysia is the bioethics issues with the aim to balance the enthusiasms of research and development in modern biotechnological development with the good ethical values in science. Malaysia has its National Bioethics Council which was established in 2010. However, the institutionalisation of this Bioethics Council is yet to be seen in the biosafety context as it seems there is lack of this Council's participation in the biosafety decision-making process. From the website, it can be seen that Malaysia is still at the early developing stage of this National Bioethics Council presumably at the education and awareness level towards its staff and joint co-operation with other Bioethics Council in other countries.

It is submitted that the importance of this Bioethics Council could not be emphasised more, coupled with the fact that Malaysia is a multi-ethnics, multi-religious and multi-cultural countries. It is not just about respecting consumer choice per se (which could be done inter alia through labelling) but

also reflecting the public participation in the biosafety decision-making process as part of democratic process.

Another important findings is the institutional approach that can be deduced from Malaysian biosafety as mentioned above is that it is the usual Malaysian top-down approach whereby laws and regulations are to be abide and implemented from Ministry of Natural Resources and Environment to the National Biosafety Board with GMAC's advice. NRE and NBB are the decision makers whereas GMAC Malaysia plays an influential advisory besides an administrative role in scientific matters mostly in GMO application. Apart from scientific risk assessment, a limited public and NGOs' views are said to be taken into account in the biosafety decision-making process. This seems to be an element of civil regulation which is formerly discussed in Chapter 4. The only problem is the transparency and effectiveness of those mediums.

From these biosafety related institutions, it seems the primary biosafety regulatory approach is still the command and control approach, whereby the central Ministry either in Malaysia or Singapore are given the statutory power to regulate and are also equipped with the administrative roles and responsibilities with fines and imprisonment power are given to punish those individuals or institutions that breach the said Acts.

Besides having its primary command and control approach Singapore laws and regulations are more liberal and open with not so much restrictions,

especially on LMOs. Singapore in GM food consumption adopts the Codex substantial equivalence approach rather than Malaysia Biosafety Act 2007 that adopts the more cautious precautionary approach. This approach is in line with the United States approach on GMOs.[648] The issue on which approach is better, is outside the scope of this research. However, in Singapore, there are elements of smart regulation whereby there is voluntary adherence to the non-binding Guidelines, where parties concerned usually follow.

In Malaysia, there is a binding Biosafety (Approval and Notification) Regulation 2010 where parties are bound to follow. This is the difference between Malaysia and Singapore and questions might arise as to the effectiveness of these different measures which are yet to be seen in the future.

Malaysia biosafety regulation applies some elements of smart regulation strategy and 'regulatory pluralism' as there is various strategies and actors involved. Smart regulation strategy can be seen in the public also interested groups awareness and participation in biosafety decision-making process. However, other smart regulation instruments such as disqualifications, notices, warnings, persuasion might not be applicable or even suitable, unless those are purely administrative measures in compliance with the law and regulations.

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[648] Restrictions on Genetically Modified Organisms: United States, which can be found online at <https://www.loc.gov/law/help/restrictions-on-gmos/usa.php**>** accessed on 20th November 2018.

Reflexive and meta-regulation strategy, i.e. the 'steering rather than rowing' function of the regulator , can be seen from the GMO application to the NBB as NBB are advised by GMAC who gives opinion based on risk assessment.

Civil regulation in biosafety decision-making process through public awareness and participation further adds to the democratic involvement. However, this should not be seen effective solutions as the public and NGOs in Malaysia are only seen able to exert pressure but not as powerful like in the Europe, to change policy or making differences. A more systematic and organised public awareness and participation together with the consumer associations and environmentalists could provide more effective pressure towards the regulators asserting their rights and beliefs.

Model licence propounded by Gunningham, Kagan and Thornton are examining corporate behaviours towards the environment. This regulatory, social and economic licences, like the civil regulation also of little application in Malaysia. It is arguably due to the low level awareness of the consumers, the environmentalists propagating more political rather than environmental issues and many more reasons. However, due to the Malaysians ('netizens') recent trend of high level of time spent and engagement on social media such as Facebook and Twitter, it is predicted that in future, provided that the level of education, awareness and education on GMO is widespread, the licence model could be realised.

Singapore

As for Singapore, the existing biosafety legal and institutional framework is summarised as follows. Singapore has two sets of laws one for biosecurity another for biosafety. Biosecurity law, especially on BA and toxins, is regulated by BATA 2005 whereas biosafety law regulated by GMAC

Guidelines on Research and Agriculture. BATA 2005 besides providing the laws for biosecurity, regulation of BA and toxins, also provides the institutional framework for biosafety and biosecurity. GMAC Guidelines on Research and Agriculture provides rules and regulations for GMO regulation, also the GMAC and relevant government ministries, departments and agencies also IBC as the essential biosafety institutional framework. BATA 2005 details out the transport, handling, biosafety level, for BA and toxins also the fines and punishment for non-compliance. This is a command and control approach to the biosecurity governance. However, on the biosafety issues, it seems more flexible as soft laws such as Guidelines are being used for adherence, thus boost up modern biotechnology especially on GMOs research at the same time allowing research freedom.

From the institutional discussion above, it can be seen that the Ministry of Health under Biosafety Branch that provides the secretariat of National Biosafety Committee plays a major regulatory including administrative roles and responsibilities in relation to the working of biosafety decision-making with the implementation of BATA 2005. However, it is observed that GMAC plays a significant role as advisory although mostly scientific advice such as scientific risk assessment and also non-scientific perspective. It is important to stress again that the two (2) GMAC guidelines on research and agriculture are non-binding as the final approval lies with GMAC. Moreover, there are other institutions such as AVA or MOH respectively depends on whether it is related to agriculture or research matters on biological agents and toxins. Even though the adherence to GMAC is voluntary however it seems the parties that deals with these biological agents seem to adhere to these guidelines.

In line with the regional biomedical hub plans, Singapore maintains a high standard of biosafety lab procedure in biomedical research and development. It is important to note here that on biomedical research

Singapore has its own Bioethics Advisory Committee (BAC) that offers more comprehensive ethics review. Singapore has its Code of Ethical Practice 2009 for biomedical researches. Thus Singapore has institutionalised its ethics issues more efficiently than Malaysia. However again BAC works as an advisory body not deciding on any biomedical proposals.[649]

Singapore's approach in the GMOs is more towards soft law and there is no umbrella legislation on GMOs only GMAC Guidelines on Agriculture and Research. These Guidelines have no binding effect as they are not Acts of Parliament as such but customarily being followed by those parties who would like to apply for GMOs in agriculture and research in Singapore.

Among the advantages of these soft laws are research and development are expected to grow in line with Singapore economic aspiration, at the same time controlling the critical safety features of GMOs release in Singapore. In the release of GMOs in agriculture, the parties obtain the approval from GMAC together with the scientific risk assessment. Thus it seems here GMAC, apart from being only advisor role, also have a strong institutional influence on biosafety. This is the same compare to Malaysia.

Singapore's stance towards biosafety seems almost like the United States approach. The US however does not have specific federal laws that relate to the GMO regulation. In the US, the LMOs are treated equal like the

[649]Bioethics Advisory Committee Singapore. 'What do we do' (2016) <http://www.bioethics-singapore.org/index/about-us/what-we-do.html> accessed on 17 March 2015.

conventional products which regulations are contained in the health, safety and environmental aspects. This further explains the fact that the US being the world's number one producer of GMO products. The law is favourable to the development and commercialisation of the modern biotechnological products. There are little restrictions for GMOs "that differs significantly in structure, function, or composition from substances found currently in food," thus a premarket approval of the product is required.[650]However, recently in December 2018, the United States Department of Agriculture (USDA) laid out it first ever requirement labelling of LMO or GMO food to be implemented in 2020.[651] The U.S. Secretary of Agriculture Sonny Perdue on 20th December, 2018 announced the National Bioengineered Food Disclosure Standard following the National Bioengineered Food Disclosure Law, which was passed by Congress in July 2016. The law directed USDA to establish this national mandatory standard for disclosing foods that are or may be bioengineered.[652]This big step by the world's largest producer of GMO produced should be applauded, following the consumers' outcry for greater transparency in food consumption.

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[650] Restrictions on Genetically Modified Organisms: United States
can be found at <https://www.loc.gov/law/help/restrictions-on-gmos/usa.php> accessed on 20th November , 2018

[651] Reuters, 'USDA Outlines First-Ever Rule for GMO Labeling, Sees Implementation in 2020' (2018) <https://www.reuters.com/article/us-usa-gmo-labeling/usda-outlines-first-ever-rule-for-gmo-labeling-sees-implementation-in-2020-iduskcn1oj2tf> accessed on 20th April 2019

[652] United States Department of Agriculture, 'BE Disclosure' (2018) <https://www.ams.usda.gov/rules-regulations/be> accessed on 20th April 2019

However when dealing with biosecurity in Singapore, i.e. Biological Agents (BA) and toxins, they have to adhere to BATA 2005 that imposed strict punishment for non-compliance. This is due to the fact of SARS incident that occurred previously thus Singapore is taking a strict approach to controlling BA and toxins. This biosecurity law reflects a command and control approach. Besides that, Singapore also adopted the smart regulations elements such through penal sanctions and educating the public awareness and participation as elaborated in Chapter 5. 'Regulatory pluralism' can also be seen from the Singapore biosafety and biosecurity strategies. The NBC played the important role in educating the Singapore public on biosafety and biosecurity from the school level. The business community as self regulators abide the GMOs guidelines rather than strict laws. The role of third parties such as the public and consumer associations, such as through GMAC membership, even though currently there is no strong opposition from them towards the biosafety regulator, adds to the more democratic involvement in Singapore biosafety.

The reflexive regulation through IBC and GMAC risk assessment is another practice for biosafety administration. There is also element of self-regulation in Singapore Biorisk Association as a society that regulates its membership with its own rules and regulations to fulfil its objectives. The civil regulation in Singapore is formalised as one of the GMAC members is a representative from the consumer association (as discussed in Chapter 5) for LMOs approval committee for research and release. The licence models of social, economic and regulatory could be of application in Singapore biosafety and biosecurity. The business sects may lose their regulatory licence if they do not comply with the GMO guidelines or worse contravene BATA 2005 as sanctions and punishments can be imposed. The social licence by the public and consumers on their wary against LMO products if ignored by the biotechnology companies can drive them out of business. The

economic licence can be used by the public to pressure the biotechnology companies such as a campaign against Monsanto worldwide.

It is submitted here that these are possible regulatory strategies applicable in biosafety governance in Malaysia and Singapore by analysing the legal and institutional framework. The issue of whether in reality these strategies play little or important roles in Malaysia and Singapore respectively, is very much dependant on the current social, economic and political conditions of both countries. It is in line with Gunningham's view that the political, social, economic and scientific contexts in which biotechnology and environmental regulation must operate are very different.[653] This is especially true even though Malaysian and Singaporean share a lot of similarities; however they might have different attitudes, perspectives and level of trust towards the government. For example, even though there is no formal requirement of public participation in the LMO application (as an element of civil regulation) in Singapore (unlike in Malaysia), the Singapore public instead are being informed of the types of LMOs approved through the websites. It seems here the Singaporeans have higher trust in their government to decide what is best on the citizens' behalf. The effectiveness of these regulatory strategies either traditional or new governance, is beyond the scope of this thesis. It could be an interesting area for future research.

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[653] Gunningham N, 'Regulating Biotechnology: Lessons from Environmental Policy' (2007) in Somsen, H, *The Regulatory Challenge Of Biotechnology: Human Genetics, Food And Patents* (Edward Elgar 2007).

It can be concluded that due to the sensitive and changing nature of modern biotechnology also severity and unpredictable of the damage towards human health and environment, there are new strategies of regulation rather than the usual command and control approach.

It can be seen that the changing trend of regulation is perhaps to accommodate many stakeholders, provides transparency, better reception and perception to the public.

Furthermore, with modern information technology communication nowadays not just from mainstream media but widespread usage of social media, leaving the consumers to search for the unlimited modern biotechnology information at the tip of their fingers. Thus public instead of being indoctrinated by the regulator or the government through mainstream media will get access to various types of information that can shape their opinions and views also beliefs.

Another trend observed is the emergence of various global regulatory agreements such as Cartagena Protocol on Biosafety as it affects transboundary movement of LMOs to provide better global governance. These agreements once negotiated and agreed later to be ratified and signed then implemented by countries' national laws.

Malaysia and Singapore shape their own national biosafety laws even though both countries were part of the negotiating parties but in the end have different stance towards the Cartagena Protocol on Biosafety. The national biosafety laws are enacted accordingly with differences in breadth and depth.

There might be similarities and differences of both biosafety laws as discussed and there are various reasons for that practice which is discussed below.

2. An analysis of Malaysia and Singapore difference stance towards Cartagena Protocol on Biosafety

The result of this study indicates that, firstly, the main ministries involved reflect the countries' leading focus and priorities. This perhaps shapes the different approaches of biosafety laws in Malaysia and Singapore.

For Malaysia, the primary focus besides research and development in modern biotechnology is the preservation of biodiversity and further commercialisation of Malaysian abundant natural resources and agricultural products. Thus that is the reason the Ministry of Natural Resources and Environment being the main ministry in charge of biosafety instead of Ministry of Health (MOH) or previously Ministry of Science and Technology (MOSTE). Although Malaysia also conducts research and development of modern biotechnology products, the primary focus now seems on the further R&D of important staple food such as rice, also main export product such as rubber and palm oil.

In contrast, Singapore's primary ministry that deals with biosafety is the Ministry of Health. This reflects Singapore concerns over SARS, H1N1 and issues concerning public health like Anthrax threat that occurred in the United States. The fact that biomedical industry is the focus of modern biotechnology research and later commercialisation is due to Singapore limited land resources that unable to expand its agrobiotech business. Apart from MOH, there are other primary agencies that deals with biosafety namely AVA, MOH, Ministry of Manpower (MOM) and National Environmental Agency (NEA). AVA deals with agriculture and veterinary GM related products and MOH in relation to research and development of biological agents and public health issues for concerns over biosecurity and bioterrorism. MOM is perhaps directly related to the recruitment of many

international scientists and researchers from all over the world to Singapore's billion investments in research and development. NEA is understandably responsible for the release of biological agents in the Singapore environment.

Apart from the economic aspiration factor above, it has been discussed in Chapter 5 that Singapore's involvement with the existing WTO agreements related to GMOs such as TBT, GATT and SPS are among the reasons of the different stance taken by Singapore in not ratifying the Cartagena Protocol on Biosafety. Coupled with the facts of billion dollars investment in modern biotechnology research and development mainly for intellectual property and further product commercialisation, this Singapore stance seems the right strategy for a wider market liberalisation and acceptance. These scenarios perhaps also provide the reason for Singapore's different approach towards biosafety laws.

Malaysia and Singapore implementation of the key biosafety issues

Thus, the next question is the Malaysian and Singaporean formulation of crucial biosafety issues into national biosafety laws namely as follows:

Scientific risk assessment

From the legal and institutional biosafety framework of Malaysia and Singapore, both countries placed importance stress on the scientific risk assessment on the approval of GM related products. Primarily the GM products are tested on their allergenicity, toxicity and safety. The only issue is on the breadth and width of these scientific risk assessment by Malaysia and Singapore, whether they are sufficient to cover the biosafety risks concerns. It is submitted that beside the scientific part, the details of the risk assessment in Malaysia should cover the socio-economic considerations that are relevant to Malaysia.

Public participation in Malaysia

Biosafety Act 2007 provides for public participation. In Malaysia, GM approval report contains feedbacks from the public and NGOs with not many details. More controversy in Malaysia in this regard is the release of the GM mosquito in Pahang, Malaysia that raises the issue of the effectiveness of the provision of public participation in biosafety decision-making process. GMAC Malaysia consists of members from the universities that perhaps could give the public feedback on biosafety.

However, to what extent the Malaysian public are being informed as to the LMOs are still issues especially on the GM mosquitoes in Pahang. By looking at Malaysian biosafety website, advertisements are inviting Malaysians public to involve in the GMOs decision-making process. The Malaysian GMAC reported that there are some inputs from the concerned public on those issues. Another issue here is to what extent did the Malaysians participate? This public consultation is advertised in the two leading local newspapers and website. In light of the current IT era whereby newspapers are rarely being bought physically, this practice seems appropriate. The problem lies to those who are illiterate on information technology especially the rural areas. The awareness and sufficiency of the biosafety information are doubted.

GMAC reported that there were some inputs from the public and some consumer associations presumably TWN and CAP, but to what extent GMAC and NBB incorporated Malaysian public views in the decision-making process, is questionable. This is based on GM mosquito in Pahang also the lack of details report from GMAC.

Another issue is on labelling that relates to consumer choices preferences, belief, religion and also cultural. Thus there are two main issues

here namely the extent of public concerns is being taken into decision-making process also the type of information and education given to the public on GMOs.

Further issue that is being overlooked is the socio-economic considerations that are closely related to the small farmers' views that almost unheard of in Malaysia but also raising concerns. With limited capital and access to the recent research and development in agriculture, the introduction of better seeds and cultivation seems could be either a threat or opportunity depending on the circumstances. The fact that some local and indigenous people live in the intended area or agriculture related to LMOs also small farmers' living, are issues that should not be just ignored. It is submitted that in future these are the areas of concerns that should be further to be taken into consideration by the regulators.

Public participation in Singapore

As for Singapore, the earlier public consultation was done on BATA Bill 2005. GMAC provides Subcommittee for Public Awareness that educates the public. There are also members of the Press and consumer association. Presumably Singaporeans are more liberal and open towards GM products rather than Malaysian who seem to be more sensitive especially on religious and cultural concerns.

However, GMAC also states that public involvement only when it is needed. Thus there is not so much room for public participation in GMOs release in agriculture. It is up to GMAC to decide based on the risk assessment done to evaluate before approval of the effect of LMOs on human health and environment for Singapore.

Thus on this issue, for those countries that join Cartagena Protocol, there are rooms for public participation. The only issue is how efficient that medium is being used as part of the decision-making process. For those countries that did not sign the Cartagena Protocol like Singapore, perhaps the biosafety institutions are educating the public on GMOs rather than making the public to participate in the biosafety decision-making process. It is the country that decides for the good of the people rather than the public themselves on the issues of human health and environment.

Labelling

While Malaysia is going towards mandatory labelling of GM products from its Biosafety Act 2007, and Food Regulation 1985 that makes it mandatory for GM food that enters Malaysia to be labelled, Singapore has no such labelling ruling. The labelling concern in Malaysia partly due to some active consumer associations and environmentalist NGOs such as Consumer Association of Penang (CAP), Third World Network (TWN), Muslim Consumers' Association (PPIM) and few others. Issues raised were religious, cultural, ethical also environmental concerns that pressured the government for mandatory labelling also government consultation with these bodies.

In Singapore on the other hand, there is no active consumer group's opposition.[654] Singapore authorities follow internationally proven science-based standards in enacting the regulatory framework for approving the imports of agriculture-related GMOs. Singapore tends to follow the lead of

[654]USA Foreign Agricultural Service, Singapore Biotechnology Agricultural Biotechnology Report 2006 (Global Agriculture Information Network SN6006, 2006)7.

developed countries and international bodies like Codex Alimentarius in allowing the entry of GMOs into the country.[655] This is because Singapore adopted the substantial equivalence concept for GMOs food rather than being cautious. Singapore has no labelling of GMOs unless it contains BA and toxins thus being labelled as Biohazards.

Liability and redress

Malaysia is one of those developing countries that voice upon the issues of liability and redress over the side effects of the GM products during the Cartagena Protocol on Biosafety negotiation process. The fear of being dumping grounds of GM products also the unintentional transboundary movement made Malaysia of imposing fines up to Ringgit Malaysia 500,000.00 for non-compliance with Malaysia Biosafety Act 2007. However, to date, Malaysia due to its lack of building capacity has not ratified The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

As for Singapore, those parties need to follow GMAC Guidelines on Agriculture for the release of GMOs. Moreover, as for contained use or research, they have to follow GMAC Guidelines on Research in which the relevant IBC only notifies GMAC for LMOs research. However, for breach of BATA 2005 on BA and toxins, Singapore imposed severe penalties for breach of the laws and regulations. This is much more related to biosecurity rather than biosafety.

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[655] ibid.

Socio-economic considerations

In recent years there are growing socio-economic considerations issues being discussed namely ethics, bioethics, religious, cultural, the effect on local agriculture apart from scientific assessment in Malaysia perhaps due to the fact Malaysia is party to Cartagena Protocol on Biosafety whereas Singapore is not. According to the Protocol, there are mentions on the socio-economic issues to be taken into consideration by the signing countries with guidelines on how to implement them. However, it seems that it is still up to countries' laws on how to go about dealing with socio-economic issues. Thus the legality or non-legality of these laws will only arise when any countries challenge in the court or WTO. In a study by Gupta and Falkner, the socio economic requirement in the WTO or other international medium argued by developing countries during the negotiations of the Cartagena Protocol on Biosafety '…are not officially voiced as a reason to restrict trade or domestic GMO releases.' Simultaneously, '…such concerns are constantly present as the backdrop to domestic application of scientific risk assessment processes and decisions about uptake.'[656]

As for Singapore, being a developed country also obligations towards WTO as discussed in Chapter 5, this socio-economic considerations perhaps is not a key issue compared to a developing country.[657] Perhaps that is the reason as to why Singapore takes the same stand in Cartagena Protocol on Biosafety like other developed countries such as the US. In Singapore

[656]Gupta A and Falkner R, 'The influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa' (2006) 6(4) Global Environmental Politics 49.
[657]ibid.

biomedical research as mentioned above, BAC plays an essential role in giving bioethical views. This organised bioethics involvement in Singapore biomedical research as part of biosafety should be applauded and lesson learnt by Malaysia to improve the institutionalisation of bioethics in Malaysia.

Economic impact

The economic impact of Malaysia's modern biotechnology is to be taken into account considering its exports of agricultural products mainly rubber and palm oil and involvement in the WTO. The socio-economic considerations as in Cartagena Protocol on Biosafety outlines on the impact of modern biotechnology products on the local and indigenous people which are later inserted in the Malaysian Biosafety Act 2007. Malaysia then needs to balance between the country's aspiration to generate growth based on modern biotechnology products and the need to protect human health and the environment. For example, the import of cheaper GM products resulting from the new Comprehensive and Progressive Agreement for Trans-Pacific Partnership, for instance, will affect the Malaysian agriculture especially the small agriculture industries.

As for Singapore, a country gearing towards being a biomedical hub in the region, with less local and indigenous people issue to be taken into account, this economic impact of modern biotechnology is going towards a positive direction. This started from billions of money invested in modern biotechnology research later further commercialised, even though Singapore is a city-country with limited land, unlike Malaysia.

Precautionary approach

Malaysia adopts the precautionary principle as being a party to Cartagena Protocol on Biosafety. This precautionary approach is said to be

trade restrictive[658] compared to other WTO agreements. Malaysia's view seems to be in line with the European Union's reliance on the precautionary principle towards the GMO products. However, the European has a comprehensive and strict legal regime on the GMO regulation due to it sceptical consumer, farmers and environmentalists.[659] It is argued that Malaysia should have its own liberal stance towards GMO regulation i.e. neither be too open like the Singaporean and the US, nor too strict like the European Union. Each country has their different approaches in regulating modern biotechnology. An interesting comparison is between the more optimists US and the pessimist European Union. Their philosophical differences have shaped their origins of rule legal and institutional biosafety framework.[660] The same is true for Malaysia and Singapore. Malaysia should take a medium approach in taking advantage in commercialising its biodiversity through modern biotechnology and protecting its rich biological resources.

As for Singapore that adopts substantial equivalence principle in GM food consumption, this difference in approach perhaps attracts more countries to trade with Singapore more freely than with Malaysia.

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[658]ibid 29.

[659] Acosta L, 'Restrictions on Genetically Modified Organisms: United States Mayis 16(2014)2015 can be found online at <https://www.loc.gov/law/help/restrictions-on-gmos/eu.php> accessed on 20 November 2018.

[660]Young TR, 'National Experiences with Legislative Implementation of the Protocol'(2013) in Cordonier Segger, MC and Others (ed), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (Cambridge University Press 2013) 331.

In summary, Malaysia, like other developing countries (also the European Union), adopt stricter measures than the Cartagena Protocol on Biosafety as can be seen from its subject matter and administrative procedures[661] presumably to protect its natural biodiversity from being exploited by other developed countries. Singapore on the other hand is in agreement with other developed countries like the US adopt an open and liberal approach in the biosafety and biosecurity laws. This in part explains the economic growth of these countries' revenue from GMO business worldwide.

3. Some recommendations on Malaysia biosafety law

From the analysis of Malaysia compliance report with Cartagena Protocol on Biosafety, it can generally be observed that while improving its biosafety capacity building, Malaysia made various efforts to fulfill it. Despite those efforts to implement the essential biosafety issues, enormous amount of country's budget and outside funding are needed. Some recommendations for future development on biosafety legal and institutional framework are suggested.

Legal framework on biosafety

As stated earlier the primary biosafety laws of Malaysia are the Biosafety Act 2007 and Biosafety (Approval and Notifications) Regulation

[661] ibid.

2010. The inadequacies of the laws have been highlighted and identified as follows:

a) the adequacy of the enforcement labelling of GMOs. This is to reflect ethics principles of consumer choices that reflect beliefs, religious and cultural preferences in a multi-cultural society in Malaysia. This labelling should be more effective if the consumers are educated in the LMOs rather than leaving them curious and unsatisfied.

b) public participation element and to what extent they are transparent and have been incorporated in the biosafety decision-making process. It is suggested that the public in giving input should be well informed of the product or process of the LMOs or products for them to give an active contribution. It is suggested that the LMOs in contained use should be left within the expertise of science and technology unless it is related to human and environment whereby bioethics consideration to be taken into account.

As for release with the environment, the public should be actively involved especially in relation to the area of release involved. As for import control of LMOs, the factors of local agriculture business should be taken into paramount consideration as it might significantly affect local farmers. As for export of LMOs, Malaysia should abide by the WTO agreements, the Cartagena Protocol also other international guidelines, the proposed countries laws, regulations and guidelines. This is with a view that Malaysia will be answerable and liable for any claims later if standard international procedures are followed.

c) The importance of bioethics and biosafety education could not be stressed more. Thus the efforts by the organs or enforcers of the laws and bodies that provide biosafety information should be strengthened to build up Malaysia

capacity building in biosafety. As mentioned earlier this should start with a firm stance on bioethics then to formulate Malaysia's own bioethics policy.

d) As socio-economic considerations are unique to Malaysia as discussed in the previous Chapter 3 and 4, thus it is time for Malaysia to seriously consider to include the detail of socio-economic impact assessment if necessary. It was previously discussed in Chapter 3 that socio-economic considerations 'may' be taken into consideration as stated in Section 35 of the Biosafety Act 2007 with no details in its application. Regulation 25 of the Biosafety (Approval and Notification) Regulations 2010 list out several socio-economic considerations that may be taken into account by the NBB or Minister namely:

a) changes in the existing social and economic pattern, means of the livelihood of the communities

b) effects on the religions, social, cultural and ethical values by the introduction of the LMOs.

The discussion of these possible social-economic considerations in Malaysia has been much discussed in Chapter 3.

It can be summed up these areas of concern are of paramount important namely:

i) The LMOs that involve Malaysia's main agriculture commodities namely palm oil, rubber and rice

ii)The small farmers ventures with limited capital as compared to big agriculture companies

iii)It is submitted that without much emphasis on either the product or process of LMOs, according to the religious view in Islam, provided that it complies with the general ruling in Islam for instance in slaughtering no cruelty against animal, 'halal' (permissible) food consumption requirement, LMOs should be accepted for the betterment of human life and the environment. However, if

modern biotechnology does more harm than good as against the five (5) main necessities in Islam namely religion, progeny, aql' (mind), life and property, even though it adheres to the general Islamic ruling, thus it should be prevented. For example the betterment of LMOs palm oil will cause quality seed monopoly, driving the poor small scale farmers poorer, perhaps development in modern biotechnology should not be stopped only mechanisms should be improved.

In short, it can be summarised that the Islamic ruling on LMOs should be based on the general ruling on food consumption as mentioned above. Apart from that the five (5) necessities should be adhered to. Thus the Islamic ruling can be based on the general and specific ruling based on the cicumstances of the case, it can be broad and flexible and it can be rigid as well. Based on the 'maslahah' (importance) and various methods of Islamic ruling, the Islamic scholars are to be advised by the scientists on the working of the products or process of LMOs in order to give the Islamic ruling or 'fatwa'. Practically in Malaysia, the ultimate labelling of 'halal' apart from LMO labelling, determines the Muslim consumerism issues. Thus it can be said that there are two (2) important aspects of the Islamic ruling :

i)as religious views from the Muslim scholars for the Muslim consumers (as Islamic laws in Malaysia is only applicable to the Muslims only).

ii)Labelling of 'halal' upon checking the premises, ingredients, process or procedures etc by the JAKIM officers based on the general Islamic ruling and Malaysian 'halal' labelling.

Thus it is important for the National Bioethics Council to involve the Muslims scholars (from IKIM, JAKIM and the muftis (Islamic scholars) and other religion scholars for different views on LMOs.

The LMOs acceptance do not go against the Malaysian multi-religious beliefs such as Muslim, Christian, Hindus and Buddhists on special dietary requirement especially vegetarian, vegans, etc. While social, cultural and

ethical can be closely related with religions, the discussion can be broaden in the Malaysian context from the various religions' view abovementioned.

The social, cultural and ethical issues are inter-related depending on the religions and ethnicity. A dialogue among the various religious scholars also representative is desirable in giving out especially controversial areas of LMOs. For instance the genetic engineering inter breed between plants and animals that are considered as holy (such as cows for Hindus) or 'haram' (such as pork consumption for Muslim).

In other probabilities when it involves the more diverse ethnics of Sabah and Sarawak also the aborigines living near the jungle in Peninsular Malaysia that have their own social, cultural beliefs based on their established religions, paganism or aninisminic. This is especially true when the LMOs is released or directly affected their economic and means of livelihood. Thus perhaps a special attention should be estbalished involving the leaders of these tribes with the biosafety regulators.

However, it is submitted that the assessment should not hinder growth in research and development of modern biotechnology development that could generate income for the country's economy. It is submitted that a comprehensive social, economic, religious, cultural and ethical that best suits the multi-ethnics Malaysians be established. While religious and cultural might be specific on races and religions of Peninsular and the East Malaysia, it can start off with a clear ethical stance like Norway's practice on LMOs as discussed in Chapter 3. As a start, a code or guide on the standard good bioethical practice on modern biotechnological research and development should be developed. It is suggested that a working committee between the researchers and National Bioethics Council should be established to produce the very own Malaysian bioethics.

The same is with the general social and economic stance on biosafety, perhaps a national policy that reflects all these concerns should be

formulated as a start. Thus the specific Guidelines based on religions and cultural will complement that policy. In this regard the biosafety framework should not be seen as rigid as the policy and guidelines to legalise Malaysia stance on biosafety for future law enactment also to encourage research and development in modern biotechnology. This strategy might be seen as smart regulation that allows more stakeholders' views for biosafety decision making process for public acceptance and trust for biosafety regulators to decide what is best for the nation and country's economy. On the other hand a further enactment of these concerns into Malaysian biosafety laws might add to the command and control approach but legalise Malaysia efforts in case Malaysia's actions is questioned by any WTO members. It is hoped that it will be developed further in future in Malaysia. A socio-economic impact assessment might be seen to be too ambitious so do trade and modern biotechnology research and development restrictive. Thus a detailed study and justification for inclusion of the socio-economic impact assessment as part of the risk assessment if it is necessary in the future.

e) A broad and comprehensive national biosafety policy should be in place. Thus it would cater for the future issues of biosecurity and bioterrorism like Singapore for dangerous biological agents and toxins. Beside, a good biorisk management according to the international standard should be formulated to complement the policy and laws.

f) The law[662] provides for any applicants who are dissatisfied to appeal towards the decision of the National Biosafety Board but to the Ministry of Natural Environment and Resources on notification procedures on LMOs.

[662] Biosafety Act 2007 s34

Thus if the applicants are still not satisfied with the NBB and Ministry decision, options for judicial review is open to them. However, it is argued that court's decision upon review of the LMOs application should be guided based on scientific and relevant socio-economic considerations as provided by the law. The court of law is to balance those considerations unless there are glaring errors of law and facts in principles and implementation.

Institutional framework on biosafety

Apart from the laws, rules and regulations of biosafety, the institutional framework of Malaysia should not be neglected. The primary boards namely the National Biosafety Board (NBB) and Genetic Modification Advisory Committee (GMAC) are seen to be in place. However, it is suggested that GMAC should be more democratic involving the fields of social science, consumer association also members of the National Bioethics Council as well. The National Bioethics Council should widen its scope and contribution towards the biosafety decision-making process. The inclusion of the Islamic views on biosafety such as from IKIM, JAKIM and Muftis is desirable taking into account that Malaysia is a majority Muslim population. The views of other religions from various ethnics in Malaysia are equally important that shape Malaysian public social, cultural and ethical beliefs.

4. Harmonisation of national biosafety laws

Harmonisation of the various national biosafety laws among the ASEAN countries especially between Malaysia and Singapore is crucial especially when there are dealings between the parties and non-parties to the Cartagena Protocol on Biosafety. While the parties are tied to compliance towards the Protocol, the non-parties on the other hand possibly have their obligations towards WTO as previously mentioned in Chapter 1.It is argued

while there are fewer issues for members that are already parties to the Cartagena Protocol on Biosafety, the main problems lie for non-parties. This is because the essential biosafety issues are dealt with their respective national laws. The only difference is that the way the countries legislate their national laws and institutions are diverse, provided that they comply with the Protocol.

Thus for dealings among the parties and non-parties on transboundary movement of LMOs, the relevant international agreement by WTO should be adhered to such as GATT, TBT and SPS. However, it is anticipated that there might be future conflicts on these dealings as arguably these WTO agreements might conflict with Cartagena Protocol on Biosafety in some aspects. Thus it is for the countries to settle the disputes by their national laws provided that they do not contradict with the Cartagena Protocol on Biosafety and the WTO agreements. Consequently, any conflicts will end in the case of EC Biotech as previously explained in the Introductory Chapter, as the countries will further pursue their claims at the WTO trade dispute or another international medium.

It is argued that while the need for harmonisation should be conceptually examined, the Cartagena Protocol on Biosafety itself provided a model national biosafety laws for countries to follow. The only difference perhaps is how the ASEAN countries would approach the risk assessment, socio-economic considerations and other issues in line with their capacity

building. In line with the report by Bumiratna[663] there are some important aspects of harmonisation for the South East Region which is summarised as follows:

a) the structure of the LMOs food-processing industry
b) the policy and institutional framework
c) issues, challenges and trends
d) recommendations for policy options, viable mechanism for capacity building, coordination and reviewing

At the ASEAN level, there are three (3) different bodies namely:

i. Senior Officials Meeting - ASEAN Ministers on Agriculture and Forestry (SOM-AMAF)
ii. ASEAS Senior Officials on Environment (ASOES) and
iii. ASEAS Committee on Science and Technology (COST), from three different perspectives: agriculture, environment and science and technology.

This rather seems a fragmented attempt and a lack of holistic approach can also be found at the national level. There is also no concrete action plan for systematic monitoring of GMOs.[664] Thus harmonisation of

[663] Bhumiratana S, *Report on Biosafety Policy Options and Capacity Building Related to Genetically Modified Organisms in the Food Processing Industry of ASEAN* (UNIDO 2002).
[664] ibid.

biosafety laws at the ASEAN level should integrate those policy and institutional aspects for better biosafety coordination.

There is the Asia Pacific Biosafety Association that comprises of countries across the Asia Pacific region, and beyond including Malaysia and Singapore also Australia, New Zealand and other countries with the headquarters in Singapore. This Asia Pacific Biosafety Association which was founded in 2005 is the forum of discussion among the biosafety experts and practitioners for the promotion of biosafety and biosecurity and exchange of information. Thus a harmonised biosafety and biosecurity will facilitate this cooperation among countries and reduce further future conflicts. This Biosafety Association is seen as a suitable medium that arguably could prevent any issues of conflict among countries through discussion and information exchange.

In a publication of the Asia Pacific countries biosafety regulations, there are some biosafety vital issues reviewed which is outlined as follows:

a) risk assessment and management
b) monitoring and inspection
c) public information and participation

It seems it narrowed down the broad range of biosafety issues as compared to the Cartagena Protocol on Biosafety. This is understandably because some of the Asia Pacific countries are not members of the said Protocol.

It was suggested that for future regulatory management at the Asia Pacific level these measures are necessary namely:

a) establishing National Regulatory Systems
b) infrastructure and Human Resource Development

c) reducing compliance cost
d) regional cooperation

These measures should be regarded as ways ahead of harmonisation at the Asia Pacific level. This should be further complemented by the ASEAN cooperation on biosafety as mentioned above.

In relation to Cartagena Protocol on Biosafety harmonisation it is essential as Malaysia is a signatory and party to the Protocol whereby Malaysia should show support, not in opposition. The only issue is whether the harmonisation is enough or not, i.e. the content of Malaysia Biosafety Act 2007 in relation to Cartagena Protocol on Biosafety whether they cover the essential elements or doing it otherwise. This is examined in detail in the previous Chapter 3 on the legal framework on biosafety. This is further complemented by Chapter 4 on the institutional aspect of implementation on biosafety.

Malaysia compliance of the Cartagena Protocol on Biosafety is anticipated. Malaysia even defended in their publication stating Malaysia does not go over and above the Cartagena Protocol on Biosafety but in line with it. This is proven by some examples given in relation to Biosafety Act 2007 and Biosafety Regulations 2010. Malaysia harmonisation of various laws related to biosafety, biotechnology and biodiversity should be prioritised in the future. This should be done to producing better biosafety regime which is not just protective of its biodiversity but for biotechnology growth. Thus a call for a more comprehensive biosafety to protect human health and the environment is needed to cover more complex issues of biosecurity and bioterrorism.

However when dealing with issues with harmonisation with Cartagena Protocol on Biosafety at the South East Asia level perhaps it is anticipated

future conflicts may arise for the non-ratifying countries to the Protocol namely Singapore and Brunei.

As to South East Asia or Asia Pacific Biosafety as there are no formal agreements on biosafety to be agreed upon, however, it governs the diplomatic relationship with the countries. There is some consensus on some issue of biosafety to be agreed upon at the South East Asia level. Thus the move towards harmonisation of South East Asian biotechnology laws[665] or biosafety should be applauded as it should strengthen each countries biosafety laws regardless whether they are a party to the Cartagena Protocol on Biosafety or not. Thus collective actions towards other regimes of biosafety laws are right to safeguard the biosafety interest of that region mainly South East Asian (SEA) region. It is important to note here that each country has their national priorities and aspiration with the different capacity building. If the same areas of interests, concerns, priorities in biosafety are harmonised, it is for the benefit of the regions thus that should be highlighted. For instance, if the ASEAN countries agreed to prioritise on SARS epidemic thus various steps in that regard should be uniformed to produce efficiency and effectiveness in combating SARS in that region.

5. Biosafety in East Asia

There were three SARS incidents in 2003 and 2004. This shows that biosafety will be a material concern in East Asia. Each incident could have

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[665] Jusoh S, 'Developing Biotechnology Legal Systems in Developing Countries: The Case for Malaysia (Part I)' (2006) 3(4) Journal of International Biotechnology Law 160.

elicited effects comparable to a biological weapon attack or a natural disease outbreak.

However, the best overall national commitment to biosafety in East Asia is provided by Japan, China and Singapore as the regulatory biosafety coverage is extensive.[666] In East Asia overall, however, biosafety regulations are lacking. In East Asia, it is clear that biosafety lags dangerously behind expansions in the biotechnology industry. As more laboratories and scientists are assigned to address the region's infectious disease problems, whether of natural origin or biological weapons-related, it is vital that such research not increase the risk of outbreaks occurring by accident.

Dual use issue

The issue of dual-use of LMOs should be looked into by Malaysia and Singapore for the non-peaceful purposes, i.e. military purposes. The dual-use issue should be discussed further not just in both countries context but also the ASEAN and the Asia Pacific level. The awareness and method to deal with this issue in future should be learnt from other developed countries that are more advanced in knowledge, expertise and implementation.

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[666] "Preventing Accidental Disease Outbreaks: Biosafety in East Asia", APSNet Policy Forum, September 07, 2006,available online at <http://nautilus.org/apsnet/0631a-enemark-html/>accessed on 27th May 2017.

South East Asian biosafety co-operations

Apart from Malaysia biosafety experts' involvement in Asia Pacific Biosafety Associations, Malaysia needs to take advantage of the South East Asia cooperation in biosafety. This should be done with a view even though short of European Community uniforms laws on biosafety, this cooperation is a window to regional harmonisation and cooperation on biosafety. Thus the uniforms rules and regulations by South East Asian countries should set the standard by which the countries are dealing with these countries.

6. Contribution to the body of knowledge

This study examines the biosafety legal and institutional framework from a regulatory aspect namely risk regulation and its possible strategies from the traditional command and control to the new governance. The study adds to the existing body of knowledge from the analysis of the important issues from the Cartagena Protocol on Biosafety to be complied by Malaysia and the identification of relevant biosafety regulatory strategies. This thesis analysing the existing Malaysia and Singapore's legal framework in light of the regulatory theory. It provides a useful examination of the essential aspects of biosafety implementation in Malaysia from the country's report on the decision on LMOs also the compliance report to the Cartagena Protocol on Biosafety.

A comparison with Singapore biosafety law using Cartagena Protocol on Biosafety as a biosafety governance model further adds to the existing knowledge.

7. Future directions for research

As biosafety rules and regulation is still at the developing capacity building stage, there are broad areas for future research in Malaysia and South East Asia region. However the most vital issues of future research are identified as below.

It is hoped that in future detailed analysis of the relevant socio-economic factors to be taken into consideration by Malaysia will be carried out in order for legitimising the inclusion of such factors in the decision-making process. The public participation study in biosafety is also essential to pave the way for future effective participation. Another possible interesting of research is the possible future conflicts of Cartagena Protocol on Biosafety with the various WTO agreements signed by Malaysia. This future research is useful to prevent Malaysia from being liable for any possible legal actions or trade sanctions for transboundary movement of LMOs from or outside Malaysia. A further research of harmonisation among ASEAN countries is desirable for better biosafety governance at that region.

8. Conclusion

Malaysia has a long way to build up its capacity in its biosafety from human resources, lab and safety procedures, rules, regulations, and implementing various aspects as contained in the Cartagena Protocol on Biosafety.

This thesis, while acknowledging the importance of the scientific risk assessment and management, also argued the need for socio-economic considerations to be taken into account. The inclusion of the socio-economic considerations should be adequately consulted with the relevant socio-economic expert also the relevant stakeholders thus a useful and efficient

guideline is produced that will legitimise Malaysia inclusion of those considerations.

It is hoped that Malaysia is not so ambitious in developing modern biotechnology thus neglecting the long term effects on the human health and the environment. The current legal and institutional framework, biosafety regulatory strategies are in place only need more funding, expertise and research to broaden its scope of implementation.

As from the regulatory aspect, the 'regulatory reconfiguration' in the area of biosafety marks the new era of modern biotechnology governance should be applauded as the new trend of regulation. The traditional command and control approach still plays a dominant role in biosafety governance as the adverse effect of the modern biotechnology is irreversible towards human health and the environment. The various mixed of the new governance strategies in biosafety regulation such as smart regulation, licence model, civil regulation reflexive and meta-regulation even though is found challenging in its application , complements it and provides 'regulatory pluralism' for better biosafety governance. These regulatory strategies even though have considerable effect on environmental governance are relevant in biosafety regulation but with limitations and weaknesses.[667] It is hoped that the best combination of both strategies could be achieved through the improvement of the existing biosafety legal and

[667]Gunningham N, 'Regulating Biotechnology: Lessons from Environmental Policy' (2007) in Somsen, H, *The Regulatory Challenge Of Biotechnology: Human Genetics, Food And Patents* (Edward Elgar 2007).

institutional framework in order to achieve the desired ends, i.e. better protection of human health and environment from the adverse effects of modern biotechnology.

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