

DISSERTATION

ECONOMICS, POLITICS AND ECOLOGY

OF BIOTECHNOLOGY IN MALAYSIAN AGRICULTURE

Submitted by

Chubashini Suntharalingam

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Doctoral Committee:

Advisor: Gregory Graff

Patrick Byrne  
Dawn Thilmany  
Stephen Davies

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## ABSTRACT

### ECONOMICS, POLITICS AND ECOLOGY OF BIOTECHNOLOGY IN MALAYSIAN AGRICULTURE

Malaysia has been moving from an agricultural, resource extraction, and manufacturing based economy in the 1980s toward a service-oriented, post-industrial, knowledge-based economy, with greater emphasis on skilled human capital, technology, and intangibles. Assessing Malaysia's current economic and policy regimes are crucial to help chart the next course of actions for Malaysia to set its economic goals. The patent landscape analysis showed Malaysia's economy evolution over the past six decades. Primarily dependent on the chemicals and petroleum sector between 1953 and 1985, the economy, currently is dependent on two sectors, i.e. electronics, semiconductors and computing, and chemicals and petroleum.

Generally, the commercial sector dominates the patenting activities in Malaysia, in the economy wide patenting arena and also in the agbiotech and agchemicals technologies. High patenting trends by foreign commercial entities is to avoid imitations to their inventions in the Malaysian market attributable to their high FDI investment and export share. Within the agricultural sector, patents in agbiotech are relatively low and overshadowed by patents in agchemicals. The higher number of agchemicals technologies patented in Malaysia is due to the long history of European MNCs in Malaysia. And, the low number of agbiotech patented in Malaysia, mainly by non-commercial entities is due to two reasons: (1) misalignment of policies

promoting the use of modern biotechnology in the Malaysian agricultural sector, and (2) ecological risks of cultivating transgenic crops in Malaysia, a rich-biodiversity country.

A political economy framework was utilized in understanding the misalignment of policies promoting the use of modern biotechnology and examining the influence of relevant stakeholder groups on the decision making process concerning regulations overseeing the cultivation of transgenic crops. Two Malaysian Giant conglomerates, Sime Darby Berhad and Felda Holdings Berhad, dominate world palm oil exports and local oil production, and inevitably, have a strong policy influence of the Malaysian agricultural sector. The world's two dominant agchemicals players, Bayer and BASF, also play a major role in the agricultural policy making process in Malaysia. Bayer is one of the leading players that dominate the agchemicals patents in Malaysia. BASF, meanwhile has formed a strategic alliance with the Malaysian Agricultural Research and Development Institute (MARDI) and developed a new herbicide resistant Clearfield rice variety to tackle weedy rice outbreak in Malaysia. These two special interest pressure groups, oil palm and agchemicals producers face large welfare impact if Malaysia adopts transgenic crops. With risk of losing their market shares in Malaysia and their relatively small number, these groups have been able to converge and exercise influence over the stalled commercialization process of transgenic crops.

The other reason attributable to the low number of granted agbiotech patents in Malaysia pertains to ecological risk concerning deployment of transgenic organisms on Malaysia's rich biodiversity. Scientific assessments carried out on transgenic rice and papaya suggest that transgenic rice and papaya lines can potentially exert positive and/or negative ecological impacts, i.e., non-target organisms, transgene escape, heteroencapsidation, and RNA

recombination. However, the studies reviewed in this dissertation call for long-term assessments to determine the longer term impact of transgenic rice and papaya on non-target organisms and transgene escape. In addition to this, majority of ecological studies carried out on non-target organisms have been limited to third trophic interaction. Considering the fact that Malaysia is a mega-diversity country, ecological studies concerning higher trophic level are required to assess the impact transgenic rice and papaya has on these populations and the food-web dynamics. Studies on heteroencapsidation and RNA recombination of papaya ringspot virus (PRSV) resistant transgenic papaya is also limited even though PRSV-resistant transgenic papaya has been in the market for over fifteen years.

Ultimately, while transgenic rice and papaya do carry ecological risks, the decision to cultivate these crops lies on the benefits brought upon by these crops. World food supplies demand intensive crop production due to increased population growth, climate change, pest and disease challenges, political unrest, deterioration of soil quality, drought and flood. Ultimately, the benefits and challenges in cultivating transgenic crops need to be considered on a case-by-case basis. Cultivating transgenic crops has potential to decrease reliance on external inputs and reduce ecological risk. As such, until we can derive a balance between the two, we must strive to continue to improvise the transgenic technology to suit these two goals.

For future research, it is recommended to determine the funding mechanisms of studies reviewed for the ecological assessments of transgenic rice and papaya in order to assess the objectivity of the study findings.

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## DEDICATION

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## TABLE OF CONTENTS

ABSTRACT.....	ii
ACKNOWLEDGMENTS.....	v
DEDICATION.....	vi
CHAPTER 1: INTRODUCTORY REMARKS.....	1
REFERENCES.....	4
CHAPTER 2: PATENT LANDSCAPE ANALYSIS.....	5
2.1 Introduction.....	5
2.1.1 <i>Malaysia’s Agricultural Sector Development Strategy</i> .....	6
2.1.2 <i>Quantifying Innovation using Patent Data</i> .....	8
2.1.3 <i>Patents and Malaysian Intellectual Property Law</i> .....	11
2.2 Methods.....	16
2.2.1 <i>Methods for Landscape Analysis of Economy-Wide Patenting Trends in Malaysia</i> .....	17
2.2.2 <i>Methods for Patent Landscape Analysis of Agricultural Technologies in Malaysia</i> .....	23
2.3 Results and Discussion of Economy Wide Patenting Trend in Malaysia.....	25
2.3.1 <i>Malaysian Patents Granted, Filed and Earliest Filing Date</i> .....	25
2.3.2 <i>Patent Assignees</i> .....	30
2.3.3 <i>Distribution of Patent Assignment</i> .....	44
2.4 Results and Discussion of Agricultural Technologies Patenting Trend in Malaysia.....	49
2.4.1 <i>Patenting Trend in the Malaysian Agriculture and Food Sector</i> .....	49
2.4.2 <i>Patenting Trend of Agbiotech and Agchemicals Technologies</i> .....	51
2.4.3 <i>Malaysian Agbiotech and Agchemicals Technologies’ Patent Assignees</i> .....	52
2.4.4 <i>Distribution of Patent Assignment to Agbiotech and Agchemicals Technologies</i> .....	65
2.5 Synthesis and Conclusion.....	68
2.5.1 <i>Economy Wide Patenting Trend in Malaysia</i> .....	68
2.5.2 <i>Agricultural Technologies Patenting Trend in Malaysia</i> .....	71
REFERENCES.....	73
CHAPTER 3: POLITICAL ECONOMY OF AGBIOTECH POLICIES.....	78



3.1 Introduction .....	78
3.2 What is Agbiotech? .....	80
3.3 Agbiotech Policy and Progress in Malaysia .....	81
3.3.1 <i>National Biotechnology Policy</i> .....	81
3.3.2 <i>Research and Development Investments in Agbiotech in Malaysia</i> .....	83
3.3.3 <i>Current Status of Research and Development of Transgenic Crops in Malaysia</i> .....	83
3.3.4 <i>Current Patent Status of Transgenic Crops in Malaysia</i> .....	88
3.3.5 <i>Approved Transgenic Events and Products in Malaysia</i> .....	89
3.4 Malaysian Biosafety Regulations .....	90
3.5 Conflict of Policies.....	91
3.6 Brief Background of Political Economy Models.....	93
3.7 Methods.....	97
3.8 Background of Oil Palm, Rice and Papaya Industries in Malaysia .....	98
3.8.1 <i>Malaysian Palm Oil Industry</i> .....	98
3.8.2 <i>Malaysian Rice Industry</i> .....	101
3.8.3 <i>The Papaya Industry</i> .....	102
3.9 Assessing Welfare Impacts and Influence over Regulators.....	102
3.9.1 <i>Consumers</i> .....	102
3.9.2 <i>Food Retailers</i> .....	103
3.9.3 <i>Oil Palm, Rice and Papaya Producers</i> .....	103
3.9.4 <i>Major Biotechnology Suppliers and New Biotechnology Innovators</i> .....	103
3.9.5 <i>Competing Input Suppliers (Agchemicals)</i> .....	104
3.9.6 <i>Scientists</i> .....	108
3.9.7 <i>Activists and Environmental Welfare</i> .....	108
3.10 Conclusion.....	108
REFERENCES.....	111
CHAPTER 4: ECOLOGICAL RISKS OF TRANSGENIC CROPS.....	119
4.1 Introduction .....	119
4.2 Brief Background on Rice and Papaya .....	121

4.3 Mechanism Discussed in the Scientific Literature .....	123
4.3.1 <i>Effects on the Third Trophic Level</i> .....	124
4.3.1.1 Insect-resistant rice .....	126
4.3.2 <i>Effects on Soil Community</i> .....	135
4.3.2.1 Insect-resistant rice .....	137
4.3.2.2 Herbicide-resistant rice .....	139
4.3.2.3 Virus-resistant transgenic papaya .....	142
4.3.3 <i>Effects on Non-Target Herbivorous Pests</i> .....	144
4.3.3.1 Insect-resistant rice .....	145
4.3.4 <i>Effects of Transgene Escape</i> .....	150
4.3.4.1 Insect-resistant rice .....	151
4.3.4.2 Herbicide-resistant rice .....	157
4.3.4.3 Virus-resistant transgenic papaya .....	161
4.3.5 <i>Other Impacts</i> .....	163
4.3.5.2 RNA recombination .....	164
4.3.6 <i>Indirect Impact of Changing Agricultural Practice on the Environment</i> .....	165
4.3.6.1 Positive .....	165
4.3.6.2 Adverse .....	166
4.4 Synthesis and Analysis of Discussion .....	171
4.4.1 <i>Gaps in Knowledge and Mechanism/approach to address the gaps</i> .....	181
4.4.2 <i>What Constitutes a Sufficient Body of Information?</i> .....	184
4.4.3 <i>Implications of Scientific Literature for Regulating the Commercial Release of Transgenics in Malaysia</i> .....	185
4.5 Conclusion .....	186
REFERENCES .....	188
CHAPTER 5: CONCLUDING REMARKS .....	201

## CHAPTER 1: INTRODUCTORY REMARKS

Malaysia is moving from a manufacturing-based economy to one that is service-oriented, with a vision of becoming a developed knowledge economy by 2020. In doing so, biotechnology has been positioned as a new key engine of growth by policymakers (MOSTI 2005). There are a couple of strategic reasons for this.

Malaysia is rich in biodiversity and has been identified as one of the twelve mega-diversity countries in the world, which together comprise 70 percent of the world's species diversity, (Polski 2005, Krishnapillay et al. 2003) a source of natural capital which can be utilized in developing many biotechnology products of the future. Second, the Malaysian agriculture sector is important both for contribution to GDP and for food production. In terms of GDP, the agriculture sector contributed approximately USD 17 billion, which is 7.6 percent of total GDP in 2011 (EPU, 2012). Yet, in terms of food production, Malaysia does not have self-sufficiency for major food commodities such as rice (72 percent), vegetables (44 percent), fruits (66 percent), beef (29 percent), mutton (11 percent) and milk (5 percent) (MOA 2012).

There are concerns that in recent years, growth in agricultural productivity has been slowing in several key commodities globally (Hossain 2007). In coming years, climate change, limited fertile lands and, emerging pests and diseases are expected to pose additional challenges to Malaysian agriculture (Jaganath and Bakar 2012). While Malaysia is not currently facing any food security crisis, researchers from the Malaysian Agricultural Research and Development Institute (MARDI) have identified transgenic crops to play a significant role in helping to solve some of these problems, increase food output by using fewer resources as well

as to enhance nutritional and therapeutic content, taste and quality of some of these crops in Malaysia (Jaganath and Bakar 2012, The Sun Daily 2012). Endowed with such a wealth of natural biodiversity and an agricultural sector with much unrealized potential, the development of agricultural applications of biotechnology, in particular have been proposed as a way to transform and enhance value creation of the agricultural sector.

However, while biotechnology is anticipated to drive innovation, and thus economic development, in Malaysia, the policy framework is not in place to achieve this agenda. One of the biggest impediments being voiced to the development of transgenic varieties in Malaysia are ecological concerns over the potential impact of transgenic crops on Malaysia's natural wealth. These concerns, and the resulting policy stalemate, have resulted in no commercial release of transgenic crops in Malaysia to date. Malaysia's policy regime seems to be not fully in line with stated economic development goals.

This dissertation explores several important questions raised by these observations: To what extent is progress being made in innovation in biotechnology in Malaysia? Is it in fact forging ahead? And if so, who is making progress? What does scientific analysis say about the objective risks that transgenic crops pose to Malaysia's ecology? Ultimately, what factors explain why the policy regime for research, development, and commercialization of transgenic crops is not in line with stated aspirations for the development of a Malaysian agricultural biotechnology sector?

Chapter 2 aims to understand the dynamics of innovation both going on within Malaysia and being introduced to Malaysia from abroad. The levels and trends in patenting activities are analyzed to characterize and quantify the innovation landscape in the Malaysian economy

overall, and in the agricultural biotechnology sector. This study specifically wishes to investigate patenting activities in the agricultural biotechnology areas such as the variation in patenting activities, the type of patents filed and granted, the technologies or process that are filed for patent, the types of firms that innovate (local vs foreign; commercial vs non-commercial), the productive fields and the emerging fields. The landscape patenting activities in agricultural biotechnology from Chapter 2 will provide insights to Chapter 3.

Chapter 3 intends to understand the composition and extent of support for and opposition to policies conducive to the innovation of agricultural biotechnology in Malaysia. This chapter utilizes patent findings drawn from Chapter 2 coupled with a political-economy framework to identify the stakeholders within Malaysia whose economic welfare is likely to be affected by the innovation and commercial introduction of transgenic crops and their respective roles in the policy making process.

It is envisaged from Chapters 2 and 3 that one of the reasons contributing to stalled transgenic crops commercialization efforts is stringent regulatory approvals due to Malaysia's wealth of natural biodiversity. As such, the purpose of Chapter 4 is to review the scientific literature concerning ecological risks of transgenic crops. This review effort aims to assist policy makers make science based decisions on regulations concerning the interaction between transgenic crops and Malaysia's biodiversity.

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## CHAPTER 2: PATENT LANDSCAPE ANALYSIS

### 2.1 Introduction

Malaysia has been moving from an agricultural, resource extraction, and manufacturing based economy in the 1980s toward a service-oriented, post-industrial, knowledge-based economy, with greater emphasis on skilled human capital, technology, and intangibles. The Malaysian economy has experienced these significant changes, mainly due to its economic developmental policies but also due to natural forces of globalization and economic growth (Choung and Hwang 2000, Park et al. 2005, Nagano 2006, Asgari and Wong 2007).

Assessing the nation's current economic and policy regimes is crucial to help chart the next course of actions for Malaysia to set its economic goals. Often, GDP contributions have been an effective indicator to measure economic progress. In recent times, the development of science and technology indicators through the exploitation of patent data has been used to measure economic evolution and progress.

As such, this study aims to learn Malaysia's economic evolution and the type of knowledge generated in Malaysia, i.e. within and outside of Malaysia through the use of patent data. Specifically, this study will analyze the types and trends of patenting behavior to characterize and quantify innovation activities that are occurring in Malaysia. Additionally, assessing commercial and non-commercial entities involvement is crucial in determining the drivers of economic and innovation progress in Malaysia.

The patent assessment is taken a step further into the Malaysian agricultural sector. Why the agriculture sector? Primarily because of its historical and projected contributions to

Malaysia's economy and social conditions. In the early 1950s to 1970s, agricultural sector was the driver of economic growth. The push towards industrialization in the mid-1980s neglected developmental efforts in this sector. Nevertheless, the Asian financial crisis in 1997 heightened the awareness on the consequences of a lagged agricultural sector in providing food for the nation during a crisis. To revitalize the agricultural sector, biotechnology has been identified as a key technology. Utilization of patent data will offer insights on the type of innovation that is being generated within the agricultural sector to help understand the role biotechnology plays. To understand the actors that are driving innovative behavior in this sector, this study will examine the roles of commercial and non-commercial sectors.

This chapter will first, provide a brief background on Malaysia's agricultural sector, using patent data to quantify innovation and short introduction on patenting in Malaysia. Subsequently, methods utilizing patent data will be discussed. This chapter will continue with results and discussion focusing initially on economy wide patenting trend and then moving on to agricultural sector patenting trend. It will conclude by synthesizing the economy wide and agricultural patenting trends, and a brief general conclusion.

### ***2.1.1 Malaysia's Agricultural Sector Development Strategy***

Malaysian agricultural sector was the main contributor (often greater than 50 percent) to Malaysia's gross domestic product (GDP) from the 1950s to the late 1970s. However, the drive towards industrialization in the mid-1980s into the 1990s left Malaysia's agricultural sector as a smaller proportion of the economy (Ahmad and Suntharalingam 2009). The contribution of agriculture to GDP was 20.8 percent in 1985 and 13.6 percent in 1995 (Alam et al. 2012). In 2011, Malaysia's agriculture sector contributed approximately USD 17 billion, or 7.6



percent of the country's total GDP (EPU 2012). The average agricultural sector contribution to Malaysian GDP was 5.2 percent between 2000 and 2010 (MOA 2011). Although the share of agricultural sector to Malaysian GDP has declined significantly since the 1950s, agriculture still plays a crucial role in ensuring food security, generating employment, improving socioeconomic conditions, and increasing economic activity, particularly in rural regions of Malaysia.

Biotechnology has been identified to have the potential to play an important role in the agricultural sector, and offer opportunity for innovation and growth as a move towards a knowledge-based economy. This aspiration is also shared by the Ninth and also Tenth Malaysia Plan (2011-2015) along with National Biotechnology Policy and the National Agro-Food Policy (2010-2020) which aim to utilize biotechnology to build a more conducive environment for agricultural R&D and industry development leveraging Malaysia's existing areas of strengths, e.g. rich biodiversity, cost-competitive labor, and strong agricultural base and financial system. One of the nine thrusts of the National Biotechnology Policy is pertaining to agricultural biotechnology (agbiotech), in which biotechnology will be the key technology used to transform and enhance the value creation of the agricultural sector. This includes improving the nation's food security, increasing commercialization efforts for economic growth, as well as raising its competitive position in the global agricultural markets with quality products. The government of Malaysia aims to achieve its agbiotech goals via several key measures, i.e. financing a public research system, enhancing the innovative capacity (both human and physical capacity) of the national biotechnology research program through public investment, and establishing institutions and formulating friendly regulations that will foster growth in this sector (MOSTI 2011, Frost and Sullivan 2009). The National Biotechnology Policy projects that the

biotechnology sector is expected to employ 160,000 workers and contribute five percent towards national GDP, with a revenue of RM248 billion (USD83 billion) in 2020. The agricultural sector on the other hand is projected to employ approximately 670,000 workers, and contribute 5.8 percent towards national GDP, with an export value of RM161 billion (USD \$54 billion) in 2020 (MOA 2011).

According to the European Commission (2014), biotechnology has been identified as a key enabling technology that offers great opportunity for innovation and growth for knowledge-based economy. This is because innovation and creativity (through sharing of ideas) act as catalysts in moving knowledge based economy agenda forward.

### ***2.1.2 Quantifying Innovation using Patent Data***

Quantifying innovation remains a challenge for innovators and policymakers alike (WIPO 2011 ). Given the intrinsic difficulty of observing and measuring knowledge and intangibles, science and technology (S&T) indicators or intellectual property (IP) statistics are used as approximate measures or proxies of innovation. Following the representation of R&D as a production process (Pakes & Griliches 1980, 1984), a number of R&D input and output proxies can be used in measuring innovation activities. Research and development expenditures and numbers of scientists or engineers can serve as input proxies. Numbers of scientific and trade publications, patents, other types of IP, clinical or field trials, regulatory approvals, and new products or processes introduced to the market can serve as output proxies.

There are a number of different major types of IP, including utility patents, utility models, industrial designs, copyrights, plant variety rights, and trade secrets (Table 2.1). Several of these can serve as innovation indicators; recent evolution in creative industries and

technological innovation processes have been accompanied by the increased filing of IP applications in Europe, Japan, and the United States in the order of more than forty percent (OECD 2004).

**Table 2.1: Brief Description of Major Forms of IP**

<b>Main forms of IP</b>	<b>Subject matter</b>	<b>Acquisition of right</b>	<b>Nature of right: prevent others from ...</b>
<b>Patents and utility models</b>	Inventions that are new, non-obvious and industrially applicable	Granted by government authority, typically following substantive examination	... making, using, selling, offering for sale or importing
<b>Industrial designs (ID)</b>	ID that are new and/or original	Granted by government authority upon registration, with or without substantive examination	...making, selling or importing
<b>Copy right</b>	Creative expressions	Automatically, upon creation	... reproducing and related acts
<b>Trademarks</b>	Brand names	Through usage in marketplace and/or registration of the mark with trademarks office	using the mark rightfully
<b>Utility model</b>	Minor inventions	Filed through national IP office	commercially using the protected invention without authorization from right holder
<b>Plant variety protection</b>	Plant varieties that are new, distinct, uniform and stable	Granted by government authority following substantive examination	...using and multiplying propagating materials
<b>Trade secrets</b>	Any valuable confidential business information	Automatically, upon creation	... unlawfully disclosing

Source: WIPO (2011, 2014a, 2014b) and Evenson (2004)

Much of the economic research on IP policy has focused on patents (WIPO 2011). A major reason is the availability of patent data. Patent data provides a good measure of inputs and outputs of a firm and, as discussed above, can be related to other S&T indicators such as R&D expenditures, productivity growth, profitability or stock market value of a firm (Griliches 1998). Moreover, patent data conveys information about the commercial potential of inventions. The increasing trend of establishing patents in businesses and, public research organizations is mainly to protect their inventions with the goal of encouraging further investments in innovation and fostering knowledge dissemination (OECD 2004). Following these reasons, this study aims to utilize patent data to characterize innovation trends within the Malaysian economy, including that of one of its most traditional industries, agriculture.

### ***2.1.3 Patents and Malaysian Intellectual Property Law***

To understand the nature of patent data, it is important to consider briefly what patents are as legal instruments, and how they are governed under Malaysian law.

A patent is a document, issued by an authorized governmental agency, granting the right to exclude anyone else from the production or use of a specific new device, apparatus, or process for a stated number of years. According to Evenson (2004), in order for a patent to be granted, the invention must demonstrate novelty (the first of its kind), useful (it can be incorporated into a useful device), and has an inventive step (unobvious to a practitioner skilled in the art). The grant is issued to the inventor of a device or process after an examination that focuses on both the novelty of the claimed items and its potential utility (Griliches 1998).

Basically, in order for a patent to be granted, the invention must not be obvious to a skilled practitioner of the relevant technology and it should demonstrate potential commercial value (Hall et al. 1999). Evenson (2004) discusses the features of a granted patent:

- i. It is a “right to exclude” others from making or using the invention, and not a right to actually make and use the invention
- ii. The right to exclude is limited in time. Patent right expires after 20 years from date of application, based on the World Trade Organization (WTO)- rules
- iii. The right to exclude means the invention is removed from secrecy.

In Malaysia, a patent is defined as a grant issued to the owner of an invention that provided him exclusive rights to exploit and control the patented invention for a period of twenty years in return for the disclosure of his invention (MyIPO 2012). Generally, a patent is an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem. Specifically, a patent is granted if an invention meets the following criteria:

- i. new, which means that the invention has not been publicly disclosed in any form, anywhere in the world
- ii. involves an inventive step, that is to say the invention must not be obvious to someone with knowledge and experience in the technological field of the invention; and
- iii. industrially applicable, meaning it can be mass produced.

A patent is denied if the invention involves any of the following subject matter:

- i. Discoveries, scientific theories and mathematical methods;
- ii. Plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;
- iii. Schemes, rules or methods for doing business, performing purely mental acts or playing games;
- iv. Methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body.

The two subject matter exclusions above, (ii) and (iv) are expressly provided for in Article 27.3 of the Trade Related Aspect of Intellectual Property Rights (TRIPS) Agreement. Subject matter exclusion (ii) is provided by the Malaysian Protection of New Plant Varieties Act (PNPVA) 2004. The TRIPS Agreement is one of the three main pillars of WTO and to date the most comprehensive multilateral agreement on intellectual property. The placement of IP in WTO means that non-compliant WTO members would face trade sanctions if they do not adhere to its rules.

Malaysia became a signatory to the Paris Convention (PC) on 1 January 1989. The main element of the PC concerns national treatment, which means that all participating members are discouraged from discriminating between the citizens of the country who grant the IP rights and foreign nationals. Malaysia became a member of the Patent Cooperation Treaty (PCT) on August 16 2006. The World Intellectual Property Organization (WIPO) administers the PCT. The PCT is between more than 148 Paris Convention countries. The PCT makes it possible for

member countries to seek protection for an invention simultaneously in each member countries by filing a single “international” patent application rather than filing several separate national or regional patent applications. The national or regional patent office controls the granting of the patent in what is called the “national phase”.

The implementation of legislations concerning patents is the Patent Act of 1983 and the Patents Regulations of 1986. The Patent Act has been amended six times over the period of twenty nine years while the Patent Regulations have been amended twice over the period of twenty six years. Both were primarily amended to comply with the TRIPS Agreement. The Patent Act recognizes employers, including publicly funded institutions, to be designated as the rightful owners of IP created by employees in the course of employment.

According to Adams (1995), the Patent Regulations brought complex transitional arrangements for applications filed before and after 1986, once the Act came into force.

The patent system of Malaysia is based on the British colonial policy and empire-building (Drahos 2002). Thus, prior to 1 October 1986, patent protection was obtained by re-registering United Kingdom patents within Malaysia (Adams 1995). As a result, the numbering of Malaysian patent application and granted patents changed significantly during the transitional period in the late 1980s.<sup>1</sup>

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<sup>1</sup> The application number series followed the format of annual series with year suffix, variable length (e.g. 1234/94 or 12345/1994). Meanwhile, the publication number format followed the series identical to application number (e.g. 12345/94) with a MY prefix (country code). During this periods, the application date and publication date recorded in the International Patent Documentation Center (INPADOC) are the same, and they are not reliable (INPADOC is an international patent collection that contains patent families and legal status information). This is because if there were any missing data, INPADOC inserted a dummy date of 31 December of the year of registration. The priority date recorded corresponded to the United Kingdom granted patent from which the re-registration was derived. Upon gaining independence, Malaysia customized its patent system taking into account its economic and industrial interests (George 2009). The new application number format is of an annual series with year prefix, fixed length (e.g. 9400123). The new publication number format follows the type A format which is a closed series, variable length (e.g. 123456) and began with 100001 in 1988 (Adams 1995).



Today, the Intellectual Property Corporation of Malaysia (MyIPO) administers the patent application and granting process. MyIPO was established due to the rapid growth and development of IP rights in the global and domestic arena. The Ministry of Domestic Trade, Cooperatives and Consumerism (formerly the Ministry of Domestic Trade and Consumer Affairs) is responsible for the administration and functionalities of MyIPO. The Intellectual Property Corporation of Malaysia Act 2002 guides MyIPO.

The patent application and granted procedures in Malaysia follow the following sequence:

- i. Assignee files a patent application.
- ii. The application is assigned an application number.
- iii. Upon approval of preliminary examination and after 18 months of filing or from earliest priority date (whichever is earlier), the application is laid open for public inspection. The purpose of this inspection is to create public awareness of an invention that has been filed for patent protection in Malaysia. This information can be accessed via MyIPO on-line system.
- iv. Subsequently, the patent application is examined by patent examiners for approval or rejection.
- v. If the patent application is approved, then the patent is assigned a granted patent number.

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For example, under the old (re-registration) system, from 153-1988, the application number was 149/88-A and publication number was MY 149/88-A. Under the new date from 26<sup>th</sup> October 1988, application number is 8700290/87-A and publication number is 100002 (Adams 1995)

## 2.2 Methods

A patent landscape analysis is an analysis of a population of patents and the relationships between those patents and other sets of S&T indicators over a particular time period, technology, or geographic region (Bubela et al. 2013). Other commonly employed S&T indicators include scientific articles, clinical or field trials, regulatory approvals, and actors or institutions.

Patent landscape analyses tend to focus on a specific technology or geographic region. A set of patents can be defined and collected that measures a specific technology or set of technologies while a geographically defined set of patents can measure technological developments across all industries within that geography, including, for example, an entire national economy. Regardless of scale, landscape patent analysis seeks to encompass, as much as possible, an entire population of relevant data rather than a limited random sample drawn from that population. The data can either be visualized graphically or comprise counts of indicators across selected dimensions of time, geography, technology, or economic sector. According to Bubela et al. (2013), the most effective patent landscape analysis aligns scope and methodology to address a specific question of policy relevance.

This study utilized the Thomson Innovation (TI) database, a proprietary database by Thomson Reuters. TI has a comprehensive collection of patent data, including all major patent authorities and nations (Thomson Reuters 2014). Malaysian patents were made available via TI in 2013. Previously, Malaysian patent data was only available directly from MyIPO at a cost.

The steps involved in this patent landscape methodology follow closely many patent landscape studies, including (1) data search and collection, (2) data cleaning and curation, and

(3) data analysis (Graff et al. 2003, Bergman & Graff 2007, Gold and Baker 2012, Bubela et al. 2013). Patent landscape analysis is an iterative process depending on the breadth or specificity of research questions.

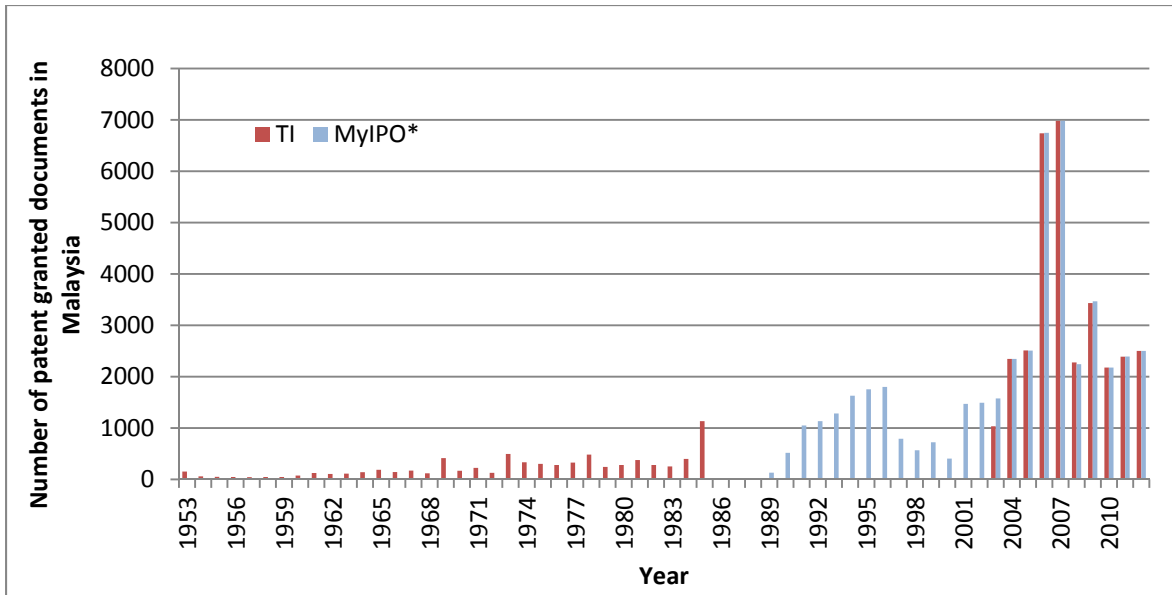
This methods section is divided into two, i.e. 1.2.1 discusses methodology for the Malaysian economy wide patenting trend and 1.2.2 discusses methods for the Malaysian agbiotech and agchemicals patents.

### ***2.2.1 Methods for Landscape Analysis of Economy-Wide Patenting Trends in Malaysia***

Given our interest in learning the innovation dynamics of Malaysian economy, we sought all patents documents filed in Malaysia with the use of “MY” prefix search over patent document numbers, with no pre-determined time scale. We were interested in obtaining all available granted Malaysian patent documents. The result was 40,185 Malaysian patent documents issued between the years 1953-1985 and 2003-2012. From 1986-2002, data was missing in TI although MyIPO reported data for those years.<sup>2</sup> However, data from the earlier period (1953-1985) was not available from MyIPO, but TI reported data for those years. The number of patent document observations downloaded from TI is very close to the number of observations reported for MyIPO data for the later period (2003-2012). (See Figure 2.1)

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<sup>2</sup> Attempts were made to obtain the missing Malaysian patent data for 1986-2002 from a public domain database, Espacenet, developed by the European Patent Office, but the data was also missing in Espacenet. Even outside of that time range, the number of observations on granted Malaysian patent documents was fewer than what was available in TI.



**Figure 2.1: Patent Records Available in TI and MyIPO**

Note: \*MyIPO data consist of granted patents and utility patents

Upon retrieving the data, it went through an extensive cleaning process. All 40,185 patent documents were reviewed and just five duplicate patent granted documents were found. These five were dropped to arrive at a final dataset of 40,150 granted Malaysian patent documents. The data fields that constituted the dataset, as well as an example of the data content of a single patent record, are listed in Table 2.2.

For the purpose of assessing inventorship of technologies, we identified the ‘assignee-at-issue’ for each patent document. Identification of patent assignees was recorded in the patent data by the MyIPO patent authority as it issued the patent. An assignee is the recipient of ownership of the patent to which the inventor(s) have signed over their property rights to the invention. Often, an inventor is an employee who is obligated to formally assign invention rights to the employer under their employment contract with that employer (Nottenburg 2007).

**Table 2.2: Data Fields of Malaysian Patent Documents Downloaded from TI**

Data Field	Example of Patent Record
INPADOC Family ID	20061228AU2006260107A1
Application Number	MY2006PI2834A
Publication Number	MY147682A
Title	GAS-LIQUID SEPARATION DEVICE OF ENGINE
Priority Number	JP2005183596A   JP2005183605A
Priority Date	2005-06-23   2005-06-23
Application Date	6/15/2006
Publication Date	12/31/2012
IPC - Current	F01M001300   H05F000302   H04W008000
Assignee/Applicant	HONDA MOTOR CO LTD   SAMSUNG
Title (English)	GAS-LIQUID SEPARATION DEVICE OF ENGINE
Abstract	(O 6 GAS-LIQUID SEPARATION DEVICE OF ENGINE A BEARING HOLDER 66 HAVING A BEARING 67 ROTATABLY SUPPORTING A CRANKSHAFT 14 IS FIXED SO AS TO FACE AN OPENING 11K OF THE ENGINE 5 CASE 11. A GAS-LIQUID SEPARATION CHAMBER 83 IS FORMED BETWEEN A COVER MEMBER 68 COVERING THE OPENING ILK AND THE BEARING HOLDER 66. THEREFORE, BY UTILIZING THE BEARING HOLDER 66 AS A PART OF THE WALL SURFACE OF THE GAS-LIQUID SEPARATION CHAMBER 83, THE GAS-LIQUID SEPARATION CHAMBER 83 CAN BE PARTITIONED WITHOUT 10 INCREASING THE NUMBER OF COMPONENTS AND WITHOUT FORMING A SPECIAL WALL SURFACE IN THE ENGINE CASE 11.)
Assignee/Applicant First	HONDA MOTOR CO LTD
Assignee Count	2
Inventor	SATO YOSHIKAZU   KAWAGUCHI NOBORU
Inventor Count	2
Publication Country Code	MY
Publication Kind Code	A
Publication Month	12
Publication Year	2012
Application Country	MY
Application Month	6
Application Year	2006
Priority Country	JP   JP
Priority Date - Earliest	6/23/2005
Priority Month	06   06
Priority Year(s)	2005
Earliest Priority Year	2005
IPC Class	F01
IPC Class Group	F01M0013

**Table 2.2, Continued: Data Fields of Malaysian Patent Documents Downloaded from TI**

<b>Data Field</b>	<b>Example in 2012</b>
IPC Section	F
IPC Subclass	F01M
IPC Subgroup	F01M001300
IPC Current Full	F01M001300
IPC Current Full (4 Characters)	F01M
INPADOC Family Members	MY147682A   AR54495A1   AU2006260107A1   AU2006260107B2   BRPI0612512A2   CA2608640A1   CA2608640C   CN101194094A   CN101194094B   EP1895136A1   EP1895136A4   EP1895136B1   JP04283251B2   JP04573712B2   JP2007002740A   JP2007002748A   KR2008007401A   KR951422B1   PA8681901A1   PE20070257A1   TWI323312B   US20090064642A1   US8123829B2   WO2006137520A1

Following the process adopted by Graff et al. (2003) on standardizing each assignee organization's name, the information of an assignee organization in the "Assignee/Applicant" data field was examined and adjusted to reflect a uniform version and had the correct spelling. Then, all documents assigned to smaller entities that were known to be wholly owned by larger entities were aggregated under the names of the respective parent organization's name. Such aggregation was not done for international subsidiaries of multinational corporations: in this case the subsidiary entity listed as assignee was not changed to reflect the parent corporation's name and country. For example Sony (Malaysia) Sdn Bhd of Malaysia was not aggregated under the parent organization Sony Corporation of Japan, as this Malaysian Sony subsidiary is fully operationalized firm in Malaysia. In most cases, the patent document that was assigned to this entity originated from inventors in Malaysia. However, for entities that had been fully acquired, for joint venture that carried a new name, and for entities that changed their name, their names in the dataset were adjusted to reflect the current name of the new entity. For example, the Minnesota Mining and Manufacturing Co, Minnesota Mining and Manufacturing, and 3M

Innovative Properties Company, were all standardized under “3M”. Each assignee was reviewed manually to determine their current status.

Each patent record could have one or more assignees listed in the Assignee/Applicant data field. To ensure that all assignees were represented, the first three assignees listed under the assignee/applicant field were considered separately. Of the total 40,150 patents granted in Malaysia, 38,665 were assigned to one assignee, 1,328 were assigned to two assignees, 139 were assigned to 3 assignees. Only 42 patent documents had more than 3 assignees. This resulted in 41,870 separate assignee designations.

In the majority of patent records, the data recorded in the “Assignee/Applicant” field included a two-letter country code for each assignee listed, identifying the nation in which that entity is incorporated. However, for that share of the 41,870 assignee designations that lacked such information, the assignee records were reviewed to identify the home country for each of assignees that did not already have a country code provided in the assignee field. As in the step above, this step was carried out manually by reviewing each assignee and determining their country of origin and for subsidiaries, the country in which they are operating.

Then, all of the 41,870 assignee designations were once again reviewed manually to categorize them according to the type of entity. This typology identified whether the entity belongs to the commercial sector, i.e. if it is a firm or an individual, or if it belongs to the non-commercial sector, i.e. if it is a university, a research institute, or a governmental organization. The primary purpose of this step is to be able to identify the extent to which non-commercial entities are engaged in patenting. An additional purpose of this step is to be able to identify when inventions arise as the result of collaboration between commercial and non-commercial

organizations.<sup>3</sup> Commercial type entities include firms and individual inventors and their primary purpose of establishment is profit oriented. Universities, research institutes and governmental organization were classified under non-commercial entities in which their primary purpose is not profit making.

The original patent data does not indicate whether patent protection remained in force for a given granted patent or whether rights have been subsequently transferred from the original assignee to other assignee(s), whether through licensing, sale or other transactions (Graff et al. 2003). Although licensing has been cited as the most commonly used transaction in the public (i.e. non-commercial) sector, such transactions are not recorded in the patent office data and are generally not publicly accessible (Graff et al. 2003).

The next step in this process was to carry out patent analysis, including exploratory or summary statistics per data field. This was done using Microsoft Access and Excel by first using queries, and filters to identify specific data needed to answer each respective research question. In a novel patent landscape analysis, such as this, even simple summary statistics can be very valuable indicators in helping construct and communicate evidence of innovation activities that are going on in Malaysia.

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<sup>3</sup> Often, policymakers and scholars would categorize such efforts as “public-private partnerships.” However, due to the legal nature of some Malaysian firms as state owned enterprises, some confusion may arise with such terminology. It was therefore decided to categorize all assignee entities as either “commercial” or “non-commercial” rather than “private” or “public” and thus be able to identify the results of collaboration between commercial and non-commercial entities separately from their legal nature.



### **2.2.2 Methods for Patent Landscape Analysis of Agricultural Technologies in Malaysia**

In order to learn about the patenting trends in the Malaysian agricultural sector, we had to first categorize the top International Patent Classifications (IPCs) into five major industrial sectors: Agriculture & Food; Medical & Pharmaceutical; Chemicals & Petroleum; Engineering, Manufacturing & Construction; and Electronics, Semiconductors & Computing. IPC classifies patents and utility models according to different areas of technology. To do this exercise, firstly, all the IPCs listed under the "Current IPC" field of the 40,150 patent granted documents were broken down into single records. For example, from Table 2.2, the data string "F01M001300 | H05F000302 | H04W008000" were listed singly by removing the delimiter (|). Subsequently, all these IPCs were counted to determine how many times each IPC appeared. Then, the total number of each IPCs was ranked to obtain the top 50 IPCs. Subsequently, the 8-digit IPCs were broken down into 3-digit or 4-digit IPCs to enable them to be categorized into the 5 major industrial sectors mentioned above. The 3-digit or 4-digit IPCs associated with the major industrial sectors are:

- i. Agriculture/Food = A01, A23, C11
- ii. Medical/Pharmaceutical = A61
- iii. Chemicals/Petroleum = B01, C01, C02, C07, C08, C09, C10, C23, G01N
- iv. Engineering/Manufacturing/Construction = B23, B29, B32, B65, B66, C04, E21, F16,
- v. Electronics/Semiconductors/Computing = G06, G01R, G02, G11, H01, H04, H05

Then, five new dummy variable fields were created in an Excel spreadsheet that also had "Publication Number" and "Current IPC" for each patent. Text filter were used over "Current IPC". Whenever a granted patent's Current IPC field contains the text strings "A01" or

"A23" or "C11" that granted patent was assigned "1" in the dummy-variable field for "Agriculture/Food". The text filter exercise was repeated for each 3-digit or 4-digit string. The total number of patents that were identified as involving agriculture and food technologies was 2,755.

The discussion on the patenting trend in the agriculture and food further emphasizes the patenting of agbiotech and agchemicals technologies. To identify patents over agbiotech and agchemicals technologies, a separate further exercise was carried out. From the 2,755 records categorized broadly under the agriculture and food sector, four new dummy variables were created in the Excel sheet that also had "Publication Number" and "Current IPC" for each patent. Text filter was used over "Current IPC". Whenever a granted patent's "Current IPC" field contained the text string that is affiliated with agbiotech or agchemicals or food or others sub-sectors that granted patent was assigned "1" in the dummy variable field for that particular sub-sector. The text filter exercise was carried out for all 2,755 patent documents for each 8-digit string associated with agbiotech and agchemicals technologies and 4-digit string associated with food technologies. All remaining were designated as "other" agricultural and food technologies. Out of the agricultural and food patent documents, only 103 were categorized as agbiotech and 1, 109 were categorized as agchemicals technologies.

To determine the assignees of the agbiotech and agchemicals patents, we followed the same exercise carried out for the economy wide patenting. In the economy wide patenting, one patent document could be designated one or more assignees, and as such we included only the first three assignees listed under the "Assignee/applicant" field in the original data.

Since the patent documents were already classified according to whether their assignees were commercial entities, i.e. firm and individuals, and non-commercial entities, i.e. universities, research institutes and governmental organizations during the economy wide patent exercise, we reviewed the 115 agbiotech patent assignee designations and 1,150 agchemicals patent assignee designations to verify accuracy.

## **2.3 Results and Discussion of Economy Wide Patenting Trend in Malaysia**

### ***2.3.1 Malaysian Patents Granted, Filed and Earliest Filing Date***

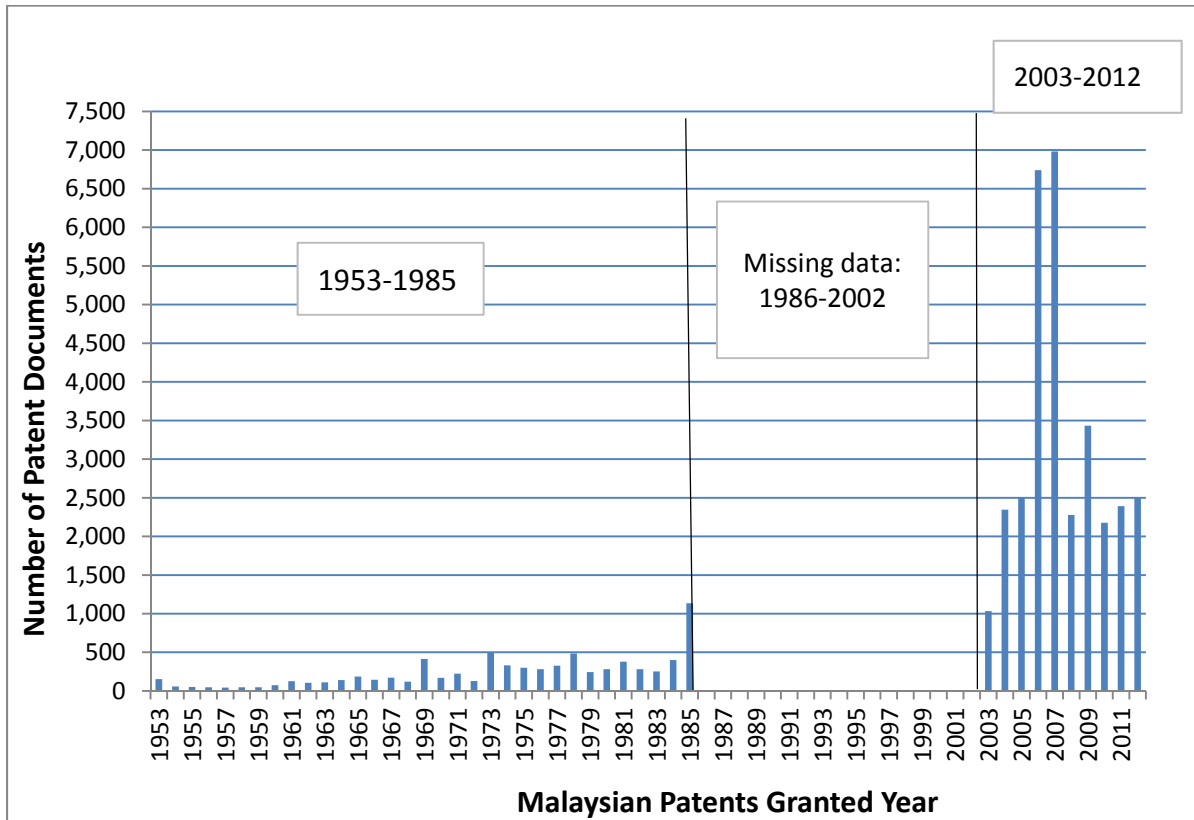
To determine the trend of innovations being introduced to the Malaysian economy, we needed to first learn how many patents are filed, granted in Malaysia and the first filing date of these inventions. The number of patents granted is similar to patents filed from 1953-1985 (Figure 2.2). However, there was a gap in the patent data between 1986 and 2002.<sup>4</sup> From 2003 onwards, the number of patents granted increased and subsequently peaked during the 2006-2007 period. The peak was due to the hiring of new patent examiners who assisted in clearing all backlogs of filed patents (personal communication with MyIPO officer in 2014). New intake of patent officers or examiners depends on the demand for the technological fields filed. Since new technologies are developing rapidly, technological changes tend to occur more quickly and as such the probability of hiring new officers will appear to be continuous.

Interestingly, the average annual grant rate during the later time period (at 3,239 patents/year) was over 13 times the average annual grant rate during the earlier time period

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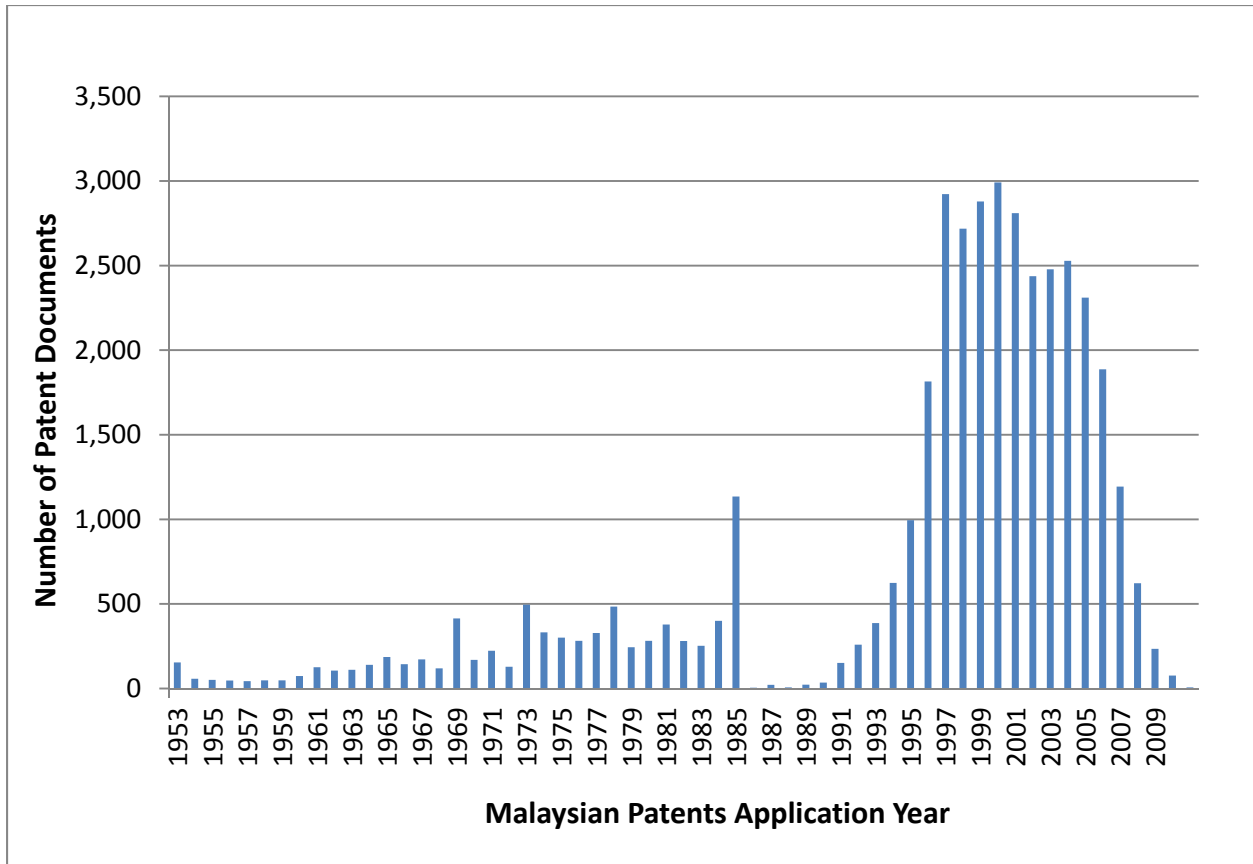
<sup>4</sup> This gap was verified to also occur in Malaysian patent data listed at the European Patent Office's database, Espacenet. While it was not possible to verify the cause, according to one source, this gap was attributable to the insufficient number of patent examiners at MyIPO to process patents filed (personal communication with MyIPO officer in 2014).

(at 235 patent/year). Even considering just the average grant rate of the last five years of the later period, from 2008 to 2012, to avoid outliers due to the backlog at MyIPO, the average annual grant rate (at 2,556 patents/year) compared to the last five years of the earlier period, from 1981-1985 (at 489 patents/year), was still five times greater.



**Figure 2.2: Number of Patents Granted in Malaysia from 1953-2012**

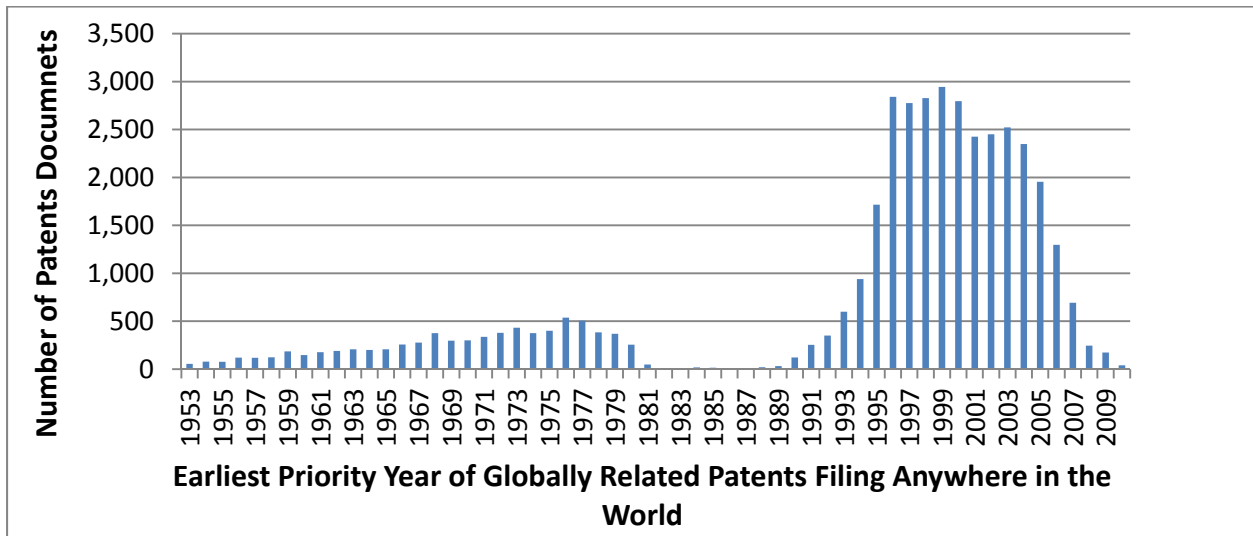
Figure 2.3 (below) shows the 40,180 Malaysian patent records in the dataset, in this case, according to the year in which the patent was applied for in Malaysia. The trend is similar to the one seeing in Figure 2.2, with a slight shift of the series to the left. The number of patents filed in Malaysia during the later period, from 1986 to 2011 (32, 421 patents), was approximately four times the numbers filed between 1953 and 1985 (7,759 patents).



**Figure 2.3: Number of Patents Filed in Malaysia from 1953-2010**

When seeking patent protection for the same invention in several countries, the legal rule of priority (or “first-to-file”) comes into play. An inventor/applicant does not have to file an application in all countries in which patent protection is desired at the same time. According to WIPO, one who files the application first for a given invention is granted the patent. The Paris Convention for the Protection of Industrial Property provides that once an applicant file an application in a country party to the Convention, he/she is entitled to claim priority for a period of twelve months and the filing date of that first application is considered the “priority date”. Figure 2.4 shows that. Therefore, when an inventor applies for protection in other member countries (signatories to the Paris Convention) during those twelve months, the filing date of his/her first application is considered to have “priority” relative to subsequent applications filed

after that date for the same invention. In such a case, the applicant still succeeds in being the first-to-file in other member countries, even if there are other applications filed before the filing date of his/her application in those countries.

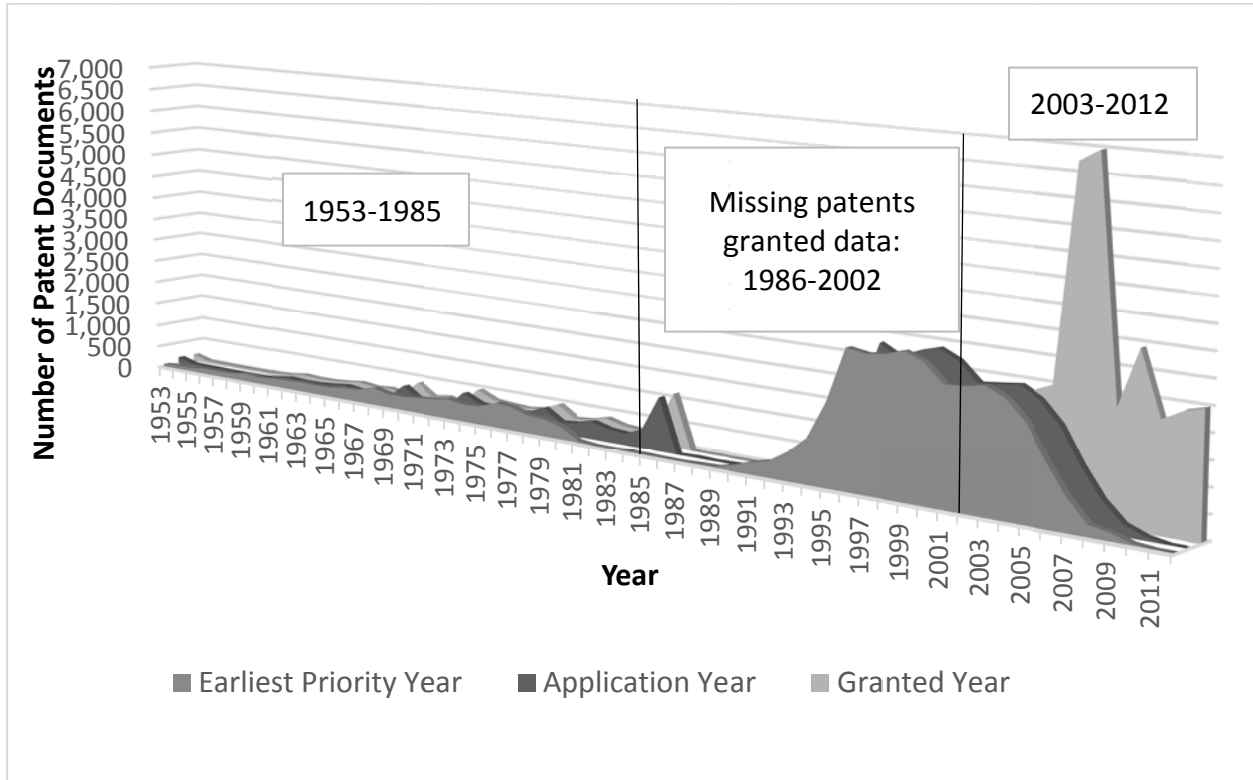


**Figure 2.4: Number of Patents Granted Earliest Priority Date from 1953-2010**

Figure 2.5 shows that earliest priority date follows closely with application dates and that granted follow closely with application date. Between the two periods (1953-1985 and 2003-2012), the time lag from earliest priority date (anywhere in the world) to application date (in Malaysia) has significantly reduced from 6 years to just 10 months in recent years (2008-2012). This could be attributable to several possibilities discussed by several other scholars (Pavitt 1980, 1985, Basberg 1987, Griliches 1990, Archibugi 1992):

- i. If assignees are filing for patent protection of their inventions in Malaysia first, hence the application date would be the same as the earliest-priority date. Such inventions are probably those generated in Malaysia, with inventors' home country designated as Malaysia, and thus it makes sense for the inventor/applicant to file for patent protection in Malaysia (home advantage).

- ii. Foreign inventors/applicants are filing for patent protection earlier in Malaysia than previously, so as to maximize their net returns in the Malaysian market.
- iii. Foreign inventors/applicants are filing for patent protection in Malaysia so to avoid imitations to their inventions in the Malaysian market.



**Figure 2.5: Comparing the Annual Number of Patent Records by (i) Earliest Priority Date Globally, (ii) Filing Date in Malaysia, and (iii) Grant Date of the Malaysian Patent, 1953- 2012**

The pendency period between application and publication dates between 1953 and 1985 was not accounted since as previously mentioned, the patent granted process during that period was based off re-registering United Kingdom’s patents. However, between 2008 and 2012, the pendency period between application and publication dates for a patent filed for protection in Malaysia is within the lag times observed in the two most growing patent applications offices, i.e. USPTO and JPTO. Table 2.3 demonstrates this. According to WIPO

(2011), in 2007, the average pendency time for a patent to be granted was 2 years and 8 months in USPTO while it was 3 years and 9 months in JPTO. Our findings suggest that MyIPO is performing well on the patent approval process despite the increase number of patents filed. MyIPO seems to have been able to cater to the growing technological patent complexities, reduce patent backlogs and shorten time lags.

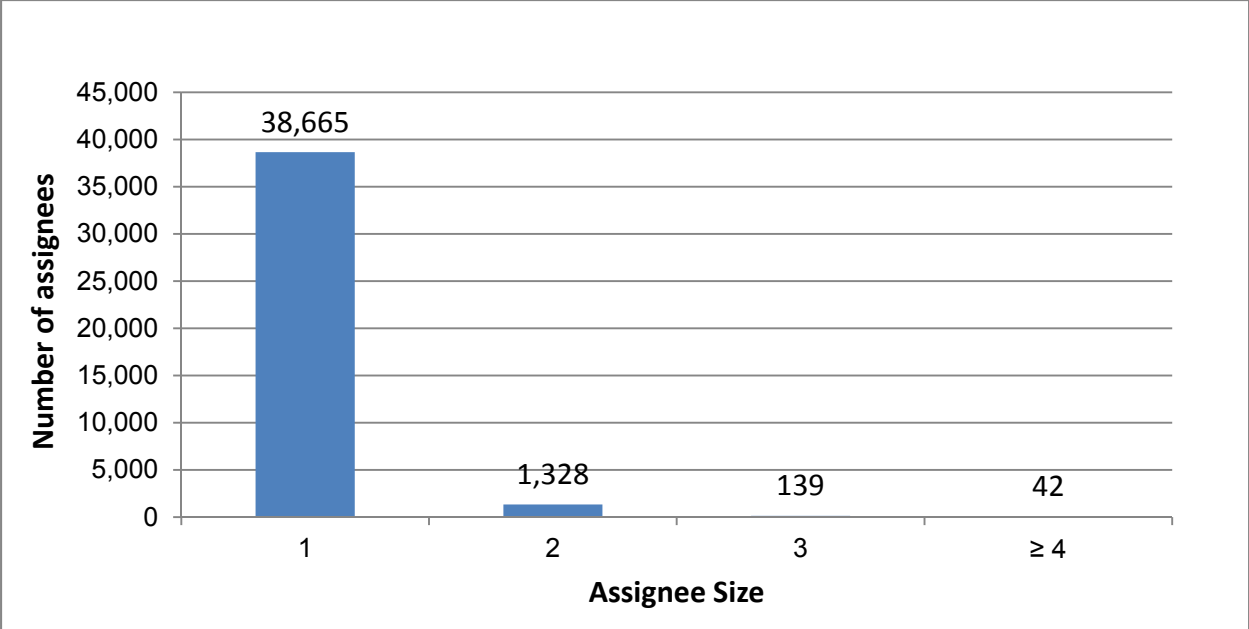
**Table 2.3: Pendency Period of Patents Filed in Malaysia**

<b>Period</b>	<b>Earliest Priority Date Globally to Malaysian Application Date</b>	<b>Malaysian Application Date to Malaysian Publication Date</b>	<b>Total Number of Patents Granted in Malaysia</b>
1953-1985	6 years	n/a	7,759
2008-2012	10 months	2 years and 9 months	12,779

### **2.3.2 Patent Assignees**

As mentioned previously, an assignee could be an individual and/or an organization assigned the rights of the patent. Additionally, the records in the assignee data field were cleaned, standardized, categorized as commercial and non-commercial entities and were assigned country identifications. Patents granted in Malaysia were mostly assigned to one assignee (38,665) followed by 1,328 patents assigned to two assignees, 139 patents assigned to 3 assignees and remaining 42 patents were assigned to between 4-8 assignees (Figure 2.6).





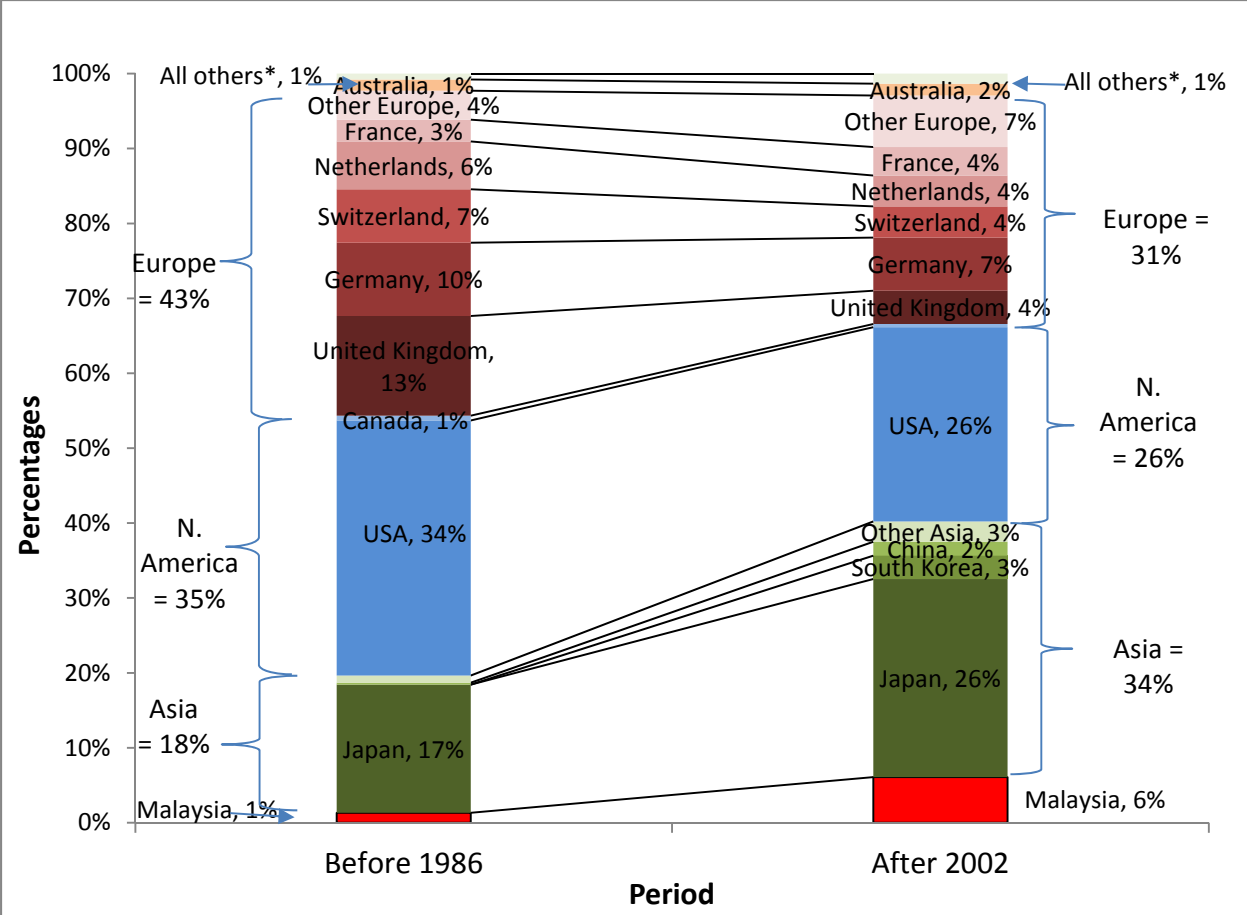
**Figure 2.6: Distribution of Numbers of Assignees per Patent**

Among the assignees that file for patent protection in Malaysia, many are based in Asia, Europe and North America (Figure 2.7). Fully 94 percent of patents granted by MyIPO are assigned to foreign firms and individuals. At present, Malaysian firms and individuals attained only six percent of the total share, an increase from 1 percent in the years 1953 through 1985. While it is relatively low, the 6 percent patent share is a significant increase for Malaysian inventorship.

The percentage of total foreign assignees' share has reduced from 99 percent in the earlier period (1953-1985) to 94 percent in the latter period (2003-2012). In 1953 and 1985, Europe owned a large chunk of the share of patents granted (43 percent) with United Kingdom (UK) dominating the bigger slice with 13 percent, followed by Germany with 10 percent, Switzerland 7 percent, Netherlands 6 percent, France 3 percent and other European countries with the remaining 4 percent. Interestingly, while Europe is still a big player in the Malaysia IP protection agenda, it no longer dominates. Additionally, other European countries have taken

over UK's position as the leader in this region. UK is not the only country within the European region that has reduced its share portion in the Europe from 13 percent to 4 percent, Germany has too from 10 percent to 7 percent, Switzerland from 7 percent to 4 percent, and Netherlands from 6 percent to 4 percent. However, France has increased its share from 3 percent to 4 percent and the other European countries have increased their share 4 percent to 7 percent.

The most fascinating piece of the patent story lies in Asia. It only owned 18 percent of the granted patents share between 1953 and 1985, with Japan holding the lion share. Japan still continues to dominate the share of patent granted to Asian assignees, between 2003 and 2012. Overwhelmingly, the percentage of Asian shares has increased, from 18 percent in the earlier period to 34 percent in the latter period. South Korea and China assignees are the 2 new comers within the Asian region that are beginning to make a mark in the Malaysian IP agenda. Singapore and India each with 1 percent share are the other 2 assignees within Asia that have also made a mark in Malaysia's IP stage. United States, continues to dominate the North America share with a smaller share. Its share was 34 percent during 1953-1985 and declined to 26 percent between 2003 and 2012.



**Figure 2.7: Assignee Countries: Comparison of Two Periods**

The increase of patents granted to assignees from Japan, US, South Korea, China and Australia (Figure 2.8) can be attributed to increases in imports from these countries between 2008 and 2012 (Figure 2.9). A firm’s decision to file for patent protection in destination countries depends, in part, on its export shares to those countries (Smith 2001, Yang and Kuo 2008). It will seek to protect its innovations if its exports and foreign direct investment increases in a particular country. To ascertain this, we carried out a Pearson Correlation analysis and obtained a coefficient correlation of 0.6 between average top assignees countries granted Malaysian patents and average Malaysia’s import between 2008 and 2012. This is an indication

that a relationship does exist between top assignee countries granted Malaysian patents and average Malaysia's import from these assignee countries.

As mentioned earlier, the reason being is because patenting in a foreign jurisdiction involves a much higher cost as compared to patenting in an applicant's home country. To justify filing for patent protection in a destination country, it is very much dependent on the firm's potential return on investment on its strategy for further innovation or other commercial activity in the destination country.

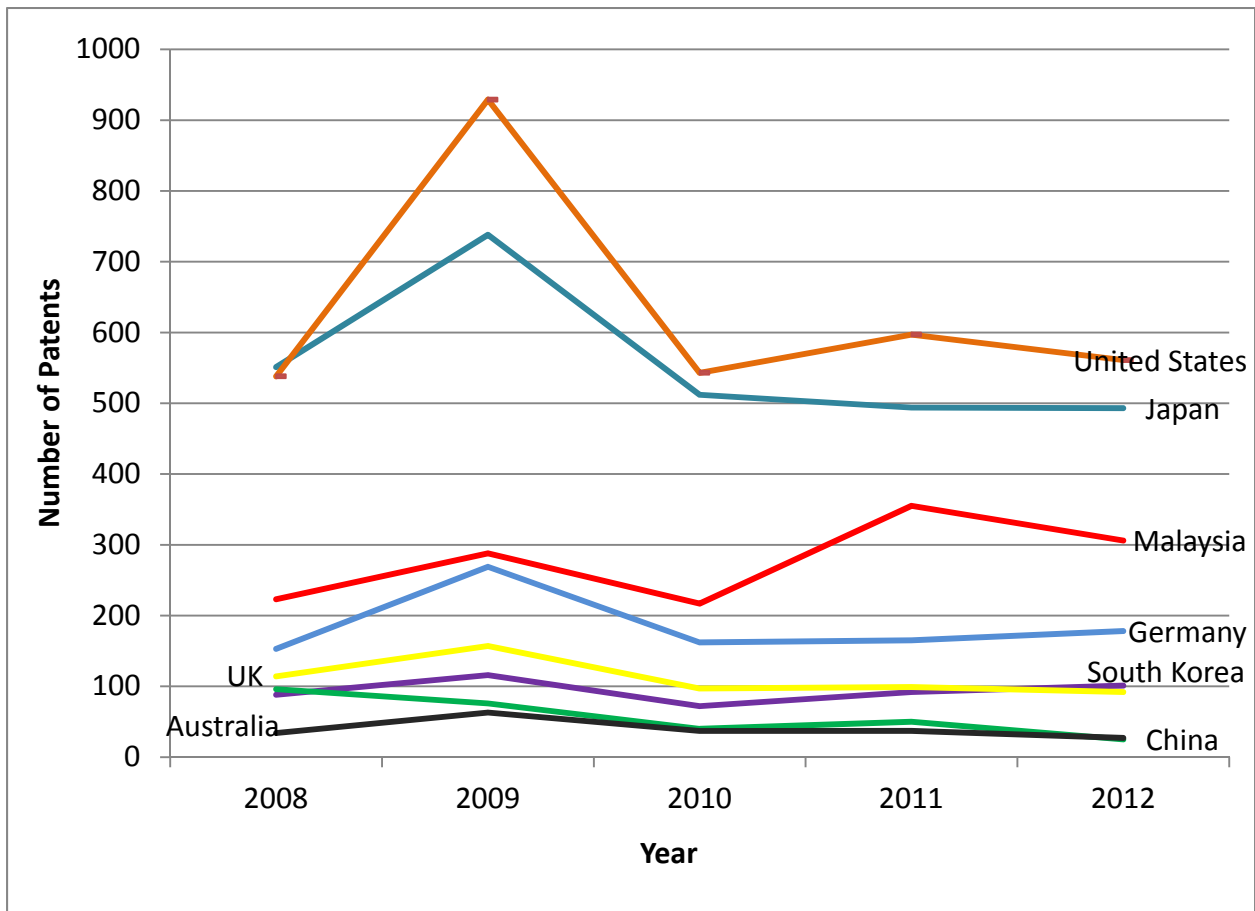
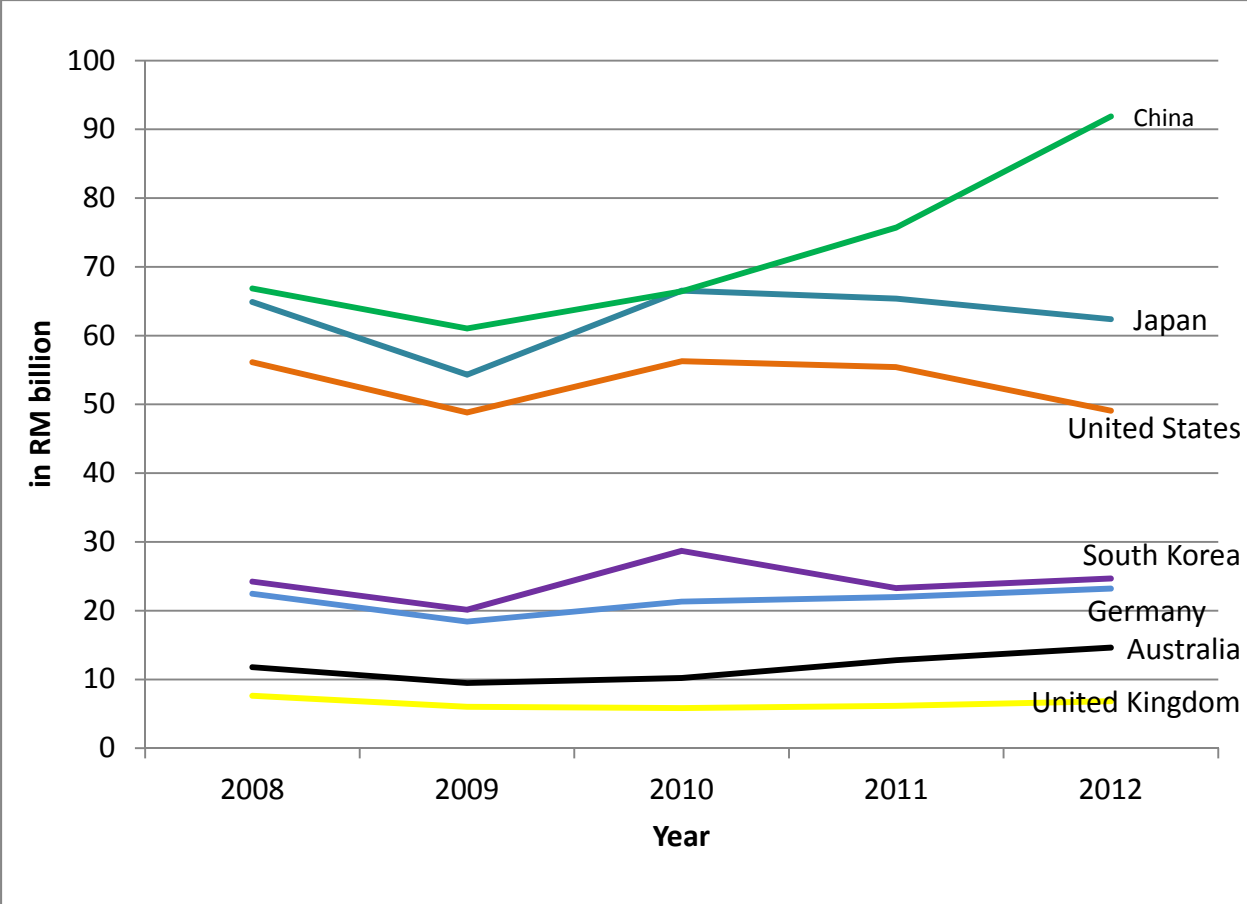


Figure 2.8: Top Assignee Countries of Patents Granted in Malaysia from 2008-2012

On average between 2008 and 2012, Asian sources account for approximately 62 percent of Malaysia's imports, with China having the bigger slice (14 percent), followed closely by Japan with 12 percent and South Korea with 5 percent (Table 2.4). Malaysia imports 10.5 percent of its total imports from North America and US holds the big bulk of that regional share (10 percent). Imports from Europe represent only 7.5 percent of Malaysia's total imports with Germany dominating the largest piece of Europe's share (4 percent), followed by France (2 percent), United Kingdom and Netherlands, 1 percent respectively. Import share from Australia is approximately 2 percent of total Malaysia's imports. The other contributing reason to high share of patents granted to U.S. and Japanese assignees is the foreign direct investment history of US and Japanese firms in Malaysia (Govindaraju and Wong 2011). South Korea also showed an increasing patenting trend due to their increasing presence in Malaysian manufacturing industry in recent years.



**Figure 2.9: Malaysia's Imports from 2008-2012**

Source: EPU 2012 and 2013

**Table 2.4: Malaysia's Imports and Percentage of Imports from 2008-2012**

Region/Country	2008		2009		2010		2011		2012		2008-2012	
	Imports	% of Total	Imports	% of Total	Imports	% of Total	Imports	% of Total	Imports	% of Total	Imports' Average	% of Total Average
<b>Asia</b>	<b>320.7</b>	<b>61.7%</b>	<b>275.5</b>	<b>63.4%</b>	<b>341.5</b>	<b>64.6%</b>	<b>353.3</b>	<b>61.6%</b>	<b>370.3</b>	<b>61.0%</b>	<b>332.2</b>	<b>62.4%</b>
Japan	64.9	12.5%	54.3	12.5%	66.5	12.6%	65.4	11.4%	62.4	10.3%	62.7	11.8%
South Korea	24.2	4.7%	20.1	4.6%	28.7	5.4%	23.3	4.1%	24.7	4.1%	24.2	4.5%
China	66.9	12.9%	61.0	14.0%	66.4	12.6%	75.7	13.2%	91.9	15.1%	72.4	13.6%
Other Asia	164.7	31.7%	140.0	32.2%	179.8	34.0%	189.0	32.9%	191.4	31.5%	173.0	32.5%
<b>North America</b>	<b>59.4</b>	<b>11.4%</b>	<b>51.1</b>	<b>11.8%</b>	<b>59.1</b>	<b>11.2%</b>	<b>58.2</b>	<b>10.1%</b>	<b>52.0</b>	<b>8.6%</b>	<b>56.0</b>	<b>10.5%</b>
USA	56.1	10.8%	48.8	11.2%	56.3	10.6%	55.4	9.7%	49.1	8.1%	53.1	10.0%
Canada	3.3	0.6%	2.3	0.5%	2.9	0.5%	2.8	0.5%	2.9	0.5%	2.8	0.5%
<b>EU</b>	<b>46.9</b>	<b>9.0%</b>	<b>14.7</b>	<b>3.4%</b>	<b>49.4</b>	<b>9.3%</b>	<b>41.2</b>	<b>7.2%</b>	<b>48.1</b>	<b>7.9%</b>	<b>40.1</b>	<b>7.5%</b>
United Kingdom	7.6	1.5%	6.0	1.4%	5.8	1.1%	6.1	1.1%	6.8	1.1%	6.5	1.2%
Germany	22.5	4.3%	18.4	4.2%	21.3	4.0%	22.0	3.8%	23.2	3.8%	21.5	4.0%
Netherlands	3.7	0.7%	3.5	0.8%	3.4	0.6%	3.6	0.6%	5.0	0.8%	3.8	0.7%
France	7.6	1.5%	7.1	1.6%	6.3	1.2%	9.5	1.7%	13.0	2.1%	8.7	1.6%
Other Europe	5.6	1.1%	-20.3	-4.7%	12.6	2.4%	0.0	0.0%	0.0	0.0%	-0.4	-0.1%
<b>Australia</b>	<b>11.8</b>	<b>2.3%</b>	<b>9.5</b>	<b>2.2%</b>	<b>10.2</b>	<b>1.9%</b>	<b>12.8</b>	<b>2.2%</b>	<b>14.6</b>	<b>2.4%</b>	<b>11.8</b>	<b>2.2%</b>
<b>All others</b>	<b>81.09</b>	<b>15.6%</b>	<b>83.9</b>	<b>19.3%</b>	<b>68.7</b>	<b>13.0%</b>	<b>108.1</b>	<b>18.8%</b>	<b>122.4</b>	<b>20.1%</b>	<b>92.8</b>	<b>17.4%</b>
<b>TOTAL</b>	<b>519.8</b>		<b>434.7</b>		<b>528.8</b>		<b>573.6</b>		<b>607.4</b>		<b>532.9</b>	

Source: EPU 2012 and 2013

Between 1953 and 1985, amongst the top patent granted assignees in Malaysia, 11 firms were US based and in total they owned approximately 15 percent of the total patent documents filed (Table 2.5). This was indeed surprising considering the fact that UK dominated the country share in Malaysia's patent scene during this period. Majority of the patenting activities took place in the Medical/Pharmaceutical industrial sector in which was led by European and US firms.

In the latter period (2003-2012), assignees from the electronics, semiconductors and computing sector dominated the patenting activities in Malaysia with 13 percent market share (Table 2.6). The country mix for the patent protection in this sector varied, with 4 Asians, 3 Europeans and 3 Americans.



**Table 2.5: Top Patent Assignees in Malaysia from 1953-1985**

Organization	Country	Industrial Sector	% of Total	Rank
Novartis	Switzerland	Medical/Pharmaceutical	3.0%	1
Akzo Nobel	Netherlands	Chemicals/Petroleum	3.0%	2
Dunlop	United Kingdom	Engineering/Manufacturing/Construction	2.9%	3
Sony	United States	Electronics/Semiconductors/Computing	2.4%	4
Yoshida	Japan	Engineering/Manufacturing/Construction	2.3%	5
Pfizer	United States	Medical/Pharmaceutical	2.0%	6
Texas Instrument	United States	Electronics/Semiconductors/Computing	1.8%	7
Suwa Seikosha	Japan	Electronics/Semiconductors/Computing	1.7%	8
Sanofi	France	Medical/Pharmaceutical	1.6%	9
Bayer	Germany	Medical/Pharmaceutical	1.4%	10
Eastman Kodak	United States	Engineering/Manufacturing/Construction	1.4%	11
Du Pont	United States	Chemicals/Petroleum	1.3%	12
ExxonMobil	United States	Chemicals/Petroleum	1.3%	13
Hitachi	Japan	Electronics/Semiconductors/Computing	1.2%	14
Colgate-Palmolive	United States	Engineering/Manufacturing/Construction	1.1%	15
Shell	Netherlands	Chemicals/Petroleum	1.0%	16
Union Carbide	United States	Chemicals/Petroleum	1.0%	17
Eli Lilly and Company	United States	Medical/Pharmaceutical	1.0%	18
Hoffman La Roche	Germany	Medical/Pharmaceutical	1.0%	19
GlaxoSmithKline	United Kingdom	Medical/Pharmaceutical	0.8%	20
Honeywell	United States	Engineering/Manufacturing/Construction	0.8%	21
Dart Industries	United States	Engineering/Manufacturing/Construction	0.7%	22
Malaysian Rubber Board	Malaysia	Agriculture/Food	0.6%	23

**Table 2.6: Top Patent Assignees in Malaysia from 2003-2012**

Organization	Country	Industrial Sector	% of Total	Current Rank (Previous Rank)
Sony	Japan	Electronics/Semiconductors/Computing	2.2%	1 (4)
Ericsson	Sweden	Electronics/Semiconductors/Computing	2.0%	2
BASF	Germany	Chemicals/Petroleum	2.0%	3
Matsushita	Japan	Electronics/Semiconductors/Computing	1.8%	4
Samsung	South Korea	Electronics/Semiconductors/Computing	1.5%	5
Technicolor	France	Electronics/Semiconductors/Computing	1.5%	6
Unicharm	Japan	Chemicals/Petroleum	1.3%	7
Shell	Netherlands	Chemicals/Petroleum	1.1%	8 (16)
IBM	United States	Electronics/Semiconductors/Computing	1.0%	9
Royal Philips	Netherlands	Electronics/Semiconductors/Computing	0.9%	10
ExxonMobil	United States	Chemicals/Petroleum	0.9%	11
Intel	United States	Electronics/Semiconductors/Computing	0.9%	12
Novartis	Switzerland	Medical/Pharmaceutical	0.7%	13
Toshiba	Japan	Electronics/Semiconductors/Computing	0.6%	14
Unilever	United Kingdom	Engineering/Manufacturing/Construction	0.6%	15
Honda	Japan	Engineering/Manufacturing/Construction	0.6%	16
Qualcomm	United States	Electronics/Semiconductors/Computing	0.6%	17
Colgate-Palmolive	United States	Engineering/Manufacturing/Construction	0.5%	18
Procter & Gamble	United States	Engineering/Manufacturing/Construction	0.5%	19
Interdigital Technology Corporation	United States	Electronics/Semiconductors/Computing	0.5%	20
3M	United States	Electronics/Semiconductors/Computing	0.5%	21
Hitachi	Japan	Electronics/Semiconductors/Computing	0.5%	22
Hoffman-La Roche	Switzerland	Medical/Pharmaceutical	0.5%	23

In the earlier period, within the Malaysian top patent assignees, patenting activities were mainly concentrated in the Agriculture/Food Sector, with the Malaysian Rubber Board (MRB) owning a large share (61 percent) of the total granted to Malaysian assignees (Table 2.7).

However, in the latter period (2003-2012), the Malaysian academic sector dominated the patent ownership share (12 percent) of Malaysian assignees (Table 2.8) in Malaysia. Malaysian Palm Oil Board and Universiti Putra Malaysia are two newcomers and both of them combined owned 10 percent of total Malaysian patent documents assigned to Malaysian assignees. Ironically, both never made it to the top Malaysian assignees in the earlier period. MRB patent ownership declined by almost 60 percent in the latter period, with less than 1 percent patent ownership share. Universiti Malaya, the sole academic institution that made it to the top Malaysian assignee chart during the 1953-1985 period had a 4 percent patent ownership during the earlier period (within the Malaysian assignees) but recently, its share has reduced to 2.4 percent in the latter period. According to Graff et al. (2007), research institutes and universities in Malaysia are ahead of peer countries such as Philippines in terms of IP management.

**Table 2.7: Top Malaysian Patent Assignees in Malaysia from 1953-1985**

<b>Organization</b>	<b>Industrial Sector</b>	<b>% of Total Assigned</b>	<b>% of Malaysian Total</b>	<b>Rank (within Malaysia)</b>
Malaysian Rubber Board	Agriculture/Food	0.63%	61%	1
Kepong Plantations	Agriculture/Food	0.04%	4%	2
Universiti Malaya	Academic	0.04%	4%	3
Rothmans (Malaysia)	Engineering/Manufacturing/Construction	0.04%	4%	4
Khoo Tian	-	0.03%	2%	5
Sime Darby	Agriculture/Food	0.03%	2%	6
Tronoh Mines	Engineering/Manufacturing/Construction	0.03%	2%	7
Poly Plastics (Malaya)	Engineering/Manufacturing/Construction	0.01%	1%	8
Associated Aluminium & Metal Industries Sdn Bhd	Engineering/Manufacturing/Construction	0.01%	1%	9
Century Plastic Sdn Bhd	Engineering/Manufacturing/Construction	0.01%	1%	10
Fe Zuellig (Malaysia)	Medical/Pharmaceutical	0.01%	1%	11
Insulations (Malaya)	Engineering/Manufacturing/Construction	0.01%	1%	12
Lee Choong Wah	-	0.01%	1%	13
Mac & Lai Company Sdn Bhd	-	0.01%	1%	14
Malayan Tin Dredging	Engineering/Manufacturing/Construction	0.01%	1%	15
Pernas Charter Management	Engineering/Manufacturing/Construction	0.01%	1%	16
Petronas	Chemicals/Petroleum	0.01%	1%	17
Selangor Pewter	Engineering/Manufacturing/Construction	0.01%	1%	18
Socfin	Agriculture/Food	0.01%	1%	19
Syarikat Gibson Perniagaan	Engineering/Manufacturing/Construction	0.01%	1%	20
Ting Ted Add	-	0.01%	1%	21
Universiti Sains Malaysia	Academic	0.01%	1%	22
Ya Mei Hung	-	0.01%	1%	23

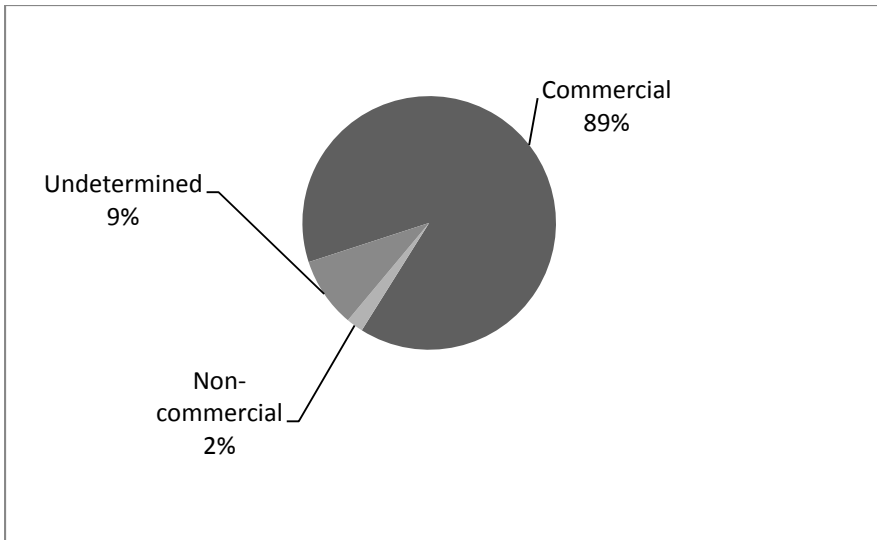
**Table 2.8: Top Malaysian Patent Assignees in Malaysia from 2003-2012**

<b>Organization</b>	<b>Industrial Sector</b>	<b>% of Total Assigned</b>	<b>% of Malaysian Total</b>	<b>Rank (within Malaysia)</b>
Malaysian Palm Oil Board	Agriculture/Food	0.28%	4.9%	1
Universiti Putra Malaysia	Academic	0.27%	4.7%	2
MIMOS	Electronics/Semiconductors/Computing	0.23%	4.1%	3
Universiti Malaya	Academic	0.14%	2.4%	4
Telekom Malaysia	Electronics/Semiconductors/Computing	0.12%	2.1%	5
Universiti Sains Malaysia	Academic	0.10%	1.8%	6
Sony (Malaysia)	Electronics/Semiconductors/Computing	0.10%	1.7%	7
SIRIM	Engineering/Manufacturing/Construction	0.09%	1.6%	8
Universiti Kebangsaan Malaysia	Academic	0.09%	1.6%	9
Petronas	Chemicals/Petroleum	0.08%	1.5%	10
Universiti Teknologi Mara	Academic	0.08%	1.4%	11
Harn Marketing Sdn Bhd	Engineering/Manufacturing/Construction	0.06%	1.1%	12
Institut of Technology Petronas	Academic	0.04%	0.7%	13
Matsushita (Malaysia)	Electronics/Semiconductors/Computing	0.04%	0.7%	14
International Islamic University Malaysia	Academic	0.03%	0.5%	15
Silterra Malaysia Sdn Bhd	Electronics/Semiconductors/Computing	0.03%	0.5%	16
Malaysian Agricultural Research and Development Institute (MARDI)	Agriculture/Food	0.02%	0.4%	17
Malaysian Rubber Board	Agriculture/Food	0.02%	0.4%	18
Purecircle Sdn Bhd	Agriculture/Food	0.02%	0.4%	19
Trek Systems Sdn Bhd	Electronics/Semiconductors/Computing	0.02%	0.4%	20
Agro-Bio Fibre Sdn Bhd	Engineering/Manufacturing/Construction	0.02%	0.3%	21
Forest Research Institute of Malaysia (FRIM)	Agriculture/Food	0.02%	0.3%	22
Institute for Medical Research Malaysia (IMR)	Medical/Pharmaceutical	0.02%	0.3%	23

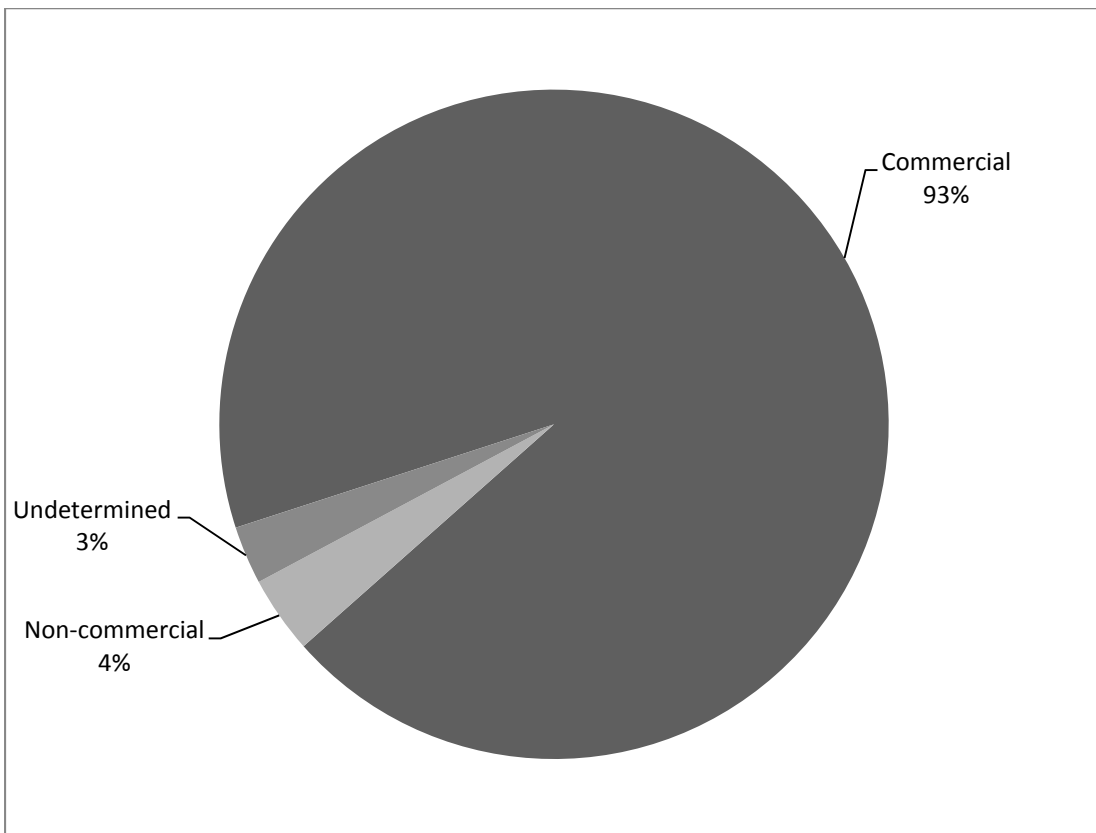
### **2.3.3 Distribution of Patent Assignment**

Each assignee entity was classified according to organizational type, commercial and non-commercial. Commercial type entities include firms and individual inventors and their primary purpose are profit oriented. Academic establishments, research institutes and government organization are classified under non-commercial entities in which their primary purpose is not profit making.

The distribution of Malaysian granted assignee share between commercial and non-commercial entities has evolved over 59 years. From 1953-1985, 89 percent of the share was owned by commercial entities (Figure 2.10). These entities continue to dominate the assignee share distribution, its share portion increased to 93 percent (Figure 2.11) during the 2003-2012 period. Non-commercial share increased to 4 percent in the later period from 2 percent in 1953-1985. The high percentage of patent ownership share assigned to firms is not surprising considering the fact that there are a large number of them in Malaysia (Ghapar et al. 2013). Comparatively, the number of patent documents assigned to commercial entities is greater in Malaysia as compared to US or Europe. In US, over half of the innovations in the pipeline are generated by private sector and in Europe, over a third (Graff et al. 2009)



**Figure 2.10: Distribution of Commercial and Non-Commercial Patent Assigned to Malaysian Patent Granted Assignees from 1953-1985 of 7,892 patents**



**Figure 2.11: Distribution of Commercial and Non-Commercial Patent Assigned to Malaysian Patent Granted Assignees from 2003-2012 of 33,945 patents**

Table 2.9 illustrates the number of granted patent documents listed under these two organizational types. One patent document can be assigned to a number of entities. Between 1953 and 2012, the number of patent documents assigned to non-commercial entities has increased from 170 to 1269. This is an increment of 7.5 times. Foundations/Research Institutes dominated the assignee share within the non-commercial sector in the past. In recent times, universities dominate the patent ownership landscape in Malaysia. In the recent 5 years (2008-2012) alone, non-commercial assignee share reached 7 percent, an indication that the entities classified under this category are filing for more patent protection, with universities assigned half of the patent documents' share in this sector. This finding is not surprising as globally, academic institutions are increasingly becoming major players in the patent arena (Baldini et al. 2006, Singh et al. 2009). The increase in patent filings of academic inventions in European universities was driven by biotechnology revolution and the Bayh-Dole Act-like regulations which were aimed at encouraging patenting in academic institutions (Powell and Owen-Smith 1998, Mowery et al. 2001, Geuna & Nesta 2006). In the US, the rampant growth of patenting activities and licensing of public funded research has been regarded as a new model of academic research, one that fosters economic and social returns from universities (Sampat 2006). In Malaysia, commercialization of public research began with the implementation of the Sixth Malaysia Plan (1991-1995). The Malaysian government emphasized that public R&D programs should be more market oriented and exploit the commercialization process of research and technology (Govindaraju 2010). To do so, government of Malaysia provided avenues for universities and research institutes to own inventions.



**Table 2.9: Number of Malaysian Granted Patent Documents Assigned by Type of Assignee Entity**

<b>Type of Organization</b>	<b>1953-1985</b>	<b>2003-2012</b>	<b>Total</b>
<b><i>Commercial</i></b>			
Firm	6,537 (82.8%)	30,118 (88.7%)	<b>36,655 (87.6%)</b>
Independent Inventors	481 (6.1%)	1,607 (4.7%)	<b>2,088 (5.0%)</b>
<i>Subtotal</i>	<i>7,018 (88.9%)</i>	<i>31,725 (93.5%)</i>	<b><i>38,743 (92.6%)</i></b>
<b><i>Non Commercial</i></b>			
Foundation/Research Institute	91 (1.2%)	447 (1.3%)	<b>538 (1.3%)</b>
University	10 (0.1%)	618 (1.8%)	<b>628 (1.5%)</b>
Government	69 (0.8%)	204 (0.6%)	<b>273 (0.7%)</b>
<i>Subtotal</i>	<i>170 (2.1%)</i>	<i>1,269 (3.7%)</i>	<b><i>1,439 (3.4%)</i></b>
<i>Undetermined</i>	<i>704 (8.9%)</i>	<i>951 (2.8%)</i>	<b><i>1,655 (4.0%)</i></b>
<b>Total</b>	<b>7,892</b>	<b>33,945</b>	<b>41,837</b>

The Malaysian government placed great importance on public-private collaboration since the 1980s, initiated through the Fourth Malaysian Plan. Among the 40,150 patent documents, the percentage of them assigned to a single entity was 95 percent (Figure 2.6). Within the single entities, firms dominate the patent granted assigned in the commercial sector (92 percent) while foundations/research institutes and universities dominate the non-commercial sector (Table 2.10). Out of the patent documents that are jointly assigned, majority of them are collaborations between commercial entities themselves, either through firm-firm, individual-individual or firm-individual (Table 2.11). The propensity for non-commercial to collaborate with non-commercial is higher (23 percent) as compared to propensity for commercial to collaborate with the non-commercial sector (4 percent). The finding of the patent data is further substantiated by the number of alliances formed between academic and research institutes in Malaysia. Universities and research institutes have increased their

collaboration over the years, with a 25 percent growth observed between 2008 and 2009 (MOSTI 2011). The alliances formed by universities and research institutions are found to be essential in leading to new technology development and economic advantages and as such, are fundamental to the economic development of countries (Zuniga 2011). According to Montobbio (2009), research institutes patent because open science is insufficient to impact industry and generate industrial innovation. The rationale behind universities patenting is to facilitate the exploitation of scientific discoveries through utilization of proprietary rights over inventions. Often, inventions generated by universities are in early stages and requires further investment for development (Jensen and Thursby 2001, Colyvas et al. 2002). Hence, commercial sector is reluctant to invest in inventions that could be appropriated or imitated by third parties which could then eat into their potential net returns (Feldman et al. 2007). These types of investments fall into high risk category, as the practicality of the inventions or their market demand have yet to be proven.

Partnership between commercial and non-commercial sectors in the Malaysia innovation arena (at least according to the patent data) is still much desired as a policy strategy by the Malaysian government.

**Table 2.10: Number of Malaysian Granted Patent Documents Assigned to Single Entities**

<b>Organization</b>	<b>Number of MY patent documents</b>	<b>Percentage of total</b>
<b>Commercial</b>		
Firm	35457	92%
Individual Inventors	1756	5%
<i>Subtotal</i>	<i>37,213</i>	<i>97%</i>
<b>Noncommercial</b>		
Foundation/Research Institution	427	1%
Unversity	498	1%
Government	213	1%
<i>Subtotal</i>	<i>1,138</i>	<i>3%</i>
<b>Total</b>	<b>38,351</b>	<b>100%</b>

**Table 2.11: Number of Malaysian Granted Patent Documents Assigned to Multiple Entities**

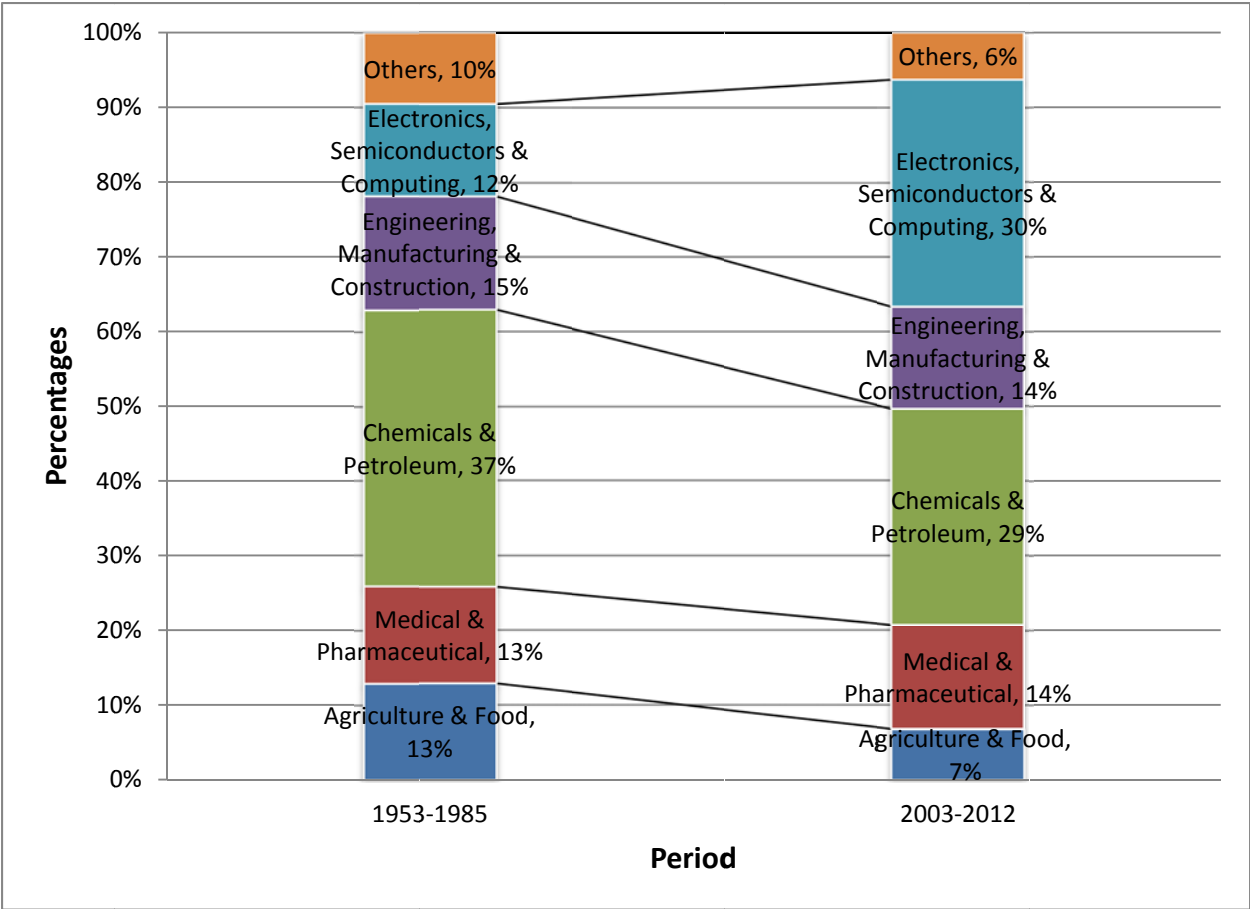
<b>Collaboration</b>	<b>Number of MY patent documents</b>
Commercial-commercial	1, 141
Noncommercial-commercial	209
Noncommercial-noncommercial	51
<b>Total</b>	<b>1, 401</b>

## 2.4 Results and Discussion of Agricultural Technologies Patenting Trend in Malaysia

### 2.4.1 Patenting Trend in the Malaysian Agriculture and Food Sector

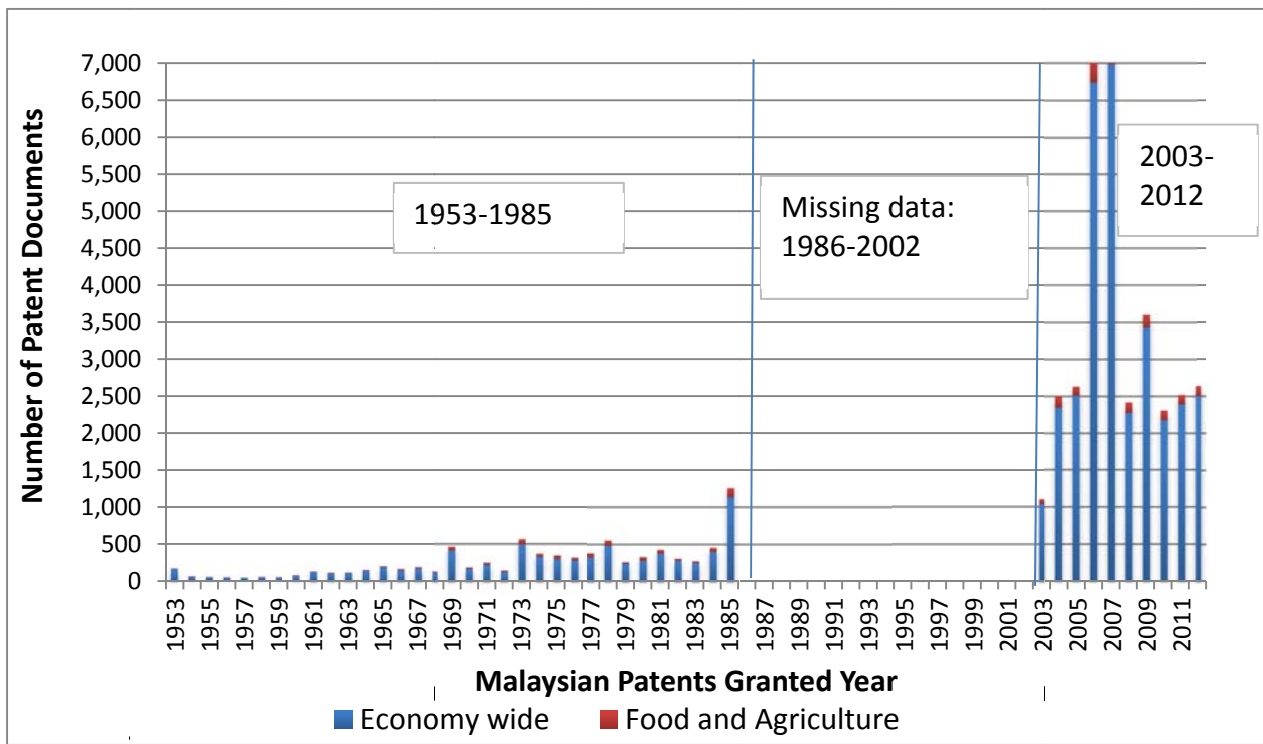
As discussed in Section 1.2.2., in order to learn about patenting trends of agbiotech and agchemicals technologies, we first had to learn what is happening in the patenting scene within the Malaysian agricultural and food sector. Agriculture and food sector experienced a declination of assigned patent share from 13 percent before 1986 to 7 percent after 2002. The shift of Malaysian economy towards industrialization beginning in the mid 1980s is evidenced by the drop in patent share assigned to the agriculture and food sector and the increase of patent share assigned to the electronics, semiconductors and computing sector between these

two periods. The electronics, semiconductors and computing sector granted patents share increased to 30 percent after 2002 from 12 percent before 1986 (Figure 2.12) from 12 percent between 1953 and 1985. Similar to agriculture and food sector, the patenting trend in the chemicals and petroleum sector also experienced a declination between the two periods. It was assigned 37 percent of total patents granted in Malaysia before 1986 and its patenting share declined to 29 percent between 2003 and 2012. Medical and pharmaceutical, and engineering, manufacturing and construction sectors, however, seem to have a stable share of Malaysian patents assigned during these two periods.



**Figure 2.12: Distribution of 40,150 Patents Assigned to Major Industrial Sectors in Malaysia: Comparison of Two Periods**

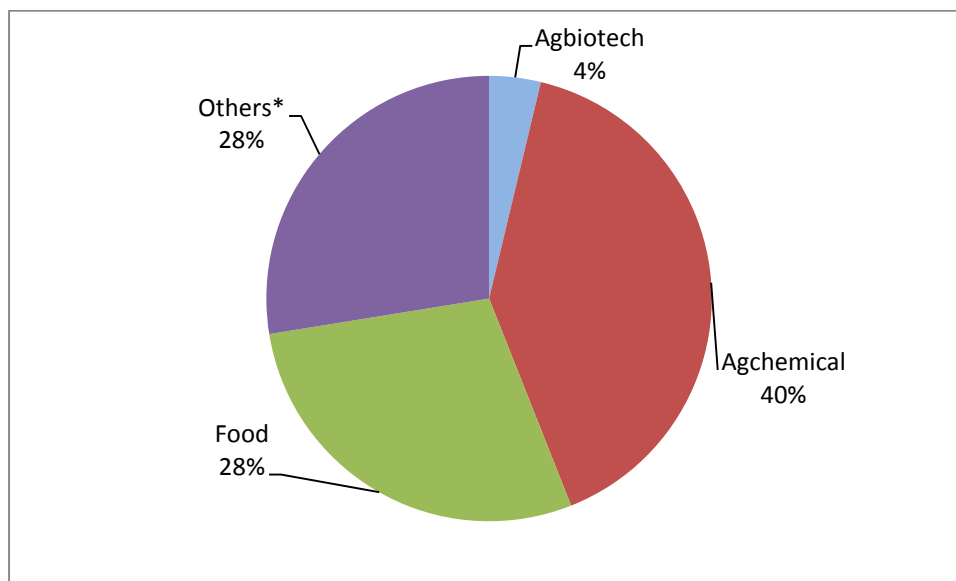
In comparison to the total number of patents granted in Malaysia, the number of patents granted to the agriculture and food sector is substantially low (Figure 2.13). The highest number of patents assigned to this sector was 407 and 521, in 2006 and 2007, respectively. The high numbers might not necessarily mean that the number of patents filed for agriculture and food sector increased but rather attributable to the increase number of patent examiners hired during 2006 and 2007 to process backlog patents.



#### 2.4.2 Patenting Trend of Agbiotech and Agchemicals Technologies

Within the agriculture and food sector there were 2,755 patents granted. This number includes some patent documents affiliated to one or more technologies from within the agriculture and food sector. Agbiotech was only associated with 4 percent of patent granted share while agchemicals had 40 percent (Figure 2.14). Granted patent share of both food and

others' were 28 percent, respectively. The discussion that follows in this section will emphasize on the patenting trend of agbiotech and agchemicals technologies. The reason in doing so is because since the largest percentage of patents granted share within the agriculture and food sector is from agchemicals, hence a discussion about the patenting trends of agbiotech technology is not complete without including agchemicals.



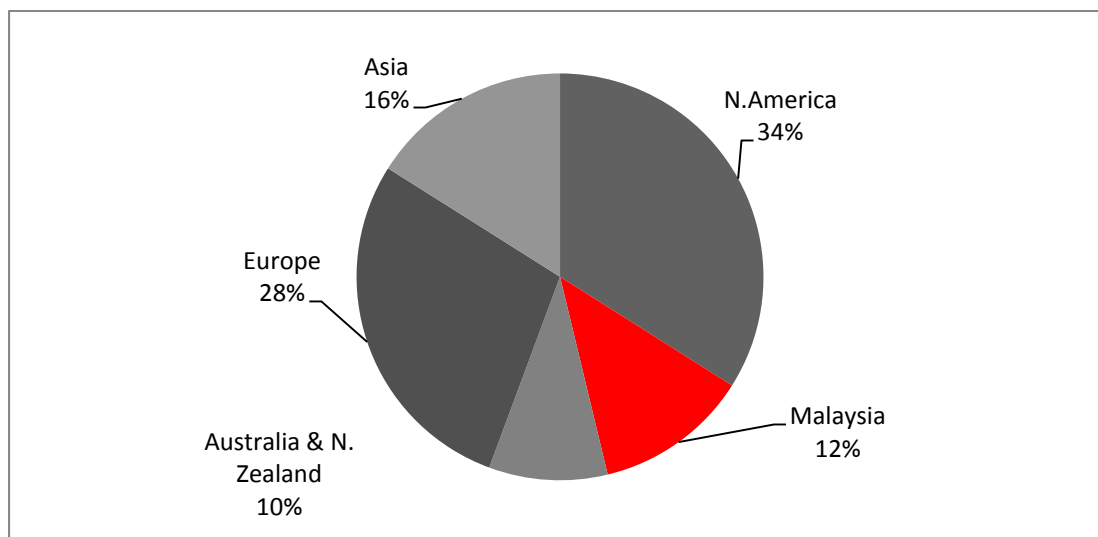
**Figure 2.14: Distribution of 2,755 Malaysian Granted Patents of Agricultural and Food Technologies**

Note: \* Include horticulture, cultivation of vegetables, flowers, fruits etc., watering, harvesting, mowing, soil working in agriculture or forestry, animal husbandry, and many other sub-industry classification related to production based agriculture other than agbiotech and agchemicals.

### **2.4.3 Malaysian Agbiotech and Agchemicals Technologies' Patent Assignees**

As mentioned in Section 1.2.2, an assignee could be an individual and/or an organization who/that holds the right to the patent. The maximum number of assignees assigned to agbiotech and agchemicals patent was three. As such, we included all the assignees assigned to all agbiotech and agchemicals patent documents. As a result, 115 patent documents were designated as agbiotech and 1,150 as agchemicals.

How many of the Malaysian granted patent designated as agbiotech was distributed between foreigners and locals? Between 1953 and 1985, there were only six Malaysian agbiotech patent documents granted and all were assigned to non-Malaysian assignees. Between 2003 and 2012, Malaysian assignees represented 12 percent of the total Malaysian agbiotech patents while 88 percent were assigned to non-Malaysian assignees (Figure 2.15). North America as a region dominated the Malaysian agbiotech patent granted share in this period.

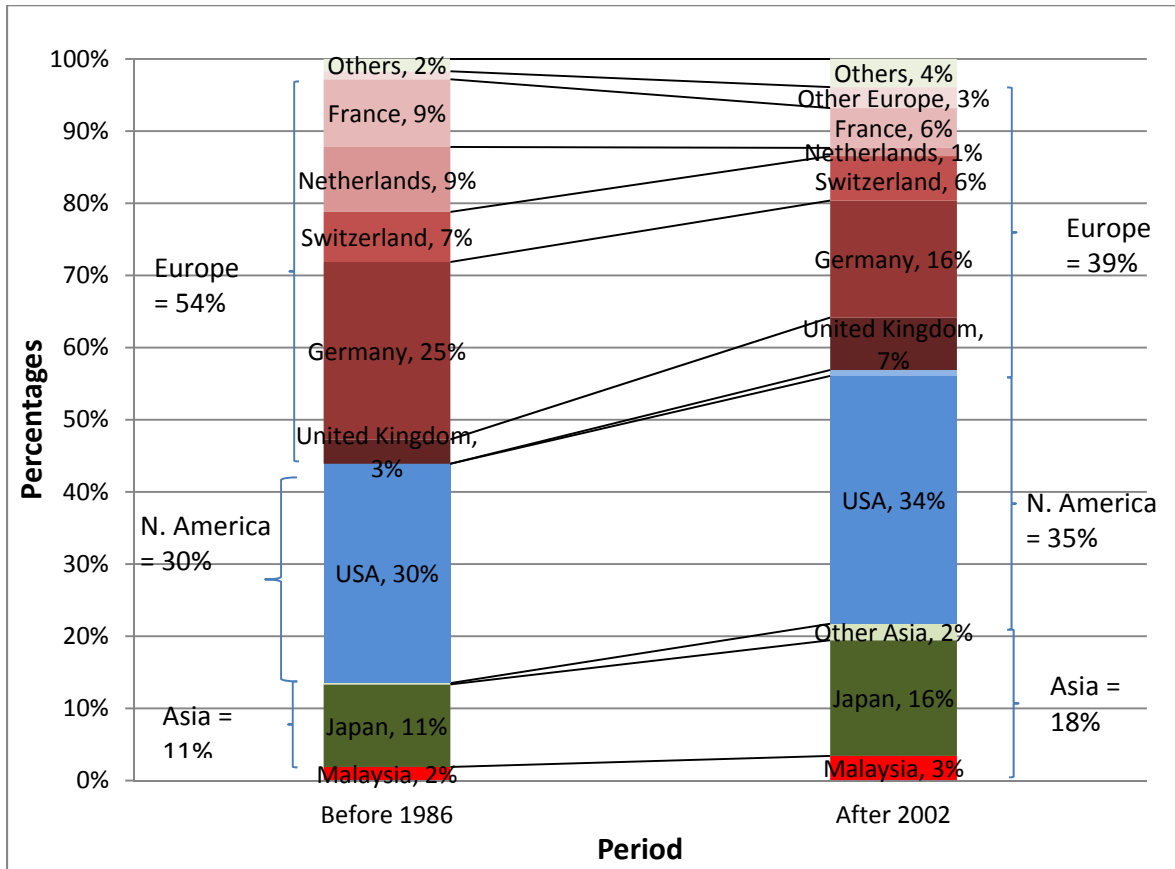


**Figure 2.15: Distribution of 109 Malaysian Agbiotech Granted Patents to Malaysian and Non-Malaysian Assignees between 2003 and 2012.**

Meanwhile, in agchemicals, in the two periods, again, patents were mainly assigned to non-Malaysian assignees. Between 1953 and 1985, Europe dominated the large chunk of the share with 54 percent, followed by US with 30 percent and Japan 11 percent (Figure 2.16).

Although Europe continued to dominate the Malaysian agchemicals patent share in the latter period, its percentage of share declined to 39 percent from 54 percent. United States share increased from 30 percent from 1953-1985 to 35 percent from 2003-2012. Similarly,

Japan's patent assigned share also increased from 11 percent in the earlier period to 18 percent in latter period.



**Figure 2.16: Patenting Trends of Agchemicals Technologies: Comparison of Two Periods**

Between 1953 and 1985, all the six Malaysian agbiotech patent documents granted to non-Malaysian assignee patents were emphasized in the area of traditional agricultural biotechnology, e.g. tissue culture, disease resistant and peptides from plants. The picture, however, is slightly different when it comes to the actual top assignee dominating the Malaysian agbiotech patent share between 2003 and 2012 (Table 2.12). Instead of a US entity (since US dominated the country share), MPOB and Syngenta, were granted the most agbiotech patents with 6.4 percent share, respectively, followed by Bayer with 5.5 percent, and Viva America Marketing, Monsanto, Du Point, Dow Agrosience and Arkion Life Sciences with 2.8



percent share, respectively. Pfizer and BASF were the only two entities which had the least amount of Malaysian agbiotech patents.

In agchemicals designated patents, in the early period, Bayer dominated the patent assigned share with 17 percent, followed by Sanofi with 9 percent and Monsanto with 6 percent. Sumitomo Chemical, Akzo Nobel, Syngenta and BASF each had 5 percent patent share of the agchemicals patent (Table 2.12). These seven firms were assigned with 52 percent of the Malaysian agchemicals granted patents. In the latter period, as shown by Table 2.12, in this sub-sector, Bayer continued to dominate the patents share with 12.6 percent, followed by Syngenta 4.9 percent, Monsanto 4.4 percent, Pfizer 3.2 percent, BASF with 2.8 percent, Du Pont with 2.3 percent, Dow Agrosience with 1.6 percent, Arkion Life Sciences with 1.1 percent and Viva America Marketing with 0.5 percent.

**Table 2.12: Top 10 Malaysian Agbiotech and Agchemicals Patent Assignees from 2003-2012**

<b>Organization</b>	<b>Country</b>	<b>% of Total Malaysian Agbiotech Patents Assigned</b>	<b>% of Total Malaysian Agchemicals Patents Assigned</b>	<b>Ratio of Total Malaysian Agbiotech to Malaysian Agchemicals Patents Assigned</b>
Malaysian Palm Oil Board	Malaysia	6.4%	0.6%	175.0%
Syngenta	Switzerland	6.4%	4.9%	17.5%
Bayer	Germany	5.5%	12.6%	7.7%
Viva American Marketing	United States	2.8%	0.5%	100%
Monsanto	United States	2.8%	4.4%	11.1%
Du Pont	United States	2.8%	2.3%	21.4%
Dow Agroscience	United States	2.8%	1.6%	30.0%
Arkion Life Sciences	United States	2.8%	1.1%	42.3%
Pfizer	United States	1.8%	3.2%	10.0%
BASF	Germany	0.9%	2.8%	7.1%

To describe the patenting trends and tell a compelling story of the differences between innovation occurring between agbiotech and agchemicals technologies, our analysis is focused on the latter period (2003-2012).<sup>5</sup> Between 2003 and 2012, all the top ten patent assignees had their Malaysian patents granted designated as agbiotech and agchemicals (Table 2.13). Among the nine players, all of Bayer's granted Malaysian agbiotech patents were also designated as agchemicals. The same scenario is observed with Viva American Marketing and Arkion Life Sciences. Among a total of forty patents that were assigned to BASF, only one patent document was associated with both agbiotech and agchemicals technologies. This particular invention was developed for crop protection, i.e. combating pests in an aquatic environment.

The difference between the shares of Malaysian granted agbiotech and agchemicals patents varied between entities (Table 2.12). MPOB is the only entity that had more agbiotech patents as compared to agchemicals patents. This is indeed obvious as MPOB is the custodial of the oil palm industry and entrusted with meeting the palm oil industry challenges through R&D and services. As such, their focus is more on the R&D of the crop itself, which includes improvement of new varieties, i.e. engineering oil composition towards increased oleic acid at the expense of palmitic acid (Cheah et al. 1995, Sambanthamurthi et al. 2000, Parveez 2003). Other targeted transgenic oil palm outputs are stearic acid, ricinoleic acid and biodegradable plastics (Parveez et al. 1999). Bayer and BASF, two German entities' primary activities are concentrated in the chemicals sector, and as such their Malaysian patents granted tend to have more inclination towards agchemicals seem obvious. Similarly, Syngenta, a Swiss company, has

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<sup>5</sup> Since there were only 6 patents designated as agbiotech between 1953 and 1985, carrying out an analysis to compare the agbiotech and agchemicals during this period would be unduly biased. In fact, the earliest inventions in agbiotech, globally, were made beginning only in the mid-1980s (See Graff et al, 2003).

a bigger share of its Malaysian patent granted concentrated in the agbiotech technology is also not surprising considering its involvement in biotechnology and genomic research. The weightage of the US based entities towards Malaysian agbiotech patent is also obvious considering their focus on agbiotech. Within the US, Du Pont and Monsanto hold the largest US patents granted share with 14 percent and 13 percent respectively (Graff et al. 2003).

**Table 2.13: Patent Documents of Top 10 Malaysian Agbiotech Patent Assignees from 2003-2012**

Assignee(s)	Title of patent document	Agbiotech	Agchemicals
MPOB	Method of controlling rhinoceros beetle, using metarhizium anisopliae formulated in nutrient-supplemented pellets	/	/
MPOB	Regulation of gene expression	/	
MPOB	A method for disseminating entromopathogens	/	/
Imaspro Biotech Sdn Bhd MPOB	Oil in water pesticide formulation	/	/
MPOB	Use of oil palm prexiredoxin gene	/	
MPOB	Method of controlling rhinoceros beetle, using metarhizium anisopliae formulated in clay powder	/	/
MPOB	Method and compositions for the production of transgenic plants	/	
Syngenta	Cloning and characterization of maize herbicide promoter	/	
Syngenta	Insecticidal matrix and process of preparation	/	/
Syngenta	Hybrid seed production	/	
Syngenta	Insecticidal mixtures containing gamma-cyhalothrin	/	/
Syngenta	Composition containing paraquat	/	/
Syngenta	Herbicide resistant plants	/	/
Syngenta	Seed treatment pesticidal compositions	/	/
Bayer	Herbicidal compositions	/	/
Bayer	Insecticidal combinations	/	/
Bayer	Biological and chemical agents to combat rodents	/	/
Bayer	Bacterial insecticidal protein	/	/
Bayer	Rodent control formulation using microorganism	/	/
Bayer	Composition for luring and controlling anthropods	/	/

**Table 2.13, Continued: Patent Documents of Top 10 Malaysian Agbiotech Patent Assignees from 2003-2012**

<b>Assignee</b>	<b>Title of patent document</b>	<b>Agbiotech</b>	<b>Agchemicals</b>
Viva America Marketing	Method of preparation of biologically active ginkgo biloba product	/	/
Viva America Marketing	Dietary supplementation and methods for preparation of yeast-derived selenium salts	/	/
Viva America Marketing	Nutrition supplement containing lactobacillus acidophilus, yeast and soy protein	/	/
Monsanto	Storage stable composition containing exogenous chemical substance	/	/
Monsanto	Method of protecting seeds treated with a phytotoxic agent	/	
Monsanto	High lysine maize compositions	/	
Du Pont	Method of the production of propanediol by recombinant microorganisms	/	
Du Pont	Method for controlling particular insect pests by applying anthranilamide compounds	/	/
Du Pont	Methods for using dominant gene suppression transgenes	/	
Dow Agrosience	Insecticidal protein toxins from xenorhabdus	/	/
Dow Agrosience	Use of spinosyns as soil-acting insecticides	/	/
Dow Agrosience	Regulatory sequences for transgenic plants	/	
Arkion Life Sciences	Highly purified cytokine activating factor and methods of use	/	/
Arkion Life Sciences	Method of deterring birds from plants and structural surfaces	/	/
Arkion Life Sciences	Method for treating cotyledonous plants	/	/
Pfizer	Coated pesticidal agents, process for their preparation and compositions containing them	/	/
Pfizer	Antibodies	/	
BASF	Non-aqueous concentrated spreading oil composition	/	

The following discussion will focus on Malaysian assignees pertaining to the agbiotech technology. There were no Malaysian agbiotech patents assigned to Malaysian assignees during 1953-1985. Between 2003 and 2012, 13 of the 109 Malaysian agbiotech granted patents were assigned to four Malaysian non-commercial and two Malaysian commercial entities. As mentioned earlier, MPOB held the largest patenting share (53.8 percent) of the agbiotech followed by MRB (15.4 percent). UPM, Malaysian Agri Hi-Tech Sdn Bhd and Imaspro Biotech Sdn Bhd, each had 7.7 percent patenting share of the agbiotech technology.

Between 1953 and 1985, only three Malaysian entities patented ten patents designated as agchemicals. Between the three entities, one entity was from the non-commercial sector, i.e. MRB and the other two were from the commercial sector, i.e. Chemara Plantations Limited and Petronas. Similar to the Malaysian economy wide patenting trend, MRB held the largest percentage share (70 percent). Of the agchemicals designated patents, Chemara Plantations Limited had 20 percent share and Petronas ten percent. Between 2003 and 2012, altogether there were 21 patents granted to 16 Malaysian entities. Ten patents were assigned to six Malaysian non-commercial entities, i.e. MPOB, MARDI, MCB, IMR, UPM, and UM, and 11 patents were assigned to 10 Malaysian commercial entities. Within the non-commercial sector, MPOB held the largest patenting share (19 percent), followed by UPM with ten percent, and the remaining four non-commercial entities held approximately five percent patenting share each (Table 2.14). Out of the ten commercial entities, five were assigned to firms (with 6 patents) and five were assigned to individual inventors (with 5 patents).

**Table 2.14: Malaysian Assignees Granted Malaysian Agbiotech and Agchemicals Patents from 2003-2012**

<b>Assignee</b>	<b>% of Total Malaysian Agbiotech Patents Assigned to Malaysian Assignees</b>	<b>% of Total Malaysian Agchemicals Patents Assigned to Malaysian Assignees</b>
MPOB	53.8%	19.0%
MRB	15.4%	-
UPM	7.7%	9.50%
MOSTI	7.7%	-
Malaysian Agri Hi-Tech Sdn Bhd	7.7%	9.50%
Imaspro Biotech Sdn Bhd	7.7%	4.80%
MARDI	-	4.80%
MCB	-	4.80%
IMR	-	4.80%
UM	-	4.80%
Antimos Technology Sdn Bhd	-	4.80%
Nasmech Technology Sdn Bhd	-	4.80%
Yeohata Machineries Sdn Bhd	-	4.80%
Gan Seong Liam	-	4.80%
Goh Chu Keng	-	4.80%
How Kok Seong	-	4.80%
Hoo Siew Khuan	-	4.80%
Loh Boh Lee	-	4.80%

Among the non-commercial entities, three engaged in collaborations (Table 2.15). Out of the three, two involved foreign non-commercial entities and one, a Malaysian local commercial entity. Between the two collaborations involving foreign entities, one was between MRB with University of Hertfordshire, United Kingdom, and the other involved MOSTI and Massachusetts Institute of Technology (MIT). These two collaborations, respectively, resulted in agbiotech technological patents. Meanwhile, MPOB collaborated with a local Malaysian firm, Imaspro Biotech Sdn Bhd and their patent was designated as both agbiotech and agchemicals technologies. Within the commercial entities, four engaged in collaborations. All four entities



were individual inventors and the two patents that were assigned to them were associated with the agchemicals technology.

The number of Malaysian non-commercial entities (4) patenting agbiotech technologies (11) is greater than the number of Malaysian non-commercial entities (6) patenting agchemicals technologies (10). This roughly translates to one Malaysian non-commercial entity patenting 2.75 agbiotech technologies and 1.67 agchemicals technologies. This observation could possibly be attributable to a couple of reasons. The high number of Malaysian non-commercial entities involved in patenting agbiotech technologies and the high number of agbiotech patents assigned between them might be a result of the Malaysian government's intervention in driving agbiotech growth via channeling public funds to the public research system. However, the intention of the government could be a set back to the commercial entities involved in patenting agchemicals technologies. The incentives for them to patent are constrained due to greater emphasis placed on agbiotech, which includes limited public funds available for agchemicals.

**Table 2.15: Patent Documents of the Malaysian Agbiotech and Agchemicals Patent Assignees from Malaysia between 2003 and 2012**

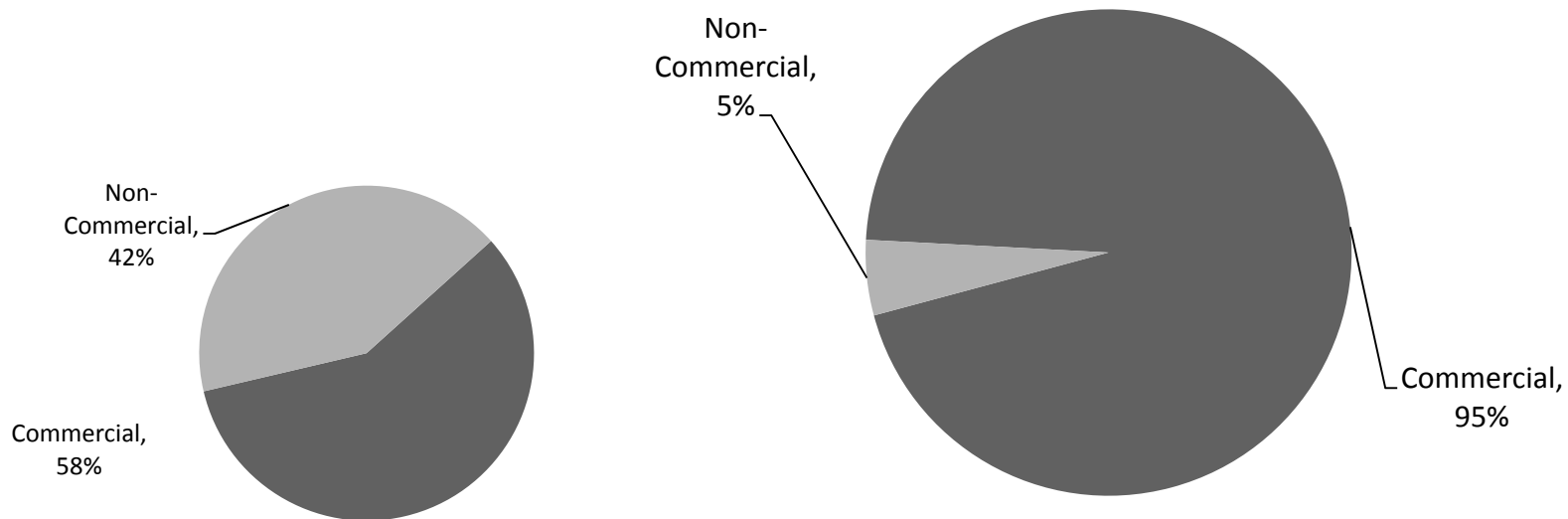
Publication Number	Assignee(s)	Title of patent document	Agbiotech	Agchemicals
MY124303A	MRB University of Hertfordshire, UK	Method for production of protein in plant fluids	/	
MY139558A	MRB	Allergenic protein of natural rubber	/	
MY135549A	MCB	Microbial formulation as biocontrol agent		/
MY124496A	MARDI	A method for retaining artificial color in a plant for artwork		/
MY134264A	MIT, US MOSTI	Methods and compositions for identifying genetic markers in eurycoma spp	/	
MY131122A	UPM	Method to produce controlled release formulation of 1-naphthaleneacetate, a plant growth regulator		/
MY133162A	UPM	Seed treatment reagent for direct seeding paddy rice	/	
MY146392A	UPM	A herbicide formulation		/
MY145803A	Universiti Malaysia	Antimicrobial compounds and medicament derives thereof		/
MY146819A	Malaysian Agri Hi-Tech Sdn Bhd	Composition for biological control of plant diseases	/	/
MY145060A	Malaysian Agri Hi-Tech Sdn Bhd	A plant root system improving composition		/
MY142750A	Imaspro Biotech Sdn Bhd MPOB	Oil in water pesticide formulation	/	/
MY125572A	Yeohata Machinerics Sdn Bhd	Improvement in mosquito coil production		/
MY147340A	Nasmech Tehnology Sdn Bhd	Method of productin oil and bio charcoal from oil palm empty fruit bunches		/
MY134596A	Antimos Technology Sdn Bhd	An improved composition and process for manufacturing insect repellent		/
MY133746A	Loh Boh Lee Gan Seong Liam	Growth regulator and method for the use thereof		/
MY143361A	Hoe Kok Seong Goh Chu Keng	A disposable anti-microbial thin glove		/
MY144023A	Hoo Siew Kuan	Insect repellent device		/

#### ***2.4.4 Distribution of Patent Assignment to Agbiotech and Agchemicals Technologies***

Generally, between 2003 and 2012, substantially, there were more commercial entities (both foreign and locals) involved in patenting agchemicals technologies in Malaysia (Figure 2.17). This pattern is similar to Malaysian assignees patenting trend in the general economy wide patenting in Malaysia. The pie-charts reflect the number of patents affiliated with both technologies, i.e. agbiotech had 109 patents while agchemicals had 617. Due to the nature of agbiotech and agchemicals technologies, there is an overlap of commercial and non-commercial entities patenting in both technologies. The percentage of share distribution between commercial and non-commercial is weighted more towards the commercial sector, i.e. 88 percent versus 12 percent in the non-commercial sector attributable to the fact that there are more commercial entities that patent.

Table 2.16 illustrates the number of granted patent documents listed under these two organizational types between 2003 and 2012. One patent document can be designated as agbiotech and/or agchemicals technologies and assigned to a number of entities. Generally, within the non-commercial sector, the number of Malaysian universities involved in patenting is two, i.e. UPM and UM. UPM has both technological patents. Among Malaysian research institutes, MARDI and IMR are the only two that have patented their inventions. Additionally, the governmental organizations that have patented in either or both technologies are MPOB, MRB, MCB and MOSTI. Among the 78 firms that are assigned to Malaysian granted patents designated as agbiotech, only two involved Malaysian firms, i.e. Malaysian Agri Hi-Tech Sdn Bhd and Imaspro Biotech Sdn Bhd. The number of Malaysian firms patenting agchemicals technologies is even smaller, i.e. five out of 574. However, the number of Malaysian individual

inventors patenting agchemicals technology is considerably high, i.e. five out 11, representing approximately 45 percent of individual inventor entities.



**Figure 2.17: Distribution of Malaysian Granted Patents to Commercial and Non-Commercial Entities Involved in Patenting of Agbiotech and Agchemicals Technologies from 2003-2012**

**Table 2.16: Number of Malaysian Granted Patent Documents Assigned by Type of Entity Involved in Patenting Agbiotech and Agchemicals Technologies from 2003-2012**

Type of Organization	2003-2012		
	Agbiotech	Agchemicals	Total
<b>Commercial</b>			
Firm	78 (71.6%)	574 (93.0%)	<b>652 (89.8%)</b>
Independent Inventors	3 (2.8%)	11 (1.8%)	<b>14 (1.9%)</b>
<i>Subtotal</i>	<i>81 (74.3%)</i>	<i>585 (94.8%)</i>	<i><b>666 (91.7%)</b></i>
<b>Non Commercial</b>			
Foundation/Research Institute	3 (2.8%)	8 (1.3%)	<b>11 (1.5%)</b>
University	14 (12.8%)	13 (2.1%)	<b>27 (3.7%)</b>
Government	11 (10.1%)	11 (1.8%)	<b>22 (3.0%)</b>
<i>Subtotal</i>	<i>28 (25.7%)</i>	<i>32 (5.2%)</i>	<i><b>60 (8.3%)</b></i>
<b>Total</b>	<b>109</b>	<b>617</b>	<b>726</b>

## 2.5 Synthesis and Conclusion

### 2.5.1 Economy Wide Patenting Trend in Malaysia

The patent landscape analysis clearly showed Malaysia's economy evolution over the past six decades. Primarily dependent on the chemicals and petroleum sector between 1953 and 1985, the economy, currently is dependent on two sectors, i.e. electronics, semiconductors and computing, and chemicals and petroleum.

In the early period, EU dominated the patenting scene in Malaysia, and between 2003 and 2012, two nations, US and Japan, respectively dominated the patenting scene. The long FDI history of US and Japanese firms in Malaysia, coupled with their high exports to Malaysia were reasons attributing to their high patenting trends in Malaysia. Asian share increased from 18 percent (1953-1985) to 34 percent (2003 -2012) with Japan owning the large chunk of share between these two periods. Two new comers, China and South Korea, each contributed three

percent and two percent shares to the Asian market share. North America, primarily dominated by US, has reduced its share from 35 percent to 26 percent. Malaysians, on the other hand has increased their patenting activities from one percent in the earlier period to six percent in the later.

Generally, between 1953 and 1985, the top patent assignees granted Malaysian patents were US-based (15 percent). The medical and pharmaceuticals sector had the most patents granted, dominated mainly by American and European firms. While foreign based companies continue to dominate the patenting scene in Malaysia, there were more Asian and European entities during 2003-2012. Moreover during this period, electronics, semiconductors, and computing sector was the most active sector engaged in patenting activities in Malaysia. Cumulatively, they held approximately 13 percent of all Malaysian granted patents. Japanese firms were the patent leaders in this sector.

Govindaraju and Wong (2011) cited two reasons attributable to the higher patenting activities by foreign firms as compared to locals in Malaysia. Either locals do not have the capabilities to generate genuine ideas for patenting, or there is lack of incentives for locals to file for patents in Malaysia. According to Wong and Goh (2012), the over reliance on foreign technologies for development has resulted in the inability of Malaysian local-firms to produce higher value added knowledge based activities. This has resulted in the relative ratio of patenting activities by Malaysians.

In the local patenting trend, MRB lead the scene with 61 percent share between 1953 and 1985. Due to the high patenting activity of MRB, the agriculture and food sector had the most amount of patents granted to locals. However, in recent years (2003-2012), universities

have been actively patenting, and as a result, increased the patenting share of academic institutions to 12 percent.

Generally, the commercial sector dominates the patenting activities in Malaysia during both periods. More firms are assigned patents as compared to individual inventors, primarily due to the cost involved in patenting. The number of non-commercial entities involved in patenting has also increased from 170 (1953 and 1985) to 1269 (2003 and 2012), approximately 7.5 fold. Foundations and research institutes dominated the patenting scene in the earlier period while academic institutions dominate the current scene. Our findings follow the global patenting trend in which academic institutions are increasingly patenting their inventions.

In Malaysia, commercialization of public research began with the implementation of the sixth Malaysia Plan, in which encouraged public R&D to be geared towards market-oriented and exploit the commercialization process of research and technology. Government policies and funding opportunities facilitated non-commercial entities receiving recognition for their inventions. The Malaysian government emphasizes public-private collaboration, but our patent landscape analysis reveals otherwise. The propensity for non-commercial entities to collaborate with non-commercial entities is much higher than for commercial entities to collaborate non-commercial entities. The low collaboration between commercial and non-commercial entities could be attributable to the high risk associated with the inventions generated by non-commercial sector. Commercial sector is reluctant to invest in inventions that could be appropriated or imitated by third parties which could result in lower net returns (Feldman et al. 2007).



### **2.5.2 Agricultural Technologies Patenting Trend in Malaysia**

Malaysia was traditionally an agriculture based economy but the move towards industrialization has taken a toll on the agriculture sector. Our patent landscape demonstrates that patenting trend in agriculture dropped to seven percent between 2003 and 2012 (seven percent is also the agriculture contribution Malaysian GDP) from 13 percent between 1953 and 1985. MRB held the largest patenting share among Malaysian assignees patenting in Malaysia during 1953-1985.

The number of patents designated as agchemicals technology is ten folds greater than what is designated as agbiotech. Between 2003 and 2011, there were only 115 agbiotech technologies patented as compared to 1,150 agchemicals technologies patented. Foreign entities dominate the patenting trend of these technologies with North America (primarily driven by the US) actively patenting agbiotech technology. Both Europe and North America are the dominant players in the patenting trend of the agchemicals technology. MPOB and Syngenta are the two dominant players of the agbiotech technology followed by other US firms, i.e. Du Pont, Dow and Monsanto). During recent years, MPOB has been actively engaged in patenting of agbiotech and agchemicals technologies. Infact, MPOB has more agbiotech patents than agchemicals, reflective of MPOB primary goal of developing the palm oil sector focusing on R&D of the crop itself. This includes improvement of new varieties. Bayer and BASF hold the majority of Malaysian granted patents designated as agchemicals.

Generally, the commercial sector dominates the patenting activities in Malaysia, in the economy wide patenting arena and also in the agbiotech and agchemicals technologies. The thirteen patents granted to Malaysian assignees that were designated as agbiotech technology,

four involved non-commercial entities and two commercial entities. Of the 21 patents granted to Malaysian assignees that were designated as agchemicals technology, six involved non-commercial entities and ten commercial entities. The high number patents granted to non-commercial entities in agbiotech is in line with the government of Malaysia aspiration of utilizing public funds to drive biotechnology in the agriculture sector.

The patenting share of assignees patenting agbiotech technology in Malaysia is relatively smaller as compared to patenting of agchemicals technology. The higher number of agchemicals technologies patented is due to the long history of European MNCs in Malaysia. Additionally, the low number of agbiotech technologies patented in Malaysia is probably due to the misalignment of policies promoting the use of biotechnology in the Malaysian agricultural sector. This discussion is covered in Chapter 2.

From our patent analysis, it can be deduced that since MPOB, a local government entity, dominates the patenting of agbiotech technology in Malaysia, it holds a strong political will to set the stage for agbiotech innovations in Malaysia. The role MPOB plays in the Malaysia's political economy arena is covered in Chapter 2.

Malaysia's economy is primarily dependent on electronics, semiconductors, and computing, and, chemicals and petroleum sectors. As such leveraging on these sectors to develop knowledge might be the appropriate strategy to pursue.

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## CHAPTER 3: POLITICAL ECONOMY OF AGBIOTECH POLICIES

### 3.1 Introduction

Research and development on transgenic crops has been on-going from 1985 in various countries around the world (Bakar 2007). The first commercially grown transgenic crop was in 1996. Since that time, global area planted with transgenic crops has reached 175.2 million hectares, involving twenty seven countries (James 2013). These commercially cultivated transgenic crops include maize, soybean, cotton, canola, sugar beet, alfalfa, papaya, squash, poplar, tomato, sweet pepper and brinjal.

Several other countries in Asia have developed regulatory frameworks, engaged in R&D on agricultural biotechnology, and have begun to allow the commercial cultivation of transgenic crops. In South Asia, three countries have actively cultivated transgenic crops, i.e. India, China and Pakistan (James 2013). Bangladesh recently approved cultivation of transgenic brinjal (The Daily Star 2014). India has cultivated 11 million hectares of transgenic cotton, China has 4.2 million hectares of transgenic cotton, papaya, poplar, tomato, and sweet pepper, and Pakistan has cultivated 2.8 million hectares of transgenic cotton. Meanwhile, in South East Asia, only two countries have commercially cultivated transgenic crops, i.e. Phillipines has cultivated 0.8 million hectares of transgenic maize and Myanmar has cultivated 0.3 million hectares of transgenic cotton. Yet, most of the countries in Southeast Asia, including Thailand, Vietnam, Cambodia, Indonesia, and Malaysia have not approved the cultivation of biotechnology.

The Malaysian government identified biotechnology in The Ninth Malaysia Plan (2006 - 2010) as a key technology to revitalize the agricultural sector in Malaysia. Yet, while the



government of Malaysia endorses agricultural biotechnology at this level, no transgenic crops have yet been submitted, approved, or released for commercial cultivation in Malaysia. The focus on biotechnology as a source of economic growth began in the mid-1990, and in 2005, the agricultural sector emphasized the use of biotechnology in the agricultural sector to attain projected economic goals (MOSTI 2005). The Biosafety Act became fully operationalized in 2007 to address environmental concerns pertaining to transgenic crops.

What is the reason for the lack of progress in the commercialization process? Two explanations can be advanced. First are concerns over the environmental impact, and particularly on Malaysia's rich biodiversity, of the deployment of transgenic organisms within Malaysia's tropical environment. This however, has not precluded commercial cultivation in other tropical countries in the Americas or Asia. And this question will be analyzed with regards to the ecological risks in Chapter 3. Second, however, could it be due to relevant stakeholders whose perceptions have not been considered but might have contributed to the adoption and implementation of the regulations controlling the cultivation of transgenic crops? It has long been recognized that regulatory systems and regulators' decision-making tend to reflect the influences of the various economic and social interest groups to whom they answer, including the interests of the very industries they regulate (Stigler, 1971).

This chapter follows this second line of reasoning and aims to understand the composition and extent of support for and opposition to policies conducive to agricultural biotechnology (agbiotech) innovation in Malaysia. This chapter will utilize a general political economy framework, following the literature initiated by Stigler and others, to identify the stakeholders within Malaysia whose economic welfare is likely to be affected by commercial

introduction of transgenic crops and their respective roles in influencing the policy making process.

This chapter will first provide a brief primer on agbiotech, followed by an update on the current status of agbiotech policy and progress in Malaysia. Subsequently, it will provide context to the Malaysian Biosafety Regulations and offer some insights on the conflict of policies related to agbiotech. Then, the chapter will discuss the general political-economy frameworks and then focus on the framework utilized in this study. Discussion related to the political-economy situation of agbiotech in Malaysia will follow subsequently and the chapter will conclude with a discussion of implications for policy.

### **3.2 What is Agbiotech?**

Biotechnology can be defined as the integrated use of molecular genetics, biochemistry, microbiology and process technology employing micro-organisms, parts of micro-organisms, genes, cells, and tissues of higher organisms to supply goods and services (Sahai, 1999). Agricultural biotechnology, also commonly known as agbiotech, is a range of scientific techniques used to improve plants, animals, or microorganisms for specific agricultural purposes (Ives et al. 2001). These techniques include tissue culture, vaccines for humans and livestock, molecular diagnostics, molecular markers, and genetic modification (also known as genetic engineering or transgenics). Generally, agbiotech enables genetic improvements in crops and livestock that are not possible via traditional crossing of related species (Ives et al. 2001).

Genetically engineered or transgenic crops are developed by transferring specific DNA sequences that encode desirable traits or characters between organisms using recombinant

DNA (rDNA) technology. The five major steps in the development of transgenic crops are: (1) identification and isolation of desired genes for the traits of interest; (2) development of a recombinant DNA insertion construct that includes the gene of interest along with other necessary components to control its expression; (3) transfer of that construct with the gene of interest into the cells of the targeted crop such that it becomes stably inserted into one of the chromosomes of the plant cell (known as a transformation “event”); (4) regeneration of a viable plant from the plant cell that successfully took up the transgenic construct; and finally, (5) breeding with that plant and its progeny in order to put the transgenic trait into commercially useful varieties. The two primary methods for the gene-transfer process into plant cells are: (1) particle bombardment, and (2) use of the bacterium *Agrobacterium tumefaciens*.

Although agbiotech is, by definition, broader than just transgenic crops, for the purpose of this chapter, the focus will be on transgenic crops. To understand the developments that are taking place with regards to the development and utilization of agbiotech in Malaysia, the following section will provide a background on the use of agbiotech policy and progress in Malaysia.

### **3.3 Agbiotech Policy and Progress in Malaysia**

#### **3.3.1 National Biotechnology Policy**

The government of Malaysia targeted biotechnology as a national priority, with goals that it would help to enhance productivity and sustainability of the economy and promote economic growth (MOSTI, 2005). Biotechnology is envisioned as one of the core technologies that can facilitate and accelerate Malaysia’s transformation into a knowledge-based economy. The focus on biotechnology as a source of economic growth began in the mid-1990 under a National Biotechnology Policy, which developed an initiative called the BioNexus network,

encompassing three main fields of applications of biotechnology: (1) pharmaceuticals and nutraceuticals; (2) agbiotech; and, (3) genomics and molecular biology. As members of the BioNexus network, companies are able to leverage the facilities, infrastructure, and capabilities of local universities and research institutes, and receive more targeted government support (Ahn and York, 2011).

The National Biotechnology policy agenda has emphasized the use of biotechnology in the agricultural sector to attain projected economic goals (MOSTI 2005). Currently, Malaysia's agricultural sector is experiencing low crop productivity due to the emergence of new strains of pests and disease (Jaganath and Bakar 2012).

The Malaysian Biotechnology Corporation (BiotechCorp) was created, as a national agency, to lead the development Malaysia's biotechnology industry. The National Biotechnology Policy has developed a three-phase program over 15 years to establish Malaysia as a global leader in the biotechnology field. Phase-1 (2006-2010) of the program focused on building capacity and infrastructure. Phase-2 (2011-2015) is geared towards commercialization of biotechnology and Phase-3 (2016-2020) is directed towards targeting Malaysia as an emerging global biotechnology participant.

In the 1990s, plant tissue culture was agbiotech priority research area due to its vast application in plant breeding and production of elite planting materials (Bakar et al. 2005). With the introduction of modern biotechnology such as molecular techniques and rDNA, local scientists began adopting these new methods as early as the mid-1980s (Bakar et al. 2005). The limitations of conventional breeding techniques initiated the usage of modern biotechnology in producing new crop varieties with enhanced plant traits.

### ***3.3.2 Research and Development Investments in Agbiotech in Malaysia***

The Malaysian government was the primary contributor financing domestic R&D in agricultural biotechnologies with an allocation of RM2.6 billion (USD775 million) was set aside for the agbiotech sub-sector from 2006 – 2010. In 2011, R & D expenses in the agbiotech sector was RM24.5 million (USD 8.2 million) and in 2012, it increased to RM35.9 million (USD 12 million), accounting for 47 percent growth (BiotechCorp 2013). There has been no specific allocation set aside for R & D in agbiotech in the Tenth Malaysia Plan (2011-2015), although the government anticipates more private sector involvement during this period.

### ***3.3.3 Current Status of Research and Development of Transgenic Crops in Malaysia***

Research and development on agricultural crops in Malaysia is mainly carried out by public research institutions and universities (Hashim et al. 2002, Hautea and Escaler 2004). The three governmental boards/research institutes, i.e. The Malaysian Palm Oil Board (MPOB), the Malaysian Rubber Board (MRB) and the Malaysian Cocoa Board (MCB), respectively, are responsible for the development, promotional and marketing of the three respective commodities mentioned above, i.e., Oil palm, rubber and cocoa. These boards' research efforts and outputs are geared towards the goals and aspirations of development and marketing of the commodities they are accountable for. Research and development of food crops, livestock and ornamental flowers are undertaken by the Malaysian Agricultural Research and Development Institute (MARDI). MARDI primary goal is to serve and protect the interests of the farming community.

The Seventh Malaysian Plan (1996-2000) identified specific target traits to be developed for the following crops:

- i) oil palm: oil quality and secondary plant products
- ii) rubber: disease resistance, yield, production of high-value products
- iii) rice: disease resistance, yield
- iv) ornamentals: senescence, flower color, disease resistance
- v) fruits: shelf-life, disease resistance, fruit quality
- vi) cocoa: insect and disease resistance, butter content, and cocoa flavor
- vii) forest species and medicinal plants: nutraceutical and pharmaceutical products

Research and development on transgenic crops in Malaysia has focused on five major crops including rice, papaya, rubber, oil palm and orchid, all of great significance to Malaysia (Table 2.1). Nevertheless, among them, transgenic development on rice, papaya and oil palm has been intensified (Hashim et al. 2002) due to their important contribution to Malaysia's economy or agriculture landscape. Rice is Malaysia's staple crop, while papaya is a leading horticultural crop export, and Malaysia's oil palm is the leading agricultural crop export worldwide. Among these crops, papaya and rice have demonstrated a higher likelihood of commercial release and cultivation as these transgenic varieties have reached more advanced stages of research and development (Hashim et al. 2002). While there have been improvements in oil palm genetic engineering breeding research in Malaysia as shown in Table 2.1, commercialization of GM oil palm is not anticipated until in 2020 (Sambanthamurthi et al. 2009). This is due to its nature of being a perennial crop coupled with stringent field requirements in Malaysia (Sambanthamurthi et al. 2009).

The development of these transgenic crops is at various stages of development, such as gene cloning and transformation, and evaluation. Although some of these processes have

already been patented (Othman, 2009), commercialization of transgenic crops has not taken place. The closest activity prior to the commercialization process that has taken place is the contained field trials undertaken for delayed ripening papaya and herbicide tolerant oil palm in 2002. The transformed papaya developed by with antisense ACC (aminocyclopropane carboxyl) oxidase cDNA sequence was found safe to be consumed and not hazardous to the broader agriculture sector or the environment (National Biosafety Board 2013). Malaysian Agricultural Research and Development Institute (MARDI), the technology innovator was given the approval by the risk assessment council to proceed with a confined field release to be carried out in a netted house (Jailani, 2003). However, no status updates on the field release were reported. Meanwhile, in the case of oil palm, the application for confined field release of transgenic oil palm by the Malaysian Palm Oil Board is pending. The risk assessment council requested additional information pertaining to the crop and required the innovator to submit a new location for the confined field trials (Jailani, 2003). Thus far, work on transgenic rice has mainly been in the laboratory.

**Table 2.1: Current Status of Transgenic Plant Development in Malaysia**

Crop and objectives	Gene of interest (Responsible Institution(s))	Status
<b>Rice (MARDI)</b>		
Resistance to rice tungro spherical virus (RTSV)	Coat protein and polymerase genes of RTSV	Stable (Taipei 309) transgenic lines, T147-3 and T147-4, carrying truncated and full-length polymerase genes, respectively (Ong et al. 1997)
Resistance to rice tungro bacilliform virus (RTBV)	Coat protein and polymerase of RTBV (Ong et al. 1998)	Transformation and screening ongoing
Resistance to sheath blight disease (Rhizoctonia oryzae)	Chitinase gene <sup>a</sup> (Zulkipli et al 1999)	Transformation and screening ongoing
Tolerances to herbicides	<i>bar</i> gene (Hamidah et al. 1998)	Transformation and screening ongoing
Resistance to insects	Bt gene <sup>a</sup> ; cowpea trypsin inhibitor (CPTi)	Transformation and screening ongoing
<b>Papaya (MARDI)</b>		
Resistance to papaya ring spot virus (PRSV)	Coat protein of local isolates of PRSV (Vilasini et al. 1998)	Transgenic plants obtained, in tissue culture; ready for greenhouse screening
Improved shelf-life	ACC oxidase gene (antisense) (Bakar and Lam 1996)	Transgenic plants went for a field trial in March 2002
Improved shelf-life	ACC synthase gene	Transformation ongoing (Bakar and Lam 1996)
<b>Rubber (MRB)</b>		
Specific proteins (e.g. pharmaceuticals)	n/a	Transformation system developed (Arokiaraj et al. 1997, Arokiaraj et al. 1998)



**Table 2.1, Continued: Current Status of Transgenic Plant Development in Malaysia**

Crop and objectives	Gene of interest (Responsible Institution(s))	Status
<b>Oil palm (MPOB and Universiti Kebangsaan Malaysia)</b>		
Oil quality improvement	Stearoyl-ACP desaturase and $\beta$ -keto-acyl synthase 1	Transformation system developed (Farida and Arni 1997, Farida 1998, Jalani et al. 1998)
Herbicide tolerance	n/a	Transformation system developed (Parveez et al. 1998)
Insect resistance	CPTi <sup>a</sup> ; Bt gene <sup>a</sup> (Ruslan et al. 1997; Ruslan et al. 2000; Rashdan and Abdullah 2000)	Transgenic plants obtained (4 1/2 year old), in planthouse; ready for screening (Ruslan et al. 1997, Ruslan et al. 2000, Rashdan and Abdullah 2000)
Insect resistance	<i>cry</i>	Expression of Bt insecticidal protein gene in transgenic oil palm (Lee et al. 2006)
Fungal resistance (Ganoderma)	Chitinase (Ruslan et al. 1997, Ruslan et al. 2000, Rashdan and Abdullah 2000)	Transgenic plants obtained (3 year old), in planthouse; undergoing screening (Ruslan et al. 2000, Rashdan and Abdullah 2000)
<b>Orchid (MARDI and Universiti Putra Malaysia)</b>		
Improved flower color	Chalcone synthase (CHS)	Gene construct prepared (Manickam et al. 1999)
Improved shelf-life	Flavanone-3-hydroxylase (F3H)	Transformation ongoing
Improved shelf-life	ACC oxidase (Hasnida et al. 1999)	Transformation ongoing

Source: Hashim et al. 2002 and Lee et al. 2006

Note:

MARDI – Malaysian Agricultural Research and Development Institute

MPOB – Malaysian Palm Oil Board

MRB – Malaysian Rubber Board

### 3.3.4 Current Patent Status of Transgenic Crops in Malaysia

Results from Chapter 2 showed that several of the top agbiotech players in the world are also the leading sources of patented agricultural bio-technologies in Malaysia. Syngenta was granted the most agbiotech patents in Malaysia with 7 patents, followed by Bayer with 6 patents, and Monsanto and Du Pont each with 3 patents (Table 2.2). In total, these four players dominate the patenting of agricultural biotechnologies with 17.5 percent share. MPOB, the custodian of the Malaysian oil palm industry, is entrusted with meeting palm oil industry challenges through R&D and services, is the other top player (with 7 patents) actively engaged in patenting agricultural biotechnologies in Malaysia.

**Table 2.2: Agbiotech Patent Assignees in Malaysia from 2003-2012**

Organization	Country	Total patents	% of Total Malaysian Agbiotech Patents Assigned
Malaysian Palm Oil Board (MPOB)	Malaysia	7	6.4%
Syngenta	Switzerland	7	6.4%
Bayer	Germany	6	5.5%
Viva America Marketing	United States	3	2.8%
Monsanto	United States	3	2.8%
Du Pont	United States	3	2.8%
Dow Agroscience	United States	3	2.8%
Arkion Life Sciences	United States	3	2.8%
Suntory Holdings	Japan	2	1.8%
Pfizer	United States	2	1.8%
Nestle	Switzerland	2	1.8%
Malaysian Rubber Board (MRB)	Malaysia	2	1.8%
Eli Lilly and Company	United States	2	1.8%
Agency for Science Technology and Research	Singapore	2	1.8%
Yuen Foong Yu Paper Manufacturing	Taiwan	2	1.8%
Others	-	60	55.0%
<b>Total</b>		<b>109</b>	<b>100%</b>

### 3.3.5 Approved Transgenic Events and Products in Malaysia

According to Dardak and Otheman (2007), Malaysian was among the first few countries within the Association of South East Asian Nations (ASEAN) to approve the use of transgenic food crops for human and animal consumption. As of August 2013, there are nine approved transgenic products for import into Malaysia for purposes of food, feed and processing (Letchumanan 2013). Table 2.3 lists these products. Monsanto has dominated the Malaysian transgenic product market with 50 percent of market share followed by Bayer with 20 percent and Syngenta, Du Pont and Suntory each with ten percent market share. Among the three types of transgenic crop, there were 6 maize products on the market, 2 soybean products and one carnation flower.

**Table 2.3: Transgenic Products Sold in Malaysia**

Product	Crop	Purpose	Applicant
GTS-40-3-2 Roundup Ready Soybean	Soybean	Food, feed and processing	Monsanto
NK 603 Roundup Ready Maize	Maize	Food, feed and processing	Monsanto
MON 810 YieldGard Maize against Corn-Borer	Maize	Food, feed and processing	Monsanto
MON 863 Yield Gard Rootworm Maize	Maize	Food, feed and processing	Monsanto
MON 89788 Glyphosate Tolerant (Roundup Ready 2 Yield)	Soybean	Food, feed and processing	Monsanto
SYN-Bt011-1 YieldBard Maize	Maize	Food, feed and processing	Syngenta
ACS-GM5-3 Herbicide tolerant Soybean (A2704-12)	Soybean	Food, feed and processing	Bayer
T25 Herbicide Tolerant Maize	Maize	Food, feed and processing	Bayer
TC 1507 Herbicide Tolerant and Insect Resistant Maize	Maize	Food, feed and processing	Du Pont
Genetically modified carnation, <i>Dianthus caryophyllus</i> L	Carnation	Esthetic	Suntory Holdings

The players that are actively engaged in the patenting of agricultural biotechnologies in Malaysia were also the ones that have obtained approvals for their transgenic products to be sold in the Malaysian market. Absence of transgenic palm oil or rice crop products in the Malaysian market is an indication that innovations of these crops have not made it to the commercial market. Additionally, the presence of US and South American crop products in the Malaysian market shows that the market in Malaysia for transgenic products is largely for importation, feeding and processing. Although MPOB is one of the local players that is actively engaged in patenting agricultural biotechnologies, its innovation is in infancy stage, largely focusing on the transformation process of transgenic oil palm (Table 2.4). Transgenic rice, on the other hand has not yet had any patent assigned to it.

**Table 2.4: Agbiotech Patent Documents Assigned to MPOB from 2007-2012**

Document Number	Granted Year	Title of patent document
MY134504A	2007	Method of controlling rhinoceros beetle, using metarhizium anisopliae formulated in nutrient-supplemented pellets
MY137397A	2009	Regulation of gene expression
MY142119A	2010	A method for disseminating entromopathogens
MY142750A	2010	Oil in water pesticide formulation
MY145579A	2012	Use of oil palm prexiredoxin gene
MY146451A	2012	Method of controlling rhinoceros beetle, using metarhizium anisopliae formulated in clay powder
MY146503A	2012	Method and compositions for the production of transgenic plants

### 3.4 Malaysian Biosafety Regulations

The Biosafety Bill was approved by the Malaysian Cabinet in December 2005, upon the launch of the National Biotechnology Policy in April of the same year. However, the Biosafety Act was only passed in 2007 and implemented in 2010. The Biosafety Act is a platform to

address concerns pertaining to transgenic crops. Among the main component of the Biosafety Act are risk assessment, risk management and an emergency response plan. The delay in passing and implemented the Act was a result of the restructuring that took place in Malaysia in 2004, splitting the former Ministry of Science, Technology and the Environment into two separate ministries, i.e. Ministry of Science, Technology and Innovations, and Ministry of Natural Resources and Environment (MNRE). MNRE is responsible for administering the implementation of the Biosafety Act.

Due to lack of the nation's human resource capacity in the area of risk assessment, risk management, risk communication, and administrative and regulatory implementation of the Biosafety Act, the Conservation and Environmental Management Division under MNRE with support from UNDP Malaysia carried out a capacity building project. Specifically, the project assisted in developing national capacities in biosafety by investing in appropriate scientific and technical skills, implementing risk management activities, evaluating and strengthening the legal and regulatory frameworks, developing infrastructure for information exchange and data management, as well as achieving broad social participation in biosafety matters. The goal of this project was to enable Malaysia to achieve its vision of utilizing biotechnology for sustainable development and as a new source of economic growth (UNDP-GEF-GOM 2007).

### **3.5 Conflict of Policies**

Malaysia is moving from a manufacturing based nation to a service oriented one with great emphasis on the knowledge economy. The Malaysian economy has experienced numerous shifts and significant changes, mainly driven by developmental policies. In the early 1960s through 1980s, the Malaysian economy was primarily focused on agriculture and primary

commodities but subsequently transitioned to a manufacturing and export driven economy in the late 1980s-early 2000s. Currently, it is moving towards a post-industrial knowledge-based economy (Choung and Hwang 2000, Park et al. 2005, Nagano 2006, Asgari and Wong 2007). The Malaysian agricultural sector was the main contributor (50 percent) to Malaysia's gross domestic product (GDP) from the 1950s to late 1970s. However, the drive towards industrialization in the mid 1980s into the 1990s left the Malaysian agricultural sector in the back seat of the economy (Ahmad and Suntharalingam 2009). The contribution of agriculture to the GDP was 20.8 percent in 1985 and 13.6 percent in 1995 (Alam et al. 2012). It contributed approximately USD 17 billion, which is 7.6 percent of the country's total GDP in 2011 (EPU, 2012) and its average sectoral contribution to Malaysian GDP averaged 5.2 percent between 2000 and 2010 (MOA 2011). With the agriculture sector lagging behind in the Malaysian economy, is it possible to leverage agricultural biotechnology to help attain a knowledge based economy by 2020?

Malaysia has been identified as a nation that has an influential voice among developing countries as well as in the Islamic world (Cottrell and Hoh 2010). As such, its ambition of becoming a global player in the biotechnology industry by the year 2020 can be powerful and also be a vocal advocate of biotechnology in the international arena. However, the conflict of policies between the National Biotechnology Policy and the Biosafety Act has stalled the commercialization progress of transgenic crops in Malaysia. The National Biotechnology Policy actively supports utilization of biotechnology in the agricultural sector but the Biosafety Act advocates for stringent regulation of transgenic crops cultivation. According to Gressel and Hoh (2005), the enforcement of the Biosafety Act challenges the adoption of unified, transparent

and science-based legislation and regulations that will allow commercialization of biotechnology products. As such, there is a high chance with the Biosafety policy in its current form could discourage potential investors from investing in agricultural biotechnologies in Malaysia. In summary, confusing signals about the development of agbiotech in Malaysia could hamper the nation's ambition of becoming a knowledge based economy leveraging on biotechnology.

This raises the question that, while the government of Malaysia attempts to facilitate the required ground- and frame- work to advance the Malaysian agbiotech agenda, no transgenic crop has been commercialized in Malaysia. What is the reason for the lack of progress in the commercialization process? Is it because of ecological concerns that the commercialization process is hampered? or Could it be possible that the misalignment of national policies is a reflection of relevant stakeholders whose influence contributed to the stalled commercialization progress?

Chapter 4 will carry out a scientific review addressing the ecological concerns of major transgenic crops that could potentially be grown in Malaysia. And the discussion that follows in this chapter will utilize a political economy framework to identify and include relevant stakeholder groups in Malaysia that might play a role in contributing to the stalled commercialization progress of transgenic crops in Malaysia.

### **3.6 Brief Background of Political Economy Models**

The political economy approach to policy analysis emerged in economics when the “economic approach” on political pressure groups, introduced by Bentley, was widely adopted by economists such as Stigler (1971), Peltzman (1976) and Posner (1974) on building models of

political competition among pressure groups (Becker, 1983). This section will focus on political-economy literature, starting with a partial equilibrium model and then moving on to a political economy approach.

According to Goolsbee et al. (2013), partial equilibrium analysis is the determination of equilibrium in a particular market that assumes there are no cross-market spillovers. In the partial equilibrium framework, it is possible to calculate and compare changes in consumer and producer surplus resulting from changes made to the system, such as the introduction of a new production technology. However, due to different model assumptions, regional disaggregation and different assumed price elasticities of supply and demand, results could vary between one study and the other (Qaim and Traxler 2005, Price et al. 2003, Falck-Zepeda et al. 2000, Moschini et al. 2000).

As such, to overcome limitations in partial equilibrium analysis, the political economy framework, which includes relevant stakeholders' perspectives is suggested. This approach focuses on how various interest groups interact in a specified political setting with specific policies as the outcome. This technique characterizes outcomes under differing conditions. This framework began with a number of theories advanced by economists and political scientists who observed that economic choices are generally determined by markets and political systems. These theories explain the behavior of regulators and the shape and strength of policies they make (Grossman and Helpman 2001). One such theory of regulation, known as the "capture theory" (Posner 1974, Stigler 1971) is related to situations where a regulator is captured by a single interest group, in which the regulator is responsible to regulate. Other more complex political-economic models were designed to accommodate multiple features of



the political systems (Becker 1983, Grossman and Helpman 2001, Peltzman 1976, Zusman 1976).

Anderson et al. (2004) in his study on understanding the different policy adoption across North America and European Union toward transgenic foods adopted a political economy model similar to the one designed by Grossman and Helpman (2001). The political economy model in the study by Anderson et al. (2004) explicitly accounts for the political influence of special interest groups, most notably farmers. Farmers are assumed to lobby for more-permissive or more stringent regulations depending on how farmers' commercial interests are reflected. Additionally, their study adopts a strategic trade framework and allows consumer preferences for standards to vary. However, some limitations to the analysis were that it ignored the environmental and consumer lobby groups, and the important role played by agricultural biotechnology firms, who have a clear incentive to promote transgenic adoption.

In overcoming the limitations faced by Anderson et al. (2004), Graff et al. (2009) formulated a political economy model for agbiotech to analyze agricultural biotechnology policies using the approach suggested by Zusman (1976). The approach taken by Graff et al. (2009) was based on a utility maximization framework, as shown in the function below:

$$\rightarrow \max \text{regulator welfare} = f(A_1 \text{ consumers' surplus}, A_2 \text{ food retailers' producer surplus}, A_3 \text{ farmers' producer surplus}, A_4 \text{ major biotechnology suppliers' producer surplus}, A_5 \text{ new biotech innovators' producer surplus}, A_6 \text{ competing input suppliers' producer surplus}, A_7 \text{ academic institutions'/scientists' benefits}, A_8 \text{ activist organizations' benefits}, A_9 \text{ environmental welfare})$$

where:

$A_k$  = weight of influence of each group  $k$  has over the regulator's decisions making process,

This approach broadly views decisions and policies made by governments as rational relative responses to the array of pressures and inducements arising from various segments of society. In this model, the agbiotech regulator's problem is a weighted welfare maximization and the regulator is not necessarily indifferent to his or her own welfare.

The consumer surplus is measured in the typical manner, which accounts for heterogeneity of tastes and preferences amongst consumers. The coefficient  $A_1$  is the relative weight given by politicians to consumers, reflecting consumers' influence over the politician's ability to get re-elected. Consumers might relatively be "rationally ignorant" (Stigler 1971) on the welfare impacts of agbiotech and thus, not motivated to have a significant collective action related to this issue. They instead will exercise their single action individually via their purchase decisions and votes.

Producers' interests on the other hand are quite heterogenous, between different segments and within a segment of production. As such, producers are disaggregated into different groups that have potentially competing interests. This is done by separating those whose levels of producer surplus are likely to be affected differently by the adoption of biotechnology in agriculture, i.e., those who adopt biotechnology in agriculture and those who do not. At a minimum, the producers and supply side stakeholders are divided into five groups: (1) food retailers ( $A_2$ ); (2) farmers ( $A_3$ ); (3) current supplier of GM crops ( $A_4$ ); (4) small agbiotech companies introducing new innovations ( $A_5$ ); and, (5) competing input suppliers ( $A_6$ ) i.e., chemical pesticide manufacturers.

The scientific community ( $A_7$ ) weighs in on policies affecting innovation and new technologies (Graff and Zilberman 2007), and that they tend to benefit differently under

different biotechnology regimes (Graff et al. 2009). Public-sector agricultural research can either gain or lose in terms of public funding, royalty income, and/or relevance and prestige within the agricultural sector. They also have influence over regulators as their published research and policy advice are consulted during the policymaking process.

The activist organizations ( $A_8$ ) and environmental surplus ( $A_9$ ) are distinguished between direct benefits accorded to activist organizations, i.e., donations, grants, and benefits that accrue from a better environment to society. Generally, interest groups weigh in on issues in ways that support and advance their own priorities, and when possible, in ways that enable them to capture economic surpluses resulting from the shape and structure of the newly formed policies.

The political economy model by Graff et al. (2009) offered great insights to political economy situations of agbiotech sectors in different countries. This then provided us the opportunity to follow the model's general tenets to learn and understand the political economy arena of agbiotech in Malaysia.

### 3.7 Methods

The model in this study follows closely the model formulated by Graff et al. (2009) by including three major crops in Malaysia, i.e. Oil palm, rice and papaya. These crops offer important contribution to Malaysia's economy, as previously discussed. Following is the model:

$$\begin{aligned} \rightarrow \max \text{ regulator welfare} = & \sum_{j=1}^3 f(A_{1j} \text{ consumers' surplus}_j, \\ & A_{2j} \text{ food retailers' producer surplus}_j, \\ & A_{3j} \text{ farmers' producer surplus}_j, \\ & A_{4j} \text{ major biotechnology suppliers' producer surplus}_j, \\ & A_{5j} \text{ new biotech innovators' producer surplus}_j, \end{aligned}$$

$A_{6j}$  competing input suppliers' producer surplus,  
 $A_{7j}$  scientists' benefits,  
 $A_{8j}$  activist organizations' benefits,  
 $A_{9j}$  environmental welfare)

where:

$A_k$  = weight of influence of each group  $k$  has over the regulator's decisions making process,

$j = 1$  = oil palm;  $j = 2$  = rice;  $j = 3$  = papaya.

The two main criteria that are used to identify relevant interest groups are power and resources the relevant groups hold (Becker 1983, Oates and Portney 2003). The economic logic of these criteria is that the relevant interest groups can exert their influence via power and resources (money, non-monetary contributions) on the policy decision.

### **3.8 Background of Oil Palm, Rice and Papaya Industries in Malaysia**

The Malaysian agricultural sector is dichotomous in nature, with the oil palm sector dominated by large plantations while rice and papaya sectors mainly comprised of smallholders. Large plantation companies are professionally managed and small farmers are not as professionally or efficiently managed.

The rice industry is very much protected by the government. The oil palm industry has strong governmental support while the papaya industry is left to industry players to manage.

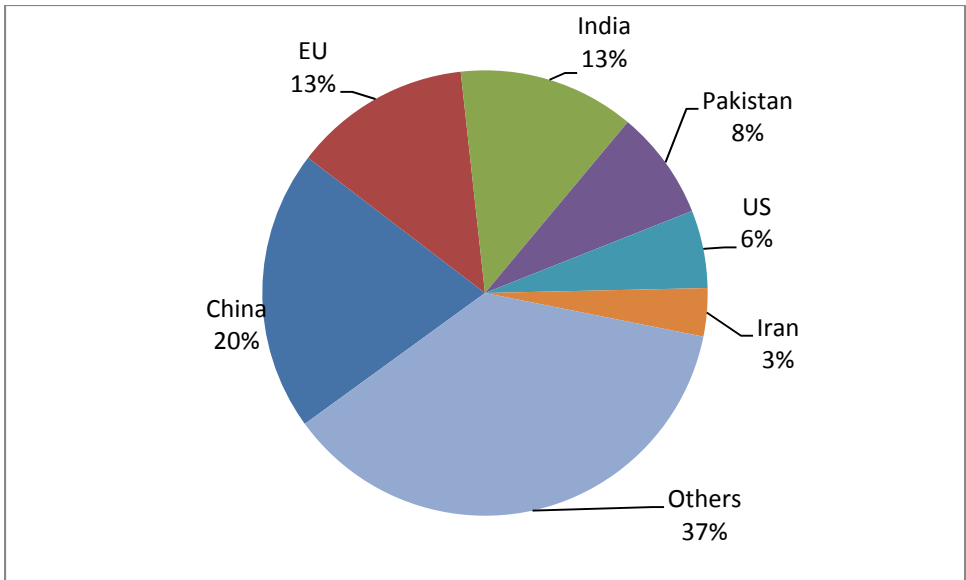
#### **3.8.1 Malaysian Palm Oil Industry**

The government of Malaysia introduced land settlement schemes for planting oil palm as a means to eradicate poverty for the landless farmers and smallholders between the 1950s

and 1960s. Currently, the oil palm plantations in Malaysia are largely based on the estate management system (MPOC 2014). In 2006, during the implementation of the Ninth Malaysian Plan (2006-2010), three Malaysian conglomerates from the oil palm sector merged. The merger was between Sime Darby Berhad, Kumpulan Guthrie Berhad and Golden Hope Plantations Berhad. The new entity retained the name Sime Darby Berhad and it is a state-owned enterprise (Sime Darby 2006). The reason behind this merger was to revitalize the agricultural sector, i.e. transforming traditional farming into modern and commercial farming. As a result of the merger, Sime Darby Berhad became one of the world's leading public-listed oil palm plantation groups.

Palm oil is the biggest contributor (37 percent) to Malaysian agricultural GDP in 2011 (DOS 2013a). Palm oil is an edible oil and palm kernel oil is extensively used in the oleochemical industry. Globally, Malaysia is the largest exporter of palm oil and the second largest producer of oil palm products (Abdullah and Lazim 2006). Malaysia's palm oil contributed to 11 percent of the world's oils and fats production, and 27 percent of total global trade of oils and fats in 2011 (Sime Darby 2013).

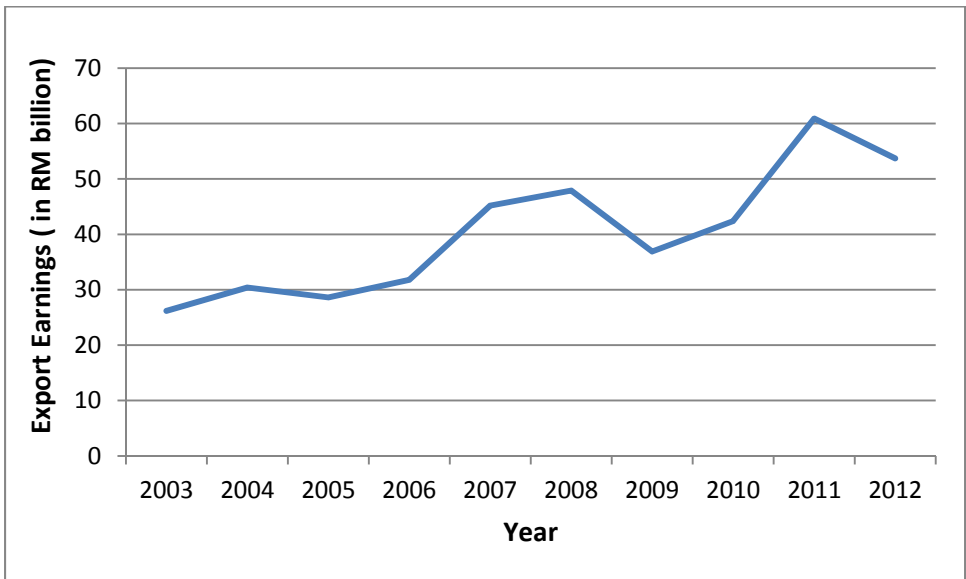
Domestic consumption of palm oil in Malaysia is relatively low, and as such, the majority of palm oil is exported, with China as the largest importer followed by the European Union and India (Figure 3.1).



**Figure 3.1: Major Export Destinations for Malaysian Palm Oil in 2012**

Source: MPOB 2014

Being the largest exporter, Malaysia palm oil industry contributed RM53.7 billion (USD 17.9 billion) to the economy (Figure 3.2) in 2012 (DOS 2013b), and employs approximately 570,000 people (Sime Darby 2013).



**Figure 3.2: Malaysian Palm Oil Export Earnings from 2003-2012**

Source: MPOB (2008, 2014), DOS (2013b)

Note: 1 USD = RM3

### **3.8.2 Malaysian Rice Industry**

In 2011, Malaysia is still not self-sufficient in rice, or more specifically, 28 percent insufficient (MOA 2012). Rice is mainly produced by smallholders with an average farm size of 1.06 hectares (NAP 1998). The rice industry has been accorded special treatment due to the fact that rice is a staple food crop. This industry was regulated and promoted through the establishment of specialized bodies beginning with the Rice Commission in 1933, the Federation of Malaya Rice Committee in 1955 and subsequently the National Paddy and Rice Board (LPN) in 1971. Investments were made on infrastructure, and various price and income support measures were provided to attain self-sufficiency in rice (NAP 1998). In 1994, LPN was corporatized and in 1996, its commercial activities were divested to the private sector and government retained regulatory function of LPN. However, the re-structuring of the paddy industry did not help Malaysia to reach a self-sufficient level in rice. The Government support to the rice industry include credit facilities, subsidized retail prices, a guaranteed minimum price, extension services, fertilizer subsidies, and irrigation investments. The price subsidy is set at RM248.10 per tonne, irrespective of paddy grade. The fertilizer subsidy at 300 kg per ha is available to farmers with farm holdings of less than 2.43 ha (MOA 2012).

Despite the special treatment accorded to this sector, as early as the first Malaysian plan (1966-1970) to the recent Tenth Malaysia Plan (10MP), Malaysia's rice production is still inefficient in terms of cost and production yield (Fahmi et al. 2013). Malaysia has a relatively higher cost of rice production than other rice producing countries within the ASEAN region. This is attributable to two major reasons, escalating agricultural input prices and labor shortages.

### **3.8.3 The Papaya Industry**

Generally, the fruit industry in Malaysia is a small-holder based industry involving 270,000 farmers (NAP 1998). In 1987, the Malaysian Agricultural Research and Development Institute (MARDI) successfully developed a small, high quality papaya targeted for the export market (Chan, 1987). The new variety was called 'Eksotika' and it offered tremendous export earnings. In 1986, the year before 'Eksotika' was released; the export revenue of papaya was a mere RM 3 million. The export revenue climbed steadily every year since then, and in 2004, papaya export value was RM120 million (USD 40 million) (FAOSTAT 2006). During that year, Malaysia was the second most important exporter of papaya in the world in 2004 with a total volume of 58,149 metric tonnes accounting for 21 percent of the global trade (Chan and Baharuddin 2010). However, in 2005, papaya production declined rapidly for two reasons: (1) the outbreak of the Bacterial Dieback (*Erwinia*) disease and, (2) fruit fly quarantine restrictions from China (Chan and Baharuddin 2010). Cumulatively, these two reasons affected 60 percent of Malaysia's export. Malaysia's papaya global export was 24,301 metric tonnes in 2009 (Evans and Ballen 2012). Currently, the papaya industry in Malaysia is relatively insignificant compared to the overall agricultural sector.

## **3.9 Assessing Welfare Impacts and Influence over Regulators**

### **3.9.1 Consumers**

Consumers in Malaysia are relatively hesitant to accept GM foods due to the risks involved and moral issues concerning GM food (Amin et al. 2011). The average consumer could



remain “rationally ignorant” of this fact and not be aware of the welfare impact of agbiotech, and as a result, consumers collectively would not take significant action relative to this issue.

### ***3.9.2 Food Retailers***

Food retailers ultimately will base their decisions on the choices that consumers make.

### ***3.9.3 Oil Palm, Rice and Papaya Producers***

Oil palm producers ultimately rely on the decision to cultivate transgenic crops on the plantation companies that manage them.

Although the number of rice farmers might be large but due to the way they are organized (very much dependent on governmental support), individually, they will not take collective action related to this issue. Additionally, considering the fact that the rice industry is accorded special treatment, the decision of whether to cultivate transgenic rice will lie on the government itself. Hence, in order to not to jeopardize the special treatment accorded to the rice farmers, the government will continue to provide them other types of special treatment or in worst-case-scenario provide them a smooth exit pathway from the rice industry.

Papaya farmers, on the other hand, are relatively insignificant, as previously discussed. Since they are such a diffused group, they might not mount to collective action pertaining to this issue.

### ***3.9.4 Major Biotechnology Suppliers and New Biotechnology Innovators***

The top world agbiotech players, i.e. Syngenta, Monsanto, Du Pont and Dow Agrosience, are not as influential as the oil palm and agchemicals producers in Malaysia due to the following reasons: (1) the oil palm producers are Malaysian conglomerates and they have

tremendous support from the government; (2) European agchemicals companies have a long history in Malaysia; and, (3) US agbiotech products are new entrants into the Malaysian markets and as such, these companies do not have influence over agbiotech regulations in Malaysia.

The patent data reveals that the number of new biotech innovators is small and mainly driven by local non-commercial entities (MPOB and MRB) and foreign agbiotech and agchemicals companies (Table 2.2). As mentioned earlier, MPOB is the custodial of Malaysian palm oil industry and as such, it has a strong influence on the policy making process of agbiotech in Malaysia.

### 3.9.5 Competing Input Suppliers (Agchemicals)

Among the top ten companies (Table 2.5) that dominate the global agchemicals trade market share, six of them (i.e., Bayer, Syngenta, BASF, Dow Agroscience, Monsanto and Du Pont) are known as the big six companies in the global crop protection industry. They are also the ones that are actively engaged in patenting agbiotech and agchemicals technologies in Malaysia (Table 2.6).

**Table 2.5: Top 10 Agchemicals Companies in the World in 2007**

Company	Sales (in USD million)	Global Market Share
Bayer	7,458	19%
Syngenta	7,285	19%
BASF	4,297	11%
Dow Agroscience	3,779	10%
Monsanto	3,559	9%
Du Pont	2,369	6%
Maktheshim Agan	1,895	5%
Nufarm	1,470	4%
Sumitomo	1,209	3%
Arysta Lifescience	1,035	3%
<b>Total</b>	<b>34,396</b>	<b>89%</b>

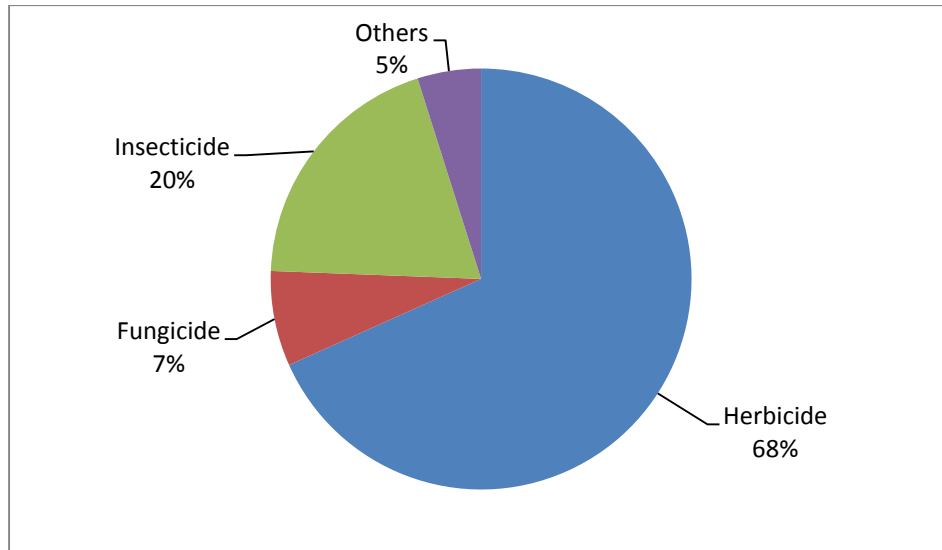
Major agchemicals suppliers in Malaysia\*

Source: ETC Group (2008)  
 Note: \* Big Six Companies in Global Crop Protection Industry

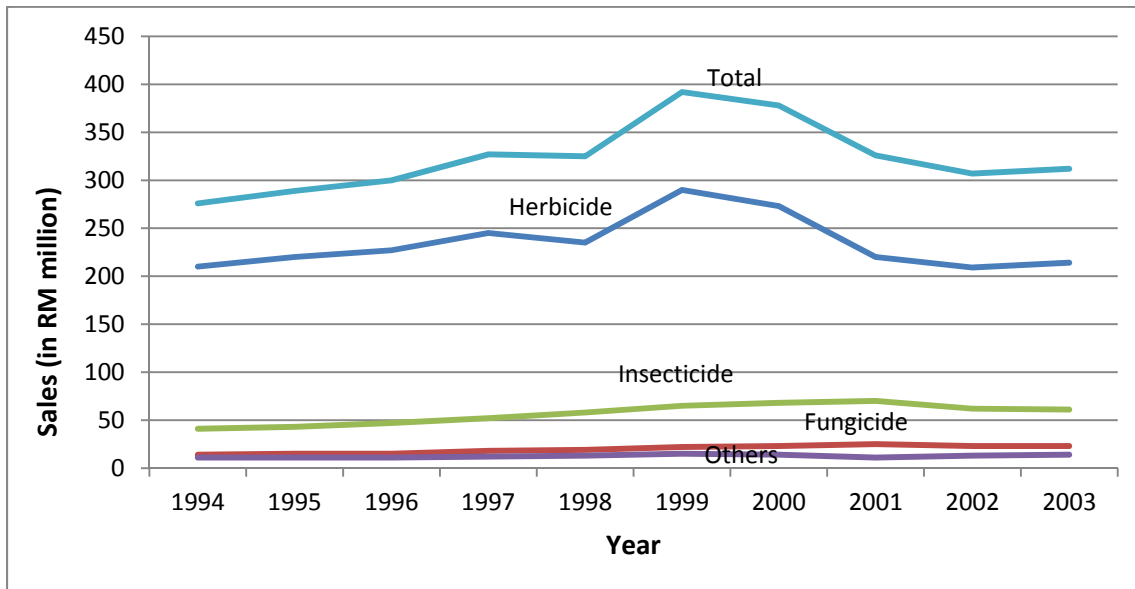
**Table 2.6: Top Malaysian Agbiotech and Agchemicals Patent Assignees from 2003-2012**

<b>Organization</b>	<b>Country</b>	<b>% of Total Malaysian Agbiotech Patents Assigned</b>	<b>% of Total Malaysian Agchemicals Patents Assigned</b>	<b>Ratio of Total Malaysian Agbiotech to Malaysian Agchemicals Patents Assigned</b>
Bayer	Germany	6 (5.5%)	78(12.6%)	7.7%
Syngenta	Switzerland	7 (6.4%)	40 (4.9%)	17.5%
Monsanto	United States	3 (2.8%)	27 (4.4%)	11.1%
BASF	Germany	1 (0.9%)	17 (2.8%)	7.1%
Du Pont	United States	3 (2.8%)	14 (2.3%)	21.4%
Dow Agroscience	United States	3 (2.8%)	10 (1.6%)	30.0%
Malaysian Palm Oil Board	Malaysia	7 (6.4%)	4 (0.6%)	175.0%

In 2003, herbicide dominated the market share of agchemicals sale in Malaysia (Figure 3.3), with RM56 million (USD17 million). Figure 3.4 illustrates that agchemicals sale reached its peaked in 1999 with RM392 million (USD103 million), with herbicides accounting for 74 percent of sales. This demonstrates that agchemicals sale in Malaysia have declined between 1999 and 2003 and this is attributable to three factors: (1) a global agchemicals price drop; (2) illegal pesticides trade in Malaysia; and, (3) enforcement of good practices of agchemicals usage by the government of Malaysia (Watkin 2004). Herbicides are mainly used in oil palm, rubber and rice. However, with the outbreak of weedy rice in 1988, there was no selective herbicide to control it prior to the advent of an imidazolinone tolerant variety (IMI-TR). There was a major outbreak of weedy rice in 2002 (Azmi et al. 2012). To overcome this problem, a new rice variety (local IMI-TR rice) was developed, a collaborative project between MARDI and (Malaysia) Sdn Bhd (Azmi et al. 2012). IMI-TR Line No. 1770 from USA was crossed with a popular local rice cultivar MR 220 using conventional breeding techniques and this collaborative effort started in 2003. Two locally developed IMI-TR varieties, namely MR 220CL1 and MR 220CL2, together with the technique known as Clearfield Production System (CPS), were officially launched on July 8<sup>th</sup> 2010 (BASF-MARDI Press Release 2010). The CPS consists of three main components: (1) Clearfield certified seeds; (2) OnDuty herbicide; and, (3) stewardship guide.



**Figure 3.3: Distribution of Agchemicals Sale by Product Type in Malaysia, 2003**  
Source: Watkin (2004)



**Figure 3.4: Agchemicals Sale in Malaysia from 1994-2003**  
Source: Watkin (2004)

Insecticide is also heavily used in rice production systems to control leaf-folders (*Cnaphalocrocis medinalis* (Guenée)), brown plant hoppers (*Nilaparvata lugens* Stål), white-backed plant hoppers (*Sogatella furcifera* (Horvath)), and golden apple snail (*Pomacea canaliculata* (Lamarck)) (Watkin 2004). Rhinoceros beetle (*Oryctes rhinoceros* L.) has become a

serious pest problem in oil palm plantations for over a decade (Norman and Basri 2000) and insecticides are widely applied to control the outbreak (Watkin 2004).

### **3.9.6 Scientists**

Scientists will most likely have their interests aligned with their primary source of funding and main client base for their R&D efforts.

### **3.9.7. Activists and Environmental Welfare**

Activist organizations in Malaysia, similar to others globally, promise to advocate for the self-interest of consumers and farmers. However, in reality, they depend on donor organizations for funding and as such, they align their interest to match their donors.

## **3.10 Conclusion**

The Malaysian oil palm industry is dominated by large plantation companies with Sime Darby Berhad owning the largest percentage of shares. With strong governmental support and because they are a major contributor to Malaysia's GDP, the palm oil stakeholders have a strong influence on the agricultural policy making process in Malaysia. Currently, there is no transgenic oil palm in the market and the strategy used by Malaysia in marketing its palm oil as "GM-free" has proven to be advantageous as it continues to dominate the world export market of oils and fats. With EU being one of the major destinations of Malaysian palm oil, the palm oil players in Malaysia have been cautious about disclosing R&D breeding of transgenic oil palm. MPOB began R&D on transgenic oil palm since 1987 with the intention of increasing oleic acid content (Cheah et al. 1995, Sambanthamurthi et al. 2000, Parveez 2003). Other targeted transgenic oil palm outputs are stearic acid, palmitoleic acid, ricinoleic acid and biodegradable

plastics (Parveez et al. 1999). MPOB has generated more patents in agbiotech as compared to agchemicals technologies, an indication that it has ventured into breeding of transgenic oil palm in Malaysia.

The prevalence of agchemicals players in the Malaysia agricultural sector is evident by the sales of agchemicals in Malaysia, coupled with patents assigned to them. The dominance of European agchemicals companies in Malaysia is highly visible. With Bayer dominating the agchemicals technology patenting scene in Malaysia, and with BASF collaboration with MARDI on the Clearfield rice variety, they have shown their influence in the agricultural sector. Cumulatively, the ratio of both these companies' agbiotech patents to agchemicals patents in Malaysia is low as compared to US dominated companies, i.e., Syngenta, Monsanto, Du Pont and Dow. The collaboration between BASF and MARDI has been strategic. MARDI is primarily responsible for R&D in food crops, including rice and it is the primary public agency that carries out rice research. With its recent collaboration with BASF, it seems as though MARDI is endorsing BASF's initiative in assisting with increasing Malaysia's rice sector productivity.

Sime Darby Berhad, the world largest listed palm oil company, measured by planted palm hectares, accounts for five percent of world crude oil palm output (Satish 2013). Felda Holdings Berhad, the world's second largest oil palm plantation company is also based in Malaysia. With two Malaysian Giant conglomerates, Sime Darby Berhad and Felda Holdings Berhad, dominating world palm oil exports, it is evident that these two players dominate the oil palm scene in Malaysia. As such, they inevitably influence the policy making process of the Malaysian agricultural sector. The world's two dominant agchemicals players, Bayer and BASF, also play a major role in the agricultural policy making process in Malaysia. As Stigler (1971)

points out, organized producers are always more persuasive in a regulatory making process and in doing so, helps them to shape regulations that are favorable to them. This situation depicts the current scenario that is happening in Malaysia. The two special interest pressure groups, oil palm and agchemicals producers, have high-stake interests in the agbiotech scenario in Malaysia due to the large welfare impact agbiotech (i.e., transgenic crops) could have on them. However, due to their small number, they have the capacity to be highly organized and hence, are better able to influence regulations related to commercialization of transgenic crops.

This chapter provided insights on the stalled commercialization progress of transgenic crops in Malaysia. The two big interest groups, i.e., oil palm and agchemicals producers, were able to exert their influence via power and resources (money, non-monetary contributions) on the policy decision making process related to transgenic crop commercialization in Malaysia.

While transgenic crops have been recommended to contribute to future agricultural productivity, a complete understanding on the intensive use of transgenic crops on the environment remains unclear (Wolfenbarger et. al., 2010). In order to better understand the ecological consequences as a result of adoption of transgenic crops, a summary of ecological research is necessary and that is the focus of the following chapter.



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## CHAPTER 4: ECOLOGICAL RISKS OF TRANSGENIC CROPS

### 4.1 Introduction

Genetically modified (GM) crops, also known as transgenic crops, were first commercially cultivated in 1996. In 2013, the global area planted with transgenic crops has reached 175.2 million hectares, involving twenty-seven countries (James 2013). According to James (2013), commercially cultivated transgenic crops include maize (*Zea mays* L.), soybean (*Glycine max* L.), cotton (*Gossypium hirsutum* L.), canola (*Brassica napus* L.), sugar beet (*Beta vulgaris* L.), alfalfa (*Medicago sativa* L.), papaya (*Carica papaya* L.), squash (*Cucurbita pepo* L.), poplar (*Populus sp.*), tomato (*Lycopersicon esculentum* Mill.), sweet pepper (*Capsicum annuum* L.) and eggplant (*Solanum melongena* L.). Within the Southeast Asian region, only two countries have commercially cultivated transgenic crops, the Philippines (maize) and Myanmar (cotton).

The introduction of transgenic crops into agricultural lands is a complex challenge to understand because the effects of such crops on ecological processes are uncertain. Conflicting assessments and incomplete substantiation of benefits, risks and limitations pertaining to the release of transgenic crops into the environment have resulted in varied national and international regulations (FAO/WHO Secretariat 2004).

As of the current date, no transgenic crops have been commercially released in Malaysia. Transgenic papaya has undergone contained field evaluations for proof-of-concept, but it is only recently that such activity taking place is brought out in the open. No status updates on the field trials have been reported thus far. This raises the question of why there have been no updates on the field trials and no commercial release of transgenic crops in

Malaysia. Is it because, among other reasons, the lack of scientific evidence on the effects of transgenic crops on the environment and ecological processes has hindered decision making? According to Davey et al. (2010), concern for ecological safety is one of the primary factors that have led to public mistrust of transgenic technology. However, according to this author, many of these concerns originate from misinformation or appear unsubstantiated. Highly restrictive regulation has increased the costs and difficulty, particularly for public institutions, to conduct field trials on transgenic crops (Davey et al. 2010). Similarly, regulations governing general releases of transgenic crops have inhibited deployment by public institutions as the approval process is costly and time consuming.

With this in mind, this chapter aims to provide a scientific review of the ecological risks of transgenic crops in Malaysia. The purpose of this assessment is to assist local policy makers in adopting a science based approach in regulating the interaction between transgenic crops and Malaysia's environment.

Most of the extant ecology literature on the effects of transgenic crops on tropical agriculture addresses rice and papaya. This is likely due to trends. Research on transgenic rice and papaya development has been intensified (Hashim et al. 2002) and these crops have been identified as important contributors to either Malaysia's economy or Malaysia's agriculture landscape. Rice is the staple crop of South East Asia including Malaysia, while papaya is a leading horticultural export crop. Among these crops, papaya and rice have demonstrated a higher likelihood of commercial release and

cultivation as these transgenic lines have reached more advanced stages of research and development (Hashim et al. 2002).

This chapter will firstly, provide a brief background on rice and papaya cultivation, and pest and disease concerns related to these crops. Subsequently, the mechanisms involving the potential ecological consequences of cultivating these crops will be discussed. This chapter will conclude with a synthesis and analysis of literature reviewed.

The sources utilized in this chapter mainly comprised publications from peer-reviewed scientific journals, followed by conference proceedings, reports and other scientific materials.

#### **4.2 Brief Background on Rice and Papaya**

*Oryza* L. is a genus of seven to twenty species of grasses and includes ten different genome types, i.e., AA, BB, CC and BBCC, CCDD, EE, FF, GG, JJHH, and JJKK genomes (Lu 1999, Vaughan 1994, Ge et al. 1999). Malaysian cultivated rice, *O. sativa* L., has its origin in South and Southeast Asia and is grown worldwide in the tropics, subtropics and some temperate regions (Lu et al. 2003). The cultivated varieties grown globally belong to the subspecies *japonica* and *indica*. In Malaysia, the popular subspecies is *indica*. The wild and weedy rice species of Malaysia are *O. rufipogon* Griffiths, and *O. sativa* (Bakar et al. 2000). All three groups *O. sativa* subsp. *japonica*, *O. sativa* subsp. *indica*, and *O. rufipogon* contain the AA genome, making them relatively easy to cross with one another. In theory, transgene escape from transgenic rice lines will only occur with species having the AA genome (Lu et al. 2003). Flowering habits of cultivated rice in different parts of the world vary depending on local cultivation time and seasons, and also depending on type. In fact, the flowering time and pollinating time of different wild rice species or different populations of the same species also vary significantly

across different geographic regions (Lu et al. 2003). This has also been found to be true within Malaysia, despite similarities in weather patterns. Watanabe et al. (2000) reported that the flowering time between wild and cultivated rice varieties in Malaysia varies. In the east, the difference in flowering time between the two overlaps (in December) and they exist within the same vicinity, while in the northern area, they do not coincide (Watanabe et al. 2000).

The rice pests in regions growing rice, particularly in Asia, vary substantially, based on geographical area and production system (Savary et al. 2000). Rice pests belonging to the orders Hemiptera, Diptera, Lepidoptera, and Coleoptera are of regional or local significance (Dale 1994). Lepidopteran stem borers are chronic pests in all rice ecosystems. In Asia, the damaging pest species include the yellow stem borer (*Scirpophaga incertulas* (Walker)), striped stem borer (*Chilo suppressalis* (Walker)), and leaffolders, *Cnaphalocrocis medinalis* (Guenée) and *Marasmia* spp. Typically, the damage caused by leaffolders is highly visible and to control them, insecticides are applied (Way and Heong 1994, Matteson 2000). According to Dale (1994), other Asian rice insect pests are brown planthopper (*Nilaparvata lugens* Stål), whitebacked planthopper (*Laodelphax striatellus* (Fallén)), green leafhopper (*Nephotettix virescens* (Distant)), the rice bug (*Leptocorisa* spp. (Latreille)), Asian rice gall midge (*Orseolia oryzae* (Wood-Mason)) and the rice water weevil (*Lissorhoptrus oryzophilus* (Kuschel)).

*C. papaya* is a popular tropical fruit belonging to the Caricaceae family, a small dicotyledonous family consisting of four genera. *Carica* L. is the largest genus with twenty-three described species (CERA 2014). The center of origin of papaya is most likely from the Southern part of Mexico and the Northern region of Central America (Badillo 1993). It is grown from the seed. The papaya plant requires sufficient water supply and grows well in deep loamy soils rich

in plant nutrients, well drained, good air flow and lots of sunlight (Rivera 2005). There are two types of papaya varieties, i.e., small and big. Fruit of small varieties, also known as solo, weigh approximately 500 grams while big fruits are named after their place of cultivation and weigh above 500 grams. Both of them can be consumed fresh, and most big varieties are used for processing and canning.

Papaya is propagated with seeds. There are no reliable characteristics to distinguish male, female and hermaphrodite plants until they bear flowers. The major papaya disease is the papaya ringspot virus (PRSV) (Gonsalves et al. 2010). PRSV is found in all areas of the world where papaya and cucurbits are cultivated. It is an aphid-transmitted plant virus that belongs to the genus Potyvirus, family Potyviridae (Tripathi et al. 2008). This virus initially appears as oil streaks on papaya stem and petioles and once it is in the advanced stage, leaves will develop a prominent mosaic pattern and chlorosis. Papaya trees that are infected at a young stage will either remain stunted and will not flower, or die (Rivera 2005, Gonsalves et al. 2010). Fruit from infected trees have bumps and often have 'ringspots', the basis for the disease's common name (Gonsalves et al. 2010).

#### **4.3 Mechanism Discussed in the Scientific Literature**

Transgenic rice and papaya, similar to other transgenic crops are subject to biosafety regulations pertaining to their potential impact on the environment. Some of the risks posed by transgenic crops include:

- i. Impact on the third trophic level, - including natural enemies such as predators and parasitoids
- ii. Impact on soil microbial community

- iii. Impact on non-target herbivorous community
- iv. Effect of transgene escape to cultivated, weedy and wild varieties and populations
- v. Other impacts related to papaya – heteroencapsidation and RNA recombination
- vi. Indirect impact of changing agricultural practice as a result of cultivating transgenic crops.

#### **4.3.1 Effects on the Third Trophic Level**

The groups that are most at risk are non-target herbivores, beneficial insects such as pollinators and natural enemies (Ferry and Gatehouse 2009). *Bacillus thuringiensis* Berliner (*Bt*) insecticidal toxins (Cry1Ab, Cry1Ac and Cry1B) could be transferred to natural enemies, i.e., beneficial predators through nonsusceptible or sublethally affected herbivorous prey feeding (bioaccumulation) on *Bt* host plants (Schuler et al. 1999, Head et al. 2001, Jiang et al. 2004a, Jiang et al. 2004b). Some organisms belonging to the orders of Lepidoptera, Homoptera, Hemiptera, Thysanoptera and Tetranychidae could be non-target secondary pests, which might not be affected directly by the transgenic crop, but could expose the next trophic level to it and create an effect. The effect is, however, dependent on the presence of *Bt* receptors in the first instance, and to-date, it is unclear whether such receptors are present in non-target herbivores (de Maagd et al. 2001). Moreover, the effect of the toxin ingestion by non-target herbivores is also unclear as it depends on the susceptibility of the herbivore to the transgene product. This effect will then determine whether this toxin causes an impact on the third trophic level, in particular predators and parasitoids (Ferry and Gatehouse 2009, de Maagd et al. 2001).

Over the past decade, synthetic genes *cry1Ab*, *cry1Ac* and *cry1B* derived from *Bt* have been incorporated into commercial varieties of *indica* or *japonica* rice subspecies to protect them from being attacked by striped stem borer (SSB), *C. suppressalis*, and yellow stem borer (YSB), *S. incertulas* (Fujimoto et al. 1993, Wunn et al. 1996, Ghareyazie et al. 1997, Nayak et al. 1997, Wu et al. 1997, Cheng et al. 1998, Datta et al. 1998, Alam et al. 1999, Breitler et al. 2000, Khanna and Raina 2002), two serious rice pests in temperate and subtropical Asia (Dale 1994). *B. thuringiensis* is a diverse group of soil dwelling bacteria in which different strains colonize and kill a variety of host insects with a high degree of specificity (Ferry and Gatehouse 2009). Individual Cry toxins have a defined spectrum of activity, normally restricted to a few species within one particular insect order. Currently, toxins for insects that fall in the orders of Lepidoptera (butterflies and moths), Diptera (flies and mosquitoes), Coleoptera (beetles and weevils) and Hymenoptera (wasps and bees) have been identified (de Maagd et al. 2001). A small number of toxins showing adverse effects on nematodes have also been identified (Gatehouse et al. 2002)

The commercialization of the first three *Bt* crops (i.e., maize, cotton and soybean) in 1996 intensified the debate on benefits and risks of transgenic crops (Shelton and Sears 2001). Much of the debate in relation to the ecological safety of transgenic insecticidal plants expressing Cry toxins from *B. thuringiensis* has focused on non-target organisms, including herbivorous insect pests and their natural enemies (biological control agents) such as predators and parasitoids that help control populations of pest insects in rice ecosystem. This section only covers studies pertaining to insect-resistant rice lines on the third trophic level as there have

been no studies reported on the impact of herbicide-resistant rice lines or PRSV-resistant transgenic papaya on tri-trophic interactions.

#### 4.3.1.1 Insect-resistant rice

A field study was carried out in China by Liu et al. (2006) on three transgenic rice lines (MSA, MSB and MSA4) and one transgenic rice hybrid (KF6-304). All three transgenic lines had fused double genes of *cry1Ac* and *sck* (*cry1Ac/sck* rice). The purpose of the study was to assess the effects of MSA, MSB, MSA4 and KF6-304 on the parasitoid communities in paddy fields in comparison with their respective control varieties (MH86 was the control for MSA, MSB and MSA4; II-YM86 was the control for KF6-304). Results demonstrated that there were no significant differences in the overall situation and temporal dynamics (species richness, diversity, evenness, dominance indices of the parasitoid communities in and total number of individuals) between the transgenic lines and their respective control lines. Nevertheless, the *cry1Ac/sck* rice lines had a decreased number of parasitoid individuals in the middle rice growth stage. However, the results showed that MSA and MSA4 increased the number of individuals of egg parasitoids at the beginning of late rice growth stage. Although all the *cry1Ac/sck* rice lines had a reduced number of parasitoid individuals that parasitized the target pest *C. medinalis*, none of them had significant adverse effects on other parasitoid functional groups. The study did not report the reason for the decrement, i.e., due to target pest being small or less healthy.

Bai et al. (2012) carried out the first field assessment on the potential impact of *cry1Ab* rice plant residues on abundance and diversity of aboveground non-target arthropod communities during postharvest seasons. Two independent field trials were carried out near the Xiema Agricultural Farm of Southwest University in Beibei District, Chongqing, China. One



was conducted in the 2006/07 postharvest season near Xiaomoton village while the other was carried out near Pingqiao village during the 2007/08 postharvest season. Two transgenic *Bt* rice lines, KDML (*Bt*-1) and KMD2 (*Bt*-2), and one non-transgenic rice parental variety, XS11 (non-*Bt*), were the three genotypes studied in these field trials. The two *Bt* lines were derived from a Chinese commercial variety, XS11, a member of the *japonica* rice subspecies. Both *Bt*-1 and *Bt*-2 were homozygous and contained *cry1Ab* gene under the control of a maize *ubiquitin* promoter (Cheng et al. 1998). The pitfall trap technique was adopted to measure the activity and relative abundance of above ground arthropods. Their findings suggested that the arthropod communities were not negatively impacted by the exposure of rice plant residues to the Cry1Ab protein during postharvest season. Overall, there were no significant differences ( $P>0.05$ ) in the total non-target arthropod captures among the three rice genotypes for both trials, despite demonstrating differences in total captures between the two trials (e.g., in 2006/07 season, the total number of individuals captured was 8,974, while in 2007/08 season, the total number of individuals collected was 43,412). Additionally, regardless of trial seasons or sites, there was no significant difference ( $P>0.05$ ) in Shannon-Weaver diversity index among the three rice genotypes. The same was found for the dominance concentration index, in which there were no significant differences ( $P>0.05$ ) among the three rice genotypes for both trials. Hence, it was concluded that a high similarity in the abundance and diversity of arthropod communities among *Bt* and non-*Bt* rice plots for both trials existed. Furthermore, among the arthropod community, in both trials, the detritivore sub-community was the dominant guild (accounting for 90 percent of total arthropod captures), followed by predators and phytophages (accounting for three to five percent of total captures) and parasitoids (accounting for one

percent of total captures). Generally, the findings of this study showed that plant residues of *Bt* rice had no adverse impact on the arthropod communities during the postharvest period of the two trials. Although Bai et al.'s study was conducted in small plots, which might not demonstrate the actual conditions of the real rice ecosystem, this study showed that *Bt* rice is safe to arthropod communities in paddy fields during postharvest season, at least in the short term.

Liu et al. (2003) also found that planting of *Bt* rice generally did not have any adverse effects on the rice arthropod community. This study was carried out in four locations in China over a period of two years involving two transgenic rice lines (TT9-3 and TT9-4) of the *indica* subspecies along with their parental control variety, IR-72. The significant difference found between *Bt* and non-*Bt* plots was the dominance of *Braconidae* and *Ichneumonidae* families in the phytophagous, parasitoid and detritivorous guilds. The dominance of *Braconidae* and *Ichneumonidae* in the *Bt* rice plot was lower than in the control plot. However, in most cases, no significant differences were observed between the transgenic lines and the non-transgenic control on guild dominance, family composition and species richness, diversity index, evenness index, dominance index, and temporal dynamics. Additionally, while there exists some dissimilarity between the guilds' sub-communities between *Bt* and non-*Bt* rice plots, as a whole, the dissimilarities were negligible.

Meanwhile a field study in China by Tian et al. (2008) suggested that *Bt* rice with *cry1Ab* gene might demonstrate negative effects on dominant species of parasitoid wasps, especially braconids. This study investigated the dominance, number and seasonal changes of parasitoid density. Results determined that *Braconidae* was the dominant family. While the number of

parasitoid braconid wasps in the *Bt* rice plots was lower than the non-*Bt* rice plot, there was no significant difference observed between *Bt* rice plots and control plots in terms of family composition and dominance. Additionally, during peak period, (not defined in the article), the density of braconids in *Bt* rice plots was significantly lower than in the non-*Bt* rice plots.

*Propylea japonica* (Thunberg), is a very common and abundant beneficial predator (natural enemy) in rice fields, preying on insects such as leaf-folder, planthopper (including the brown planthopper) and aphid (Song et al. 1988), among the most serious rice pests in temperate and subtropical Asia. Since *P. japonica* is a non-target beneficial predator to rice pests, its fitness (survival, development and reproduction) is important for the cultivation of the rice crop. Hence, in order to determine the effects of *Bt* rice-fed prey, the brown planthopper (*N. lugens*) on *P. japonica*, laboratory feeding experiments using transgenic rice lines possessing the *cry1Ab* gene were carried out (Bai et al. 2006a). KMD1 and KMD2 were the two homozygous *Bt* rice lines that were used in these experiments along with non-transgenic parental variety, XS11. XS11, KMD1 and KMD2 were transplanted in a greenhouse on the Huajiachi Campus of Zhejiang University in mid-June 2003. During booting stage, the plants were transferred to the laboratory and served to *N. lugens* which was fed to *P. japonica*. The enzyme-linked immunosorbent assay (ELISA) technique was used to determine the Cry1Ab concentration in the *N. lugens* feeding on KMD1 and KMD2 rice plants. Results showed that the concentration of Cry1Ab was significant in both leaves and stems of KMD1 and KMD3 plants during the plants' growth stage. The toxin concentration in the rice leaves and stems of each of these two lines increased significantly from booting to grain filling stage. Although the concentration decreased as plants developed during grain filling and mature stages, the change

was only significant in KMD2 stems. ELISA detected Cry1Ab in nymphs and adults of *N. lugens* during its feeding on KMD1 and KMD2. This observation showed that Cry1Ab in *Bt* rice can be transferred to herbivorous (phytophagous) insect *N. lugens* and then to its predator, *P. japonica*. The developmental time of preimaginal stages (pupation, adult eclosion, pupal and adult weight) and male-adult locomotive activity of *P. japonica* that preyed on *Bt* rice lines KMD1-fed and KMD2-fed *N. lugens* larvae nymphs were not significantly different from those that preyed on non-*Bt* rice variety XS11-fed nymphs. The findings of this study suggest that prey *N. lugens* and predator *P. japonica* are exposed to the Cry1Ab toxin from the transgenic rice lines, KMD1 and KMD2, but the development of *P. japonica* was not affected by the toxin through prey-mediated effect (tri-trophic interaction). The reasons why there is no significant adverse impact on *P. japonica* development is either Cry1Ab is not toxic to *P. japonica* or *P. japonica* was not exposed to sufficient concentration of the Cry1Ab toxin to have a toxic effect.

Naturally, *P. japonica* feeds on insect prey, however if this class of prey is scarce, then the beneficial beetle predator uses plant pollen as a supplemental food source (Li et al. 1992). To understand the effects of *Bt* and non-*Bt* rice pollen on the fitness of *P. japonica*, Bai et al. (2005) carried out an experimental study. The transgenic rice lines used in this experiment were KMD1 and KMD2 and the non-transgenic cultivar was XS11. The adults of *P. japonica* were harvested from rice plants during their flowering stage on the experimental farm of Zhejiang University in August 2003. The three experimental treatments were 1) KMD1 pollen with aphid (KMD1-pollen), 2) KMD2 pollen with aphid (KMD2-pollen), and 3) XS11 pollen with aphid (XS11-pollen). ELISA was used to determine the concentration of Cry1Ab toxin in anther powder (containing pollen). This experiment demonstrated that *Bt* rice pollen had no adverse impact on

the fitness of the non-target beneficial predator beetle, *P. japonica*, when used as a supplemental food source.

A laboratory study using 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> instar larvae of *C. suppressalis* (striped stem-borer) fed on transgenic rice (KMD1) as host for parasitoid *Apanteles chilonis* (Munakata) (natural enemy) was carried out to determine whether there was any effect of the Cry1Ab toxin on the parasitoid (Jiang et al. 2004a). The experiment demonstrated that the parasitized rates of the 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> instar host larvae that were fed on KMD1 were either significantly lower (3<sup>rd</sup> instar) or very significantly lower (4<sup>th</sup> and 5<sup>th</sup> instar) than larvae fed on the control rice genotype. The percentages of cocoon formation from the 3<sup>rd</sup> and 4<sup>th</sup> instar larvae that fed on transgenic rice were also significantly reduced. The developmental period of the parasitoid pupa from the 3<sup>rd</sup> instar larvae that fed on KMD1 was significantly shorter. Additionally, the 5<sup>th</sup> instar larvae that fed on KMD1 shortened the longevity of the male parasitoid wasp. The length of the parasitoid wasp cocoon was significantly shorter than the control as a result of the KMD1 treatment. Despite these negative effects on the parasitoid, there were no significant differences detected between *Bt*-rice and non-*Bt* rice in the developmental period of egg to larvae, cocoon mass size, wasp emergence rate and sex ratio of the parasitoid.

Another laboratory study (Jiang et al. 2005) investigated the effect of transgenic *sck* + *cry1Ac* rice (MSB) on the biological characteristics of *A. chilonis* through its host, striped stem borer (SSB). The experiment showed that the parasitism rate of *A. chilonis* on the 4<sup>th</sup> instar larvae fed on MSB was significantly lower than that of the control. The pupal duration was significantly longer and length of cocoon was significantly shorter for the parasitoid that

parasitized the 5<sup>th</sup> instar larvae that fed on MSB as compared to the instar larvae that fed on the parental variety (MH86). No differences were detected between parasitoids that parasitized the SSB feeding on MSB or MH86 in terms of pupa formation percentage, egg and larva duration, cocoon number or simple cocoon mass, wasp emergence rate, male/female ratio, longevity and forewing length of wasps. In summary, this study concluded that no differences were detected in some of the biological characteristics of the parasitoids that parasitized SSB which fed on either MSB or MH86.

Another field study was carried out by Chen et al. (2007) to investigate the impacts of homozygous transgenic *japonica* rice line KMD1 expressing the *cry1Ab* gene along with its non-transgenic parental rice variety, XS11, on three planthoppers, *Sogatella furcifera* (Horvath), *N. lugens*, and *L. striatellus*, and the natural enemy, *Cyrtorhinus lividipennis* (Reuter). This field evaluation was conducted at three different sites (Anji County, Experimental Farm of Zhejiang University, and Huajiachi Farm of Zhejiang University) in Zhejiang Province, China, over a period of two years (2002-2003). Two sampling methods, vacuum-suction machine and Malaise trap, were used to collect the three species of planthoppers and beneficial predator from *Bt* and non-*Bt* field sites. The population densities of each of the three planthoppers and their natural enemy, *C. lividipennis*, were not significantly affected by rice type (*Bt* and non-*Bt*), regardless of field sites, year and sampling methods. In fact, in some cases, it was observed that the overall densities of planthoppers were lower in *Bt* rice plots as compared to those in the non-*Bt* rice plots, suggesting that planthoppers are less of a problem in causing damage to *Bt* rice plants than in non-*Bt* rice plants. The two sampling methods found *S. furcifera* as the predominant species among the three planthoppers since it comprised >50 percent of the planthoppers at

each of the three sites. In general, over the two year sampling period, inconsistent impacts were observed of *Bt* rice and *Bt* rice x sampling date interaction on population dynamics of the predominant planthopper species *S. furcifera* and predator *C. lividipennis* (nymphs and adults). In spite of this general observation, in 2002, the population dynamics of *S. furcifera* adults collected with Malaise trap and *C. lividipennis* adults collected with vacuum suction at the Experimental Farm of Zhejiang University were significantly affected by *Bt* rice. However, the effect could be attributable to many reasons, either the *Bt* rice line or statistical analysis or small plot size. The findings of this study were similar to those of a previous study carried out by Liu et al. (2002) in 2000 using the vacuum suction method. The field evaluation by Liu and her team showed that during the growing season of rice, there were no significant differences in the population densities of adult *S. furcifera* (planthopper prey) and *Nephotettix cincticeps* (Uhler) (predator) in the plots of two *Bt* rice lines, i.e., TT9-3 and TT9-4 (both contained a fused gene of *cry1Ab* and *cry1Ac* from *Bt*) and their parental control IR-72. The nymph densities of *S. furcifera* (early middle season) and *N. cincticeps* (middle late season) were significantly higher in the TT9-3 rice plots than IR-72 rice plots. However, there were no significant differences between the nymph densities of *S. furcifera* and *N. cincticeps* in the TT9-4 and IR-72 rice plots. Additionally, this study also showed that there were no significant differences on the population dynamics of five dominant spider species between the TT9-3 and TT9-4 rice lines, and IR-72 rice variety.

While there have been many studies carried out on assessing the impact of *Bt* toxin through tri-trophic interactions, bioaccumulation of *Bt* toxin at various trophic levels has not been determined. The field studies carried out by Chen et al. (2009) at the Experimental Farm

of Zhejiang University in Hangzhou, China from 2002 to 2004 evaluated 1) biotransfer and bioaccumulation of Cry1Ab toxin in a food chain comprising two *Bt* rice lines on the herbivore *C. medinalis* and the predator *Pirata subpiraticus* (Bösenberg & Strand) , 2) binding activity of Cry1Ab to *P. subpiraticus* brush border membrane vesicles (BBMVs), 3) effect of Cry1Ab on the development and fecundity of the predator *P. subpiraticus* under laboratory conditions, and 4) ecological impact of Cry1Ab on *P. subpiraticus* in a three-year field study. The two homogeneous transgenic *Bt* rice lines used in this study were KMD1 and KMD2 along with their non-*Bt* parental variety, XS11. Cry1Ab was detected in the herbivore, *C. medinalis* and the predator, *P. subpiraticus*, using ELISA. This suggests that in “worst-case” scenario, the Cry1Ab toxin expressed in the KMD1 and KMD2 rice lines could be transferred to the herbivore *C. medinalis* which is then transferred to the predator *P. subpiraticus*. Nevertheless, as feeding or preying time increased (from 1 to 5 days), the tendency of Cry1Ab toxin to bioaccumulate in both herbivore and predator did not increase. Additionally, although the Cry1Ab toxin binds to several BBMV proteins in the midgut of the herbivore, *C. medinalis*, Cry1Ab did not bind in BBMVs of predator *P. subpiraticus*, suggesting that predator *P. subpiraticus* is equipped with an enzyme system in its midgut to protect itself from being harmed by a *Bt* toxin. The laboratory feeding experiment showed that the survivorship and fecundity of *P. subpiraticus* was not significantly affected by either rice genotype (*Bt* or non-*Bt*). This means that whether *P. subpiraticus* preyed on *C. medinalis* that fed on KMD1, KMD2 or XS11, its survival and reproductive capacity was not affected. Interestingly, the total development time of *P. subpiraticus* was significantly longer when it preyed on KMD1-fed and KMD2-fed *C. medinalis* as compared to when it preyed on XS11-fed *C. medinalis*. The longer developmental time of *P.*



*subpiraticus* was attributable to the lack of binding receptors of Cry1Ab in the BBMV of *P. subpiraticus* midgut, which was due to an indirect effect of host quality rather than direct toxicity effect of Cry1Ab. Since it was unclear whether a slower developmental time caused a chronic effect on *P. subpiraticus* population in fields, the three year field trial that was carried out indicated that *P. subpiraticus* population density was very similar between *Bt* and non-*Bt* rice fields, hence demonstrating that developmental effect has no relation with population density. Moreover, the interaction between sampling date and rice type did not have an adverse effect on the predator, *P. subpiraticus* population.

#### **4.3.2 Effects on Soil Community**

Other than the impact of insect-resistant transgenic crops on tertiary beneficial insects, soil dwelling insects may also be exposed to the *Bt* toxin (Palm et al. 1996, Crecchio and Stotzky 1998, Saxena et al. 1999). While most studies show no differences in mortality or body mass of soil bacteria, fungi, protozoa, nematodes and earthworms or carabid beetles exposed to *Bt*, ultimately, it depends on whether these soil organisms mediate the toxin exposure to predators (Saxena and Stotzky 2001, Ferry et al. 2007).

There is also a growing concern on the impacts of transgenic crops on soil biota and microbial processes such as nutrient cycling and potential risk of horizontal gene transfer (HGT) (McGregor and Turner 2000, Sengelov et al. 2001). It has been reported that when transgenic crops are planted in the same soil for a period of time, there is a possibility of them altering the rhizospheric microbial metabolism, causing negative effects on soil quality, structure, and function, affecting enzyme synthesis and activity, including soil decomposition and mineralization of litter (Siciliano and Germida 1999, Callaghan and Glare 2001, Cowgill et al.

2002, Macalady et al. 2002, Dunfield and Germida 2004, Sessitsch et al. 2004, Wu et al. 2004, Flores et al. 2005).

It is also important to note that differences in population densities of nematodes and collembolans on soils planted with transgenic crops have also been observed (Donegan et al. 1997, Donegan et al. 1999). Depending on crop types, transgenic crops may exert ecological effects on the microbiota and microbial soil processes. One reason that prevents transgenic crops from being commercialized in some countries is the threat of potential HGT. Exposure of non-target arthropods to insecticidal transgenic proteins could occur via direct consumption of transgenic plant tissues or pollen (Ferry and Gatehouse 2009). Transgenes can spread from transgenic crops to soil microorganisms, which inevitably changes genotypic diversity of the microbiota, resulting in new populations that could interfere with natural processes which then may displace natural populations (Bertolla and Simonet 1999, Callaghan and Glare 2001, de Vries et al. 2001).

There have been numerous studies carried out to assess HGT from transgenic crops to soil microorganisms, and some of these studies established that antibiotic resistance genes such as *nptII* were transferred from transgenic crops to microorganisms (Smalla et al. 1994, Badosa et al. 2004). However, there is still insufficient information on HGT from transgenic crops to soil bacteria to conclude that HGT poses risk to soil microorganisms. As such, this section aims to provide some insights to the literature concerning transgenic rice and papaya on soil microorganisms. Since there have been considerable studies reported on impact of herbicide-resistant and insect-resistant rice genotypes on soil microorganisms, this section will

discuss the impact based on these two genotypes followed with a review on impact of transgenic papaya (PRSV) on soil microorganisms.

#### 4.3.2.1 Insect-resistant rice

In a study by Bai et al. (2005), two collembolan species, *Entomobrya griseoolivata* (Packard) and *Bourletiella christianseni* (Bank) were collected from paddy fields in China. The population densities of *E. griseoolivata* found in the KMD1 and KMDs (transgenic) rice field were significantly higher compared to population densities observed in the XS11 (control) rice field. Laboratory analysis showed the Cry1Ab insecticidal protein was detected in *E. griseoolivata* feeding on *Bt* rice tissue. However, results from laboratory studies suggested that there were no significant differences on the predation and functional responses of *Microvelia horvathi* (Lundblad adults) that predated on *E. griseoolivata* (either fed with *Bt* or control tissue). The study did not report results of *M. horvathi* feeding on *B. christianseni*.

Meanwhile, in another study in China by Bai et al. (2006b), in September 2003, during grain filling stage, two collembolan species, *E. griseoolivata* and *B. christianseni* were collected from leaf litter of *Bt* (KMD1 and KMD2) and non-*Bt* (XS11) rice at soil surface by using an arthropod-sucking machine. The population densities of *E. griseoolivata* from KMD1 and KMD2 (transgenic lines) rice fields were significantly higher than those collected from XS11 field. In April 2004, during post-harvest season, four collembolan species (*E. griseoolivata*, *B. christianseni*, *Hypogastura matura* and *Isotoma monochaeta*) were collected from bags containing rice stem-leaf litter that were placed in the rice fields during harvest season. It was reported that population densities of *E. griseoolivata* and *H. matura* from transgenic lines, KMD1 and KMD2 rice fields were significantly higher than those from XS11 rice field. This

conclusion was reached based on the significantly greater biomass loss that was observed in stem-leaf litter of KMD1 and KMD2 rice fields as compared to stem-leaf litter found in XS11 rice field. Liu et al. (2003) carried out a two-year study to examine population densities between detritivores population in IRGM (TT9-3 and TT9-4) and parental rice (IR-72) genotypes in four locations in China. The scientist and her team reported that there were no significant differences in species richness and diversity, and evenness and dominance indices between detritivores population in the two *Bt indica* lines (TT9-3 and TT9-4) with a fused gene of *cry1Ab/cry1Ac* and their parental rice variety (IR-72).

Wang et al. (2007) carried out a field study to evaluate the impact of aerobic and anaerobic (flooded) conditions on the degradation of purified Cry1Ab protein from *Bt japonica* rice (KMD) in five rice soils (S1- quaternary red soil, S2-red sandstone soil, S3-fluvio-marine yellow loam soil, S4-coastal saline soil and S5- pale muddy soil). The soils were obtained from Zhejiang Province, China. This study also carried out laboratory analysis on the stability of the same protein in aqueous solutions, characterized by pH and initial protein concentration. Between the two types of conditions (aerobic and anaerobic), rapid degradation of Cry1Ab occurred under aerobic conditions in which the half-lives ranged from 19.6 to 41.3 days. The Cry1Ab protein dissipated fastest in the alkaline soil (S4) and substantially slower in the acidic (S2) and neutral (S3) soils. The degradation of the Cry1Ab protein was not directly related to soil property (pH) but probably attributable to soil microorganism. This finding suggests that the degradation of Cry1Ab protein is largely biotic and influenced by adsorption of the protein to soil particles. In the anaerobic condition, degradation of Cry1Ab protein was significantly prolonged as compared to aerobic conditions, with half-lives extending from 45.9 to 141 days.

Among the three soil types (S1, S2 and S3), Cry1Ab protein dissipated fastest in S3 as compared to S1 and S2. This observation demonstrated that under aqueous solutions, the hydrolysis rate of Cry1Ab protein was inversely correlated with the pH solution but positively correlated with initial concentration of Cry1Ab protein. This study was first of its kind to assess the degradation of Cry1Ab protein from *Bt* rice in paddy soils under anaerobic conditions. The findings of this study concluded that rapid dissipation of Cry1Ab protein from *Bt* rice under field conditions may most likely occur during aerobic conditions, when the soil is drained (between harvest of mature crop and following planting of rice seedlings). Minimal degradation of the Cry1Ab protein might be expected during anaerobic condition when field is flooded (during plant growth), indicating that soil microbial organism are exposed longer to Cry1Ab protein.

Meanwhile, a laboratory study by Xu et al. (2004) showed that transgenic *Bt* rice (KMD) straw could significantly increase the number of hydrolytic-fermentative bacteria and anaerobic nitrogen-fixing bacteria in anaerobic (flooded) condition in rice fields. Xu and his team studied the impact of transgenic *Bt* rice straw on anaerobic microbial populations and enzymatic activities in rice soil using several methods, including the Hungate anaerobic technique, anaerobic most probable number, roll tube and spectrophotometer.

#### 4.3.2.2 Herbicide-resistant rice

Herbicide-resistant crops which accounts for a large portion of crop lands worldwide (James 2010) are a major concern pertaining to their ecological impacts on soil ecosystems (Wolfenbarger and Phifer 2000, Lilley et al. 2006). Past studies pertaining to impact of herbicide-resistant crops on soil microbials have mainly focused on traits related to glyphosate or glufosinate as the active ingredient.

According to Chun et al. (2012), since very little information is known about the impact of protoporphyrin oxidase (PPO) inhibiting herbicides on soil microbiota, he and his team carried out a field study examining the effects of *Myxococcus xanthus* (*Mx*) PPO transgenic rice on soil microbial community in bulk and rhizosphere soils. In addition, Chun and his team also carried out analysis to learn whether microbial composition differs between transgenic and non-transgenic crops. The field experiment included one transgenic line (*Mx* PPO) and one non-transgenic parental rice variety (Dongjin). Both of these genotypes were grown in a field site at Korea Research Institute of Bioscience and Biotechnology, Cheongwon-gun, Chungcheongbuk-do, Korea during 2006-2007. The seeds of these rice plants were germinated for 40 days in a greenhouse. On 1 June and 29 May of 2006 and 2007, respectively, the seedlings were then transplanted into three replicate plots adopting randomized complete block research design. In 2007, the team harvested roots of five plants randomly chosen from each of the three plots. The harvested roots were shaken to remove large adhering soil particles. Since the preliminary analysis in 2006 did not observe any significant effects, the team continued the study in 2007 by sampling rhizosphere soil whereby microbes are most likely to be affected by root exudates. The Shannon's and Simon's diversity indices of bacterial and fungal communities varied significantly depending on growth stage and sampling time. The richness and diversity of the fungal community oscillated from stage to stage while those of the bacterial community showed slight decrement in the tillering stage of 2006 and in the maturing stage of 2007. However, within each growth stage, there was no significant difference in relation to diversity and richness between non-transgenic and *Mx* PPO transgenic rice. In regards to the composition of bacterial and fungal communities, there was no difference between *Mx* PPO

transgenic rice and Dongjin non-transgenic parental rice. Sampling time was found to be the dominant factor in determining microbial community composition. Meanwhile, the yearly variations within the microbial community could be associated with differences in temperature and precipitation between years and shifts in sampling plan.

A field study was carried out in Korea to examine the impacts of transgenic rice lines on soil microbial communities and determine whether there is horizontal gene transfer from transgenic rice lines to bacteria (Kim et al. 2008). The experiment comprised six rice genotypes of which two were glufosinate-resistant transgenic plants, i.e., Iksan 483 and Milyang 204, and four non-transgenic plants, i.e., Junam, Anjung, Dongjin and Sindongjin. The rice plants were planted in early April of 2006, and soil samples were obtained in the middle of April, August, October, and December. Results showed that the total viable counts of bacteria, fungi and actinomycetes in soils planted to transgenic and non-transgenic rice were not significantly different over the entire study duration. In addition, the denaturing gradient gel electrophoresis of polymerase chain reaction, which amplified 16S RNA genes, revealed no difference in band patterns between transgenic and non-transgenic rice soils indicating similarity in bacterial communities of soils planted to transgenic and non-transgenic rice. The phospholipid fatty acid profile indicated that the structure of the soil bacterial community was more affected by soil heterogeneities and seasonal changes rather genetic modification. Although there was no detection of horizontal gene transfer from transgenic rice to soil bacteria, some *bar* gene sequences were observed in the soil for several months, which could potentially undergo natural transformation. As suggested by Kim et al. (2008), this phenomenon can only be demonstrated through a continuous long-term study.

#### 4.3.2.3 Virus-resistant transgenic papaya

A study examining the influence of papaya ringspot virus (PRSV) resistant transgenic papaya on soil microbial population was carried out in August 2004 (Hsieh and Pan 2006). Soil samples were obtained from the Agricultural Research Institute, Tai-Chung, Taiwan. Upper layers (0-15 cm) and lower layers (15- 30 cm) of soil samples were collected from three planting areas, i) around the transgenic papaya planting area, ii) around the non-transgenic papaya planting area, and iii) from soils in which plants were not grown. In total, microbial populations from six different soils (3 planting areas x 2 layers) were obtained. Generally, the microbial populations were all high in the upper layer soils. The total population count of fungi and actinomycetes were highest in the upper layer soil surrounding the transgenic papaya planting area and lowest in lower layer soil, in which plants were not grown. Amplified fragment length polymorphism, amplified ribosomal DNA restriction analysis, terminal restriction fragment length polymorphism, and denaturing gradient gel electrophoresis analyses demonstrated that the soil microbial population in the upper layer soils surrounding transgenic papaya planting area and non-transgenic papaya planting area was more than 80 percent similar. Interestingly, similar result was observed in the lower layer soils as well. The findings of this study suggest that the PRSV-resistant transgenic papaya has a minimal impact on soil microbial population. It did not demonstrate any significant effect on the total count and diversity of actinomycetes in either the upper or lower layer soils. This could be attributable to the low quantity or no secretion of the coat protein from the transgenic papaya. However, to verify the results of this study, further experiments need to be carried out.



Another study by Wei et al. (2006) on transgenic papaya was carried out in Guangzhou, China. The purpose of this study was to examine the effects of transgenic papaya and non-transgenic papaya on soil chemical properties, microbial communities and enzyme activities under field conditions. There were significance differences ( $p < 0.05$ ) in organic matter and major plant nutrients between soil planted with transgenic papaya and non-transgenic papaya. Soil of transgenic papaya had significantly lower total nitrogen and sulfur, and higher electrical conductivity (EC), as compared to non-transgenic papaya soil content. There were significant differences ( $p < 0.05$ ) in the total number of colony forming units (CFUs) of bacteria, actinomycetes, and fungi between soils planted with transgenic papaya and non-transgenic papaya, attributable to the *nptII* marker gene (which confers kanamycin resistance) which seeped into the soil through litter and root exudates. Additionally, the CFUs of bacteria, actinomycetes, and fungi in soil planted with transgenic papaya were also significantly higher by 0.43, 0.80 and 0.46 times, respectively. In terms of enzyme activities, soil planted with transgenic papaya had also significantly higher activities of arylsulfatase (5.4 time), alkaline phosphatases (0.5 time), invertase (0.5 time), phosphodiesterases (0.16 time). Lower activities were demonstrated for proteases (2.1 time), polyphenol oxidases (1.4 time), and urease (0.16 time). The results of this study concluded that transgenic papaya with the *nptII* antibiotic gene could alter soil chemical properties, microbial communities and enzyme activities, suggesting that these risks could cause undesirable and unpredictable ecological effects. Meanwhile, a laboratory study (greenhouse conditions) reported that there was no distinct differences of microbial community found in soil samples from Thailand where transgenic and non-transgenic papaya were grown (Phironrit et al. 2007). Soil samples were collected from the rhizosphere

level, 15 cm depth, in 30-day interval until plant fruiting stage. This conclusion was based on analyses carried out on the types and number of soils bacteria, and population profile characterization.

A study by Lo et al. (2007) suggested that either a very small or no occurrence of bacterial transformation in soil samples collected from an isolated field in Taiwan where transgenic papayas were planted. Lo and his team used real-time PCR to detect the presence of three transgene fragments in the soil samples. (Lo et al. 2007). The three DNA fragments were of different molecular sizes, 35S-P/PRSV-CP, pBI121/NOS-T and NOS-P/*nptII*. Two of the three fragments (35S-P/PRSV-CP and NOS-P/*nptII*) were detected at very low levels (30 pg per gram of soil) and the pBI121/NOS-T fragment was present at 60 ng per gram of soil. The soil DNA extracts did not transform two *Acinetobacter* spp. due to the very low concentration of transgenic *nptII* observed in the extract.

#### **4.3.3 Effects on Non-Target Herbivorous Pests**

Some transgenic traits such as the pesticidal toxins expressed by *Bt* genes, may affect non-target species as well as crop pests. Discussion to some extent on the impact of transgenic lines on non-target pests has been exhaustive and as such this review will not be complete without a scientific review pertaining to this subject matter. This section only covers studies pertaining to insect-resistant rice lines on non-target herbivorous pests as there have been no studies reported on the impact of herbicide-resistant rice lines or transgenic papaya (PRSV resistant) on non-target herbivorous pests.

#### 4.3.3.1 Insect-resistant rice

The first field trial (Bashir et al. 2004) of different transgenic lines of local *indica* Basmati rice (B-370) expressing *cry1Ac* and *cry2A* genes was carried out under field conditions over two consecutive years at the National Centre of Excellence in Molecular Biology, Lahore, Pakistan. The primary purpose of the study was to determine the performance of B-370 against the two most destructive insects in the Indo-Pak subcontinent, i.e., yellow stem borer (YSB) (*S. incertulas*) and rice leaf folder (RLF) (*Cnaphalocrocus medinalis*), both from the insect order Lepidoptera. Both these pests belong to the insect order Lepidoptera. Other objectives of the study were to determine the effects of *cry1Ac* and *cry2A* genes on non-target insects. Results of the study showed that transgenic plants were 96 percent more resistant than control plants, demonstrating successful control of YSB and RLF. Additionally, transgenic rice did not impact the survival of non-target pests (*Leptocorisa acuta* (Thunberg), *S. furcifera*, *N. cincticeps*, *Cofana spectra* (Distant), *Hieroglyphus banian* (Fabricius), *Oxya hyla* (Serville), *Oxya velox* (Fabricius), *Atractomorpha crenulata* (Fabricius), and *Acrida exaltata* (Walker)). Although the first year of trial recorded a slight disruption on the survival of non-target insects by transgenic plants as compared to the control, the damage was found to be insignificant. This infers that *cry* genes are highly specific to target insects as compared to chemical pesticides.

Another study (Chen et al. 2006) was carried out in three field sites in Zhejiang Province, China over two years to assess the impacts of *Bt* rice that expressed a fused gene of *cry1Ab* and *cry1Ac* on non-target pests, planthoppers and leafhoppers. The field experiments were carried out in 2003 and 2004 at three sites (Anji, Jiande and Hangzhou) in Zhejiang Province, China. The three sampling techniques used were yellow sticky card trap, Malaise trap and vacuum suction

machine. Complete randomized design was the research design adopted in this field study. The planthopper species that were collected at all three sites were *S. furcifera* (white backed), *N. lugens*, and *L. striatellus*. The leafhopper species collected at Hangzhou were *N. cincticeps*, *N. virescens*, *Thaia subrufa* (Motschulsky), and *Recilia dorsalis* (Motschulsky). *N. virescens* along with *N. cincticeps* and *R. dorsalis* were collected at Anji and Jiande. The yellow sticky card trap sampling which measures the dispersal of adult arthropods showed no significant differences between *Bt* (TT9-3) and non-*Bt* (IR-72) rice plots in either species' composition or densities in the three planthoppers and leafhopper species, throughout the whole sampling period. The Malaise trap and the vacuum suction machine samples also demonstrated no significant differences between *Bt* and non-*Bt* plots in species structure of planthoppers and leafhoppers or in population changes of *S. furcifera*, *N. cincticeps* or *N. virescens* in most sampling dates. It was noteworthy to learn that densities of planthoppers and leafhoppers were significantly affected by year and site but not by *Bt* rice. Additionally, the yellow sticky card trap also showed that there were no noticeable differences found in the total dispersal densities of each species of planthoppers and leafhoppers between *Bt* and non-*Bt* rice plots. This finding was supported by a study carried out by Liu et al. (2002). Liu and her team reported that through the use of vacuum suction sampling method in 2000, they did not find significant differences in adult and nymph densities of *S. furcifera* and *N. cincticeps* between *Bt* (TT9-3 and TT9-4) and non-*Bt* (IR-72) rice plots in China. The field study by Chen and his team concluded that the *Bt* rice line TT9-3 did not have a negative effect on the population dynamics of the non-target planthoppers and leafhoppers. The results of these studies imply that fitness parameters of planthoppers or leafhoppers might not be significantly associated with *Bt* rice. Planting of *Bt*

rice might not necessarily lead to higher populations of non-target planthoppers or leafhoppers, or increase the damage caused by these non-target arthropods. With this in mind, it can be inferred that while planthoppers and leafhoppers are available in both *Bt* and non-*Bt* rice fields, the abundance of natural enemies of these arthropods may not be impacted by *Bt* rice. This inference is supported by the study carried out by Liu et al. (2002) which demonstrated that no significant differences were observed in the abundance of five common spider species (regarded as important predators of planthoppers and leafhoppers) between the *Bt* rice and non-*Bt* rice plots in China. The study by Chen et al. (2006) concluded that their field assessments showed that the *Bt* rice line did not demonstrate adverse effects on the population of insects studied. As such, the management of planthoppers and leafhoppers in a *Bt* rice field can be handled in the same manner as practiced in a non-*Bt* rice field. Chen and his team did acknowledge some limitations to their study: 1) the experiments were designed to observe large differences among the two types of insect classification, 2) the two year period under study was relatively short, and 3) the field plots and number of replications were small.

A study by Tan et al. (2006), compared the susceptibility of two homogeneous genotypes of transgenic *indica* rice, B1 and B6, with their non-transgenic parental cultivar, Jiazao 935 against the white-backed planthopper *S. furcifera*. An electronic monitor was used to measure the developmental duration, oviposition behavior and fecundity of *S. furcifera* on B1, B6 and Jiazao 935. The findings demonstrated that the total developmental time of female and male nymphs were significantly longer for insect grown on both *Bt* lines as compared to their parental variety. Additionally, it was found that there were no significant differences in the oviposition frequency, the duration per oviposition and total oviposition period of *S. furcifera*

among B1, B6 and Jiazao 935. The choice test indicated that while female adults preferred to lay more eggs on B1 as compared to Jiazao 935, the opposite was true for B6 and Jiazao 935. Nevertheless, under the no-choice test, there were no significant differences found between B1 and B6, and Jiazao 935. Under both choice and no-choice tests, B1 and B6 did not also show any adverse effect on the hatching rate of *S. furcifera* in comparison with Jiazao.

A similar observation was made in a study by Chen et al. (2003). Chen and his team assessed the impact of the same transgenic rice lines (B1 and B6) and one other transgenic restorer line of hybrid rice (MSA) along with their respective non-transgenic parental cultivars, Jiazao 935 and Minghui86 on the feeding and oviposition behavior of their non-target insect, *N. lugens* in a laboratory. The experiment demonstrated that the oviposition behavior (oviposition preference and the number of eggs laid) by *N. lugens* on both transgenic rice types (B1 and B6) and MSA were not significantly different than their corresponding parental cultivars (Jiazao 935 and Minghui86). However, the lab experiment also showed that *N. lugens* fed less on transgenic rice lines as compared to their respective parental cultivars. This study concluded that while the three transgenic rice lines had no effect on *N. lugens* oviposition behavior, they had an adverse effect on *N. lugens* feeding behavior.

Thrips species are considered pests to the rice crop as they attack the rice panicles (Akhtar et al. 2013) but they are not a target arthropod of *Bt* rice. In order to understand the potential effects of six *Bt* rice lines on four different non-target thrips species (*Frankliniella intonsa* (Trybom), *Frankliniella tenuicornis* (Uzel), *Haplothrips aculeatus* (Fabricius), and *Haplothrips tritici* (Kurdjumov)), Akhtar et al. (2013) carried out a two year experiment at the Experimental Farm of Zhejiang University, Hangzhou, China in 2008 and 2009. The six transgenic

rice lines were encoded with the Cry1Ab protein or fused protein of Cry1Ab and Cry1Ac. These six lines and their respective rice parental control cultivars were categorized into three groups. Huachi 2000 B1 (B1) and Huachi 2000 B6 (B6) which express the Cry1Ab protein and *indica* Jiazao 935, the non-transgenic parental control comprised the first group. The transgenic lines, TT9-3 and TT9-4 expressing a fused protein of Cry1Ab/Cry1Ac and their rice parental control *indica* IR-72 were placed in the second group. Meanwhile the transgenic rice lines, KMD1 and KMD2 expressing the Cry1Ab protein were placed in the third group along with their parental control, the *japonica* line Xiushui 11. The whole experiment had a total of nine experimental plots in a 3 treatment (2 transgenic rice line and 1 non-transgenic rice variety) by 3 replications completely randomized design. Two sampling methods, beat plate and plastic bag, were used to monitor the population densities of the four thrips species during the two-year experiment. The experimental results indicated that the seasonal average densities of the four non-target thrips in *Bt* rice plots were significantly lower than or very similar to those from the non-*Bt* rice plots, depending on rice genotypes, sampling methods, and years. Among all the six tested *Bt* rice lines, B1 and KMD2 might be the preferred candidates to be used in a rice integrated pest management system. This is because not only did they demonstrate high resistance to lepidopteran pests (Ye et al. 2001a, Ye et al. 2001b, Ye et al. 2003), but also in comparison with their non-*Bt* parental rice cultivars, B1 and KMD2 lines could significantly suppress the population densities of these thrips in the rice ecosystem.

A comparable observation was made in the study carried out by Akhtar et al. (2010) on determining the impact of the above six *Bt* rice plants on thrips species, *Stenchaetothrips biformis* (Bagnall) under laboratory and field conditions. These thrips attack rice plants during

seedling and tillering stages. This study was carried out in 2008 under similar conditions as the study carried out by Akhtar et al. (2013), e.g., location was in Experimental Farm, Hangzhou involving similar non-transgenic rice varieties categorized in three groups using beat plate and plastic bag sampling methods. Regardless of sampling methods, the seasonal average densities of *S. biformis* on all six *Bt* rice lines were significantly lower than their corresponding non-*Bt* varieties.

The findings of the studies reviewed above are fascinating because although the *Bt* rice lines developed were not targeted at non-target pests, some of these lines showed potential in controlling non-target pest populations.

#### **4.3.4 Effects of Transgene Escape**

Transgene escape from a transgenic crop to non-transgenic varieties (cultivated, weedy and wild crops) has aroused worldwide debate (Ellstrand et al. 1999, Ellstrand 2001, Ellstrand 2003, Lu and Snow 2005, Wang et al. 2006).

According to Gealy et al. (2002) and Gealy et al. (2003), rice is primarily self-pollinating but outcrossing between weedy rice and cultivated rice or between cultivated rice plants occur commonly. The major pathway of transgene escape between transgenic rice and non-transgenic rice or wild relatives is through cross-pollination (Lu et al. 2003). Generally, according to Dale et al. (2002) and Lu et al. (2003), for transgene escape to occur, it has to fulfill the following criteria: 1) transgenic rice and non-transgenic rice (including wild relatives) should have a close relationship (biologically or sexually compatible) and the resulting interspecific hybrids should be able to reproduce normally, 2) temporally, the flowering time (flower duration within a year and flowering time within a day) between transgenic rice and non-



transgenic rice (including wild relatives) should be synchronized (overlap). Meanwhile, Lu et al. (2003) added another criteria 3) spatially, transgenic rice and non-transgenic rice (including wild varieties) should be sympatrically distributed (grow in the same vicinity). Lu et al. (2003) also observed that crop-to-wild and crop-to-weedy transgene escape occur at different frequencies depending on species and populations involved.

#### 4.3.4.1 Insect-resistant rice

To examine the frequencies of pollen-mediated gene flow, a field trial involving three insect-resistant (IR) transgenic lines and their respective non-transgenic rice varieties was carried out by Rong et al. (2006) in Fujian Province, China from June – October 2004. The IR transgenic rice lines were KeFeng6 (MSR+), IYouKeFeng6 (HY1+) and 21KeFeng6 (HY2+) and the non-transgenic varieties were Minghui-86 (MSR-), IYouming-86 (HY1-) and Liangyou-2186 cry (HY2-). Each of the three transgenic lines contained two tightly linked and single-inserted transgenes for insect resistance, *Bt* gene (*cry1Ac*) from *B. thuringiensis* and cowpea trypsin inhibitor (*CpTI*) gene modified from *Vigna unguiculata* L., with a constitutive ubiquitin (for *Bt*) promoter and a constitutive Act1D for *CpTI* promoter. The two transgenes were linked to the selectable marker gene *hpt* for hygromycin resistance regulated by the promoter, CaMV 35S (Chen et al. 2006). All plants from the line MSR+ are homozygous (restorer line). Meanwhile, the two other IR transgenic rice lines, HY1+ and HY2+ were hybrid rice lines and all plants were heterozygous (Rong et al. 2005). In this study, the three IRGM rice lines were pollen donors and their respective counterparts were receivers of transgenic pollen. MSR- is a male-sterile restorer variety while HY1- and HY2- are hybrid varieties. All three non-transgenic varieties are widely cultivated in China rice production. All six rice genotypes are isogenic. Each transgenic

and non-transgenic rice pair (MSR+ vs MSR-, HY1+ vs HY1-, HY2+ vs HY2-) has similar growth and flowering timing, hence maximum opportunities for transgene flow is guaranteed. Four plots of different sizes were used to examine gene flow from each of the three transgenic lines to non-transgenic varieties, totaling to twelve treatments. The three plots bearing transgenic lines located adjacent to the 640 m<sup>2</sup> plot bearing non-transgenic varieties were 400 m<sup>2</sup>, 200 m<sup>2</sup> and 100 m<sup>2</sup>, respectively. The remaining plots bearing transgenic lines were rectangular and measured 380 m<sup>2</sup> against the square plot (1216 m<sup>2</sup>) of non-transgenic varieties.

The twelve plots were randomly assigned in the field with at least 30 m between neighboring plots to minimize gene flow coming from outside the plot. The plots were arranged along the prevalent wind direction in order to maximize gene flow. Harvested seeds were first soaked in fresh water for two days and placed in a seed germination chamber without hygromycin B at 37°C for one to two days. The germinated seeds were then cultured in Petri dishes containing 0.5 x Murashige and Skoog (MS) liquid medium with macronutrients and micronutrients, in addition to 50 ug ml<sup>-1</sup> hygromycin B for c. five days in an illuminated growth chamber at 25°C and 27°C. The surviving individuals were considered to be transgenic plants containing the hygromycin-resistance gene (*hpt*). The *hpt* marker was used to screen seeds from non-transgenic rice rows at different distance intervals from transgenic rice plots. Examination of more than 2.1 million germinated seeds demonstrated that the highest gene flow frequency, for the three rice pairs (i.e., 0.28 percent from HY2+, 0.06 percent from MSR+, and 0.04 percent from HY1+) was recorded at a separation distance of 0.2 m. Clearly, short distances between transgenic rice lines and non-transgenic rice varieties provided an avenue for cross-pollination to occur as a result of physical contact and pollen dispersal through air

currents. However, at separation distances greater than 6.2 m, gene flow frequency declined dramatically to less than 0.01 percent with variation across distance intervals. At 10.2 m, the maximum distance examined, gene flow frequency was extremely low at 0.0021 percent. This study clearly demonstrated that transgene flow frequencies reduced tremendously with increasing separation distance between transgenic rice lines and non-transgenic rice varieties. Interestingly, rice genotypes and plot size had no effect on such trend. Short spatial isolation was suggested as an effective mean of minimizing crop-to-crop gene flow in rice fields. Additionally, low frequency crop-to-crop gene flow in rice may be attributable to the nature of the rice crop mating system (self- and wind-pollination) and very low outcrossing rate.

To quantify transgene flow from IR transgenic rice line to non-transgenic rice varieties, Rong et al. (2005) investigated gene flow frequencies between these two genotypes with different mixed-planting proportions within small plots in Fujian and Hainan Province, China. The rice materials used in this study were the same as the ones used in the study by Rong et al. (2006). The *hpt* gene was also used in this study as a selective marker for identifying hybrids. The field experiments were carried out in 2003, in an 8 x 8 m<sup>2</sup> plots. The planting distance between adjacent transgenic and non-transgenic rice plants were 20 cm in all the plots. Three experimental patterns were adopted in this study. Experiment A consists of 9 individual rice plants in a unit within a field plot. A unit contains 8 transgenic rice seedlings adjacently surrounding 1 non-transgenic rice seedling (8 transgenic : 1 non-transgenic). This layout was considered the extreme case for crop-to-crop transgene flow. In experiment B, although the total number of individual rice plants within a unit is the same as experiment A, the planting proportions was different. In each unit, one transgenic rice seedling was adjacently surrounded

by 8 non-transgenic rice seedlings (1 transgenic : 8 non-transgenic). Meanwhile, experiment C contained equal number of transgenic and non-transgenic rice seedlings (1 transgenic : 1 non-transgenic). The seedlings were mixed before being transplanted into plots. The results of this study demonstrated that although transgene flow between the 3 *Bt/CpTI* transgenic rice and their relevant counterparts (non-transgenic rice) did occur, the frequency was generally very low, ranging from 0.05-0.79 percent. This finding was based on a total of 645,775 seeds collected from the 2 field sites. Even in the extreme case of close spacing, where the proportion of transgenic to non-transgenic was 8 : 1, the transgene flow frequencies were below one percent. This study concluded that the magnitude of transgene flow between transgenic and non-transgenic rice is closely associated with relative pollen density of pollen donor (transgenic rice) and not rice planting areas (close or distant planting space between transgenic and non-transgenic rice).

A field experiment was carried out in Shanghai, China to observe the general performance of hybrids between weedy rice and insect-resistant transgenic rice, and to determine any advantage that transgenic hybrids has over weedy parents (Cao et al. 2009). The experiment involved three weedy rice accessions, two transgenic rice lines and  $F_1$  hybrids of weedy and transgenic rice lines. The three weedy rice accessions obtained from South Korea were wa (YW2428), wb (YW2508) and wc (YW2730). All of them have similar growth duration. The two homozygous insect-resistant transgenic rice lines were *CpTI* and *Bt/CpTI*. Six combinations of three weedy rice accessions and two transgenic rice lines (*wa x CpTI*, *wb x CpTI*, *wc x CpTI*, *wa x Bt/CpTI*, *wb x Bt/CpTI*, and *wc x Bt/CpTI*) were used to produce the  $F_1$  hybrids *via* hand-pollination. The three weedy rice accessions were female parents while the two

transgenic rice lines were male parents. Four types of planting arrangements were adopted in this field study: i) a weedy parent grown in monoculture ii) a hybrid combination planted in monoculture, iii) hybrids and their weedy parents planted alternately in 1 : 1 mixture, and iv) a transgenic rice parent planted in monoculture. A total of seventeen treatments were involved in the experiment and each treatment included three replicates, where each replicate was arranged in a 1.2 m x 1.2 m paddy plot. Thirty-six rice plants were cultivated in each plot with a distance of 20 cm between rows and hills. A complete randomized design was adopted for all the plots in the field. Local farmers followed routine field management procedure, without any application of insecticide throughout the experiment. Results of the study demonstrated that in general, the  $F_1$  hybrids had a slightly better performance than their weedy rice parents regardless of planting arrangements (monoculture or mixed planting). Additionally, although  $F_1$  weedy transgenic hybrids had better advantage as compared to their weedy or transgenic parents during vegetative stage (hybrids had taller plants and produced more tillers than their weedy parents and hybrids were more vigorous than transgenic parents), the advantage might not be related to the insect-resistance transgene since the insect pressure observed was low in the field. The  $F_1$  hybrid superior performance might be more affiliated with hybrid vigor (heterosis). As such, the findings of this study suggest that with the aid of slightly increased relative fitness in  $F_1$  hybrids, the transgenes from transgenic rice can persist and introgress into weedy rice populations through recurrent crop-to-weed gene flow. Hence, the authors of this study suggest that future like-minded studies should focus on the fitness of hybrids and their later progeny to provide convincing results on the potential transgene introgression into weedy rice populations.

Existing cultivated rice (*O. sativa*) and its close relative (*O. rufipogon*) containing the AA genome co-exist in many parts of the world, including Malaysia. Wild rice populations could have either lengthy flowering period or synchronized flowering with cultivated rice, depending on locality. Studies relating to this subject mainly focused on gene flow from transgenic rice-to-non-transgenic rice, non-transgenic rice-to-wild rice, and non-transgenic rice- to-weedy rice. According to the author's knowledge, transgene escape from transgenic rice-to-wild rice has not been extensively investigated (a preliminary study was carried out by Lu and Yang 2009, and their findings are discussed below). With that in mind, this section is only able to discuss implications of transgene flow from transgenic rice-to-wild rice based on findings from studies on transgenic rice-to-non transgenic rice, non-transgenic rice-to-wild rice, and non-transgenic-rice-to-weedy rice. Theoretically, it has also been established that transgene flow from crop to wild species could occur through weedy rice acting as a genetic bridge, but this avenue of transgene flow has yet to be examined (Lu and Snow 2005).

Lu and Yang (2009) conducted an experiment to analyze the content of Cry1Ac protein in three transgenic rice lines that contained a *Bt* transgene, their F<sub>1</sub> hybrids with common wild rice (*O. rufipogon*), and F<sub>2</sub> progeny at different growth stages (Lu, unpublished data). The location of the study was not mentioned. Based on ELISA, they found that the average content of Cry1Ac protein in leaf samples of wild rice populations ranged between 0.016 percent and 0.069 percent during the entire growth period, while protein in stems varied between 0.12 percent and 0.39 percent. Their study also demonstrated a great variation in Cry1Ac protein content among individuals of F<sub>1</sub> hybrids and F<sub>2</sub> progeny (0.0075 percent–0.22 percent in leaf and 0.054 percent–0.96 percent in stem samples), with some wild individuals showing

dramatically higher level of *Bt* toxin than the cultivated transgenic rice. Their preliminary research findings demonstrated that insect-resistance *Bt* transgene can express normally in hybrids crossed with common wild rice and that higher amount of *Bt* toxin was detected in some individuals of the crop-wild hybrids and F<sub>2</sub> progeny. Since their findings suggest that the likelihood of transgene to express normally or exceedingly in wild rice relatives is high, they recommended that further assessments of environmental consequences caused by *Bt* transgene escape to wild rice to be carried out.

Studies by Song et al. (2003, 2004) assessing gene flow between cultivated rice (Minghui-63) and wild rice (*O. rufipogon*) under experimental conditions in China showed that maximum frequency of transgene escape from Minghui-63 to *O. rufipogon* (adjacent) was less than three percent. They also reported that 95 percent of the crop-wild hybrid seeds occurred on *O. rufipogon* only when *O. rufipogon* plants are within 30 m of Minghui-63 plants. One hundred and ten meters is the maximum distance in which pollen flow was detected between these two plants. They concluded that low levels of crop-to-wild transgene flow could occur when *O. rufipogon* is within approximately 50 to 100 m of the Minghui-63 and only when these two varieties' flowering times are synchronized.

#### 4.3.4.2 Herbicide-resistant rice

Wheeler et al. (2000) conducted three experiments in 1998 and 1999 to ascertain whether the glufosinate-tolerant (*bar*) gene will outcross between transgenic white rice lines to eight red rice accessions and the rate of outcrossing. The study was carried out in Arkansas. The three transgenic lines were Gulfmont (T1), 'Cypress' (T2), and 'Bengal' (T3) while the eight red rice accessions were Stuttgart strawhull (R1), 11 D (R2), 15 A (R3), Stuttgart blackhull (R4), 14 F

(R5), TX 4 (R6), 10 A (R7), #8 (R8). The transgenic rice were seeded as a hill into the centers of small plastic pools and all the eight red rice were seeded in pots as hills and placed in circular design around the transgenic rice hill in each pool. Each hill had ten plants of one of the three transgenic rice plants. The red rice pots were approximately 25 cm from the transgenic rice. A total of six experiments were carried out (two plastic pools for each transgenic rice x three transgenic rice lines). The plants were grown freely until flowering season, in which upon completion of flowering, heads on the plants of all hills were bagged and brought into the greenhouse until they were fully matured. Results were only reported for experiments carried out in 1998. Wheeler and his colleagues found red rice seedlings expressing the phenotype of resistance to the *bar* gene in all red rice and transgenic rice combinations, an indication of occurrence of outcrossing between transgenic rice and red rice. The mean level of outcrossing ranged from 0.8 to 19.7 percent.

Messeguer et al. (2004) investigated the influence of wind on pollination frequency of the cultivated rice variety, Senia with transgenic pollen from transgenic line S 1B in Spain. The S 1B line was derived from the transformation event S-B, exhibiting resistance to ammonium glufosinate and expressing the *gusA* gene, which encodes with  $\beta$ -glucuronidase. Results showed a gene flow occurrence of  $0.086 \pm 0.007$  percent between transgenic rice and cultivated rice, averaged over all wind directions. Gene flow appeared to decrease with increasing distance (1, 2, 5 and 10 m) between the two rice plants under the prevailing wind conditions. Wind influence on gene flow *via* cross-pollination and pollen dispersal was a major component in the study. Results also showed that the safe isolation distance between the two rice plants varied according to compass direction. As such, precise meteorological assessment of wind during the



blooming period is crucial and must be taken into account when deciding on a safe isolation distance.

Messeguer et al. (2004) also carried out another study to determine the frequency of pollen-mediated gene flow from the transgenic S 1B to the red weedy rice in the Spanish japonica cultivar, which had similar morphological and agronomical similarities with the cultivated rice variety, Senia. A field trial with circular planting design was set up to assess the influence of wind on pollination frequency of red weedy rice with transgenic pollen. Results showed a gene flow occurrence of  $0.036 \pm 0.006$  percent between transgenic rice and red weedy rice, averaged over all wind directions. Nevertheless, cross-pollination rates between transgenic rice and red weedy rice in this study were lower as compared to study carried out by Wheeler et al. (2000). This is probably because red weedy rice grows in isolation or in patches surrounded by transgenic rice, and as such their spikes are very close to each other, a condition which maximize gene flow. Another reason could be that the flowering period of transgenic and red weedy rice plants overlaps (for ten days). The study recommended that in order to avoid gene flow occurrence between transgenic rice and weedy rice, which could result in ecological consequences, control practices such as destroying red weedy rice and/or wild rice plants in the borders, acting as a reservoir of transgenes, should be implemented.

In order to determine gene flow frequency between transgenic rice and weedy rice (*O. sativa* f. *spontanea*), Chen et al. (2004) carried out two field experiments. One site was in Kyongnsan, South Korea and the other was in Hunan Province, China. The field conditions mirrored the natural rice farming ecosystem in Asia. Long grain subspecies *indica* and short grain subspecies *japonica* of various plant heights and heading dates were used in this study.

Although this study also assessed the gene flow frequency between cultivated rice and wild rice, this section of the study is not covered in this review since the cultivated rice was not of a transgenic species. The transgenic rice that was used in this study was a HT line, Nam29/TR18, containing the *bar* gene that expresses resistance to glufosinate ammonium (trade name Basta<sup>®1</sup>). Nam29/TR18 was developed through a single cross between an elite rice variety (Nam29) and the transgenic rice line (TR18) (Li et al. 1996). The transgenic rice-weedy mixture (CWM) population was replicated three times in South Korea with a paddy plot size of 5 x 20 m<sup>2</sup>. Complete random block experimental design was adopted, in which Nam29/TR18 was planted with 35 hills per row and mixed with one variety of weedy rice (out of 14 accessions) in each block. Six or seven rows of Nam29/TR18 were planted as a protecting zone surrounding each replication to ensure a sufficient population of pollen donor (Nam29/TR18). The experimental findings demonstrated that the detected gene flow frequencies from rice line Nam29/TR18 to various weedy rice accessions were between 0.011 percent and 0.046 percent, an indication of very low gene flow. The gene flow distance was not mentioned in this study. Additionally, due to unsynchronized flowering time and different plant heights, there was no indication of transgene flow from Nam29/TR18 to some weedy rice accessions. Although, gene flow between transgenic rice and weedy rice exists, the scientists of this study believe that the out-crossing rate between weedy and cultivated rice in large populations under natural conditions might be more significant than that observed in this study. This is because under natural conditions, due to the features of weedy rice as a result of cross-pollination and genetic recombinations, the flowering time, plant height and other features of weedy rice will tend to be similar (adaptive) to rice grown in the same field. Additionally, since the data generated

from this study was only of one generation, with limited number of plants in small scale plots, the findings might not reflect the gene flow frequency in general. Through generations, frequency of hybrids as a result of gene flow could accumulate and increase. Hence, this study recommended that transgenic rice should not be released under circumstances when the inserted genes could significantly enhance the ecological fitness of weedy rice in regions already abundant with weedy rice.

#### 4.3.4.3 Virus-resistant transgenic papaya

The majority of commercial PRSV resistant transgenic papaya planted in Hawaii are hermaphrodites, which are largely self-pollinated (Manshardt 2002, Souza et al. 2005, Gonsalves 2006, Fuchs and Gonsalves 2007, Mendoza et al. 2008). According to Manshardt (2002), the edible part of a papaya fruit always has the same genetic constitution of the tree that produces it. This means that if a tree is not genetically engineered, the edible fruit from it will not be genetically altered by cross-pollination, regardless of the pollen source. If a flower is pollinated by a genetically engineered plant, the seed inside the fruit may be genetically engineered but the genetic character of the edible part of the fruit will not change. To determine the transgene flow between transgenic (Rainbow) and non-transgenic papaya (Sunrise), a field study was carried out in 1995 in Puna, Hawaii (Manshardt 2002). The field trial consisted of a large solid block of Rainbow (transgenic papaya) surrounded by six adjacent rows of non-transgenic papaya. Of the seeds analyzed from non-transgenic plants, the transgene was detected in 43 percent of female plants and in 7 percent of hermaphrodite plants. The results demonstrated that cross-pollination did occur between transgenic and non-transgenic papayas grown in immediately adjacent fields (within 26 m of the transgenic papaya field) if

female plants are present in non-transgenic field. The nearest row of non-transgenic papaya tree was approximately 3 m away from rows of transgenic trees. The study also suggested that the cross pollination rate is higher on female plants as compared to hermaphrodite plants, and if commercial fields of hermaphrodite plants are more than 400 m in distance, cross-pollination could not be possibly detected between transgenic and non-transgenic papayas. Manshardt's explanation to this finding was that hermaphrodite plant, self-pollinate before flower buds open. Hence, if commercial fields are planted with hermaphrodites, the cross pollination will be low under normal conditions. However, he suggested that for seed production purposes, the best way to prevent contamination by pollen from other sources is to cover the unopened flower bud with a light bag secured with a string or twist-tie until after the flower opens and petals fall off. Another ongoing study in relation to monitoring movement of transgene pollen is being carried out in Puna (Gonsalves, unpublished data). Seeds were sampled from border or close to border non-transgenic papaya trees growing adjacent to Rainbow orchards. Thus far, the transgene has not been detected in any of the 447 sampled non-transgenic trees (the distance measuring the transgene flow was not mentioned). While this study findings are still preliminary, it suggests that transgene flow is minimal in non-transgenic papaya orchards growing close to commercialized transgenic papaya orchard. Coexistence of transgenic and non transgenic papaya in Hawaii has been routinely and successfully practiced (Gonsalves 2006, Fuchs and Gonsalves 2007). A similar transgene flow study is being carried out in the Philippines between long-shelf life transgenic papaya and non-transgenic papaya, but the results of this study are not publicly available (Mendoza et al. 2008).

While cross pollination occurs between transgenic papaya and non-transgenic papaya, the rate is higher on female plants when compared to hermaphrodite plants. Cross-pollinations will be extremely low if hermaphrodite papaya plants are planted more than 400 m away from non-transgenic papaya. If adopted, this management practice will assist in reducing cross pollination during flowering season. Meanwhile to reduce cross pollination in seed production fields, it is suggested to cover the unopened flower bud until the flower blooms and petals fall off.

#### **4.3.5 Other Impacts**

##### **4.3.5.1 Heteroencapsidation or transcapsidation**

According to Fuchs and Gonsalves (2007), heteroencapsidation or transcapsidation refers to the encapsidation of the genome of one virus by coat protein of another virus. Heteroencapsidation may occur due to interaction between coat protein (CP) expressed by the transgene and another virus infecting the same plant. Theoretically, emergence of new virus epidemics could result from heteroencapsidation (Fuchs and Gonsalves 2007). Theoretically, it is possible the CP protein produced by transgenic papaya carrying the *cp* gene may interact with PRSV-W virus strains, because PRSV-P and PRSV-W are closely related potyviruses. PRSV-P as discussed in this review infects papayas and cucurbits while PRSV-W infects only cucurbits and not papaya. Under screen house conditions, Warin et al. (2007) used ELISA tests to determine the possibility of infection by a PRSV-W on the Thailand transgenic papaya NK 11/5 R<sub>4</sub> and R<sub>5</sub> lines, containing to PRSV-P *cp* gene. Warin and his team concluded that heteroencapsidation in transgenic papaya NK 11/5 R<sub>4</sub> and R<sub>5</sub> lines did not occur as they did not

observe disease symptoms and complete absence of PRSV-W. This study's findings were substantiated with no reports of emergence of virus species with undesirable characteristics, based on 10 years commercialization of PRSV-resistant transgenic papaya in Hawaii (Fuchs and Gonsalves 2007). According to Suzuki et al. (2007), there are two major aphid-transmitted potyvirus that could infect papaya in Hawaii. One is tospovirus *Tomato spotted wilt virus* and the other is *Papaya leaf distortion mosaic virus (PLDMV)*. Although there have been reports of tospovirus *Tomato spotted wilt virus* in Hawaii, it is uncommon and the PLDMV does not occur in Hawaii. The PLDMV CP protein is also not serologically related to that of PRSV (although they both belong to the same group) which in return may limit heteroencapsidation in nature.

#### 4.3.5.2 RNA recombination

RNA recombination is an active natural viral evolutionary process. Allison et al. (2000) carried out an initial experiment to determine whether a viral transgene was physically available to a replicating virus for recombination. The experimental results showed the viral transgene for RNA recombination to replicating viruses exists in virus resistant transgenic plants. Although smaller transgenes might be less likely to be involved in recombination events, the likelihood of a transgene combination being prevented is not apparent. Moreover, since the transgene is turned on all the time (in plants with constitutive promoters), opportunities for recombination events are likely greater as compared to natural occurring infections. To avoid possible adverse consequences, it is suggested that virus resistant transgenic plants, including virus resistant transgenic papaya be monitored for development of new viruses.

### **4.3.6 Indirect Impact of Changing Agricultural Practice on the Environment**

#### **4.3.6.1 Positive**

This section discusses the positive impacts obtained from transgenic rice and papaya studies and also draws pointers from other transgenic crops' studies.

The impact of transgenic crops in comparison to other weed, insect and pest control strategies, i.e., chemical pesticide application, is considered in this section. Although pesticides brought tremendous benefits to crop productivity (yield improvements), they had undesirable non-target effects in some cases (Devine and Furlong 2007). Benefits of IR crops vary depending on crop and pest pressure. According to Fernandez-Cornejo and Caswell (2006), when pest pressure is high, planting of IR crops leads to fewer insecticide treatments and less insect damage, which as a result could reduce potential environmental damage.

Bashir et al. (2004) reported that *cry* genes from the transgenic indica Basmati rice B-370 are highly specific to target insects unlike chemical pesticides. Another study by Ye et al. (2003) suggested that transgenic rice line KMD2 demonstrated better protection (e.g. high resistance and no folded leaves) from rice leaffolder as compared to chemical insecticide treatments. Huang et al. (2005) also concluded that IR transgenic rice reduced the number of pesticide applications by 86 percent. All these findings infer that the potential adoption of IR transgenic rice to control pest pressure could reduce the application of pesticides, especially when pest pressure is high. Hence, adoption of transgenic lines could potentially benefit beneficial organisms and the environment.

In regards to herbicide-tolerant (HT) crops, utilization of glyphosate as the primary active ingredient in controlling weeds, has brought the benefit of displacing use of more toxic

herbicides (Fernandez-Cornejo and Caswell 2006). HT crops also facilitated the adoption of low-till and no-till agriculture, allowing topsoil to remain intact and protected from rain or wind disturbances (Farrell et al. 2006, Ervin et al. 2010).

#### 4.3.6.2 Adverse

The adverse impact of adopting IR and HR rice, as well as PRSV resistant transgenic papaya have not been reported and as such this section draws pointers from previous studies carried out on other transgenic crops.

Application of an insecticide facilitates insect resistance to that particular insecticide, regardless of whether the insecticide is organic, synthetic or genetically engineered. This depends on the exposure of target insects to the insecticide, i.e., frequency and duration of insecticide application (Tabashnik 1994, Tabashnik et al. 2008, Carriere et al. 2010, Bagla 2010, Storer et al. 2010). While some scientists predict that pest resistance to *Bt* crops will occur in a few years, global pest monitoring data suggest that insects would take more than a decade to develop resistance to *Bt* crops (Tabashnik et al. 2008, Carriere et al. 2010). However, due to more than a dozen years of widespread of *Bt* crop cultivation, at least five major target pests (year first detected), e.g. *Helicoverpa zea* (Boddie) (2002), *Spodoptera frugiperda* (Smith) (2006), *Busseola fusca* (Fuller) (2007), *Pectinophora gossypiella* (Saunders) (2008) and *Diabrotica virgifera virgifera* (LeConte) (2009) have been reported to have developed resistance to two *Bt* crops, i.e., corn and cotton (Tabashnik et al. 2013).

Currently, insect-resistant transgenic crops express *Bt* toxin constitutively in most tissues and through-out the life stages of a plant (de Maagd et al. 2001). This has resulted in accelerated evolution of insect populations that have resistance towards the *Bt* toxin. Although



efforts have been intensified to delay the evolution of insect resistance via the refuge strategy, the development of resistance is inevitable and has already occurred (Ferry and Gatehouse 2009). The refuge strategy has been prescribed to help in delaying the evolution of target pest resistance to *Bt* crops. The reason behind this is because refuge strategy creates refuges from non-*Bt* crops (crops that do not produce *Bt* toxins) to promote survival of susceptible insects (Carriere et al. 2010). The basis of this strategy is that most of the rare resistant pests surviving on *Bt* crops will mate with susceptible pests from refuges of host plants without *Bt* toxins, producing hybrid offspring. If the hybrid offspring inherits the resistance that is recessive, then it will be killed by *Bt* crops, hence slowing the evolution of resistance. However, if resistance to *Bt* crops evolved quickly, then one or more assumptions of the refuge strategy have not been met, e.g., resistance is not recessive. Another deviation is that the high-dose (concentration) of toxin in *Bt* crops may not always have occurred. Still another factor is that implementing inadequate size of refuges of non-*Bt* crops hastened resistance of target pests. A challenge in implementing the refuge-strategy is that farmers' compliance with the requirement of planting refuges of non-*Bt* host crops is not enforced. To overcome the limitation of refuge-strategy implementation by farmers, the refuge-in-a bag strategy has been introduced in which farmers buy the *Bt* and non-*Bt* seeds together in the same bag. Newer *Bt* crop cultivars are designed to produce two or more toxins in order to assist in delaying resistance and kill a broader spectrum of insect pests (Carriere et al. 2010). Another suggested alternative strategy, especially when refuges are scarce or absent is releasing sterile insects to mate with resistant insects (Tabashnik et al. 2010). However, the success of this alternative requires creative multidisciplinary

integrated approaches, involving entomologists, geneticists, physiologists, biochemists, and ecologists and it is too early to predict its effectiveness (Ronald 2011).

HT crops facilitate the overuse of a single herbicide which can lead to evolution of weeds that are resistant to that herbicide. Switching to another herbicide application, using a mixture of herbicides, rotating the use of herbicides, and using alternative weed control methods are among crop management strategies recommended to help manage evolution of weed resistance and to improve the durability of effectiveness of particular HT crops (Ronald 2011). Ervin et al. (2010) also suggested the following practices to delay the evolution of weed resistance: 1) adopt herbicide rotation, herbicide application sequences and tank-mixes of more than one herbicide, 2) use herbicides with different modes of action, method of application, and persistence, 3) adopt cultural and mechanical control practices (to segregate between transgenic and non-transgenic crops), and 4) adopt equipment cleaning and harvesting practices (to segregate between transgenic and non-transgenic crops). To help with weed management practices, record keeping and knowledge of herbicide groups are important to be shared via log books, web portals and/or direct communication with extension agents so as to formulate appropriate plans.

Lin et al. (2008) reported a novel method of detecting and terminating transgenic rice selectively by using a registered agrichemical, bentazon, herbicide used for rice weed control. In this method, the gene of interest is a glyphosate tolerance gene *G6* (gb:EU169459), a synthetic 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene from *Pseudomonas putida* fused with a chloroplast transit peptide at its N-terminus. Driving the expression of this gene is the polyubiquitin-1 promoter of *Zea mays*. *G6* is used as the transformation selection marker as well

as the gene of interest for conferring glyphosate tolerance to facilitate weed control of the transgenic rice. The *G6* gene is tagged with RNA interference (RNA-i) cassette which consists of the cauliflower mosaic virus 35S promoter (CaMV35S) and inverted repeat sequence of 207 bp of the rice cytochrome P450 gene *CYP81A6*. The T-DNA plasmid pG6-450i was used to transform the local rice cultivar Xiushui 110 (*O. sativa* subspecies *japonica*). The RNA-i cassette suppresses the expression of the bentazon detoxification enzyme *CYP81A6* and thus transgenic rice becomes sensitive to bentazon. The transgenic rice plants generated from this method were highly sensitive to bentazon but tolerant to glyphosate, indicating that their reactions were found to be opposite of conventional rice. According to Duncan's multiple-range test, the suppression of *CYP81A6* does not have statistically significant side effects on the performance (growth, development and yield) of the transgenic rice plants in field. This finding demonstrates that there is no difference in the performance of the transgenic rice plant and its non-transgenic control. Field trials of these transgenic rice plants demonstrated that all of them were efficiently killed by one spray of bentazon at a regular dose which is the similar dosage used for controlling conventional rice weed. The authors of this paper suggest that this is a simple, reliable and inexpensive method in developing a built-in strategy for containing transgenes in transgenic rice plants. As a precaution, Lin and colleagues (2008) recommended additional studies to be carried out in order to determine the accurate calibration of bentazon dosage required to terminate transgenic rice plants. This is because the dosage may differ between transgenic rice lines depending on genetic make-up, growth conditions and growth stages.

In the crop-to-wild gene flow literature alone, there is a gap on the number of wild taxa studied. This is also apparent in examining transgene escape from transgenic rice or papaya to wild rice or papaya populations. The amount of backcrossing and introgression has not been examined thoroughly in any system. In spite of these shortcomings, it is safe to suggest that the extent of pollen-mediated transgene flow from cultivated rice to many of its wild rice and weedy rice relatives is reasonably low (zero to one percent for weedy rice and up to three percent in wild rice and the distance over which cross-pollination can occur is also short (less than 30 m). Greene and Smith (2010) suggested that buffer zoning, careful timing of crop planting and crop monitoring will help minimize the potential of accidental contamination between transgenic lines and non-transgenic crops (including organic). Even if spatial, temporal, and biological requirements for rice transgene escape are fulfilled in rice growing areas, establishing an effective buffer zone of wider than 110 m between transgenic rice lines and non-transgenic rice varieties (including wild varieties) is a necessary strategy to help avoid or minimize transgene escape to the environment (Lu et al. 2003). Tall crops such as sugar cane have been suggested to act as an effective buffer crop between transgenic rice and its wild relatives as it limits the dispersal distance of transgenic pollen (Lu et al. 2003). According to Lutman (1999), pollination declines sharply with distance from pollen source and use of buffer zones helps in reducing the probability of transgenic pollen reaching other crops. However, this strategy might not work if pollen is transported by insects which could occur in papaya plants.

While fitness change associated with transgene introgression into wild or weedy rice is depicted to bring the most ecological consequences, little is known about this factor. Further monitoring and assessments on environmental consequences caused by transgene escape from

transgenic rice to its wild and weedy rice is necessary, and more so especially in the tropics and subtropics where rice is cultivated extensively. The evolutionary potential of a transgene in wild populations under various environmental conditions should also be studied. At the point when this review was completed, it was not clear whether low frequencies of transgene escape from cultivated rice populations to weedy or wild rice populations could result in damaging and possibly irreversible environmental effects.

#### **4.4 Synthesis and Analysis of Discussion**

Among the eleven studies that were discussed on impact of IR rice on third trophic interaction, the majority of them (Liu et al. 2002, Liu et al. 2003, Bai et al. 2005, Jiang et al. 2005, Bai et al. 2006a, Chen et al. 2009, Bai et al. 2012) showed that IR transgenic rice had no adverse effect on natural enemies, i.e., predators and parasitoids (Table 4.1). Three of the studies (Jiang et al. 2004b, Liu et al. 2006, Chen et al. 2007) reported that the impact of transgenic rice on beneficial organisms varied, depending on the growth or developmental stages of the beneficial organisms (i.e., parasitoids) and also on the interaction between pests (planthopper) and predator (natural enemy). Only one study by Tian et al. (2008) demonstrated adverse impact of the transgenic rice on parasitoid wasps.

**Table 4.1: Summary of Studies Observing Effects of Insect-Resistant Rice on the Third Trophic Level**

Study	No adverse effects	Varied effects	Adverse effects
Liu et al. 2002	√		
Liu et al. 2003	√		
Bai et al. 2005	√		
Jiang et al. 2005	√		
Bai et al. 2006a	√		
Chen et al. 2009	√		
Bai et al. 2012	√		
Jiang et al. 2004b		√	
Liu et al. 2006		√	
Chen et al. 2007		√	
Tian et al. 2008			√
<b>Total</b>	<b>7</b>	<b>3</b>	<b>1</b>

Seven studies were discussed on trying to establish the type of effect transgenic rice has on soil microorganisms. Four of them were IR rice (Liu et al. 2003, Xu et al. 2004, Bai et al. 2005, Bai et al. 2006b, Wang et al. 2007) and two were HR rice (Kim et al. 2008, Chun et al. 2012). Four out of the six transgenic rice studies (Liu et al. 2003, Bai et al. 2005, Bai et al. 2006b, Kim et al. 2008) showed no adverse impact (Table 4.2). Among these seven studies, one HR rice study by Chun et al. (2012) showed varied results, suggesting that sampling time influence composition and growth stages of microbial communities. The remaining two IR rice studies carried out by Xu et al. (2004) and Wang et al. (2007) established that aerobic and anaerobic conditions influence microbial exposure to toxin. Soil microbials are exposed to the toxin longer if they are in an anaerobic condition (flooded-during plant growth stage). This is because the toxin in the *Bt* rice soil takes a longer time to dissipate. In relation to transgenic papaya, studies by Hsieh and Pan (2006), Lo et al. (2007) and Phironrit et al. (2007) showed that transgenic

papaya had no adverse impact on soil microbials while study by Wei et al. (2006) indicated otherwise.

**Table 4.2: Summary of Studies Observing Effects of Transgenic Rice and Papaya on Soil Microorganisms**

Study	Type of crop	No adverse effects	Varied effects	Adverse effects
Liu et al. 2003	Insect-resistant rice	√		
Bai et al. 2005		√		
Bai et al. 2006b		√		
Kim et al. 2008	Herbicide-resistant rice	√		
Chun et al. 2012			√	
Hsieh & Pan 2006	Virus resistant papaya	√		
Lo et al. 2007		√		
Phironrit et al. 2007		√		
Wei et al. 2006				√
<b>Total</b>		<b>7</b>	<b>1</b>	<b>1</b>

Among the seven studies relating to the impact of IR rice on non-target herbivorous pests, four (Liu et al. 2002, Bashir et al. 2004, Chen et al. 2006, Tan et al. 2006) showed no adverse impacts, indicating that transgenic rice had no negative effect on non-target pest population densities (Table 4.3). Two studies (Akhtar et al. 2010, Akhtar et al. 2013) showed adverse effects and one by Chen et al. (2003) demonstrated varied results, in which transgenic rice had minimal negative effect on non-target pests' oviposition behavior but adverse effect on their feeding behavior.

**Table 4.3: Summary of Studies Observing Effects of Insect-Resistant Rice on Non-Target Herbivorous Pests**

Study	No adverse effects	Varied effects	Adverse effects
Liu et al. 2002	√		
Bashir et al. 2004	√		
Chen et al. 2006	√		
Tan et al. 2006	√		
Akhtar et al. 2010			√
Akhtar et al. 2013			√
Chen et al. 2003		√	
<b>Total</b>	<b>4</b>	<b>1</b>	<b>2</b>

In summary, a majority of the studies (18) reviewed on non-target organisms, i.e., third trophic level, soil microorganisms and non-target herbivorous pests demonstrated that transgenic rice and papaya have no deleterious effects on beneficial insects, implying that exposure to these transgenic lines might not necessarily imply an adverse impact on these insects (Table 4.4). However, since some of the studies showed that transgenic rice have either varied (5) or adverse (4) impacts on beneficial organisms, it is not appropriate to conclude that transgenic rice or papaya is safe to beneficial organisms. Additionally the discussion also demonstrated that transgenic crops could cause damage to non-target pests (2 out of 7 studies). This suggests that if there is potential for IR rice to cause a negative effect to non-target pests, there is a possibility that it could cause damage to beneficial organisms in the long run.



**Table 4.4: Summary of Studies Observing Effects of Transgenic Rice and Papaya on Non-Target Organisms**

Type of Non-target Organisms	Number of studies		
	No adverse effects	Varied effects	Adverse effects
Third Trophic Level	7	3	1
Soil Microorganisms	7	1	1
Herbivorous Pests	4	1	2
<b>Total</b>	<b>18</b>	<b>5</b>	<b>4</b>

The studies discussed on non-target organisms, i.e., third trophic level, soil microorganisms and non-target herbivorous pests were carried out in China (majority), Taiwan, Korea and Spain (four geographical locations), involving two years or less, in small plots with small number of replications. Hence, these studies do not represent all rice and papaya ecosystems and do not demonstrate actual conditions of rice and papaya ecosystems. Some studies were only designed to observe large differences of species under study, and some were not descriptive of the actual effect on all types of beneficial organisms (e.g. article mentions studying two species type but only reported findings of one species). Additionally, target and non-target species vary based on location, crop type and crop variety, an indication that study findings are highly specific and generalizations might not apply. Almost of all of the studies reviewed call for long-term assessments to determine the longer term impact of transgenic rice and papaya on non-target organisms.

In the three studies by Messegeur et al. (2004), Rong et al. (2005) and Rong et al. (2006) on transgene flow between transgenic rice-to-cultivated rice, findings demonstrated that transgene flow frequencies ranged between 0.04 percent-0.093 percent between transgenic and cultivated rice. Among the three studies, two were IR rice and one was HR rice. Additionally, scientists of these studies observed that transgene flow could decrease with

increased separation distance between transgenic and cultivated rice. However, this depends on wind direction. Wind plays an important role in gene flow via cross pollination and pollen dispersal. Precise meteorological wind assessment is crucial during flowering period of rice before a decision is made on a safe isolation distance. Although the two studies by Rong et al. (2005) and Rong et al. (2006) suggested that only relative pollen density influences the magnitude of transgene flow between transgenic lines and non-transgenic rice varieties, and not rice planting areas, rice species and plot size, this is a little far-fetched. This is because while these two studies studied similar rice genotypes, but different planting areas and plot sizes, their studies showed that the transgene flow frequencies between transgenic rice lines and cultivated rice varieties varied. If only pollen density influences transgene flow, then the transgene flow between these similar rice genotypes should not differ, regardless of planting areas and plot size. However, that is not true.

Among the four studies carried out in relation to transgenic rice and weedy rice, three studied transgene flow frequency ( Wheeler 2000, Chen et al. 2004, Messegeur et al. 2004) and one (Cao et al. 2009) observed the factors influencing transgene flow between transgenic rice and weedy rice. Among the four, three were HR rice and one was IR rice. Low transgene flow frequencies (ranging from 0.011 percent - 0.97 percent) were observed between transgenic rice and weedy rice as compared to cultivated rice and weedy rice which could range from 1 to 52 percent (Oka and Chang 1961). Among the reasons cited for the low rates were unsynchronized flowering time, different plant height, and wind influence and planting design. However, outcrossing rate between transgenic rice and weedy rice would be more significant in large populations and under natural conditions. This is because flowering time and plant height of

weedy rice would be similar to transgenic rice under this situation, as weedy rice is known to adapt to the rice variety grown in the same field. Wind influence is less significant to transgene flow between transgenic rice and weedy rice in rectangular rice fields as compared to circular planting fields, because weedy rice grows in patches and isolation, surrounded by transgenic rice variety. As such, while transgene flow between weedy rice and transgenic rice is potentially high if weedy rice is grown in the same vicinity as transgenic rice in a commercialized field (under natural conditions and involving large population), wind influence is predicted to have a lesser significant impact on the transgene flow if transgenic rice is grown in rectangular planting design. It was observed that increased relative fitness in  $F_1$  hybrids of transgenic rice and weedy rice could influence transgene flow between transgenic rice and weedy rice via introgression. As such, to avoid such potential impact, it has been recommended that transgenic rice should not be grown in weedy rice abundant areas, so that hybrids involving transgenic rice and weedy rice do not occur and accumulate through generations.

Studies on potential impact of transgene flow between transgenic rice and wild rice have not been extensively investigated. However the study by Lu and Yang (2009) observed that likelihood of transgene from IR rice to express normally or exceedingly in wild rice relatives is high. Meanwhile, in IR rice studies by Song et al. (2003, 2004), it was suggested that crop-to-wild transgene flow will only occur when both lines flowering time overlaps and are planted close to each other (50 to 100 m). This observation is naturally true for transgenic rice lines and non-transgenic varieties, as they have similar growth and flowering time.

Long-term studies assessing the persistence of crop alleles in wild rice populations are necessary to determine the potential for introgression of transgenes (Lu and Snow 2005).

Additionally, studies focusing on hybrids between transgenic rice lines and non-transgenic rice varieties, and their progeny are also crucial to be carried out to demonstrate the potential transgene introgression into weedy and wild rice populations. Data generated for the studies in this review is of limited generations and with restricted number of plants in small scale plots, hence not being able to predict with certainty the transgene flow frequency.

Basically, to anticipate or predict transgene escape and ecological risks with higher accuracy and effectiveness, it is crucial to understand geographical distribution patterns, spatial distribution, flowering habits, genetic relationships and actual gene flow frequencies between transgenic and non-transgenic rice (including wild varieties).

Essentially, the extent of ecological consequences as a result of transgene flow depends on whether the transgene 1) will normally express in wild rice relatives, 2) will change the fitness of wild or weedy populations that have received the transgene, under favorable or unfavorable selection pressure. Preliminary research findings of Lu and Yang (2009) demonstrated that in IR rice the *Bt* transgene can express normally in hybrids crossed with common wild rice, and that higher amount of *Bt* toxin was detected in some individuals of the crop-wild hybrids and F<sub>2</sub> progeny. This indicates that the likelihood of transgene to express normally or exceedingly in wild rice relatives is high.

The persistence of crop genes introduced into wild rice populations is dependent on survival and fecundity of crop-wild hybrids, and also by specific genes' fitness effects from the crop (Lu and Snow 2005). Fitness change associated with transgene introgression into wild or weedy rice is depicted to bring the most ecological consequences. Although introgression could

occur between crop and wild species, the disadvantage of the F<sub>1</sub> hybrids is anticipated to slow the rate of introgression into wild populations.

According to Ellstrand (2003), if a transgene has a strong fitness advantage despite very low rates of cross-pollination from cultivated rice variety, it could spread quickly through wild or weedy rice populations. Meanwhile, Lu et al. (2003) shared that, the ecological risks caused by transgene flow from transgenic rice to wild variety will be aggressive if the transgenes enhance ecological fitness of wild species and occur via natural selection (i.e., first generation of transgenic rice variety - resistance to biotic and abiotic stresses such as drought and salt tolerance, herbicide resistance, and pest and disease resistance). On the other hand, transgene flow will be minimal if it involves second generation transgenic rice variety (i.e., rice encoded with traits such as high protein content, special vitamins, and better grain quality). The ecological consequences will be significant if several fitness genes are stacked in the same individual wild or weedy rice species. Occurrence of aggressive weeds is greater under this circumstance as they are not receptive to human intervention and control. The endangered wild rice population has a high probability of extinction if the transgenes escape to wild rice population via out-crossing.

Studies on transgenic and non-transgenic papaya related to transgene escape are limited. Majority of cultivated papaya are hermaphrodites. To lower cross pollination between hermaphrodite papaya and PRSV resistant transgenic papaya, it is suggested that hermaphrodite papaya plants are planted at a distance more than 400 m and away from PRSV resistant transgenic papaya. This practice will help in reducing cross pollination during flowering

season. In seed production fields, to reduce contamination or cross-pollination, it is recommended to cover the unopened flower bud until the flower blooms and petals fall off.

Gene flow from cultivated commercial crops to their relatives living in near proximity has always occurred, and is the source of biological diversity (Thies and Devare 2007). However, the vast majority of major cultivated crops have neither wild nor weedy relatives outside of their centers of origin (Gressel 2008) and for some crops grown in areas where gene flow may occur, farmers have the option to choose the land they want to cultivate on. Gene flow from agroecosystem to natural ecosystem is inevitable where crop and related wild species coexist, regardless of whether a transgenic crop is involved in the equation. Hence, with the adoption of transgenic crops, the suggestion for farmers to change cultivation practices puts a constraint on the farmer to adopt transgenic crops.

Benefits of IR crops depend on crop and pest pressure. When pest pressure is high, it is good to plant IR crops as they lead to reduced insecticide and pesticide treatments.

Additionally, IR crops provide better protection (Ye et al. 2003) and they are highly specific to target insects, unlike pesticides (Fernandez-Cornejo and Caswell 2006). Herbicide tolerant or resistant crop usage displaces toxic herbicides and facilitates the adoption of low and no till agriculture (Fernandez-Cornejo and Caswell 2006).

Adverse impact of IR crops includes insect resistance to particular insecticide, but this concern also applies to insecticide that are produced organically, synthetically or genetically engineered. After eighteen years of transgenic crop adoption, four major target pest species have evolved to some *Bt* crops. One reason is because of the way *Bt* toxins are expressed. Currently IR crops express *Bt* toxins constitutively, in all tissues and through-out their life stage,

and as such has resulted in accelerated evolution of insect populations. Refuge strategy has been highly recommended to tackle or delay the evolution but enforcement of this strategy is a challenge. Farmers do not always comply with the requirement of planting non-*Bt* crops. To overcome this challenge, refuge-in-a-bag has been implemented in which farmers buy a bag of seeds that has both IR crop seeds and non-IR crop seeds, they just need to follow directions on the bag to plant them. Another strategy suggested is introducing stacked transgenic crops that will tackle a broader spectrum of insects and/or releasing sterile insects to the environment.

Evolution of weeds is a common problem due to overuse of a single herbicide. To overcome this challenge, several strategies have been recommended. These include switching the use to another herbicide application, using mixture of herbicides, rotating use of herbicide, using alternative weed control, practicing harvest equipment cleaning and adopting good weed management practices.

#### ***4.4.1 Gaps in Knowledge and Mechanism/approach to address the gaps***

There is a lack of studies on HR rice and PRSV-resistant transgenic papaya covering third trophic interactions and non-target herbivorous pests. In addition, studies on heteroencapsidation and RNA recombination of PRSV-resistant transgenic papaya is even more limited considering the fact that PRSV-resistant transgenic papaya has been in the market since 1998.

Most studies on ecological impact of transgenic rice have been conducted in China and a very small amount reported in South Korea, Pakistan, Taiwan, US and Spain. Additionally, other than Hawaii, Thailand, Taiwan and China, no studies have been reported on transgenic papaya. Studies similar to those reviewed in this chapter or extension of these studies covering larger

scale, longer duration and varied environmental conditions should be conducted in other countries prior to the release of transgenic rice and papaya lines to farmers. Research on impact of transgenic rice has also mainly focused on non-target hemipteran pests, i.e., planthoppers and leafhoppers. It has been suggested that impact on non-target hemipteran herbivores and other insect orders should also be carefully evaluated after commercialization. Long term data from commercialized plots will either substantiate current findings on the impact of transgenic crops on non-target organisms, or report new ones. Either way, the findings from such plots will bring tremendous benefits so as to manage the consequences of transgenic crops on non-target organisms.

More studies are required to define appropriately the ecological or environmental implications of long term and large scale planting of transgenic lines. Interaction between transgenic crops and their surrounding environment are unpredictable. Short and long term continuous and rigorous case-by-case transgenic crop assessments are necessary so as to develop appropriate and safe management strategies and techniques in handling transgenic crops.

Geographic variations in pest incidence should be taken into account in future studies of the possible fitness effects of transgene outcrossing and of impacts on rice field communities (Cohen et al. 2008).

Detailed study is also needed for transgene flow to determine the influences of other weather parameters such as wind speed range, i.e., down-wind orientation on distribution of rice pollen flow under different field conditions. Knowledge on vertical rice pollen flow is also



limited. Longer term studies are also necessary to evaluate the potential for introgression of transgenes in wild rice populations.

Simulation modelling of local cropping system could provide information about suitability of different management strategies of delaying evolution of pest or weed resistance (Olofsdotter et al. 2000). An interactive simulation model would even be greater as it would be able to substitute long-term field studies, and new information obtained can be fed back into the model to provide better predictive accuracy.

According to Kumar et al. (2008), full assessment of HR rice is required from the following areas: 1) Morphological and phenological characterization of wild rice present in natural areas, 2) Information on current geographic distribution of cultivated and wild rice species, and their time of flowering so as to predict the likelihood of transgene escape from HR rice to wild and cultivated rice, 3) Evaluation of hybridization rates between HR rice and its wild and weedy relatives, 4) Information on frequency and distance of outcrossing from HR rice to wild and weedy relatives in order to mitigate risks associated with gene flow using spatial isolation, and 5) Research for development of integrated management strategies to minimize risk of development of herbicide-resistant rice in weed populations

One of the challenges in carrying out scientific review on transgene escape is the vagueness and ambiguity of some articles in clearly describing the type of crop involved in the transgene escape study. Some articles were clear that the plants under study were transgenic while others were not. One way to address this confusion is to be clear whether the study involved transgenic crops or non-transgenic crops in the abstract and introduction of an article.

One of the challenges of adoption of transgenic crops pertains to the gene construct. Lots of efforts have been focused on gene promoters. During early transformation assessments, choice of promoter was based on promoter availability, i.e., *nos* and CaMV35S. Most promoters that are currently used in gene constructs are constitutively expressed. Constitutive promoters constantly express transgene in most tissues of the plant, although the expression levels vary between plant tissues, individual plants and over time. As a consequence, incorrect time of expression may pose serious negative effect on plant development in commercial cultivars (Davey et al. 2010). As such, inducible promoters (target specific cells, tissues, or stress conditions) are suggested to overcome the challenges and problems brought by constitutive promoters. Promoters that are associated with interaction of plants and microorganisms are also highly sought after. The availability of a broad spectrum of promoters that differ in ability to regulate temporal and spatial expression patterns of transgenes could increase the success of transgenic technology dramatically. Advances in transcriptomics, proteomics and genome sequencing can contribute to future development of promoters to derive gene expression in specific cells and tissues.

#### ***4.4.2 What Constitutes a Sufficient Body of Information?***

Determination of a sufficient body of information for transgenic crops is a work-in-progress. This is because as and when information pertaining to a certain type of transgenic crop is made available and is accessible to all, only then the impact of that particular crop type on the receiving environment can be ascertained. Due to the fact that this technology is not widely adopted globally, there is so much more to discover, learn and observe from it before

any conclusion can be made of it. In-fact, this calls for a better way to manage the information that we have at hand so progress concerning this technology can be made incrementally.

An agricultural biotechnology clearing house mechanism focused on the tropics and sub-tropics is needed to push forward the progress and development of this technology in most developing countries which have similar climatic conditions that grow similar crops. This mechanism can be a technology pool to allow scientists deposit their findings and use it as a reference point for them to gain required knowledge, practice, resource, expertise, materials for the advancement of their research in relation to transgenic crops.

#### ***4.4.3 Implications of Scientific Literature for Regulating the Commercial Release of Transgenics in Malaysia***

The scientific literature covered in this chapter provides a good basis for Malaysian policy makers and scientists to take heed of. The findings of these studies offer measures to address limitations. Assessing and modifying steps in the studies carried out in this review will be a good step forward for Malaysian scientists to emulate similar studies in Malaysia.

However, it is important to note that due to varied ecological conditions, even though similar steps (as in the studies reviewed) are adopted, they will not result in similar findings.

The long term surveillance approach adopted by Argentina (Chamberlin 2010) in monitoring the effects of transgenic plants in the market and production areas should also be adopted by Malaysia as large scale production of transgenic plants might encounter different results as compared to pre-commercialization testing or risk assessments.

## 4.5 Conclusion

Scientific assessments carried out on transgenic rice and papaya suggest that transgenic rice and papaya lines can potentially exert positive and/or negative impacts on the environment. Some of the adverse environmental impacts can be managed through effective and careful knowledge-based crop management strategies and practices. It is important to note that while transgenic rice and papaya do carry risks, we need to consider whether the risks outweigh the benefits of cultivating these crops.

World food supplies will demand intensive crop production due to increased population growth, climate change, disease, political unrest, deterioration of soil quality, drought and flood. Ultimately, the benefits and challenges in cultivating transgenic crops need to be considered on a case-by-case basis. Cultivating transgenic crops has potential to decrease reliance on external inputs and reduce ecological risk. As such, until we can derive a balance between the two, we must strive to continue to improvise the transgenic technology to suit these two goals. When genetic engineering is adopted along with conventional breeding methods and advanced data analysis tools, it is hoped that crop production will increase and current agricultural production setbacks are tackled, i.e., low yields due to pests and disease, climate change, short shelf life.

Thus far, most studies pertaining to transgenic rice and papaya were mainly carried out via experimental and empirical testing. However, the actual ecological consequences and evolutionary processes on community dynamics relies on long term studies using an integrated approach, combining empirical studies with mathematical models such as the one utilized by Neuhaser et al. (2003). This is where new fields such as bioinformatics come into play. This

approach expands the scope of biological investigation from studying gene-to-gene or protein-to-protein to studying genome-wide (all genes or proteins) at once, using high-throughput methods (Hieter and Boguski 1997).

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## CHAPTER 5: CONCLUDING REMARKS

Malaysia has been moving from an agricultural, resource extraction, and manufacturing based economy in the 1980s toward a service-oriented, post-industrial, knowledge-based economy, with greater emphasis on skilled human capital, technology, and intangibles. The Malaysian economy has experienced these significant changes, mainly due to its economic developmental policies but also due to natural forces of globalization and economic growth.

Assessing the nation's current economic and policy regimes are crucial to help chart the next course of actions for Malaysia to set its economic goals. Often, gross domestic production contributions have been an effective indicator to measure economic progress. In recent times, the development of science and technology indicators through the exploitation of patent data has been used to measure economic evolution and progress.

With this in mind, Chapter 2 (patent landscape analysis) explored the use of patent data to demonstrate Malaysia's economy evolution over the past six decades. Primarily dependent on chemicals and petroleum between 1953 and 1985, the economy, currently (between 2003 and 2012) is dependent on two sectors, i.e. electronics, semiconductors and computing, and chemicals and petroleum. Generally, the commercial sector lead by foreign firms dominated the patenting activities in Malaysia, economy wide and in the agricultural sector. Foreign commercial entities patent in order to avoid imitations to their inventions in the Malaysian market attributable to their high FDI investments and export shares.

Between 1953 and 1985, within the economy wide patenting scene, European countries held the largest number of patents granted in Malaysia. Although as a region, Europe

dominated the patenting scene, the top patent assignees in this earlier period were US-based firms. And medical and pharmaceutical firms from US and Europe had the most number of patents granted in Malaysia. Among Malaysian firms that were granted patents during this period, The Malaysian Rubber Board was the most active and as a result, the agriculture and food sector had the greatest number of patents granted to Malaysians.

Between 2003 and 2012, US and Japan, primarily dominated the patenting scene in Malaysia. Additionally, there were more Asian and European entities that patented during this period as compared to the earlier period. The most active sector engaged in innovation activities in Malaysia during this period was electronics, semiconductors, and computing. Also, during this period, among Malaysian entities, academic institutions, dominate the patenting share of Malaysians.

The economy wide patent landscape analysis demonstrated that while commercial entities continue to hold the most number of patents granted between the earlier and latter periods, the patenting trend by non-commercial entities showed an upward trend, an increase of 7.5 fold during these periods. Government policies and funding opportunities facilitated non-commercial entities patenting behavior. Additionally, while there has been emphasis on public-private collaboration, the patent landscape analysis demonstrates that partnership between these two entities is low. The propensity for non-commercial entities to collaborate with non-commercial entities is greater than for commercial entities to form partnership with non-commercial entities. We conclude that high risk inventions by non-commercial entities are considered as a contributing factor to low collaboration between commercial and non-commercial entities.

Malaysia's economy was primarily dependent on agriculture in the early 1950s and 1970s. The push towards industrialization in the mid-1980s neglected developmental efforts in this sector. The patent landscape analysis that was carried out in the agricultural sector demonstrated this pattern. Patenting trend in agriculture dropped from 13 percent between 1953 and 1985 to seven percent between 2003 and 2012. Patents in agbiotech are relatively low and overshadowed by patents in agchemicals technology. The patent landscape analysis for agricultural technologies was only focused between the years 2003 and 2012. This is due to the fact that there were only six patents designated as agbiotech between 1953 and 1985, carrying out an analysis to compare the agbiotech and agchemicals during this period would be unduly biased. In fact, the earliest inventions in agbiotech, globally, were made beginning only in the mid-1980s.

Between 2003 and 2012, the number of patents granted to agbiotech was 115 while agchemicals had 1,150 technologies patented. The higher number of agchemicals technologies patented by foreign firms in Malaysia was primarily dominated by European and US firms. Bayer has the most number of agchemicals granted patents, followed by Syngenta, Monsanto, Pfizer, BASF, Du Pont, Dow Agrosience, Arkion Life Sciences, Malaysian Palm Oil Board and Viva American Marketing. Malaysian non-commercial entity, i.e., MPOB and US commercial entity, i.e., Syngenta hold the most number of agbiotech patents granted followed by other foreign firms, i.e., Bayer, Monsanto, Du Pont, Dow Agrosience, Arkion Life Sciences, Viva American Marketing, Pfizer and BASF. MPOB active engagement with agbiotech patents is reflective of MPOB's primary goal of developing new varieties of oil palm. Collectively as a region, North American firms hold the most number of agbiotech and agchemicals patents.

Although Europe, as a region, does not dominate the patenting scene of agbiotech and agchemicals technologies in Malaysia, the patents granted to European entities are dominated by two firms, i.e., Bayer and BASF.

It is important to note that although the number of granted patents designated as agbiotech is relatively lower as compared to granted patents designated as agchemicals technology, there is a strong drive by Malaysian non-commercial entity, i.e., MPOB engagement in agbiotech innovations.

The low number of granted agbiotech patents in Malaysia was narrowed down to two reasons; (1) misalignment of policies promoting the use of modern biotechnology in the Malaysian agricultural sector, and (2) ecological risks of cultivating transgenic crops in Malaysia, a rich-biodiversity country.

Chapter 3 (political economy of agbiotech policies) explored reason (1) with the utilization of a political economy framework and insights drawn from the patent landscape analysis carried out in Chapter 2. The framework follows closely the literature initiated by Stigler and other economists. The political economy framework helps in identifying and assessing the influence of relevant stakeholder groups whose economic welfare is likely to be affected by the decision making process concerning regulations overseeing the cultivation of transgenic crops in Malaysia.

The two stakeholder groups, oil palm and agchemicals producers were identified to face large economic welfare impact if Malaysia adopts cultivation of transgenic crops. It should be noted that the Malaysian oil palm industry is dominated by two Malaysian Giant conglomerates, Sime Darby Berhad and Felda Holdings Berhad. Both these firms dominate

world palm oil exports and local oil production, and inevitably, have a strong policy influence of the Malaysian agricultural sector. The prevalence of agchemicals producers in the Malaysian agricultural sector is evident by the sales of agchemicals in Malaysia, coupled with the number of Malaysia granted agchemicals patents assigned to two dominant agchemicals players, i.e., Bayer and BASF. Bayer, a global leader in the crop protection market, dominates agchemicals patenting scene in Malaysia. BASF also a leader in the global crop protection market formed a strategic alliance with Malaysian Agricultural Research and Development Institute (MARDI) and developed a new herbicide resistant Clearfield rice variety to tackle weedy rice outbreak in Malaysia. The cultivation of transgenic crops in Malaysia will likely reduce agricultural producers' dependency on agchemicals. Reduce applications of agchemicals will reduce agchemicals sales in Malaysia, which in return will affect Bayer's and BASF's dominance in agchemicals sale in Malaysia, which means that there is a high likelihood their economic welfares would be affected.

To overcome negative welfare externalities associated with the adoption of transgenic crops, oil palm and agchemicals producers exercised their power and resources (money and non-monetary contributions) in exerting their influence to the stalled transgenic crops commercialization efforts in Malaysia. Their relatively small number allowed them the advantage to be highly organized, and as a result, enabled them to converge and influence the regulator's decision making process concerning transgenic crops.

The other reason attributable to the low number of granted agbiotech patents in Malaysia pertain to ecological risk concerning deployment of transgenic organisms on Malaysia's rich biodiversity. Chapter 4 (ecological risks of transgenic crops) carried out scientific

assessments on transgenic rice and papaya to assist local policy makers adopt a science based approach in regulating the interaction between transgenic crops and Malaysia's environment.

The scientific review suggests that transgenic rice and papaya lines can potentially exert positive and/or negative ecological impacts, i.e., non-target organisms, transgene escape, heteroencapsulation, and RNA recombination.

Studies concerning non-target organisms, i.e., third trophic level, soil microorganisms, and non-target herbivorous pests were mainly carried out in China (majority), Korea, Pakistan and Spain. Most studies were conducted in less than two years involving small plots with small number of replications. This suggests that not all rice and papaya ecosystems were represented and hence not depicting the actual conditions of rice and papaya cultivation. While most studies reported detailed findings, some only reported large differences observed among species under study while others were not descriptive about the actual effect of transgenic crops on all types of non-target organisms. One common theme that came out of the review concerning non-target organisms was target and non-target species vary based on local geographical distributions, crop type and crop variety, an indication that study findings are highly specific and generalizations might not apply. Additionally, the majority of ecological studies carried out on non-target organisms was limited to third trophic interactions. Considering the fact that Malaysia is a mega-diversity country, ecological studies concerning higher trophic level are required to assess the impact transgenic rice and papaya on these populations and the food-web dynamics. Before a conclusion can be made on the ecological risks associated with transgenic crops, scientists call for long-term assessments to determine the longer term impact of transgenic rice and papaya on non-target organisms.



To anticipate or predict transgene escape and ecological risks between transgenic varieties and non-transgenic varieties with higher accuracy and effectiveness, it is crucial to understand geographical distribution patterns, spatial distribution, flowering habits, genetic relationships and actual gene flow frequencies between transgenic and non-transgenic varieties (including wild varieties). Most of the studies reviewed for transgene escape were carried out on rice. Studies on transgenic and non-transgenic papaya related to transgene escape are limited.

The transgene flow between transgenic rice and cultivated rice varieties varies depending on pollen density, planting areas and plot size. Due to the high likelihood that transgene flow between transgenic rice and weedy rice is great, it has been recommended that transgenic rice should not be grown in weedy rice abundant areas. Studies on the impact of transgene flow between transgenic rice and wild rice has not been extensively investigated. Preliminary findings suggest that transgene flow between transgenic rice and wild rice will only occur when both genotypes flowering times overlaps and are planted closely with each other.

Essentially, the extent of ecological consequences as a result of transgene flow in rice varieties depends on whether the transgene; 1) will normally express in wild rice relatives, 2) will change the fitness of wild or weedy populations that have received the transgene, under favorable or unfavorable selection pressure.

Studies on transgenic and non-transgenic papaya related to transgene escape are limited. Majority of cultivated papaya are hermaphrodites. To lower cross pollination between hermaphrodite papaya and PRSV resistant transgenic papaya, it is suggested that hermaphrodite papaya plants are planted at a distance more than 400 m and away from PRSV

resistant transgenic papaya. This practice will help in reducing cross pollination during flowering season. In seed production fields, to reduce contamination or cross-pollination, it is recommended to cover the unopened flower bud until the flower blooms and petals fall off.

Ultimately, gene flow from agroecosystems to natural ecosystems is inevitable where crop and related wild species coexist, regardless of whether a transgenic crop is involved in the equation. Hence, with the adoption of transgenic crops, the suggestion for farmers to change cultivation practices puts a constraint on the farmer to adopt transgenic crops.

Studies on heteroencapsidation and RNA recombination of papaya ringspot virus (PRSV) resistant transgenic papaya is also limited even though PRSV-resistant transgenic papaya has been in the market for over fifteen years.

Benefits of insect resistant (IR) crops depend on crop and pest pressure. When pest pressure is high, it is good to plant IR crops as they lead to reduced insecticide and pesticide treatments. Additionally, IR crops provide better protection and they are highly specific to target insects, unlike pesticides. Herbicide tolerant or resistant crop usage displaces toxic herbicides and facilitates the adoption of low and no till agriculture. Potential adverse impacts of IR crops include insect resistance to particular insecticide, but this concern also applies to insecticide that are produced organically, synthetically or genetically engineered. After eighteen years of transgenic crop adoption, four major target pest species have evolved to some *Bt* crops. One reason is because of the way *Bt* toxins are expressed. Currently, IR crops express *Bt* toxins constitutively, in all tissues and through-out their life stage, and as such has resulted in accelerated evolution of insect populations. Refuge strategy has been highly recommended to tackle or delay the evolution but enforcement of this strategy is a challenge. Farmers do not

always comply with the requirement of planting non-*Bt* crops. To overcome this challenge, refuge-in-a-bag has been implemented in which farmers buy a bag of seeds that has both IR crop seeds and non-IR crop seeds, they just need to follow directions on the bag to plant them. Another strategy suggested is introducing stacked transgenic crops that will tackle a broader spectrum of insects and/or releasing sterile insects to the environment.

Evolution of weeds is a common problem due to overuse of a single herbicide. To overcome this challenge, several strategies have been recommended. These include switching the use to another herbicide application, using mixture of herbicides, rotating use of herbicide, using alternative weed control, practicing harvest equipment cleaning and adopting good weed management practices.

Ultimately, while transgenic rice and papaya do carry ecological risks, the decision to cultivate these crops lies on the benefits linked to these crops. World food supplies demand intensive crop production due to increased population growth, climate change, disease, political unrest, deterioration of soil quality, drought and flood. Ultimately, the benefits and challenges in cultivating transgenic crops need to be considered on a case-by-case basis. Cultivating transgenic crops has potential to decrease reliance on external inputs and reduce ecological risk. As such, until a balance between the two is derived, continuous improvement of the transgenic technology to suit these two goals is necessary.

Malaysia faces considerable economic, political and ecological uncertainties in utilizing biotechnology to drive agricultural growth and productivity. Malaysia is a new player in the modern biotechnology arena, evidenced by the patent landscape analysis and the progress made concerning transgenic crops regulations. The misalignment of policies mainly driven by

strong oppositions from oil palm and agchemicals producers is a force to reckon with. However, with strong institutional and financial will from the government, the likelihood of Malaysia becoming a global agbiotech player lies ultimately on oil palm producers initiatives to drive the transgenic technology. MPOB, a local government entity, dominates the patenting of agbiotech technology in Malaysia and as the gatekeeper of the oil palm industry, it holds a strong political will to set the stage for agbiotech innovations in Malaysia. Ultimately, Malaysia is predicted to lead in the cultivation of transgenic oil palm and would be a leading adopter of transgenic rice and papaya, dependent on global scenario.

For future research, it is recommended to determine the funding mechanisms of studies reviewed for the ecological assessments of transgenic rice and papaya in order to assess the objectivity of the study findings. There is increasing concern that funding source may influence research design and resulting conclusions. Thus, such exploration will contribute to the political economy discussion surrounding this sector.