

# **UNIVERSITI PUTRA MALAYSIA**

## LOW LEVEL PRESENCE OF GENETICALLY MODIFIED CROPS IN FOOD AND FEED TRADE IN MALAYSIA

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**IKDPM 2019 4** 



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By

JOHNNY ANAK ANDREW

Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Doctor of Philosophy

July 2019

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Doctor of Philosophy

## LOW LEVEL PRESENCE OF GENETICALLY MODIFIED CROPS IN FOOD AND FEED TRADE IN MALAYSIA

By

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#### July 2019

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Genetic engineering technology has been applied extensively on crops. Although widely traded, the commercialization of genetically modified (GM) crops is subjected to domestic regulatory approval. Considering that the authorization processes are not synchronized across countries or better known as asynchronous approval, the mixture of authorized and unauthorized GM crops along the supply chain cannot be avoided. The possible implication is that GM crop authorized in one country might be found in another country that has not yet given authorization, thus creating a low level presence (LLP) situation. In light of this development, the research aimed to investigate these issues through its specific objectives.

For the first objective, which is to examine trade impacts from asynchronous approvals of GM crops, the research has developed a Protectionism Index for 31 countries to reflect the stringency of GM crops regulatory mechanisms that cause asynchronous approval problems. Together with other observable variables and based on panel data structure, the index was empirically tested in a gravity model of trade. It was found that in general, asynchronous approval has a negative impact on trade particularly for maize. The second objective focuses on evaluating the welfare effect using bilateral trade data based on changes in consumer surplus and costs to the government giving the change in LLP tolerance. The results demonstrate that non-zero tolerance for LLP can increase the consumer surplus and reduce the cost to the government in implementing the regulations to monitor LLP occurrence. Overall, these will lead to an increase in welfare effects. The third objective is to investigate factors that could lead the LLP policy formulation direction. Data were collected using the questionnaire and from the interviews, mainly targeted respondents from the government sector, industry, and non-government organization. Based on the analyses, several factors are found to be critical. In particular, the Partial Least Square modeling indicated the applicability of the policy with existing laws as well as its consistency with existing international guidelines were found to be significant. Institutional capacity also plays an important role to make a practical policy. Findings also suggested public awareness and availability of resources should not be neglected.

Several implications have emerged from the findings. By studying impacts from asynchronous approval and LLP, empirical data on the broader question of how policymakers address science and new technologies related issues are made available. The research findings are relevant and can assist policymakers in Malaysia to understand better about the existing magnitude of LLP as well as the issues and challenges that the government is facing and will be facing when formulating and implementing LLP policy. The results also provide policymakers with a different perspective on LLP tolerance options together with its trade and regulatory consequences. Higher LLP tolerances can restrain trade disruptions and related economic costs but may be feasible only when no substantial food, feed or environmental safety concerns be present. Meanwhile, lower tolerances imply higher costs as segregation becomes more costly and trade disruption more likely. Thus, being an importer of maize and soybean, Malaysia should have a clear policy direction. A practical LLP management strategy is not only crucial to keep food and feed safe, but also can provide transparency and predictability for imports and minimizing disruptions to trade.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

## KEHADIRAN TAHAP RENDAH TANAMAN DIUBAHSUAI SECARA GENETIK DALAM PERDAGANGAN MAKANAN DAN MAKANAN HAIWAN DI MALAYSIA

Oleh

#### JOHNNY ANAK ANDREW

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# Pengerusi:Profesor Madya Normaz Wana Ismail, PhDFakulti:Institut Kajian Dasar Pertanian dan Makanan

Penggunaan teknologi kejuruteraan genetik pada tanaman telah berkembang dengan begitu pesat. Meskipun diperdagangkan secara meluas, pengkomersialan tanaman diubahsuai secara genetik (genetically modified, GM) tertakluk pada kelulusan kawal selia domestik. Memandangkan proses kelulusan adalah berbeza dari satu negara ke satu negara yang lain atau juga dikenali sebagai ketidakseragaman kelulusan (asynchronous approval), campuran tanaman GM yang telah dan belum diluluskan di sepanjang rantaian bekalan tidak dapat dielakkan. Implikasinya, terdapat kemungkinan tanaman GM yang telah diluluskan di satu negara dijumpai di negara lain di mana kelulusan belum diperolehi, seterusnya menimbulkan keadaan kehadiran tanaman ini pada tahap rendah (low level presence, LLP). Bersandarkan perkembangan tersebut, kajian ini disasarkan untuk menyelidiki isu-isu di atas menerusi objektif-objektif spesifik yang ditetapkan.

Untuk objektif pertama, iaitu bagi meneliti kesan ketidakseragaman kelulusan tanaman GM terhadap perdagangan, kajian ini telah membangunkan Indeks Perlindungan (Protectionism Index) untuk 31 negara bagi melihat sejauh mana mekanisme perundangan tanaman GM yang ketat menjadi punca kepada masalah ketidakseragaman kelulusan. Bersama-sama dengan pembolehubah yang lain serta berasaskan struktur data panel, indeks ini telah diuji secara empirikal mengunakan pendekatan model graviti perdagangan. Didapati bahawa secara umumnya, ketidakseragaman kelulusan mempunyai kesan negatif ke atas perdagangan khususnya untuk jagung. Objektif kedua pula memberi tumpuan pada penilaian kesan kebajikan berdasarkan perubahan dalam lebihan pengguna menggunakan data perdagangan dua hala serta kos kepada kerajaan apabila berlakunya perubahan pada toleransi LLP. Keputusan menunjukkan bahawa pada tahap toleransi LLP bukan sifar, didapati lebihan pengguna meningkat dan kos kepada kerajaan dalam melaksanakan undangundang untuk memantau kejadian LLP berkurang. Secara keseluruhannya, ini akan membawa kepada peningkatan terhadap kesan kebajikan. Manakala objektif ketiga adalah untuk menyiasat faktor-faktor yang boleh dipertimbangkan dalam membangunkan dasar berkaitan LLP. Pengumpulan data dibuat menerusi borang soal selidik dan temuramah, disasarkan kepada responden mewakili sektor kerajaan, industri serta organisasi bukan kerajaan. Berdasarkan analisis yang dijalankan, beberapa faktor secara statistiknya adalah signifikan. Khususnya, pemodelan PLS (*Partial Least Square*) menunjukkan kebolehgunaan dasar dengan undang-undang sedia ada serta kesesuaiannya dengan garis panduan antarabangsa yang ada, didapati signifikan. Keupayaan institusi juga memainkan peranan penting dalam menentukan dasar yang praktikal. Penemuan juga mencadangkan kesedaran awam dan ketersediaan sumber harus diambil kira.

Beberapa implikasi telah dikenalpasti dari hasil kajian. Dengan mengkaji kesan daripada ketidakseragaman kelulusan dan LLP, data empirikal mengenai persoalan yang lebih luas tentang bagaimana pembuat dasar menangani sains dan isu berkaitan teknologi baru, dapat disediakan. Penemuan kajian adalah relevan dan boleh membantu pembuat dasar di Malaysia untuk memahami lebih baik tentang magnitud semasa LLP serta isu dan cabaran yang sedang dihadapi dan bakal dihadapi oleh kerajaan dalam merangka dan melaksanakan dasar LLP. Hasil kajian juga menyediakan pembuat dasar dengan perspektif yang berbeza tentang pilihan toleransi LLP berserta implikasinya terhadap perdagangan dan kawal selia. Toleransi LLP yang lebih tinggi boleh menghadkan gangguan perdagangan dan kos ekonomi yang berkaitan tetapi mungkin hanya praktikal sekiranya tidak timbulnya isu keselamatan makanan, makanan haiwan atau alam sekitar. Sementara itu, toleransi LLP yang lebih rendah dikaitkan dengan kos yang lebih tinggi oleh kerana kos pengasingan menjadi lebih mahal serta kecenderungan berlakunya gangguan perdagangan. Justeru, Malaysia sebagai pengimport produk jagung dan kacang soya perlu mempunyai matlamat dasar yang jelas. Strategi pengurusan LLP yang praktikal bukan sahaja penting untuk memastikan makanan dan makanan haiwan selamat, tetapi juga dapat memberikan ketelusan dan kebolehramalan untuk import di samping mengurangkan gangguan perdagangan.

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## LIST OF ABBREVIATIONS

AAFC	Agriculture and Agri-Food Canada
BCH	Biosafety Clearing House
DOB	Department of Biosafety
DOC	Department of Chemistry
CBD	Convention on Biological Diversity
CEPII	Centre d'Etudes Prospectives et d'Informations Internationales
CERA	Center for Environmental Risk Assessment
СРВ	Cartagena Protocol on Biosafety
СРТРР	Comprehensive and Progressive Agreement for the Trans-Pacific Partnership
DNA	Deoxyribonucleic acid
EU	European Union
FAO	Food and Agriculture Organisation
FAOSTAT	Food and Agriculture Organisation Corporate Statistical Database
FE	Fixed Effects
FFP	Food, Feed and Processing
FSQ	Food Safety and Quality Division, Ministry of Health Malaysia
GDP	Gross Domestic Production
GM	Genetically Modified
GMAC	Genetic Modification Advisory Committee
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
IMPACT	International Model for Policy Analysis of Agricultural Commodities and Trade
ISAAA	International Service for the Acquisition of Agri-biotech Applications
IUCN	International Union for Conservation of Nature
LMO	Living Modified Organism
LLP	Low Level Presence

MAQIS	Malaysian Quarantine and Inspection Services
MEA	Multilateral Environmental Agreements
MKAK	National Public Health Laboratory
МОН	Ministry of Health Malaysia
MRL	Maximum Residue Level
NAP	National Agriculture Policy
NBB	National Biosafety Board
NBP	National Biotechnology Policy
NGO	Non Governmental Organization
NKL SP	Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress
NPBD	National Policy on Biological Diversity
NTM	Non Tariff Measures
OLS	Ordinary Least Squares
PLS	Partial Least Squares
PPML	Poisson Pseudo-Maximum-Likelihood
R&D	Research and Development
RE	Random Effects
rDNA	Recombinant-deoxyribonucleic acid
SEM	Structural Equation Modeling
SPS	Sanitary and Phytosanitary Measures
STS	Science and Technology Studies
TPPA	Trans-Pacific Partnership Agreement
TRAINS	Trade Analysis and Information System
UN	United Nations
USA	United States of America
USDA	United States Department of Agriculture
WHO	World Health Organization
WITS	World Integrated Trade Solution
WTO	World Trade Organization

#### **CHAPTER 1**

#### INTRODUCTION

#### 1.1 Background

The world's population currently exceeds seven billion and is estimated to reach nine billion by 2050. The United Nations Food and Agriculture Organization (FAO) anticipates that in order to feed everyone, farmers should produce 70% more food by then. Annual demand for cereals alone will reach 3 billion tonnes or 30% more than in 2012. Annual demand for meat is also expected to exceed 450 million tonnes by 2050, an increase of over 150 million tonnes (FAO, 2009). How to meet this demand is significant concern to governments and their people.

Agricultural biotechnology techniques such as genetic engineering technology are being adopted in many countries around the world to help meet this need and address food security concerns. However, the introduction of new crops using this technology has always been associated with possible trade disruptions to agricultural trade due to potential biosafety risks new crops can pose to human and animal health. The following sections explore this issue in depth by providing an overview of genetically modified crops, its issues in global food and feed trade as well as its development status in Malaysia.

## 1.1.1 Overview of Genetically Modified (GM) Crops

The discovery that genes are made up of DNA<sup>1</sup> and can be copied, isolated and manipulated has led to a new era of modern biotechnology. The developments in modern biotechnology led to the creation of living modified organisms<sup>2</sup> (LMO) or genetically modified organisms (GMO) and has been applied to the production of genetically modified food crops. Consistent with fast developments in modern biotechnology, many genetically modified (GM) crops<sup>3</sup> have been developed and authorized for release for the purpose of commercial cultivation (FAO, 2014). GM crops, also known as transgenic or biotech crops became a major topic and source of debate for many people and institutions around the world, especially related to its potential benefits and risks.

<sup>&</sup>lt;sup>1</sup> Deoxyribonucleic acid or in short DNA, is present in almost all living cells and contains information coding for cellular structure, organisation and function (IUCN, 2003).

<sup>&</sup>lt;sup>2</sup> Malaysia uses LMO (living modified organism) in the Biosafety Act 2007 instead of GMO. Malaysia has made a declaration in the Convention of Biological Diversity that the former term gives meaning to the latter (Idris, 2013).

<sup>&</sup>lt;sup>3</sup>A genetically modified (GM) crop also refers to a recombinant-DNA plant. It is a plant in which the genetic material has been modified using in-vitro nucleic acid techniques with the objective to introduce a new trait into the plant that does not occur naturally in the species (FAO, 2014). In this study, the terms "biotech", "biotechnology", "genetically modified" and "genetically engineered" are used interchangeably.

The earliest generation of GM crops focused on insect resistance and herbicide tolerance traits according to four types of crops, namely canola, maize, cotton and soybean. The insect resistance trait introduced into these crops enable them to produce a chemical from the bacterium *Bacillus thuringiensis* (Bt) in a naturally occurring way, which is poisonous to ordinary agricultural pests such as the European maize borer, but is not dangerous to humans and is considered environmentally safe (Raybould, 2012). By producing the toxin, insect resistant crops kill pests with no application of pesticides by farmers. The herbicide tolerance crops express tolerance to glyphosates, low toxicity herbicides. When such tolerance is introduced into maize, soybean and canola, farmers are able to eliminate and control weeds more effectively. If crops are not given herbicide tolerance varieties, farmers have to expend more resources and effort in controlling weeds before crop emergence (Rao, 2017). Table 1.1 compares the global area of GM crops by trait between 2011 and 2016.

Trait 2011 Percentage 2016 Percentage +/-% change - 7.4 Herbicide tolerance 93.9 47% 59% 86.5 ↓ 8% Stacked traits 42.2 41% +33.2↑ 78% 26% 75.4 Insect resistance 23.9 15% 23.1 11% - 0.8 ↓ 3% Virus < 1< 1% < 1 < 1% resistance/Others Total 160.0 185.1

 Table 1.1: Global area of GM crops by trait between 2011 and 2016 (million hectares)

Source: ISAAA<sup>4</sup> (2017).

However, the increase in GM crop cultivation globally has led to a broad range of issues and concerns not only related to food and feed safety but also on environmental impacts and socioeconomic aspects. The concerns related to food safety or human health include possible allergenicity and toxicity of GM foods and its products (Lusk et al., 2018). From the environmental risks perspective, concerns include the impact of genetic contamination or admission of the transgenes into the environment or natural field, effect on gene flow, impact on non-target organisms, loss of biological diversity and pest resistance evolution (Brookes & Barfoot, 2018). The socioeconomic issues from social and ethical perspectives are mainly concern restriction of access to new technologies and genetic resources, traditions loss (e.g. saving seeds for future cultivation), a monopoly by the private sector and income loss for farmers that are poor in resources. Table 1.2 provides a summary of arguments in favour of and against GM crops.

According to Barrows et al. (2014), opinions in agreement or in opposition to the acceptance of GM crops have not much changed since the technology introduced in the 1980s. From one side, opponents highlight concerns that the technology exposes negative environmental impacts and put at risk the health of people who take the GM foods. From the other side, proponents stress potential benefits from increasing output and reduction in prices of food for consumers (Smyth et al., 2015). Notwithstanding

<sup>&</sup>lt;sup>4</sup>The International Service for the Acquisition of Agri-biotech Applications (ISAAA) is a non-profit international organization that shares agricultural biotechnology, focusing on genetic engineering. http://www.isaaa.org/

that, the commercial planting or cultivation of GM crops has been expanding since its first introduction in 1996, not only in industrialized countries but also in developing countries (Aldemita & Hautea, 2018).

countries (Aldennita	x Hauca, 2010).	
Table 1.2: Benefits	and risks of GM crops	
Concern	Arguments in favour	Arguments against
Human and animal health	<ul> <li>no proven risks for human or animal health</li> <li>future consumer benefits (second generation products):         <ul> <li>improved nutritional value</li> <li>improved taste</li> <li>longer shelf life</li> <li>wider choice of food products</li> </ul> </li> </ul>	<ul> <li>potential human and animal health hazards:</li> <li>resistance to antibiotics</li> <li>potential allergies</li> <li>no significant consumer benefits</li> </ul>
Environment	<ul> <li>effective control of pests and weeds</li> <li>less tillage needed (soil damage minimized)</li> <li>reduced use of pesticides</li> <li>the type of pesticide used (glyphosate) is relatively harmless</li> </ul>	<ul> <li>use of GM crops leads to insect and weed resistance to pesticides</li> <li>genetic "contamination" or "pollution" through pollen or seeds</li> <li>changes in the ecosystem</li> <li>threat to biodiversity</li> </ul>
Socioeconomic issues	<ul> <li>agricultural costs of production (for example, labor) reduced</li> <li>solution of world hunger through new varieties (for example, drought tolerance crops)</li> <li>enhanced food supply worldwide</li> <li>labeling mechanism in place</li> </ul>	<ul> <li>agribusiness and monoculture; threat to traditional farming</li> <li>GM seed market controlled by few multinationals, price manipulation possible</li> <li>dependence of developing countries on technologies which they cannot afford</li> <li>religious issues</li> </ul>
Ethical and legal considerations	<ul> <li>genetic engineering is an extension of traditional breeding</li> <li>deemed worthy as level of risk is low</li> </ul>	<ul> <li>genetic engineering is unnatural and means "playing God"</li> <li>inter-species gene transfers cause religious concerns (for example, genes from non-Halal sources)</li> </ul>

Table 1.2: Benefits and risks of GM crops

Source: Adapted from Ramjoue (2006).

In 2016, global areas that were cultivated with GM crops reached 185.1 million hectares involving more than 18 million farmers in 26 countries (ISAAA, 2017). The major growers of GM crops include the USA, Brazil and Argentina, while India, Canada and China are also important producers. The cultivation area and type of GM crops cultivated by these top countries are summarized in Table 1.3.

Rank	Country	(mil	Area lion hecta	res)	GM crops
		2014	2015	2016	
1	USA	73.1	70.9	72.9	Maize, soybean, cotton, canola,
					sugarbeet, alfalfa, papaya, squash
2	Brazil	42.2	44.2	49.1	Soybean, maize, cotton
3	Argentina	24.3	24.5	23.8	Soybean, maize, cotton
4	Canada	11.6	11.0	11.6	Canola, maize, soybean, sugar beet,
					alfalfa
5	India	11.6	11.6	10.8	Cotton
6	Paraguay	3.9	3.6	3.6	Soybean, maize, cotton
7	Pakistan	2.9	2.9	2.9	Cotton
8	China	3.9	3.7	2.8	Cotton, papaya, poplar, tomato,
					sweet pepper
9	South Africa	2.7	2.3	2.7	Maize, soybean, cotton
10	Uruguay	1.6	1.4	1.3	Soybean, maize

 Table 1.3: Global area of GM crops by major producing countries

Source: ISAAA (2017).

If measured proportionately based on the type of crops cultivated in 2014, the total area planted with GM soybean was 91 million hectares or 82 percent of the global area for soybean cultivation. This is followed by GM cotton at 68 percent, 30 percent for GM maize and 25 percent for GM canola (refer Table 1.4).

#### Table 1.4: Proportion of GM crop to total crop individual area, 2014

Crop	GM events		Area (million hec	tares)
	commercialized	Global	GM crop cultivated	Percentage GM
Canola	34	36	9	25%
Cotton	51	37	25.2	68%
Maize	142	184	55.2	30%
Soybean	31	111	91	82%

Source: ISAAA (2017).

Table 1.5 shows the proportion of GM maize and GM soybean as a percentage of each crop's individual area in major GM producing countries. One of the concerns commonly pointed out by opponents to GM crops is the limited focus on four main crops and two traits, herbicide tolerance and insect resistance.

	Table 1.5: Ma	ijor GM maize and	GM	soybean	producing	countries, 2014
- F						

Country		Cultiva	ation area 201	4 (million he	ctares)	
	Maize	Global	GM ratio	Soybean	Global	GM ratio
		share			share	
Global	1,038.5	100%	30%	306.4	100%	82%
Argentina	33.1	3.2%	80%	53.4	17.4%	99%
Brazil	79.9	7.7%	79%	86.8	28.3%	83%
Canada	11.5	1.1%	81%	6.0	2.0%	60%
South Africa	14.3	1.4%	87%	0.9	0.3%	90%
USA	361.1	34.8%	93%	106.9	34.9%	94%

Source: FAOSTAT (2015) and PG Economics Ltd (2015).

Nonetheless, it can be noticed for the last five years that there has been a considerable widening of the number and type of GM crops already commercialized (Menozzi et al., 2017). New additions include a large hectarage of sugar beet and alfalfa together with persistent small hectarages of squash, papaya, eggplant and poplar (Parisi et al., 2016). Until 2016, a total of 29 crops had been genetically engineered and commercialized as GM products (ISAAA, 2017).

## 1.1.2 GM Crops in Food and Feed Trade: Asynchronous Approval and Low Level Presence Issues

Certain provisions of multilateral environmental agreements (MEAs) are in conflict with the World Trade Organization (WTO) rules. This is because these two sets of legal instruments were developed to meet different standards (Ansari & Mahmod, 2008). A number of countries now have their own national regulatory framework that deals with the requirement for authorization of the use of GM crops. Most of these countries impose conditions for domestic authorization that involve an environmental risk or safety assessment before a crop is allowed to be released into the environment, for example, for the purpose of commercial cultivation. Generally, authorizations for commercial cultivation in every country happen separately at different timings. Thus, at any given time, there is a possibility that GM crops authorized in one country for commercial cultivation might have not been authorized in other countries with which the country that has given authorization trades agricultural commodities.

By o	country	Number of incidents	By c	rop	Number of incidents
1)	Germany	37	1)	Rice	134
2)	USA	27	2)	Maize	98
3)	France	24	3)	Canola	40
4)	UK	19	4)	Soybean	37
5)	Canada	16	5)	Flax	26
6)	Netherlands	14	6)	Papaya	18
7)	Australia	13	7)	Cotton	14
8)	Austria	13	8)	Grass	4
9)	Italy	13	9)	Sugar beet	4
10)	Sweden	13	10)	Arabidopsis thaliana	3

Table 1.6: GM contamination incidents by countries and crops, 1997-2013

Source: Price and Cotter (2014).

This situation, particularly when it involves GM crops, is usually known as asynchronous approval. It simply means approvals or authorizations given by one or more countries but still pending in another. Asynchronous approval can happen due to the time taken for the approval process being different from one country to another country or may occur because approval was never submitted to or given by the countries that are involved in the import of agricultural commodities. The disruption occurs when trace amounts of an unauthorized genetic trait is detected in grain or seed shipments, or in an ingredients or finished food products. Such a situation can result in costly fines, lost revenue on the total grain shipment, expensive testing and clean-up, unsold or destroyed grain or seed, product recalls in importing countries, and the loss of export market share as the importing country sources grain from another country. The GM Contamination Register<sup>5</sup> for example, has recorded 396 GM contamination incidents from 1997 to 2013 across 63 different countries, as summarized in Table 1.6 (Price & Cotter, 2014).

In the future, incidents due to asynchronous approvals could become more common as more new GM crops are commercialized and more countries start cultivating GM crops. At the moment, most countries apply a zero tolerance approach when dealing with the presence of unauthorized GM crops in its territory (Smyth, 2017). This is consistent with the survey conducted by the FAO (2014) where 72% of the countries participated in the survey responded that they apply a zero tolerance approach for unauthorized GM crops. Generally, a zero tolerance approach or policy implies that ingredients or components of any imported food or feed products cannot contain even trace amounts of GM materials in which authorization has not been given by the importing country. Several countries have proposed low level presence related policies and measures while at the same time continuing to warrant the safety of food and feed products. Food in this context refers to grain or any food products produced from agricultural crops for human consumption, whereas feed or animal feed is fodder for livestock produced from crop and crop residues.

Even though there are no globally agreed upon definitions (Roberts, 2011), in general, low level presence (LLP) attributes to low presence of those LMOs that have gone through a food safety assessment in accordance to the Codex Guidelines in one particular country or another that might be inadvertently present in food in importing countries in which the food safety of the related recombinant-DNA plants has not been assessed (Codex, 2003). Kalaitzandonakes (2011) defines LLP as the unintentional presence of a GM crop at low levels that have obtained regulatory approval for commercialization or market use in one or more countries but has not been approved for any use in an importing country. Adventitious presence, as occasionally addressed as LLP, on the other hand, refers to the unintended presence of LMOs that have yet to be authorized by any countries for any use on the basis of the international guidelines for safety assessment (FAO, 2014).

LLP of unauthorized GM crops can originate from a variety of natural or unnatural causes during production of seed of plant varieties and from the agricultural commodities production process. It can happen throughout the cycle of commercial cultivation to harvest, transportation, or shipment of crops and commodities. Since comingling<sup>6</sup> of grain cannot be completely avoided in agricultural production and transport, new GM crop products approved in the country of cultivation may be unintentionally present in small amounts in shipments to countries that have not yet approved them. Moreover, due to complexity in the supply chain of the agricultural

<sup>&</sup>lt;sup>5</sup>The GM Contamination Register was established by GeneWatch UK and Greenpeace International as a global systematic monitoring of GM contamination incidents. The website is searchable database used by individuals, public interest groups and governments.

<sup>&</sup>lt;sup>6</sup> Comingling occurs when commodity grain produced in one place mixes with grain produced elsewhere, as in a common storage container or shipment.

sector (Fraiture et al., 2017), it is not easy to establish the true original cause of any particular LLP incident in agricultural commodities.

In particular, the seed industry has striven to minimize the incidence of LLP in seeds by adopting best practice approaches for trait development, breeding, field trials, seed production and testing to ensure the purity of the seeds (Kalaitzandonakes & Magnier, 2013). If the seed industry could completely get rid of LLP, it would do this to mitigate unproductive costs resulting from LLP situations, including those that may arise in the post-harvest food production system. Nonetheless, even with the implementation of these quality control mechanisms, it is not always possible to avoid unintentional mixing of seeds during the agricultural production cycle systems due to the complexity of modern agriculture as explained above. Testing at various points in the production system can yield contradictory results due to sample quantification or error limits. This may lead to unpredictability as to the effectiveness of best practice approaches, and thereby restricting the ability to identify LLP in any batch or shipment of seed given.

There are also differences in the number of GM crops authorized in different countries and at the time of their authorization. Main GM crops such as soybean, maize, cotton and canola that are the most internationally traded crops, not only provide significant export revenues for many countries and industries, but have become a critical source of cheap food and feed for many importing countries. Carter and Smith (2007) characterized four different types of unauthorized GM crop events<sup>7</sup> that can be found in food and feed supply. Firstly, there are GM crops that have received regulatory approval for some uses, for example feed, but not for other uses like food. Secondly, there are GM crop events that have been approved for all possible uses in one or more countries, for example, the USA, Brazil and South Africa, but not in other countries, for example, Malaysia, are a common case of asynchronous approval. Third, the experimental GM crop events contained in laboratories, greenhouses or field trials that are unpredictably found in the commercial supply chain of food or feed. Usually, these events have not yet received regulatory approval in any country. Lastly, there are GM crop events that have been granted time limited regulatory approvals for which the validity period for approvals has expired.

As there are no standardized and harmonized guidelines to facilitate international trade of commercialized GM crops and its products (Viju et al., 2017) mainly because of the extensive distinction in the national laws and regulations, problems have emerged at the international level. For example, in the USA and Canada, only food products that contain more than 5% of authorized GM crop material can be categorized as GM. In contrast, all food products with more than 0.9% in the European Union (EU) and with more than 1% in Australia, Brazil, China, New Zealand and South Africa, authorized GM crop material must be labelled as GM (Ramessar et al., 2008).

<sup>7</sup>GM event refers to the unique DNA recommendation event that took place in one plant cell, which was then used to generate entire GM plants. Every cell that successfully incorporates the gene of interest represents a unique "event" (GMO Compass Glossary, 2016).

The Cartagena Protocol on Biosafety (CPB) that was adopted under the aegis of the United Nation's Convention on Biological Diversity (CBD) is regarded to be central to the issues related with asynchronous approvals and LLP (Demeke et al., 2006). The scope of the CPB as articulated in Article 4 of the protocol applies "to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health" (CBD, 2000). The CPB has been enforced since September 2003 after ratifications by 50 countries. Since then, CPB has received strong support and steadily progressed in its implementation. Malaysia became a member or party to CPB after signing the protocol on 24 May 2000, followed by ratification on 3 September 2003. On 15 October 2010, the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress (NKL SP) was adopted to supplement the CPB. NKL SP defines the measures to be taken in response to the damage caused by LMO that find their origin in a transboundary movement<sup>8</sup>. The NKL SP came into force on 5 March 2018.

Countries with significant grain exports such as Argentina, Australia, Canada and the USA are not party to the protocol. Nonetheless, if these countries wish to continue trading with countries who are parties to the CPB, they will have to fulfil the requirements as mandated by the CPB. The CPB categorizes the transboundary movement of LMOs that can be in the form of seed and grain, according to the intended use. These depend on whether grain is for food, feed, or processing as per Article 18.2a; contained use such as for research as stated in Article 18.2b; or introduction into the environment of the importing country that is done intentionally as per Article 18.2c. Regardless of the purpose of use, each must be accompanied with LMO specification or documentation of one form or another. This is to provide assurance of environmental protection. In addition, there should also be ample information on the identity, traits and characteristics of LMOs, that include their safe handling, storage, transportation and use, as well as information on imports and exports. Article 18.2a in particular has a key impact on the international grain trade and has become a major concern to some countries and also to grain production and export industry.

Table 1.7 provides a summary of LMO's regulatory frameworks for selected countries. These countries include the USA, Canada, Argentina and Brazil as the top producers of maize and soybean in the world. Australia, the EU and Japan are known for having a stringent procedure on LMO's approval with strong enforcement capability. The development and prospects of GM crops in China (Pray et al., 2018) and India are considered promising while the rest of the countries are top importers of maize and soybean in Southeast Asia.

<sup>&</sup>lt;sup>8</sup>Transboundary movement is any intentional and/or unintended physical movement or transport of any LMO or its products, across national boundaries.

Country	Party to CPB	Lead governing agency	GM labeling (threshold)	LLP policy (tolerance)	
USA	No	Department of	Voluntary	Case-by-case	
USA	INO	Agriculture; Food and	(5%)	approach	
		Drug Administration;	(370)	(though no	
	Environmental Protection Agency			toleranceset but	
				prefer 5%)	
Canada	No	Environment and	Voluntary	2-tier approach	
Canada	INO		•		
		Climate Change Canada	(5%)	(action level up to 0.2% and tolerance	
				level until3 to 5%)	
Angenting	No	Ministry of Agriculture	Voluntory	No	
Argentina	INO	Ministry of Agriculture	Voluntary (not disclosed)	(zero-tolerance)	
Descril	Vac	Ministry of External	· · · /		
Brazil	Yes	Ministry of External	Mandatory No		
FU	N/	Relations	(1%)	(zero-tolerance)	
EU	Yes	European Commission	Mandatory	Yes	
Directorate G			(0.9%)	(zero-tolerance but	
A / 1º	N	Environment		0.1% for feed)	
Australia	No	Department of Health	Mandatory	No	
	**		(1%)	(zero-tolerance)	
India	Yes	Ministry of	Mandatory	No	
		Environment, Forests	(not disclosed)	(zero-tolerance)	
<u></u>	37	and Climate Change		37	
China	Yes	Ministry of	Mandatory	Yes	
		Environmental	(not disclosed)	(zero-tolerance)	
		Protection			
Japan	Yes	Ministry of	Mandatory	Yes	
		Environment	(5%)	(1% for feed and	
				has been approved	
				by other countries )	
Malaysia	Yes	Ministry of Natural	Mandatory	datory No	
		Resources and	(3%)	(zero-tolerance)	
r 1 ·	17	Environment	M 1.	NT	
Indonesia	Yes	Ministry of	Mandatory	No	
		Environment and	(5%)	(zero-tolerance;	
T1 1 1	37	Forestry		drafting stage)	
Thailand	Yes	Office of Natural	Mandatory	No	
		Resources and	(5%)	(zero-tolerance)	
		Environmental Policy			
<b>X</b> 7' /	N	and Planning	M 1.4	N	
Vietnam	Yes	Ministry of Natural	Mandatory	No	
		Resources and	(5%)	(zero tolerance but	
		Environment		exception for GM	
				event approved in 5	
Dhilinn'	V	Denante ( f	Manalt	countries)	
Philippines	Yes	Department of	Mandatory	No	
0.		Agriculture	(5%)	(zero-tolerance)	
Singapore	No	Agri-Food and	No specific	Not disclosed	
<u>a</u> .1 II		Veterinary Authority	regulation		
South Korea	Yes	Ministry of Foreign	Mandatory	Yes	
		Affairs	(3%)	(0.5%)	

Table 1.7: LMOs regulatory frameworks in selected countries

Souce: Demeke et al. (2006), Gruère (2007), Ramessar et al. (2008), Kamle and Ali (2013), de Faria and Wieck (2015), BCH (2016).

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In September 2012, 13 countries that include Australia, Argentina, Brazil, Canada, Chile, Costa Rica, Mexico, Paraguay, Philippines, Russia, USA, Uruguay and Vietnam agreed on an International Statement on LLP as one of the concerted efforts to tackle the trade risk arising from the occurrences of LLP. In supporting the statement, these countries pledged to continue to work together to address the overall problem of asynchronous approvals of GM products while at the same time attempting to minimize the impact of LLP incidents on food and feed (USDA, 2012).

Prior to that, in 2008, the Codex Alimentarius Task Force on Foods Derived from Biotechnology presented an international guide that was detailed as Annex III on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food (Codex Annex). The Codex Annex provides guidelines for food safety assessment of GM crop events that were authorized as safe for food and feed purposes in one or more countries, including the producing or exporting country, but have not been authorized by the importing country. The Codex Annex anticipates that importing countries can carry out a simple or shortened risk assessment during an LLP situation of GM products that have received regulatory approvals in the exporting country according to the procedures that are consistent with the Codex risk assessment guidelines. If suitable, importing countries can proclaim the low presence of unauthorized GM crop event as safe for the purpose of food and feed while waiting for the thorough regulatory process to be completed.

Table 1.8 and Table 1.9 show potential uses of GM crops (maize and soybean) in food and feed, respectively. Generally, feed represents a huge percentage of the production cost in any livestock industry. In the case of Malaysia, production of raw materials for animal feeds is not done domestically. Thus, the intensive livestock industries (refer to Figure 1.1), in particular non-ruminants (poultry and pork), are dependent on the import of feed stuffs. These feed stuffs materials can be cereal grains, vegetable and animal proteins as listed in the Table 1.9, which are used to improve feed efficiency and growth.

Crop	Derivatives, uses in food
Maize	Derivatives: maize syrup, maize fructose, maize oil, maize starch and flour.
	Examples of processed foods that contain maize derivatives: alcohol, baking
	powder, breads, candy, cereals, chips, cookies, ice cream, infant formula,
	margarine, powdered sugar, salad dressings, soft drinks, soy sauce, tomato sauces
	and vanilla.
Soybean	Derivatives: soy lecithin (used as an emulsifier in bakery products, chocolate,
	margarine and powdered milk), soybean oil, soy flour and soy protein.
	Examples of processed foods that contain soy derivatives: breads, candies, cereals,
	chocolates, cookies, crackers, fried foods, ice cream, infant formula, margarine,
	sauces, soy sauce and tofu.

#### Table 1.8: Potential uses of GM crops in food

Source: Cummins & Lilliston (2004).

Crop	Feed product	Product description
Maize	1) Maize gluten feed	Produced from the wet-milling of maize grain for starch (or ethanol) production.
	2) Maize gluten meal	Produced from the manufacture of maize starch by the wet-milling process. Used as a source of protein, energy and pigments for livestock species including fish.
	3) Maize distillers grain	Produced from the distillation of alcohol from maize grain.
	4) Maize bran	Produced from various maize processing industries that include starch and ethanol production.
	5) Maize cobs	Products from the maize cropthat consist of the central fibrous rachis of the female inflorescence.
	6) Maize germ meal	Produced from the oil extraction from maize germs obtained from maize processing.
	7) Maize grain	The main feed grain and a typicalpart of livestock diets.
	8) Maize green forage	Contains the stalks and leaves.
	9) Maize stover	Consists of the residues of maize plants left in a field following the harvest of the grain. It includes stalks, leaves, husks, and cobs.
Soybean	1) Soybean forage	Soybean varieties bred for forage are late maturing and taller than grain varieties.
	2) Soybean hulls	Produced from the extraction of oil from soybean seeds.
	3) Soybean meal	Produced from the extraction of soybean oil. The most important protein source used to feed farm animals.

Table 1.9: Potential uses of GM crops in animal feed

Source: Feedipedia<sup>9</sup> (2016).



**Figure 1.1: Production of livestock and aquaculture in Malaysia (2010-2015)** Source: Agrofood Statistics Malaysia (2015).

<sup>&</sup>lt;sup>9</sup>A programme by INRA (French National Institute for Agricultural Research), CIRAD (French Agricultural Research Center for International Development), AFZ (French Association for Animal Production) and FAO. http://www.feedipedia.org/

By focusing on the number of commercialized events for maize and soybean globally, Table 1.10 summarizes the total number of GM events approved between 2000 and 2014. The table shows a fairly dynamic development of the process of approving new GM events, especially for maize, with the number of approved events increasing from 21 in 2000 to 142 in 2014. With regard to soybean, the number of approved events increased from 9 to 31 within the same period. Since not all approved events are available in the market, a significant increase in the number of approved events worldwide does not necessarily lead to a noticeable increase in commercialization of GM products (de Faria and Wieck, 2015).

Table 1.10 also highlights main exporting and importing (in the Southeast Asia region) countries that the study is considering. In 2000, the USA appeared as the leaders in the approval of new GM crops, while only a few countries had approved GM events for maize or soybean. These figures shifted noticeably by 2010, as other countries moved towards the adoption of LMO regulations and subsequently implemented an approval process for GM events. As an example, Malaysia had not approved any GM events prior to 2010. However, after establishing the necessary regulatory mechanism in 2010, the situation changed quickly. By 2014, Malaysia was one of the key players in the Southeast Asia region in terms of the number of approved GM events for maize and soybean. The USA and Canada maintained their positions as leaders in approved events for soybean.

Country			Maize				1	Soybear	1	
Country	2000	2004	2010	2012	2014	2000	2004	2010	2012	2014
Global	21	32	108	120	142	9	9	17	24	31
Argentina*	4	5	13	20	29	1	1	1	4	5
Brazil*	1	1	15	19	21	1	1	6	6	6
Canada*	12	15	24	27	31	4	4	8	14	18
China	0	8	12	13	14	0	1	3	5	7
EU	5	5	24	29	39	0	0	3	7	7
Russia	0	0	9	10	12	0	0	4	5	6
South Africa*	0	7	10	29	36	0	3	3	7	11
United States*	16	21	28	32	35	5	5	9	15	20
Uruguay*	0	2	2	9	9	1	1	1	2	2
Indonesia	0	0	0	6	6	0	0	0	2	2
Malaysia	0	0	3	4	6	0	0	1	3	6
Philippines*	0	9	33	36	44	0	1	5	7	11
Thailand	0	0	0	0	12	0	0	0	0	3
Vietnam	0	0	0	0	14	0	0	0	0	8

Table 1.10: Number of approved GM events by country, product and year

\* GM producing countries

Source: Compiled from ISAAA and BCH

As seen from Table 1.10, the leading players in international trade are also the major players in the approval of GM events. In particular, countries like Argentina, Brazil, Canada, South Africa and the USA are the producers of GM crops. Within the Southeast Asia, Philippines is not only the leader in term of the number of approved GM events but also the first country to cultivate or produce GM crop in the region.

Nevertheless, even among the most active countries, the number of approved events varies significantly, which means asynchronous approvals exist as do the associated potential for trade disruptions. The impact of asynchronous approval on trade depends extensively on the stringency of GM crop regulations adopted by the importing countries. Therefore, the above analysis has taken into account the existing regulatory practices in these countries. For that purpose, the scores for the Protectionism Index were calculated, which quantifies the difference of GM event approval status for a country pair and also takes into account the strictness of approval status of the importing country. Although relatively new, the extant literature shows that the use of indices to assess regulatory heterogeneity across countries is growing (de Faria & Wieck, 2015). However, in some studies, the development of the indices does not consider the validity of the GM event approvals that is maintained and can be retrieved from certain LMO related databases.

A Protectionism Index value different from one demonstrates the existence of asynchronous approval across countries. For instance, a Protectionism Index value greater than one shows that potential trade disruption may arise from the asynchronous approval because the importing country is more restrictive than the exporting country in terms of regulatory practice. On the other hand, a Protectionism Index value less than one indicates that the importing country is less stringent than the exporter: thus very minimal trade disruptions are expected.

The analysis of the Protectionism Index for pairs of countries (as summarized in table form under Appendix A), takes into account the main players in the international trade of maize and soybean. Looking at the results as a whole, it can be noticed that there is a trend toward a more synchronized approval status for several importing countries, especially for soybean. Focusing on Malaysia, Philippines and Thailand as the importers, it can be observed that they had lowered their indices and became less strict than some other exporters. The case of soybean could show the approach of major importing and exporting countries, especially exporting countries, to address asynchronous approval. As highlighted by Berwald et al. (2006), this lowering of indices and reduced strictness can reduce trade disruptions by selecting GM events for commercialization only when the loss of sensitive import markets does not pose a serious threat. In view of the small number of GM events for soybean that are currently commercialized, and the fact that several countries in North and South America dominate the export of these products, it is easier to harmonize the approval of GM events in major importing countries or to strategize by waiting for approval from the main importing countries. As for maize, for which more GM events are commercialized and for which international trade is not really concentrated in several countries, international coordination is not easy to accomplish, as reflected in the index values.

Most of the Protectionism Index values are higher than one for the two products, signifying that on average, the importing countries are stricter than the exporting countries. It is worth mentioning that even countries that adopt quite similar GM crop regulatory systems, overall, as shown by Vigani and Olper (2013), has a quite different Protectionism Index for regulatory approval. Although Malaysia ranks alongside the USA in Vigani and Olper's (2013) GMO regulatory index, it demonstrates higher

values than the USA in the Protectionism Index score (see Appendix B for more). A similar pattern is observed in many other countries, which indicates significant differences in regulatory requirements between countries, especially with regard to the amount of time required for review and approval of new GM events.

Another interesting finding is the number of importing countries that had lowered their index values below one, which indicates that they have harmonized the status of their GM events. The case of soybean is exemplary of this synchronicity, given that in 2014, Malaysia and Philippines were found to be less restrictive in their approval status of GM events than some of the exporting countries. By calculating the average of the country index scores for each importing and exporting country over total approved GM events globally, a measurement of the extent and the strictness of the asynchronous approval for each sample country are made available. Appendix B shows these results. In them, it can be noticed that there is a significant discrepancy in the Protectionism Index values across countries. For this calculation, if the value of the Protectionism Index is one, then the country has a very strict regulation and no single GM event authorized for commercial use in that particular year. A Protectionism Index close to zero indicates that the country is less restrictive.

In 2000, the USA and Canada are the least restrictive countries with lower index values for the two products. At that time, these countries were leaders in approving new GM crops, and there were only a few countries that had approved GM events for maize or soybean. These numbers have changed significantly in 2010 because other countries made progress in adopting the regulation of LMOs and therefore a comprehensive GM approval process is being implemented. For example, in the Philippines and Malaysia, after establishing their regulatory framework in 2006 and 2009 respectively, they showed a steady decline in the values of their indices due to the rapid approval of new GM events. In 2014, both countries appeared in a group of countries that are considering less restrictive in particular for soybean. A different pattern can be observed for the USA and Canada, especially for maize, showing that the differences between the USA and other countries, as well as between Canada and other countries, have decreased over this period. Exploring some major countries in the international trade of maize and soybean, three different behaviours can be observed. Argentina, Malaysia, the Philippines and South Africa reduced the value of their Protectionism Index for all products and, on average, became less restrictive. On the other hand, Indonesia, India, Thailand and Vietnam retained or increased the value of their index for all products, while the EU and Russia presented quite similar patterns in which they lowered the value of their index for maize.

#### 1.1.3 Biotechnology, Biosafety and GM Crops in Malaysia

The agriculture sector in Malaysia has changed over the years (refer to Figure 1.2). National Agriculture Policy (NAP) plans that were introduced since 1984 contributed to the sector's development. For example, the Third National Agriculture Policy (NAP3) implemented between 1998 and 2010, emphasized the significance of human resource development as a key factor to produce innovative and highly skilled workers in emerging and latest sciences including modern biotechnology and genetic engineering. Under the National Agri-Food Policy for 2011-2020 for instance, GM

technology is acknowledged as one of the ways to make sure food security exists in a sustainable industry (Idris, 2013). Since then, biotechnology has been accepted as a new and promising technology that can take the agricultural sector to a different level with desired changes. It was augmented when the direction and development of biotechnology occupies an important place in the national policies in Malaysia.



**Figure 1.2: Evolution of the agriculture sector in Malaysia** Source: BiotechCorp (2009).

The National Biotechnology Policy (NBP) launched in 2005 acknowledges the government's commitments on biotechnology development to reach the goal of being an innovation-led economy. NBP makes available a platform and guidance for a conducive environment primarily for research and development (R&D) and industry growth by maximizing the country's capabilities and existing strength (Arujanan & Singaram, 2018). The implementation of NBP was carried out in three phases with the projected total revenue of USD90 billion contributing 5% to the total gross domestic production (GDP) of Malaysia (BiotechCorp, 2010). For example, under Phase I of the NBP, Malaysian Biotechnology Corporation Sdn. Bhd. (BiotechCorp) (now known as Malaysian Bioeconomy Development Corporation Sdn. Bhd.) was established and acts as the one-stop centre for biotechnology industry development in Malaysia. With the implementation of NBP, few national biotechnology institutes have also been formed, such as the Agro-Biotechnology Institute Malaysia, the Genome Malaysia and the Malaysian Institute of Pharmaceuticals and Nutraceuticals. Apart from the NBP, the importance of the biotechnology sector also highlighted in the 9<sup>th</sup> (2006-2010) and 10<sup>th</sup> (2011-2015) Malaysian Plans.

Since Malaysia recognizes biotechnology as one of the new engines of growth for the nation and embarks on its drive to pursue this field, biosafety has become gradually more important. Biosafety in this context includes the safe transfer, handling and use of LMOs. The National Policy on Biological Diversity (NPBD), which was launched in 1998, has called for the sustainable utilization of the nation's biological resources, one of the methods being through biotechnology. The NPBD reflects, as a megadiverse country, that Malaysia made the nation's biological resources a top priority to ensure that they are well safeguarded. Biosafety plays a role in minimizing the potential adverse effect of modern biotechnology or managing it in a manner that will not cause a negative impact on human health and biological diversity. In 2016, an improved NPBD was launched to replace the 1998 policy. The improved policy paid great attention to biosafety since it was included as a policy goal in three action plans.

Under its legislative and regulatory framework development component, the NBP also acknowledges concerns from biotechnology applications. To create an enabling environment, the component recommends the consistent review of the nation's regulatory framework and guidelines in line with international standards and good approaches. Also recommended is developing an effective intellectual property system that can support R&D and efforts for commercialisation. Thus, both NBP and NPBD created a facilitative environment to maximize benefits from modern biotechnology, which at the same time minimizes potential risks to human health and the environment. These efforts were further strengthened with the insertion of a strategy to enhance the biosafety capacity in the  $11^{\text{th}}$  (2016-2020) Malaysian Plan by taking into consideration increasing R&D in the biotechnology sector.



Figure 1.3: Approval process to import GM crops to Malaysia Source: Malaysia Biosafety Clearing House (2016).

In response to the need for a dedicated regulatory framework to keep the environment and health safe from potential adverse effects of modern biotechnology applications, the Biosafety Act (Act) was passed by the Parliament on 11 July 2007. The Act came into effect on 1 December 2009, whereas the Biosafety (Approval and Notification) Regulations 2010 were gazetted a year later to support the implementation the Act. Both signify a new mechanism for the domestic regulation of LMO and its products as well as to fulfil Malaysia's obligation as a party to the CPB (Ramatha, 2011). The National Biosafety Board (NBB), empowered under the Biosafety Act 2007 is the regulatory body in Malaysia for making decisions about importing GM crops to Malaysia. The decision to permit the import of these GM crops is based on a technical or scientific assessment provided by the Genetic Modification Advisory Committee (GMAC), after taking into account inputs from relevant government agencies and the general public. The NBB issues permits for the import of GM crops after the assessment results show a lack of evidence that the import may pose a threat to the well-being of humans, plants and animals, as well as to the environment and biological diversity. Risks are identified and risk management strategies are evaluated to ensure effective management of identified risks (Ramatha, 2011). The decisions made by the NBB also take into considerations inputs or feedbacks given by relevant government agencies as well as public that were collected during the consultation period. Currently, the approval process takes a maximum of 180 working days to be completed as illustrated in the flowchart in Figure 1.3.

	Сгор						
Year	Mai	ize	Soybean				
rear	Volume	Value (US\$)	Volume	Value (US\$)			
	(metric tonnes)		(metric tonnes)				
2006	3,286,346	397,712,000	389,642	163,702,000			
2007	2,658,469	610,044,000	506,244	217,485,000			
2008	2,100,948	670,171,000	503,219	306,284,000			
2009	2,628,054	567,636,000	491,477	244,737,000			
2010	3,076,957	766,550,000	637,726	319,048,000			
2011	2,862,546	933,618,000	637,286	383,360,000			
2012	3,031,156	931,265,000	588,994	362,058,000			
2013	3,389,079	995,599,000	556 <mark>,9</mark> 44	350,683,000			
2014	3,822,338	961,458,000	576,824	343,857,000			
2015	3,577,736	772,346,000	726,586	318,045,000			

Table 1.11: Import of maize and soybean by Malaysia, 2006-2015
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Source: FAOSTAT (2016).

This study focuses on maize and soybean because at the moment, authorized GM events in Malaysia are mostly from these two crops. Moreover, products of maize and soybean are widely traded internationally. Malaysia, on average, imports three million metric tonnes of maize and 500 thousand metric tonnes of soybean for various purposes that range from food to feed and processing (Table 1.11). Globally, Malaysia is the 10<sup>th</sup> largest importer of maize and 14<sup>th</sup> largest importer of soybean. The increasing trend of GM crops production brings the high possibility of more GM products being imported into Malaysia.

Currently, international databases that can track the movements of GM commodities or GM products and non-GM counterpart are very limited. Nonetheless, available bilateral trade data (as shown in Table 1.12 and Table 1.13) can be used for this purpose together with information on regulatory differences and adoption patterns for GM crops to estimate the portion of trade that is possibly GM (Gruère & Sengupta, 2009).

 Table 1.12: Import of maize from key GM producing countries, 2010-2014

Country	GM	Year (metric tonnes)						
	ratio	2010	2011	2012	2013	2014		
USA	89%	18,279	13,437	7,367	7,190	55,982		
Argentina	86%	1,514,875	1,211,544	1,350,651	1,427,315	1,579,032		
Brazil	73%	888,505	648,720	686,952	1,020,529	1,594,505		
Uruguay	94%	53,211	8,020	64,843	20,613	0		
Paraguay	50%	0	25,030	15,349	24,854	41,969		

Source: FAOSTAT (2015).
Country	GM	Year (metric tonnes)				
	ratio	2010	2011	2012	2013	2014
USA	93%	349,317	372,046	297,474	213,317	223,383
Argentina	99%	106,705	86,119	16,776	45,581	43,124
Canada	72%	103,666	63,884	68,856	68,328	85,982
Brazil	84%	785	2,143	11,304	94,855	62,482
Paraguay	98%	0	44,334	56,231	77,924	104,233

Table 1.13: Import of soybean from key GM producing countries, 2010-2014

Source: FAOSTAT (2015).

The NBB, until 2016, has approved 14 events for GM maize, seven events for GM soybean and one event for GM canola (Table 1.14). Importation of GM products from these events into the Malaysian market is allowed but only for the purpose of food, feed, and processing (FFP). However, the approval is subjected to strict conditions on the handling of the GM products, such as immediate follow up action for spillage and the prohibition of cultivation.

Crop	Tra	it	Event	Developer	Year
Maize	1)	Herbicide tolerance	NK603	Monsanto	2010
	2)	Insect resistance	MON810	Monsanto	2010
	3)	Insect resistance	MON863	Monsanto	2010
	4)	Insect resistance	Bt11	Syngenta	2012
	5)	Herbicide tolerance	T25	Bayer	2013
	6)	Herbicide tolerance x Insect resistance	TC1507	Du Pont	2013
	7)	Insect resistance	MON89034	Monsanto	2015
	8)	Insect resistance x Herbicide tolerance	MON88017	Monsanto	2015
	9)	Insect resistance	5307	Syngenta	2016
	10)	Insect resistance	MIR604	Syngenta	2016
	11)	Insect resistance	MIR162	Syngenta	2016
	12)	Herbicide tolerance	GA21	Syngenta	2016
	13)	Thermostable enzyme	3272	Syngenta	2016
	14)	Insect resistance x Herbicide tolerance	DAS59122-7	Du Pont	2016
Soybean	1)	Herbicide tolerance	40-3-2	Monsanto	2010
, in the second s	2)	Herbicide tolerance	MON89788	Monsanto	2012
	3)	Herbicide tolerance	A2704-12	Bayer	2012
	4)	Herbicide tolerance	CV127	BASF	2013
	5)	Herbicide tolerance	A5547-127	Bayer	2014
	6)	Herbicide tolerance	FG72	Bayer	2014
	7)	Herbicide tolerance	SYHT0H2	Syngenta	2016
Canola	1)	Herbicide tolerance	MS8FR3	Bayer	2016

Table 1.14: LMOs approved for food, feed and processing in Malaysia

Source: BCH<sup>10</sup> (2016).

These management strategies are necessary and may need to be reviewed over time to ensure that the currently proposed practices are adequate and that handling safeguards

<sup>&</sup>lt;sup>10</sup>The Biosafety Clearing-House (BCH) is an international mechanism that exchanges information about the movement of genetically modified organisms, established under the Cartagena Protocol on Biosafety. https://bch.cbd.int/about/countryprofile.shtml?country=my

exist to ensure there will be no unintended release to the environment (BCH, 2016). In 2016, 388 events from 29 types of crops were commercialized worldwide. Out of this number, 154 events are from GM maize and 36 events from GM soybean. Based on the latest approval status as shown in Table 1.15, Malaysia has approved 9.1% and 19.4% of these events, respectively.

Сгор	Commercialized Approved GM events in Malaysia				Percentage
	GM event globally	FFP	Cultivation	Total	
Soybean	36	7	-	7	19.4%
Maize	154	14	-	14	9.1%
Canola	38	1	-	1	2.6%
Cotton	58	-	-	-	-
Total	373	22	-	22	5.9%

Table 1.15: Proportion of approved GM events to total events commercialized,2016

Source: ISAAA (2017) and BCH (2016).

The approval status and other on-going LMOs related activities indicate a positive progress of GM technology applications in Malaysia. However, several issues may require attention if Malaysia plans to continue or move forward in applying the technology. Apart from LLP management issue, other relevant issues include enforcement and detection capacity, coordination between agencies, liability and redress, socioeconomic considerations, labelling, regulatory mechanism and public perception of LMOs (Idris, 2013).

## 1.2 Problem Statement

In general, the commercialization of new GM crops are subjected to regulatory approval in many countries. Usually, approval or authorization procedures are different from one country to another. Even though two applications for the same GM crop events may be submitted to two different countries at the same time, they will not get approved simultaneously in both countries. This is what known as asynchronous approval of GM crops, an issue that has become a major concern globally due to its potential impacts on food and feed trade. Asynchronous approval can lead to LLP, a situation in which small traces or an insignificant quantity of new GM crops present in agricultural commodities are destined for export to countries where these GM crops have not been authorized. When this happens, these countries may reject or stop the shipments. As a consequence, the supply chain operators might incur economic losses with the worst scenario leading to trade disruptions that can subsequently deny the right of entry to specific markets. On that basis, the current study attempts to explore three issues pertaining to asynchronous approval and LLP management strategies in Malaysia.

The first issue here is the problem of asynchronous approvals and its potential trade impacts to Malaysia. Based on facts and figures, there is an increasing trend in the number of GM crop events being developed all over the world primarily for commercial production. At the same time, there are a growing number of countries that have formulated procedures for risk assessment exclusively to permit the import of GM crops including its products. However, every country has a unique requirement when it comes to designing a GM crop's regulatory framework. Thus, it is almost impossible to get all GM crop regulations to harmonize. Due to these facts and the gaps that currently exist in GM crop regulations, the asynchronous approvals issue is unavoidable. Furthermore, many countries have yet to provide or adopt any specific procedure or strategy to handle the unintended presence of unauthorized GM materials in the import of agricultural commodities. The most common strategy used to encounter these situations is to apply a zero tolerance policy or approach. As there is no practical solution to asynchronous approvals issue, besides potential impacts it can create on food and feed trade, problems arise because of asynchronous approvals place a huge burden on the importing country's enforcement bodies when detection has to be done on unauthorized GM crops. With the increasing number of land areas cultivated with GM crops and countries adopting this technology apart from the number of GM events itself, problems related to asynchronous approvals may become more prevalent. China and India, for example, are almost at the final stage to commercialize its own locally produced GM crops. Even if these GM crops are planned for the domestic market, it may end up unintentionally in shipments destined for international trade and enter other countries, including Malaysia.

Potential impacts of asynchronous approval on food and feed trade were analysed in several studies. Some studies focused on impacts of asynchronous approval in the European food industry where the zero tolerance approach is applied (Brookes, 2008; Landmark Europe, 2009; Freitag et al., 2011; Kalaitzandonakes, 2011; Hobbs et al., 2014). One of these studies (Landmark Europe, 2009) measures costs associated with the low presence of unauthorized GM maize that originated from the USA in the EU import. The potential costs are estimated to be between 5 and 46 million Euros, not including other related costs such as indirect costs due to the shortage in supply or factory shutdowns. Moreover, maize and soybean particularly, together with products derived from these two crops, represent a significant share in the materials for feed productions. Costs to produce the feed are regarded as the most critical input costs for livestock farmers, estimated between 50 and 80 percent from total production costs. As shown in Table 1.11, Malaysia on average imports 500 thousand metric tonnes of soybean and 3 million metric tonnes of maize annually for local consumptions between years 2006 to 2015. As an importer of maize and soybean products, what could be the potential impacts of asynchronous approvals on Malaysia?

The second issue relates to the practicability of current practices in Malaysia to deal with LLP situations. Under the existing regulatory mechanism, any GM crop product must obtain the National Biosafety Board (NBB) approval before it can be released or enter the Malaysian market. The law implies that maize and soybean shipments cannot contain even trace amounts of unauthorized GM crop events. If the low presence of these unauthorized GM events are detected, it will be regarded as regulatory non-compliance that must be subject to full regulatory processes regardless whether or not such GM event may pose any potential risk to human health and environment. The regulatory process involves a thorough assessment of potential risks and risk management strategies proposed. Therefore, in LLP situations, the technology developers are required either to provide operational mechanisms to remove or destroy the unauthorized GM products from the market and the environment if it was placed into cultivation or to seek for approval from the Malaysian authority.

For this reason, the practicability of a zero tolerance policy for LLP may need to be examined and the possibility of non-zero LLP tolerance levels can be explored. However, what constitutes an acceptable and operational LLP tolerance depends on individual countries. Furthermore, the setting of LLP tolerance is a complex process because it involves both economic and risk considerations. High LLP tolerance level is expected to minimize trade disruptions and relevant economic implications but is only practical if there are no concerns with regard to food, feed or environmental safety. On the other hand, a low tolerance level implies significant costs due to higher segregation costs and impacts that arise from trade disruptions that become more likely. Thus, a comprehensive evaluation on the impacts of LLP tolerance options is critical and should become a part of LLP management approaches and strategies. In Malaysia, the existing law suggests it is a zero threshold for LLP or in other words has a zero tolerance policy. What will be the economic and regulatory implications for a different threshold of LLP, particularly in terms of regulatory costs to the government and effects to consumer surplus?

The third issue touches on the complexity in the policy-making process when it involves science and technology or GM technology in particular. In general, the law on biotechnology is developed in maintaining a balance between public safety and biotechnology development. However, it is not easy to regulate the biotechnology industry due to the dynamic nature of the industry. Therefore, any particular law used to govern this industry must consistently change and evolve to make it relevant and effective. Andanda (2006) suggests three main factors that can be considered when developing a policy or legislation for biotechnology, which include wider consultation processes that will compile views from all relevant stakeholders. A result will be the ability to maintain flexibility but not to compromise the establishment of a concise and credible policy framework that will become the foundation for the regulatory framework.

This makes the process of developing a policy or law on GM crops more complex. Moreover, the existence of a GM crop is a cross-sectoral issue for many countries including Malaysia. The GM issue such as LLP is not only related to agriculture and environment but also to human health, trade, and consumerism. All related stakeholders have a right to an opinion in designing and formulating the policy thus thorough consultation is necessary. In relation to that issue also, the adequacy and applicability of existing laws may need to be examined. Is the existing law applicable or can it adequately address LLP situations in Malaysia? Some of the issues that need further investigation include coordination between agencies, enforcement capacity in particular detection mechanisms, socio-economic considerations and the approval procedures. In this regard, what could be the determinants to develop an operationally practical LLP management approach for Malaysia? If Malaysia continues to apply the existing laws, what could be the issues and challenges faced by the government and relevant industries?

# **1.3** Research Objectives

The general objective of this study is to investigate the impacts of asynchronous approvals of GM crops on food and feed trade, and low level presence management strategy in Malaysia. The specific objectives are -

- 1) To examine the trade impacts of asynchronous approvals of GM crops;
- 2) To evaluate the economic effects of low level presence tolerance options for unauthorized GM crops; and
- 3) To examine the factors that affect policy development on low level presence of unauthorized GM crops.

## 1.4 Significance of the Study

## 1.4.1 Empirical Perspective

This study builds on contributions from existing literature in exploring the policy options for low level presence of unauthorized GM crops by offering an in-depth and systematic comparative analysis that takes into account earlier policy developments, and characteristics that are uncommon in studies to date. Moreover, this research adds to the rapidly developing field of social science-based research on the social and political issues raised by science and new technologies. GM crop policy as a research area emerges where science (genetics), technology (genetic engineering), and society (public policy) converge. By studying impacts from asynchronous approval and LLP, empirical data on the broader question of how policy-makers address science and new technologies can be generated. Finally, this study is a contribution to the body of literature analysing LLP policy options in depth.

### **1.4.2** Theoretical Perspective

On the basis of sovereignty, each country can independently decide which regulatory framework to use within its jurisdiction. Despite that, when GM products enter into an international food and feed trade, conflicts of different regulatory requirements arise. Discussions about regulatory regimes become an internationally controversial legal issue. Such discussions, combined with controversies about the use of GM technology in agriculture, have aroused great interest among legal scholars who have studied and discussed regulatory systems for LMOs. Some of them provided a fairly comprehensive analysis of how the LMO should be regulated, how such legislation was shaped and what type of regulatory legislation should be adopted. The controversies of dealing with LLP situations have been highlighted in these studies but they are smallscale investigations. Specialized discussions of LLP policies can be found in a limited number of academic papers, while books related to LLP policies are much less common. This study develops an analytical framework that makes use of approaches containing several elements. Using these approaches together enables the study to consider the importance of policy developments proceeding the era of GM crop, the role of international agreements in formulating regulatory mechanisms, as well as the importance of various other factors in determining operationally practicable policy option. The contribution of this research brings these elements together to explain the LLP impacts and management as well as factors to be considered for policy options.

#### **1.4.3** Practical Perspective

Governments around the world proactively looking at ways to enhance the regulatory system that will continue to protect human and animal health and the environment while not unnecessarily impeding innovation and trade. Therefore, the outcome from this research is important in that it assists policy makers in Malaysia to understand better the existing magnitude of LLP as well as the issues and challenges that the Malaysian government is facing and would be facing while formulating and implementing LLP policy. This research also can provide policymakers with a different level of tolerance for the low presence of unauthorized GM crops products and its trade and regulatory consequences. This is timely since Malaysia is one of the signatories to the Comprehensive and Progressive Agreement for the Trans-Pacific Partnership<sup>11</sup> (CPTPP). Under the CPTPP's original text, the LLP issue is highlighted and covered under Chapter 2 on National Treatment and Market Access for Goods Chapter. The government will have to consider views from all stakeholders before coming to a decision to ratify or implement the agreement in the future. This study probably can help to provide an analysis of a different group of stakeholders, and on their perspectives and preferences for LLP policy that can be used as guidance for policy formulation.

## 1.5 Organization of the Study

The thesis is organized into five chapters. The first chapter commences with a global perspective and explains the future development of GM crops and then highlights the evolution of GM crops in Malaysia. Subsequently, GM crops in food and feed trade and issues of asynchronous approval and LLP are investigated. At the end of this chapter, the problem statement, objectives of the study, significance of the study and organization of the study are explained. Chapter 2 provides a literature review of studies related to asynchronous approvals of GM crops, including what causes it to happen and potential impacts arising because of it. It also elaborates on the LLP tolerances for GM crop and relates how it can affect the price, perceived safety, and cost of enforcement. Finally, this chapter highlights factors influencing LLP policy options. Chapter 3 describes methods used to achieve the stated objectives and provides a justification for the selected methodology. Chapter 4 presents and explains the results and analysis of the study. Finally, Chapter 5 summarizes all major findings and gives the conclusion and policy implications as well as presents recommendations for the future.

<sup>&</sup>lt;sup>11</sup> Formerly known as Trans-Pacific Partnership Agreement or TPPA. The agreement was signed by 12 countries on 4 February 2016. Following the USA withdrawal in January 2017, ministers of the 11 TPP countries agreed on further actions to implement the TPP and reached an agreement on the latest text of the Agreement, known as CPTPP. The CPTPP will include the original TPP Agreement, with the suspension of several provisions.

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Johnny Andrew was born in Sri Aman, Sarawak on 25<sup>th</sup> July 1978. He received the Bachelor and Master degrees in accounting from the Universiti Teknologi MARA, in 2001 and 2004, respectively. He started his career in August, 2001 at Ernst and Young as a Tax Consultant and obtained his Chartered Accountant. In December 2004, he joined the Federal Government Civil Service as an Administrative and Diplomatic Officer and has been with the Ministry of Natural Resources and Environment since then. During his employment period with the ministry, he has represented Malaysia in several international meetings related to biosafety issues.

Mr Johnny is a member of Malaysian Institute of Accountants (MIA), Malaysian Administrative and Diplomatic Service Association, and Malaysian Biosafety and Biosecurity Association. In 2015, he has been awarded a scholarship by the Government of Malaysia to pursue his PhD degree and enrolled at the Institute of Agricultural and Food Policy Studies, Universiti Putra Malaysia (UPM) in the same year.

## LIST OF PUBLICATIONS

#### Publication

#### **Journal Article**

Johnny Andrew, Normaz Wana Ismail, and Marcel Djama. An Overview of Genetically Modified Crop Governance, Issues and Challenges in Malaysia. *Journal of the Science of Food and Agriculture*, 98(2018), 12–17.

## **Chapter in Book**

Johnny Andrew, Normaz Wana Ismail, Nitty Hirawaty Kamarulzaman, and Zahira Mohd Ishan. Asynchronous Approvals of Genetically Modified Crops: Issues and Challenges for Malaysia in *Transactions of Persatuan Genetik Malaysia*, No. 8, pp. 45-50, 2018, Accelerating Synergies in Plant Breeding, Genetics and Biotechnology.

#### **Paper Presented**

- "Zero Tolerance for Unauthorized Genetically Modified Organism: The Malaysia Case" at the 3<sup>rd</sup> International Conference on Science and Technology (ICOSAT 3), 1 November 2018, UPM Serdang.
- "Managing low level presence of genetically modified crops from Malaysia's perspective" at the 4<sup>th</sup> International Conference on Agricultural and Food Engineering (CAFEi2018), 7-8 November 2018, Hotel Everly, Putrajaya.
- "Asynchronous Approvals of Genetically Modified Crops: Issues and Challenges for Malaysia" at the 4<sup>th</sup> International Plant Breeding Conference (IPBC2018), 13-14 November 2018, Hotel Bangi-Putrajaya, Selangor.



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