THAI LEGAL CONTROL AND LIABILITY OF LIVING MODIFIED ORGANISMS: A CASE STUDY OF LMO PRODUCTS*

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Abstract

Nowadays the modern biotechnology has a significant role in several fields. However, despite of several advantages, there are also concerns about the risks of Living Modified Organisms (LMOs) to the environment and human health. Accordingly, the Cartagena Protocol on Biosafety (CPB) and the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Supplementary Protocol) were issued. Since Thailand is the Party to the CPB and is considering to ratify the Supplementary Protocol, Thailand has the obligation to provide necessary and appropriate legal control and liability regarding all operations associated with LMOs. Yet, Thailand still has no specific law regulating LMO products, but relying on the existing regulations which resulting in an unsystematic control system. Therefore, this article will point out the drawbacks and obstacles to the application of current regulations and propose the adequate legal control and liability on LMO products in Thailand.

Keywords: Living Modified Organisms (LMOs), Biosafety, Cartagena Protocol, Nagoya-Kuala Lumpur Supplementary Protocol

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1. Introduction

While the world population has significantly increased and agricultural areas are limited, there is a belief that LMO products will resolve a food shortage. However, since a genetically modified technology is considered as a very new technology and, still, no scientific evidence affirming that LMOs are safe, there are some concern about 'safety' of LMO products whether LMO products will cause any risks to human health, the environmental contamination, etc.

Moreover, there is also a controversial that some countries may use such concern as a tool of trade barrier.[1] That is to say, some countries may reject to import other countries' products by alleging that they concern about the biosafety of LMO products. As a result, it will impact not only LMO products, but also traditional agricultural and organic farming products. Accordingly, every sector is of the opinion that there should be the legal control of LMO products.

In Thailand, the adoption of current laws to control LMO products still has several obstacles and drawbacks. Therefore, this article aims to propose adequate legal measures controlling LMO products by studying the relevant factors and contexts more profoundly including the analysis of current legal control on LMO products in Thailand.

2. Specific Natures of LMOs

2.1 The Capability of Transferring or Replicating Genetic Materials

A term 'LMOs' is always used as a synonym of 'GMOs', but GMOs seems a broader term. The word 'living' emphasizes that LMOs contain an ability of self-reproduce[2] whereas GMOs encompass both living and dead

[1] Pariyaporn Thengprasert, 'Legal Measure in relation to Import and Export of Genetically Modified Products' (Master of Laws, Thammasat University 2008) 21

[2] MoonSook Park, 'A Comparative Study of GMO Labeling and Liability Systems in the US, EU, and South Korea: The Circumstances and a Future Potential for Harmonization'

organisms. Since the CPB[3] aims at preventing any effects that may occur due to the self-reproduction of living modified organisms, it adopts a term 'LMOs' instead of 'GMOs'.[4]

2.2 The Uncertainty of Risks

Until now, no scientific certainty affirms the risks of LMOs. The risks assumed to derive from LMOs are recognized as potentially-but not yet proven to be- harmful. So, LMO products should be subject to the precautionary principle which arises from the concept of avoiding or minimizing the environmental damage by careful planning to prevent potential harms on the environment and human health derived from the future activities.[5]

2.3 Serious and Irreversible Damages[6]

This is one reason for a legal control on LMO products. LMOs contain a gene-altered from the original species and capable of reproduction, if LMOs had been released to the environment without control, it might be cross-breeding with the original species resulting in the alteration or extinction of the original ones and the loss may not be restorable or reversible.

(Theses and Dissertations. Paper 4, Maurer School of Law, Indiana University 2014) 1 < https://www.repository.law.indiana.edu/etd/4/> accessed 3 March 2018

[3] The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter 'the CPB')

[4] IUCN, *Current Knowledge of the Impacts of Genetically Modified Organisms on Biodiversity and Human Health* (2007) 6 <https://cmsdata.iucn.org/downloads/ip_gmo_09_2007_1_.pdf > accessed 12 March 2018

[5] The Standing Committee on Science, Information Technology and Mass Communication of the National Legislative Assembly, 'Report of the Consideration on "the Draft of Biosafety Act B.E...."' (The Standing Committee's Report) (2016) 6

[6] The Standing Committee's Report (n 5)

1. Purpose of Legal Control on LMO Products

Although there is still no scientific evidence affirming the safe or risk of LMOs, LMO products have a very close relation to our daily life; we even consume products having LMOs as an ingredient such as tofu, soy milk, and corn. Thus, the legal control measures of LMO products should be carefully stipulated and encompass every related process with the main objective of preventing the environment and human or animal health from potential adverse effects derived from LMOs.

4. International and Foreign Legal Controls on LMO Products

4.1 International Standards

The CPB and the Nagoya-Kuala Lumper Supplementary Protocol[7] have been issued to control the transboundary movement of LMO products. including the control of transboundary, transport, packaging, identification and the safe utilization of Living Modified Organisms (LMOs).

4.1.1 The Cartagena Protocol (CPB)

The CPB is one of the most important international agreement representing the collaboration of the world community to control the transboundary, transport, packaging, identification and the safe utilization of LMO products. The CPB controls all LMOs except LMO pharmaceuticals for humans addressed by other relevant international agreements or organizations.[8] Since LMOs may spread in any area, the transboundary movements of LMOs between Parties and non-Parties to the CPB shall also subject to this Protocol.[9]

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[7] The Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (hereinafter 'the Supplementary Protocol')

[8] CPB, art 5

[9] Ibid. art 24 (1)

The CPB applies the Advance Informed Agreement (AIA) procedure to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. The AIA relies upon the "risk assessment".[10] A risk assessment process is a precautionary approach by studying any potential impacts before the decision of consent to proceed such activity would be taken. The concept of this measure is to prevent the potential damages in advance which is better than to remedy when the damage has already occurred.[11]

4.1.2 The Nagoya-Kuala Lumpur Supplementary Protocol

The Supplementary Protocol imposes the Parties to provide the domestic law on 'administrative approach' and 'civil liability' in a case there is a sufficient likelihood of damage to occur as well as when the damage has occurred.[12]

4.1.2.1 Administrative Approach

In the event of damage, the operators must inform the competent authority immediately, evaluate the damage, and take appropriate response measures.[13] In a case there is a sufficient likelihood of damage, the operators are required to take appropriate response measures to avoid such damage.[14] If the operator fails to do so or the operator of LMOs in question cannot be identified, the competent authority must implement the appropriate response measures to remedy such damage.[15]

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[10] Ibid. art 15

[11] Tanchanok Kongdenfa, 'Obligation of Thailand regarding Biosafety Control Measures under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity 1999' (Master of Laws, Thammasat University 2009) 67

[12] Supplementary Protocol, Introduction; art 5

[13] Ibid. art 5

[14] Ibid. art 5, para 3

[15] Ibid. art 5, para 4

4.1.2.2 Civil Liability

Regarding civil liability for damage caused by LMOs, there are 3 alternatives to implement the Supplementary Protocol. Firstly, the Party may apply its general law on civil liability if there is no specific law on this issue. Secondly, the Party may apply or develop civil liability rules and procedures specifically for the damage caused by LMOs. Thirdly, the Party may apply or develop a combination of both general and specific rules and procedures.[16]

4.2 Existing Legal Control in Foreign Countries

The different experiences of each state resulting in the different perspectives toward LMO products and causing different levels of LMO products legal control in each country.

4.2.1 European Union (EU)

The EU, one of the Party to the CPB, has established the strictest legal control on LMO products which, sometimes, being criticized as a trade barrier. The EU allows the cultivation, import, or distribution of LMO products only when there is the risk assessment certifying the safety of such product and it has been approved by the EU's authorized entity (EFSA).[17]

A 'zero-tolerance' policy applies to food and feed products; the LMOs contamination level must be 0% for imported food and must not exceed 0.1% for feed products. In addition, food and feed containing LMOs higher than 0.9 % of the food ingredients must be labeled.[18]

4.2.2 United States (U.S.)

The U.S. applies same legislation as conventional products to LMO products because of the perspective toward LMO products is as same as conventional products. For example, the production and distribution of

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[16] Ibid. art 12, para 1

[17] Regulation (EC) 1829/2003 on genetically modified food and feed (22 September 2003)

[18] Ibid

LMO plants will be regulated by the Animal and Plant Health Inspection Service (APHIS) and may be supervised by the Environmental Protection Agency, and LMO food products shall be subject to the review of the FDA according to the Federal Food, Drug, and Cosmetic Act.

However, the U.S. applies a mandatory basis to LMO-labeling control allowing the manufacturers to disclose LMO information on their products by text, symbol, or electronic or digital link.[19] Nevertheless, these alternatives to labeling are criticized as not indeed protect the consumer right to know.

4.2.3 Japan

As the Party to the CPB, Japan enacted the Japanese Cartagena Act to control LMO products. The LMOs used in the opened system such as LMOs for conveyance and cultivation of food or feed shall be supervised by the Ministry of Environment joined with other competent ministries depending on the purposes of use. The approval will be considered by the experts, and the public consultation must be conducted before the approval of the cultivation or distribution of the LMOs in question.[20]

Japan adopts the mandatory basis of LMO labeling when any product has LMO as "the top three ingredients" exceeding 5% of total weight of 'final product'. The label disclosing the LMOs containment information must display in Japanese.[21]Furthermore, the imported food containing GM DNA or protein between 1% and 5% must label as

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[19] National Bioengineered Food Disclosure Act, 7 USC 1639b, s 293 (b)(2)(D)

[20] Alien species and LMO Regulation office, Ministry of the Environment, 'Biosafety Regulations in Japan-From Application to Approval of Type 1' <http://www.biodic.go.jp/bch/english/cartagena/s_04.html> accessed 12 March 2018

[21] Wendan Wang, 'International Regulations on Genetically Modified Organisms: U.S., Europe, China and Japan' (2016) <www.foodsafetymagazine.com/magazine-archive1/ junejuly2016/ international-regulations-on-genetically-modified-organisms-us-europe-china-and-japan/> accessed 12 March 2018

"genetically modified organisms not segregated", and the products containing less than 1% do not need to label.[22]

5. The Current Situation of LMO Products Legal Control in Thailand and Recommendations

Nowadays, Thailand seems to have an anti-LMO policy toward LMO products; the government has never allowed the cultivation of LMO plants for commercial purpose in Thailand. Nevertheless, although the cultivation of LMOs for commercial purpose is prohibited, the LMO contamination in agricultural fields has been discovered in our country several times.[23] As a consequence, the agricultural products exported from Thailand were rejected and restricted the importation by the import countries for various cases due to the contamination of LMOs in those products.[24] This matter causes the critical economic problem to Thailand since many foreign countries, ban our agricultural products because of biosafety and human health concerns.

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[22] 'Status in Japan – the issues of displaying genetically modified food in Japan' <http://altertrade.jp/alternatives/gmo/gmojapan> accessed 11 March 2018

[23] Natwipa Ewsakul, 'ย้อนรอยจีเอ็มโอ 18 ปี: ภัยคุกคามอธิปไตยทางอาหารของประเทศไทย 18 years of GMO: Thailand's food sovereignty threat)' (2013) <www.greenpeace.org/seasia/th/PageFiles/505377/18-year-of-gmo.pdf> accessed 12 March 2018

[24] Ajaree Thavornmas, 'EU Regulations on food safety: The challenge of Thailand for the export of agricultural and food products to the EU market' (2013) 27 <www2.thaieurope.net/wp-content/uploads/2013/10/Food-safety-paper-by-Ajaree-Tavornmas-final-22.08.2013-word97-version.pdf> accessed 12 March 2018

See also Case Adams, 'Which Countries Ban GMO Crops or Require GE Food Labels?' (August 2, 2016) <www.realnatural.org/many-countries-ban-gmo-crops-require-ge-food-labels/> accessed 29 November 2017

At the international level, as one of the Parties to the CBD, Thailand has done the accession to be a party to the CPB since 10 November 2005.[25] Thailand, therefore, has to implement the CPB by providing legal measures controlling LMOs.[26] Nevertheless, until now, Thailand does not have a specific law controlling LMO products; the LMOs control is subject to the existing laws as far as applicable. The application of current regulations may not respond to the objective of the CPB and this situation causes several issues in controlling LMO products.

First, no law defines 'LMO' as an object controlled under the law resulting in the issue of interpretation whether 'LMO' can be an object controlled by such regulation or not.

Second, LMO products have been controlled under different laws. So, the responsible agencies are scattered among various ministries causing the duplicate of law enforcement and the overlap of authority.[27]

Therefore, to standardize LMOs controlling measures, it is recommended to regulate LMO products by providing a specific law. The law should define a term 'living modified organism' as the controlled object, and the 'National Biosafety Committee' should be established to be in charge of providing suggestions regarding legal control on LMO products.

In addition, the law should regulate the LMOs associated operations as follows;

5.1 Measures of Import and Export Control

At present, the import and export of LMO products are regulated under various regulations depending on the type and the intended use of each product. For examples, the *Notification of Ministry of Agriculture and*

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[25] 'Country Profile' <http://bch.cbd.int/about/countryprofile.shtml?country=th> accessed 12 March 2018

[26] CPB, art 12

[27] Charunwit Wipawin, 'Legal Measure of Thailand to Protect Agriculture from Genetically Modified Plant Contamination' (Master of Laws, Thammasat University 2007) 128

Cooperatives Re: Specification of plants from certain sources as prohibited articles, of exceptions and conditions under the Plant Quarantine Act B.E. 2507 (No. 10) B.E. 2553 prohibits the import of 85 genetically modified plants. However, according to the scope of each law, it cannot cover the import of all LMO products. For instance, no legal control of the imported LMO animals except LMO aquatic animals under the Emergency Decree on Fisheries B.E. 2558.

There is also an opinion to apply the Hazardous Substance Act B.E.2535 to LMO products.[28] However, there may be an argument that LMOs are not hazardous substance because the potential risks derived from LMOs are just a 'likelihood' of harms.

To regulate LMO products comprehensively, it is recommended to prohibit the import and export of LMO products unless it has been approved by the competent authority. The Advance Informed Agreement (AIA) should be applied by imposing the importers and exporters to submit a 'permission request' together with 'the risk assessment report' before the import or export.

5.2 Measures of Production and Distribution Controls

Currently, the genetically modified food containing the Cry9C DNA Sequence and the food containing such substance as ingredient shall be prohibited to produce, import, or distribute in Thailand.[29] Besides, the import for commercial cultivation of LMO seeds is prohibited unless it had been scientifically proven on biosafety and food safety.[30] However, the existing regulations seem too narrow and too limit to control LMO products.

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[28] Tanchanok (n 11) 218

[29] The Notification RE: Specification of Food prohibited to produce, import, or distribute imposed that the genetically modified food containing the Cry9C DNA Sequence and the food contained such substance as ingredient shall be prohibited to produce, import, or distribute in the Kingdom of Thailand (No. 345) B.E. 2555 (2012)

[30] The Resolution of the International Economic Policy Committee (IEPC) Conference No. 5/2542 (1999)

It is recommended to specify that production and distribution of LMOs are generally prohibited. Any person who intends to produce or distribute LMO products in the Kingdom must apply for a permission request which must be submitted together with 'a risk assessment report' and the plan of appropriate response measures to prevent the contamination of LMOs under his possession into the environment and the neighbor conventional farms. Moreover, in a case that LMO has been considered as safe, the public consultation must be conducted before approval of such LMOs.

5.3 Measures of the Traceability and Labeling

As same as Japan, Thailand applies the mandatory basis of LMO labeling to the products containing LMOs from 5 % up of each top three main ingredients. This measure encompasses only soybean and corn products specified in the regulation whereas there are also other LMO products placing on the market.[31] Therefore, it is recommended to expand the mandatory basis to all products containing LMOs at the level specified by the law.

5.4 Measures of Liability and Compensation

Since Thailand is considering to ratify the Nagoya-Kuala Lumpur Supplementary Protocol, we should prepare the rules and regulations for the forthcoming obligations after the ratification.

The adoption of current civil liability provisions in the cases related to LMO products may not appropriate. For example, the tort liability in Section 420 of Thai Civil and Commercial Code which lies on 'fault-based' liability may result in the impossibility to prove the damage because the plaintiff who has a burden of proof cannot access the information and does

[31] Notification of the Ministry of Public Health Re: Labeling of food obtained through certain techniques of genetic modification / genetic engineering (No. 251) B.E. 2545 (2002)

not have advanced technology and scientific knowledge about such LMOs. Hence, it is considered more appropriate to apply a strict liability to the damage caused by LMOs related activities with some appropriated exemptions such as an act of God or *force majeure*.

It is recommended to provide the specific liability and compensation provisions regarding LMO products both in case of damage and there is a sufficient likelihood of damage to conform with the specific natures of LMOs and correspond with the objective of the Supplementary Protocol. Furthermore, as the operations related to LMOs always involved with many sectors, the author is of the opinion that the provision should determine the operators who must be liable for LMOs related operations to encompass any person in direct or indirect control of the LMOs in question.

Apart from the civil liability, the administrative approach is also a mechanism to prevent or mitigate the potential damage derived from LMOs.

In addition to the event of damage, in order to prevent, minimize, or avoid the adverse effects, it is also necessary to provide response measures in a case there is a sufficient likelihood of damage.

According to the Supplementary Protocol, it is recommended that Thai law should provide the provision addressing the response measures in the event of damage, and in the event that there is a sufficient likelihood of damage as follows;

"In a case of damage to human or animal health, or biodiversity resulting from activities involving the LMOs, the operators shall, subject to any requirements of the competent authority, to take these 3 actions;

(a) Immediately inform the competent authority;

(b) Evaluate the damage; and

(c) Take appropriate response measures.

In a case there is relevant information, including available scientific information or information available in the Biosafety Clearing-House, indicates that there is a sufficient likelihood that damage will result if timely response measures are not taken, the operator shall be required to take appropriate response measures so as to avoid such damage."

In addition to above recommendations, the author thinks that the causes of the failure of establishing the specific law on biosafety in Thailand are not only the drawbacks of the draft law but also the public perspective toward the LMOs. To date, most of the people that concern about the safety of LMO products does not indeed have sufficient knowledge about the LMOs.

So long as the public does not have enough knowledge, comprised with the lack of confidence and trust on the transparency of the legislative process, the opposition will continue to occur, especially in a case of the legislation involved with the environment or public health.

Therefore, the public participation is essential for the policy-making procedure to assure the transparency of the government and to provide the accurate information to the public. It is recommended that the government should guarantee that everyone has equal right to access the information about LMOs and biosafety including materials and activities relating a severe impact on the environment that may occur or likely to occur.

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