A COMPARATIVE ANALYSIS OF THE REGULATORY SYSTEMS BETWEEN THE PHILIPPINES AND BANGLADESH FOR APPROVING BIOTECH CROPS

By

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A thesis submitted to the Department of Mathematics and Natural Sciences in partial fulfillment of the requirements for the degree of
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Declaration

It is hereby declared that

1. The thesis submitted is my original work while completing my degree at Brac University.

2. The thesis does not contain material previously published or written by a third party, except where this is appropriately cited through full and accurate referencing.

3. The thesis does not contain material which has been accepted, or submitted, for any other degree or diploma at a university or other institution.

4. I have acknowledged all main sources of help.

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Approval

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Ethics Statement

No animal was harmed during this experiment.

Abstract

Many countries have adopted Genetically Engineered (GE) crops and their products. Before cultivation, these crops must go through a regulatory approval system, which varies from country to country. Here, the regulatory process of the Philippines, a mega GE crop cultivating country from Asia, is analyzed. The National Committee on Biosafety of the Philippines (NCBP) was established in 1990, whereas the approval process was established in 2002. The Philippines ratified the Cartagena Protocol on Biosafety (CPB) in 2006. The first GE crop approval came in December 2002. Till date, GE approval was given for many events, of which some are for commercial cultivation and the others are for FFP. In 2021, the Philippines became the first country to approve the cultivation of Golden Rice. In Bangladesh, Bt Eggplant was approved in 2013 and Golden rice is also under regulatory pipeline. With similar crop events, the Philippines being South-Asian pioneer in GE crop approvals, the regulatory system of the Philippines was compared with the regulatory system of Bangladesh. The Biosafety guidelines of Bangladesh established the regulatory committees involved in the GE crop approvals in Bangladesh. The National Biosafety Framework (2007) later detailed the policies and approval process. Both countries have implemented the CPB in their National Biosafety Frameworks. With the vast experience of GE crop approval and cultivation, nowadays, the Philippine approval process has brought several changes.

Keywords: Regulatory System; GE crop regulation; Bangladesh; Philippines.

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Table of Content

Acronyms

BARI	Bangladesh Agricultural Research Institute
BC	Biosafety Committees
BCC	Biosafety Core Committee
BCC	Biotechnology Coordination Committee
BCH	Biosafety Clearing House
BPI	Bureau of Plant Industry
BRRI	Bangladesh Rice Research Institute
Bt	*Bacillus thuringiensis*
CBD	Convention on Biological Diversity
CDB	Cotton Development Board
CFT	Confined field trial
CPB	Cartagena Protocol on Biosafety
DA	Department of Agriculture
DENR	Department of Environment and Natural Sciences
DILG	Department of Interior and Local Government
DOH	Department of Health
GE	Genetically Engineered
GM	Genetically Modified
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
IR	Insect Resistant
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agri-biotech Applications
JAG	Joint Assessment Group
MOEFCC	Ministry of Environment, Forest and Climate change

NBC	National Biosafety Committee
NBF	National Biosafety Framework
NCA	National Competent Authority
NCB	National Committee on Biosafety
NTCCB	National Technical Committee on Crop Biotechnology
SABP	South Asia Biosafety Program

Chapter 1: Introduction

1.1 Genetically engineered Crops: Prospects and Gains

World agriculture has always faced challenges to feed the increasing world population due to the effects of climate change and, at the same time, scarcity of resources. Furthermore, the pandemic, several wars, and the emergence of new diseases and pests of agriculturally important crops have added to the pressures of ensuring food and nutritional security in the recent years. Whether it is about combating climate change and developing stress-tolerant plants or producing enough food for the world while maintaining micro-nutrients in food crops, modern biotechnology can provide innovative and effective solutions to global crises in the agriculture sector through Genetically Engineered (GE) crops.

GE crops have consistently proven themselves promising by improving yield while at the same time reducing pesticide and herbicide use (Barrows et al., 2014) and the harmful environmental effects of the active ingredients (Brookes & Barfoot, 2020a, 2020b). In 2018, insecticide use for Insecticide Resistant (IR) maize and cotton was reduced to a total of 29.2 million kg. Since 1996, there has been a massive decrease of 775.4 million kg in the use of pesticides on GE crop areas compared to the expected use of pesticides on conventional crop areas (Brookes & Barfoot, 2020a, 2020b). Adoption of GE crops ultimately increased the farm level income and gross domestic production while maintaining sustainable environment and health benefits (Chaparro Giraldo, 2014; Komen et al., 2020). Moreover, over the years, GE crops have made significant contributions in reducing the agricultural eco-footprint and thus have reduced climate change effects (Brookes & Barfoot, 2020b). According to the 2019 ISAAA report, biotech crop production increased 112-fold in the last 24 years, and a total of

71 countries either grew or imported biotech crops, which makes it the most rapidly adopted crop technology globally (ISAAA, 2019).

1.2 Concerns related to GE Crops

Despite having many positive impacts and great potential to improve agricultural biotechnology, there remains a considerable amount of potential risk associated with GE crops, which raises concerns regarding sustainable use and conservation of biodiversity. Moreover, food and feed derived from GE crops might have effects on human and animal health.

Since GE crops are engineered to survive better in harsh environments, there remains a chance that they might become agricultural weeds by invading natural habitats. Moreover, genetic traits are transferred to the progeny and can be passed on to related, compatible plant species. As a result, if proper confinement is not maintained, gene-flow may even contribute to resistance conferring in non-target organisms, posing a threat to biodiversity (Mishra & Kumari, 2018).

The protein products expressed in GE crops, if not substantially equivalent to the other food proteins found in their counterparts, might trigger allergenicity or toxicity upon consumption (Mishra & Kumari, 2018). Moreover, certain modifications might interact with other molecular pathways or components in the plant, which might require in-depth analysis (Kumar et al., 2018). Thus, food and feed safety assessments are needed. Moreover, socio-economic concerns need to be addressed properly (Craig et al., 2011). So, the development and introduction of GE crops under specific regulations demand utmost priority to mitigate the potential risks associated with them.

1.3 International Treaty to ensure Biosafety: Cartagena Protocol on Biosafety (CPB)

Several international environmental treaties exist, including the Convention on Biological Diversity (CBD), which was approved in response to rising concern over global biodiversity loss and the deterioration of ecosystem services in the 1990s. In addition to that, on January 29, 2000, at the first Extraordinary Meeting of the COP, the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) was adopted to assure that modern biotechnology commodities can be traded without endangering human health or environmental safety. The CPB, which went into force on September 11, 2003, attempts to assure the safe handling, transport, and use of Living Modified Organisms (LMOs) emerging from modern biotechnology that may have detrimental consequences on biodiversity while also taking human health into consideration. It also provides advice and support, particularly to the developing countries that lack the capacity to establish and administer specific domestic GMO regulations. There are now 173 nations that are parties to the protocol, and the parties are required to follow the protocol and have domestic laws, regulations, and agencies in place for the safe handling, transport, and use of LMOs (Secretariat of the Convention on Biological Diversity; Craig et al., 2013).

Prior to the implementation of the CPB, a few nations already had domestic rules or comparable safety principles in place to safeguard environmental, food, and feed safety in consideration of modern biotechnology technology and its products. However, the majority of the parties (countries who are signatory of the CPB) were required to establish or modify domestic rules and regulations in light of CPB. Moreover, despite having ratified the CPB around the same time, the number of GE crop approval events varies significantly among the signatory countries. Some countries have become mega-countries (growing 50,000 hectares or more) in producing GE crops and harnessing the benefits from them, whereas others are still in the process of developing and improving their operational biosafety systems.

1.4 Competency of Regulatory System for GE Crop approval

Since the entry into the force of CPB, the approval process for GE crops, whether they are produced domestically or imported, differs from country to country. Generally, for the commercial approval of GE crops, applications require that they go through a biosafety regulatory package for approval prior to cultivation. The competent national authorities take part in the evaluation and finally give biosafety approval for the event. More or less, the evaluation is fundamentally based on a few key assessment criteria that are required for the environmental, food, and feed safety assessments. In some cases, the involvement of other relevant legal instruments and socio-economic considerations is required (Akinbo et al., 2021; Craig et al., 2013).

The approval system requires being swift as well as having to adeptly consider potential risks. Moreover, the approval systems are constantly evolving to suit the changing requirements while at the same time conforming to a set of rules that helps to make the process standardized across the globe (Nap et al., 2003). On the other hand, statistical analysis showed that developing countries are getting more benefits than developed countries from allowing access to GE crops. The majority of GE crop approval events occurred in developing countries, indicating that they expressed interest in biotech crops and accepted them accordingly (Aldemita et al., 2015; De Groote, 2012). A report shows that 38% of GE crops are produced by developing countries (Alam, 2019). However, farmers, consumers, and researchers from developing countries cannot reap the expected benefits due to its lengthy regulation, which is also costly. The estimated total cost, starting from gene discovery to commercialization, of a GE event in the period from 2017 to 2022 is $115.0 million, and the time required is 16.5 years. The regulatory phase consumed 37.6% of total costs and 51.1% of total time (AgrobioInvestor, 2022).

1.5 Different Factors affecting the GE Crop approval

Over the years, different studies have been conducted on the regulatory regime around GE crops to understand the development of regulatory oversight in specific countries. These studies in various countries also shed light on the various factors influencing the approval of GE crops. In the earlier period of the regulatory development the administrative system and the regulatory framework were not well established. Thus, some early research in biosafety indicated the lack of functional biosafety systems and experience for handling applications as a cause of delay in decision making (Araya-Quesada et al., 2012; Rosado and Craig, 2017; Obonyo et.al, 2011). Moreover, at that time, countries worldwide were in different stages of policy development, whereas the developing countries seemed to be paying more attention to international trade concerns when formulating biosafety legislation (Craig et al., 2013). Similarly, many other factors play crucial roles in the development and advancement of a functional regulatory system for GE crop approval.

Apart from the legal framework and an operational biosafety system, technical and regulatory capacities also play a very important role (Obonyo et al., 2011). Beside this, for the successful commercial release of GE crops, they need close collaboration, the interaction between the biosafety competent authorities and the variety release authorities by observing the regulatory framework and varietal release system in those countries. (Akinbo et al., 2021)

There is also relationship between regulatory system and GE crop adoption. The regulatory timeline to approve GE corn continued to increase instead of decreasing which indicated a lack of information and technical knowledge sharing among the regulatory agencies of the approving countries. In a research, Gleim and his group also found that commercial approvals face strict regulation which also requires more expensive and longer research phases compared to the food and feed approvals (Gleim et al., 2016).

If multiple committees are involved in the approval process of a GE event, then lack of synchronization may lengthen the approval timing of that specific event.

In different approval systems of different countries, the time required for the processing of application varies due to the evaluation of applications differently which in turn makes the overall process comparatively faster or slower than the other.

Moreover, there are differences in the approaches taken for the approvals. Two types of approaches can be found for assessment of GE crops: process based and product based approach. Moreover, some countries follow the concept of familiarity and the comparative risk assessment approach for risk assessments (Capalbo et al., 2020; Hilbeck et al., 2020). For the approval of GE crops, most of the countries follow event-based registration which helps in the early release of products in the market. In contrast, some other countries follow a variety-based registration system in which each of the varieties of the same product must be approved individually after the field test (Shelton et al., 2018).

In Table 1.1, summary of the identified factors affecting the GE crop Approval from the literature review in terms of the state of the biosafety regulation, compliance or the implementation of the biosafety regulation, evaluation criteria and other factors involving a country has been presented.

Table 1.1 Factors influencing the regulatory approval of the GE crops (Based on literature review)

Factors identified in literature		Author (Listed in chronological order)
State of Biosafety System	**(Lack of) Functional biosafety systems**	Araya-Quesada et al. (2012) Rosado and Craig (2017) Obonyo et al. (2011)
	(Lack of) Experience and Expertise	Obonyo et al. (2011) Araya-Quesada et al. (2012) Rosado and Craig (2017)
Regulation related factors	**(Lack of) interaction/ synchronisation among the competent authorities**	Araya-Quesada et al. (2012) Akinbo et.al (2021)
Criteria for Evaluation	**Method of Approval**	Shelton et al., 2018
	Risk Assessment	Capalbo et al., 2020; Hilbeck et al., 2020
	Familiarity with traits	Gleim et al., 2016 Capalbo et al., 2020; Hilbeck et al., 2020
Factors involving a country	**(Lack of) financial resources/Expensive system**	Gleim et al., 2016 Araya-Quesada et al. (2012)
	(Lack of) Technical and Regulatory Capacity	Obonyo et al. (2011) Araya-Quesada et al. (2012)

1.6 Objective of the Study

Under these circumstances, the objective of this study is to see how regulatory systems have impacted the approval of GE crops and to figure out the crucial factors within the regulatory system of one of the mega-countries for the approval. Here, the research and development facilities going on in these countries will not be considered; rather, the regulatory system will be the main focus where differences in the structure and function of the system can be compared. Moreover, variation in the implementation of Cartagena Protocol on Biosafety can also be revealed.

The objective of the present study includes:

- Selection of a GM cultivating mega-country to study the regulatory system as a model.
- Understanding the regulatory framework including regulatory authorities involved in the studied counties (selected country and Bangladesh)
- What are the factors inside the regulatory system that are aiding approval system?
    - What is the structure of the regulatory bodies?
    - What is the regulatory framework?
- Comparative analysis of the approval systems (regulatory bodies/ agencies and processing)
    - Efficiency of agencies involved in GE crop approval

Chapter 2: Methodology

This study has considered the countries which are signatory of Cartagena Protocol on Biosafety (CPB) and commercial cultivator of Genetically Engineered (GE) plants. Then those countries were listed on the basis of certain characteristics including the number of GE events approved, their acreage and percentage etc. This resulted in listing the mega cultivating countries. One such country among those was selected to be studied here.

Then related data were collected and a comparative analysis was performed. The summary of the steps followed for this study is presented below.

1. Choosing mega countries in biotech crop production
    a) Commercially cultivated crops and their percentage
2. Studying the existing regulatory system in the selected countries
    a) Studying the existing regulatory documents
    b) Regulatory Authority: Number of committees and size of the committees, Key person in the committee and their functions
    c) Functional system: Application processing, regulation process, time required for processing, Applications, Approvals, Meeting frequency
3. Comparison between the existing regulatory systems: Findings from 2(a), (b) and (c)
4. Identifying regulatory challenges faced by Bangladesh

2.1 Country Selection

Initially, the mega countries were selected based on the crop acreage and percentage of GE crop in the arable land. The International Service for the Acquisition of Agri-biotech Applications (ISAAA) GM approval database was utilized. Data for area planted with GE crops were retrieved from the Royal Society. Percentage of total arable land was calculated using data from the World Bank.

2.2 Studying the Existing Regulatory System

2.2.1 Regulatory Documents

Regulatory documents were collected from the respective national websites of the regulatory agencies and other related websites. The Biotechnology Clearing House (BCH) also holds information, downloadable documents, and links to important legislation in a specific country. Here, in the table presented below (Table 2.1), a list of the sources for the regulatory documents used in this study is provided.

Table 2.1 Source of Regulatory Information

Country	Documents
The Philippines	JDC No.1, S2021 JDC No.1, S2016 Administrative order (AO 08) Executive Order No.514 (2006)
Bangladesh	Biosafety Guidelines of Bangladesh (2007) The National Biosafety Framework (2007) Biosafety Rules of Bangladesh (2012)

2.2.2 GE Crop Approval Data Collection

A database of approvals is necessary for examining the time required for the regulatory approvals of GE crops. For this study, the International Service for the Acquisition of Agri-biotech Applications (ISAAA) GM approval database was utilized.

To obtain the application and approval dates along with the traits of GE crop events, the websites of the competent national authorities were utilized. For collecting all the necessary information, some other documents, including risk assessment data and other decision documents, have been consulted from the Biosafety Cleaning House (BCH). Events until December, 2022 are included.

2.3 Comparison of the Regulatory System between the Philippines and Bangladesh

Finally, the regulatory systems of the Philippines were compared with the regulatory system of Bangladesh. From the existing regulatory documents, a comparison of the Regulatory authorities and Functional system were made.

Chapter 3: Result and Discussion

3.1 Countries with highest GE Crop Acreage, Percentage, and Approvals

Since the study was related to the implementation of CPB, at the very first step the world's leading GE crop producers, for example the USA, Argentina and Australia, were excluded from this study. Even though they were at the top of the list as mega countries, they are not signatory to the CPB and hence unrelated to this study.

Since the objective of this study is to understand the regulatory system of the countries with the highest GE crop events and to figure out the crucial factors within the regulatory system for their fast approval system, countries that have the most experience in approving GE crops were selected for this study (Table 3.2).

If the total number of events that were approved is taken into account, Mexico has the most approvals. Then, Brazil, the Philippines and Colombia have more than hundreds of GE crop approvals. However, as in this study only the regulation of commercial GE crop approval processes were compared, only commercial cultivation approvals hold significance.

On the other hand, though Paraguay and Uruguay have the highest GE crop acreage and percentage of area planted with GE crop is also high, the total event approvals are low compared to the other countries. However, since the number of commercially approved GE crop seeds exceeds that of the Philippines, South Africa and Colombia, despite being small developing countries (Paraguay area: 406,752 km^2; Uruguay: 176,215 km^2), it is indicative of significant GE crop approval activities. Due to unavailability of data, these countries were not included in the study.

Thus, only South Africa, Brazil, Colombia, and the Philippines were selected based on the crop acreage and number of events approved. Among these the Philippines have approved GM crops which are either approved or under the regulatory approval process in Bangladesh. Therefore, the Philippines was selected for this study. And to compare the selected country with our country, Bangladesh's regulatory process was also studied to compare the system.

3.2 Existing Regulatory System in the Philippines

3.2.1 Regulatory Authority in the Philippines

- **Responsible Ministry/Department**: Department of Agriculture
- **Final Decision-making entity:** Bureau of Plant Industry (BPI)

On October 15, 1990, Executive Order 430 was issued, creating the National Committee on Biosafety of the Philippines (NCBP). The NCBP is composed of representatives of the Departments of Agriculture (DA); Environment and Natural Resources (DENR); Health (DOH), Science and Technology (DOST), Interior and Local Government (DILG) and scientists and members from relevant fields. After that Executive Order 514 (2006) was issued establishing the National Biosafety Framework. The approval of GE crops in the Philippines have been processed under Administrative Order No.08 or AO 08 (which has been nullified on December 8, 2015) and under Joint Departmental Circular 1 2016.

3.2.2 Regulatory Framework in the Philippines

According to the revised circular, the applications for commercial release must be submitted to the Biotechnology Unit of the Bureau of Plant Industry (BPI) with necessary documents. After receiving the application BPI evaluates the documents. If any document is missing, the applicant is advised to submit the required document. If the documents are satisfactory, the application form is published on the NCBP and BPI website.

3.2.3 Personnel involved in the Approval Process

Several committees are involved in the regulatory approval process for GE crops in the Philippines. They are the National Committee on Biosafety of the Philippines (NCBP), Bureau of Plant Industry (BPI). Apart from these, there is the Institutional Biosafety Committee (IBC).

The NCBP is composed of 10 members who are representatives from the five national departments- DOST, DA, DENR, DOH, and DILG. The committee is chaired by the DOST undersecretary. The members include 1 biological scientist, 1 environmental scientist, 1 physical scientist, 1 social scientist, 2 respected members of the community, and 1 representative each from the DA, DENR, DOH and DILG to be designated by the respective departments.

Each institution intending to work with GE crops must have an IBC. The IBC shall be composed of at least five members. Among these five, three are scientists and the other two are community representatives.

3.2.4 Meeting of the Committee and Frequency of Meetings

Regular meetings are mandatory for the timely approval of the events and to keep moving forward with the approval process. In the study country, the approval process includes meetings of several committees as a part of the decision-making process. The NCBP seats for regular meetings.

3.2.5 Time taken for the Approval of the GE Crops

The time allocated to process the commercial release approval applications varies among the study countries. A very short time allocated for GE crop approval can be found in the Philippines.

These observations indicate that the Philippines, have an efficient operational regulatory system for commercial approvals of GE crops. These GE crops producing mega countries are examples of active participants in agricultural biotechnology and by handling numerous applications they have become experienced.

3.2.7 Regulation of stacked Events: Regulation based on Determination of Novelty

The decision will definitely reduce the approval time and thus ease the approval and commercialization process for GE crops produced by stacking to be approved in the Philippines. An analysis solely based on the regulatory structure might not hold much significance in most of the cases other than a few exceptions.

3.3 Existing Regulatory System in Bangladesh

3.3.1 Regulatory Authority in Bangladesh

- **Responsible Ministry/Department**: Ministry of Environment, Forest, and Climate Change (MoEFCC)
- **Final Decision-making Entity:** Ministry of Environment, Forest, and Climate Change (MoEFCC)

The National Biosafety Framework of the People's Republic of Bangladesh, the Bangladesh Biosafety Rules 2012, and Biosafety Guidelines of Bangladesh 2007 and other documents provide information on current biosafety regulations in Bangladesh. The Cartagena Protocol on Biosafety (CPB) was signed by Bangladesh on May 24, 2000, and it was approved on May 5, 2004, four years later. As the Competent National Authority for carrying out the duties under the CPB, the government subsequently delegated responsibility for implementation of the biosafety guideline to the Ministry of Environment, Forest, and Climate Change (MoEFCC). The Biosafety Rules of Bangladesh is made under the Environment Conservation Act (1995), and published in the National Gazette in 2012, governs biosafety in Bangladesh. On the other hand, the National Biosafety Framework of the People's Republic of Bangladesh 2007 describes the steps involved in getting an application approved by one of these committees.

3.3.2 Regulatory Framework in Bangladesh

Applications for cultivation pass progressively through all biosafety regulatory committees from the institute to the Ministry of Agriculture (MoA) before being sent to the Ministry of Environment, Forest and Climate Change (MoEFCC) for ultimate approval.

The detailed application of the field trial is submitted to the Institutional Biosafety Committee (IBC) who after reviewing will send the form to National Technical Committee on Crop Biotechnology (NTCCB). Then, analyze the research findings and suggest NCB in accordance with the suggestions of the Core Committee. The Core Committee on Crop Biotechnology gives suggestions to NTCCB outlining any environmental safety issues with the application that ought to be brought up to NCB within 60 days. Application sent to BCC for technical evaluation; after receiving BCC recommendations, NCB decides whether to take application and BCC suggestions into consideration within 60 days. Perform a preliminary analysis of the dossier, create recommendations, and submit them to NCB. At last in case of Confined Field Trial Applications the application is approved or not approved.

3.3.3 GE Crop Research Advancement in Bangladesh

Bangladesh released its first genetically engineered crop Bt Brinjal to farmers in 2013 (Table 3.8). With the release of BARI Bt Brinjal-1, Bangladesh became the 29th nation to grow GE crops. Following the approval of Bt Brinjal-1, Bt Brinjal-2, Bt Brinjal-3 and Bt Brinjal-4 were also released (Ahsanuzzaman and Zilberman, 2018).

Bangladesh is now conducting confined field trials of a few more GE crops. 3R Potato from BARI, developed in collaboration with Michigan State University (MSU), was supposed to undergo a confined field trial in the 2021-2022 growing season. (South Asia Biosafety Program Newsletter, May, 2021)

Bangladesh Cotton Development Board (CDB) has applied for commercial release after completing the confined field trials of Bt Cotton. Under a Material Transfer Agreement (MTA) signed between CDB and Hubei Provincial Seed Group Co. Ltd, Wuhan, China work with Bt hybrid seed for contained trials began in 2015. CDB signed another MOU with JK Agri-Genetics Limited (JKAL), India for Bt cotton hybrids in February 2018. The Cotton Research and Development Board obtained NCB permission to conduct the contained trials with the Bt cotton seeds obtained from JKAL. In the contained trial, which was carried out in the BARI research facility during March-June, 2019, JKCH1947 and JKCH1050 seed lines showed satisfactory efficacy (SABP Newsletter, June, 2020). The confined field trial approval was issued in March, 2020 following which the confined field trial was conducted during 2020-21 in Sreepur, Gazipur Cotton research centre. Currently, Bt cotton event awaits multi location trial approval from NCB. (South Asia Biosafety Program Newsletter, April, 2021)

Chapter 4: Conclusion

Genetically engineered crops have become an effective solution for meeting the increasing demand for food - owing to the increasing population of today's world - by elevating the yield with reduced usage of pesticide and herbicide, at the same time contributing to maintaining a sustainable environment. However, concern regarding the conservation of biodiversity is still present if proper GMO regulations are not being followed. The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) is the solution towards the safe use of living modified organisms and efficient guidelines to developing countries for regulations of GE crops and their products. This protocol ensures potential risk assessment before approval of the GE crop being released in the environment or for commercial cultivation. The approval process differs from one country to the other based on multiple factors. In this research, comparison between the regulatory system of the Philippine and Bangladesh is done. In future, analysis can be performed based on the risk assessment guidelines of these two countries to further deepen the understanding of the implementation of CPB in the Philippines.

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