A Comparative Study of Environment Risk Assessment (ERA) Guidelines of Developing and Developed Countries Including Bangladesh

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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Department of Mathematics and Natural Sciences

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Declaration

It is hereby declared that

1. The thesis submitted is my own original work while completing 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.
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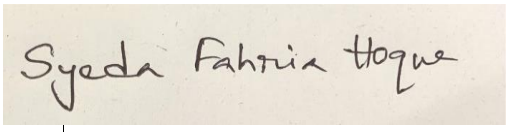

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Approval

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of Fall, 2017 has been accepted as satisfactory in partial fulfillment of the requirement for the degree of Master of Science in Biotechnology on 12th May 2021.

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Ethics Statement

No human or animal model was used in this study.

Abstract

Genetically Engineered (GE) plants are the demand of time for increased demand of food. According to the report of International Service for the Acquisition of Agri-biotech Applications (ISAAA), a total of 29 countries produce GE plants in 2019. A complete set of regulations need to be followed from the development of a GE plant to its release into the environment. The whole regulation system is categorized into separate stages for maintaining the proper biosafety. Environmental Risk Assessment (ERA) is one of such crucial stage in the whole process. ERA identifies potential risks and its impacts through science based evaluation process where it is done in a case by case study. All the countries which deal with GE plants follow specific guidelines to conduct a successful ERA. In this study, ERA guidelines of **4 developing** and **4 developed countries** including Bangladesh were compared. ERA guidelines of countries such as India, Canada, Australia, the European Union, Argentina, Brazil and US were considered as model to conduct the comparison study with Bangladesh. Initially, ten parameters were detected to compare the required data and information among all the guidelines. Surprisingly, an adequate amount of data and information requirements (e.g. If the intended modification/new traits of interest has been achieved or not, Growth habit of GE plants, Consequences of any potential gene flow upon the cultivation of GE plants to sexually compatible plant species, Potential adverse effects on the human health etc.) matched between all the countries. However, a few differences of data requirement (e.g. Agronomic conventions of non-transformed plants, Applicants should clearly describe experimental procedures followed etc.) were also observed in the study. Moreover, it was found that only a few countries provide instructions on the quality of the data used for ERA. If these similarities are recognized in a more framed manner then the approval pathway of GE plants can be shared.

Keywords: GE plants, ERA, Harmonization, ERA guidelines, Information and data requirements.

Dedicated to my parents

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~Syeda Fahria Hoque Mimmi

May, 2021

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List of Acronyms

GE	Genetically Engineered
ERA	Environmental Risk Assessment
CPB	Cartagena Protocol on Biosafety
CBD	Convention on Biological Diversity
LMO	Living Modified Organism
GMO	Genetically Modified Organism
rDNA	Recombinant DNA
ORF	Open Reading Frame
HGT	Horizontal Gene Transfer
GOI	Gene of Interest
NCB	National Committee on Biosafety
BCC	Biosafety Core Committee
ISAAA	International Service for the Acquisition of Agri-biotech Applications
OECD	Organisation for Economic Co-operation and Development
SABP	South Asia Biosafety Program
BARRI	Bangladesh Agricultural Research Institute
FAO	Food and Agriculture Organization

Chapter 1: Introduction

Chapter 1: Introduction

1.1 Overview:

Once Masanobu Fukuoka said, “The ultimate goal of farming is not the growing of crops, but the cultivation and perfection of human beings.” It’s not surprising that agricultural practice is always changing according to the need. Variety ranges of agricultural techniques and methods have been used over the past decades to produce an adequate amount of food to meet the need of the increasing population.

The increased need for food is more evidently visible in the projection reports of the Food and Agricultural Organization of the United Nations where it indicates that, around 70% increase of food yield is required by the year 2050 for about 9.1 billion people (Lusser et al., 2012). Initially, people used hybridization to increase the yield as well as the quality of the food. Hybridization is the process of inter-breeding between two different plant species to combine two or more desired characters. But challenges are faced when the desired character is not found within the compatible species. However, modern biotechnology allows the precise modification at genetic level overcoming the sexual compatibility barrier and produce genetically engineered (GE) or transgenic plants with desired changes (B. Rashid et al., 2017).

The main goal of producing GE plants is to increase the productions, minimize the use of chemical fertilizers, improve the nutritional values and finally to win over the adverse effects of biotic and abiotic stresses on plant varieties. People all around the world realized the importance of GE plants to survive in the challenging period and started to practice modern biotechnology. Additionally, until now total 29 countries are producing GE plants for food or feed. Interestingly, 24 (56% of total yield) of them are developing countries whereas there are only 5 (44% of total

yield) developed countries (ISAAA, 2020). Besides, 42 countries all over the world import GE plants or its products though do not grow them (ISAAA, 2020). The cultivation of GE plants has been increased drastically over the past years which is precisely 112-fold higher (ISAAA, 2020). According to the report of ISAAA, total amount of yield is 190.4 million hectares during the year 2019 which slightly declined by 0.7% compared to the year of 2018 when the total produce was 191.7 million hectares (ISAAA, 2020). On the other hand, the initial produce was 1.7 million hectares in 1996 (*Biotech Crop Highlights in 2018*, 2019). 91% of the total 190.4 million hectares' global biotech crops was planted by the top 5 GE plants producing countries-USA, Brazil, Argentina, Canada, and India in 2019 (ISAAA, 2020). Moreover, the most common GE plants harvested globally in 2019 include soybeans, maize, cotton, canola, alfalfa, sugar beets, papaya, squash, eggplant, potato, apples, pineapple, safflower and sugarcane (ISAAA, 2020). Besides, 45% of these GE plants are modified for herbicide tolerance (ISAAA, 2020). It is certain that these GE plans would be traded globally as genetic modification is not only a tool of agri-science but also a medium of doing business around the world. As a result, there is a high chance of transboundary movements of incorporated genes which may have an adverse effect on human health and ecosystem. So, it's very crucial to conduct the whole process of developing and introducing transgenic plants under regulatory oversight.

Furthermore, these modern biotechnology products could be traded efficiently if both the human health and environmental safety are fully ensured. Therefore, an international agreement was concluded in the year 2000 (*About the Protocol*, 2012) named **The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD).** Total 173 countries (*About the Protocol*, 2012) agreed on the accord till date. Bangladesh has given its consent to the consensus in 2000 (*Parties to the Cartagena Protocol and Its Supplementary Protocol on*

Liability and Redress, n.d.). This treaty includes all the required information regarding the safe handling and transportation of living modified organisms (LMOs) (most commonly known as genetically modified organisms, GMOs) across the borders. Moreover, CPB allows both the decision makers and consumers to make an informed choice if they want to accept the products or not. Not to mention, GE plants or transgenic plants are no different from GMOs. Thus, all the rules and regulations of GMOs development as well as handling are applicable for GE plants as well.

A very important part of CPB is to conduct Environmental Risk Assessment (ERA) to make precise decision on national level. ERA is a systemic process that evaluates quantitative and qualitative impacts of GE plants on the environment as well as on human health. The main purpose of ERA is to identify any potential risk of GE plants which can be direct or indirect and immediate or delayed prior to its release (Craig et al., 2008). According to Annex III of CPB, adequate data of ERA is mandatory for the governing authority and controllers to release GE plants into the respective environment. In addition to this, a proper framework with obligatory clarifications is also there to direct ERA of transgenic plants (Hill & Sendashonga, 2003). The principles of ERA must have strong scientific basis and explanation. Besides, specific case by case investigation is required as GE plants may vary in terms of their nature (trait combination), intended use and the receiving environment. The purpose of ERA does not end here. Post-monitoring of transgenic plants is essential once they are introduced into the environment and eco-system (Craig et al., 2008). The whole procedure of ERA from the evaluation to its release and after release must be carried out in an explicit manner.

Every country that produces GE plants follows some guidelines which are made in accordance with the laws, regulations, and policies of respective country and CPB. These guidelines portray

a thorough, straightforward and science-based framework by which regulators can recognize potential damages that may be caused by GE plants. Moreover, these principles gather applicable scientific information relating to the nature and seriousness of any harm and reliably describe the degree of potential risks possessed by its use.

The aspects of conducting ERA for both the export and import of GE plants vary widely among the countries due to the different law systems, country policies and the geographical environment. The GM crops need to be assessed accordingly during both export and import as well as while trading inside the country according to the guidelines (*Text of the Cartagena Protocol on Biosafety*, 2021). As these guidelines are made in accordance with CPB, there must be some similarities for conducting the assessment. These modern biotechnology products are being assessed for environmental risks before exporting as well as importing. Moreover, the overall procedure requires a good amount of money, time and labor for all the laboratory and outdoor experiments. So, comparing these guidelines from different countries will give the opportunity to eliminate the sections which have been assessed already. As a result, harmonization can be established among the guidelines of target countries. Thus, harmonization will accelerate the time of marketing the GE plants and also the cost and labor will be reduced remarkably.

The purpose of this study is to explore the possibilities of harmonization among US, Australia, Argentina, Brazil, Canada, European Union (EU) and Bangladesh in terms of the information and data required for the ERA of GE plants.

1.2 Objective of the Study:

The main objective of the study is to analyze the possibilities for harmonization of all the data and information on ERA regulatory documents of the studied countries; Bangladesh, India, Argentina, Australia, Brazil, Canada, US and the European Union. However, a few more objectives have also been targeted to achieve.

1.3 Specific Aims:

- Collecting information and data from all the available regulatory protocols of ERA for GE plants of stated countries
- Comparing the gathered data and information to find out the similarities and dissimilarities
- Exploring the possibilities of harmonizing data and information of ERA guidelines among all the 8 countries

1.4 Background Information:

1.4.1 Plant Breeding:

It is a matter of wonder that from where our agricultural harvests originated. Furthermore, how they were many years back, or several years ago. Our food crops today are in certainty different state from the first wild plants from which they were attained. Moreover, mankind is almost absolutely dependent on plants for food. The things we eat virtually without exception are either plant materials or derived directly from plants. On the other hand, the methods and techniques of farming have changed along with the increasing amount of population over the past decades. The more technological advancement has been achieved over time, the more people tend to depend on it for farming. For instance, 53% of the total population of USA which was 38,558,371 used

to be involved in agricultural work in the year 1870 (*History of Agricultural Biotechnology: How Crop Development Has Evolved | Learn Science at Scitable*, 2012). Surprisingly, this scenario was completely different in 2000 when only 1.8% people of total population 275,000,000 seemed to get occupied in farming (*History of Agricultural Biotechnology: How Crop Development Has Evolved | Learn Science at Scitable*, 2012). This is definitely an evidence that shows the development of agricultural practice.

The world felt the importance of improving the yield and quality of plants with the increase of number of population to feed. That is when Gregor Mendel proved that genes (carries specific phenotypes) can transmit to its offspring independently (*History of Agricultural Biotechnology: How Crop Development Has Evolved | Learn Science at Scitable*, 2012) and the idea of plant breeding came. Plant breeding is not only science but also a form of art. The aim of plant breeding is specific and predetermined. It is defined as the genetic improvement of plants to create desired varieties that are better suited for cultivation as well as give better yields (Hansen et al., 2014). Another reason of plant breeding is to develop plant species which are competent of withstanding specific natural hurdles (B. Rashid et al., 2017).

Initially, the main focus was to detect a type of plant that has the potential to achieve the desired characteristics. Sometimes, two or more plant varieties were used to hybridized in order to attain a specific feature such as resistance to pests or diseases, tolerance against abiotic stresses (Duvick, 2007). In this purpose, pollen containing desired gene is transferred from one plant variety to another that contains the other gene of interest. This type of breeding practice is known as selective breeding. However, one of the major drawbacks of this method is that the crosses cannot be controlled and the nature of resulted offspring is unpredictable. DNA (the basic molecular structure of all organisms' genetic material) from wild plant variety recombines in a

random manner and undesired hybridization may take place (*History of Agricultural Biotechnology: How Crop Development Has Evolved | Learn Science at Scitable*, 2012). As a result, some other unintended traits such as yield, nutritional value etc. might be compromised. Besides, the time required to develop a new variety following this technique was 12-15 years on average (Duvick, 2007). So, scientists thought of improving the method by introducing mutations into plant cells.

Mutation means the change of genetic composition of a plant. The goal of inducing mutation was to alter the DNA sequences of a particular plant cell (Hansen et al., 2014). Consequently, new plant variety with desired traits was obtained by using chemicals or radiations in order to cause mutations (*History of Agricultural Biotechnology: How Crop Development Has Evolved | Learn Science at Scitable*, 2012). Then, a new era expanded when modern biotechnology came up with the discovery of recombinant DNA (rDNA) technology.

rDNA technology is the process of joining two or more DNA molecules of closely or distantly related species. Once the DNA molecules are combined, then it is inserted into a compatible host cell to get new variety of plant with desired characteristics or GE plants. Two most common and used techniques to transfer DNA into plant cell are- using a modified organism *Agrobacterium* & particle gun method. Firstly, *Agrobacterium* is a convenient medium to insert desired gene (functional unit of heredity; composed DNA sequences) into plant cell. *Agrobacterium* is found in nature and contains the DNA sequence responsible for causing crown gall disease (Gelvin, 2003). When the bacterium infects plants, it inserts that disease causing DNA into the host plant cell. Thus, that plant gets the disease crown gall (*Modern Biotechnology: A Brief Overview - Canadian Food Inspection Agency*, 2014). So, this disease causing feature is used in rDNA technology to transfer the gene of interest (GOI) into the plant cell. However, the DNA sequence

responsible for disease is removed and replaced by the sequence of GOI (Gelvin, 2003). As a result, it delivers the GOI instead of disease causing sequence into the cell and the plant grown from this cell can be determined by specific characteristics of the transferred GOI. Secondly, another efficient method to transfer modified DNA is the use of particle gun. Some tiny metal particles in a particle gun are coated with GOI and then directly bombarded onto the plant cells (Mookkan, 2018). As a consequent, the plants that grew from these bombarded cells show the feature of GOI. Both the methods are very popular and used frequently. However, more stable and higher efficient integration rate have been observed in terms of using Agrobacterium mediated method than using particle gun (Gao & Nielsen, 2013).

1.4.2 GE Plants:

GE plant was the demand of time and solution for food & feed emergency situation. It didn't happen overnight. Scientists and researchers have worked hard for so many years and eventually they were able to develop transgenic plants. The amount of producing GE plants was insignificant initially in the year 1996 which was 1.7 M ha (*Biotech Crop Highlights in 2018 | ISAAA.Org*, 2019) and it has been increasing upwards with the passage of every year till date. Surprisingly, in 2019, developing countries produced 56% (106.6 Mhas) of the total global yield, while developed countries occupied the 44% (83.8 Mhas) portion (ISAAA, 2020). It is evident that developing countries have harvested more GE plants than the developed ones. Moreover, it can be predicted that the scenario will also continue in the upcoming years due to the increasing number of developing countries adopting transgenic plants.

The top five countries which are the highest producers of GE plants in 2019 are US (71.5 Mhas, 95% adoption), Brazil (52.8 Mhas, 94% adoption), Argentina (24 Mhas, 100% adoption),

Canada (12.5 Mhas, 90% adoption) and India (11.9 Mhas, 94% adoption) (ISAAA, 2020). US always has been remained at the top of the chart of planting GE plants and currently occupy 38% of total global yield (ISAAA, 2020). Besides, according to ISAAA report'2019, 19 countries out of 29 were considered as mega-countries as they produced at least 50,000 hectares in that year. Three new African countries (Malawi, Nigeria, and Ethiopia) to join transgenic plants producing group have planted GE cotton (ISAAA Brief, 2020). Significant upward growth rates (got doubled) were recorded in Vietnam, the Philippines, and Colombia in 2019 (ISAAA Brief, 2020). In the previous year, Indonesia planted drought tolerant sugarcane for the first time and got an increased yield about 20-30% (*Beyond Promises: Facts about Biotech/GM Crops in 2018 - ISAAA Publications | ISAAA.Org*, 2019).

Until now, total 32 GE plants (*GM Crops List - GM Approval Database | ISAAA.Org*) and 530 GE events (*GM Crop Events List - GM Approval Database | ISAAA.Org*) have been approved by the competent authorities of 44 countries (*Countries with GM Crop Approvals - GM Approval Database | ISAAA.Org*). Here, the term GE event stands for the act of transferring modified gene into a particular cell type to develop a transgenic plant. Among all the GE plants, soybeans, cotton, maize, canola and alfalfa are the most popular and commonly harvested as well as enlisted as major biotech crops. GE Soybean occupied almost half of the portion of total GE plant's yields and the global area planted was 91.9 Mhas by total 8 countries from all over the world which is considered 4% decrease compared to the produce in 2018 (ISAAA, 2020)(*Biotech Crop Annual Update - ISAAA Publications | ISAAA.Org*, 2021). Moreover, the increase in income benefits for farmers producing GE soybean from the year 1996 to 2018 was US$74.5 billion where US$7.5 billion in 2018 alone (*Biotech Annual Updates 2019-Soybean*, 2019). Similarly, a significant amount of GE cotton was produced in 2019 and total 18 countries

have grown 25.7 Mhas GE cotton (*Biotech Annual Updates 2019-Cotton*, 2019). Farmers were able to earn US$65.8 billion during this 23 years till 2018 (*Biotech Annual Updates 2019-Maize*, 2019). Additionally, GE Maize has showed not only 1% increase in yields from 2018 but also the total global area of harvesting was 60.9 Mhas in total 14 countries (*Biotech Annual Updates 2019-Maize*, 2019). Moreover, the income was greater than before which is US$65.8 billion until 2018 (*Biotech Annual Updates 2019-Maize*, 2019). On the contrary, the progress of producing GE canola and GE alfalfa is not as high as other three crops. However, immense promise has been observed during the past years. The total area of planting GE canola was 10.1 Mhas and the total income was increased to US$7.1 billion in the year 2018 where US$0.62 billion is in 2018 only (*Canola*, 2020). According to the report, the area for producing alfalfa is expanding day by day and an increase of 32% was observed in 2019 from 2018 (*Biotech Annual Updates 2019-Alfalfa*, 2019). Furthermore, Argentina joined USA and Canada to produce Alfalfa in the same year 2019 (*Biotech Annual Updates 2019-Alfalfa*, 2019). Most recently in 2020, the Philippines has approved three new GE plants- GE potato (Disease resistant + Modified product quality) (*Y9 | GM Approval Database- ISAAA.Org*), GE cotton (Herbicide tolerant + Insect resistant) (*GHB614 x T304-40 x GHB119 x COT102 | GM Approval Database- ISAAA.Org*) and GE corn (Herbicide tolerant + Insect resistant) (*Bt11 x MIR162 x MON89034 x GA21 | GM Approval Database- ISAAA.Org*) for food, feed & processing. Moreover, it has become the first ever country (*GR2E | GM Approval Database- ISAAA.Org*) to release golden rice which is the most waited GE rice variety containing high amount of vitamin A. Many more ongoing researches are going on all over the world so that people can win over critical conditions regarding food and nutrition.

1.4.3 GE Plants in Bangladesh and Ongoing Research:

Bangladesh is a small developing country with total area of 147,570 km^2 having around 170 million populations. It faced one of the worst famines of twentieth century after the independence. Since then, Bangladesh government took food security as the first priority and achieved self-sufficiency in food production though it had to depend on import of food from other countries at the time of independence. One of the major improvements in plant yield and annual income was observed when Bangladesh adopted modern biotechnology in its agricultural practice. The first implementation of biotechnology was observed with the tissue culture of jute in late 1970s (Nasiruddin, 2012). Bangladesh is far behind as a GE plant producing country and planted less than 0.1 Mhas (*Biotech Crop Highlights in 2018 | ISAAA.Org*, 2019) transgenic crops during 2017. It was Bangladesh that released first GE plants among the Asian countries while was 29^{th} in terms of approving GE plants worldwide (M. H. O. Rashid, 2018).

The regulation of GE plants follows the biosafety rules enlisted under the **Environment Conservation Act, 1995** (*Bangladesh Biosafety Clearing-House (BDBCH)*) and further explained in **Bangladesh Biosafety Guidelines**. The guideline was finalized in the year of 2012. There is a proper explanation of conducting ERA in the section 3.1 (*Bangladesh Biosafety Clearing-House (BDBCH)*) of this guideline. The whole responsibility regarding GE plant oversight is authorized by the **Ministry of Environment and Forest, Bangladesh.** Responsible authorities for example **National Committee on Biosafety (NCB), Biosafety Core Committee (BCC)** etc. work together with the purpose of maintaining biosafety in the environment and ecosystem. Moreover, these committees also monitor the whole ERA process before and after releasing the GE plant into environment.

After researching for several years, Bangladesh was able to release its first GE plant varieties BARI Bt Brinjal-I, II, III & IV (resistant to pod borer) during 2013(Shelton et al., 2018). Initially, respective authorities faced difficulties to reach people with these GE plant's benefits. However, over the period of times, the popularity has increased immensely and until 2018, total 27,012 farmers (*5-Yr after Releasing Its First GM Crop Bangladesh Says Farmers Gain by Adopting Bt Brinjal | Dhaka Tribune*, 2019) which is 17% (Shelton et al., 2018) of all brinjal farmers were able to get access of Bt brinjal seeds as well as enjoying its benefits. Another GE plant world's first zinc-rich rice variety BRRI dhan-62 was released during the same year and consequently BRRI dhan-86 (increased yield rice variety) was released in 2017 (M. H. O. Rashid, 2018) (*BRRI Releases World's First High Zinc Rice | Dhaka Tribune*, 2013). Other than these, Late blight resistant potato, golden rice and Bt cotton are in the pipeline of releasing into the environment (M. H. O. Rashid, 2018)(*Bangladesh Close to Releasing Golden Rice | Dhaka Tribune*, 2019). Currently, these GE plants are in the field trial stage and there is a high chance of their release in near future. It is expected that the export of potato will increase 10 times higher once the GE potato variety is released. Bangladesh Cotton Development Board has tested single gene Bt cotton hybrid extracted from Chinese Hubei Seeds in the years 2015-16. Following this, the scientists of Bangladesh infused the GE cotton seeds imported from Hubei Provincial Seed Group Company (M. H. O. Rashid, 2018) with the genetic trait responsible for fighting bollworm; a harmful caterpillar that destroys cotton produce. Besides, numerous researches for producing more GE plants are going on in limited number in private and public universities as well as research institutions. Some of the common plants of research are jute, pulses, rice, tomato, sunflower, peanuts, potatoes, gerbera, cotton and many more. Moreover, most popular genetic traits being used are herbicide tolerance, insect resistance, improving yield

quality, salinity resistance etc. It is commendable that Bangladesh is contributing efficiently in modern biotechnology research despite of being a developing country.

1.4.4 Risk Assessment:

With the increase progress of modern biotechnology and GE plant production, the concern for possible risks has also increased. Almost everything in the world may have both advantages and disadvantages. If both the aspects are compared in terms of GE plants, benefits are more evident than the adverse effects. However, maintaining a sound environment is also essential. That's why, scientists and researchers are trying their best to develop and release these GE plants in a way so that the environment and human health as well as the needs are not compromised. Moreover, risk assessment and risk management are functioning to monitor and minimize all the potential risks that can arise from experiments involving GE plants and its use. All the information and data needed to conduct these assessments are mentioned clearly in the CPB on both national and international levels.

It's a matter of fact that not only GE plants but also non-GE plants which are being harvested from the very beginning may have adverse effect on the environment and ecosystem. So it's very important to compare the potential risks of both GE and non-GE plants while conducting ERA (Hill & Sendashonga, 2003). One of the main purpose of developing transgenic plants is to bring out a sustainable alternative of the existing wild plant (Craig et al., 2008). As a result, if any difference found comparing both the risks, then further investigation might be required for taking decision whereas there might be no need of further information if it does not indicate any unintended harm (Johnson et al., 2007). Not to mention, all the differences don't indicate harm to the environment and human health. It's the governing body who will decide whether the risk is

negligible or not. However, it becomes easier for the decision makers once the risks are compared efficiently.

Problem formulation (PF) is an important part of ERA. It's a multi-step framework which facilitates the logical organization of ERA. Moreover, it helps to sort out key questions useful for evaluating the decision of releasing a particular GE plant for a specific purpose. PF also accelerates the identification of data that is compulsory to assess the risks associated with GE plants. ERA turns out to be robust and transparent with the help of PF and as a result, the stakeholder could see the authentic information before making their decisions (Fitzpatrick et al., 2009). Both the developer and reviewer of GE plant require a PF prior to the ERA. They need to follow a series of steps to establish it for a certain transgenic plant.

The very first step is to form the context. While establishing the context it is mandatory to consider the guideline of the respective country and the proposed use of GE plant (Wolt et al., 2010). Additionally, the mentioned measure to identify any potential risk must be there in ERA (Wolt et al., 2010). The next step is to collect relevant information for the assessment. Data of all the materials used for instance, recipient plant, genetic elements utilized in the modification, the GE plant etc. must be gathered properly (Fitzpatrick et al., 2009). Information must be accurate, raw and scientifically detailed with related references. Moreover, relevance of the information used in ERA is obligatory. Then, an initial characterization is made by observing the gathered information on potential risks associated with that GE plant. Lastly, the assessors can conclude with a risk hypothesis if all the provided information is enough to determine or they must collect additional data to complete the PF. Once the PF is established, the assessors start evaluating potential risks taking the hypothesis into account (Figure 1.1)

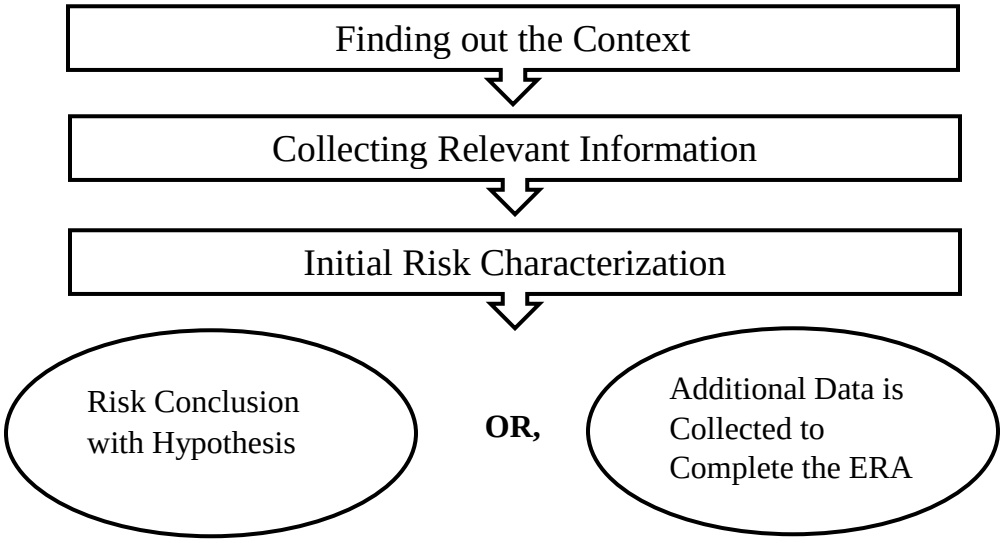


Figure 1.1: *The Problem Formulation (PF)*

The total number of steps in ERA varies among the countries but the overall idea and process are same everywhere. Firstly, the assessors identify any possible risk by considering the relation among GE plant for cultivation, the environment and the risk. Risk identification must be comprehensive and rigorous and any substantial over-emphasizing needs to be avoided (Craig et al., 2008). However, any kind of harm that does not result from GE plant development process (Hill & Sendashonga, 2003) (Garcia-Alonso et al., 2007) or if the harm is not related to the cultivation of GE plants then it is not a matter of consideration. Moreover, the assessors need to decide if the potential risk needs further verification depending on the seriousness of it.

Then, as soon as any potential risk has been identified, its severity needs to be investigated. A scale is used to indicate the level of seriousness that follows the hierarchy–

marginal ⟶ minor⟶ intermediate⟶ major. Here, marginal level indicates minimal or no increase of risk, minor means minor increase of risk, marginal stands for a significant increase of risk and lastly significant increase in severe risk to environment or human health is denoted by major level (Guidelines for the Environmental Risk Assessment of Genetically Engineered

Plants, 2016). Moreover, sometimes other points like how big the environmental change is due to the risk, if the occurrence is frequent or not, the time length of its occurrence whether there are any chances of repetition and the nature of the risk.

In the next step, the nature of potential risk and its link with the GE plant for cultivation is evaluated comprehensively. The assessment can be categorized into four parts according to the possibility of the risk to occur which facilitate the identification of how the harm should be handled (Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016). Highly unlikely and unlikely indicate that harm can occur in very rare or limited circumstances (Hill & Sendashonga, 2003). On the other hand, likely and highly likely represent the chances of encountering harm in many or most of the cases (Hill & Sendashonga, 2003) and special importance must be given to assess these harms.

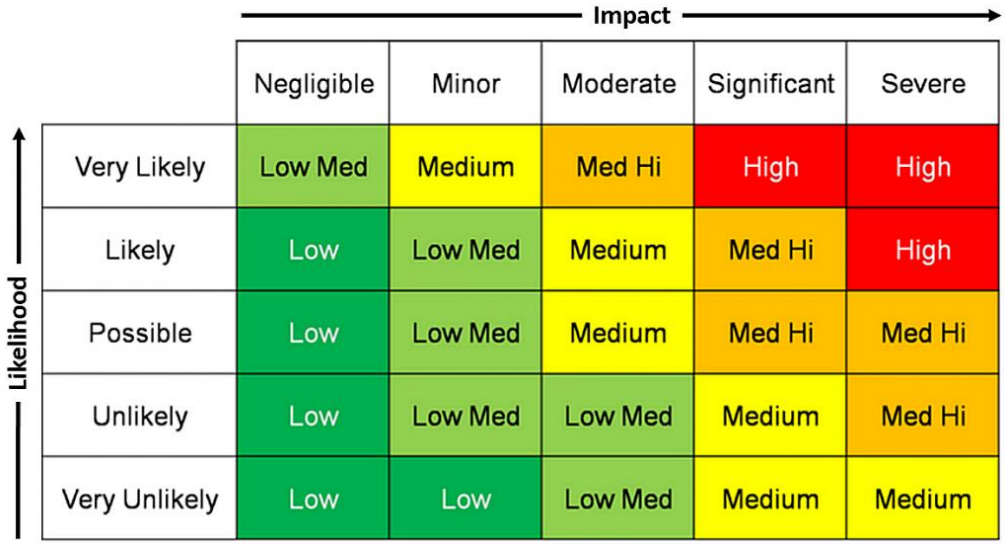


Figure 1.2: Representative Risk Matrix followed during Risk Assessment (*Beyond the Risk Matrix | ARMS Reliability*, 2017)

Lastly, by observing the data and information gathered in these three steps, a final call is made if the GE plant possesses any potential risk or not (Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016)(Hill & Sendashonga, 2003). Further evaluation is conducted if needed according to risk type. During this time, both greenhouse and confined field trial are employed so that the decision makers could make a complete informed decision. After finishing all the assessments, a final report is made by the respective authority. Moreover, the severity of the risk is also mentioned in the final report with proper and accurate scientifically sound evidence (Johnson et al., 2007). Every measure used for the ERA and all the results & concerns must be enlisted in the final report. Some relevant strategies to overcome the potential risks are also advised there. However, the process of ERA even continues after the GE plant is accepted for the cultivation into the environment. Efficient monitoring after the release of GE plant is a must to tackle if any uncertainties occur. The assigned authority needs to report its update to the decision maker party on a time to time basis.

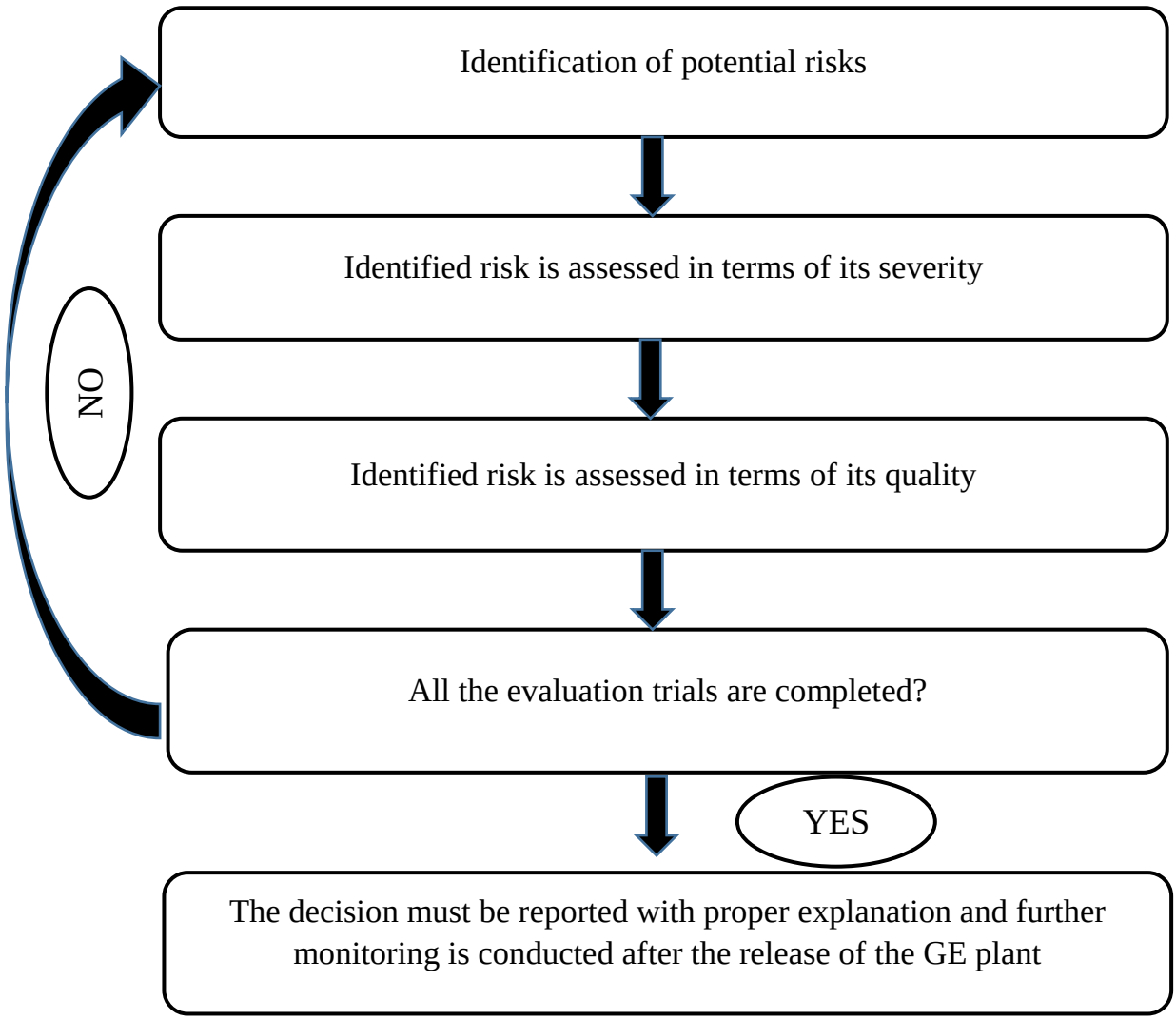


Figure 1.3: *The steps of Environmental Risk Assessment (ERA) of GE Plants*

Chapter 2: Materials and Method

Chapter 2: Materials and Method

2.1 Materials:

This comparative research study has been conducted between Bangladesh, India, Argentina, Australia, Brazil, Canada, United States and the European Union based on the available information & data about the ERA of transgenic plants. The main resources found are the guidelines on ERA developed by the studied countries to regulate GE plants into the environment. Not to mention, some of the countries keep their regulatory documents for very implicit access. As a result, the information and data requirements for ERA of GE plants could not be collected explicitly. However, plenty of related research works as well as reports were found online. Moreover, several case studies on permitted transgenic plants are there on the regulatory websites of respective countries.

Besides, several organizations also work to harmonize the data and information requirements for ERA of GE plants. They arrange workshops, meetings routinely in order to be successful in the purpose of harmonizing. These organizations publish their analysis reports accordingly which have also been used in this comparative study.

Such regulatory documents as well as reports used in the study are as follows and are in accordance with its respective countries and organizations that published the required information:

2.1.1 Bangladesh:

The regulation of GE plants is managed by a National Committee on Biosafety (NCB) in Bangladesh. Further, Biosafety Core Committee (BCC) is responsible for providing NCB with

all the required technical information and analysis regarding the release of GE plant. Briefly, all these committees are regulated by the **Ministry of Environment and Forest, Government of the Republic of Bangladesh** and they publish all the necessary guidelines and regulations for managing the transgenic plants. The main document which was used in this study is the protocol for the ERA of GE plants published by the Department of Environment, Ministry of Environment and Forest, Government of the Republic of Bangladesh. Moreover, available documents relating the ERA of GE plants in Bangladesh on the website of Bangladesh Biosafety Clearing House (BDBCH) and South Asian Biosafety Program (SABP) were utilized in this comparative analysis study.

2.1.2 India:

The regulation of GE plants in India is similarly governed by the **Ministry of Environment, Forests and Climate Change (MoEF&CC), Government of India**. However, there are six competent agencies that ensure the successful use of all rules & regulations provided by MoEF&CC. These rules and regulations are collectively called "Rules 1989". The mainly used resources in this study are the guidelines for ERA of GE plants published by the Department of Biotechnology, MoEF&CC. Besides, some research article regarding ERA of GE plants in India were also assessed online.

2.1.3 United States:

The main and important regulatory authorities for GE plants are **Animal and Plant Inspection Service (APHIS), US Department of Agriculture (USDA) and US Environmental Protection Agency (USEPA)**. The required information was collected browsing the available data regarding ERA of GE plants on these websites. Moreover, data was gathered from available

US regulatory websites mentioned on SABP portal (E.g. Program for Biosafety Systems (PBS), International Service for the Acquisition of Agri-biotech Applications (ISAAA), Food and Agriculture Organization (FAO) etc.). Not only these website portals but also related research articles were accessed to collect data and information on ERA of GE plants.

Furthermore, the Organization for Economic Co-operation and Development (OECD) is an intergovernmental organization which works to co-ordinate and harmonize policies, discuss issues of mutual concern. US is also one of the representatives in the organization and effectively participates in this cause as well as all the meetings. Thus their regularly published reports and articles give brief insight into ERA carried out by US for GE plants. Moreover, MoEF&CC, Government of India studied and published a study report on the multi-country comparison of information & data requirement for the ERA of GE plants. It was analyzed to find out and collect information.

2.1.4 Canada:

Canadian Food Inspection Agency (CFIA) is mainly responsible in taking decisions on ERA of transgenic plants. Interestingly, US and Canada follow a bilateral agreement on agricultural biotechnology and thus the regulation for ERA of GE plants are closely similar in both countries. That is why, same reports, research articles, websites etc. could be used to gather information and data in so many cases for both US and Canada. However, the most essential resources analyzed in this comparative study are provided on the website portal of CFIA. Not to mention, CFIA is very particular in mentioning all the requirements of ERA and thus provides a detailed explanation for the whole process from developing GE plants to its ERA.

2.1.5 Brazil:

The release and use of GE plants are assessed by **National Technical Biosafety Commission (CTNBio), under the Ministry of Science and Technology** in Brazil. The authority of Brazil does not provide explicit information on ERA of transgenic plants. As a result, required data were collected by exploring related research articles along with the provided information on CTNBio's official website. Besides, both the SABP and Biosafety Clearing House (BCH) portals were accessed to find out related data for ERA of GE plants in Brazil.

2.1.6 The European Union:

The European Union guidelines for ERA of GE plants are very elaborate and easily accessible. **European Food Safety Authority (EFSA)** is mainly responsible for taking all the actions and decisions regarding GE plant releases in Europe. They published a guideline including all the required information and data to ensure the safe ERA of GE plants. Moreover, guidance on the post-release environmental monitoring of transgenic plants, documents for scientific panel & necessary assessment requirements for stacked transformation events are separately mentioned by EFSA as well. Most of the information used in the study was gathered from these guidelines. However, a few online journals were also utilized in this comparative study.

2.1.7 Argentina:

All the data and information used in the study were collected from the website of **the Comision Nacional Asesora de Biotecnologia Agropecuaria (the National Advisory Committee on Agricultural Biosafety; CONABIA).** CONABIA was created by **the Secretary of Agriculture, Livestock and Fisheries (SAGyP)** to make it easy for ERA of GE plants in Argentina.

Moreover, SAGyP falls under **the Ministry of Agriculture, Livestock and Fisheries (MAGyP)** and responsible for taking ultimate decision on the release and use of GE plants. Some of the data was also gathered from **the National Service of Agri-food Quality and Health (SENASA)** which carries out assessment of the material as food or feed for human and/or animal consumption in Argentina.

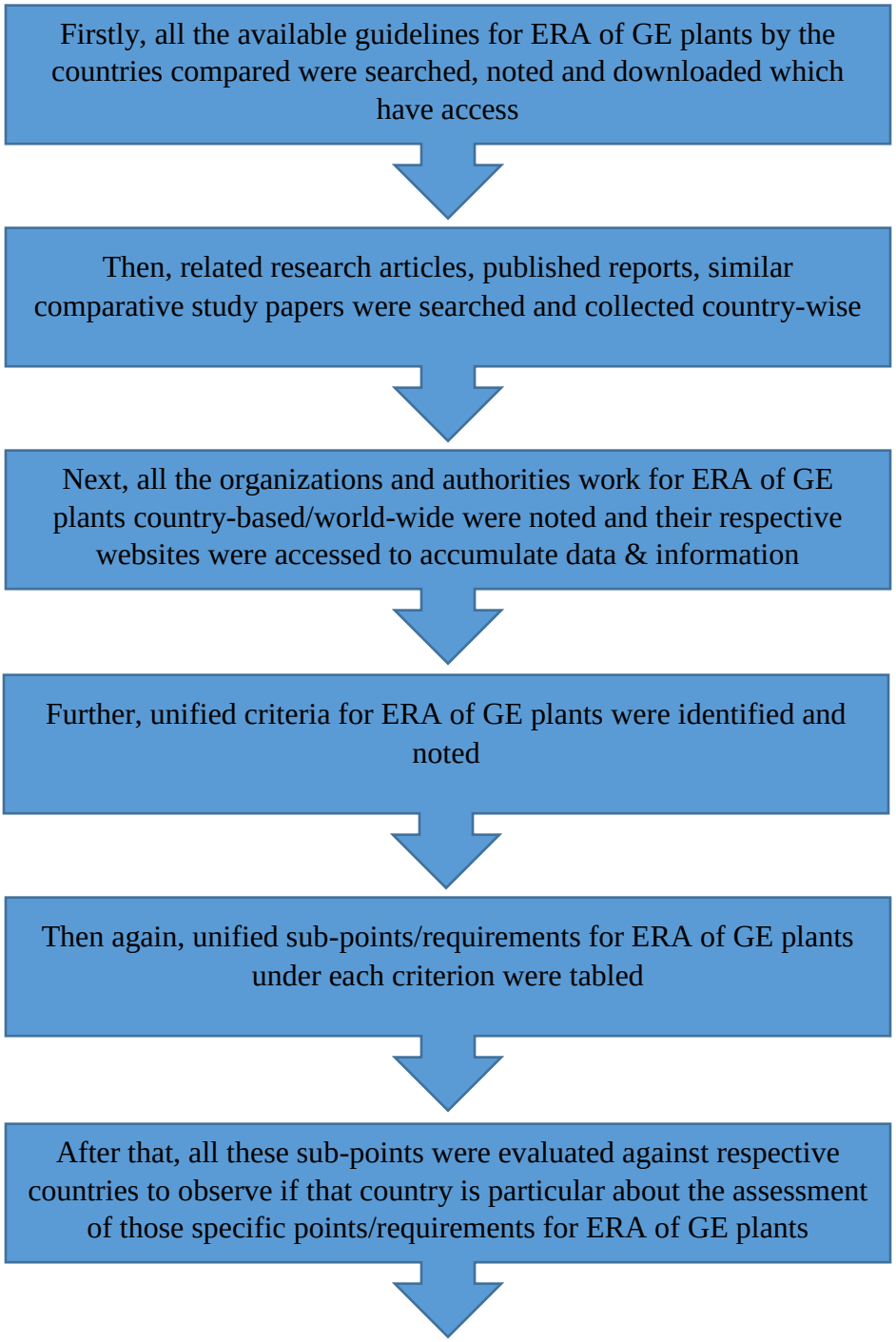
In addition to this, information was noted from available research works online regarding ERA of GE plants in Argentina. Further, published comparison studies and reports were also considered. To be specific, the research article on the multi-country comparison of information & data requirement for the ERA of GE plants by MoEF&CC, Government of India was analyzed in this study.

2.1.8 Australia:

Fortunately, Australian regulatory authority for ERA of GE plants publishes almost all of the required data on their official website that is **the Office of the Gene Technology Regulator (OGTR).** OGTR provides data requirements in accordance with specific events for ERA of GE plants and separate guideline documents can be found on their website. All these documents were used in collecting information to conduct the respective comparison study. Moreover, related research articles, reports etc. were also evaluated where needed. The study on the multi-country comparison of information & data requirement for the ERA of GE plants by the Ministry of Environment, Forest and Climate Change, Government of India was very helpful in this regard. The website portals of SABP, BCH, and International Service for the Acquisition of Agri-biotech Applications (ISAAA) etc. were accessed to accumulate data apart from studying official guidelines, research articles and reports.

2.2 Method:

The method used to carry out this comparative study is quite simple but lengthy as the amount of guidelines, articles etc. analyzed is large in number. The steps followed here are as below:



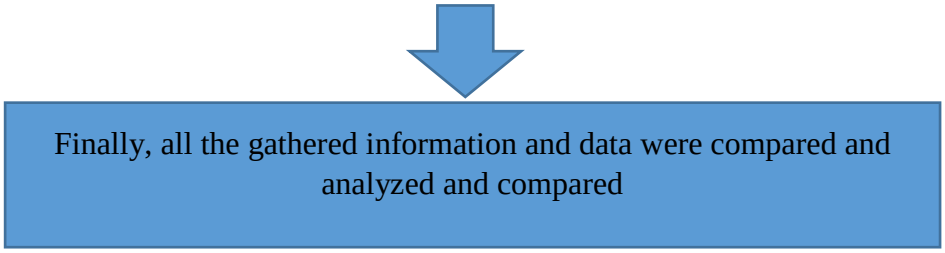


Figure 2.1: *The Method and Steps of the Comparative Study*

Chapter 3: Results

Chapter 3: Results

3.1 Analysis of Environmental Risk Assessment (ERA) Criteria:

The main purpose of ERA is to identify and evaluate the potential risks of transgenic plants during its cultivation, use and also after the release in the environment. These potential harms are addressed based on case-by-case studies prior to the release into the surrounding environment. For this purpose, relevant counterpart of wild plants is used to differentiate between transgenic and non-transgenic plants. In addition, adequate information related to the biological characteristics, cultivation practices, genetic data, impact on biodiversity etc. is required for both the transgenic & non-transgenic plants. The potential harms to be assessed can be considered more or less same among all the countries that follow an established ERA regulation:

- Gene flow from transgenic plants to wild relatives
- Impacts of transgenic plants on the environment and non-target organisms
- Agricultural or environmental practices associated with transgenic plants
- Possibility of developing resistance against respective GE plant

Comparison among the information and data of regulatory protocols for ERA developed by targeted countries is required to conduct the study. Several points are highlighted based on the information and data that needs to be addressed to identify potential harms and these can be denoted as risk factors. The risk factors are as follows:

1. Description of the biology of the non-transformed plant species
2. Description of donor organisms
3. Description of genetic modification and characterization of transgene

4. Phenotypic characteristics of the GE plant
5. Cultivation conventions of the GE plant
6. Impact of outcrossing with sexually compatible relatives
7. Potential adverse effects on non-target organisms
8. Post-release environmental monitoring
9. Instructions on data quality
10. Treatment of stacked events

The data in the following tables are collected from different biosafety protocols for transgenic plants regulation of the respective countries as well as from related research works and company data (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)(Rocha et al., 2013)("Guidance on the Environmental Risk Assessment of Genetically Modified Plants," 2010)(Pachico, 2003)("Guidance on the Agronomic and Phenotypic Characterisation of Genetically Modified Lants," 2015)(*Directive 94-08 (Dir 94-08) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits - Canadian Food Inspection Agency*, 2018)(*Stacked Traits in Biotech Crops | ISAAA.Org*, 2020)(Pilacinski et al., 2011)(USDA FAS, 2019)(OGTR, 2007)(Silva, 2019)(Mcallister, 2013)(*Directive 94-08 - Appendices - Canadian Food Inspection Agency*, 2018)(Points to Consider for Consensus Documents on the Biology of Cultivated Plants, 2008)(Fitzpatrick et al., 2009)(OGTR, 2002)(Technology et al., 2019)(Lewi & Vicién, 2020)(*Ministerio De Agroindustria Secretaría De Agregado De Valor*, 2017)(Hilbeck et al., 2011)(Naegeli et al., 2021)(*Segunda Fase De*

Evaluación Documento De Decisión, 2012)(Ley, 2018)(*Revisions to USDA-APHIS 7 CFR Part 340 Regulations Governing the Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms*, 2019)(Nepomuceno et al., 2019)(*Approval of Mycogen/Dow Petitions 03-036-01p and 01-036-02p Seeking Determinations of Nonregulated Status for Insect-Resistant Cotton Events 281-24-236 and 3006-210-23 Genetically Engineered to Express Synthetic B.t. Cry1F and Cry Ac, Respectively*, 2004)(Andrade et al., 2014). Most of the information was mapped from the available guidelines for ERA of GE plants. Unfortunately, some of the countries do not make their guidelines accessible online. Thus, research studies conducted on ERA of GE plants in those respective countries were analyzed. Remarks were used to highlight the attributes effectively where necessary.

In the following tables, "Y" stands for the information or data requirement that is mentioned in the regulatory documents/guidelines published by the competent authority or stated clearly in the related research studies.

Likewise, an "I" indicates that the information or data requirement included may not be explicitly identified in the regulatory documents or research articles. Additionally, there is a possibility that it may be a parameter that is encompassed within a broader category of information/data that is required by regulatory authorities. For instance, the rate of reproduction may be indicated by the number of days of onset of flowering, the number of days for flowering and the number of days until maturity (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014).

Furthermore, blank space or "___" was used when the information or data requirement was not found in the regulatory guidelines or related research articles and reports.

However, some data requirements are not mandatory all the time. Such data are important under specific conditions. That case by case elective information is denoted by "E".

3.1.1 Description of the Biology of the Non-transformed Plant Species:

One of the most important parameters that must be reviewed during the process of ERA of GE plants is to analyze the biology of the non-transformed or wild plant species. Initial understanding of plant biology facilitates to presume of any potential harm beforehand. There is a possibility that existing species-specific characteristics may affect the novel trait in such a way that it may develop weedy features later on. As a result, it can be harmful for the existing ecosystem and thus the surrounding environment.

In addition to this, the interaction between the plant and other living organisms can be predicted by analyzing its biological details. Moreover, potential measures to reduce the presumed risks can be constructed accordingly. Several numbers of documents containing the biology of crop species are being made by relevant organizations or institutions.

One of such consensus documents describing the biology of wild plant species have been prepared and published by **the OECD** (Points to Consider for Consensus Documents on the Biology of Cultivated Plants, 2008). These documents can be used as reliable sources for evaluating the biological details of the plant species under research. Besides, these documents can be used to prepare many newer monographs with updates on it. Countries for instance

Australia, Canada, India have already prepared such consensus documents on the biology of different crop species (*Crop Biology Documents – Bangladesh Biosafety Portal*). These crops include rice, tomato, rubber, potato, maize, cotton, wheat, sugar beet, apple, lentil, alfalfa, barley, papaya, canola, sugarcane and many more (*Crop Biology Documents – Bangladesh Biosafety Portal*). In order to review the biology of non-transformed plants, generally some specific features are examined and noted.

Detailed information on the taxonomy, geographical origin, genetics, reproductive biology and naturally occurring crosses are enlisted on the documents. Moreover, characteristics like cultivation practices in respective regions, interaction with other life-forms etc. are also highlighted on the consensus papers.

Table 3.1: *Required data and information on the description of the biology of the non-Transformed plant species:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)(Pachico, 2003)(*Directive 94-08 (Dir 94-08) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits - Canadian Food Inspection Agency*, 2018)(Points to Consider for Consensus Documents on the Biology of Cultivated Plants, 2008)(*Ministerio De Agroindustria Secretaría De Agregado De Valor*, 2017)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Common/usual names; scientific name and taxonomy	Y	Y	Y	Y	Y	Y	Y
General biology/agronomy/ecology of the plant species	Y	Y	Y	Y	Y	Y	Y
Geographical origin, genetic diversity & domestication	Y	Y	Y	Y	Y	Y	I
Breeding & seed production ways	Y	Y	___	___	___	Y	Y
Agronomic conventions	Y	Y	___	___	___	Y	___
Reproductive biology	Y	Y	Y	Y	Y	Y	Y
Weediness	Y	Y	Y	Y	I	Y	Y
Intra- & inter-specific hybridization	Y	Y	Y	Y	Y	Y	Y
Gene flow	Y	Y	Y	Y	Y	Y	Y
Relationship with other life forms (e.g. Pollinators, birds, soil microbes & insects, fungi etc.)	Y	Y	Y	Y	Y	Y	Y
Chronicle of use and/or dissemination in the country proposed use	___	___	Y	Y	Y	Y	Y

3.1.2 Description of Donor Organisms:

Donor organism(s) is defined as the organism(s) from which the genetic material of interest is obtained and transferred to the targeted recipient. The proper information and data is very essential to conduct an effective ERA of GE plant. The genetic material/novel trait taken from the donor organism may have impact on the recipient plant. As a result, it may show unexpected alterations in the resulted transgenic plant (which contains the genetic material/novel trait).

Such alterations could be the development of weediness that may persist in the environment forever or may invade the natural ecosystem in the long run. Besides, the possibility for unknown risks to human health is also there. So, a lot of the potential harms can be presumed by reviewing the characteristics of donor organism(s) and thus key approaches can also be made to mitigate those risks if needed. Moreover, the pattern of interaction between the genetic material and surrounding's life-forms can also be forecasted. It is very important to indicate if the genetic component encodes any known allergen or pathogenicity factor or not.

Description of donor organism(s) can be found on the database of the **BCH** (*Search for LMOs, Genes or Organisms*). Furthermore, new monographs can also be made based on the information found on the database.

Table 3.2*: Data requirement analysis on the description of Donor Organisms:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants,* 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh,* 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016) (*Directive 94-08 (Dir 94-08)*

Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits - Canadian Food Inspection Agency, 2018)(Mcallister, 2013)(*Directive 94-08 - Appendices - Canadian Food Inspection Agency*, 2018)(Fitzpatrick et al., 2009)(OGTR, 2002)(Technology et al., 2019)(*Ministerio De Agroindustria Secretaría De Agregado De Valor*, 2017)(Hilbeck et al., 2011)(Naegeli et al., 2021)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Scientific & common name	Y	Y	___	Y	___	Y	Y
Taxonomic classification	Y	Y	___	___	___	I	___
Chronicle of safe use of the donor organism/components	Y	Y	Y	Y	Y	Y	Y
If the introduced genetic element is present in other GE food/feed in respective/other countries	Y	Y	I	Y	I	Y	I

3.1.3 Description of Genetic Modification and Characterization of Transgene:

Another important factor that needs to be assessed is the genetic modification and characterization of the transgene. An effective ERA of transgenic plants is almost impossible without the detailed information of these two analyzing factors. Both the genetic modification method and transgene can have effect on the GE plant as well as on the environment. Some of the impacts can be known from the data and others can be presumed based on it.

Firstly, the specific modification method used in the process (e.g. if its *Agrobacterium* mediated or direct transformation method) must be presented. Moreover, the purpose of this modification

needs to be stated explicitly so that the changes due to this method can be forecasted. For example, if any amino acid sequence is changed due to the method then the expression of the respective protein may also be altered (*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016). All this information can be used to assess the risks due to the GE plants. Then, description of all the genetic materials/transgene along with their sources is needed to be considered.

The DNA sequence of transgene should be mentioned as well as the details of the vector (e.g. size, coding and non-coding sequences etc.) that carries that transgene. Some of the factors which are quite essential to know about the transgene are the size, location, orientation in the vector, number of insertion site, its function and many more (*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016). Moreover, information about any potential open reading frame is also needed to evaluate the possibility of generating fusion proteins. Thus, any chances of risks can be identified at the genetic level and it will enhance the credibility of the assessment.

Besides, the report on the sequence homology of transgene with any allergen may have to be checked. Any history of harm due to the transgene needs to be enlisted as well. All the required data about the transgene and anything related the modification can be accessed from the website of the **BCH** (*Search for LMOs, Genes or Organisms*).

Table 3.3: *Data requirement on the description of Genetic Modification and Characterization of transgene:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the*

Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)(Guidance on the Environmental Risk Assessment of Genetically Modified Plants, 2010)(*Directive 94-08 - Appendices - Canadian Food Inspection Agency*, 2018)(Points to Consider for Consensus Documents on the Biology of Cultivated Plants, 2008)(Fitzpatrick et al., 2009)(OGTR, 2002)(*Ministerio De Agroindustria Secretaría De Agregado De Valor*, 2017)(Naegeli et al., 2021)(*Segunda Fase De Evaluación Documento De Decisión*, 2012)(Ley, 2018)(*Revisions to USDA-APHIS 7 CFR Part 340 Regulations Governing the Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms*, 2019)(Nepomuceno et al., 2019)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
The details of modification to be introduced and specific method used for it	Y	Y	Y	Y	I	Y	Y
Details of the inserted sequence (portion, size, function & it's source)	Y	Y	Y	Y	I	Y	Y
The location, order & orientation of GOI in the vector (site of insertion, no. of inserted site)	Y	Y	Y	Y	I	Y	Y
If the genetic component is responsible for disease/injury to plants/other organisms	Y	Y	Y	Y	I	Y	Y
Sequence homology of GOI* with known allergen sequences	Y	Y	I	Y	___	Y	Y
Identification of any ORFs* within the inserted DNA/created by insertion including	Y	Y	Y	Y	I	Y	Y

any possible fusion proteins							
Any expressed substance in the GE plant (eg. Protein or untranslated RNA; it's function)	Y	Y	Y	Y	I	Y	Y
The level & site of expression of the expressed gene product and it's metabolites in the edible part	Y	Y	Y	Y	I	Y	Y
If the intended modification/new traits of interest has been achieved or not	Y	Y	Y	Y	Y	Y	Y
If any other gene(s) in the host has been affected by the transformation	Y	Y	Y	Y	I	Y	Y

Note: GOI*-Gene of Interest, ORF*- Open Reading Frame

3.1.4 Phenotypic Characteristics of the GE Plants:

It is very crucial to analyze the phenotypic features (all intended and unintended) of GE plant before reviewing it at a genetic level. These phenotypic attributes may change over the period of time. Molecular analysis can be used to identify the phenotypic changes and routine check is also needed. However, a counterpart of GE plant on the study is also a prerequisite to conduct the comparative phenotypic characteristics study. In addition to this, the phenotypic analysis of transgenic plant gives an initial overview as a whole in terms of the yield, seed dormancy & germination rates, plant height, flowering duration/maturity, susceptibility/resistance to diseases, tolerance to abiotic stresses, alterations in the susceptibility to pests, seed loss etc. (Guidance on the Agronomic and Phenotypic Characterisation of Genetically Modified Plants, 2015)(*Risk Assessment of LMOs - Training Manual: Module 3*).

These data facilitate the ERA of GE plant specially when the chances of weediness, invasiveness into the biodiversity as well as any possibilities for causing diseases to other life-forms. Almost all the countries which produce transgenic plants are very particular and conscious on enlisting required information regarding the phenotypic characteristics of GE plants.

Among the countries that are considered in this comparison study, Australia, US, Canada, India and Bangladesh publish the information and data for phenotypic features of GE plants very explicitly (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014) (*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016) (Pachico, 2003). On the contrary, other countries are not particular in providing information on every parameter except some general requirements such as changes in reproductive biology, seed/pollen dispersal, outcrossing and how the favorable insects are affected (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014).

Table 3.4: *Comparative analysis of data requirement on the phenotypic characteristics of the GE plants:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)(Pachico, 2003)(*Directive 94-08 (Dir 94-08) Assessment Criteria for*

Determining Environmental Safety of Plants With Novel Traits - Canadian Food Inspection Agency, 2018)(USDA FAS, 2019)(Fitzpatrick et al., 2009)(OGTR, 2002)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Growth habit (Basic morphology and changes if there is any)	Y	Y	Y	I	I	Y	Y
Changes in Life-length (annual, biennial and perennial)	Y	Y	Y	I	I	Y	Y
Vegetative vigor (e.g. Plant height, crop biomass)	Y	I	Y	I	I	Y	Y
Ability to overwinter	Y	I	Y	I	I	Y	Y
Number of days to onset of flowering; Number of days for flowering	Y	I	Y	I	I	Y	Y
Number of days until maturity of fruit/seed (e.g. time required for harvesting)	Y	Y	Y	I	I	Y	Y
Seed parameters (e.g. seed production, length of time of seed/fruit production, seed dormancy, seeding emergence)	Y	Y	Y	Y	I	Y	Y
Proportion surviving from seedling to reproduction	Y	I	Y	I	I	Y	Y
Changes in outcrossing frequency (intra- & inter-specific)	Y	___	Y	Y	Y	Y	Y
Impact on pollinator species (e.g. Changes in pollinator, changes in flower morphology, color, fragrance etc.)	Y	Y	Y	Y	Y	Y	Y

Pollen parameters (e.g. amount of pollen, proportion of viable pollen, longevity, stickiness, shape, weight)	Y	Y	___	Y	I	Y	Y
Fertility-acquired or lost	Y	___	Y	I	I	Y	Y
Self-compatibility	Y	___	___	I	I	Y	Y
Asexual reproduction (e.g. vegetative reproduction, parthenocarpy)	Y	___	Y	Y	Y	Y	Y
Seed dispersal factors (features like seed shattering/dispersal by animals)	Y	Y	Y	Y	Y	Y	Y
Symbionts (e.g. Vesicular-arbuscular Mycorrhizal fungi, rhizobia)	___	___	___	Y	Y	Y	Y
Stress adaptation (Biotic & abiotic, changes in disease susceptibility)	Y	Y	Y	Y	Y	Y	Y
Add/subtract substances to/from soil	___	___	___	Y	Y	___	___

3.1.5 Cultivation Conventions of the GE Plants:

Due to the specific modifications during the production of GE plants, the cultivation practices also may need alterations. Such modifications in cultivation practices may include methods of pest and weed control, crop rotation, soil fumigation, the management system for growing the transgenic plants, water management etc. (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(Pachico, 2003) and these practices can be used to investigate the impacts of GE plants into the environment. Moreover, it can be assessed if the biodiversity is being invaded by these impacts. In order to conduct the assessment, the non-transformed counterpart of GE plant is

compared in terms of the location, basic plant growing conditions, any new developed ecosystem, alterations in insects & herbicide management practices and many more (*Risk Assessment of LMOs - Training Manual: Module 3*).

Then, potential risks to the environment as well as the living forms (including human health) due to the practical changes in the modified plant cultivation are evaluated. Sometimes depending on these data, new strategies and management requirements are developed to facilitate the production of GE plants and mitigate the risks as well. So, it is very important to collect the data for cultivation conventions in a step wise manner and to make it available to others if possible.

Table 3.5: *Required data and information on the cultivation conventions of the GE plants:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)(Guidance on the Environmental Risk Assessment of Genetically Modified Plants, 2010)(*Directive 94-08 (Dir 94-08) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits - Canadian Food Inspection Agency*, 2018)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Description of the location where the GE plant will be grown	Y	Y	Y	Y	Y	Y	Y
Identification and description of any new ecosystems where the GE plant will be	Y	Y	I	Y	Y	Y	Y

cultivated							
Description of changes in cultivation practices for the GE plant	Y	Y	I	Y	Y	Y	Y
Discussion on transgenic volunteers if it may require altered management practices for succeeding crops	Y	Y	I	Y	Y	Y	Y
Description of any deployment strategies recommended for the GE plant	Y	Y	I	Y	Y	Y	Y
Management plans for insect resistance crop	Y	Y	___	Y	Y	Y	Y
Management plans for herbicide resistant crop	Y	Y	___	Y	Y	Y	Y

3.1.6 Impact of Outcrossing with Sexually Compatible Relatives:

The risk of transferring genetic material from GE plant to non-transformed plant as well as other life-forms is a significant concern and that is why the impacts due to such gene transfer needs to be assessed. Unintentional cross may occur whenever any sexually compatible plant is available there in the region where GE plants are grown. Such compatible plants can be non-transformed wild type species or their hybrid offspring. The effects on the environment, biodiversity and other living organism are unknown. Thus any kind of alterations around the environment must be noted and evaluated the reason(s) behind this. However, horizontal gene transfer can be occurred from GE plants to other living forms such as microorganisms, insects, human etc.

The transgenic plants that are produced targeting specific organisms such as resistant to insects or pests and sometimes resistant to nematode may also have adverse impacts not only on the environment but also on the targeted organisms. In that case, such impacts are needed to be

examined as well. Moreover, these negative impacts may cause bio-pollution which has the ability the disrupt the unique characteristics of natural species (Pachico, 2003). So, case by case analysis is mandatory to evaluate the impacts of outcrossing with sexually compatible relatives as well as other living organisms.

Among the countries in the analysis study, there is a broad similarity on the data for the impacts on outcrossing with sexually compatible relatives.

Table 3.6: *Impact of Outcrossing with Sexually Compatible Relatives:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)(Points to Consider for Consensus Documents on the Biology of Cultivated Plants, 2008)(*Ministerio De Agroindustria Secretaría De Agregado De Valor*, 2017)(*Segunda Fase De Evaluación Documento De Decisión*, 2012)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Presence of sexually compatible species in targeted location for cultivation	Y	Y	Y	Y	Y	Y	Y
Characteristic(s) of introduced trait that could change the ability of the GE plant to interbreed with other plant species	Y	Y	Y	Y	Y	Y	Y
Consequences of any potential gene flow upon the cultivation of GE plants to sexually	Y	Y	Y	Y	Y	Y	Y

compatible plant species							
Possible changes in likelihood of horizontal gene transfer (HGT)* to unrelated species	Y	Y	___	Y	Y	___	Y

Note: HGT*- Horizontal Gene Transfer

3.1.7 Potential Adverse Effects on Non-target Organisms:

In this part of the study, potential risks on non-target organisms are evaluated in a detailed manner on a case by case study. A range of non-target organisms are appropriate for eco-toxicity testing. All the potential species for instance birds, freshwater fish, soil invertebrates, pollinators, predators, aquatic invertebrates, crop pests, nematodes and many more are considered in the analysis (*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)(*Risk Assessment of LMOs - Training Manual: Module 3*). Information and data on the trait used in transgenic plants is used to determine if there are any chances of adverse impacts on non-target living forms or not. Moreover, if any harmful attribute is observed in the laboratory condition, then confined field trial under test conditions is necessary for further investigation.

Adverse impacts due to the use of GE plants as food & feed, its raw or processed products are also taken under consideration during the analysis. As a result, such impacts are examined by comparing the impacts of its counterpart (non-transformed plants) with of the transgenic plants.

Almost all the countries considered in this comparison study gave explicit information regarding the potential adverse effects on non-target organisms as follows:

Table 3.7: *Data requirement of potential Adverse Effects on Non-Target Organisms:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
If the gene product is a part of human/animal diet	Y	Y	Y	Y	Y	Y	Y
If gene product produces a toxin/other products (directly/indirectly) that have effects on metabolism, growth, development or reproduction of animals, plants or microbes	Y	Y	Y	Y	Y	Y	Y
Any possible physiological & behavioral effects to non-target organisms	Y	Y	Y	Y	Y	Y	Y
Potential adverse effects on the human health	Y	Y	Y	Y	Y	Y	Y

3.1.8 Post-release Environmental Monitoring:

Approval of a GE plant for release is not the last step of the assessment for environmental risk. It is very important to monitor all the aspects related to the GE plant even after its successful release. This monitoring should be hypothesis driven and must be evaluated on the basis of scientific & statistically relevant data. However, there is no need to examine all the factors every time. The transgenic plants those seemed to have adverse impacts in trials before release need to be in close case by case observation. Relevant data must be collected and analyzed time to time.

On the other hand, the transgenic plants that seemed to be safe before release also need to be under observation for any reported potential risks. In some cases, the governing authority itself mentions requirement of examination before approving the GE plant to release into the environment or unconfined field trial looking at the possibility of occurring such adverse impacts. For example, GE plant expressing insecticidal proteins (Bt Toxin) collected from *Bacillus thuringiensis* requires monitoring plans such as insect resistance management to be approved by the decision makers (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants,* 2014). In some other cases, the authority approves the GE plant without having the need of any post-release monitoring. The reason behind such decision is related to the previous release of same transgenic species or combination of already marketed single event of that species. Moreover, authority may change their decision of growing the marketed GE plant if any adverse effect is reported and proved to be harmful.

Countries tend to show more or less different opinions in terms of regulating post-release environmental monitoring.

Table 3.8: *Analysis of data on Post-release Environmental Monitoring:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh,* 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India,* 2016)("Guidance on the Environmental Risk Assessment of Genetically Modified Plants," 2010)(*Directive 94-08 (Dir 94-08) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits -*

Canadian Food Inspection Agency, 2018)(OGTR, 2002)(*Ministerio De Agroindustria Secretaría De Agregado De Valor*, 2017)(*Segunda Fase De Evaluación Documento De Decisión*, 2012)(*Approval of Mycogen/Dow Petitions 03-036-01p and 01-036-02p Seeking Determinations of Nonregulated Status for Insect-Resistant Cotton Events 281-24-236 and 3006-210-23 Genetically Engineered to Express Synthetic B.t. Cry1F and Cry Ac, Respectively*, 2004)(Andrade et al., 2014)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
A case-by-case post-release environmental monitoring (familiarity with plant species & trait will be considered)	Y	Y	Y	Y	Y	Y	Y
Post-release environmental monitoring should address relevant protection goals	___	Y	Y	Y	I	I	Y
Specific potential risk posed by the GE plant should be focused	I	Y	Y	Y	Y	Y	Y
Specific risk hypotheses that can be tested with data should be mentioned	Y	Y	Y	Y	Y	Y	Y
Specific measurement endpoints should be there to determine once an effect has been detected	___	Y	Y	___	I	I	Y
A termination date should be mentioned for monitoring if the risk hypotheses are accepted or rejected	___	Y	___	___	Y	___	___
A series of questions should be provided	___	Y	___	___	Y	___	Y
Post-release environmental monitoring plans	Y	Y	Y	I	I	Y	Y

are implemented for other purposes							
Non-hypotheses driven monitoring where causality cannot be determined	___	___	___	___	Y	___	Y
The regulatory authority should be notified of any new event that arises after the authorization for the unconfined release	___	Y	Y	Y	Y	Y	Y

3.1.9 Instructions on Data Quality:

Initially the ERA is based on collected required information & data and experimental trial is carried out based on this information when needed. So, it is essential that all the collected data are of authentic sources such as published regulatory documents by the governing body themselves or peer-reviewed scientific publications.

In addition to this, the assessment process becomes faster whenever provided data is authentic and scientifically sound as it facilitates the developing of ERA framework as well as potential risks evaluation methods.

It seems that not all the countries (including in the analysis study) are on the same page of required information relating to the data quality.

Table 3.9: *Instructions on Data Quality:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh,* 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India,* 2016)(Rocha et al., 2013)(Guidance on the Environmental

Risk Assessment of Genetically Modified Plants, 2010)(*Directive 94-08 (Dir 94-08) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits - Canadian Food Inspection Agency*, 2018)(Mcallister, 2013)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
The quality of data submitted with application should be equivalent to that submitted for peer-reviewed scientific publications	Y	Y	___	___	___	Y	Y
Applicants should clearly describe experimental procedures followed	Y	Y	___	___	___	Y	Y
Statistically valid experimental designs and protocols should be employed in the generation of all field trial and trials should be conducted in a manner consistent with the proposed agricultural practices for the GE plant	Y	Y	___	___	___	Y	Y
The details of all confined field trial protocols, including designs & sampling procedures should be submitted	Y	Y	___	___	___	Y	I

3.1.10 Treatment of Stacked Events:

Stacked events are defined as the condition when more than one traits or genes are combined or stacked to produce a GE plant (Taverniers et al., 2006). Stacked traits may be used as Combination of novel traits which is a result of conventional crossbreeding. Such stacked traits can be generated from the cross of two approved GE plants (Pilacinski et al., 2011). The use of stacked events in transgenic crops is rare. However, this phenomenon is getting popular day by day in biotech industries due to its benefits. Such events are also having to be considered in the

ERA protocols like the other parameters (Pilacinski et al., 2011). Assessment practices for stacked event risks due to GE plants contrast among the countries here in the comparison study.

Some countries are very rigid about their policy regarding assessing stacked events while others are not. Moreover, some countries follow entirely different assessment regulations for stacked traits used in the transgenic plants. On the contrary, other countries require no extra regime to observe such events.

Almost all the countries compared below have requirements to assess stacked events to some extend whereas both Bangladesh and India seem to have no additional plan for such events.

Table 3.10: *Needful data analysis on the treatment of Stacked Events:* (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-Bangladesh*, 2016)(*Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants-India*, 2016)("Guidance on the Environmental Risk Assessment of Genetically Modified Plants," 2010)(*Directive 94-08 (Dir 94-08) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits - Canadian Food Inspection Agency*, 2018)(*Stacked Traits in Biotech Crops | ISAAA.Org*, 2020)(Pilacinski et al., 2011)(USDA FAS, 2019)(OGTR, 2007)(Silva, 2019)

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Approval permission for stacked events	___	___	Y	Y	Y	E	Y
New environment information is required for stacked event products	___	___	E	E	E	___	Y

Chapter 4: Discussion

Chapter 4: Discussion

4.1 Discussion:

All the countries producing GE plants are trying their best to keep the balance with **the CPB to the CBD** to conduct the ERA appropriately. However, difference of the ERA protocols in various countries limits the export-import of their produced GE plants. Keeping that in mind, it is very essential to develop a collective ERA guideline which can be followed by the countries during export-import of the transgenic plants. Not to mention, only the countries whose ERA will be communized can export-import their transgenic plants between each other. It has already been mentioned that harmonization among ERA protocols of different countries is the main objective of this study. The result of the comparison research shows very interesting findings among the ERA guidelines of Bangladesh, India, Argentina, Australia, Brazil, Canada-US and the European Union.

Ten parameters were determined as key highlights to initiate the comparison. Then, various factors related to those parameters were analyzed. Firstly, Table 3.1 describes the biology of the non-transformed plant species. This is one of the initial data requirements to assess the risks due to transgenic plants. It is observed that all the countries in this study provide explicit data related to the biology of non-modified plants. However, only a few data were not mentioned by few of the countries.

The attributes such as breeding and seed production practices of non-transformed plant species are not assessed in Argentina, Australia and Brazil according to their ERA guidelines. Moreover, these countries also do not require information on agronomic practices of non-transgenic plants along with the European Union. In addition to this, information on the history of use and/or

distribution in the proposed country of the GE plant is not needed by the ERA authority of Bangladesh and India. On the contrary, all the factors are assessed by the mentioned countries in this comparison study. If any country feels the need of assessing the missing information during the export/import of GE plants, then they may have to evaluate those factors only. However, they can skip to monitor these data if they think it is not mandatory for the ERA of the respective country.

Secondly, details of donor organisms are represented in the Table 3.2. From the table it is analyzed that Argentina, Australia, Brazil and the European Union do not require the data on taxonomic classification of GE plant while Argentina and Brazil also do not ask for the information of its scientific & common name. However, these three countries assess the information of all other attributes. Furthermore, the other countries need data on all the points mentioned on the table. As mentioned earlier, the governing authority of ERA can decide if they have to investigate the unassessed information or not according to the corresponding country's policy.

Then, Table 3.3 stands for the description of genetic modification and characterization of transgene. All the countries are very strict in monitoring these two attributes according to the data on the table. It is observed that all the countries require every information related to the genetic modification & transgene used. However, Brazil seems to skip collecting information about the sequences of GOI that are homologous to the known allergen sequences. As the toxic and adverse effects of the transgene are analyzed based on the other factors mentioned on the table, the authority might overlook the missing data on sequence homology of Brazil. Moreover, the factor "if the GOI is responsible for disease/injury to plants/other organisms" is also related to the concerned attribute to some extent. So, the authorities of the respective country for

export/import have to decide the intensity of the attribute and whether they require its information or not. Another point of consideration is that marker gene is also used along with GOI as a detector. These marker genes usually possess antibiotic resistance and give signal of successful transformation. However, it is suggested not to use the marker gene encoding antibiotics specific for any disease causing bacteria such as vancomycin for the treatment of certain staphylococcal infections (Craig et al., 2008).

Furthermore, Table 3.4 represents the description of phenotypic features of the GE plant. Variety of differences can be seen when all the points for this attribute are evaluated. To begin with, the regulatory authority of Bangladesh, India and Argentina does not seek information on the GE plant's symbionts as well as on the addition/subtraction of substances to/from soil. Surprisingly, Canada, US and the European Union also do not require data on the addition/subtraction of substances to/from soil. However, all the target countries assess evidence about the changes in outcrossing frequency, fertility-acquired or lost, self-compatibility and asexual reproduction but India. Moreover, not only India but also Argentina does not monitor self-compatibility of the transgenic plant. Argentina seems to be liberal about collecting data on pollen parameters as well. On the other hand, the studied countries show similarities regarding almost all the other attributes of GE plant's phenotypic characteristics. So, the decision making authority might have to be very careful on finalizing the ERA criteria for the export/import of the transgenic plants.

The next table which is "Table 3.5" contains the facts of the cultivation practices of the GE plants. it is one of the most important parameters for the ERA of GE plants because the environment can be affected severely if these GE plants are cultivated in a wrong way. May be this is the reason why all the countries agree on investigating all the elements relating to cultivation conventions of the transgenic plants. However, it is observed that the governing body

of Argentina does not mention the data requirement on the management plans of insect & herbicide resistant plants. So, this information must be evaluated if any country wants to import any insect & herbicide resistant GE plant from Argentina.

After that, all the impacts of outcrossing with sexually compatible relatives are enlisted on the Table 3.6. According to the data of the table, the assessment of all the reeves is very essential for all the reported countries. However, this scenario is different in terms of possible changes in the likelihood of HGT to unrelated species. The ERA regulating authority of Argentina, Canada and US does not require any information on this factor. As a result, the authorities of other countries may have to assess the information on HGT to unrelated species if it is mandatory by the respective country's regulatory guideline. In addition to this, HGT assessment is based on literature and is not conducted experimentally. The *in-vitro* observation of HGT following the containment field trial may add reliability to the decision making process.

A potential adverse effect of GE plants on non-target organisms is another very important feature to monitor the ERA of any country producing GE plants. The related information of these impacts is drafted and observed in the Table 3.7. Surprisingly, all the 8 countries under the comparison study agree on collecting data of all the points covered by the table. Thus, the regulatory concern does not need to worry about the investigation of this attribute during the export/import of the transgenic plants.

Then, Table 3.8 is developed by covering all the necessary data requirements of post-release environmental monitoring. Sometimes it is mistaken that all the assessment steps are completed once the GE plant is released into the environment. However, post-release monitoring is equally important. Keeping that in mind, many decision making authorities approve GE plants only if the producer agrees to monitor it after the release. Moreover, the findings from the post-release

monitoring are needed to be reported to the governing authority on a time to time basis. Not only the post-monitoring reports but also the monitoring plans need to be reviewed after a definite time frame (Guidance on the Environmental Risk Assessment of Genetically Modified Plants, 2010). The review has to be case specific (Guidance on the Environmental Risk Assessment of Genetically Modified Plants, 2010). When table 3.8 is analyzed, diverse outcomes are observed. Firstly, only Brazil and the European Union conduct non-hypotheses driven monitoring where causality cannot be determined. Similarly, a termination date is needed to monitor if the risk hypotheses are accepted or rejected only by the authority of India and Brazil. A series of questions should also be provided according to these two countries along with the European Union. On the other hand, the regulatory guideline of Bangladesh again does not mention about the data requirement of relevant protection goals of post-release environmental monitoring, specific measurement endpoints and notification of any new event that arises after the authorization for unconfined release to the regulatory authority. Australia seems to join Bangladesh regulatory authority's requirement in terms of the need of specific measurement endpoints. Considering the differences in the results, the decision makers need to assess close checking while dealing with post-release environmental monitoring.

The ERA continues with the evaluation of data quality which is noted on the Table 3.9. As it is mentioned earlier, reliable and authentic data sources must be used to establish the ERA. However, the analysis shows that the ERA guidelines of Argentina, Australia and Brazil do not require any evidence of data quality where as other countries do. Not to mention, the data used in this comparison research have been collected from respective country's ERA regulatory guideline. Some of the countries do not provide access to their regulatory protocol. Thus, data has been gathered from authentic scientific journals and reports in such circumstances. Research

articles and workshop reports from various biosafety regulating committees have been used as well. For instance, the OECD, the SABP, the FAO and many more (*International Biosafety Documents – Bangladesh Biosafety Portal*). The concerned authority should consider the data quality while making the decision of exporting/importing the GE plant in accordance with the regulatory guidance.

Lastly, Table 3.10 indicates the specifics while monitoring the assessment of stacked events. Such assessment is conducted only if more than one traits are stacked into a single GE event. However, data from Table 3.10 presents that both the guidelines of Bangladesh and India do not state anything regarding stacked event treatments. On the contrary, the authorities of Argentina, Australia, Brazil, Canada, US and the European Union require the information on such treatment while Canada and US do not demand for any new environmental information of the stacked event. Importantly, the factors (denoted by "E") are monitored only under specific conditions by some of the countries (Argentina, Australia, Brazil, Canada and US). Sometimes it is observed that binary success rate can be achieved when traits are combined.

Moreover, it adds an advantage of conferring several problems related to crops at a time. For example, combination of glyphosate resistance gene *epsps* with the *pat* gene conferring resistance to herbicide glufosinate and/or with the *dmo* gene conferring resistance to herbicide dicamba by biotech crop developer (*Stacked Traits in Biotech Crops | ISAAA.Org*, 2020). Thus, it enhances the chances of defeating the corresponding herbicide. Furthermore, rice was stacked with three carotenoid genes in order to design the whole biosynthesis pathway for provitamin A (beta carotene) (*Stacked Traits in Biotech Crops | ISAAA.Org*, 2020). So, it is very important to adapt with this gene combination technology as well as to include it in the regulatory protocol of ERA for GE plants. As a result, the respective authority will be able to make decision in an

effective way without the need for assessing this attribute again during the time of exporting-importing.

Among all the studied GE plant producing countries here, only a few provide explicit information regarding the attributes for ERA. For instance, Bangladesh, India, Canada, US, the European Union provide very detailed information about the ERA of transgenic plants whereas countries such as Argentina, Brazil, Australia do not publish their ERA protocols in an accessible manner. However, they regularly publish related research works, workshop reports, annual reports, update reports etc. which can be reachable easily. Moreover, they also provide some decision documents of their permitted GE plants.

The decision of allowing the GE plants solely depends on the governing authority of ERA regulation. If they feel that a specific unassessed factor is related with any assessed one and thus no risk concern is involved with it, then they may give permission to release the plant. Moreover, the authority also may allow the transgenic plant for export-import. On the other hand, the data of a reeve which is not explicitly discussed by the respective country (the producer/exporting country), the regulatory body may assess its related risks once again to be confirmed.

4.2 Limitations of the Study:

The comparison study is an honest and heartiest effort to collect all the data & information from the mentioned country's regulatory guidelines of ERA for GE plants. This is completely based on the data & information of available protocols and research articles online. Thus it may lack quality relating some of its information. Moreover, due to the unavailability of sufficient documents, the indications as "I" and "Y" may be interchangeable. However, it should not have

a significant impact on the quality of the study because “I” already means the presence of related information though it’s not very explicit.

Chapter 5: Conclusion and Future Direction

Chapter 5: Conclusion and Future Direction

Briefly, all the countries -Bangladesh, India, Australia, Argentina, Canada, Brazil, US and the European Union regulate the ERA of GE plants on a case by case study basis. Furthermore, comparative analysis and familiar incidents have great importance in their regulatory frameworks. The explicit guidelines such as of Canada, US, the European Union etc. provide vivid information and data on the regulation of ERA which facilitates the whole comparison analysis. Both similarities and differences can be observed among these guidelines.

Post-release environmental monitoring is still an evolving issue in all the participating countries. Every country is trying to improve this arena of ERA in accordance with the need of their environment. However, all the post-release monitoring must on case by case basis and hypothesis driven. Another point of consideration is the regulation of stacked events. Most of the developed countries are very concerned about its potential risk but developing countries like Bangladesh and India lack behind in assessing such combination events. Not only that, they do not even mention the assessment need and steps for any stacked events on their ERA guidelines.

However, this comparison study presents a lot of similarities among the ERA of GE plants in the corresponding countries. By exploring all the data requirements for ERA followed by these studied countries, it has been observed that a good amount of assessments are alike in all the countries. Moreover, same attributes are assessed again while importing that GE plants which were checked earlier by the producer country(ies). So, it can be suggested, all these similar assessments for same factors might be excluded by the regulatory authorities if the same assessment has been done previously by producer/another country. As a result, uniformity of data requirements for ERA of GE plants can be developed among all the countries and thus harmonization as well. The regulatory authorities may also reconsider if it is actually necessary

to assess the same factors again and again by every country while the assessment processes are equivalent. Besides, such harmonization may reduce the time for release, total cost and also labor behind the ERA in the future. Thus, it can be hoped that the whole ERA regulation can be simplified among all the GE plants producing countries.

In addition to this, the useful data and information about the guidelines of ERA for GE plants will be available on a single document. Thus it will ease the ERA process of transgenic plants during export-import. The countries that are still establishing their protocols for ERA can also have assistance from this study. Moreover, it will save much more time for searching all the required information. However, additional arrangements should be made to develop a harmonized document of ERA of GE plants among all concerned countries.

Time to time meetings and workshops on ERA guidelines harmonization should be called. All the responsible personnel concerned with ERA guidelines from different countries must be present in these meetings and workshops so that representatives from all the participating countries can agree on the similar idea. Moreover, representatives from corresponding countries can discuss the unavailable data and as a result will leave no room for misinterpretation of their ERA protocols. A few organizations like the OECD are already trying to arrange such meetings and workshops. They have developed a consensus document as a series of harmonization on regulatory oversight in biotechnology named "Points to Consider for Consensus Documents on the Biology of Cultivated Plants" ("Points to Consider for Consensus Documents on the Biology of Cultivated Plants," 2008). Moreover, they are in process of making another guidance document which is "Environmental Considerations for the Risk/Safety Assessment for the Release of Transgenic Plants" (*A Multi-Country Comparison of Information and Data Requirements for the Environmental Risk Assessment of Genetically Engineered Plants*, 2014).

Lastly, harmonization of data and information requirements for ERA of GE plants among the guidelines of all the studied countries has a high chance to facilitate and benefit the entire ERA process along with the corresponding countries. For now, new possibility for harmonization can only be suggested from this comparative study. So, the regulatory authorities should investigate more and take needful actions if harmonization of data requirements for ERA can be considered.

Chapter 6: References

Chapter 6: References:

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