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RESEARCH ARTICLE

A COMPARATIVE STUDY OF ENVIRONMENT RISK ASSESSMENT GUIDELINES FOR GENETICALLY ENGINEERED PLANTS OF DEVELOPING AND DEVELOPED COUNTRIES INCLUDING BANGLADESH

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ABSTRACT

Genetically Engineered (GE) plants are the demand of time for increased need of food. The regulation system, followed from the development of a GE plant to its release into the environment is categorized into separate stages for maintaining the proper biosafety including Environmental Risk Assessment (ERA). ERA identifies potential risks and its impacts through science based evaluation process where it follows a case by case study. All the countries dealing 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 in terms of required data and information against ten criteria. Surprisingly, an adequate amount of data and information requirements (e.g. if the intended modification has been achieved or not, growth habit of GE plants, potential adverse effects on the human health etc.) matched between all the countries. However, a few differences of data requirement such as agronomic conventions of non-transformed plants, clear description of experimental procedures followed etc. were also observed in the study. Moreover, the result indicates that only a few countries provide instructions on the quality of the data used for ERA. Thus, if the 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.

1. INTRODUCTION

It is important to evaluate every possible risk prior to the release of Genetically Engineered (GE) plants into the environment. Such evaluation includes a systemic process that analyzes the quantitative and qualitative impacts of GE plants on the environment as well as on human health. Several structured steps, pertained by the systemic process, are followed till the final decision making and is collectively called Environmental Risk Assessment (ERA). It is an essential part of the Cartagena Protocol on Biosafety (CPB) which provides a unified source of required information for the safe handling and transportation of GE organisms including plants. The main purpose of ERA is to identify any potential risk of GE plants that can be direct or indirect and immediate or delayed beforehand (Craig et al., 2008). The principles of ERA must have strong scientific basis and explanation. Besides, specific case by case investigation is required because GE plants may vary in terms of their nature (trait combination), intended use and the receiving environment. Moreover, the overall procedure of ERA, from the development of GE plant to its release and after release must be carried out in an explicit manner.

Specific guidelines have been established to conduct an effective ERA. These guidelines portray a thorough, straightforward and science-based framework by which regulatory authority can recognize potential risks. Additionally, the framework gathers applicable scientific information relating to the nature and seriousness of any harm and reliably describes the degree of potential risks possessed by its use.

The aspects of conducting an ERA for GE plants vary widely among the countries due to the different law systems, country policies and the geographical environment. According to the guidelines, the GE plant needs to be assessed before both export and import and during the trading inside countries as well (CBD, 2021). As these guidelines are made in accordance with CPB, there must be similarities for conducting the assessment. 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 find out the similarities and dissimilarities among them. As a result, there is a probability that the guidelines can be shared; accelerating the time of releasing the GE plants and also the cost and labor will be reduced remarkably. The purpose of this study is to explore the ERA guidelines of developed (US, Australia, Canada, the European Union-EU) and developing countries (India, Argentina, Brazil); further to compare these with ERA guideline of Bangladesh (developing country) which was gadgeted by the government of Bangladesh in 2016. Finally, the main objective was to outline and analyze the similarities and dissimilarities among these guidelines.

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2. Background Information

2.1 Distribution of Genetically Engineered (GE) Plant

A total of 72 countries are utilizing GE plants as food and feed where 29 of them are producing it by themselves. In 1996, the amount of produced GE plants was 1.7 Million Hectares (Mha) and it has been increasing upwards with the passage of every year till date, precisely 112-fold higher (ISAAA, 2021b). Surprisingly, in the year of 2019, developing countries produced 56% (106.6 Mhas) of the total global yield, while developed countries occupied the 44% (83.8 Mhas) portion (ISAAA, 2021b). 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 GE plants.

The top five countries which are the highest GE plant producers 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, 2019). US have always been remained at the top of the chart for planting GE plants and currently occupy 38% of total global yield (ISAAA, 2019). Recently, the African countries, Malawi, Nigeria and Ethiopia have planted GE cotton and it was their very first GE plant to be harvested (ISAAA, 2020a). Moreover, a significant increase in growth rates was recorded by Vietnam, the Philippines, Colombia and Indonesia upon adopting GE plants (ISAAA, 2020a).

On the other hand, Bangladesh planted less than 0.1 Mhas GE crops in 2017 (ISAAA, 2021b). However, Bt Brinjal has already been approved by the government of Bangladesh and Late blight resistant potato, golden rice and Bt cotton are in the pipeline for being released into the environment (Shelton et al., 2018;Rashid, 2018;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. In addition to this, most recently, Australia approved another biotech canola (ISAAA, 2021a). Besides, the European Union has not released any GE plant yet but has a well designed and actively functioning regulatory protocol.

Until now, total 32 GE plants and 530 GE events have been approved by the competent authorities of different countries (ISAAA, 2021a). Among all the GE plants, soybeans, cotton, maize, canola and alfalfa are the most popular and commonly harvested and recognized as major biotech crops.

2.2 Environmental Risk Assessment

2.2.1 Problem Formulation (PF)

Being a multi-step framework, Problem Formulation (PF) plays an important role in ERA and facilitates the logical organization of the assessment. Moreover, it helps to sort out key questions useful for evaluating the decision of releasing a particular GE plant for a specific purpose. Besides, PF helps ERA to be robust and transparent and as a result, the regulatory authority could identify the authentic information before making their decisions (Fitzpatrick et al., 2009).

The very first step is to form the context and it consists of specific measures to identify potential risk related to the GE plant. While developing the context, it is mandatory to consider the policy protection guideline set out by the country and the proposed use of GE plant (Wolt et al., 2010). The next step is to collect relevant information of all the materials involved, for instance, recipient plant, genetic elements used in the modification and the GE plant for the assessment (Fitzpatrick et al., 2009). Information must be accurate, raw and scientifically detailed with proper references (UNEP, 2012). Then, an initial characterization about the potential risks is made by observing the gathered information. Lastly, the regulatory authority may conclude with a risk hypothesis whether all the provided information is enough to determine or they must collect additional data to complete the PF. Once the PF is established, the regulatory authority starts evaluating potential risks by taking the hypothesis into account.

2.2.2 Steps of Environmental Risk Assessment (ERA)

The total number of steps in ERA varies among the countries but the overall idea and process are same everywhere. Firstly, the regulatory authority identifies possible risks by considering the hypothesis from the PF. However, any kind of risk that does not result from GE plant development process or if the risk is not related to the cultivation of GE plants, then it is not a matter of consideration (Hill and Sendashonga, 2003;Garcia-Alonso et al., 2007). Moreover, depending on the seriousness of the identified risk, the regulatory authority needs to decide if it requires further verification after the exposure of GE plant into the environment.

Next, the nature of the identified risk and its link with the GE plant is evaluated comprehensively. For fulfilling this purpose, the severity of the risk is investigated and then usually expressed by a scale or matrix (Figure 1) (Hill and Sendashonga, 2003). In this scale, the potential impacts of identified risks are evaluated against the likelihood of these risks. For example, very unlikely and unlikely indicate that risk can occur in very rare or limited circumstances. In contrast, likely and very likely represent the chances of encountering risk in many or most of the cases and that is why particular importance must be given to assess these risks. Factors like how severe the environmental change are, if its occurrence is frequent or not, the time lengths of its occurrence, whether there is any chance of repetition, need to be considered during the risk evaluation. Besides, both greenhouse and confined field trials are employed to assess potential risks under low exposure conditions considering the severity of the risk.

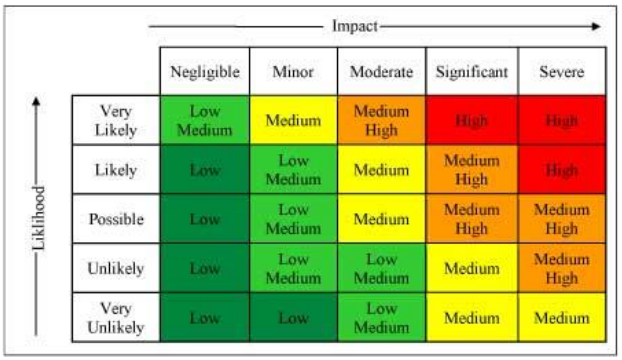

Figure 1: Representative Risk Matrix followed during Risk Assessment, Source- (Boers, 2017)

Lastly, by observing the gathered data and information, a final call is made if the GE plant possesses any potential risk or not and the decision is reported with proper and accurate scientifically sound evidence (Johnson et al., 2007). Every action involved in the ERA and the severity of identified risk(s) are mentioned in the final report. Relevant precautions to overcome the identified risk(s) are also suggested there. The process of ERA even continues after the release of GE plant into the environment and the assessment is reviewed at a regular interval.

3. Materials and Method

3.1 Materials

The main resources used in this study were the guidelines of ERA developed by the countries to regulate GE plants. Besides, various search engines like journal articles, case studies, books, digital news papers and reliable websites were explored as well. Governments and organizations such as Organization for Economic Co-operation and Development (OECD) publish various consensus documents as well as reports; these have also been used in the comparative study.

3.2 Method

A descriptive qualitative analysis and comparison depending on library research was followed. Initially, a total of 10 criteria were identified by exploring all the ERA guidelines and resources and then outlined into tables, containing unified data requirements for each of the ten criteria. Finally, the data requirements under each criterion were compared among the guidelines to find out the similarities and dissimilarities. Then the result was noted and analyzed for all the studied countries.

4. Results

4.1 Analysis of Environmental Risk Assessment (ERA) Criteria

The following tables recognize the risk factors which are highlighted based

on the information and data of ERA guidelines and are needed to be addressed to identify potential risks. Moreover, Bangladesh, India, Argentina, Australia, Brazil, Canada, United States and the European Union were identified as BD, IN, ARG, AUS, BRA, CAN, US and EU, respectively. Further, the information and data requirement that is mentioned in the regulatory documents was indicated as "Y" whereas a blank space or "__" was used for the information and data requirement which could not be found.

4.1.1 Description of the Biology of Non-transformed Plant Species

Initial understanding of the biology of non- transformed plant, which is the receiver of the transgene facilitates the comparison of changes between the non-transformed and transformed plants. Once this factor was compared, the ERA guidelines showed maximum similarities. All the findings are summarized in Table 1.

Table 1: Required data and information on the description of the biology of non-transformed plant species

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	Y
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	Y	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

Sources: (Pachico, 2003;Government of India, 2014;Government of Bangladesh, 2016;Government of India, 2016;Ministerio de Agroindustria, 2017;Government of Canada, 2018b)

4.1.2 Description of Donor Organisms

Due to the transgene taken from the donor organism, there is a possibility of transferring undesired elements along with the transgene into the receiver plant. Thus, weediness could be developed and may persist in the environment forever or may invade the natural ecosystem in the long run. The outcomes of comparing this criterion are enlisted in Table 2.

Table 2: Data requirement analysis on the description of donor organisms

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Scientific & common name	Y	Y	__	Y	__	Y	Y
Taxonomic classification	Y	Y	__	__	__	Y	__
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	Y	Y	Y	Y	Y

Sources: (OGTR, 2002;Mcallister, 2013;Government of Bangladesh, 2016;Government of India, 2016;Government of Canada, 2018b;OGTR, 2019;Naegeli et al., 2021)

4.1.3 Description of Genetic Modification and Characterization of Transgene

Both the genetic modification method and transgene can have effect on the GE plant as well as on the environment. So, the specific modification method used in the process (e.g. if its *Agrobacterium* mediated or direct transformation method) and the purpose of this modification must be presented explicitly. Moreover, the DNA sequence of the transgene should be mentioned along with the details of its vector (e.g. size, coding and non-coding sequences etc.). According to the compared data, all the countries are very strict in monitoring these two attributes (Table 3).

Table 3: Data requirement on the description of genetic modification and characterization of transgene

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	Y	Y	Y
Details of the inserted sequence (portion, size, function & it's source)	Y	Y	Y	Y	Y	Y	Y
The location, order & orientation of GOI[1] in the vector (site of insertion, no. of inserted site)	Y	Y	Y	Y	Y	Y	Y
If the genetic component is responsible for disease/injury to plants/other organisms	Y	Y	Y	Y	Y	Y	Y
Sequence homology of GOI with known allergen sequences	Y	Y	I	Y	__	Y	Y
Identification of any ORFs[2] within the inserted DNA/created by insertion including any possible fusion proteins	Y	Y	Y	Y	Y	Y	Y
Any expressed substance in the GE plant (eg. Protein or untranslated RNA; it's function)	Y	Y	Y	Y	Y	Y	Y
Level, site of expression of the expressed gene product and it's metabolites in the edible part	Y	Y	Y	Y	Y	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	Y	Y	Y

[1]GOI-Gene of Interest, [2]ORF-Open Reading Frame

Sources: (OGTR, 2002;EFSA, 2010;Government of India, 2014;Government of Bangladesh, 2016;Government of India, 2016;Ministerio de Agroindustria, 2017;Government of Canada, 2018a;OGTR, 2018;USDA, 2019;Nepomuceno et al., 2019;Naegeli et al., 2021)

4.1.4 Phenotypic Characteristics of the GE Plants

The phenotypic analysis of GE plant is required when assessing any increased tendency to weediness, competitiveness or invasiveness. It gives an initial overview as a whole in terms of the yield, seed dormancy and germination rates, plant height, flowering duration/maturity, susceptibility/resistance to diseases, tolerance to abiotic stresses, alterations in the susceptibility to pests, seed loss etc (EFSA, 2015). All the

data requirements for phenotypic characteristics of GE plants are summarized in Table 4.

Table 4: Comparative analysis of data requirement on the phenotypic characteristics of the GE plants

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Growth habit (basic morphology and changes if there is any)	Y	Y	Y	Y	Y	Y	Y
Changes in life-length (annual, biennial and perennial)	Y	Y	Y	Y	Y	Y	Y
Vegetative vigor (e.g. Plant height, crop biomass)	Y	Y	Y	Y	Y	Y	Y
Ability to overwinter	Y	Y	Y	Y	Y	Y	Y
Number of days to onset of flowering; number of days for flowering	Y	Y	Y	Y	Y	Y	Y
Number of days until maturity of fruit/seed (e.g. Time required for harvesting)	Y	Y	Y	Y	Y	Y	Y
Seed parameters (e.g. Seed production, length of time of seed/fruit production, seed dormancy, seeding emergence)	Y	Y	Y	Y	Y	Y	Y
Proportion surviving from seedling to reproduction	Y	Y	Y	Y	Y	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	Y	Y	Y
Fertility-acquired or lost	Y	—	Y	Y	Y	Y	Y
Self-compatibility	Y	—	—	Y	Y	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-arbuscularMycorrhizal 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	—	—

Sources: (OGTR, 2002;Pachico, 2003;Government of India, 2014;EFSA, 2015;Government of Bangladesh, 2016;Government of India, 2016;Government of Canada, 2018b;Yankelevich, 2019)

4.1.5 Cultivation Conventions of the GE Plants

Because of the specific modifications during the production of GE plants, the cultivation practices such as methods of pest and weed control, crop rotation, soil fumigation, the management system for growing the transgenic plants, water management etc. also may need alterations (Pachico, 2003)(Government of India, 2014). In this case, almost all the countries agree on investigating all the data requirements (Table 5).

Table 5: Required data and information on the cultivation conventions of the GE plants

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

Sources: (EFSA, 2010;Government of India, 2014;Government of Bangladesh, 2016;Government of India, 2016;Government of Canada, 2018b)

4.1.6 Impact of Outcrossing with Sexually Compatible Relatives

Unintentional cross may occur whenever any sexually compatible plant (non-transformed wild type or hybrid offspring) is available in the region where GE plants are grown. Unfortunately, its effects on the environment, biodiversity and other living organism are unknown. The only parameter- the likelihood of Horizontal Gene Transfer (HGT) is not required to assess by Argentina, Canada and US (Table 6).

Table 6: Impact of Outcrossing with Sexually Compatible Relatives

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 compatible plant species	Y	Y	Y	Y	Y	Y	Y
Possible changes in likelihood of HGT[1] to unrelated species	Y	Y	—	Y	Y	—	Y

[1]HGT- Horizontal Gene Transfer

Sources: (OECD, 2008;Government of India, 2014;Government of Bangladesh, 2016;Government of India, 2016;Ministerio de Agroindustria, 2017;USDA, 2019)

4.1.7 Potential Adverse Effects on Non-target Organisms

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 organisms other than the target ones, known as Non-target Organisms (NTOs). All the eight countries evaluate such impacts explicitly and Table 7 recognizes all the data relating to any possible effects on NTOs.

Table 7: Data requirement of potential adverse effects on non-target organisms

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

Sources: (OECD, 2008;Government of India, 2014;Government of Bangladesh, 2016;Government of India, 2016)

4.1.8 Post-release Environmental Monitoring

Post monitoring is conducted upon the release of GE plant on a case by case study basis and it should be hypothesis driven. In some cases, the regulatory authority approves a GE plant with the requirement to maintain its post-release monitoring. India, Brazil and the European Union were found to assess nearly all data on post-release monitoring while other countries were observed to have differences in opinions (Table 8).

Table 8: Analysis of data on post-release environmental monitoring

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	Y	Y	Y
Specific potential risk posed by the GE plant should be focused	Y	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	—	Y	Y	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 are implemented for other purposes	Y	Y	Y	Y	Y	Y	Y
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

Sources: (OGTR, 2002;USDA, 2004;EFSA, 2010;Andrade et al., 2014;Government of India, 2014;Government of Bangladesh, 2016;Government of India, 2016;Government of Canada, 2018b)

4.1.9 Instructions on Data Quality

Initially, the ERA is based on collected required information and data and then 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 or peer-reviewed scientific publications. Moreover, scientifically sound information is mandatory to ensure an effective ERA. The findings indicate that only Bangladesh, India, Canada, United States and the European Union need evidence of data quality (Table 9).

Table 9: Instructions on data quality

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 and sampling procedures should be submitted	Y	Y	—	—	—	Y	Y

Sources: (EFSA, 2010;Mcallister, 2013;Rocha et al., 2013;Government of Bangladesh, 2016;Government of India, 2016)

4.1.10 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). In this purpose, stacked traits may be used as combination of novel traits which is a result of conventional crossbreeding or can be generated from the cross of two approved GE plants (Pilacinski et al., 2011). It's

advantage of conferring several problems at a time, making it more popular in biotech industries day by day. According to the results reported in Table 10, the authorities of Bangladesh and India do not require information on such treatment while other countries do.

Table 10: Needful data analysis on the treatment of stacked events

Information/Required Data	BD	IN	ARG	AUS	BRA	CAN-US	EU
Approval permission for stacked events	___	___	Y	Y	Y	E[1]	Y
New environment information is required for stacked event products	___	___	E[1]	E[1]	E[1]	___	Y

[1]E- Case by case elective data requirement

Sources: (OGTR, 2007;EFSA, 2010;Pilacinski et al., 2011;Government of India, 2014;Government of Bangladesh, 2016;Government of India, 2016;Government of Canada, 2018b;Silva, 2019;Yankelevich, 2019;ISAAA, 2020b)

5. Discussion

With the increased progress of modern biotechnology and GE plant production, the concern for possible risks on the environment as well as on the human health has also increased. So, ERA plays an inevitable role for all the countries in order to release GE plants into the environment. Several consensus documents containing detailed information to facilitate ERA are being published by relevant organizations and institutions. For example, the OECD published documents describing the biology of wild plant species (OECD)**;** the database of the Biosafety Clearing House (BCH) contains information about the description of donor organisms and the transgene (BCH)**.** Moreover, the OECD is in process of publishing another guidance document which is entitled as "Environmental Considerations for the Risk/Safety Assessment for the Release of Transgenic Plants".

All the countries- Bangladesh, India, Australia, Argentina, Canada, Brazil, US and the European Union, put an effort to establish an effective ERA practice. Interestingly, the findings of this comparative study revealed a significant amount of similarities and dissimilarities among the ERA guidelines. Most of the common risk factors such as description of the biology of non-transformed plant species, donor organisms and genetic modification method and characterization of transgene, phenotypic characteristics of the GE plant, cultivation conventions of the GE plant, impact of outcrossing with sexually compatible relatives, potential adverse effects on NTOs, and post-release environmental monitoring, were observed to have maximum amount of similarities with few dissimilarities.

The results from the comparison of the biology of non-transformed plant indicate that among the various categories where the assessment is done, most of the criteria are common among the countries. However, at three points, there are some variations such as breeding and seed production ways, agronomic conventions and chronicle of uses (Table 1). Interestingly, in terms of the description of donor organism, the scientific and taxonomic classification is not required by many of the guidelines (Table 2). However, in this case, history of safe use of the donor organism is much more important (Table 2). While comparing the description of gene modification and characterization of transgene, only Brazil was identified not to mention the requirement for sequence homology with known allergen (Table 3). The outlined findings in Table 4 for phenotypic characteristics of GE plants disclosed that India does not need information on changes in outcrossing frequency as well as on fertility. Further, both India and Argentina do not require information on self-compatibility whereas only Australia and Brazil seek data on substances in soil.

On the other hand, new strategies and management requirements are developed, if needed to facilitate the GE plant production depending on the data for the changes of cultivation practices. In this regard, all the data are similar except Argentina on the management plans for insect and herbicide resistant crops (Table 5). Almost all data requirements, enlisted in Table 6, are same for the outcrossing with sexually compatible relatives which is actually related to the gene flow concerns. Upon the comparison of the issues that are concerned after the release of GE plants into the environment, it was found that huge issues are dealt in the post-release environmental monitoring. There are three criteria (e.g. specific measurement endpoints, a termination date for monitoring, requirement for a series of questions) which are only important to India, Brazil and the European Union (Table 8). However, other countries do not recognize these as an important assessment point during the post-release monitoring.

Surprisingly, data requirements of all the guidelines reflect 100% similarity for risk factor, potential adverse effects on NTOs. The findings specify that NTOs related concerns are equally important and expressed equally in the guidelines (Table 7). However, this scenario is different in case of dealing with stacked events. Assessment for potential risks needs to be conducted for stacked events that are involved with the GE plant as the use of gene combination may be associated with unknown risks (Pilacinski et al., 2011). Nevertheless, not all the countries use stacked events yet, but Argentina, Australia, Brazil require information on the approval permission of stacked events while the European Union is concerned about both the approval permission and new environment information of stacked events (Table 10).

Furthermore, the quality of collected data is very crucial during the ERA and also during the post-release condition. However, the risk factor, instructions on data quality (summarized in Table 9) was estimated to exhibit mostly dissimilarities as Argentina, Australia, Brazil have not mentioned any such requirements while other countries explicitly do.

Briefly, the ratio of similarities is evidently higher between the ERA guidelines of all these eight countries which indicate that it can pave the pathway for harmonization.

6. Conclusion

The findings of the comparative study showed similarities as well as dissimilarities among the ERA guidelines of developing and developed countries. To be specific, the similarities were observed more frequently. Therefore, the study suggests that it may open a scope towards establishing harmonization and in future, more research needs to be done to look into in details of the assessment criteria to find out the possibility for it. As a result, harmonization may reduce the time for release of GE plant, total cost and labor behind the ERA in future. Besides, if these similarities are recognized in a more framed manner then the approval pathway of GE plants can be shared and thus it will ease the whole ERA process for GE plants.

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