BIOSAFETY REGULATIONS AND LEGISLATIONS OF TRANSGENICS IN INDIA AND ABROAD

Authors

Ritu Rani
Department of Agricultural Botany
Vasantrao Naik Marathwada Krishi Vidyapeeth
Parbhani,Maharashtra, India
riturani2278@gmail.com

Mukesh Raj
Division of Genetics
ICAR- Indian Institute of Agricultural Biotechnology
Ranchi, Jharkhand, India
muku51427@gmail.com

Udavant R N
Department of Agricultural Entomology
Vasantrao Naik Marathwada Krishi Vidyapeeth
Parbhani, Maharashtra, India
udavant.rajesh1997@gmail.com

I. INTRODUCTION

The crops that are produced by transferring the genes from one organism to others through genetic engineering is known as transgenic crop or genetically engineered crops. The primary challenge facing the globe is to supply nutritious food because of the alarming rate of population growth. An estimate says that all over the world 800 million people are facing malnutrition problems among these 98% belong to developing Nations (Sinha et al.,2019). Apart from this around 2 billion people globally suffer from hidden hunger because of improper supply of vital micronutrients in their day-to-day diet. This is ultimately affecting their physical and mental development which is very dangerous for the future of a country. An economic and feasible solution to this problem is to produce a transgenic crop known as a biofortified crop and gives biofortified food to the populations. Through the production of biofuels or fuel blending, GM crops minimize the need for pesticides, and the use of agricultural fossil fuels, and potentially cut world fossil fuel use by up to 65%.

Developing countries like India spent a humungous amount of money (spent USD 119.2 billons in 2021- 22) importing fossil fuels. Nowadays due to Russia Ukraine war, the crude oil price is hiking exponentially due to which the whole economy of Asia Pacific countries, especially Indian subcontinental countries like Sri Lanka, Pakistan, Nepal, Bangladesh, etc., is on the verge of collapse. In light of this, the Indian government has unveiled a new biofuel strategy with the illustrative goal of mixing 20% ethanol and 5% diesel by 2030. This may be done by cultivating high-yielding transgenic biofuel plants, producing new or improved feedstock, upgrading biofuel production processes, and creating advanced biofuels. Generating enzymes and microorganisms for better biofuel yields, etc. Cost-effective biofuel technology can also be made in these ways. Genetically modified crops are also used to reduce the use of pesticides in agriculture Crops in first-generation transaction crops are developed only due to this purpose.

The ISAA survey found that 29 nations worldwide were cultivating about 189.5 M/hect. of GM crops, with 5 of those countries being industrialized (making contributions 44% of the overall) and 24 being developing (contributing 56% of the total). The USA top the list with total coverage of 71.5 million hectares followed by Brazil and Argentina in second and third position. India ranked fifth which a total plantation of 11.9 million hectares of transgenic crops.

Although this technology full-fill the greatest challenge associated with the increasing population economically and feasibly, with the use of this technique, new gene or genome sequences may be introduced into nature which may cause potentially harmful effects on human health, the environment, and other non-target species and biological diversity. This may cause serious biosafety concerns.

II. RISK ANALYSIS

While handling GMOs, there is an obvious consideration of potential risks associated with them. There is always a chance to escape transgenic varieties or organisms from human control and their invasion nature. Fortunately, till now, no such major case is reported affecting a great extent but some organizations doubt the evolution the of covid-19 virus that it may be genetically engineered due to its large size, and caused a great pandemic throughout

the world. Due to GMOs, there is another potential risk of production of toxic or allergic biochemical by such organisms and it may cause a great hazard to the human and animal population, whether it is released deliberately or by chance in the environment or as a result of their consumption. The avoidance, reduction, or elimination of the above said hazards call for an effective risk management plan, which is often put into practice as measures that adhere to certain rules. The upkeep of both biosafety and biosecurity at greater tiers is one of the crucial factors in the creation and usage of new organisms produced through biotechnology. In a broader context, risk analysis includes the entire process of risk assessment, combined with risk management and risk communication [OGTR, 2013]. These three processes—Risk assessment, Risk management, and Risk communication—are carried out in stages.

1. **Risk assessment:** During the risk assessment process, the info in the GMO application, pertinent prior approvals, current scientific understanding, and recommendations from a wide range of experts, organizations, and officials, including scientists, farmers, consumers, climate activists, NGOs, etc., are all taken into consideration. Here, the potential for genetic drift to non-transgenic kinds and creatures is also evaluated, along with any potential consequences. The severity and likelihood of any injury are both examined. In addition to relying on research, risk assessment frequently depends heavily on judgment.

   It assesses the potential and anticipated effect of rDNA research and hazard identification to concerned workers and the product of research\transgenic product on health and environment. During laboratory research work risk can be assessed in 2 steps:

   - Initial risk assessment.
   - Comprehensive risk assessment.

   Initial risk assessment is done by the investigator by the development of risk groups (1-4) to the organisms on which he proposes to conduct rDNA experiments. A comprehensive risk assessment is done after the initial risk assessment to decide an appropriate level of containment for the particular rDNA experiment.

   The Cartagena Protocol's Article 15 outlines precise objectives for risk assessment about identifying any potential negative consequences that an LMO might cause. Annex III of the Protocol lists four basic risk assessment principles:

   - "Risk assessment should be conducted in a transparent, scientifically sound manner and can take into consideration professional advice from, and recommendations developed by, relevant international organizations".
   - "Lack of scientific understanding or consensus should not always be taken into account as signifying a specific amount of risk, a lack of risk, or an acceptable level of risk".
   - "The risks posed by unmodified recipients or parental organisms in the most likely potential receiving environment should be taken into consideration when evaluating risks connected with living modified organisms or products thereof".

- Risk evaluation ought to be done on a case-by-case basis. Depending on the LMO in question, its intended purpose, and the most likely prospective receiving environment, depending on the circumstances, the kind and amount of depth of the required information may change.

2. **Risk Management:** In order to determine if measures are required to protect the environment and the people as well as what steps should be done for a given risk, the risk management process builds on the findings of the risk assessment. It is used during the systemic development and evaluation of an organism, from stages of field testing to commercialization. Once GMO is to be produced then recognition of DNA sequences determining the desired trait, selecting the marker gene, regulatory sequences expressing transgene, and gene transfer method, all should be considered. When one is using antibiotic-resistant genes or another marker gene that may cause hazardous effects, should be removed before GM crops and products thereof are commercialized. In addition, there are several promoter sequences already identified which have the property to turn on the gene for expression in specific stages/tissues of the organism. The method of transformation should be selected in such a manner that it shouldn't introduce extraneous DNA sequences, transfer the segment directly into the nucleus, and precise copy number. The proper risk assessment and management plan should be kept in mind from the Initiation of rDNA research and appropriate integration in the research plan should be done for the production of GMOs.

3. **Risk communication:** To ensure public acceptance of GMOs, risk communication is an essential component of biosafety concerns. Interaction with the public about the associated risks and the control measures taken to minimize them before the announcement of GMO field trials and their commercialization is important.

   Following communication strategies must be followed for effective risk communication:

   - Treat critics with respect and accept the public as a real partner.
   - Coordination, collaboration, and information dissemination using reliable sources
   - Don't hide secrets, be honest and forthright and own your faults.
   - People's concerns should be heard and acknowledged.
   - Be proactive, speak clearly, and use a well-rounded, practical information strategy.
   - Identifying and educating communicators while satisfying the media's needs.

   An effective risk analysis approach must include risk monitoring to follow the speculations about the potential harm of transgenic and their consequences. Specific sampling regimes and testing procedures are designed to make a dynamic monitoring plan.

III. BIOSAFETY CONCERN

Transgenic crops are being used more frequently every day due to their advantages over conventional breeding. However, this also expressed its concern regarding a potential risk to both humans and the environment. The term "biosafety" refers to a collection of guidelines, protocols, and policies that must safeguard public health and the environment from any potential negative consequences of contemporary biotechnology products.

Some of the important biosafety concerns are listed here-

1. **Concerns about biosafety that affect both human and animal health:** This concern is mainly related to antibiotic resistance, allergenicity, and toxicity. In general, if a gene product does not contain an allergen that is known to cause allergies, it will not become allergic-causing when expressed in a transgenic plant and can therefore be used in commercial production. After testing for allergens, a gene product that is known to cause allergies cannot be allowed for commercial use since, if produced in a transgenic plant, it will become allergenic. For example, when the methionine-producing gene extracted from Brazil nut is transferred to soybean, it boosts allergic response and so the commercial release of this product was banned. Sometimes proteins are expressed in transgenes, not found in the human diet, or genes products that are naturally antibiological agents, that may cause toxicity on consumption.

   Concerns have also been expressed about the transfer of selectable markers for antibiotic resistance genes to microbes, which could exacerbate the health issues caused by antibiotic resistance in disease-causing organisms. Despite the exceedingly low likelihood of such a transmission, measures are being done to lower the risk by gradually ceasing their use.

2. **Ecological Concerns:** Chance cross-pollination between transgenic varieties and local varieties could contaminate traditional local varieties with transgenes, which would lead to the loss of traditional varieties in a worst-case. Concerns become more serious, if this type of hybridization occurs between weed crops and transgenic crops, genes from the transgenic crops may increase the fitness of the weed crops, which would become more invasive and leads to environmental damage in minimum time.

   Insecticidal transgenes expressed by transgenic plants to control agricultural pests could potentially affect organisms that are not intended targets. For example, when exposed to milkweed (Asclepias curassavica) leaves covered in Bt-containing corn pollen, monarch butterfly larvae (Danaus plexippus) experienced lower rates of feeding, growth, and survival than when exposed to non-transgenic corn pollen. Concerns for the environment have also been expressed regarding the emergence of higher levels of weediness, virus resistance, and insect resistance after the introduction of transgenic crops.

IV. BIOSAFETY REGULATION

In 1973 the first successful use of transgenic technology or recombinant DNA technology was accomplished. The world’s scientific community recognizes its beneficial effect but as they realize their associated potential risk, they start a discussion to bring this technology under regulation, at a meeting in Asilomar, California. In this regard, the National Health Institute of America in 1976 issued guidelines related to regular genetic engineering technology in the USA. In 1982, when the first transgenic plant was created, the Economic Cooperation and Development Organization (ECDO) issued a study on the possible danger of allowing genetically modified organisms directly into the environment. Later, in 1986, it released a study titled "Recombinant DNA Safety Consideration," popularly known as the

"blue book," which served as the first set of international safety standards for using recombinant DNA organisms in the environment, agriculture, and industry.

The Cartagena Agreement on Biosafety triggered the formation of a biosafety regulatory framework in numerous developing nations. By the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, genetically modified organisms that result from contemporary biotechnology are handled, transported, and used safely to minimize any negative effects on human health and the environment. The protocol gives a precautionary approach to the issue of the transfer of living modified organisms from one country to another. On January 29, 2000, this protocol was adopted, and on September 11, 2003, it went into effect. As of June 2020, 173 countries have rectified this protocol. India rectified this protocol on January 23, 2003, and the competent national authority that deals with the matter of CPB in India is the Ministry of Environment, Forest and Climate Change (MOEF&CC), Indian Government.

V. CARTAGENA AGREEMENT ON BIOSAFETY HIGHLIGHTS

The Agreement Article 1 addresses "the transboundary movement, transit, handling, and use of all living modified species that may have harmful consequences on the conservation and sustainable use of the biological variety, taking into account hazards to human health."

Article 7 talks about the Advanced Informed Agreement (AIA) which is the Protocol’s main mechanism. Before the initial intentional cross-border migration of LMOs into the ecosystem of the importing country, this procedure should be followed.

Article 18 deals with LMO handling, shipping, packaging, and identification.

Article 20 deals with the Biosafety Clearing House (BCH), a website administered by the Convention's Secretariat. The goal was to make it easier for Parties to implement the Protocol by encouraging the sharing of knowledge in the fields of science, technology, the environment, law, and LMOs.

Article 22 talks about Capacity Building. To successfully implement the Protocol, evolving countries and island emergent states are encouraged to work together to exchange resources and institutional capacity on biosafety, including biotechnology.

Article 23 talks about “Public Awareness and Participation”.

Article 26 talks about “Socio-economic Considerations”.

Article 27 deals with the issues of accountability and compensation for damage brought on by the transboundary movement of LMOs.

Article 34 talks about Compliance

VI. BIOSAFETY REGULATION IN INDIA

1. Acts, Rules, Procedures, and Guidelines governing the transgenic crops in India are

- Environment (Protection) Act,1986 (EPA)
- The EPA's Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Modified Organisms or Cells, Rules 1989.
- Biological Diversity Act, 2002
- National Seed Policy, 2002
- Plant Quarantine Order, 2003
- Food Safety and Standard Act, 2006
- Foreign Trade Policy, 2006-09
- National Biotechnology Development Strategy, 2014.
- rDNA Safety Guidelines, 1990.
- Revised Guidelines for Research in Transgenic Plants, 1998
- Guidelines and Standard Operating Procedure (SOPs) For Confined Field Trials of Regulated Genetically Engineered (GE) Plants, 2008.
- Reliance For Safety Assessment of Foods Drive from Genetically Engineered Plants, 2008.
- Guidelines And Handbook for Institutional Biosafety Community (IBSCs), 2011
- Protection of Plant Varieties and Farmers Rights (PPVFR), 2001
- The Seed Bill, 2010 (draft)

The Environment (Protection) Act (1986) serves as a general piece of legislation designed to safeguard and enhance the environment as a whole. “Rules for the Manufacture/ Use/ Import/ Export and Storage of Hazardous Microorganisms, The "Genetically Modified Organisms or Cells Rules," also known as "Rules 1989," were published under the Environment (Protection) Act of 1986 to govern all operations involving genetically altered organisms and their products. Sections 6, 8, and 25 of the EPA's 1986 regulations announced the "Rules for Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Modified Organisms or Cells Rules, 1989." These guidelines govern all activities involving genetically altered organisms and their products.

2. Mandate & Functions of Ministers/ Departments-

- Ministry of Environment, Forest and Climate Change- Nodal authority for implementing “Rules 1989” and “Cartagena Protocol on Biosafety”.
- Department of Biotechnology (under Ministry of Science and Technology)- Nodal department responsible for promoting the biotechnology program. Support the execution of biosafety regulations using scientific evidence. Provide service in the area of research infrastructure, and generation of human resources.
- Ministry of Agriculture- Monitoring the agronomic advantages of transgenic technology and the post-release performance of GM crops is the responsibility of the Indian Council of Agriculture Research.

- Ministry of Health and Family Welfare- Policies intended to safeguard and keep an eye on human health. The Indian Food safety and standard Authority of India are in charge of policing and regulating genetically modified foods.
- Ministry of Commerce and Industries- Boost international trade by implementing export-import policies and responsible for carrying out DGFT notification on GMOs.
- Central Board of Excise and Customs, Department of Revenue (Ministry of Finance)- Enforce the regulations governing the transboundary movement of GMOs/ LMOs at the point of entry.

3. Key Features of Rules, 1989

- These regulations govern both the study of GMOs and their products as well as their widespread use.\
- Regulate all activities involving research/import/ exports /contained use/ field trials manufacture /storage of GMOs and products thereof.
- It covers all types of organisms (microorganisms, plants, animals, insects, etc.)
- Approval requirement for stages of research, safety assessment, field trials, and environmental release and monitoring.
- The six competent authorities, their makeup, and the rules by which they handled various elements of the regulations were also mentioned in these rules. The six competent authorities, their mandate & functions describe in the law our follows.

Competent Authorities	Mandate & Functions
Recombinant DNA Advisory Commission (RDAC)	• Offers GEAC technical support and guidelines. • Examine international and national advancements in biotechnology. • Periodically recommend pertinent and acceptable safety regulations for India about recombinant research, usage, and applications.
Institutional Biosafety Committee (IBSC)	• Implementation of institute-level monitoring systems for genetically modified organisms research at each institution. • Responsible for ensuring that rDNA safety regulations are followed, experiments are carried out at the authorized site by approved protocols, and an on-site emergency plan is prepared by manuals or RCGM recommendations.
Committee for the Review of Genetic Manipulation (RCGM)	• Assesses and directs the nation's appraisal of biosafety for biotech development and research. • Responsible for publishing manuals and guidelines that outline the proper way to conduct GMO research, use, and industrial application to protect the environment, as well as for establishing rules that restrict or forbid the production, sale, import, and use of GMOs as specified in the 1989 Schedule of Rules. • Authorized to examine all active rDNA studies, approve trials with proper containment that fall into the risk category III or above, and authorize the import of GMOs or transgene for

	research.
Genetic Engineering Appraisal Committee (GEAC)	• The apex nodal organization operating under MOEF &CC is in charge of carrying out the "Environment Protection Rules of 1989" and is also the one who has the final say on whether or not GMOs are approved. • Authorized to examine, supervise, and approve any operations involving the extensive use of potentially harmful microbes, recombinant research, and industrial production, including the importation, exportation, transit, manufacturing, use, or sale of GMOs and environmentally friendly goods.
State Biotechnology Coordination Committee (SBCC)	• Set up a structure in each state where the study and use of GMOs are being considered, and work with the federal ministry to coordinate local GMO initiatives. • Commissioned by the nodal Department, the State Pollution Control Board, or the Directorate of Health/Medical Service to perform inspections, investigate violations of the law, and apply punishments.
District Level Committee (DLC)	• Set up in each district where GMO research and applications are being considered. • Authorized to create informational charts, identify hazards and dangers associated with each of these facilities, and plan steps to be taken in the event of an emergency. • Authorized to monitor and inspect the safety regulations in installations using genetically modified/hazardous organisms and their uses.

The IBSC, RCGM, and GEAC are involved in regulatory and approval tasks, while the RDAC serves as an advisory body. Monitoring GMO-related actions at the state and district levels is the responsibility of SBCC and DLC, respectively.

4. Recombinant DNA Safety Guidelines

- Considering the advancement of biotechnology research, the Department of Biotechnology formulated this guideline in 1990. The standards were later amended in 1994 to encompass include R&D activities involving genetically modified organisms (GMOs), transgenic crops, large-scale production of GMO plants, animals, and products, deliberate release of GMO products into the environment, as well as shipments and imports of GMOs for laboratory research.
- Based on the associated potential risk, the research activities of the guidelines have been classified into three categories.

Category I - involves actions like employing strains to self-clone and inter-species cloning amongst organisms in the same exchange group.
Category II - involves activities that fall within containment levels II, III, and IV.
Category III - involves the practice of cloning genes to produce toxins, vaccines, and other studies.

5. Revised Guidelines for Research in Transgenic Plants, 1998

- It offers directions for rDNA plant research, such as how to build molecular and field assessments of transgenic plants, import and export GE plants for transgenic plant research, and fully construct a contained greenhouse.
- Three categories have been created for GE plant experiments. -

Category A- covers the common cloning of specified genes, non-coding DNA segments, and open reading frames of defined genes in hosts like E. Coli or other bacteria or fungi. These are all universally acknowledged to be non-toxic to humans, animals, plants, and the environment.

Category B- Includes research done using defined DNA pieces that are not harmful to humans or animals for genetically modifying plants including crop species and modal species in labs and greenhouses or net houses.

Category C- Contains high-risk experiments where the spread of new genetic features the result of which cannot be fully predicted could lead to a performed change in the biosphere the equal system of plants and animals. This also covers the high-risk experiment carried out in the greenhouse and under open field conditions.

6. National Seed Policy, 2002: Section number 6 of the national seed policy talks about transgenic plant varieties. Before the commercial release of transgenic crop varieties in the market, their agronomic value should be tested for at least two crop seasons by the ICAR (under All India Coordinator Trial), in coordination with the test for "Environment and Biosafety Clearance, EPA".

"The Ministry of Agriculture" and "State Department of Agriculture" continuously evaluate the performance of transgenic cultivars after their commercial release for a minimum of three to five years. Like non-transgenic varieties, transgenic varieties may be protected under PVP regulations following their introduction for commercial cultivation.

VII. BIOSAFETY REGULATION IN CHINA (PEOPLE'S REPUBLIC OF CHINA)

The Protocol was ratified by China on April 27, 2005. Chinese rules that are compliant with the Biosafety Protocol are being developed and implemented under the direction of the Ministry of Environmental Protection (MEP).

1. Acts, Rules, Procedures, and Guidelines governing transgenic crops in China are-

- Agricultural Biological Genetic Engineering Safety Administration Implementation Regulation, 1996
- This Regulation seeks to minimize potential risks posed by GMOs and their products to human health and the environment, both of which are necessary to sustain human life and the balance of agricultural ecology. It also increases safety administration and encourages research and development in the field of agricultural genetic engineering in China.
- Agricultural Transgenic Biosafety Administration Regulation, 2001

- These have been developed to improve the safe administration of GMOs, preserve the environment, promote research on agricultural GMOs, and defend the health of people, animals, plants, and microbes.
- Implementation Regulations on Labelling of Agricultural Genetically Modified Organisms, 2004
- According to the legislation, any agricultural GMO that does not have a label or whose label does not comply with certain implementation regulations will be prohibited from import or marketing.
- Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms, 2004
- It addresses the import of agricultural GMOs for use in cultivation, research, and testing, as well as for commercial use and as a raw material for processing.
- Technical Standards for Agricultural Biosafety, 2003-06
- Regulation on Inspection and Quarantine of Import and Export of Genetically Modified Commodities, 2004
- Regulation on Inspection and Quarantine of Import and Export of Genetically Modified Commodities, 2004
- Measures on Approval of Agricultural Genetically Modified Organisms Processing, 2006
- Decree 10 (CH7053) Labelling Regulation, 2007
- The appropriate labelling style and the precise wording that must appear for each label, are specified in the regulation.
- Implementing Rules for the Regulations of the People's Republic of China on the Protection of New Varieties of Plants (Agriculture Section), 2011

VIII. BIOSAFETY REGULATION IN THE USA

Three regulatory organizations—the "Environmental Protection Agency (EPA)", the "Food and Drug Administration (FDA)", and the USDA (dept. of Agriculture) are charged with regulating transgenic crops in the United States. The Coordinated Framework for the Regulation of Biotechnology, released in 1986, outlines the fundamental federal policy of the organizations (USDA, FDA, and EPA) engaged in biotechnology research and production.

"The Animal and Plant Health Inspection Service (APHIS)" and the USDA "Biotechnology Regulatory Service (BRS)" under the Federal Plant Protection Act are responsible for releasing field experiments, interstate travel, and import of GM plants into the USA. The USDA adopted a new biotechnology framework in 2020 called "Movement of Certain Genetically Engineered Organisms" (also known as the "SECURE" Biotechnology Regulations which stands for the "Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient Rule"), which seeks to reform and update the Plant Protection Act by excluding outmoded procedures and adding biotechnology requirements.

EPA controls GM plants with pesticidal substances, including Bt toxins, under the "Federal Insecticide, Fungicide, and Rodenticide Act" (FIFRA, 2020), "Federal Food Drug and Cosmetic Act" (FDCA, 1938), and "Toxic Substances Control Act".

FDA regulates food safety under the "Federal Food Drug and Cosmetic Act" (FFDCA), according to which substances that are "generally recognized as safe" (GRAS) are

exempted from food additives and this type of GM crops are exempt from pre-market review under this Act. However, the FDA has the power to impose more stringent FFDCA standards that call for the pre-market clearance of all food additives, regardless of whether they were created using biotechnology. This is because if the introduction of a transgene into a food crop result in the production of foreign proteins that differ significantly from native plant proteins in terms of their structure, function, or quality and may be harmful to human health, this might be a problem.

IX. BIOSAFETY REGULATION IN BRAZIL

Brazil passed “Law No. 8.974” in 1995, establishing requirements for human and agricultural genetic engineering's safety and inspection. Its goal is to protect the well-being of humans, animals, plants, and the environment. It identifies manipulation techniques that are not permitted.

A rule governing the labeling of food and food products intended for human consumption, as well as animal feed, when they include or were produced using genetically modified organisms was implemented in 2003. (GMOs).

Brazil established "CTNBio" in 2005 by "Law No. 11.105" to establish criteria for laboratories and authorization methods for genetically modified organisms (GMO) studies, manufacturing, and marketing, restrictions on their release into the environment, and norms for their cultivation, guidelines for reporting their official launch, safety checks and surveillance of GMO scientific research and their marketing release, implementing authorities, and licensing procedures for their release. It outlines the penalties for both criminal offenses and administrative infractions. There are about fifty GMOs whose commercial use “CTNBio” has been approved.

The Brazilian Biosafety Law ("Law No. 11/105" of March 24, 2005) was a key regulatory tool in setting the safety standards and inspection procedures for operations using GMOs and their byproducts. A previous biological safety legislation (Law No. 8974, of May 1, 1995), which was largely passed to manage the first promotional planting of glyphosate-resistant GM soybean in 1998, was completely and complementarily replaced by Decree No. 5.591, which was published on November 22, 2005.

The “National Technical Biosafety Commission” (CTNBio), the “Local Biosafety Committee” (CIBio; in Portuguese “Comisso Interna de Biossegurança”), the “National Biosafety Council” (CNBS), and the “Organizations and Entities for Registration and Fiscalization” (OERF; in Portuguese “Órgãos e Entidades de Registro e Fiscalizaço”), consists of the Secretariat of Aquaculture and Fisheries, the Ministry of Health (MS), the Ministry of the Environment (MMA), and the Ministry of Agriculture, Livestock and Supply (MAPA)., are the four primary organizations designated under the Biosafety Law as being in charge of risk assessment and management.

1. **Council for National Biosafety (CNBS):** The National Biosafety Policy is developed and put into action by the President of the Republic with the help of CNBS, which establishes guidelines and standards that include socioeconomic, political, and

opportunities of national interest connected to the commercial use of GMOs and associated goods.

2. **Commission for National Technical Biosafety (CTNB):** The "Ministry of Science, Technology, and Innovation" (MCTI; in Portuguese, Ministerio da Ciencia, Tecnologia e Innovacés), which aids the federal government in creating, updating, and offering technical and technical support, is affiliated with the multidisciplinary advisory and consultative college known as "CTNBio." provides support establishing a national biosafety policy to guide the creation of GMO products or biotech items that could lead to GMOs. Additionally, it outlines the requirements for technical safety that must be completed before research-related activities and the commercial release of GMOs are authorized. The responsibility for assessing the dangers that GMOs represent to zoo-sanitary, phytosanitary, human health, and environmental systems falls to CTNBio. Additionally, it creates risk management guidelines and grants the institution in question the Biosafety Quality Certificate, which is required for CIBio to function by legal requirements.

3. **Local Biosafety Committee (CIB):** Any organization, whether public or private, that uses genetic engineering methods and techniques to produce biotechnological goods that, at some point during their development, may end in a GMO, is obliged to establish a CIBio, which must be made up of individuals with the requisite training and education in the domains of biotechnology, genetic engineering, biosafety, or other pertinent professions.

4. **Registration and Inspection Organizations and Entities (OERF):** OERF is tasked with monitoring GMOs and their by-products by “Law No. 11/105”, within its purview, and by the decisions and technical opinions of “CTNBio”.

X. BIOSAFETY REGULATION IN ARGENTINA

Argentina enacted the first law in the world in 2015 (Resolution 173/2015) that describes how crops grown using gene editing techniques are regulated. On a case-by-case basis, CONABIA (Argentina Biosafety Commission) evaluates genetically modified crops and must report within 60 days whether the organism will be subject to GMO regulations.

Governing bodies/agencies for assessing are - “Comisio´n Nacional Asesora de Biotecnologı´a Agropecuaria”(CONABIA), “Servicio Nacional de Sanidad y Calidad Agroalimentaria” and “Instituto Nacional de Semillas, Direccion Nacional de Mercados Agroalimentarios”. While the Regulations/laws to regulate GMO crops are- Argentine Food Codex Law 18284 Decrees 1585/96, 4238, 815/99, 289/97, 511/98, and 1265/99 are examples of decrees.

XI. BIOSAFETY REGULATION IN THE EU (EUROPEAN UNION)

The foundation for the EU's regulation of GMO is laid out in Directive 2001/18/EC, Regulations (EC) Nos. 1829 and 1830/2003, Regulation (EC) No. 1946/2003, Directive 2009/41/EC, and Directive (EU) 2015/412. (European Commission, 2020).

"Regulation (EC) No. 1829/2003" restricts the entry of Transgenic organism into the European Union and requires that producers of GM plants and products label food containing more than 0.9% of GMOs, notifying consumers of the processes for its detection. This was done to allay the concerns of the European community regarding transgenic food and feed. "Regulation (EC) 1830/2003" was enacted by the European Parliament and EU Council to ensure that customers are informed about the use of GMOs in products and can make an informed purchase decision. This law also controls labelling and traceability "Directive 2009/41/EC" Supplementary "Directive 2001/18/EC" mandates mandatory monitoring after the commercial introduction of transgenic goods and requires EU members to produce information outlining their perspectives on the product to submit a report today every three years along with risk analysis, mishaps, an inspection of compliance measures, public consultations, and disposal of wastes (European Commission, 2012).

XII. CASE STUDIES

1. **Bt pollen effect on monarch butterfly:** In 1999, the monarch's issue became public. In an early laboratory investigation, milkweed leaves infected with pollen from Bt maize plants were discovered to be capable of killing monarch caterpillars that ate on them.

   Subsequent research along with the initial research in the large-scale field and laboratory conditions demonstrated that pollen from genetically modified (GM) corn plants that contain the Bt toxin does not pose a substantial threat to North American monarch butterflies (*Danaus plexippus*). The reason was also identified as due to quite heavyweight pollen, it doesn't fly long distances. Ultimately low toxicity and a lower rate of exposure results in the negligible effect of Bt corn pollen from common commercial Bt hybrids on monarch butterflies. "Knockout" variety of corn, developed by Syngenta was found harmful to another American butterfly (Papilio *polyxenes*). But due to the unpopularity of this variety, only 2% of contributions to the annual US corn crop and finally withdrawn by the manufacturer, couldn't cause many losses to butterflies.

2. **Release of Bt Cotton in India:** India approved the first release of bt cotton into the environment in 2002. The environmental assessment of Bt cotton hybrids have been done by extensive research on pollen escape mechanisms, weediness out-crossing, and aggression, impact on unintended organisms, Cry1AC protein impact on soil microorganisms, validation of the non-presence of terminator genes, and baseline sensitivity studies. According to studies on the effect on non-target insects and the presence of Cry1A, the Bt cotton hybrids have no harmful effects on them, such as sucking pests. The number of tobacco caterpillars, a secondary lepidopteron insect, was remarkably low throughout the research period in both Bt and non-Bt hybrids, according to extensive field studies at numerous locations. Spiders and ladybugs continued to exist in both Bt and non-Bt varieties. Bt cotton seed meal is just as nutrient-dense, healthy, and secure as non-Bt cotton seed meal, according to feeding trials on fish, birds, cows, and buffaloes. The biosafety and biosecurity of the Cry1Ac protein were supported by the results of the animal (mice) acute oral toxicity experiments. Even at very high dose levels (4200 mg/kg body wt.), no detectable acute effects were observed in mice given the Cry1Ac protein orally. Additionally, this large dose cannot exist in nature.

3. **Round-up Ready variety of Canolas in Australia:** In 2003, the Australian Gene Technologies Regulator approved GM canola which was herbicide-tolerant for commercial distribution. Bayer attempted to market the transgenic canola seed in Australia as Canola was manufactured using a brand-new hybrid generation system in Vigor. Male sterility (MS) line of canola that had the male sterile gene (barnase) and a fertilization restorer (RF) line that contained the fertility restorer gene served as the foundation of this system (barstar). Plants with MS restrict the growth of the anthers, the portion of canola flowers that produce pollen. When an MS line and an RF line are crossed, the suppression is overridden and the offspring become viable. The offspring were predicted to exhibit "hybrid vigor," or improved agronomic performance. was first made in a commercial setting in 2008. The following possible risks have been identified:

   - Herbicide resistance;
   - weediness;
   - toxicity and allergic effect for humans;
   - transfer of injected genes to other organisms feeding on them;

   According to numerous evaluation studies, it was highly improbable that GM canola would be more harmful or allergic to people or other animals than normal canola. As a result, it was decided that there were very few hazards and that no management restrictions for probable toxicity or allergenicity were essential. When the chemical glufosinate ammonium was not present, the inserted genes did not provide a selective advantage. It may still be possible to control canola plants that are resistant to both glufosinate-ammonium and glyphosate by using other legal herbicides or mechanical techniques.

4. **Release of Bt Brinjal in Bangladesh:** The fruit and shoot borer (FSB), *Leucinodes orbonalis*, a significant production limitation for brinjal, is protected against by an extra gene found in Bt brinjal or eggplant. A novel DNA construct was created by MAHYCO (Maharashtra Hybrid Seed Company Ltd, Jalna, India) that encodes an insecticidal protein in all tissues of the brinjal plant throughout its life. The Bt brinjal seeds were purchased by the Bangladesh government from MAHYCO and grown in greenhouses at the BARI's seven regional stations in the districts of Jamalpur, Dinajpur, Bogra, Tangail, Mymensingh, Rangpur, and Jessore. The trial's findings showed that Bt brinjal had a significant increase in yield, a significant decrease in the pest population, and no negative effects of transgenic protein on the health of people or animals fed on it. Tests to determine if Bt brinjal is safe for eating by humans revealed that it is largely equal to food and feed made from non-Bt brinjals.

XIII. CONCLUSION

The above four case studies over a different period have been chosen for demonstration of GMOs by risk assessment approaches. There is no significant hazard is caused due to transgenic gene transfer to biodiversity. A large number of nations, having different regulations and designations, possess an overall positive attitude towards this technology. Although, Cisgenesis and intragenesis can be alternatively used in place of transgenics where the genes to be introduced are taken from their gene pool or sexually

compatible plant species. Cisgenics have more public acceptance than transgenics, as proved in many surveys conducted worldwide.

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