Journal of Management & Public Policy,
Vol. 15, No. 1, September 2023, Pp. 16-32
ISSN 0976-0148 (Online) 0976-013X (Print)
DOI: https://doi.org/10.47914/jmpp.2023.v15i1.002

A Critique of Biosafety Governance in Genetically Modified Crops

Vembanan Gunasekaran*

ABSTRACT

The benefits of the technology and the assurances to contain the biosafety risks evolved by the international protocols favoured the release of Genetically Modified crops (GM) crops in the environment. The biosafety proposals established in the international forum is a managed norm after negotiations where the perception of benefits outweigh the risks it could pose to environment and human health. The differing perception of nations over the risks of GM crops and their acceptance to a global norm after protracted negotiations not only signifies the hierarchical power relations exist among nations but also the differing research capabilities of nations, their governance structure, and their socio-economic conditions to manage the risks. The perceived risks and benefits of GM crops is still a contested debate where the relations of technology with politics, policy and economy have come nearer and entangled.

KEYWORDS: Genetically Modified Crops (GM Crops), Biotechnology, Policy, Biosafety Governance, Risks

* Assistant Professor, Department of Political Science, Ramanujan College (University of Delhi), New Delhi, India **E-mail:** v.sekaran@ramanujan.du.ac.in

INTRODUCTION

The Genetically Modified (GM) crops[1] is a technological advancement in the field of biotechnology to mitigate and address issues of agriculture. The GM crops has been endorsed by many developed countries, Food and Agricultural Agency (FAO) and Codex Alimentarius for its benefits and as an innovative scientific intervention in agriculture. The debate on the biosafety issue is argued to be convincingly settled by the international protocols but still many nations have not accepted GM crops due to its perceived risks which could sooner or later harm the environment and human health. The research paper analyses the biosafety debates of GM crops from the Asilomar conference to the various international protocols evolved until the recent times. It is argued in the paper that biotechnology research and its products is a highly regulated science and technology which is promoted with accepted difference on the issues of biosafety. The study of international protocols evolved is an interplay of power politics which is rooted in the scientific capabilities of nations to withstand risks of GM crops if any in future and their concerns on environmental, socio-economic, and political realities which could influence the lives.

THE ORIGINS OF BIOSAFETY CONCERNS IN BIOTECHNOLOGY

In the 1970s and 1980s during the initial development phase of biotechnology, it was marked by doubts about its use due to apprehensions of safety associated inside the lab and its release in the environment. In 1969, the scientists of Harvard Medical School namely Jonathan Beckwith, James Shapiro and Lawrence Eron raised public awareness about the safety and benefits of biotechnological research through press conference (Beckwith, 2007).

[1]"Genetically modified organisms (GMOs) can be defined as organisms (i.e., plants, animals, or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. The artificial process or the new technique is often called as "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, also between nonrelated species. Foods produced from or using GM organisms are often referred to as GM foods" (World Health Organization, 2014).

There were many public events, conferences, and media publicity to raise awareness about the biotechnology research in laboratory and its potential benefits to the human society. It was believed that if biological and physical barriers are erected to contain the risks of the GM crops it can be of better use to the public. An important conference was held in 1973 at the Asilomar Conference Centre, Pacific Grove, California, USA which discussed the hazards for the technicians working inside the lab on tumour viruses. The conference agreed to bring in an informed consent for the lab workers and to have continuous monitoring of the risks involved in the lab and for the people who research in the lab. There was also a conference held in the same year at Gordon to discuss the effects of introducing viral DNA into bacteria.

The precursor to the Asilomar Conference II in 1975 was the risk concerns evoked by Janet Mertz, a graduate student at Stanford University and pupil of Paul Berg, in transporting animal tumour virus into bacteria. Paul Berg, who was one of the main organizers of the Conference, initially took the potential risks very casually, but when he discussed it with his colleagues, he understood the potential nature of the risks involved in transporting genes into various species which paved way for taking a strong stand in the conference (Krimsky, 2005). It was generally agreed in the Asilomar Conference II that the research should continue, but with a lot of stringent restrictions so that no organism escape the lab and cause any disturbance in nature. The organizers of the Conference claimed that the risks and fears of biotechnology research would be presented to the larger public and assessed how it should be taken forward. The Conference agreed upon to evolve a general guideline for the scientific communities engaged in biotechnology research.

THE PROMOTION OF BIOTECH RESEARCH IN UNITED STATES OF AMERICA

The US government in 1970 created the Environment Protection Agency to facilitate the introduction of new technologies and address concerns like assessing technology, science, and environmental planning. The US government also created an Office of Technology Assessment in 1972 to assess the science and technology which impacts the human beings and to serve the policy makers in devising new policies on science and technology. The National Institute of Health (NIH), under the U.S. Department of Health and Human Services, Maryland, pursued the recommendations sent by Asilomar Conference II to draft guidelines for conducting r-DNA (recombinant- Deoxyribonucleic acid) research. Accordingly, the NIH

convened the DNA Advisory Committee (RAC) in 1975 to draft guidelines for the research. The director of NIH, Dr. Fredrickson, announced the guidelines in July 1976 for in-house research in r-DNA. The guidelines put in place strict procedures to be adopted inside the lab and devised various levels of physical containment for pursing the r-DNA research. The announcement of the guidelines created a perception among the public that the risk associated with molecular research inside the lab was settled and it was safe. The release of biotechnology products in the environment was still not a settle debate in the 1980s. It was considered that the biotech products especially in transgenics crops have to be studied for the following risk factors:

"(a) Short- and long-term interaction between the transgenics and the environment.

(b) Development of allergens to human/animal health, including changes in phenotypes and altered immunity.

(c) Effect on soil and water.

(d) Loss of genetic biodiversity and gene flow to wild relatives or to non-transgenic varieties.

(e) Reduction in the efficacy of pesticides, insecticides and weedicides, and production of novel toxins and development of resistance or tolerance.

(f) Production of new pathogens/ bacteria/viruses" (Kochhar, 2012).

The National Academy of Sciences[2] in its first report on GMO research claimed, "there is no evidence that unique hazards exist either in the use of r-DNA techniques or the movement of genes between unrelated organisms. The risks associated with the introduction of r-DNA engineered organisms are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods" (National Academy of Science, 1987). The subsequent reports released in 1987 and 1989 confirmed that the risks associated with GMOs should not be accessed at the process but from the perspective of the product as a whole and claimed that the transgenic plants are not different from the normal plants.

[2]It is a private, non-profit association established by the Act of Congress, USA in 1863. Its members are scientists across the world; who are pioneers in the field of scientific research. Its headquarters is established in Washington D.C., USA.

The guidelines of the US government agencies are not mandatory for the private industry; it was made 'voluntary' in the 1980 revised guidelines of the NIH (Krimsky, 2005). The guidelines which were made 'voluntary' by NIH lost its validity by the declaration of Food and Drug Administration, under the U.S. Department of Health and Human Services, in 1992 that GMOs which are classified as foreign genes inserted into any organism or in food production as food additives are safe for human consumption. The successive US governments continued to promote GM crops and considered GM crops as safe for human consumption. The vigour and steadiness of the scientific opinion held by the US government on GM crops has continued till date and influenced other countries and various other international agencies to adopt its policies on biotechnology research. The international agency like Codex Alimentarius even though has huge membership across the world was not able to challenge the scientific rationale of US on GM crops but rather facilitated to adopt scientific rationale of US on biotechnology research.

CODEX ALIMENTARIUS

The FAO and WHO held several combined discussions on bringing in world food safety standards, protecting consumer health and removing trade barriers which gave rise to Codex Alimentarius in 1963. The agency is headquartered in the buildings of FAO, Italy, Rome. It has 188 members and one institutional member, viz., The European Union (FAO, 2019). The organization is headed by Codex Secretary, jointly appointed by the Director Generals of FAO and WHO. The FAO funds two-third of the expenditure of the agency and the WHO funds one-third of the expenses of the agency (Kimbrell, 2000). The Secretariat consists of small team of professionals, technical experts, and support staffs. The Executive Committee of the agency is the most vital wing which takes decision on important policy issues and programs of the agency. The Executive Committee consists of Chairperson and Vice-Chairperson of Codex, one member from each geographical location identified by Codex viz., Asia, Europe, Africa, Latin America and the Caribbean, Near East, North America and South West Pacific. There are various committees like General Subject Committee, Commodity Committee and Electronic Working Groups which takes assignments according to the direction of the Executive Committee.

Codex is a voluntary organization which has produced number of reports on the safety of foods for human consumption. The reports were very helpful for countries to establish food safety standards and to solve issues in international trade of food materials. The incorporation of its standards in WTO under Sanitary and Phytosanitary (SPS) measures have made the agency as legal entity since the members of WTO are bound by its policy on food standards. The standards of Codex on "food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice" (Winickoff and Bushey, 2010) had become part of WTO regulations which binds member nations. The success of developed countries in incorporating the norms of Codex in WTO has universalized the scientific rationale of food standards. The member nations of WTO have to abide by the policies of Codex which leaves no room for the developing countries to establish a scientific rationality beyond the senses of Codex. The member nations must abide by the procedures established by the Codex agency, any stern food safety measures apart from the Codex, has to be verified scientifically and approved before being implemented in trade between nations.

Codex has a set of standards for the products of biotechnology especially the GM crops (Codex Alimentarius, 2009). The agency treats the products of GM crops at par with the non-GM crops. Codex agrees that there are no internationally established procedures to access GM foods and label them; it is left to the individual governments to have their own procedures (FAO, 2017) but must match the scientific standards of Codex. FAO which is one of the prime sponsors of Codex maintain that “FAO supports a science-based evaluation system that would objectively determine the benefits and risks of each individual GMO. This calls for a cautious case-by-case approach to address legitimate concerns for the biosafety of each product or process prior to its release” (FAO, 2019). The GM product released after rigorous scientific process also necessitates continuous scientific monitoring to prove its use or ban. The responsibility of continuous monitoring the biotechnology products is not fixed anywhere in the guidelines of Codex.

BIOSAFETY DISCUSSIONS IN UNITED NATIONS

The conservation of nature is always being one of the major concerns of UN for the sustainable use of resources and preservation for future generations. The consistent efforts

of the UN have resulted in nations recognizing their equal responsibilities and duties towards nature and this is also reflected in its cautious approach behind supporting GM crops. It has stressed the developed countries to reach an understanding that nature at the present level of exploitation would not be able to sustain for future generations. It is also made evident by the agencies of UN that the riches of the underdeveloped states cannot be exploited by the developed states just because of them having high end technologies (McIntyre, 2009). A trajectory of events and the efforts of concerned nations have resulted in establishing many institutions to protect nature. The establishment of the United Nations Environment Programme (UNEP) in 1972 was meant to bring out the importance of environment in the overall well-being of all nations and to create mechanisms to rectify the uneven exploitation of the environment by any nation. The UNEP's report of *World Conservation Strategy* in 1980 ignited the government policy makers and private companies to conserve nature and maintain essential ecological process of nature (Banerjee, 2009). The *Brundtland Commission Report* (1987) titled its report as "Our Common Future" which has categorically emphasised that there should be a limit agreed upon to exploit nature. There are also various attempts on the conservation of various forms of lives on earth such as "the Convention on Wetlands of International Importance especially Waterfowl Habitat 1971 (Ramsar Convention) and the Convention Concerning the Protection of the World Cultural and Natural Heritage 1972 (World Heritage Convention) and two species-specific instruments, the Convention on International Trade in Endangered Species of Wild Fauna and Flora 1973 (CITES) and the Convention on the Conservation of Migratory Species of Wild Animals 1979 (Bonn Convention)" (Lakshmanan, 2018).

The sensitisation of UN was growing along with the introduction of various new technologies which promised to mitigate the exploitation of environment and increase its sustainability. The GM crop is one of the new technologies endorsed by UN to increase yield of crops and establish sustainability in the use of environment. The technology is even though mired with concerns of biosafety due to the unpredictable natural condition it might establish in the future, it is promoted by UN that the hazards of GM crops cannot be the excuse to postpone the benefits of the technology. The UN professed that the benefits of the technology cannot be postponed due to lack of scientific certainty. The Cartagena Protocol on Biosafety, argues that "biosafety is a term used to describe efforts to reduce and eliminate the potential risks

resulting from biotechnology and its products. For the purposes of the Biosafety Protocol, this is based on the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage" (CBD, 2017).

THE EVOLUTION OF BIOSAFETY NORMS

The biosafety concerns of GM crops were discussed in the Convention of Biological Diversity, CBD (1992) and it conveyed to the world that GM crops could be handled very safely by erecting safety mechanism and continuous monitoring for any hazards. Article 19 of the Convention discussed on various aspects of biosafety which is titled as "Handling of Biotechnology and Distribution of its Benefits". It discusses about the sharing of benefits and regulating the risks related to release of GM crops in the environment. The Convention requires each party to evolve policies on biotechnology research especially the developing countries to protect its genetic resources being used by others in the research. It also provided for the agreements between parties in exchange of genetic materials, safe transfer, and handling of any genetically modified organisms.

The Convention of CBD pursued the biosafety aspects of the technological advancement in biotechnology which resulted in the establishment of Cartagena Protocol on Biosafety (CPB) in 2003. "The Protocol seeks to protect biological diversity from the potential risks posed by living modified organism resulting from modern biotechnology. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol contains reference to a precautionary approach and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a Biosafety Clearing House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol" (CBD, 2017). The theoretical aspirations aimed in the CBD were given shape in the CPB in establishing a safe path to use biotechnology products. The protocol provides for an Advance Informed Agreement, Biosafety Clearing House, Capacity Building, Compliance Procedures, Liability and Redressal Mechanisms and various other enhancing mechanisms to adopt biotechnology products to its best use. The structural

arrangements proposed by the protocol give special emphasis to the developing countries to establish structures and optimize benefits of the biotechnology research.

The CPB aims to protect biodiversity of all states including even who are not party to it. It lay down that the parties are responsible to convey clearly what could be hazards due to genetically modified organisms for the non-parties and to assist them in case of any adversaries caused due to it. The protocol also encourages the non-party states to adopt and establish structures to make use of the potential of biotechnology research. The Conference of the Parties (COP) 10 to the CBD held in Nagoya, Aichi Prefecture, Japan in October 2010 adopted the Nagoya Protocol on Access and Benefit Sharing (ABS), a supplementary agreement to the CBD which sought to provide a transparent legal system for the use of genetic resource and compensatory provisions for states that experienced any hazards due to genetically modified organisms. "The Supplementary Protocol aims to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures for liability and redress in the event of damage resulting from LMOs. The Supplementary Protocol reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development and recognizes the need to provide for appropriate response measures where there is damage or sufficient likelihood of damage, consistent with the CPB" (Government of India, 2012).

The parties to the protocol are obligated to evolve governing administrative structure to give shape to the provisions of the article. The COP is continuously monitoring the policy developments brought in by parties and hold regular meetings to evaluate them. The protocol even though aims to create an equal benefit sharing and protection of biosafety, it has come under criticism from various circles. Scientists and private research agencies have regarded stricter guidelines of the protocol as a major challenge to initiate researches and bring in products useful to the public (Cressey, 2014). The western countries too are dismayed that the provision of the protocol is biased towards the developing countries in protecting biodiversity (Harrop and Pritchard, 2011). The developed countries also exhibited reluctance to accept the civil liability provision (Nijar, 2013) of the supplementary protocol of CPB known as "Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress". The protocol

was adopted on 15th October 2010 and came it force on 5th March 2018(Cartagena Protocol on Biosafety, 2000).

THE EVALUATION OF THE UN PROTOCOLS ON BIOSAFETY

The Convention of Biological Diversity (CBD) 1992 and its protocols were "negotiated at a time when the loss of species, pollution levels and climatic changes were reported to be alarmingly high, and when biotechnology was demonstrating its new possibilities and biopiracy had become the order of the day"(Lakshmanan, 2018). The United States which led the biotechnology industry was not party to the CBD. The non-signatory position of USA in CBD excluded it to be a party to neither CPB nor Nagoya protocol nor the supplementary protocol of Nagoya-Kuala Lumpur. Nevertheless, USA played a very active role as an observer at these forums to evolve a regulatory framework which is more acceptable in the world market and compliant with various other regulations like the Sanitary and Phytosanitary Measures (SPS) under WTO (Gupta, 2000). The concerted effort of USA was also aimed to fuel down the organized opposition to biosafety of GE crops" (National Academies of Sciences, 2016). The international regulatory framework is even though the handiwork of the developed countries it was also a demand from the developing countries regarding the safe and informed use of GMOs in international trade since they do not have any capacity to withstand the threats nor regulatory mechanism to safeguard the threats of GM crops (Aarti Gupta, 2000).

The international governance of GM crops is a deeply contested framework due to "the existence, nature and manageability of risks associated with modern biotechnology" (National Academies of Sciences, 2016). The negotiations on CPB witnessed emergence of various interest groups each representing different degrees on the biosafety of the GM crops. There were five major negotiating groups- the Miami Group (Argentina, Australia, Canada, Chile, Uruguay and the USA), European Union, Like Minded Group (almost all the developing countries), Compromise Group (Norway, Switzerland, Singapore, New Zealand and Mexico) and Central and Easter Europe- representing their domestic concerns (B.C. Nirmal, 2004). The major reason for the evolvement of various positions by groups on the biosafety of GM crops was centred on the "safe development and application of GMOs, and their safe handling, transfer and use" (Hamdallah Zedan, 2002). The difference of position on the biosafety of GM crops "makes the politics of this case more complex – and more interesting – is the fact that

concerns about the impacts of GMO/LMO products on human health and the resilience of ecosystems have given rise to major East–West differences as well as North–South differences" (Oran R. Young, 2008).

The interest groups in the CPB negotiations exhibited varied positions on the application of precautionary principle[3]. Their positions were largely shaped by the perceptions on GM foods, trade prospects, research capability in biotechnology and the unpreparedness and weak regulatory framework of the developing countries to manage the risks of GM crops. The Miami group supported a limited scope for the precautionary principle, the EU argued for a stringent precautionary principle, Like Minded Group for an inclusive scope, the Compromise Group took a middle position and the Central and the Eastern European Group supported the EU and the Compromise group on precautionary principle and various other biosafety issues (B.C. Nirmal, 2004). The "application and definition of the precautionary principle, as compared to full scientific proof, as well as the relationship of the Protocol with the international trade regime, led to protracted negotiations which were resolved only at the end of the conference, when many of the delegations had been joined by ministerial representatives" (Robert Falkner, 2000).

Ronald J Herring argues that "Articles 10.6 and 11.8 of CPB explicitly privilege precautionary logic: Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on biodiversity, taking into account risks to human health, shall not prevent a Party of import from taking a decision, as appropriate, with regard to the import of the LMO in question, in order to avoid or minimize such potential adverse effects" (Ronald J Herring, 2010). He argues that Cartagena Protocol on Biosafety (CPB) created "highly specialized regulatory nodes,

[3]Precautionary risk regulation acknowledges the inherent uncertainty involved in scientific debates on GMO risks and considers risks not only to ecological systems and human health but potentially also to cultural, social and economic systems. (Falkner). It is basically a position of scientific uncertainty which can prohibit or inhibit a nation to adopt or ban any technology until it is evident that it is free from any risks to human health and environment.

producing administrative choke points" and "legitimized precaution concerning unspecified risks to human health, food safety, biodiversity, and ecological integrity" (Ronald J Herring, 2010).Martin Qaim (2016) argues that the acceptance of precautionary principle in CPB protocol have fuelled the risks associated with GMOs and single out the technology over other biotechnology applications.

The opposition to the precautionary principle by the Miami group is based on the scientific assumption that the GMO derivatives are 'substantially equivalent'[4] to the normal food which does not need any biosafety regulation. The European Union does not agree on the argument of USA to treat GMOs as 'substantial equivalent' to the normal crop or food. It argued for stringent regulatory policy which hails that the provision of the precautionary principle in the CPB as a 'signal achievement' which would be helpful for to legitimize its domestic regulation (Aarti Gupta, No. 24, 2000). The precautionary principle in the protocol can be invoked by parties in case of scientific proofs on risks associated with GMO products. The precautionary principle is also part of SPS-WTO agreement but must be revoked in a time bound manner whereas the CPB protocol is not time bound (Aarti Gupta, 2013). USA argued for a 'saving clause' which would not affect the other international trade and environment agreements and keep CPB at par with other agreements. It was not successful to establish the same in the CPB protocol but was managed to incorporate it in the preamble. The preamble states that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements," which also paved way for EU to incorporate its position in the preamble which states that "the above recital is not intended to subordinate this Protocol to other international agreements". Thus, the final protocol was

[4]It stipulates that any new GM crop technology should be assessed for its safety by comparing it with an equivalent, conventionally bred variety that has an established history of safe use. (Torbjörn Fagerström et al. "Stop Worrying: Start Growing". *EMBO reports,* 13(6), 2012, 493–497)

able to enshrine the divergent views of dominant groups and resulted in a balancing act which saved the protocol from failure but depends on how it is going to be interpreted and practiced in the future affairs of GMOs (Aarti Gupta, 2013).

THE POLITICS OF PUBLIC POLICY

The incorporation of precautionary principle in CPB protocol indicated that science, technology, policy, and politics interact very closely to evolve global governance structure of GMOs. The negotiations on the precautionary principle formed the basis for the nations to agree upon various guidelines evolved in the CPB. The Advanced Informed Agreement (AIA) operationalizes the biosafety guidelines agreed by the parties in the CPB protocol. The AIA seeks to strengthen the regulatory mechanism of the importing nations which "requires the exporter to provide detailed information about GMO exports and obtain an importing nation's approval for initial shipments of GMOs (Article 8 and Annex I). The importing nation is under the obligation to inform the exporter of its decision based on risk assessment, in accordance with the procedures set out in the Protocol (Articles 10–13 and 15; Annex II)" (Robert Falkner, 2000). The AIA procedure is not applicable to LMOs in transit, the transboundary movement of LMOs for contained use, LMOs intended for direct use of food or feed or for processing and LMOs cleared by the biosafety clearing house (Pushpa Kumar Lakshmanan, 2018). The above structure was accepted by protracted negotiations until the last hours of adopting the protocol since it is based on the level of acceptance of GMOs. The close examination of AIA reveals the perception of nations on GMO research and its products.

The various other provisions of the protocol like the risk assessment, risk management, unintentional transboundary of movements and emergency measures, handling, transport, packaging and identification, capacity building, illegal transboundary movements, liability and redress and monitoring and reporting are also places where the science and politics closely interacted to evolve guideline. The provisions of the protocol enumerate above are mostly procedural issues which are implemented by nations once they become party to it. The outright rejection of GMO products by a signatory party seems distant possibility since the risks of GMOs are not yet proved by any parties to the CPB protocol. The ban of GMOs in European Union has attracted economic sanctions which other nations will not be able to bear it (Aarti Gupta, 2008). The rejection of GMOs based on socio-economic consideration or

its challenge to biodiversity conservation or lack of infrastructure to regulate the risks of GMOs is assured to be taken care by the protocol through the provisions on capacity building "through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement" (Cartagena Protocol on Biosafety, 2000) in the protocol.

The divergent view of EU and USA has influenced the international protocols on the biosafety of GMOs (Aarti Gupta, 2008). The transatlantic divide in the regulation of GMOs over the last two decades have also made each group to strengthen its stand over the years (Aarti Gupta, 2013). The US regulations were very stringent in the initial times of the emergence of biotechnology industry but transformed to be more liberal due to "the cultural account of government and business relations in international exports. Lobbying plays a large part in creating regulations, and effective lobbying is seen in the regulations of GE foods as companies and organizations spend millions of dollars a year to lobby against restrictive GE food regulations" (Katharine Gostek, 2016). Katharine Gostek argues that the European Union approach towards the GMO regulation is dominated by the public opposition towards GM food, and the failure to manage health issues such as mad cow disease, E-Cole, Salmonella and Dioxintainted products (Aarti Gupta, 2013). Matin Qaim argues that the stringent regulation of GMOs in Europe has evolved due to the "NGOs greater influence on policymaking processes since the mid-1980s. In addition, differences in farming conditions and consumer attitudes play a role" (Matin Qaim, 2016). Ronald J. Herring argues that the opposition to GM foods framed by groups were successful in influencing the EU regulations. The opposition groups were able to construct a negative frame of GMOs "not from science, but as a vector-sum of complex politics, including powerful influences of transnational social movements" (Ronald J. Herring, 2010).

The progress of GMOs in the two dominant nations of EU and USA signify that science is regulated at the level of society and economy. The regulations of science through society and economy are not fixed positions on each other and there were exceptions to it. The EU's stringent regulation on GMOs is not evident in pharmaceutical and even in some GM food import for feed. The ban of GMOs is continued to date even though the European Commission Report 2010 study argued that there are no health risks associated with the GM food. The

position adopted by EU cannot be taken by third wold countries since EU is not dependent on agriculture imports and ready to pay more for the type of food it wants from the global market. The USA position is dominated by the economic interest; it assures that it has a continuous vigil over the GM crops and ready to ban any GM crop which proves to be insecure to the human health and the environment. The maintenance of proactive approach towards GMOs and its reduced investment on scientific studies to identify risks does not substantiate its scientific position on GMOs. The study of Sheldon Krimsky on professional societies and scientific research papers have brought to the light that there are number of studies which confirm risks associated with GMOs. He also discussed the controversial case of Arpad Pusztai and Gilles-Eric Seralini to show the organized opposition from the proponents of GMOs to individuals which showed GMOs in poor light. He argued that "politics and corporate interests had distorted an honest inquiry into the health effects of GMO crops" (Sheldon Krimsky, 2015).

REFERENCES

Banerjee, Madhulika. (2009). United Nations Environment Programme: Rio, Johannesburg and after In Manisha Priyam, Krishna Menon and Madhulika Banerjee (Eds.), *Human rights, gender and the environment* (pp.205-218). Pearson.

Codex Alimentarius, *International Food Standards.* Retrieved 9, May 2019, from http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/

Codex Alimentarius. (2009). *Foods derived from modern biotechnology*, Secretariat of the Codex Alimentarius Commission.

Convention on Biological Diversity. *About the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress.* Retrieved 30, March 2021, from https://bch.cbd.int/protocol/supplementary/about/

Convention on Biological Diversity. *About the Protocol.* Retrieved 21, April 2017, from https://bch.cbd.int/protocol/background/

Convention on Biological Diversity. *Frequently Asked Questions (FAQs) on the Cartagena Protocol.* Retrieved 21, April 2017, from http://bch.cbd.int/protocol/cpb_faq.shtml#faq2

Convention on Biological Diversity. *Text on the Cartagena Protocol on Biosafety*. Retrieved 25, March 2021, from https://bch.cbd.int/protocol/text/

Cressey, Daniel. (2014). Biopiracy ban stirs red-tape fears. *Nature News,* 514, 7520, 14-15.

Falkner, Robert. (2000). Regulating biotech trade: The Cartagena Protocol on Biosafety. *International Affairs,* 76, 2, 299-313.

Food and Agriculture Organization of the United Nations. *FAO Statement on Biotechnology.* Retrieved 5, May 2019, from http://www.fao.org/biotech/fao-statement-on-biotechnology/en/

Gostek, Katharine. (2016). Genetically Modified Organisms: How the United States' and the European Union's regulations affect the economy. *International Law Review*, 24, 4, 761-800.

Government of India, Committee on Agriculture (2011-2012). (2012). *Cultivation of Genetically Modified Food Crops – Prospects and Effects*. Lok Sabha Secretariat.

Gupta, Aarti. (2000). Governing trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety. *Environment: Science and Policy for Sustainable Development*, 42, 4, 22-33.

Gupta, Aarti. (2008). Global biosafety governance: Emergence and evolution In Oran R. Young, W. Bradnee Chambers, Joy A. Kim & Claudia ten Have (Eds.), Institutional *interplay: Biosafety and trade* (pp.19-46). United Nations University Press.

Gupta, Aarti. (2013). Biotechnology and biosafety In Robert Falkner (Ed.), *The handbook of global climate and environment policy* (pp. 89-106). Wiley-Blackwell.

Harrop, Stuart R, & Pritchard, Diana J. (2011). A hard instrument goes soft: The implications of the Convention on Biological Diversity's current trajectory. *Global Environmental Change*, 21, 474–480.

Herring, Ronald J. (2010). Epistemic brokers, authoritative knowledge and diffusion of opposition to biotechnology: Framing the GMO In Rebecca Kolinsgivan Givan, Kenneth M. Roberts and Sarah A. Soule (Eds.), *The diffusion of social movements: actors, mechanisms, and political effects* (pp. 78-98). Cambridge University Press.

Interview with Dr. Jonathan Beckwith. (2007). *BioEssays,* 29, 1257-1268.

Kimbrell, Eddie (2000). What is Codex Alimentarius?, *AgBioForum*, 3, 4, 197-202.

Kochhar, VK, & Kochhar, Sunita. (2012) Need for management and risk assessment of Genetically Modified Organisms, *Current Science,* 102, 2, 167-168.

Krimsky, Sheldon. (2005). From Asilomar to industrial biotechnology: Risks, reductionism and regulation, *Science as Culture,* 14, 4, 309-323.

Krimsky, Sheldon. (2015). An illusory consensus behind GMO health assessment. *Science, Technology, & Human Values,* 40, 6, 1-32.

Lakshmanan, Pushpa Kumar, Implementation of the convention on biological diversity and its protocols in India In S. Burra and R. Rajesh Babu (Eds.), *Locating India in the contemporary international legal order* (pp.275-306). Springer Nature.

McIntyre, Beverly D, Herren, Hans R, Wakhungu & Judi, Watson, T (Eds.). (2009). *International Assessment of Agricultural Knowledge, Science and Technology for Development: Global Report.* Island Press.

National Academies of Sciences, Engineering, and Medicine. (2016). *Genetically Engineered Crops: Experiences and Prospects*. National Academies Press.

National Academy of Science, Committee on the Introduction of Genetically Engineered Organisms into the Environment. (1987). *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues*. National Academy Press.

Nirmal, B C. (2004). Overview of the biosafety protocol. *Journal of the Indian Law Institute,* 46, 3, 373-392.

Qaim, Matin. (2016). *Genetically modified crops and agricultural development*, Palgrave Macmillan.

Singh, Gurdial Nijar. (2013). The Nagoya–Kuala Lumpur supplementary protocol on liability and redress to the Cartagena Protocol on Biosafety: An analysis and implementation challenges. *International Environmental Agreements: Politics, Law and Economics,* 13, 3, 271–290.

Winickoff, David E, & Bushey, Douglas M. (2010). Science and power in global food regulation: The rise of the Codex Alimentarius. *Science, Technology, & Human Values*, 35, 3, 356-381.

Young, Oran R. (2008). Deriving Insights from the Case of the WTO and the Cartagena Protocol In Oran R. Young, W. Bradnee Chambers, Joy A. Kim & Claudia ten Have (Eds.), *Institutional Interplay: Biosafety and Trade* (pp. 131-158). United Nations University Press.

Zedan, Hamdallah. (2002). The road to the biosafety protocol In Christoph Bail, Robert Falkner and Helen Marquard (Eds.), *The Cartagena Protocol on Biosafety: Reconciling trade in biotechnology with environment and development?* (pp. 23-33). Earthscan.