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Legal Regime of Genetically Modified Food: Developing Country in the Context

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Abstract. Multiple challenges of Genetically Modified Organisms (GMOs) have led different countries to adopt quite different approaches for GM foods and crops. Among Developing Countries, In Bangladesh, commercial cultivation of GM crops is poised to receive approval, but the country faces constraints in reducing risks associated with the release and handling of GMOs. The primary goal of this study is to examine the various laws, policies, and regulations that Bangladesh has to regulate issues related to GM foods and to determine how current laws are applied to assess and manage risks associated with the introduction of GM crops. An analytical and qualitative approach was applied in this regard. In general, the concepts of intellectual property rights, trade, food safety, labeling, and public policy are relevant to GMOs. It is found that there are currently no laws enacted particularly to address the biosafety of GM crops and foods. Only the Biosafety Guidelines, a non-binding document, cover issues related to GMOs, but there is no effective enforcement. Apart from this, the Intellectual Property Rights Law does not comply with the requirements of TRIPS to address the environmental release of GMOs. Sanitary and phytosanitary regulation is very weak in enforcement. Additionally, the food safety law, labeling regulations, and risk assessment guidelines, principles of international environmental laws are not in application. This paper concluded that no comprehensive legal framework for dealing with biosafety-related issues exists. It recommends that Bangladesh should adopt a comprehensive law and policy governing biosafety.

Keywords: GMOs, Biosafety, CBD, Environment, Risk assessment

Abstrak. *Berbagai tantangan dari Genetically Modified Organisms (GMOs) telah menyebabkan berbagai negara mengadopsi pendekatan yang sangat berbeda untuk makanan dan tanaman GM. Di antara Negara Berkembang, Di Bangladesh, pembudidayaan tanaman GM secara komersial siap untuk menerima persetujuan, tetapi negara tersebut menghadapi kendala untuk mengurangi risiko yang terkait dengan pelepasan dan penanganan GMO. Tujuan utama dari penelitian ini adalah untuk menguji berbagai undang-undang, kebijakan, dan peraturan yang dimiliki Bangladesh untuk mengatur masalah yang berkaitan dengan makanan GM dan untuk menentukan bagaimana undang-undang saat ini diterapkan untuk menilai dan mengelola risiko yang terkait dengan pengenalan tanaman GM. Pendekatan analitis dan kualitatif diterapkan dalam hal ini. Secara umum, konsep hak kekayaan intelektual, perdagangan, keamanan pangan, pelabelan, dan kebijakan publik relevan dengan transgenik. Ditemukan bahwa saat ini tidak ada undang-undang yang diberlakukan secara khusus untuk mengatasi keamanan hayati tanaman dan makanan GM. Hanya Pedoman Keamanan Hayati, sebuah dokumen yang tidak*

mengikat, yang mencakup isu-isu terkait GMO, tetapi tidak ada penegakan yang efektif. Selain itu, Undang-Undang Hak Kekayaan Intelektual tidak memenuhi persyaratan TRIPS untuk mengatasi pelepasan transgenik ke lingkungan. Regulasi sanitasi dan fitosanitari sangat lemah dalam penegakannya. Selain itu, undang-undang keamanan pangan, peraturan pelabelan, dan pedoman penilaian risiko, prinsip-prinsip hukum lingkungan internasional tidak diterapkan. Makalah ini menyimpulkan bahwa tidak ada kerangka hukum yang komprehensif untuk menangani masalah terkait keamanan hayati. Ini merekomendasikan bahwa Bangladesh harus mengadopsi undang-undang dan kebijakan komprehensif yang mengatur keamanan hayati

Kata kunci: *GMO, Keamanan Hayati, CBD, Lingkungan, Penilaian risiko*

1. Introduction

Every day, more people want traditional foods, but to match this demand or to increase their nutritional value, we must use cutting-edge molecular biotechnology or different genetic engineering approaches. The steady increase in demand for different meals as a result offered genetically modified foods a new dimension. Plant geneticists can do this method by identifying a critical gene for drought resistance and introducing it into a new plant. The new genetically engineered plant will gain drought resistance. However, compared to wealthy countries, the prevalence of GM food is lower in developing nations. The use of biotechnology has given rise to a number of safety worries since it might be detrimental to both the environment and human health. GMOs that are resistant to insects have also sparked worries that they would threaten insect populations or lead to an excessive use of pesticides and herbicides that would be bad for the environment. Although many supporters of the technology assert that GMOs increase agricultural productivity and food security, there is little to no evidence that GMOs have any negative effects on the environment, and there is also no definitive scientific evidence that they do.[1] But, absence of evidence of harm is not evidence of absence of harm. GMOs, however, raise concerns from a socioeconomic perspective.

These concerns are being caused by the potential for non-GM crops to get contaminated through pollination, seed spillage, or unintended mixing during processing[2]. Concerns about cross-contamination make it more difficult for non-GMO farmers to stand out from the competition and retain the price advantage they need. Few international documents on biosafety problems contain the essential notion of precautionary principles, which contributes to minimizing potential damage to the environment. The Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety require Parties to guarantee that the production and transmission of GMOs would not affect the environment prior to the release of GMOs and Living Modified Organisms (LMOs). Bangladesh's government has established many laws and regulations as a signing party to the CBD. In 2018, a guidebook on GMO concerns was published, covering many trial

1 De Vendômois, Joël Spiroux, Dominique Cellier, Christian Vélot, Emilie Clair, Robin Mesnage, and Gilles-Eric Séralini. "Debate on GMOs health risks after statistical findings in regulatory tests." *International Journal of Biological Sciences* 6, no. 6 (2010): 590; Rahmann, Gerold, M. Reza Ardakani, Paolo Bàrberi, Herwart Boehm, Stefano Canali, Mahesh Chander, Wahyudi David et al. "Organic Agriculture 3.0 is innovation with research." *Organic agriculture* 7 (2017): 169-197.

2 Lee, Maria. "EU regulation of GMOs: Law and decision making for a new technology." In *EU Regulation of GMOs*. Edward Elgar Publishing, 2008.); Weimer, Maria. "Risk Regulation and Deliberation in EU Administrative Governance—GMO Regulation and Its Reform." *European Law Journal* 21, no. 5 (2015): 622-640.

issues both before and after the release of GMOs. It is now up for debate as to whether laws and restrictions will be put in place or upheld in order to ensure that GM crops do not threaten the viability of the small, organic farm.

Regarding GMO crops, many emerging nations are ambivalent, while a small number are openly antagonistic. In developing nations, GMO policies do not simply follow the US-EU regulatory dispute's binary logic. Instead, they mix components from both regulatory systems, which shows how diverse the regulatory landscape is in developing countries[3]. Compared to developed countries, developing countries have a much greater stake in these wars. In terms of the economy and ecology, developing countries typically have greater potential benefits and threats than developed countries. In a number of developed countries, GMO crops can face consumer resistance and regulatory limitations. Legislative restrictions and consumer opposition to GMOs in many wealthy nations, however, exert strong pressures that work against this.

The Cartagena Protocol on Biosafety has been ratified by Bangladesh, which has also established a number of regulatory and enabling frameworks for the management of genetically modified crops. There have been investigations into blight-resistant potatoes, Bt brinjal a genetically altered vegetable, and golden rice.[4] No soil tests conducted in any of the Bt brinjal fields to determine the types of fertilisers and dosages required and farmers were forced to use massive amounts of pesticides as instructed[5]. Pesticides are being distributed on the open market without any kind of label. Even though it is the competent authority's duty to take the appropriate emergency steps in the event that Bt brinjal has any adverse effects on the environment or public health, nothing has been discovered regarding it. Bangladeshis are familiar with BRRI Dhan 29, one of the most widely consumed varieties of boro rice. Many are unaware that this rice has undergone genetic modification to produce Golden Rice[6]. Bt brinjal is genetically modified to have higher expressions of a corn gene critical for beta carotene production (also known as pro-vitamin A). The biosafety of genetically modified crops and foods may be governed by applicable laws governing agriculture, medicine, food, import, trade,

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[3] Paarlberg, Robert L. *The politics of precaution: Genetically modified crops in developing countries*. Intl Food Policy Res Inst, 2001; Smyth, Stuart J. "Genetically modified crops, regulatory delays, and international trade." *Food and Energy Security* 6, no. 2 (2017): 78-86.

4 Fadida Akbar, *Turning Bt. Brinjal failure into a propaganda of success* 2015. Available: http://ubinig.org/index.php/home/showAerticle/76/english#sthash.wboaogNF.dpuf

[5] Mittler, Ron, and Eduardo Blumwald. "Genetic engineering for modern agriculture: challenges and perspectives." *Annual review of plant biology* 61 (2010): 443-462; Bhatnagar-Mathur, Pooja, V. Vadez, and Kiran K. Sharma. "Transgenic approaches for abiotic stress tolerance in plants: retrospect and prospects." *Plant cell reports* 27 (2008): 411-424.

[6] Farida Akhter, *GOLDEN RICE : Threat to pregnant women and foetus*. Available: http://ubinig.org/index.php/home/showAerticle/84/english/Farida-Akhter/GOLDEN-RICE-:- Threat-to-pregnant-women-and-foetus#sthash.R8fQv7pB.dpuf

and the environment, even though there are no guidelines in place at the moment. As a signatory to the Cartagena Protocol on Biosafety, the authorized authority is in charge of enforcing the necessary biosafety procedures.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is implemented nationally by the MoEF (CBD). To ensure that modern biotechnology development, including research and development (R&D), introduction, use, and transboundary movement of live modified organisms, is carried out in a manner that is ecologically safe. The National Technical Committee on Biosafety (NTCB) was established. Beside this the National Biosafety Foundation (NBF) serves as a framework for biotechnological research[7].

2. Method

Data was acquired from a range of primary and secondary sources. Interviews were conducted both formally and informally in October 2021 and in January to February 2022. Interviews were conducted in Mymensing, Rangpur, Dinajpur Chittagong, and Dhaka. The interviewees were from University Teachers, Researchers of Bangladesh Environmental Lawyers Association (BELA), Unnayan Bikalper Nitinirdharoni Gobeshona (UBINIG), member of National Committee on Biosafety (NCB), advocates and Policy makers. Interview subjects were chosen with an emphasis on gathering and covering a variety of people and their opinions by the following diversity. The number of respondents was fifty-two in number and categorized into five sectors depending on survey question. Different opinions were recorded and then systematically converted into ratio. Online surveys, in-person interviews, group discussion, and systematic observations were generally done in stages during the course of my research. International hard and soft laws that are applicable serve as the main source of knowledge.

3. International Instruments bearing on Genetically Modified Food

Convention on Biological Diversity (CBD), 1992 is an effective attempt where global community successfully legislate on international rules on biotechnology[8]

[7] Chaturvedi, Sachin, and Krishna Ravi Srinivas. "Survey on biotechnology capacity in Asia-Pacific: Opportunities for national initiatives and regional cooperation: A report prepared for UNESCO, Jakarta (UHJAK/2010/PI/H/3). Jakarta, Indonesia." (2010)..

[8] See para 16.1 Agenda 21 Report of the UN Conference on Environment and Development UN Doc A/CONF.151/21 (1992); The insertion of a specified protein chain(gene) into the DNA of another organism creating a GMO. Kirsch 2002 Int'l & Comp EnvtlL 21.

and the basic idea can be found from the controversial[9] article 19 of CBD [10]. There are few provisions denote contradiction especially on biosafety, though a biosafety mechanism was not explicitly included. As transboundary movements of GMOs had already begun with bulk exports of agricultural products, Cartagena Protocol to the CBD first addressed the safe trans-border movement of genetically modified plants, animals, and microbes (LMOs). however, there are still significant points of disagreement.[11] Concerning the breadth of the GMOs to be covered, the scope of the informed consent process prior to a trans-border movement, there was an initial lack of agreement. Regarding liability and remedy for harm resulting from the transborder movement of LMOs, some progress has been achieved. There are issues with the interpretation of socioeconomic elements, the harmonization of national biosafety rules, and standards for risk assessment and management. These problems are the focus of the Nagoya Kuala Lumpur Supplementary Protocol on Culpability and Restitution (hence the Nagoya SP) to the Cartagena Protocol.

CBD requires signatories to share technology or pay compensation to developing nations as restitution for genetic materials that have been taken from those nations. Article 19 of the convention has anything to do with security. Each party shall make all information regarding the usage and safety requirements accessible to the Contracting State into which the organisms are to be introduced.[12] On the other hand, the handling, use, and transfer of living modified organisms (LMOs) have attracted much attention to the detrimental effects on the long-term sustainability of biological variety. According to the parties' capacities, each party is required under this Convention to develop or maintain methods to regulate the risks associated release of LMOs. The parties have a duty to preserve bio diversity and maintain its sustainable use because biotechnology is anticipated to have negative effects on the environment.[13] Issuing various protocols became necessary as a result of the lack of explicit standards on GMOs or LMOs under the Convention on Biological Diversity (LMOs).

Convention on Biological Diversity (CBD) required the Parties to contemplate the convention's objectives when determining whether a biosafety procedure was

9 Views differed on the need to regulate genetically modified (GM) crops (Schnier 2001 Fordham Envtl L1

385) and the need for internationally agreed rules on biosafety (Mackenzie et a!Explanatory Guide 2) 39 United Nations Conference on Environment and Development Convention on Biological Diversity5 June 1992 UN Doc UNEP/Bio.Div/N7-INC.S/4 [91]Street 2001EnvL Rev250.

[10] UN Conference on Environment and Development, 05 June 1992

[11] FAO Organizational Chart. *Food and Agriculture Organization of the United Nations*, Available: [41] www.fao.org/newsroom/fr/news/2004/43684/index.html).

[12] UN, II REQUESTED BY. "Convention on biological diversity." *Treaty Collection* (1992). Available: https://www.ipcc.ch/site/assets/uploads/2001/09/doc4f.pdf.

[13] Id. art.8 (g).

required[14]. This policy was created to control the safe handling, application, and transportation of any LMO that might be harmful to the long-term conservation and sustainable use of biological diversity. The focus of this approach, which excludes medications for human use from its purview, is LMOs that are often used as food. In addition to adding a dimension by recognising the precautionary principle and the use of labelling in transboundary movement, this has a particular focus on GMO problems. According to articles 9 and 14, the parties are required to have domestic [biosafety] regulatory frameworks in order to execute this protocol. To help underdeveloped nations with their capacity issues, the Cartagena Protocol offers the Advance Informed Agreement (AIA) framework for the restricted transboundary transfer of GMOs.

The Protocol's main objective is to shield the environment from any risks brought on by the trans-boundary transfer of LMOs, including genetically modified organisms (GMOs), created by modern biotechnology. The Biosafety Protocol's standards show the global community's commitment to ensuring biotechnology safety generally, especially while taking environmental concerns into account. The biosafety approach includes both the precautionary principle and well-informed prior preparation. The application of precautionary principles will enable developing nations to better safeguard the security and safety of biotechnology.

Both other animals and live modified organisms will be subject to sophisticated forms of informed consent. Exporters are obligated to provide the necessary information prior to shipments to importer nations in order for them to adopt a specific technique to evaluate risk associated with current biotechnology goods.[15] But the Procedure might not always apply to LMOs if they do not affect the preservation and sustainable use of the biological variety, taking into account health issues as well.[16] The Biosafety Clearinghouse was created by the Protocol to Facilitate the Exchange of different information (Scientific, Technical, Environmental, Legal) and Experience with Living Modified Organisms. This Agreement requires industrialized countries to consider the particular needs of developing countries. Parities act as hotspots for genetic diversity.[17] Each party must indicate the LMOs that will be consumed as food, may be recognised as being introduced to the environment, and are not proposed for decisive introduction into the environment, according to the present version of Article 18, paragraph 2(a). However, under article 7, LMOs designed for immediate use as food and feed are excluded from the AIA procedure.[18] Each party can take decision if any transaction

14 Article 19(3)
15 See Biodiversity Protocol, supra note 2, arts. 7-16; 25-26.
16 Id. Art. 7(4).
17 Id. art.20 (1).
18 See id. Arts. 10-16; 25-26.

has hidden risk to human health or if there are any potential adverse effects[19] to the environment. The Protocol provides prior notification system and advanced informed agreement for risk assessment[20] and risk management. The party has to take decision within 270-day period whether they will transit or not[21] and the decisions will be based on assessment of risk.[22]

Measures for appropriate handling and packaging of GMOs, including sufficient documentation, are required under this Protocol. This convention indicates that the concerns of developing nations should get special consideration.[23] No specific penalties for inappropriate cross-border GMO transmission are included in the Protocol. Instead, it mandates that when GMOs are transferred in a way that contravenes Protocol regulations, States "must implement appropriate domestic steps geared at preventing and, where necessary, penalizing cross border transfers." It further specifies that parties who have been impacted by unauthorized transmissions have the right to ask the party of origin to pay for the costs associated with appropriately destroying or returning unauthorized GMOs. Furthermore, the Biosafety Clearing House must be notified of such cases.

International guidelines and procedures for liability are established by the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety. The organization's mission is to "create global norms and protocols in the area of culpability and remedy pertaining to live modified species, with a view to safeguarding the conservation and sustainable use of biological variety, taking into particular mind hazards to human health. It was created to make up for biodiversity loss brought on by living modified species in order to maintain life as we know it.[24] This Supplementary Protocol specifically refers to harm caused by GMOs. Any adverse effect on the preservation and sustainable use of biological variety, including risks to human health, is referred to as "damage" in this definition. However, there is no precise method for calculating the facts that may pose a risk to human health; instead, it will be relied on counting certain facts that may be seen scientifically or not.

human induced variation and natural variation[25] will be considered by a competent authority and adverse effect will be assessed based on multiple factors

19 Id. Art. 10(6).

20 Biosafety Protocol Id. Art. 16. L, supra note 2, Art. 15; Annex III [114] Id. Art. 16.

21 Id. art 10 § 3.

22 See Cartagena Protocol arts. 15 & 16, for provisions on risk assessment.

[23] Art 20(b) CBD

24 Lefeber, René. "The legal significance of the Nagoya-Kuala Lumpur supplementary protocol: the result of a paradigm evolution." *Centre for Environmental Law and Sustainability Research Paper* 2012-02 (2012). available at http://ssrn.com/abstract=2151282 [123]Supplementary Protocol art. 1.

25 Id. Art.2 & 2 (b) & Art.

such as enduring change or qualitative change of ingredients, the extent of reducing natural diversity and the possibility of any adverse impact on human health.[26] Polluters must pay for environmental harm they produce (legal responsibility on a global scale[27]) and to assess the rights and responsibility of the state's international law will be applicable. The party have to establish a causal relation between the damage incurred (evaluating damage based on scientific data, identifying the operators) and the GMO in question. Adherence to domestic legislation must guide the implementation of response measures.[28] Any damage sustained in times of war, civil unrest, or owing to an act of God, the parties may be relieved from obligation, and domestic law shall apply to determine each party's financial liability.

The ecologically responsible management of biotechnology was also the focus of Chapter 16 of Agenda 21's many objectives. The two components of Agenda 21's mission are to promote sustainable biotechnology applications and establish global guidelines for the management of biotechnology's environmental impact.[29] This is done to encourage the advancement and wise use of biotechnology. The worldwide exchange of scientific information and plant genetic resources is placed under the auspices of Agenda 21. It aims to strengthen biological variety conservation and support the Biodiversity Treaty. Toxic chemical risk management is a topic covered by Agenda 21, and it may be relevant to some biopesticides and other potentially dangerous biotechnology products.

WTO also has Trade Rules to GMO. One of the two main WTO agreements is the Application of Sanitary and Phytosanitary Measures Agreement which regulates agricultural commerce (SPS Agreement) together with The Technical Barriers to Trade (TBT Agreement).

The Sanitary and Phytosanitary is used to safeguard humans and other animals against foodborne poisons, illnesses and pests, and pest-related property damage and to "implement scientifically[30] grounded methods to protect public health, while restricting trade to the extent necessary." As per the original TBT Agreement. Unjustified trade barriers are prohibited Although SPS measures were not intended to be governed by the TBT Agreement, they might be If a GMO regulation is determined to not fall under the SPS Agreement, then it might be under TBT

26 Id.art.2 & 3.
27 Supplementary Protocol art. 11.
28 Id. art.5
29 See Agenda 21, UN Doc. A/CONF.151/26/Rev.1 (Vol. I), ch. 16, at 218 (1993).
30 Article 2 SPS

agreement[31] which is to safeguard plants, animals, health of people as well as the environment, must not unnecessarily hinder international trade.[32]

Furthermore, other relevant instruments and institutions have been established. A few legally binding and non-binding agreements that cover a wider range of biosafety concerns have been approved, such as:

1. The UNIDO Voluntary Code of Conduct (Release of Organisms into the Environment), was released in 1992, specified some rules addressing the introduction of organisms. This code requires the state parties to establish a regulatory body to ensure the use of the precautionary principle.
2. Technical Guidelines on Biotechnology Safety were issued by UNEP in 1995. The recommendations cover a wide range of subjects, including risk management, information exchange, monitoring, and biosafety research. In general, recommendations' primary purpose is to close a gap, especially when a protocol's adoption is in doubt.
3. Codex Alimentarius is a voluntary code that essentially provides guidelines for concerns like manufacturing, processing, and labelling.

However, certain committees have been established to offer helpful recommendations for the use of biotechnology-based genetic modification techniques. Some task teams are still developing their suggested food trade ethics. In 1951, first The International Plant Protection Convention was adopted. (IPPC). The issue of plant pests in products developed with modern biotechnology is really discussed at this trade fair. The major objective is to control plants and pests while staying within the law. Access to Justice in Environmental Matters is a section of the UN/ECE Convention on Access to Information and Public Participation in Decision-Making. It was approved to assist nations in ensuring compliance with the Cartagena Conference Biosafety Protocol. This agreement encourages the creation of national safety frameworks, collaborative project work, and information exchange among the state parties, as well as cooperation with other organizations. Other goals include strengthening domestic biosafety capability, enacting national rules, compiling and harmonizing various regulations, improving environmental management, and assuring public engagement.

31 TBT Agreement, supra note 60, art. 1.5 (identifying applicability limits of the TBT Agreement, as it does not apply to sanitary and phytosanitary measures defined per Annex A of the SPS Agreement).

32 Article 2 TBT Agreement

4. Legal and Policy Frameworks on Genetically Modified Food in Bangladesh

Both the Convention on Biological Diversity and Cartagena Protocol focus profoundly on state parties upholding their commitments. The regulation of laboratory research and the sale of GMOs requires a biosafety procedure. In accordance to precautionary principles, the biosafety guideline was not written. Bangladesh does not have any legislation that specifically addresses GM crops. But regulations exist that deal with the environment, forests, and agricultural output. To assess risk, Biosafety Guidelines 2000 are applied in respect of transboundary movement including transit, handling, and use of GMOs. The Guidelines develop rules for creating manuals for risk management and assessment, promoting and enforcing regulations related to GMOs, creating safety mechanisms for biotechnological products, creating principles for adopting sustainable products and process of biotechnology.

To ensure safe biotechnological management, these guidelines suggest establishing a National Committee on Biosafety (NCB). Expert advice from different international organizations should be accepted and followed. In the context of genetic material and unmodified organisms, risks connected to GMOs and LMOs can be identified. The purchasing authority is bound to follow and ensure that the principle of avoidance, reduction, assumption and transfer and standard procedure during field trail of GMOs is maintained. The party is also under an obligation to ensure disposal of waste. The Safety process stated in Article 11 of the Cartagena Protocol must be followed when utilizing GMOs or LMOs in food or feed. Lack of scientific consensus regarding the negative impacts of GMOs cannot stop a party from importing products like food or feed as long as precautions are taken to reduce any potential negative effects.

In Bangladesh, there are some policy rules GMOs or LMOs in food or feed. The first is Biosafety Rules Bangladesh 2012.[33] According to the current import/export policy rules, Rule 3 and 13 state that the parties must notify the relevant authorities prior to the import, export, or other commercial use of GMOs. Both parties have a responsibility to see to it that policies are put in place to limit harmful and unfavorable effects of genetically modified food and other products on the environment. Everyone involved in the production of GMOs or products will be held accountable for any environmental damage or harm to neighborhood management unless they can demonstrate that they had no direct involvement in the pollution.

33 http://agriexchange.apeda.gov.in/marketreport/Reports/Bangladesh_Biosafety_Rules_2012_Dhaka_Bangla desh_7-31-2014.pdf

The second is Biosafety Guidelines 2007.[34] The guidelines were to safeguard the nation`s interests with regard to GMO development and use. Recommendations under the guidelines are meant to assist and supplement national laws and regulations. Before the CPB was authorized in 2000, the Ministry of Science and Technology established Biosafety Guidelines in 1999. The third is National Biosafety Framework (NBF) 2008.[35] An administrative framework and regulatory framework are built on the National Biosafety Framework (NBF) to ensure an adequate level of human health and environmental protection against GMOs originating from contemporary biotechnology. The NBF's objectives are to provide an overview of the administrative framework for dealing with GMOs and ensure protection in the field of safe transfer, processing, and use of GMOs emerging from contemporary biotechnology. The fourth is National Biotechnology Policy, 2006. The long-term growth of agriculture, including food and other crops, nutrition, health, the environment, and people's means of sustenance, is guaranteed by this policy.

The fifth is Environment Policy, 1992. Under this policy Bangladesh is obligated to ensure the development operations to be environmentally sound, to ensure the proper exploitation of all national resources, to ensure environmentally sound practices to be used in the food production and all kinds of food process and, to ban the importation of environmentally harmful foods. The use of agrochemicals and synthetic materials having negative and adverse effects on soil, people and animals, must be regulated, and all technologies and measures used for agricultural development and food self-sufficiency must be environmentally sound. Modifications in agricultural production relations and management should be made as needed to encourage ecologically sound development and assure resource use that is environmentally sustainable.[36]

The sixth is National Biodiversity Strategy and Action Plan for Bangladesh (NBSAP), 2004. The NBSAP's main goals are to conserve and restore the country's biodiversity for current and future generations' well-being and prevent entry of invasive alien species and genetically engineered organisms. To guide actions toward accomplishing the NBSAP's goals and objectives, sixteen strategies were developed. strategy 4 is focused on developing domestic standards and procedures to address invasive alien species and genetically modified organisms. The National Biosafety Action Plan (NBSAP) makes some significant recommendations for up to three years in relation to alien species and GMOs. These proposals include creating local and national biosafety frameworks, supporting capacity building on

34 http://dbtbiosafety.nic.in/act/Bangladesh.pdf or http://www.apcoab.org/bioregulations/Bangladesh.pdf

35 http://www.unep.org/biosafety/files/Final%20National%20Biosafety%20Frameworks.pdf

36 Para 3.1, Environment Policy 1992.

the identification of invasive species, and creating national management strategies for the control and eradication of Invasive Alien Species (IAS). Another component of NBSAP is the creation of tools and procedures for local populations to use in the medium-term (4–7 years) to detect, manage, and control invasive species and GMOs.

The seventh is Pure Food Ordinance, 1959. Basic purpose of this ordinance is to control food production and distribution**.** According to this ordinance food includes any form edible article which will be utilized as food[37] and which will be declared by the Government by specific notification. Under this ordinance no clarification will be found about GM food. But Section 3 is enough to embrace genetically modified foods as 'Food. Section 18 makes it unlawful to use false labels which will mislead or deceive people. Under Section 19, it is forbidden to make false claims about food. No one is allowed to publish an ad that falsely claims to be a serving of food. if any person attempts to mislead the public about nature or quality of food then this is punishable offence according to the law. Actually, these laws do not distinguish between foods that are genetically modified and those that aren't.

The eighth is Destructive Insects and Pests Act, 1914. Rules on destructive insects and pests are used to govern exported and imported plants and plant products. Imposing Import limitations may help to lessen the possible effects of GM plants on the environment and people's health. For GM plants or to limit the potential for harmful environmental and human health repercussions from biotechnology inventions, further knowledge may be required.

The ninth is Fish and Fish Products (Inspection and Quality Control) Ordinance 1983 and Fish and Fish Products (Inspection and Quality Control) Rules, 1997. These rules govern the examination and verification of the quality of the fish and fish products exported from Bangladesh. Dealing with GM fish or fish products that are potentially detrimental to the environment or people's health would be prohibited if this provision were to be used. These regulations may help to reduce the risks associated with the use, handling, and transfer of GM fish and fish products. Currently, Bangladeshi imports of fish and fish products are not subject to quarantine regulations. These rules do not regulate the production, use under supervision, or continuous distribution of genetically modified fish or fish products that might be detrimental to the environment, biodiversity, or general public health.

The tenth is Patents and Designs Act, 1911 and Patents and Designs Rules, 1933. According to Section 3, the applicant must submit a patent application in the prescribed form along with a declaration stating that they are the real and original invention. An invention must satisfy the following requirements in order to be

[37] Section 3(5),food ordinance 1959

granted a patent: novelty, non-obviousness and utility. According to section 12, a patent grants the patentee the sole right to make, sell, and utilize the invention throughout Bangladesh and to give other people permission to do the same. Anyone with an interest in a patent may submit a petition, arguing that Bangladesh does not have enough market demand for the patented goods and requesting. The government may choose to reject the petition or refer it to the courts. A patent may be cancelled in a High Court Division suit under section 26 for factors including fraud. A court or district judge with competence under section 29 may receive a complaint for patent infringement. Some offences stated in the Penal Code, 1860, such as trademark and merchandise forgery, permit the filing of criminal charges for patent infringement in addition to the civil complaint procedure under the Patents and Designs Act, 1911.

The eleventh is The Animal and Animal Product Quarantine Act, 2005. Import or Export Policy Orders, which are periodically issued by the government in accordance with the Imports and Exports (Control) Act of 1950, contain conditions that may include quarantining animals or animal products, as well as prohibiting, restricting, or otherwise regulating their import or export. This law could be applied to prohibit or limit the import or export of GM products that are harmful to the biodiversity or public health. The Act makes it possible to create crucial laws governing the import and export of genetically modified animals.[38]

The twelfth was Bangladesh Standards and Testing Institution (BSTI) Ordinance, 1985 and Bangladesh Standards and Testing Institution (BSTI) Rules, 1989.[39] The BSTI Ordinance establishes a body in charge of product standardization, testing, quality control, grading, and marking. Section 3 of the Ordinance establishes the Bangladesh Standards and Testing Institution. Creating Bangladesh quality standards and specifications for materials, items, structures, practices, and activities is one of the Institute's main duties, as mentioned in section 5. Other responsibilities include monitoring compliance with Bangladesh Standards, implementing Bangladesh Standards through the administration of a national certification mark program, or conducting goods inspections. The concerned authority will grant, renew, reject, suspend, or cancel a license for the use of Standards. When importing food as help from foreign nations, the Directorate complies with Codex or BSTI standards.

The thirteenth is National Seed Policy 1993.[40] The government adopted this policy in response to two rising concerns: (1) insufficient public sector seed production and distribution, and (2) a lack of critical assistance for private sector seed production. NSP provides policy directives for – (1) development of higher-

[38] Sec 24

[39] http://bdlaws.minlaw.gov.bd/print_sections_all.php?id=689

[40] http://cepa.org.mw/index.php/2015-02-13-13-10-21/legislation/policy-documents?task=download&id=105

quality seeds in all sectors(public and private) as well as prompt distribution to farmers, (2) liberalization of imports of seeds and seed processing equipment, (3) seed quality control, and additional channels for research and development, and (4) establishment and maintenance of seed banks. The NSP intends to "make the best quality seeds of updated crop kinds readily and effectively available to farmers" in order to boost crop production, farmer productivity, per capita farm revenue, and export earnings. Creating, maintaining, and making available to farmers crop types that are bred for "high-input, high-output" agriculture One of the specific goals is to support the private seed industry`s efforts to produce, process, store, and use high-quality seeds. Other goals include developing high yielding varieties (HYV) and disease- and pest-tolerant seeds. The paper states that seed variety development efforts should prioritize the development of high input-output technologies. The strengthened Seed Board (NSB) is also expected to provide an administration and control mechanism by requiring mandatory registration of new seed varieties, seed dealers, labeling requirements, and mandatory requirements of breeder/foundation seeds in both the public and private sectors. Therefore, in Bangladesh, GM seeds of a recognized variety are subject to the same laws.

The fourteenth is National Agriculture Policy (NAP) 1999.[41] National Agriculture Policy was released in 1999 by the Ministry of Agriculture (MoA) (NAP). By increasing the output of all crops, particularly grains, the NAP's main objectives are to make the nation's food supply self-sufficient and establish a solid system for everyone's food security. 18 program areas, including crop production, seeds, fertilizer, minor irrigation, pest management, agriculture mechanization, research, marketing, land use, agricultural credit, government support for production and contingency plan. Moreover, food-based nutrition, environmental protection, women in agriculture, and coordination were identified in the NAP. According to the NAP, the government will continue to offer the public sector and the private sector the same chances for seed production, import, and sale. The conditional permission given to the corporate sector to trade hybrid rice seeds for expanding rice output would be further solidified "under the condition that the hybrid seeds regularly produce higher yield and bigger financial benefits to the farmers. The Integrated Pest Management (IPM) is suggested by NAP as the main strategy for controlling pests and diseases. According to the NAP, chemical pesticides will only be applied if IPM is unable to control the pests.

The fifteenth is Draft Agriculture Policy 2007.[42] The Ministry of Agriculture (MoA) released a new Draft Agriculture Policy in 2007 to address different rising difficulties and new challenges. The draft`s introduction expresses concern about

41http://www.nfpcsp.org/agridrupal/sites/default/files/National_Agriculture_Policy_1999.pdf [149] Para 2.1, National Agriculture Policy 1999.

42 ISP APPLICATIONS, http://siteresources.worldbank.org/EDUCATION/Resources/278200- [99] /547664-

a number of issues, including the need for increased agricultural production, higher growth in rural areas, and the necessity of rural development through increased commercialization of agriculture, as well as the need for scientific and technological research inputs in this sector. The specific goals include agricultural technology transfer, commercialization, research and training, and the establishment of a sustainable agriculture system. In seed sector, especially in private sector, more focus is being placed on the growth.

5. Perception of Biosafety Guidelines

In respect of evaluating the Biosafety Guidelines of different years both scholars and Members of National Board of Biosafety evaluated this in different ways. Assistant Professor Muhammad Muniruzzaman[43] says, "The Guidelines develop rules to assess risk release of GMOs/LMOs into the environment, enhance monitoring capabilities, create manuals for risk assessment, promote and enforcing regulations related to GMOs". Musferat Marja[44] stated that chronological development of biosafety guideline is highly appreciated but revised biosafety guidelines of 2018 need to be analyzed more. Advocate Sayeed Anwar[45] says, "present guidelines are comprehensive enough to reduce probable risk of biological diversity but without effective and efficient monitoring system everything shall go in vain". The opinion of experts is given in Table1.

Table 1. The opinion of experts (5 in number) Biosafety Guidelines on GMOs/LMOs.

Biosafety guidelines (are not exhaustive)	20%- 25%
Biosafety guidelines (Comprehensive)	72%
Biosafety guidelines (proposed for new guidelines)	4% -5%
Draft manual on Monitoring and Enforcement for GMOs (Exhaustive)	65%

Researchers claim that the government is adopting a different manual. That may cover loopholes in existing laws. They are assisting the reorganization of institutional structures to overcome administrative barriers and guarantee that potential environmental risks may be decreased.

Regarding perceptions of the law of GMOs as shown in Table 2, the majority of respondents said that the Biosafety Framework-2007, Biosafety Guidelines-2007, and Biosafety Guidelines-2012 were the fundamental frameworks for GMOs. Though Almost eighty-two percent of respondents indicated that there is no direct law on GMOs. Existing laws which are now part of GMOs are

43 Interviewee is a faculty member of Bangladesh University of Professionals
44 Interviewee is a faculty member of Bangladesh University of Professionals
45 Interviewee is advocate of Supreme court of Bangladesh

ambiguous and scattered. Nearly half of the thirty-three respondents represented by this ratio. However, the majority of respondents (77%) approved of the new law's implementation. They added that the laws which are under review were not created specially to state the potential hazards of GMOs/LMOs.

Table 2. Perceptions of the Law of GMOs

Statement and Responses	Response options
Laws are ambiguous and No direct law	
never / rarely / sometimes	11%
always / mostly / frequently	89%
Proposed for new Laws	
Important always / mostly	85%
Not so important	15%

In the perception of food safety laws, majority of the respondent[46] expressed their opinion that due to overlapping jurisdiction of different departments and lack of harmonization among them the food safety law is not in application. Ministry of Health, Industries and Local Government are not in proper coordination. As regards enforcement they are really worried that enforcement of food safety laws is very poor in its nature. Few respondents[47] also criticized role of mobile court. The majority (almost eighty-two percent) of interviewees[48] suggested to enact new food laws with strong enforcement to combat different offences related thereto and to ensure food safety in Bangladesh. We interviewed forty consumers of three districts but unfortunately, majority of the consumers have no idea about food safety law.

Table 3. Consumer perception of SPS (Sanitary and phytosanitary) laws.

Adequacy and Enforcement	Excellent	Good	Poor
Sanitary and phytosanitary regulation		5%	95%
The SPS legislation' implementation presents some difficulties.	lack of scientific equipment	Lack of modern laboratories.	Weak administrative wing
	6%	10%	84%

Experts[49] added that role of administrative authorities is quite disappointing one. One member of Bangladesh Environmental Lawyers Association (BELA)

46 Faculty members of Comilla and Chittagong University
47 Advocates of Supreme court
48 Member of BELA and member of focused group discussion
49 Member of BELA, faculty member of environmental science, CU

further added that lodging complaint in this issue is quite cumbersome and general people are not aware of it. Even relevant department reluctant to file suit against the violators of SPS laws. Some of the respondents[50] argue that major laws and guidelines should amend and government should adopt more policies as a signatory of WTO.

In the context of IP, IPR laws and TRIPS, two members of Department of Patent, Design and Trademarks added that it`s true that under Bangladesh's current rules place a strong emphasis on patenting processes, however TRIPS mandates patents for both methods and products. The respondent also stated that whereas TRIPS mandates 20 years of protection, current IP law only offers 16 years of protection. Abdul Karim, a member of DPDA, stated that while TRIPS permits exemption from patent on a variety of grounds, including plants, animals, and the necessity to safeguard biodiversity as well as human health as well as the environment, these grounds are not recognized under the IP law currently in effect.

In risk assessment and risk management, eighty seven percent of thirty-three interviewees replied that under present statutes there is no direct risk assessment rule and proper information about potential risk of GMOs is received. Even different stakeholders who are under an obligation to provide information are not concern about it. On the other hand, before releasing GMOs, the benefit and risks arising out of GMOs must be weighed carefully. 85% respondents [51] from different categorized groups expressed that though Risk management is both a practical and legal issue, but we didn't find any stringent movement from the government. Present biosafety protocol didn't cover risk manual unequivocally. Moreover, the majority of the interviewees[52] opined that as such there is no direct law on genetically modified organisms, some guidelines, international principles, and laws on food, fish, patent, and pest are being used to regulate GMOs.

Table 4. Nature or Approach towards Existing Regulation.

Existing regulation	Permissive	82%
	Restrictive	8%

In Bangladesh for GM crops there is no labeling[53]. Those personnel working on environmental issue focused that labelling makes a more predictable and according to biosafety rules Bangladesh is also under an obligation to ensure labelling of LMOs or GMOs. Few Members of UBINIG added that there is no uniform label requirement and a change in prey species may have an impact on the

50 Faculty members of Mymensingh Agricultural University
51 Member of NCB
52 Interviewees are faculty members of CU, DU of Genetic engineering department
53 Information was given by the researcher of UBINIG and members of BELA

predator and shift the balance of food species it consumes and this leads to a gradual change in the ecosystem.

From field visit in Rangpur and Dinajpur, we found that neither the farmers nor the consumers are aware of labelling or the negative impact of Bt brinjal. The sale of Bt brinjal without labelling, without an examination of the detrimental effects on human health and the environment. Data revealed that the farmers are not aware of banned insecticides.

Table 5. Perception of GMO governance

Tool of assessment	Excellent	Good	Not satisfactory
Impact assessment	No comment	3%-5%	97%
Public awareness and engagement	No comment	7%	93%
Regulatory system	No comment	12%	88%

Department of Patent, Design and Trademark (DPDT) acks the technological capacity and financial resources required to effectively enforce IPR-related legislation in the area of intellectual property rights (IPR) laws. Another reason people disobey IPR laws is a lack of understanding of the necessity of upholding the rights they grant and the significance of IPR laws. The provisions of this law protect the interests of Bangladeshi farmers. Therefore, it is essential to uphold current regulations in order to protect GM crops rather than modify them. For instance, Bangladesh`s Seeds Wing carries out the 1988 Seeds Rules and the 1977 Seeds Ordinance, which set national standards for the production, sale, and distribution of seeds. To ensure that seeds are pest-free, however, additional approval from the Plant Protection Wing is necessary before they may be imported. The study's conclusions indicate that the laws under consideration don't offer a thorough legal framework to deal with biotechnology and biosafety issues. It suggests that a comprehensive policy be designed with this goal in mind, along with a national biosafety strategy for Bangladesh.

6. Conclusion

Study revealed that there is no direct law governing GM crops. Different sectors' laws, norms, and policies attempt to handle GMO problems. Agriculture, trade, intellectual property, the environment, drug manufacture, and food law are all part of the GMO issue. But We must proceed cautiously to avoid unintentionally endangering Biodiversity and human health. Contradictory issues related to Genetically modified Organism and biotechnology demand international attention also. Bangladesh has a duty to safeguard environmental and human health as a signatory to the Cartagena Protocol and the Convention on Biological Diversity.

About GM and Non-GM product, the entire public should have access to these materials if independent experts determine that they are safe for humans and the environment, so that they may decide how to treat GM products. It is recommended that a comprehensive law be written to address Biotechnology and Biosafety issues. To solve the multipole concerns of GMOs, a new statute or regulation must be enacted. The government should swiftly adopt measures to implement the draft handbook on GMO Monitoring and Enforcement, 2018, or pass legislation based on risk assessment management of GMOs in particular. Under the current consumer protection statute, consumers should have the right to know about or decide whether to consume a specific item (GM foods or Non-GM foods). GMO food should be labelled, and the government should enact legislation requiring GM product and food labelling. Since the use of genetically modified organisms is not expressly prohibited by law, only biosafety guidelines and regulations are important in assessing the present situation in Bangladesh. The government should strengthen monitoring and enforcement of Biosafety Rules, or it can try to implement a few parts of the draft manual, such as Post Release Monitoring (as described in point 5 of the draught manual on monitoring and enforcement, 2018), which can be easily enforced with the help of the relevant authority. 'Release to the environment and release to the markets,' according to the draft guideline, necessitates immediate enforcement in order to decrease the likelihood of environmental danger. Some procedures need to be followed to detect risk obtained from field or lab trials or computer models, such as assessing the risk quantitatively or qualitatively.

The current IP law is incompatible with TRIPS. The TRIPS requirements should be honored when it comes to GMO patents. A law on plant variety protection has been created as a result of TRIPS, which permits the legal protection of plant varieties. This also applies to genetically modified crops. It includes measures for Bangladeshi farmers' rights. As a result, rather than altering current legislation, enforcement is critical for the preservation of GM crops. The NBF must be fully implemented, and a coordinated framework with effective interagency communication is required to make comprehensive and well-informed choices about GM crop regulation. Lastly, Bangladesh agricultural research institute (BARI) should set up an administrative structure to carry out biosafety regulations in conjunction with its many associated entities. By bolstering pertinent government institutions, such as border control, quarantine and inspection facilities, and setting up data gathering and administration facilities, the use of GMOs can be reduced.

References

Akbar, Fadida, *Turning Bt. Brinjal failure into a propaganda of success*. 2015 Available: http://ubinig.org/index.php/home/showAerticle/76/english#sthash.wboaogNF.dpuf.

Bhatnagar-Mathur, Pooja, V. Vadez, and Kiran K. Sharma. "Transgenic approaches for abiotic stress tolerance in plants: retrospect and prospects." *Plant cell reports* 27 (2008): 411-424.

De Vendômois, Joël Spiroux, Dominique Cellier, Christian Vélot, Emilie Clair, Robin Mesnage, and Gilles-Eric Séralini. "Debate on GMOs health risks after statistical findings in regulatory tests." *International Journal of Biological Sciences* 6, no. 6 (2010): 590.

FAO Organizational Chart. *Food and Agriculture Organization of the United Nations*, Available: [41] www.fao.org/newsroom/fr/news/2004/43684/index.html).

Farida Akhter, *GOLDEN RICE: Threat to pregnant women and foetus.* Available: http://ubinig.org/index.php/home/showAerticle/84/english/Farida-Akhter/GOLDEN-RICE-:-Threat-to-pregnant-women-and-foetus#sthash.R8fQv7pB.dpuf.

http://www.nfpcsp.org/agridrupal/sites/default/files/National_Agriculture_Policy_1999.pdf [149] Para 2.1, National Agriculture Policy 1999

ISP APPLICATIONS, http://siteresources.worldbank.org/EDUCATION/Resources/278200-[99] /547664.

Lee, Maria. "EU regulation of GMOs: Law and decision making for a new technology." In *EU Regulation of GMOs*. Edward Elgar Publishing, 2008.)

Lefeber, René. "The legal significance of the Nagoya-Kuala Lumpur supplementary protocol: the result of a paradigm evolution." *Centre for Environmental Law and Sustainability Research Paper* 2012-02 (2012). available at http://ssrn.com/abstract=2151282. [123]Supplementary Protocol art. 1.

Mittler, Ron, and Eduardo Blumwald. "Genetic engineering for modern agriculture: challenges and perspectives." *Annual review of plant biology* 61 (2010): 443-462.

Paarlberg, Robert L. *The politics of precaution: Genetically modified crops in developing countries*. Intl Food Policy Res Inst, 2001.

Rahmann, Gerold, M. Reza Ardakani, Paolo Bàrberi, Herwart Boehm, Stefano Canali, Mahesh Chander, Wahyudi David et al. "Organic Agriculture 3.0 is innovation with research." *Organic agriculture* 7 (2017): 169-197.

Smyth, Stuart J. "Genetically modified crops, regulatory delays, and international trade." *Food and Energy Security* 6, no. 2 (2017): 78-86.

UN, II REQUESTED BY. "Convention on biological diversity." *Treaty Collection* (1992). Available: https://www.ipcc.ch/site/assets/uploads/2001/09/doc4f.pdf

Weimer, Maria. "Risk Regulation and Deliberation in EU Administrative Governance—GMO Regulation and Its Reform." *European Law Journal* 21, no. 5 (2015): 622-640.