INTERNATIONAL LEGAL INSTRUMENTS: A BIOTECHNOLOGY PERSPECTIVE

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ABSTRACT

One of the leading industries in the world that is advancing at a faster clip is biotechnology. With the wellbeing of individuals as a guideline biological processes are used in biotechnology. The biotechnology enterprises have a significant impact on the environment ecological systems, ecological diversity, ecological safety, and scientific advancements. As the medical, agricultural, pharma, food and beverage sectors grow, the domain of biotechnology is becoming increasingly important. While biotechnology harbours benefits to human society, recent developments show that it is also currently creating a number of issues to the general public on a global scale. On new biotechnological advancements, research communities from all over the world are always working. Intellectuals propose establishing a system that ought to govern the existing difficulties confronted in this industry. In order to control the derailed innovations in biotechnology, laws and restrictions are demanded to stop the biotechnology enterprises from malfunctioning. The exploitation of biotechnological innovations caused by a disregard for scientific ethics, necessitates the creation of global legislative instruments that could successfully manage the problems, the biotechnology industry is confronting. It was analyzed in the study that although numerous international legal instruments have been developed to regulate biotechnology they have not proven to be successful. For this purpose this investigation was conducted to examine the worldwide biotechnology legal frameworks.

Key words: International, Legal Instruments, Biotechnology, Agreements, Conventions, Innovations.

1. INTRODUCTION

Biotechnology is the highly discussed subjects of the contemporary science. Currently biotechnology holds a vital role in human expansion. The biotechnology has remarkably enhanced different fields like medical, agribusiness and surroundings[1]. The conceivable implications of biotechnology go beyond technology and the ecosystem. It is effecting liberalization of worldwide businesses, intellectual property rights, rights of aboriginal population, ecological diversity and indeed global state relationships. Intellectuals suggest that modifications in the ecological diversity have been a part of the human civilization for centuries and it is not justifiable that biotechnology has given the wisdom of biological shifts. Agriculturalists around the world have been harbouring plant breeding or devising hybrid plant varieties for many years[2] . However in today's scenario various intellectuals after inspecting recent trends suggest that it is time to designate specific policies and transnational legislations on biotechnology in order to regulate the creations in this arena. In the recent trends credit has been assigned to the prospect of biotechnology in the monetary trends[3]. However the prevalent agreements state that the total effect of biotechnology on individuals and the ecosystem is yet to be analyzed. Even though assorted critiques give a scope of cons on the biotechnology creations but a preferred consensus is that biotechnology is set to form the destiny of mankind in the coming many years. Despite its significance, biotechnology hasn't drawn much attention from legal professionals worldwide. Those global legislations currently prevailing can be classified as highly flexible or liberal legal instruments on biotechnology. Biotechnology-related issues are constantly highlighted as miscellaneous issues deserving of national restrictions where these issues have garnered international attention, such as in international conflicts. The problems are no longer the appropriateness of biotechnology legislation *per se*, in fact multifarious social and ethical debates on biotechnology have stood trending in the transnational arena[4]. This investigation aims to investigate the varied legislations on biotechnology in the transnational system. The normative

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[2] ISAAA. Conventional Plant Breeding. Pocket K No. 13. (2004). https://www.isaaa.org/resources/publications/pocketk/document/Doc-Pocket%20K13.pdf

[3] Andreas Haaf, Sandra Hofmann, and Julia Schuler. Measuring the economic footprint of the biotechnology industry in Europe. Industrial Biotechnology 17(3): 117-124. 11 Jun 2021. https://doi.org/10.1089/ind.2021.29249.aha

[4] Nicolas Rigand. Biotechnology: Ethical and social debates. OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda". OECD. February 2008. https://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40926844.pdf

breadth of any workable transnational regulatory framework for biotechnology is also evaluated in the current research.

2. UNDERSTANDING THE TERM BIOTECHNOLOGY

The word biotechnology has been credited to Hungarian physicist Karl Ereky[5]. The prefix, bio- which means biological with the term technology is combined to form the compound word biotechnology. The term biotechnology has had numerous definitions since it was first tossed. In oxford dictionary biotechnology is defined as exploitation of viable cells for scientific and industrial procedure[6]. Biotechnology deals with especially, genetical modification of microbes for the creation of antibiotics, hormones etc. The term biotechnology was depicted by OECD in the year 2003, as the usance of scientific and technical concepts to the detersion of materials by ecological means to create goods and services[7]. This definition is still frequently used and is still the most accurate. The OECDs definition of biotechnology is quite broad because it encompasses not only conventional and borderline operations but also all contemporary biotechnology. Biotechnology is expressed as any technical application that employs biological strategies viable creatures or by-products thereof to manufacture or alter goods or procedures for specified uses, by the United Nations Convention on Biological Diversity[8]. Modern biotechnology is demarcated by Cartagena Protocol on Biosafety as; a) the usance of *in vitro* nucleic acid techniques including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or b) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in conventional breeding and selection[9]. The Convention on Biological Diversity is a crucial source to resort to, in the absence of a more detailed international legal definition.

3. CLASSIFICATION OF BIOTECHNOLOGY

Essentially biotechnology has four applications; agricultural and crop yield, medicinal and

[5] Alan M. Russell and John Vogler. The international politics of biotechnology: investigating global futures. Manchester University Press, UK. (2000).

[6] Oxford Learner's Dictionaries. Biotechnology noun. https://www.oxfordlearnersdictionaries.com/definition/english/biotechnology?q=biotechnology

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[8] Stanislav Stuchlik and Jan Turna. Current Status of biotechnology in Slovakia. Curr. Opin. Biotechnol., 24 Suppl 1, S14–S18. (2013). https://doi.org/10.1016/j.copbio.2013.05.012

[9] Der-Chin Horng. Biotechnology and the WTO: A Review of some Selective Issues. , 3(2): 45-56. (2006). https://doi.org/10.1515/JIBL.2006.006

health-related, ecological and industrial. Various terminologies categorize its branches. Biotechnology has been broadly categorized into four subfields green, red, blue and white biotechnology[10]. Green biotechnology links biotechnology abuse in agriculture, red biotechnology is a technique linking medicinal purpose, blue biotechnology links biotechnology to aquatic and marine environments and white biotechnology is linked to business. Such biotechnology derivatives are labeled as modern biotechnology. The term "modern biotechnology" has been adopted by international conventions to describe biotechnological methods for manipulating genetic material and fusing organisms.

4. STAGES OF DEVELOPMENT OF BIOTECHNOLOGY

In order to address the myriad demands of the population, biotechnology is now in differing steps of growth. The happening of new sciences over an occasion that are established, the use of better mechanics, breakthroughs and a better grasp of many growth-wisdom ideas, has raised the complexity of biotechnology. Biotechnology may be split into three separate stages or groups, if arranged in a timeline of progress; (1) ancient biotechnology (2) classical biotechnology and (3) modern biotechnology[11].

5. LITERATURE REVIEW ON BIOTECHNOLOGY DEVELOPMENTS

The ancient biotechnology included discoveries before or between 18th century[12]. It is estimated that around 10000 BC, during the classical phase of biotechnology activities like domestication of food crops and animals took place[13]. The ancient Egyptians used honey for respiratory infections and as an ointment for wounds[14] . Cheese and wine, made by

[10] Varsha Gupta, Manjistha Sengupta, Jaya Prakash and Baishnab Charan Tripathy. An Introduction to Biotechnology. Basic and Applied Aspects of Biotechnology, 1–21. (2016). https://doi.org/10.1007/978-981-10-0875-7_1

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[14] Joel Yupanqui Mieles, Cian Vyas, Enes Aslan, Gavin Humphreys, Carl Diver and Paulo Bartolo. Honey: An Advanced Antimicrobial and Wound Healing Biomaterial for Tissue Engineering Applications. Pharmaceutics, 14(8), 1663. (2022). https://doi.org/10.3390/pharmaceutics14081663

fermentation, are early examples of biotechnology[15] . Some traditional medicines also used organisms or parts of organisms[16]. Rancher and animal breeders started developing new hybrid plant varieties and animal breeds by crossing between species[17]. Edward Jenner developed the vaccination technique[18]. The classical biotechnology survived after the year 1800[19]. In this era genetic studies like laws of inheritance by Gregor John Mendel on pea plant was carried out[20]. This gave new opportunities to researches in the field of genetics. The cell had a nucleus was discovered by Robert Brown during this era[21]. Robert Koch propagated bacterial colonies in the year 1881[22]. Walter Hesse discovered agar as medium that could be used for cultivation of microorganism[23]. Morgan described the role of inheritance in fruit flies that was exhibited as the theory of gene[24]. The first industrial application of microbial enzymes was done by Japanese scientist Jokichi Takamine in USA[25]. In 1846, the manufacturing of Vienna process of baker's yeast has raised to achieve many developments[26]. The studies in genetics also opened the gate way to eugenics[27]. Fleming discovered antibiotics from a fungi viz. *Penicillium notatum*[28]. The modern biotechnology took rise after the Second World War[29]. After World War II

[15] Mary Hurley and Ethan Carroll. The ancient biotechnologists: how humans started changing the world. The Lovepost. (2021). https://www.thelovepost.global/biotech-change/articles/ancient-biotechnologists-how-humans-started-changing-world

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development of fermentation technology attained its height[30]. Hungarians were the first in the world to introduce beer brewing[31]. Watson and Crick gave the double helical structure of DNA[32]. Jacob and Monod gave the concept of operon[33]. Kohler and Milstein developed monoclonal antibodies[34]. Har Gobind Khorana synthesized DNA in a test tube[35]. Gene cloning came into existence and Ian Wilmut developed a cloned sheep named Dolly[36]. Craig Venter laid the foundation of sequencing the human genome[37]. Later on advancement in the field of biotechnology gave birth to bioinformatics that further led to the development of new sciences viz. proteomics and genomics[38]. In the year 1986, the Department of Biotechnology was established by the Ministry of Science and Technology for the development of biotechnology in India[39]. In the year 1979, the first patent concerning biotechnology was received by the Patent Office of America[40]. DNA and RNA vaccines are a recent advancement in medical arena[41]. The Pfizer and Moderna vaccines against COVID 19 are significant examples of novel vaccine technology[42]. Some of the important events that took place in the field of biotechnology are exhibited in table 1.

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[42] *Ibid*

Table 1. IMPORTANT EVENTS IN THE FIELD OF BIOTECHNOLOGY[43] [40]

Events			
Before Common Era	**Pre 20th century**	**20th century**	**21th century**
7000 BCE –Fermentation in beer making 6000BCE- Yogurt and cheese making by bacteria 400 BCE- patient treatment with vinegar 100AD- Chrysanthemum used as natural insecticide	1663- Living cells recorded 1675- Bacteria and protozoa described 1761- Viral small pox vaccine 1855- Escherichia coli bacterium discovered. 1870- Hybrid corn produced in lab. 1875- Theory of spontaneous generation disproved. 1881- Bacterial colonies grown on potato slices. 1888- Term chromosome coined.	1911- Cancer causing virus reported 1915- Bacteriophages discovered 1924- Eugenic movement in US 1926- Theory of gene. 1928- First antibiotic penicillin discovered 1941- Genetic engineering introduced. 1958-DNA synthesized in test tube. 1960- m-RNA discovered. 1961- Genetic code understood. 1963- Vaccine for measles. 1969- An enzyme synthesized *in vitro*. 1973- Recombinant DNA experiment using bacterial genes 1975- Monoclonal antibodies developed 1978- Recombinant human insulin produced 1980- patented genetically engineered life form 1983- Polymerase chain reaction developed 1984- DNA finger printing developed 1994- Breast cancer gene discovered 1997- Cloned sheep 'Dolly' developed 1998- Human genome map rough draft 1998- Human skin developed in lab.	2000- Human genome sequenced 2002- 'Banteng' endangered species cloned. 2003-Human Genome Project completed 2007- Vaccine for Avian flu approved 2010- Malaria resistant mosquitoes created 2011- Trachea developed from stem cells transplanted in human 2013- Human liver tissue from reprogrammed skin cells. 2014- Baby birth through womb transplant. 2016- 3D printed heart on chip 2017- Blood stem cells cultured in lab.

[43] Brain Colwell. Biotechnology timeline: Humans have manipulated genes since the 'dawn of civilization'. Genetic Literacy Project. September 9, 2022. (2022). https://geneticliteracyproject.org/2022/09/09/biotechnology-timeline-humans-manipulating-genes-since-dawn-civilization/

6. MAJOR EMERGING THREATS OF BIOTECHNOLOGY

Biotechniques integrates frequently working with an elementary standard of human prosperity. Though various notable bioproducts are being reaped by utilizing biotechnology but immense risks are also joined accompanying explicit yields[44]. Some of the arising warnings of biotechnology are argued beneath.

6.1 Exponential rising of issues

Biotech businesses typically obtain patent protection for their goods, giving them market lead time while they recoup their research and development (R&D) costs. They will have a stronger market position than their rivals once the patent protection term ends. The potential rewards are enormous. However, investors must balance the enormous threats that are there with the enormous returns that these companies may offer. First, there is a protracted period of development during which money is spent on research and development with the sole expectation that a successful product would be released. Biotech products of the pharma giant corporations must be approved by the competent authorities within the respected nations before they can put them on the market, which is a difficult and drawn-out process. Analysis on the biotechnology sector estimates that just 36% of medications make it to bypass the early stages of development[45]. R&D requires a significant time and financial commitment. Analysts struggle mightily to appropriately assess biotech companies upon given the risky development cycles they must undergo. This is a significant factor in the high volatility of the stocks of biotech companies. Even if the biotech business is successful in marketing its medicines, it still faces risks related to how the market will react to it and the prospect of legal action, should any unfavourable side effects arise as a result of usage.

6.2 Accessibility issues

The rising cost of healthcare, and the price of medications in particular, is and will continue to

[44] National Academies of Sciences, Engineering, and Medicine; Division on Earth and Life Studies; Board on Chemical Sciences and Technology; Board on Agriculture and Natural Resources; Board on Life Sciences; Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System. Preparing for Future Products of Biotechnology. Washington (DC): National Academies Press (US); 2017 Jun 28. 4, Understanding Risks Related to Future Biotechnology Products. https://www.ncbi.nlm.nih.gov/books/NBK442208/

[45] Richard G. Frank and Kathleen Hannick. 5 things to understand about pharmaceutical R & D. USC- Brookings Schaeffer on Health Policy. Thursday June, 2, 2022. https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2022/06/02/five-things-to-understand-about-pharmaceutical-rd/

be a political matter of discussion in the global arena[46]. Despite the global state authorities best efforts and assertions, a sizable portion of the public, as well as their legislators, do not appear to accept the pharmaceutical industry's claim that R&D is funded by current pricing and that price limits may ultimately impede R&D. When the worth of expensive biotech treatments for critical conditions is discussed, the objections are likely to get more heated discussions. The actual cost of medicines being manufactured by the global pharma corporation is always a matter of deep concern. The high price of prescribed drugs is serious issue with respect to the healthcare budgets[47]. The monopoly in the pharma biotech business by pharma giant corporations is a serious threat for the public health worldwide[48].

6.3 Confidentiality issues

The need to protect patient privacy is growing as a result of recent technological advancements that have made it possible to read the human genome. An increasing number of people and organizations are requesting access to individuals genetic information, as technology and our understanding of genomics have advanced[49]. As scientists are getting better at deciphering a person's genetic makeup, it's likely that damaging knowledge about a patient's future health will progressively become available. Significant issues may result from this. For instance, it will be feasible to predict that a child may experience major heart issues in the future. Now the question is, do you have a right to tell a potential employer about this? What effects would this information have on the person's capacity to obtain a job, a mortgage, or insurance?

6.4 Genetic modification issues

In the coming decades, it's anticipated that advances in biotechnology shall play a promising role to bring significant changes in plant and livestock production[50]. It is a well-known truth that in the upcoming decades, agricultural systems in emerging countries will have to supply the majority of the growing food and industrial needs of the populations in the Lesser

[46] Toon van der Gronde, Carin A Uyl-de Groot and Toine Pieters. Addressing the challenge of high-priced prescription drugs in the era of precision medicine: A systematic review of drug life cycles, therapeutic drug markets and regulatory frameworks. PLOS ONE, 12(8), e0182613. (2017). https://doi.org/10.1371/journal.pone.0182613

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[48] *Ibid*

[49] Ellen Wright Clayton, Barbara J Evans, James W Hazel, Mark A Rothstein. The law of genetic privacy: applications, implications, and limitations. J.Law Biosci., 6(1): 1–36. (2019). https://doi.org/10.1093/jlb/lsz007

[50] FAO. Food, nutrition and agriculture = Alimentation, nutrition et agriculture = Alimentación, nutrición y agricultura. Rome. (1991). https://digitallibrary.un.org/record/128951?ln=en

Developed Countries (LDCs). To meet the rising demand, it is predicted that global food demand shall increase by 50-60% by 2050[51]. Making sure that the vast potential of biotechnology is focused where it is most needed, namely to benefit farmers and the people of LDCs, represents a significant challenge. Today, genetically modified (GM) crops are produced using biotechnology[52]. In order to achieve this, researchers separate a gene from a plant, creature, or animal and splice it into other genes. As a result, they are currently aiming to gain important agricultural benefits like resistance to pesticides and herbicides, higher crop yields, and resistance to disease or drought tolerance. Numerous animals have also undergone genetic engineering in an effort to boost productivity and reduce illness susceptibility. As an illustration, salmon have been modified to grow bigger and mature faster, and cattle have been improved to show resilience to diseases like mad cow[53]. In the numerous nations genetically modified maize, canola soybean, and cotton plants are in agriculture production[54]. The consequences of GM plants, animals and other organisms are critical for the ecological diversity[55].

6.5 Social issues

Biotechnology is a field that is evolving quickly. Major biotech problems are frequently caused by the rate at which new technologies are developed being faster than the rate of regulatory adaptation and change. In both the scientific and legal worlds, there has long been discussion about whether stem cells—especially those produced from human embryos—are eligible for patent protection. The European Patent Office (EPO) has declined to issue patents for stem cells produced through the eradication of human embryos due to ethical considerations[56]. The United States Patent and Trademark Office (USPTO), on the other hand has historically issued patents for the isolation and use of various stem cells, including those from human embryos[57].

[51] Walter P.Falcon,Rosamond L. Naylor and Nikhil D. Shankar. Rethinking Global Food Demand for 2050. Popul. Dev. Rev. (2022). https://doi.org/10.1111/padr.12508

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[53] *Ibid*

[54] Graham Brookes and Peter Barfoot. Environmental impacts of genetically modified (GM) crop use 1996–2018: impacts on pesticide use and carbon emissions, GM Crops & Food, 11:4, 215-241, (2020). DOI: 10.1080/21645698.2020.1773198

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[57] *Ibid*

Despite a growing number of judicial challenges, these US patents are still in force as of right now. The range of biotechnology patent eligibility has recently been sharply limited by recent rules set by US courts.

7. INTERNATIONAL LEGAL INSTRUMENTS CONCERNING BIOTECHNOLOGY

Numerous international agreements pertaining to biotechnology are:

1. UN Convention on the Law of the Sea (UNCLOS, 1982),
2. Sanitary and Phytosanitary Measures (SPS Agreement, 1994),
3. Technical Barriers to Trade (TBT Agreement, 1994),
4. International Plant Protection Convention (1997),
5. Aarhus Convention (1998),
6. UNESCO Universal Declaration on Human Genome and Human Rights (1997),
7. UNESCO International Declaration on Human Genetic Data (2003),
8. **Convention on Human Rights and Biomedicine,** ETS No 164 (1997)
9. United Nations Declaration on Human Cloning (2005)
10. Convention on Biological Diversity (1992),
11. Cartagena Protocol on Biosafety (2000)
12. Andean Community Law (1969)
13. International Treaty on Plant Genetic Resources for Food and Agriculture (2004).
14. Trade Related Intellectual Property Rights Agreement (1995)
15. Directive 98/44/EC of the European Parliament (1998)
16. UNESCO Universal Declaration on Bioethics and Human Rights (2005).

There isn't a single complete international regulation that covers all of the criticisms that are typically levelled about biotechnology. The current legal system is a patchwork of largely non-binding, unfocused "soft law" tools. The existing instruments can be divided into four major categories, including protection of human rights, protection of intellectual property rights, protection of the environment, and protection of agriculture and unique food items.

7.1 UN CONVENTION ON THE LAW OF THE SEA (UNCLOS, 1982)

The year 1982 saw the adoption of the United Nations Convention on the Law of the Sea[58]. The United Nations Convention on the Law of the Sea was ratified on 1 November 1994[59]. Article 149 and 303 pertaining to this accord specifically relates to underwater cultural heritage, also apply to area defined as the seabed and ocean floor, and the subsoil of the seabed surpassing the limits of state frontiers (1833 U.N.T.S. 399)[60]. A comprehensive legal layout for the sea, seabed and subsoil as well as for the safeguarding of the marine ecology, its natural and cultural reserves is provided by the Law of the Sea Convention (LOSC) enacted in 1982. Law Of The Sea Convention, December 10 1982, 1833 U.N.T.S. 397 was ratified in November 1, 1994[61]. The pact balances the rights of coastal states with the rights of flag states in each sea area giving priority to coastal states in areas close to the coast. The coastal state best it recognizes the limits of the seas and borders of a coastal state[62]. Articles 149 and 303 of UNCLOS provide assorted structures concerning legal safeguarding of underwater cultural treasures in addition to maintaining a balance of jurisdiction between coastal states and flag states[63]. According to article 149 all archaeological and historical artifacts found in the area must be preserved or transferred for the benefit of all mankind, taking special account of the preferential rights of states or nations, states of cultural or historical and archaeological origin[64]. Article 303 requires member states to keep, archaeological and historical artifacts discovered at sea, and cooperate for this purpose[65].

It sets up instructions for all purposes of ocean reserves and manifests a rigorous framework for law and order in the oceans and seas. It integrates established instructions for ocean exploitation into a single document while introducing new regulatory frameworks and addressing new issues. The convention also lays the groundwork for future progress in specific areas of maritime law as the secretariat of the Law Of The Sea Convention, the Division On Ocean Affairs, and the Law of the Sea (DOALOS) of the United Nations Office of Legal Affairs render statistics, counsel, and aid to states to preferable understand the convention and analogous accords and assure their approval, harmonious execution,

[58]IMO. United Nations convention on the law of the Sea. International Maritime Organization. https://www.imo.org/en/OurWork/Legal/Pages/UnitedNationsConventionOnTheLawOfTheSea.aspx
[59]Convention on the Law of the Sea, Dec. 10, 1982, 1833 U.N.T.S. 397. https://coast.noaa.gov/data/Documents/OceanLawSearch/Summary%20of%20Law%20-%20Law%20of%20the%20Sea%20Convention.pdf
[60] *Ibid*
[61] *Ibid*
[62] *Ibid*
[63] *Ibid*
[64] *Ibid*
[65] *Ibid*

and successful discharge[66]. The division praepostors all changes allied to Convention of the Law of the Sea and maritime affairs and inform the United Nations general assembly of these blooming once a year. It further facilitates the review of these changes in the United Nations open informal advisory process on oceans and the law of the sea[67].

With regard to the maintenance and tenable use of sea, ecological assorts in fields except for state limits, the United Nations General Assembly (UNGA) resolved in 2015 to found a worldwide constitutionally binding document under UNCLOS (UNGA resolution 69/292)[68]. The United Nations General Assembly decided to hold an international conference (IGC) in consideration of implementing as fast as doable by resolution 72/249 at seventy-second gathering in 2017[69]. In order to realize this, the General Assembly also opined, the conference would originally meet for four meetings, each ending ten work days. The first gathering accepted place from September 4 to September 17, 2018, the second and after second meetings happen in 2019, and the fourth meeting happened in the first half of 2020[70]. At the command post of the United Nations in New York, the Intergovernmental Conference grasped its first gathering from September 4 to September 17, 2018, and allure second meeting from March 25 to April 5, 2019 in New York[71]. With respect to the resolution 72/249 the conference agreed to key terms: the preservation and tenable use of sea BBNJ (Biodiversity of Areas Beyond National Jurisdiction); sea hereditary possessions, containing questions about benefit-sharing with respect to Marine Genetic Resources (MGR); Area Based Management Tools (ABMT), containing marine shielded regions; Environmental Impact Assessments (EIA); and ability-construction and the transfer of sea technology[72].

7.2 SANITARY AND PHYTOSANITARY MEASURES (SPS AGREEMENT, 1994)

The Sanitary and Phytosanitary Measures Agreement, also perceived as the SPS Agreement, was signed and endorsed in Marrakech in 1994[73]and commenced in 1995[74]. This

[66] IMO, *Supra note*, 58
[67] *Ibid*
[68] *Ibid*
[69] *Ibid*
[70] *Ibid*
[71] *Ibid*
[72] *Ibid*
[73] WTO. Sanitary and Phytosanitary Measure: Introduction. Understanding the WTO agreement on sanitary and phytosanitary measures. May 1998. https://www.wto.org/english/tratop_e/sps_e/spsund_e.htm
[74] Government of India. SPS (Sanitary and Phytosanitary measures), India and World Trade Organization (WTO). International Trade. Department of Commerce. Ministry of Commerce and Industry. Government of India. https://commerce.gov.in/international-trade/india-and-world-trade-organization-

accord primarily addresses to food security, as well as plant and animal fitness. It suggests that global states formulate their own merits in relation to the SPS pact[75]. The actions taken under the SPS agreement include protecting humans and plants from ecological pollutants that cause diseases in food, protecting humans and plants from ailments, and protecting plants and animals from bugs and to prevent any injury to any state due to their entry, establishment, and development[76] .

7.3 TECHNICAL BARRIERS TO TRADE (TBT AGREEMENT, 1994)

TBT, or Technical Barriers to Trade, was bargained in the Uruguay round of trading talks. The TBT contract was enacted in 1995[77]. The core concept of this pact is to limit unwanted trade and to assert impartial norms, legislation, and assessment modalities[78]. It also recognizes WTO policies pertaining to human and environmental health protection. This pact, advices global states to enact legislation rooted in international norms in order to promote trading. It offers a clear business climate. The TBT pact prevents potential obstacles from forming, as a consequence of standard rules, certifications, and testing[79]. This agreement also allows global states to set legislations vital for plant, animal, human fitness, and consumer interests[80]. The key indicators in the provisions encompass items impartially, limiting obstacles of business, encouraging best proceedings, maintaining pellucidity for others to know, and providing technical aid and treatment to advancing nations[81].

7.4 INTERNATIONAL PLANT PROTECTION CONVENTION (1997)

IPPC or International Plant Protection Convention is a pact that was designed for safeguarding of plants[82]. This pact deploys phytosanitary obligations by global sates to safeguard plant

wto/sps/#:~:text=The%20Agreement%20on%20the%20Application,animal%20and%20plant%20health%20regulations

[75] WTO, *Supra note*, 73

[76] *Ibid*

[77] WTO. The TBT committee's six principles for the development of international standards: Are they still relevant? 14 October 2020. https://www.wto.org/english/tratop_e/tbt_e/tbt_six_principles_e.htm

[78] Arthur E. Appleton. Dispute settlement. World Trade Organization.3.10 Technical Barriers to Trade. United Nations Conference on Trade and Development. United Nations. UNCTAD/EDM/Misc.232/Add.22. (2003). https://unctad.org/system/files/official-document/edmmisc232add22_en.pdf

[79] MPEDA. SPS-TBT. Marine Products Export Development Authority. https://mpeda.gov.in/?page_id=1061

[80] *Ibid*

[81] Donald Otieno. Food Secury and Biotechnology in Africa. This project is financed by the European Union and implemented by the ACP Secretariat. Module 4. Regulation and policy approaches to biotechnology. University of Eldoret. Final Version, February 2017. https://www.rug.nl/research/irees/research/edulink-fsba/fsba-course-modules/fsba-module-4-unit-2-slides-english.pdf

[82] WTO. The WTO and the International Plant Protection Convention (IPPC). https://www.wto.org/english/thewto_e/coher_e/wto_ippc_e.htm

reservoirs from harmful bugs during transnational trading[83]. The first IPPC was adopted in the year 1951[84]. The revision of IPPC attained in 1997 and it was enforced in 2005[85]. The revised pact depicts the accountability of advanced phytosanitary guidelines concerning the SPS accord. The convention establishes universal standards correlating to phytosanitary or plant health indicators. The IPPC integrates safeguarding of agribusiness from pests, encouraging globalized phytosanitary indicators for promoting trade and achieving sustainable goals of the UN[86]. However the Sustainable Development Goals (SDGs) of the UN for 2030 are intimately related to the work of the IPPC[87]: goal one is that we must eradicate poverty worldwide; goal two is to eradicate hunger, ensure food insurance, rise nutriments and promote sustainable farming; goal eight is enabling long-term economic growth; goal twelve is to assuring sustainable producing and consuming patterns; goal thirteen is to take swift action to mitigate the effects of climate change; goal fifteen is to stop and land damage, safety restore and encourage sustainable utility of terrestrial ecology, administer woodlands, sustainably prevent logging and stop biodiversity loss; goal seventeen is to bolster exertion strategies and rekindle the international collaboration for sustainable built out. Further adding to this, it promotes to noteworthy boost the shipping of advancing nations with a view raising the least advancing nations quota in transnational shipping by 2020, that will help to strengthen the means of execution and revive the global partnership for sustainable development.

7.5 AARHUS CONVENTION (1998)

The Aarhus Convention is the primary global ecological democracy pact. The right of everyone to live in a wholesome environment is protected by the Aarhus Convention on ecological elements. It ensures the public's prime privileges on data access. The privileges of the individuals to obtain ecological data kept by public entities are referred to as access to data. Cases where individual fitness and security are impacted by the state of the ecology also include data on the state of the ecological policies or initiatives, impacting the ecological and public health and safe participation of individuals. The right of the general individuals to engage in ecological decision-establishment is alluded to as public involvement. Public authorities must permit meaningful involvement in decision-

[83] *Ibid*
[84] WIPO Lex. International Plant Protection Convention (1951) No. 1963. Food and Agriculture Organization (FAO) TRT/FAO-IPPC/003. https://wipolex.wipo.int/en/text/196534
[85] WTO, *Supra note*, 82
[86] FAO. International Plant Protection Convention. https://www.ippc.int/en/structure/
[87] *Ibid*

making on projects that have an impact on the ecological intention and initiatives related to the environment, from the general public and ecological NGOs to access justice[88]. In order to ensure that public authorities uphold the rights to ingress to data, public involvement and ecological laws in general, the public's right to review by a court or another independent agency is referred to as ingress to justice. The Aarhus pact is the cornerstone of safeguarding ecological democracy outlining a set of fundamental procedural rights for the individuals and putting requirements on public officials to make these privileges effective, improving openness and making governments more accountable to the people[89] . The goal of the ingress to ecological data directive 2003/4/EC is to make sure that the individuals has regular ingress to ecological data from the government either proactively or on demand[90]. On October 6 2021, the EU or European Union passed regulation 2021/1767 amending regulation 1367/2006 to enable NGOs and other members of the public to more easily review EU environmental legislation[91].

7.6 UNESCO DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS (1997)

On November 11, 1997 the 29th session of the UNESCO general conference overwhelmingly endorsed the Universal Declaration on the Human Genome and Human Rights[92]. The UN general assembly then approved it in the year1999 and percepts for the enforceability of the accord were embraced by UNESCO in the same year[93]. The declarations endorsement of peoples privileges and the supremacy of those rights, together with elemental liberty and peoples nobility above technical exertion dealing with the human genome precisely in the disciplines of biology, genetics and medicine is its key message. The accord places a strong emphasis on the idea of human dignity. Human dignity is concerned with the innate qualities of the individual as a human being and the practicability or essence of the person as an affiliate of the human species regulation-wise. The accord exhibits in Article 11 that it is forbidden to engage in acts that violate human dignity such as the conceptive cloning of

[88]European Union. The Aarhus Convention and the EU. https://environment.ec.europa.eu/law-and-governance/aarhus_en
[89] *Ibid*
[90] *Ibid*
[91] *Ibid*
[92]UNESCO. Universal Declaration on the Human Genome and Human Rights. https://en.unesco.org/themes/ethics-science-and-technology/human-genome-and-human-rights
[93] *Ibid*

people[94]. Nations and capable global corporations are asked to work together to identify such actions and to take the germane strides or global strides to certify that the fundamental values outlined in this pact are upheld[95]. The pact only says that certain actions like human cloning are prohibited. It makes no further recommendations to signatories. The pact is well-known and regularly brought up while talking about the human genome, despite this the document itself is not a declaration that has legal force.

7.7 UNESCO INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA (2003),

Medical research and therapeutic applications have been made possible by genetics, particularly the sequencing of the human genome[96]. Medical diagnosis, disease prevention, and population genetics research, all benefit from the utilization of genetic data[97]. Due to the individuality of each person's genetic ancestry, forensic science and the legal system also use them to identify people[98]. There are more genetic databanks than ever before, some of which have over a million records. Some are kept on a nationwide scale and have samples from almost the whole population. Many people worry that the use of human genetic data would violate their freedom and human rights in this fast evolving industry. International regulations are demanded by governments, non-governmental organizations, the academic communities, and societies at large. The International Declaration on Human Genetic Data was adopted at UNESCO's 32nd General Conference on October 16, 2003, to allay these worries[99]. The only international standards for bioethics are this Declaration and the Universal Declaration on the Human Genome and Human Rights[100]. Article 19 calls for the distribution of benefits from human genetic data "in accordance with domestic law or policy and international agreements[101]. This Declaration does not impose any legally enforceable responsibilities, just like the Declaration on Human Genome and Human Rights.

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[94] *Ibid*
[95] *Ibid*
[96] UNESCO. Resolutions Volume 1. Records of the general conference. 32nd Session. Paris, 26 September to 17 October 2003. 32 C / Resolutions. (2004). https://unesdoc.unesco.org/ark:/48223/pf0000133171.page=45
[97] *Ibid*
[98] *Ibid*
[99] *Ibid*
[100] *Ibid*
[101] *Ibid*

7.8 CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE, ETS NO. 164 (1997)

The Convention on Human Rights and Biomedicine (ETS No. 164) which protects humanity in correlation to the pertinence of biology and medicine was made available for signing on April 4 1997 in Oviedo, Spain and enforced on 1 December 1999[102]. This convention is the only global legally binding document on safeguarding individual rights in the biomedical sphere and it is based on the biological and medical equivalents of the percepts laid out by the European Convention on Human Rights[103]. It is a across the board accord that aims to protect everyone's rights and fundamental freedoms in relation to the use of biology and medicine while also convincing that, all are treated with respect for their integrity and other qualities. It lays out core ideas that apply to every day medical practice and is recognized as such in the European patient rights treaty[104]. Additionally it especially addresses genetics, organ and tissue transplantation and biomedical research[105].

7.9 UNITED NATIONS DECLARATION ON HUMAN CLONING (2005)

The UN general assembly passed resolution 10333 on human cloning in 08 March, 2005[106]. The resolution was the outcome of a protracted and contentious assembly discussion. Unlike the UNESCO general conferences unanimous proclamation, this resolution was approved by a vote of 84 in support to 34 opposed and 37 abstentions[107]. This UN declaration's main argument is that all types of human cloning as much as they are incompatible with individual dignity and the safeguarding of humanity, must be prohibited[108]. Although the pact is non binding the vocal opposition it faced sheds crucial light on the challenges of cloning-related international agreements. This is the first and only attempt to create a binding European legislative framework that addresses at least some of the fundamental fields of medicine. If not all of them, with the ratification of the UN Declaration on Human Cloning, the UN has made

[102] Council of Europe Portal. Human Rights and Biomedicine. Oviedo Convention and its Protocols. https://www.coe.int/en/web/bioethics/oviedo-convention
[103] *Ibid*
[104] *Ibid*
[105] *Ibid*
[106] United Nations. General assembly adopts United Nations declaration on human cloning by vote of 84-34-37. GA/10333. 8 March 2005. https://knowlaw.in/wp-content/uploads/2021/05/United-Nations-Declaration-on-Human-Cloning.pdf
[107] *Ibid*
[108] Adele Langlois. The global governance of human cloning: the case of UNESCO. Palgrave Commun. 3, 17019. (2017). https://doi.org/10.1057/palcomms.2017.19

an attempt to clear up the confusion[109]. The UN aimed to create a universal framework for reliable social regulation of human genetic technology[110]. The accord however falls short of putting the global frame it aimed to institute due to significant uncertainties in the declarations, non-binding language, leave governments with limited guidelines when establishing their own national laws governing human cloning[111] .

7.10 CONVENTION ON BIOLOGICAL DIVERSITY (1992)

At the Rio de Janeiro Earth summit on June 5, 1992 the Convention on Biological Diversity or CBD was made available for approval and it went enforced on December 29, 1993[112]. There are now 193 parties. All the different types of life on earth including ecological animals plants, fungi, microbes and genetical diversity that are considered components of ecodiversity are considered under the CBD. The CBD is frequently regarded as the most important international tool for sustainable development[113]. Humans should make use of ecological species and genetic reserves but only in ways that do not threaten ecodiversity. The advantages to the surrounding economy and society from ecodiversity preservation outweigh the substantial investments needed to achieve it. The conventions action plan is based on the ecosystem approach an integrated resource management method. The precautionary principle emphasizes that lack of complete scientific confidence should not be used as an excuse for delaying steps to avert or reduce such a hazard where there is a risk of severe decline or loss of biodiversity.

A comprehensive legal structure governing access to ecological reserves and the distribution of benefits accruing from their utility is also provided by this ecodiversity accord[114] . The issue of property rights and the legal standing of ecological reserves under global law are both directly tied to the issue of access[115]. As genetical engineering advances, it offers new trades to obtain intellectual property rights over ideas produced from ecological reserves, access. Since poor nations contain the majority of the world's ecodiversity, the issue of access became crucial

[109] Channah Jarrell. *No worldwide consensus: The United Nations declaration on human cloning*. Ga. J. Int'l & Comp. Law, 35, 205, (2006). https://digitalcommons.law.uga.edu/gjicl/vol35/iss1/7
[110] *Ibid*
[111] *Ibid*
[112] UNEP. Convention on Biological Diversity. Living in harmony with nature. 2011-2020 United National Decade on Biodiversity. https://www.cbd.int/undb/media/factsheets/undb-factsheet-cbd-en.pdf
[113] *Ibid*
[114] Philippe Cullet. The convention on biological diversity. International Environmental Law Research Centre. IELRC Briefing Paper 2003-1. (2003). https://www.ielrc.org/content/f0301.htm
[115] *Ibid*

during the talks for the biodiversity pact[116]. The Article 19 of CBD deals with handling of biotechnology and disbursement of its benefits[117].

7.11 CARTAGENA PROTOCOL ON BIOSAFETY (2000)

The convention on biological diversity has a licitly enforceable pact known as the Cartagena Protocol on Biosafety[118]. It was given the name Cartagena in tribute of the Colombian city, in discussions, scheduled in February 1999[119]. The pact was completed and formalized on 29 January, 2000 in Montreal Canada[120]. The accord addresses the cross border transport, governance and abuse of living altered species that adversely affect the security and sustainable use of ecological variety, taking into consideration hazards to human health[121]. It excludes LMOs, or living modified organisms, human medications covered by another pertinent universal accord or organizations and products made from LMOs such as paper manufactured by using GM or genetically modified trees[122]. The protocol's Advance Informed Agreement (AIA) requirement is its primary processing[123]. Before the first deliberate cross border migration of an LMO into the ecology of the importing state the method must follow an advisory, providing comprehensive details regarding the LMOs, past menaced evaluation of the LMOs and its managerial standing in the exporting state, must be given by the exporter to the importing state[124].

Within 90 days the importing nation should confirm acquiring the data and indicate whether the informant should move further via its own internal regulation protocol[125]. In either scenario the importing state has 270 days to determine if to approve the item with or without restrictions or to reject it[126]. The protocol also include the feature of Biosafety Clearing-Housing or BCH, that aids signatories in putting the accord into effect by facilitating the interchange with respect to scientific, technical, ecological licit and competent

[116] *Ibid*
[117] United Nations. Convention on biological diversity. (1992). https://www.cbd.int/doc/legal/cbd-en.pdf
[118] ISAAA. Pocket KNo.8: Cartagena Protocol on Biosafety. (2004). https://www.isaaa.org/resources/publications/pocketk/8/default.asp
[119] *Ibid*
[120] *Ibid*
[121] *Ibid*
[122] *Ibid*
[123] *Ibid*
[124] *Ibid*
[125] *Ibid*
[126] *Ibid*

with LMOs[127]. The protocol also facilitates with risk analysis according to the pact commitment about planned imports. Risk analysis need to be conducted in a technical way using accepted risk evaluation procedures while also taking into account recommendations made by pertinent international organizations[128] .

7.12 ANDEAN COMMUNITY LAW (1969)

The economic bonding model of the Andean community of 1969 has been followed by Ecuador, Peru, Bolivia, and Colombia. Currently Chile, Argentina Brazil, Paraguay, Uruguay, and Spain are amalgamated country members, whereas Spain is serving as an observer[129]. The basic obligation of the Andean community is to raise the living standards of individuals throughout this territory[130]. This community has been making special efforts to develop biotechnology in their territories, utilizing modern scientific and technical policies and regulations[131]. At the state level utilizing modern scientific and technical policies and regulations several projects on biotechnology have been executed[132]. However there are still some attempts required with respect to monetary and political aspects. The Andean community law in the last many years has laid down various operational promotions in various technical sectors, that include biotechnology[133]. The application of relevant rules and legislations at the community degree has encouraged biotechnology in the Andean group of nations.

7.13 INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (2004)

A novel pact pertaining to genetical reserves of plants was approved on 3 November, 2001 in Rome and it was referred to as International Treaty on Plant Genetic Resources for Food and Agriculture[134]. This accord of the Food and Agriculture Organization of the UN was enforced on June 29, 2004[135] . This treaty has certain obligations for food and agriculture and it

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[127] *Ibid*
[128] *Ibid*
[129] Juan Carlos Cuesta. Andean Community (CAN): An Overview. Boutique Business Law Firm. https://cuestalawyers.com/en/andean-community-can-an-overview/
[130] Carlos B. Aguirre. Biotechnology in the Andean Group: Common policies and instruments. J. Biotech., 31(1):17-37. (1993). https://doi.org/10.1016/0168-1656(93)90134-9
[131] *Ibid*
[132] *Ibid*
[133] *Ibid*
[134] Shawn N. Sullivan. Plant genetic resources and the law: past, present, and future. Plant Physiol., 135(1):10–15. (2004). https://doi.org/10.1104/pp.104.042572
[135] *Ibid*

establishes certain goals, which include[136]:a) to promote safeguarding of genetical reserves of assorted species of plants significant for agribusiness b) to compensate ranchers through legal aid concerning to their efforts towards plant genetical reserves. c) to establish sovereignty on plant genetical reserves such that it does not hinder interchange of genetical knowledge on plant species. d) to develop a system that is having a multilateral access benefit sharing pertaining to commercial utility. Each member state is obligated to take actions to promote and protect farmers' rights under Article 9 of the treaty, "subject to its national legislation,"[137].

7.14 TRADE RELATED INTELLECTUAL PROPERTY RIGHTS AGREEMENT (1995)

The Uruguay Round of the GATT (General Agreement on Tariffs and Trade), which began in 1986, saw the negotiation of Trade-Related Aspects of Intellectual Property Rights (TRIPS) emerging as one of the key new topics for discussion[138]. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), one of the agreements to come out of the Uruguay Round, was finally agreed upon at the ministerial meeting in Marrakesh, Morocco in April 1994 and entered into force as part of the WTO Agreement on January 1, 1995[139]. There are various obligations related to biotechnology under the TRIPS Agreement. According to Article 27 of the TRIPS Agreement, patents must be available for "Patentable Subject Matter"[140]. A few exceptions to this general rule are provided in Article 27, such as Article 27(3) (b), which allows WTO members to exclude plants and animals from patentability, while requiring them to recognize patents over microorganisms, patents for microbiological processes used in the production of plants and animals, and either patent or *sui generis* protection for plant varieties[141].

Members can choose to either give *sui generis* protection for new plant varieties, patent protection for new plant varieties, or both *sui generis* and patent protection for new plant varieties when it comes to plant variety protection[142]. In terms of the general protection of

[136] *Ibid*
[137] *Ibid*
[138] Japan Patent Office. Introduction to TRIPs agreement. Asia Pacific Industrial Property Center, JIII. (2008). https://www.jpo.go.jp/e/news/kokusai/developing/training/textbook/document/index/TRIPs_Agreement.pdf
[139] *Ibid*
[140] Simon Walker. The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper. IUCN, Gland, Switzerland and Cambridge, UK and CIEL, Geneva, Switzerland. xiv + 60pp (2001). https://portals.iucn.org/library/sites/library/files/documents/EPLP-041.pdf
[141] *Ibid*
[142] *Ibid*

innovations, Article 27(2) enables members to deny patents on inventions in order to uphold morality or public order, including in order to safeguard human, animal, or plant life or to prevent substantial environmental harm[143]. Such restrictions must not be introduced just because using the invention for commercial purposes is against national law[144]. According to Article 61 of the TRIPS agreement, members must set up criminal prosecution and sanctions at the very least in situations where trademark or copyright infringement is done intentionally and on a large scale[145].

7.15 DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT (1998)

This directive came into enactment on 31 July 1998[146] . In order to promote investment and research in the field of biotechnology, this directive lays out rules for the legal protection of biotechnological inventions. The directive is categorized into the five chapters (I) Patentability; (II) Protection scope; (III) Cross-licensing requirements; (IV) Deposit, access, and re-deposit of biological materials; and (V) Final rules. Inventions must be new, entail an innovative step, and be suitable for industrial application in order to qualify for patent protection. Even if it previously happened in nature, biological material can be the subject of an invention as long as it has been removed from its natural environment or manufactured through a technical procedure. Plant and animal varieties, as well as primarily biological methods used to produce plants or animals, are not patentable. Article 12 deals with the mandatory licenses that must be given to breeders in order for them to obtain or utilize a plant variety right without violating an earlier patent[147]. Such patents must be applied for and have the necessary royalties paid before being awarded. Article 16, also mentions the reports that must be written and sent to the Council and European Parliament by the Commission[148].

7.16 UNESCO UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS (2005).

[143] *Ibid*
[144] *Ibid*
[145] Japan Patent Office, Supra note, 138
[146] UNEP. Directive 98/44/EC of the European parliament and of the council on the legal protection of biotechnological inventions. Official Journal L 213, 30 July 1998, pp. 13-21. (1998). https://leap.unep.org/countries/eu/national-legislation/directive-9844ec-european-parliament-and-council-legal-protection
[147] *Ibid*
[148] *Ibid*

This declaration was adopted on October 19th, 2005, by the 33rd session of the UNESCO General Conference by acclamation[149]. Article 1 of the declaration discusses moral concerns pertaining to the application of medicine, life sciences, and associated technologies to people while taking into account their social, legal, and environmental implications. It also offers guidance to decisions or practices of individuals, groups, communities, institutions, and corporations, both public and private, as appropriate and relevant[150]. The objectives of Article 2 are[151]: (a) provide a universal framework of principles and procedures to guide states in the formulation of their legislation, policies, or other instruments in the field of bioethics; (b) direct the actions of individuals, groups, communities, institutions, and corporations, both public and private; and (c) promote respect for human dignity and protect human rights by ensuring respect for human life and fundamental freedom. (d) to emphasize the need for such research and developments to take place within the framework of ethical principles outlined in this declaration and to respect human dignity, human rights, and fundamental freedoms; (e) to promote multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholder groups; and (f) to recognize the value of freedom of scientific inquiry and the benefits derived from scientific and technological advancements. h) to emphasize the significance of biodiversity and its conservation as a shared concern of humanity; g) to protect and advance the interests of the present and future generations;

8. THE NORMATIVE EMPHASIS OF BIOTECHNOLOGY REGULATIONS

As the centre of regulation, international law is unclear. It is unclear whether the preservation of intellectual property or public accountability should be the main concern. Biotechnology represents a logical extension of human creativity and offers unmatched potential for people. It provides a great path that may be used in numerous food and agricultural fields, as well as in medical and the development of new pharmaceuticals. It has the potential to make a significant difference in the lives of millions of people, especially in developing nations where starvation is a constant threat. But just like the majority of other occurrences that have been observed throughout human history, the unrestrained application of biotechnology may potentially have negative effects. The claim by the biotechnology industries that their methods and products are

[149] UNESCO. Universal Declaration on bioethics and human rights. SHS/EST/BIO/06/1, SHS.2006/WS/14. United Nations Educational, Scientific and Cultural Organization . Division of Ethics of Science and Technology. Social and Human Science Sector. France. (2006). https://unesdoc.unesco.org/ark:/48223/pf0000146180

[150] *Ibid*

[151] *Ibid*

just innovations and amount to nothing more than man's evolutionary, and occasionally revolutionary, approaches to invention and progress, is true if one makes intellectual property rights protection the focus of biotechnology. Intellectual property protection is a serious matter that should not be taken lightly. As was previously mentioned, biotechnology usually involves inventions and concerns of intellectual property rights to the extent that it involves the manipulation of biological systems, live beings, or similar derivatives to manufacture or change things. We must logically recognize the right to utilize biotechnology to safeguard new inventions generally in other spheres of human endeavour. On the other hand, the problems are very different if one makes public accountability and regulation, the centre of regulation. The key question is what level of regulation is required for biotechnology to function properly without impeding innovation and human progress.

Making accountability, the main focus of regulation has the appeal that it can better balance the conflicting demands of corporate profits through the protection of intellectual property rights and the requirement to ensure community protection through a reliable system of transparency and accountability. Regardless of the topic chosen as the foundation for biotechnology regulation, the fact remains that, other from European legislation and directives, there is no reliable international instrument that controls biotechnology activities as a whole. Perhaps the relative clarity with which Europeans have tackled the biotechnology debate is unsurprising given the region's history. But the rest of the global community must learn valuable lessons from their strategy. The current international legal framework for biotechnology regulation is by no means ideal. In addition to lacking a complete or holistic approach, the existing regime lacks any strict international accountability structure. The truth about biotechnology is that it is not just global in scope, but that it will also continue to progress along with humankind's scientific understanding. It would seem that there is an urgent need to build adequate tools that comprehensively address the subject of biotechnology in all aspects given the predicted progressive advancements in man's creative capacity. The evolution of the WTO Agreement and its other multilateral and plurilateral trade accords strongly suggests that the adoption of a comprehensive biotechnology framework is feasible. The chances of a thorough worldwide biotechnology regulatory framework are favourable. The development of such an instrument must be done in accordance with the international community's adoption of an accountability-oriented regulatory approach.

9. CONCLUSION

A complex set of laws and rules known as the coordinated framework for regulation of biotechnology serves as the framework for federal regulation of biotechnology products. Although in certain instances the agencies' jurisdiction has been established in ways that potentially may leave gaps or overlaps in regulatory control. The coordinated framework appears to offer a great deal of flexibility to encompass a variety of biotechnology goods. Even if the laws do legally permit agencies to regulate these items, the instruments that are now available to regulators may occasionally make it difficult for them to do so. Almost all statutes lack sufficient legal authority for post-marketing surveillance, as they may not require product sponsors to share in the burden of generating information about product safety. The burden of proof on regulators to establish that a product is unsafe before they can take action to protect the public, or require burdensome processes or procedures, the regulators must follow before they can act. As a result, although it is likely that existing regulators will have some control over future biotechnology goods, it may be difficult for them to do so effectively and to adapt quickly to new products as they emerge. Over the past ten years, several biotechnology research and development fields have sparked various responses and choices. There are undoubtedly multiple public opinions, ethics committee recommendations, and national policy frameworks for each innovation. On the other hand, social movements and political laws vary greatly from one nation to the next and are heavily influenced by the specifics of each innovation and how it relates to relevant local, national, and individual challenges. Each biotechnological advancement in this perspective encompasses far more than just a single application of industrial, agricultural, or health, whose moral and social implications would have been resolved once and for all.

Contrarily, regulatory authorities must, and frequently do, address the ethical, social, and technical aspects of each innovation as a whole in order to win over the public. National developments in public regulations on these topics demonstrate how challenging the undertaking may be because regulators must deal not just with technical ambiguity but also with serious moral conundrums. In the majority of the nations, it’s observed, ethical committees and ad hoc commissions have contributed to the discussion of these conundrums. Many have concentrated on definitional issues, but not for formal legal considerations, but rather because defining an issue's purpose is frequently the first step in making it clearer. The recommendations made by these committees regarding stem cells or transgenic and cloned animals were heavily influenced by studies and the development of terminology for an embryo

or an animal. Committees have also been useful in determining the values at stake in moral dilemmas. Some bodies, like the Danish Council of Ethics or the Indian Council of Medical Research, have taken society's cultural and religious views into account even though they typically take a rational, global perspective. Most ethics committees have emphasized values in their work and made it apparent that a straightforward cost-benefit analysis should not be used to evaluate the ethical implications of biotechnology.

Many biotechnology advancements purport to meet ethical requirements. Genetic testing is a benefit for patient autonomy and would enable personalized and tailored medicine. Engineered animals could advance medical knowledge. Stem cell research can save lives. Biofuels should help protect the environment. Genetically modified food and crops may help fight hunger and malnutrition. However, just like any tool, these advancements could be utilized in immoral ways. Therefore, opposing viewpoints shouldn't just be written off as transient, meaningless, or the result of ignorance or irrationality. In addition to revealing deeply ingrained ethical and cultural norms that shouldn't be disregarded, they frequently indicate the internal ethical conflicts of biotechnological advancements. Even though there is some worldwide harmonization, suitable ethical debates are still necessary for the development of biotechnology in order to identify and address unique cultural and national problems and maintain public trust.