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THE IMPLEMENTATION OF BIOSAFETY AND EMERGING BIO-TECHNOLOGIES IN ETHIOPIA:

POLICY AND LEGAL FRAMEWORK

A THESIS SUBMITTED IN PARTIAL FULLFILMENT FOR THE MASTERS OF LAWS (LLM) IN PUBLIC INTERNATIONAL LAW

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Declaration

I the under signed researcher, declared this thesis is my original work and has not been presented for a degree in any other university and all sources of material in the thesis have been duly acknowledged.

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Thank you GOD to let me do this!!!

Etatey & Yayew አመሰግናለሁ።።

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List of Abbreviations

AHTEG	Ad Hoc Technical Expert Group
AIA	Advance Informed Agreement
AU	African Union
BCH	Biosafety Clearing House
BWC	Biological Weapon Convention
CBD	Convention on Biological Diversity
COP/MOP	Conference of the Parties serving as the meeting of the parties to the Protocol
DNA	Deoxyribonucleic Acid
RNA	Ribonucleic Acid
EIA	Environmental impact Assessment
EU	European Union
Ex-COP	First extra ordinary meeting of the conference of the parties
FDRE	Federal Democratic Republic of Ethiopia
GM	Genetically Modified
GMO	Genetically Modified Organisms
ICCM	International Conference Chemical Management
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
ISO	International Organization for Standardization
LMO-FFPs	Living Modified Organisms Intended for direct use as food or feed, or For Processing
MASS	Marker Assisted Selection
NGO	Non-governmental organization
OAU	Organization for Africa Unity
OECD	Organization for Economic Cooperation and Development

OMD	Oligonucleotide Directed Mutagenesis
SDN	Site Directed Nucleases
UK	United Kingdom
UN	United Nations
UNEP	United Nations Environment Program

ABSTRACT

The research assessed the existing biosafety regulatory regime with regard to emerging biotechnologies in Ethiopia by identifying the emerging biotechnologies. The research identified common characteristics and components in biosafety regulatory systems of emerging biotechnologies in Ethiopia with reference to related provisions of the Cartagena Protocol, CBD, African model law on safety technology and supplementary protocol. The study assessed that whether the Ethiopian biosafety regulatory regime does comply with the provisions of CBD, and the Cartagena Protocol by taking its rules as minimum standard and encompasses the regulation of emerging biotechnologies. In addition the study has shown that the Ethiopia biosafety regulatory regime is more comprehensive than the protocol and African model law as it regulates the international transboundary movement of MOs which are the product of emerging biotechnologies even though there is a gap of regulation with regard to the domestic development of MOs by emerging biotechnologies. Finally, the research has given recommendations on possible ways in which Ethiopia might comprehensively regulate MOs of emerging biotechnology and improve its national biosafety regulatory systems which enable the biosafety regulatory system to become more effective in protecting the environment and human health.

CHAPER ONE

INTRODUCTION

1.1. Background

The term biotechnology refers to any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for a specific use.[1] This concept is not new. Farmers have relied on selective breeding and cross fertilization to modify plants and animals and encourage desirable traits that improve food production and other human needs. Artisans have exploited traditional fermentation techniques to transform grains in to bread and beer and milk in to cheese. Such intentional modification of the natural world has contributed enormously to human wellbeing.

Over the past 50 years, the ability to alter life forms has been revolutionized by modem biotechnology. Scientists have learned how to extract and transfer strands of DNA and entire genes which contain the biochemical instructions governing how an organism will develop from one species to another. Using sophisticated techniques, they can precisely manipulate the intricate genetic structure of individual living cells[2]. In addition biotechnology refers to broad fields of knowledge (synthetic biology is a 'biotechnology' in this sense); programs of research defined by specific objectives (genetic modification (GM) of food crops is a 'biotechnology' in this sense); techniques or procedures, often associated with a distinct kind of apparatus or machinery (DNA sequencing is a 'biotechnology' in this sense); specific applications of techniques or procedures (in vitro fertilization is a 'biotechnology' in this sense); and products themselves (a Nano scale biosensor device is a 'biotechnology' in this sense).[3]

Biotechnologies are becoming one of the most promising innovative technologies that yield significant returns to businesses and offers benefits to the society. However, their benefits are not

[1] Convention on Biological diversity,(1992), Article 2

[2] Biosafety and the Environment, available at http://www.biodi v.org visited on November 25,2019, p. 4

[3] Emerging biotechnologies: technology, choice and the public good available at http://www. Nuffield bioethics .org, p 23

without risks to human and environment. Nowadays, the rapid development of biotechnology has become a main concern for a larger part of the world. When dealing with biotechnology, the first issue that comes to mind is the safeness of the technology from tip to toe about the safeness of the products of biotechnology, how they can be used on human beings and animal, and their effects on the environment.[4] Extreme positions appear to polarize the debate on biotechnology, extreme pro- and extreme anti-genetic engineering positions and emerging biotechnologies. Although, genetic engineering, emerging biotechnologies and genetically modified organisms (GMOs) are beneficial to the society, concerns remain over the risks they may pose to human, animal health and the environment. Moreover, there are many socio-economic considerations that need to be kept in view particularly in developing countries.[5]

Proponents argue that biotechnology will boost food security for the world's growing population by raising sustainable food production. It will benefit the environment by reducing the need for more farm-land, irrigation and pesticides, and others. It will also provide better medical treatments and vaccines, new industrial products and improved fibers and fuels.[6]

For many people, however, this rapidly advancing science raises a web of ethical, environmental, social and health issues. Because modern biotechnology is still so new which much is not known about how its products may behave and evolve, and how they may interact with other species. While modem biotechnology may have great potential, it must be developed and used with adequate safety measures, particularly for the environment. This is achieved with comprehensive international and national regulatory regimes, legislation and risk-assessment systems in place.[7]

Emerging biotechnologies present special challenges of uncertainty, ambiguity and transformative potential that are substantially settled in the case of established technologies.

[4] African Journal of Biotechnology Vol. 10(58), pp. 12389-12394, 30 November, 2019 Available online at http://www.academicjournals.org/AJB p.1

[5] CBD (n1) and Ibid p. 22

[6] Africa journal (n4)

[7] ibid

Emerging biotechnologies often come up against regulatory conditions that are maladapted to them and that may unnecessarily inhibit certain trajectories or compound uncertainty.[8] For many developing countries to have his comprehensive regulatory regime in modern biotechnology and its products are still difficult to achieve.

As biotechnology is a global industry, and emerging biotechnologies are traded across borders, international rules are needed as well. The Rio declaration on environment and development enshrined the precaution principle and other principles which are important to keep safety of the environment. In addition convention on biodiversity, Cartagena protocol on biosafety, Nagoya Kuala Lumpur supplementary protocol on liability and redress are established to achieve the balance of emerging biotechnology and biosafety.

Biosafety is the safe development of biotechnology products and their safe application resulting from the existence of effective mechanisms for the safeguard of human and animal health, safe agricultural production, safe industrial production, safeguard of the natural plants and animal species and the environment from negative consequences due to the practice and application of biotechnology and its products.[9]

Ethiopia, being a party to Convention to Biodiversity and the Cartagena Protocol which are part of the most important international treaties adopted and marks the commitment of international community to ensure the safe, transfer, handling and use of LMOs, has its National Biosafety Framework. The National Biosafety framework includes policy, legal, administrative and technical instruments that have been developed in order to ensure an adequate level of safety in the field of the safe transfer, development, handling and use of living modified organisms (LMOs), and their product that emanate from modern biotechnology and have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

[8] Emerging 3 page 136

[9] Two frequently asked questions on biosafety Protocol available at www.utoledo.edu/research/rsp/RC/biosafety-faq.htm. visited on 11512008 p.1

1.2. Statement of the Problem

The developments of emerging biotechnologies are fast and alarming in all aspect of life issues. These emerging biotechnologies are increasingly becoming a source of environmental risk and human health problem. The environmental risks associated with modem biotechnology and have not yet been scientifically proven as there is still insufficient evidence as to what environmental risks may pose.[10] Biosafety regulations play a key role in the sound and safe use of biotechnology.[11] However, strict laws and regulations may stifle scientific and technological innovations and prevent countries from implementing sustainable development commitments related to biotechnology.[12] The shortcomings of biotechnology might be handled through the introduction and implementation of biosafety measures and capacity building in the institutions engaged in biotechnology and related activities.

The regulation with regard to emerging biotechnology is characterized by uncertainty, ambiguity and transformative nature.[13] The regulatory regime with respect to emerging biotechnology focuses on risks and precautionary approach and other ethical considerations.[14] The legal regimes which are adopted to implement biosafety issues of emerging biotechnology, needs to be comprehensive and can strike a balance between the use of emerging biotechnology and biosafety.

1.3 Research question

Generally this research attempts to explore how the Ethiopian biosafety policy and law transpose international biosafety instruments, conference of parties' decisions, and their comprehensiveness to regulate emerging biotechnologies. The examination of the Ethiopian

[10] Ibid

[11] Ibid

[12] Ibid

[13] Emerging (n3)

[14] Ibid

biosafety policy and law would help to identify their gaps, contradictions and weaknesses. In addition the general study examines and responds to the following specific questions:

- How international biosafety legal instruments do regulate emerging biotechnologies?
- Are national legal regimes compatible and comprehensive enough to implement international biosafety instruments?
- Does Ethiopian legal regime regulate emerging biotechnologies?

1.4. Objective of the Study

The overall aim of the research is to make a comprehensive analysis of the regulatory regime of Ethiopia biosafety regulatory frameworks by evaluating how the Cartagena protocol on biosafety and other international biosafety instruments are implemented including their compliance, to show the gaps in relation to regulating emerging biotechnology and add a new perspective to the existing scholarly researches. The study does have the following specific objectives:

- Analyzes the meaning of emerging biotechnology and biosafety
- Gives an overview of the international regulation of emerging biotechnology and biosafety
- Discusses the current status of biosafety regulatory framework in Ethiopia
- Analyze the compatibility of the Ethiopian regulatory framework with the international biosafety regimes
- Shows regulatory problems that hinder biosafety implementation in Ethiopia
- Gives recommendations that facilitate the implementation of biosafety of emerging biotechnologies in Ethiopia

1.5. Literature Review

Various biosafety responses measures and regulatory rules have been developed at international and national levels to address biosafety concerns. The need for biosafety was demonstrably shown by their development and the production of an international Cartagena Biosafety

Protocol.[15] The particular contribution of the Cartagena Protocol to global biosafety is helping to ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on Transboundary movements.[16] The protocol deals primarily with GMOs that are to be intentionally introduced into the environment and with genetically modified organisms. It does not cover pharmaceuticals for humans addressed by other international agreements and organizations or products derived from GMOs.[17] There is also debate whether the Cartagena protocol regulates synthetic biology.[18] Identifying any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of living modified organisms under the Cartagena Protocol and evaluating the availability of tools to detect and monitor the organisms, components and products of synthetic biology.[19] But according to some synthetic biology is under the regime of biosafety protocol by noted that their existing biosafety laws which have been formulated based on the protocol for regulating LMOs are also applicable to living organisms that have been developed through synthetic biology.[20]

The Protocol reaffirms Principe 15 of the 1992 Rio Declaration on the Environment and Development, where there are threats or serious or irreversible damage, lack of full scientific

[15] Ruth Mackenzie, Françoise Burhenne-Guilmin, Antonio G.M. La Viña and Jacob D. Werksman in cooperation with Alfonso Ascencio, Julian Kinderlerer, Katharina Kummer and Richard Tapper, An Explanatory Guide to the Cartagena Protocol on Biosafety , (2003) available at www.cbd.int/doc/books/2003/B-01669.pd visited on december13,2020

[16] Cartagena protocol on Biosafety to the Convention on Biological diversity, (2000), article 4

[17] Ibid

[18] Convention on Biological Diversity,ad hoc technical expert group on synthetic biology, Montreal, Canada, 5-8 December 2017, Item 3 of the provisional agenda .5

[19] Ibid .5

[20] Ibid p.3

certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation.[21] Based on this concept a government may decide on the basis of precaution not to permit a particular GMO product to be imported across its borders. This is the case even if there is insufficient scientific evidence about the GMOs potential adverse effect. The Cartagena Protocol promotes biosafety by establishing practical rules and procedure for the safe transfer, handling and use of GMOs, with a specific focus on regulating movements of these organisms across borders, from one country to another.

Governments must also adopt measures for managing any risks identified by risk assessments, and they must continue to monitor and control and risks that may emerge in the future. This applies to trade as well domestically produced GMOs. The Cartagena protocol and related laws are expected to play an important role in further clarifying the consideration and operationalization of the precautionary principle in practice. The approach to precaution in the area of biotechnology and biosafety reflect the different values perceptions and judgments both on the specific area of the use of modern biotechnology and on the ways different societies relate to uncertainty and deal with risk. The need to ensure open, transparent, and participatory processes in the assessment and management of risks related to biotechnology will be a key in determining the success or failure of applying the precautionary principle to emerging biotechnologies.[22]

Emerging biotechnologies like, LMOs, by virtue of being new to nature, may create equally new useful promises or hazards to humans and the environment. Their potential usefulness makes them appealing for development. However, their potential ability to cause harm makes the regulation of their development. With regard to modern biotechnologies developing countries faces inadequacy to combating risks as it requires financial and technical capacity that the countries do not have. Most centers of origin and diversity of crops are in developing countries. It is obvious that a mistaken release of emerging biotechnology like, LMO crop variety is more

[21] United Nations Environmental Program, An introduction to Cartagena Protocol to Biosafety, (2003), Available at http: //www. unep.org visited on November 26,2019, p.6 4

[22] Supra note 3

likely to introduce the unwanted gene or genes permanently into a developing country crop gene pool than into a gene pool of a developed country.[23]

Regulators in the field of biotechnologies work to manage and mitigate the 'risks' associated with emerging biotechnologies in the one hand and to enabling, or even facilitating, the delivery of substantial, possibly transformative benefits of emerging biotechnologies on the other. A particularly influential set of concerns for the regulation of emerging biotechnologies has been physical and environmental harms described under the rubrics of 'biosafety'. Biosafety is not at all unique to emerging biotechnologies but they arise with particular force here because of the key characteristics of emerging biotechnologies as the way uncertainty, ambiguity and transformative potential simultaneously produce a culture of high expectations about benefits and high trepidation about harms, and where there are profound difficulties in predicting and identifying. Biotechnologies present obvious biosafety issues given that they are intended to affect biological systems and some of these systems are capable of experiencing harm, either directly or indirectly. However, what makes these issues particularly difficult to manage is the potential absence of a predictable, linear correlation between intervention and effect, and the uncertainty of the benefit or harm that might accrue. This is compounded as the combined effects of the special characteristics of emerging biotechnologies simultaneously create difficulties in anticipating the effect of possible regulatory designs or decisions.[24]

Ethiopia is party to international conventions and treaties including the Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety to the Convention on biological diversity (CPB). Following these, national policies and strategies have been and are being developed so as to benefit from the provisions made in these conventions and treaties. As Ethiopia is a party to CBD and CPB needs to benefit from the advantages of modern biotechnology, by managing the possible risks occasioned as a result of the application of the technology on human and animal health, biological diversity and the environment. In an attempt to implement the obligations

[23] Tewolde Berhan Gebre Egziabher, Balancing Biosafety, Trade, Economic Development Interests in the Implementation of the of the Cartagena Protocol: A Developing Country Perspective, www.cbd.int/doc/publications/bs-brochure-02-en.pdf visited on November 27,2019

[24]Supra note 3 p.139

under the protocol, the country promulgated Biosafety proclamations, regulation and Directives which regulate among other things import of GMO. [25] Ethiopian biosafety law is necessary not only for nationally implementing the CPB but also for ensuring national safety from negative impacts of imported emerging biotechnologies. Currently there is no stand-alone biosafety policy of Ethiopia. However, it is not correct to say there are no policies which address the major issues of a biosafety policy as there are policies like the Environmental Policy of Ethiopia, which emanated from the Conservation Strategy, addresses biosafety concerns.[26]

In addition to the policy legal framework; including proclamation, regulation and directives; has been developed in Ethiopia to regulate the Transboundary movement of GMOs to avert the possible risks of GMOs on biodiversity, human health and the environment. The regulatory regime for biosafety in Ethiopia includes proclamation, Convention on Biodiversity ratification proclamation, Cartagena Protocol on Biosafety Ratification proclamation no.362/2003, Biosafety Proclamation No. 655/2009, Biosafety (Amendment) Proclamation No.896 /2015; regulation, National Bio-safety Advisory Committee Establishment Council of Ministers Regulation no.411/2017; and more than five biosafety directives. The Federal Democratic Republic of Ethiopia Constitution, under article 43, 44 and 92 provides general direction as to how to address the problems on relation to biosafety.

1.6. Research Methodology

The research is doctrinal legal research. The researcher will use library sources and internet sources for collection of legal data which will be used in the thesis. The researcher makes assessment of international and national biosafety legal instruments as primary sources of data, and International national legal documents on the issue of emerging biotechnology and biosafety uses as secondary sources of data. A comprehensive analysis of the Biosafety legal regimes and

[25] Convention on Biodiversity ratification proclamation, Cartagena Protocol on Biosafety Ratification proclamation no.362/2003, Biosafety Proclamation No.655/2009, Biosafety (Amendment) Proclamation No.896 /2015; regulation, National Bio-safety Advisory Committee Establishment Council of Ministers Regulation no.411/2017; and more than five biosafety directives.

[26] The Government of the Federal Democratic Republic of Ethiopia environmental protection authority biosafety framework, Addis Ababa, August 2007

policy of Ethiopia will be carried out. This will be done by analyzing the contents of biosafety laws with regard to the substantive and administrative dimensions to assess the implementation of biosafety with regard to emerging biotechnology in Ethiopia.

1.7. Thesis Organization

The thesis will contain four chapters. The first chapter which is the introduction gives the back ground knowledge with respect to biosafety of emerging biotechnologies, frame statement of the problem of the research, state the research question, indicate objective of the research, give short and precise literature review, and research methodology. Chapter two will describe about emerging biotechnology and asses international biosafety legal instruments. In this chapter it will be state about biosafety and biotechnology. It will be also assessed about international legal instruments of CBD, CPB, African Mode Law on Safety on Biotechnology and the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress. In chapter three the researcher considers and assesses the domestic policy and legal instruments on biosafety and emerging biotechnologies and analyses the implementation of the biosafety of emerging biotechnologies focusing on biosafety legislation and policy in Ethiopia by carrying out a comprehensive analysis. Chapter four gives conclusion based on the analysis and recommendation on the implementation of biosafety on emerging biotechnologies in Ethiopia.

CHAPTER TWO

BIOSAFETY AND EMERGING BIOTECHNOLOGIES

2.1. EMERGING BIOTECHNOLOGIES

2.1.1. INTRODUCTIN

The Oxford English Dictionary defines biotechnology as "the exploitation of biological processes for industrial and other purpose, especially genetic manipulation of micro-organisms for the production of antibiotics, hormones, etc".[27] Ad hoc Biotechnology Statistics Group of OECD defined biotechnology "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services".[28] It has also defined biotechnology by listing as cell and tissue culture and engineering, gene and RNA vectors, DNA/RNA, process biotechnology techniques, bioinformatics proteins and other molecules, and Nanobiotechnology. The definition given by OECD is more comprehensive and wider in its scope by including emerging biotechnologies in its definition of biotechnology.[29]

For international community now it becomes necessary to have common understanding of the term biotechnology to answer the issues which are raised by it and to regulate biotechnology. Article 2 of the 1992 United Nations Convention on Biological Diversity defines it as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." [30] Article 3 of Cartagena Protocol on Biosafety defines modern biotechnology as:

"*The application of: (a) 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*

[27] Der-Chin Horng, International Law on Biotechnology, Institute of European and American Studies, Academia Sinica, Taiwan, R.O.C.

[28] Ibid

[29] Ibid

[30] Convention on Biological diversity,(1992)

or recombinant barriers and that are not techniques used in traditional breeding and selection."[31]

To have complete understanding of what does it means emerging biotechnology, it is important to define emerging technology in addition to biotechnology. Emerging technology can be defined as:

"a radically novel and relatively fast growing technology characterized by a certain degree of coherence persisting over time and with the potential to exert a considerable impact on the socio-economic domains which is observed in terms of the composition of actors, institutions and patterns of interactions among those, along with the associated knowledge production processes."[32]

Emerging technologies shared key attributes of radical novelty, relatively fast growth, coherence, prominent impact, and uncertainty and ambiguity.[33] In addition to the above Emerging technologies have unique characteristics which does not necessarily follow an ordered and linear path from science but the path of emergence may begin at almost any point and rarely runs straight; may emerge as the result of a convergence between well understood pre-existing techniques may cause their emergence[34]; delivering concrete applications and orientated towards solving problems ; engages different social actors and groups in unique configurations; influenced by social, as well as technical, conditions and implications; and draws on knowledge and technical expertise from a variety of fields.[35]

Biotechnology, synthetic biology and nanotechnology are some examples of emerging biotechnology which are expected revolutionize and transform agriculture, health care and

[31] Cartagena Protocol on Biosafety to the Convention on Biological diversity, (2000)

[32] Daniele Rotolo, Diana Hicks and Ben R. Martin, What Is an Emerging Technology, July 7, 2015

[33] ibid

[34] Lim Li Ching, Relevance to issues concerning emerging biotechnology, TWN Biotechnology and Biosafety Series 18 p. 136 Relevance to issues concerning emerging biotechnology)) page 136

[35] Supra note 3 p.13

energy disciplines.[36] The above and other emerging technologies helps to invent successful drugs to target or attack and destroy cancerous tumors; molecular machines which manufacture products cheaply, cleanly, and without waste; and technology of energy generation that reduces greenhouse gas emissions. These emerging technologies may also have great impact by on the production new organisms that disrupt ecosystems, toxic substances that cause cancer or self-replicating robots that cause confusion.[37] Emerging technology development needs relaxation and freedom in its research and development. But too much freedom may result to a social and regulatory dilemma, and calamity that forecloses any opportunity for the technology. So it is important simultaneously use innovation's anticipated benefits while avoiding potential risks, especially in the instances of the potential risks of the technology cannot be suitably understood till the technology further develops.[38] To have further clear understanding of the emerging technologies the researcher will describe three emerging technologies in the following parts of the research `as listing of new generations of biotechnology is long and inexhaustible as they are being rolled out continually at breakneck speed[39]`.

2.1.2. MODERN BIOTECHNOLOGY

Article 3 sub article (i) of Cartagena protocol defines Modern biotechnology as "the application of a) 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 recombination barriers and that are not techniques used in traditional breeding and selection."[40]

From the above definition it could be said Modern Biotechnology, involves the purposeful transfer of one or several genes from one species to another in order to provide enhanced traits.

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[36] Daniele (n32)

[37] Ibid

[38] Ibid

[39] Sarah Z. Agapito-Tenfen Odd-Gunnar Wikmark , Current status of emerging technologies for plant breeding: Biosafety and knowledge gaps of site directed nucleases and oligonucleotide-directed mutagenesis, (2015)

[40] Cartagena (n31) art 3

For example, agricultural crops can be genetically modified to include genes that make them pest protected, or herbicide resistant.[41]

The decade after the opening of the adoption of the Protocol has witnessed the proliferation of a new generation of more efficient and more effective technologies than the gene-splicing procedure, which the technique involves the insertion of selected genes from other organisms of the same or different species into the genes of another organism.[42] This gene-splicing technology was an important technology for its unique advantage than other technologies in the field existed.[43]

However, the emergence of novel products from new plant breeding techniques challenges our current regulations and our management practices of what we traditionally have viewed as a genetically modified organism (GMO).[44] International regulations, such as the Cartagena Protocol on Biosafety, operate with definitions of GMOs that may not be applicable to products arising from some of these new techniques.[45] The gene-splicing method of genetic engineering or other modern biotechnology techniques in general are now being overhauled and replaced by emerging technologies such as Marker Assisted Selection (MAS), Site Directed Nucleases (SDN) and oligonucleotide directed mutagenesis (ODM).[46]

Now gene-splicing technique itself, is exceeding initial expectations through the increased use of genomics (automated sequencing and analysis of genes), bioinformatics (analysis of DNA information) and proteomics (analysis of protein functions and their relationship to genes)

[41] Mackenzie, Ruth,Burhenne-Guilmin, Francoie, La Vina, Antonio G.M. and Werksman, Jacob. D. in cooperation with A. Scencio, Alfonso, Kinderlerer, Julian, Kummer, Katharina and Tapper, Richard, An Explanatory Guide to the Cartagena Protocol on Biosafety, (2003)

[42] Hailemichael Teshome and Mammo Muchie, Re-inventing the GM Debate: The Ethiopian Biosafety Law and its Implications for Innovation and Knowledge Production on Emerging Technologies Science, Technology & Society 19:1 (2014): 109–125

[43] Ibid

[44] Sarah Z.(n39)

[45] Ibid

[46] Ibid and Lim Li Chip (n34)

powered by the new information technologies like molecular breeding especially the technique known as Marker Assisted Selection (MAS).[47] Instead of transferring genes from one species to another, MAS simply speeds and improves traditional plant breeding by searching through maps of a plant's genome for sequence markers that are consistently associated with desired traits such as improved yield or disease resistance. Those markers can then be used to screen breeding stock and the progeny of traditional crosses even before they are grown or planted in the field.[48]

The second emerging technology is new plant breeding techniques, site directed nucleases (SDN); Site-direct nucleases are enzyme complexes that recognize specific DNA sequences in the genome and cleave them. The cleaved DNA is subsequently repaired by the organism's natural DNA repair systems.[49]

The second emerging technology is new plant breeding techniques, oligonucleotide directed mutagenesis (ODM); Oligonucleotide-directed mutagenesis uses oligonucleotides to induce sequence specific mutations of native genomic sequences (i.e. genome editing). The introduced DNA is complementary to the genomic target sequence with the exception of a modification that usually is a deletion, insertion or a mismatch between the introduced synthesized DNA and the genomic DNA. [50]

The underlying modes of action of all the three techniques are the plants natural repair systems and how this can be utilized to achieve genomic modifications. Herein also lays the main challenge for risk assessment our limited knowledge about the function of these systems, factors involved and potential off-target effects.[51]

[47] Hailemichael Teshome (n42)

[48] ibid

[49] Sarah Z. (n39)

[50] Ibid

[51] Ibid and Hailemichael (n42)

2.1.3. SYNTHETIC BIOLOGY

Synthetic biology is "the design and engineering of biologically based parts, novel devices and systems as well as the re-design of existing, natural biological systems."[52] It is the addition of gene fragments or genes together like building blocks, producing a living entity with desired combination of traits, as a house is constructed by putting together individual pieces which have different functions.[53] Organisms could be designed by synthetic biology by re-designing of existing natural biological systems to have enhanced or novel qualities or the original construction of new biological systems that never existed in nature. [54]Synthetic biology permits the purposeful assembly of an entire organism which is not possible by modern biotechnology as it involves the transfer of one or a couple of genes from one species to another.[55]

Synthetic biology is an emerging biotechnology which is the result of convergence of many core disciplines. It incorporates knowledge from biology, chemistry and engineering to invent new products and processes. It takes platform technologies and foundational research from molecular biology, biochemistry, biological technologies, systems engineering, microbiology, plant sciences, informatics, chemical engineering, analytical technologies; and by applying engineering design principles it integrates and builds upon these findings to produce new biological devices.[56]

The objective of synthetic biology is to utilize the diversity of biological parts; genomes and metagenomics, synthetic parts or components; to build new biological devices and systems with defined function.[57] Synthetic biology enables to engineer biological systems to perform new functions in a reliable, modular and predictable way, allowing modules to be reused in different

[52] Lim Li (n34)

[53] Ibid

[54] Ibid

[55] Ibid

[56] Chairman, UK Synthetic Biology Roadmap Coordination Group, synthetic biology road map for UK., July 2012 p.13,18

[57] Ibid

contexts.[58] Synthetic biology functions based on the core engineering concepts of Modularization which is the process of breaking down a biological system into a series of well-defined, standard parts or components as a gene, protein, a pathway, a microbe in a culture; Characterization which is the process of defining the behavior and function of these parts in particular contexts in order to understand how they can be used in human-defined design; and Standardization which means the design process is based on well-defined standard modules that can be interfaced to produce a device or system.[59]

Multilateral treaties has not been regulated specifically about Synthetic biology but there are treaties, customary rules and general principles of law and regulatory instruments and mechanisms, which could apply to all or some forms of synthetic biology. The treaties could apply to issues such as the transfer and handling of components, organisms and products result from synthetic biology techniques; the use of components, organisms and products resulting from synthetic biology techniques for a specific purpose.[60]

CBD on Decision XI/11 initiated a process by which synthetic biology could be considered by the CBD's Subsidiary Body on Scientific, Technical and Technological Advice that has considered the issue of synthetic biology once again put on the agenda for the CBD Conference of the Parties (COP 13) in December 2016. The Work of consideration of the regulation of synthetic biology has progressed by the establishment of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology and then the extension of its mandate with new terms of reference by COP 13.[61]

2.1.4. NANOTECHNOLOGY

Nanotechnology literally means any technology on a nanoscale that has applications in the real world. Nanotechnology comprises the production and application of biological systems at scales

[58] Ibid

[59] Ibid

[60] Lim Li (n 34)

[61] Ibid

ranging from individual atoms or molecules to submicron dimensions, and also the integration of the resulting nanostructures into larger systems.[62]

Science and technology research in nanotechnology makes breakthroughs in medicine and healthcare, energy and biotechnology. Building matter from the atom up allows for more precise and complex configuration of material, and permits the production of materials with different biological properties than previously possible. Certain materials develop biological and antimicrobial properties at the nanoscale. These developments have potential application in health care, medicine, environmental sciences.[63]

Nanotechnology gives potentially many benefits. However, there are also emerging concerns about the potential risks that nanotechnologies present to humans and the environment and about the ability of current legal and regulatory regimes to sustainably manage those risks. As nanotechnologies are an emergent field of science and technology, it is not yet clear precisely what risks they pose to humans, animal health and the broader environment and the ability of current legal and regulatory regimes to sustainably manage those risks. Currently because of the potential risks that have emerged, it has been increasingly recognized that there needs to be closer examination of the regulatory implications of nanotechnology. [64]

There are no national governments that have enacted specific nanotechnology legislation but there are clearly an emerging scrutinies or review of the legal and policy implications of nanotechnology in several jurisdictions including the United Kingdom, within the European Community, Australia and the United States.[65]

Until now there is no Existing international treaty that regulates and gives adequate mechanisms to address the issues of nanotechnology.[66] United Nations Consideration of nanotechnology has

[62] Leary and Pisupati (eds), the future of international environmental law, United Nations University Press, 2010, ISBN 978-92-808-1192-6

[63] Ibid

[64] Ibid

[65] Ibid

[66] Ibid

been fragmented and rudimentary which can be said there is no integrated or coordinated consideration of nanotechnology as it has largely been ad hoc and confined to particular aspects of the issue or mandated for individual international organizations. The fourth annual report on the changing global environment of UNEP which was conducted in 2007 highlighted the urgent need to adopt appropriate assessment and legislative processes to address the unique challenges posed by nanomaterials and their life cycles. The report stressing both the potential risks and benefits offered by nanotechnology, and also highlighted a number of policy recommendations for future actions by nations and international organizations including, the need to evaluate the potential environmental and human health impacts of nanotechnology.[67]

The other international consideration is held in Senegal in September 2008, as the meeting of the Intergovernmental Forum on Chemical Safety, adopted the Dakar Statement on Manufactured Nanomaterials, which contained some twenty-two recommendations that are largely inspirational or hortatory in nature, adding little if anything to the emerging debate.[68] The third international consideration of nanotechnology was Resolution II/4 on Emerging Policy Issues adopted at the second session of the International Conference on Chemicals Management (ICCM) included some eleven paragraphs to nanotechnology.[69] Apart from these very elementary programs, there has been little substantive examination of the regulatory implications of nanotechnology within the UN system. [70]

But most advanced developments are occurring outside of formal UN processes on the consideration of the regulatory implications of nanotechnology. In 2006 the OECD established a Working Party on Manufactured Nanoparticles which is currently looking at international cooperation in health and environmental safety related aspects of manufactured nanomaterial.[71] The most significant developments so far on nanotechnology regulatory implications have

[67] Ibid

[68] Ibid

[69]Ibid

[70] Ibid

[71] Ibid

occurred by International Organization for Standardization (ISO), the world's largest developer and publisher of international standards. In 2005 the ISO established a new technical committee, ISO/TC 229 Nanotechnologies, hosted by the United Kingdom, to develop international standards for nanotechnologies.[72]

The response of regulators under domestic legal systems and at the international level is very much a work in progress. As scientific understanding of both the risks and the benefits of nanotechnology develops, so legal and policy responses will also need to prepare and, developments, both internationally and within individual legal and regulatory systems, which are closely linked and correlated.[73]

2.2. BIOSAFETY OF EMERGING BIOTECHNOLOGIES

2.2.1. INTRODUCTION

The common understanding of biosafety is derived from the practical guidance issued by the World Health Organization on techniques for use in laboratories. The WHO Laboratory Biosafety Manual (LBM) considers biosafety to be "the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release."[74] The Biological Weapon Convention correlates Biosafety to the obligation under the Convention to ensure that the necessary safety precautions should be taken, to protect populations and the environment, when conducting activities not prohibited by it.[75]

Under UNEP biosafety is contextualize in relation to the Cartagena Protocol on Biosafety of the Convention on Biological Diversity.[76] Cartagena Protocol describes the concept of biosafety as "ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects

[72] Ibid

[73] Ibid

[74] Biological Weapon Convention(BWC) Implementation Support Unit, Biosafety and Biosecurity

[75] Ibid

[76] Ibid

on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements".[77]

The international community creates regulatory responses to problems and challenges arising from scientific innovation and technological change. Existing international agreements on biotechnology have adopted a set of principles, rules, guidelines, code of conduct and resolutions in response to these challenges and changes. They also generally provide a system combining legislative, administrative, judicial and adaptive functions for the implementation of these agreements. They have already established an international regime for the governance of biotechnology. Existing international biotechnology agreements have been designed and adopted to balance competing interests and to pursue sustainable development. Accordingly, they largely focus on human health, environmental protection, biodiversity and biosafety, scientific innovation, agricultural development, human rights, development needs for all applications of biotechnology. Many objectives, doctrines, principles, rules and instruments contained in these agreements are highly consistent as they are generally drawn from similar legal regulations and practices already enacted in states or international organizations. As a whole, international biotechnology agreements have already established an appropriate framework for the regulation of biotechnology in the international community.[78] But this is not true with regard to emerging biotechnologies as these new technologies are often met with highly polarized debates over how to manage the development, use, and regulation of the technology.[79]

Proponents of a given technology will argue for promoting rapid technology development, unfettered by unnecessary and costly regulation. Opponents will advocate a stringent regulatory regime to protect against the potential human health and environmental risks of the technology. [80] A primary contributor to such polarization and gridlock is the large degree of scientific

[77] Cartagena (n31)

[78] Der-Chin (n27)

[79] BWC (n74)

[80] Gregory N. Mandel, Regulating Emerging Technologies, LEGAL STUDIES RESEARCH PAPER SERIES, No. 2009-18

uncertainty that surrounds any emerging technology, and the regulatory ambiguity that results.[81] Uncertainty creates problems for all parties involved in a new technology; it creates fear and concern among members of the public and public interest groups, challenges and criticism of regulatory agencies, and limitations on industry plans for investment and development.[82] Rather than being a source of polarization, the emergent stage as characterized by a high degree of uncertainty and a low degree of attachment to a status quo, can present a unique opportunity to bring together diverse stakeholders to produce a collaborative governance product rather than a resource-draining adversarial debate.[83]

The international community has developed many international legal instruments to benefit from biotechnologies while protecting the harm posed by them on environment and human health. From many legal instruments the researcher will analysis on convention on biodiversity, Cartagena protocol, and African model law on biosafety and redress protocol as biosafety is included the sole or one of their purposes of formulation.

2.2.2. CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity promotes the development and access of biotechnology and at the same time requires Contracting Parties to establish or maintain specific means to regulate risks associated with them to have sustainable developments.[84] As appropriate and as far as possible contracting Parties are required under Article 8(g) of the Convention to establish or maintain ways to manage, regulate, or control the risks associated with the use and release of living modified organisms resulting from biotechnology that are likely to have adverse environmental impacts and which could affect the sustainable use and conservation of biological diversity, taking also into account the risks to human health.[85] It could be taken a common view from the above provision which reflects that living modified organisms are not the same as their

[81] Ibid

[82] Ibid

[83] Ibid

[84] Mackenzie (n41)

[85] Mackenzie (n41)

non-GM counterparts, and that they have characteristics which inherently require the assessment to protect the wellbeing of human and environmental risks.

Article 8(g), article 19(3) and article 19(4) of CBD regulates directly in relation to living modified organisms (LMOs). while article 19(3)) is regulating about the negotiations of the Cartagena Protocol, the other two articles, article 8(g) and 19(4), regulate the obligations applied to all Parties to the CBD independently of their becoming Parties to the Protocol. The term "living modified organism" used in the Protocol emanates from its use in the CBD, in particular Article 19(3), which is at the origin of the Protocol. The negotiators of the CBD singled out living modified organisms which are regulated under Article 19(3) of CBD for special treatment. Article 19(3) provides that the Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any LMO resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.[86] Article 8(g) regulates domestic measures generally by requiring Parties to regulate, manage or control risks associated with LMOs resulting from biotechnology which are likely to have impacts on the conservation and sustainable use of biological diversity, taking also into account the risks to human health.[87] Article 19(4) of CBD considers and regulates transfers of LMOs from one Party to another, by requiring each Party to provide information on domestic regulations concerning use and safety to any other Party to which a LMO is provided and any available information on the adverse effects which the introduction may have impact for this Party.[88] The content of the term LMO which was developed in CBD includes all LMO developed by biotechnology which was comprehensive and foreseeable.[89] Article 14 of the CBD obliges Parties to conduct environmental impact assessment for activities that are likely to have significant impacts on biological diversity with a view to avoiding or minimizing such effects, and for conservation and

[86] Ibid

[87] Ibid

[88] Ibid

[89] Ibid

sustainable use of biological diversity.[90] However, CBD COP Decision II/5 narrowed the content of the term LMO to those LMOs resulting from modern biotechnology.[91] While the CBD is comprehensive, the Conference of the Parties (COP) to the CBD narrowed it to only LMOs resulting from modern biotechnology. As article 28 allows the Parties to the CBD to decide through the CBD COP during implementation issue legal instruments like protocol for the achievement of the objectives of the CBD. Based on this establishment of the convention it is hopeful to think they will come up with a legal instrument that implements LMO of biotechnologies comprehensively.

Articles 8(g), 19(3) and 19(4) of the CBD`S biosafety provisions imposes obligations on Parties to ensure safe transfer, handling and use; establish or maintain ways to regulate, manage or control risks at a national level; and provide available information about the use and safety regulations and potential adverse impacts.[92] Based on the above provisions of CBD there were discussions on synthetic biology since 2010. During the field release of synthetic life, cell or genome into the environment, Parties, other Governments and relevant organizations were invited to apply the precautionary approach by Decision X/13[93]. Again In 2012, Decision XI/11 of CBD recognized the development of technologies associated with synthetic life, cells or genomes, and the scientific uncertainties of their potential impact on the conservation and sustainable use of biological diversity.[94] When addressing the threats of significant reduction or loss of biological diversity posed by synthetic biology; organisms, components and products, parties and other governments are commended to take a precautionary approach by this decision. In the decision also noted, based on the precautionary approach, the need to consider the potential positive and negative impacts of synthetic biology components, organisms and products based on the precautionary approach. Decision XII/24 further urged Parties and invited other Governments to establish effective risk assessment and management procedures or regulatory

[90] CBD (n30) art 2

[91] Mackenzie (n41)

[92] Lim Li (n34)

[93] Ibid

[94] Ibid

systems to regulate environmental release of any organisms, components or products resulting from synthetic biology; to approve organisms resulting from synthetic biology techniques for field trials only after appropriate risk assessments have been carried out; and to carry out scientific assessments of synthetic biology organisms, components and products that consider risks to conservation and sustainable use of biodiversity as well as human health, food security and socio-economic considerations; and that such assessments should be done with the full participation of indigenous and local communities.[95]

As it is possible that, LMOs resulting from synthetic biology techniques could cause adverse effects on the conservation and sustainable use of biological diversity, as described in CBD technical series no. 82, it is clear that applied on modern biotechnology. So based on Articles 8(g), 19(3) and 19(4) of the CBD biosafety provisions, which are regulating living modified organisms resulting from biotechnology would therefore apply to synthetic biology.[96]

2.2.3. CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Biosafety Protocol is the first international legally binding agreement on the trade of GMOs as there was no global legally binding instrument before to regulate the transfer, safe handling and use of LMOs resulting from biotechnology in the perspective of adverse effects on the environment that could adversely affect biodiversity.[97] It could be said that the most important and comprehensive international agreement on biotechnology because it encompasses, vital elements relating to regulatory approaches on modern biotechnology.[98] The Protocol was opened for signature in May 2000 and entered into force on the 11 September 2003. As of July 2020, the Protocol has 173 parties including, the state of Palestine, Niue and the EU.[99]

The protocol contains many provisions, from those, the precautionary principle , the objective of the protocol, compliance mechanism, definitions, advance informed agreement and public

[95] Lim Li Ching (n34)

[96] Ibid

[97] Der-Chin Horng (n27)

[98] Ibid

[99] Cartagena protocol on biosafety –Wikipedia en.m.wikipedia.org

participation that enable the parties to fulfill their obligation imposed by it with regard to the development, handling, transport, use, transfer and release of any LMOs and to achieve the objective of the protocol.[100]

The objective of the Protocol is to ensure, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration, an adequate level of protection in modern biotechnology and for the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, while also taking into account risks to human health by conducting the activities based on the precautionary approach especially with regard to international movement of LMOs.[101] The Protocol obliges parties to assure the development, handling, transport, use, transfer and release of any LMOs, which should be conducted in a way in which prevents or minimizes the risks to biological diversity, taking also into account risks to human health.[102] As much as the action is not contradicted with the objective of the Protocol parties are free to take action more protective than the protocol with regard to environment and the human health.[103]

Cartagena protocol on biosafety scope is focusing on modem biotechnology results of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also in to account risks of human health, and specifically focusing on Transboundary movement, safe transfer, handling and use of living modified organisms to ensuring an adequate level of protection in modern biotechnology.[104] It is an environmental and sanitary agreement that aims to provide protection against the potential risks of living organisms created by the tools of modem biotechnology by regulating trade in LMOs.[105] Even though the protocol regulates on all LMOs in principle, it is qualified by many exceptions concerning the type of activity, the type of

[100] Cartagena (n31)

[101] Der-Chin Horng (n27)

[102] Cartagena (n31)

[103] Der-Chin Horng (n27)

[104] Ibid

[105] Ibid

LMO, and the type of risk it pose on the environment and human health. In addition to LMOs which are developed through modern biotechnology and for their transboundary movement the protocol`s scope is limited to LMOs that may have adverse effects on the conservation and sustainable use of biological diversity. More over procedurally the protocol only apply to the first transboundary movement LMOs for intentional introduction into the environment while LMOs in transition or LMOs for contained use exempted even for this first intentional transboundary movement.[106] Pharmaceuticals for humans that are regulated by other treaties do not fall under the protocol's scope. It had been agreed by Cartagena that LMO-FFPs would fall under the protocol's scope. Generally for procedural scope of application there are three categories of LMOs which are covered by separate provisions of the protocol which are LMOs intended for food, feed, or further processing under article 11 and annex II; LMOs intended for contained use for research purposes, free trade as far as it follows the importing countries standards under article 6(2); and LMOs intended for introduction into the environment such as, transgenic seeds, subject to the AIA procedure under Article 7-10 and Annex I.[107]

The protocol regulates Under Article 7(1) that the AIA procedure shall apply before the first intentional trans-boundary movements of LMOs intended to be introduced into the environment of the importing party. The exporting party or the exporter is required under article 8 to notify the competent national authority of the importing party about intentional trans-boundary movements of LMOs intended to be introduced into the environment. The notification should give the information on risk assessment and information required under Annex I of the Protocol. A Biosafety Cleaning-House which serves as a multilateral information exchange mechanism is established in order to deal with the significant trade in LMOs under Article 11 and 20.[108]

Precautionary principle, contained in Principle 15 of the Rio Declaration, has developed rapidly in international environmental law in the previous couple of decades. The Cartagena protocol gives a central importance to the precautionary approach in the case of biotechnological risks by

[106] Ibid

[107] Ibid

[108] Der-Chin Horng (n27)

going much further than the convention. It not only reaffirms it in its preamble in its objective clause article 1 but also in article 10(6) and 11(8), which are more operational provisions. Article 10(6) which is determinant in the conditions for taking decisions on the first intentional Transboundary movements of LMOs states that "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the party of import, taking also into risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of that living modified organism."[109] Precautionary principle says specifically where the costs of action are low and the risks of inaction are high preventive action should be taken, even without full scientific certainty about the problem being addressed. This precautionary principle is operationalized by the protocol gives a significant role in the decision to regulate import of LMOs in the face of scientific uncertainty for setting environmental policy. This principle practically gives the governments a fair amount of discretion. During uncertainty the government must decide how high the risks are likely to be and how this compared with the costs of action, and what type of actions are justified for this typical uncertainty.[110] The importing party after deciding the justified action for that uncertainty could take a precautionary approach to deciding what restrictions they might put on the import of LMOs.[111] The importing party obliged by article 12 to review the decision in light of new scientific evidence, when the exporting party request for this, set up precautionary measures.[112] The protocol obliges states to make an effort in good faith to use the means at its disposal to prevent possible detrimental effect on the environment and to implement a decision making process ensuring precaution.[113] It is evident from protocol that the provisions on precaution are formulated not as obligations but as rights to take precautionary action. [114]

[109] Ibid

[110]Ibid

[111] Ibid

[112] Der-Chin Horng (n27)

[113] Ibid

[114] Ibid

The issue of public participation is regulated under article 23 of the protocol.[115] The protocol made regulation to contracting parties to promote and facilitate education, public awareness and participation with regard to safe transfer, handling and use of LMOs in relation to biodiversity conservation and sustainable use; guarantee public awareness and education encompass access to information on LMOs identified by the Protocol that may be imported; ask the public in the decision-making process regarding LMOs and make decisions available to public, but respecting confidential information; and each party is to striving to inform its public about access to information on Biosafety cleaning house.[116]

The protocol is not out of socio-economic issues as under article 26 lets parties to take socio-economic considerations into account in reaching a decision on the import of LMOs, if these concerns arise from the impact of LMOs on the conservation and sustainable use of biodiversity.[117]

When we specifically come to the other emerging biotechnology, synthetic biology, it is considered that living organisms resulting from current synthetic biology techniques fall under the definition of "living modified organisms" under the Cartagena Protocol for Biosafety in CBD Technical Series No. 82.[118] Currently, as living organisms resulting from synthetic biology techniques fulfill the criteria of being a living organism, possessing a novel combination of genetic material, and resulting from the use of modern biotechnology, the Cartagena Protocol on Biosafety can applicable to them.[119] So, like LMOs which are the result of modern biotechnology, the protocol`s requirements concerning the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health are apply on LMOs

[115]Ibid

[116] Ibid

[117] Lim Li (n34)

[118] Ibid

[119] Ibid

resulting from synthetic biology. [120] The Parties to the CBD, at COP 13, took note in Decision XIII/17 the conclusion of AHTEG on Synthetic Biology, established by the CBD Parties, that living organisms developed through applications of synthetic biology and currently in the early stages of research and development are similar to living modified organisms as defined in the Cartagena Protocol.[121]

The Cartagena Protocol does not apply to the transboundary movement of LMOs which are pharmaceuticals for humans and addressed by other relevant international agreements or organizations as regulated under article 5.[122] Now there are LMOs, live virus vaccines, produced through synthetic biology that is pharmaceuticals for humans. However, now there is no other relevant international agreements or organizations which regulate about organisms currently produced through synthetic biology that are intended to be used as pharmaceuticals for humans and pharmaceuticals for animals. So, they would arguably fall under the Cartagena Protocol's scope.[123] Moreover, where synthetic biology organisms are used as raw material to produce pharmaceuticals, the organisms themselves are not pharmaceuticals, but they are still LMOs produced by synthetic biology and would therefore be covered by the Cartagena Protocol.[124]

Cartagena Protocol's advance informed agreement provisions for LMOs may not applied on Some organisms resulting from synthetic biology techniques when they are in transit, intended for contained use or for direct use as food or feed, or for processing.[125] Even if the protocol provides this exemption in Article 6 of the Protocol preserves the right of a Party to regulate the transport of LMOs through its territory, and to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction.[126] Moreover, a

[120] Ibid

[121] Ibid

[122] Ibid

[123] Ibid

[124]Ibid

[125] Cartagena (n31)

[126]Lim Li Ching (n34)

Party may take a decision on the import of LMOs intended for direct use as food or feed, or for processing, under its domestic regulatory framework which is consistent with the objective of the Protocol.[127]

It is not unexpected that future technological advances of synthetic biology may lead to the creation of living organisms possessing novel combinations of genetic material, which are heritable and do not result from the use of in vitro nucleic acid techniques or cell fusion.[128] So it needs reassessment of the technology of synthetic biology with regard to the above possible outcomes.[129] While the conversation on the components and products of synthetic biology under the Cartagena Protocol, it is difficult to come up with common understanding.[130] It should be noted that they do in any case fall within the scope of the CBD and its objectives.[131]

[127]Ibid

[128]Ibid

[129]Ibid

[130] Ibid

[131] Ibid

2.2.4. AFRICA MODEL LAW ON SAFETY IN BIOTECHNOLOGY

African model law on safety in Biotechnology was finalized in May 2001, in Addis Ababa, Ethiopia by 89 participants representing 35 African countries.[132] At its 74 ordinary session convened in Lusaka, Zambia in July 2001, the OAU council of Ministers endorsed the Model Law. The mode law to get greater acceptance and to make it a basis for harmonizing the continent`s biosafety laws it has been revised in/as (2007) and (2011a).[133] These drafts are strict and more go beyond far from the protocol like the former.[134] The Council furthermore urged its member states use the Model Law as a model to draft their domestic legislations to have Africa wide biosafety regime to address the movement, transport, and import into Africa of GMOs and products by adopt high standards of safety and regulating GMOs, associated products and GMO related activities to rigorous safety assessments.[135] For the model law the rules of the biosafety protocol is the minimum requirements by fully utilizes the discretion to adopt more protective measures than the agreed minimum set out in the protocol.[136]

The model law applies to import, export, contained use, release and placing on the market of any GMO and a product of a GMO, whether it is intended for release into the environment, for use as a pharmaceutical, for food, feed or processing, by viewing the risks from all GMOs as being the same, whether used in agriculture, medicine or research, and regardless of the classification as seed, or food.[137] It requires that its AIA procedure apply to all categories of GMOs, all its related uses and products of GMOs, while the biosafety protocol requires the AIA procedure applies to the first time a GMO is imported for direct introduction into the environment of the importing party.[138] It requires the exporter or notifier impose a duty to provide information regarding the

[132] Mariam Mayet, why Africa should adopt the OAU Africa mode aw on safety in biotechnology (2003)

[133] E Jane Morris, biosafety n Africa; experiences and best practices (2017)

[134]Ibid

[135] Ibid

[136] Mariam Mayet (n132)

[137] Ibid

[138] Mariam Mayet, supra note 132 why Africa should adopt the OAU Africa mode aw on safety in biotechnology (2003)

characteristics and the risk assessment of the GMO under consideration. Comprehensive assessment should be taken about the risks posed by the GMO prior to a decision being taken on its introduction in whatever form.[139] These provisions are far more comprehensive than that required by the biosafety Protocol. This is important to know which GMOs are entering the country and for which uses. With this regard the requirements in the model law are far more comprehensive than that required by the biosafety Protocol.[140]

Even though a product of a GMO does not fail within the scope of the protocol, it is under the regulation of the model law as defined any material derived by processing, or howsoever otherwise, from any GMO or from product of a GMO.[141] The model law also deals with products of GMOs and GMOs that are pharmaceuticals in a similar manner. [142]

It adopted a precautionary approach on GMOs products which may have adverse effects on biodiversity, the environment and human health, which can be said, built on the indirect regulation of products of GMOs introduced by the protocol and the mandate provided by article 8(g) of the convention on Biological Diversity. [143]

Strict interpretation of the precautionary principle should be applied when decisions are to be made concerning GMOs and GMO uses by the model law which permission is given for exporter if there is firm and sufficient evidence that GMOs or products of GMOs pose no risk or no significant risk to human health, biodiversity and the environment.[144] Where there is uncertainty, an importing country may take a decision to ban or restrict a GMO.

Taking it as important and indispensable components of environment governance the model law regulates on public participation and access to information to enable the public engaged in the

[139]Ibid

[140] E Jane Morris (n132)

[141] Ibid

[142] Ibid

[143] Ibid

[144]Ibid

decision making process. There are regulations of labeling and traceability in the model law that African countries should use and build on.[145] The regulation of labeling can provide to end-users to refer to a GMO or GMO product's toxicity or environmental safe, and to take appropriate steps to minimize or avoid the risks.[146] With regard to traceability it enables African governments to trace a GMO back to those responsible for the import and exports, and the GMOs original development as it is important when an illegal import, release and damage is suspected or occurs from international and unintentional release.[147]

The essential elements that is contained in the model law is the liability and redress regime and the requirement to provide adequate resources for redress by furnishing evidence of insurance cover or some other adequate arrangements to meet its obligations under the law to ensure that those responsible for environment and other harm.[148] The model law provides penalty clause that impose on the responsible party prohibition from engaging in GMOs related activities or imprisonment under article 16 which important addition to the continent's regulation of GMOs.[149]

[145] E Jane Morris (n133)

[146] Ibid

[147] Mariam Mayet (n132)

[148] E Jane Morris (n133)

[149] Draft revised African mode law (august -2007) art 16 and E Jane Morris (n133)

2.2.5. Nagoya – Kuala Lumpur Supplementary Protocol on liability and redress to the Cartagena Protocol on Biosafety

The Nagoya – Kuala Lumpur Supplementary Protocol is a treaty formulated to supplement the Cartagena Protocol on Biosafety.[150] Starting from the negotiations on a biosafety protocol it was thought that, there is a need to establish liability and redress rules that specifically apply to living modified organisms or to activities involving such organisms.[151] The Supplementary Protocol is a response to and fulfillment of Article 27 of the Biosafety Protocol. In addition to Article 27 of the Biosafety Protocol it is built on, as stated in its preamble, the Principle 13 of the 1992 Rio Declaration on Environment and Development that obliges countries to "cooperate in an expeditious and more determined manner to develop further international law regarding liability and compensation for adverse effects of environmental damage caused by activities within their jurisdiction or control".[152] Article 1 of Supplementary Protocol indicates that the objective is to add in the effort of conservation and sustainable use of biological diversity, taking also into account risks to human health by establishing international rules and procedures which regulates liability and redress relating to living modified organisms.[153]

In the supplementary Protocol the definitions of damage and response measures have significant role, or at least is believed to be the core of the Supplementary Protocol.[154] Because of this the term "damage" is defined as an adverse effect on the conservation and sustainable use of biological diversity that is measurable and significant.[155] The protocol puts the way how an adverse effect is significant determined by listing factors which indicate the damage is significant.[156] Personal injury, loss or damage to property or economic interests which are

[150] The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety Adopted Nagoya, 15 October 2010

[151] Ibid preamble

[152] Ibid

[153] Ibid art 1

[154] Ibid art 2

[155] Ibid

[156] Ibid art. art2 (3)

common in third-party civil liability is not covered by the Supplementary Protocol. By giving definition to damage to biodiversity it is the first multilateral environmental agreement.[157]

Article 5 of the Supplementary Protocol indicates that, to redress damage resulting from living modified organisms it is used an administrative approach. The administrative approach uses licensing or authorization to administer the implementation of laws. When damage occurred in the environment by living modified organisms the licensing authorities take actions on license holders or take measures to prevent further damage and restore the environment.[158] The supplementary protocol`s Article 5 regulates when, who and how should take response measures in the occurrence of damage or certain likelihood of damage follow-on, from living modified organisms which are on transboundary movement.[159]

The Supplementary Protocol is important by giving elements that should be taken under consideration at national level in developing or implementing administrative, legislative or judicial rules or procedures which are important to liability and redress for damages resulting from living modified organisms on biological diversity.[160]

Parties are required to provide domestic legal basis for response measures in the event of damage resulting from living modified organisms either by enactment of a new rules or procedures specific to damage resulting from living modified organisms or applying existing domestic rules or procedures on civil liability law.[161] In the event of damage the competent authority identifies the operator, evaluate the damage; and take appropriate response measures and the restoration of biological diversity by itself, in situations where the operator has failed to do, or order the operator and provides reasons for such determination on the operator.[162] In situations when the competent authority take action because the operator failed, it has a right of

[157] Ibid

[158] Ibid. art 5

[159]Ibid

[160] Ibid art 12

[161] Ibid

[162] Ibid. art 5

recourse to recover, from the operator, costs and expenses incurred in relation to the implementation of the response measures.[163] The Supplementary Protocol defines "response measures" as "reasonable actions to prevent, minimize, contain, mitigate, or otherwise avoid damage, as appropriate; and restore biological diversity."[164] The response measures which are regulated under the supplementary protocol are provides Parties with maximum flexibility to implement their obligation and be implemented in accordance with domestic law.[165]

The Supplementary Protocol provides enabling environment for the environmentally sound application of modern biotechnology, and providing redress mechanisms when biodiversity suffers damage. The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety require Parties address damage from LMOs, including those resulting from synthetic biology techniques, where such damage falls under the definition set out in Article 2 of the Supplementary Protocol.[166]

[163] Ibid

[164]Ibid. art 2

[165] Ibid, art 5

[166] Lim Li Ching (n34)

CHAPTER THREE

IMPLEMENTATION OF THE BIOSAFETY OF EMERGING BIOTECHNOLOGIES IN ETHIOPIA

3.1. INTRODUCTION

While relevance of biotechnology to development is now at the forefront of international interest, the perceived promise and perils of biotechnology are under intense public scrutiny. The debate is widespread, complex and, frequently, inconclusive. Discussions are sometimes scientific and impartial, at other times ideological, sensational and visceral. The challenge is both technological; that requires the development of new, high productivity, environmentally sustainable production system, and policy related, as favorable policies are demanded to strengthen the efforts of agricultural, industrial, and social development.[167]

Ethiopia is a centre of diversity for a number of food crops, oil and industrial crops, medicinal plants as well as wild and domestic animals.[168] The diversity in agro ecological zones; settlement pattern and human races has helped the country to host a wide range of diversity in plant and animal genetic resources.[169] Communities of various ethnic and cultural backgrounds have been utilizing these biological resources in diversified forms.[170] Diversity in genetic resources has enabled communities in different parts of the country to cope with the various hazards and vagaries of nature that prevail every now and then.[171] However, the once rich sources of plant genetic diversity have been deteriorating over time due to genetic erosion from natural and human induced factors.[172]

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[167] Aregay Waktola (PhD) and Bayush Tsegaye, Biotechnology related policy, management and negotiation competence: Case study from Ethiopia, Noragric Agricultural University of Norway, Noragric Report No. 14-B March (2003)

[168]Ibid

[169]Ibid

[170] Ibid

[171] Ibid

[172] Ibid

Ethiopia has been part of the global discussions concerning biosafety issues since 1980s[173] on various international conventions and treaties including the (CBD), the CPB, Africa model law on safety in biotechnology and Nagoya – Kuala Lumpur Supplementary Protocol on liability and redress to the Cartagena protocol on biosafety.

To effectively incorporate the concepts enshrined in the international biosafety legal instruments Ethiopia ratified the convention on biodiversity in 1994 as the biodiversity convention Ratification Proclamation No. 98/1994. Ethiopia also ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity at its session held on 31 July, 2003 as the ‘‘Cartagena Protocol on Biosafety Ratification Proclamation No. 362/2003".[174] But it didn’t ratify Nagoya – Kuala Lumpur supplementary protocol on liability and redress to the Cartagena protocol on biosafety. Ratification of international legal instruments in Ethiopia makes the ratified legal instruments one of the law of the land and gives equal status to other primary legislations. This legal concept is regulated on FDRE Constitution under article 9 sub article 4 as international agreements ratified by Ethiopia are an integral part of the law of the land.

To comprehensively implement the above ratified treaties, international customary laws and the environmental rights provided under Articles 44 and 92 of the Constitution of the Federal Democratic Republic of Ethiopia[175], which requires that human and animal health, environmental wellbeing and, in general, the socio-economic conditions of the country be protected from risks, that may arise from modified organisms proclaimed the “Biosafety Proclamation No.655/2009” and its amendment Proclamation No.896 /2015". Based on Article 22 of the Biosafety Proclamation No. 655/2009 as amended by Proclamation No. 896/2015 (after now called the proclamation)[176] the Council of Ministers issued the “National Biosafety

[173] Ibid

[174] Cartagena (n31)

[175] FDRE constitution No. 1/1995, Federal Negarit Gazeta (Page 4962- 4975), 1st Year No.1, Addis Ababa, 1995

[176] FDRE Biosafety Proclamation No. 655/2009 as amended by Proclamation No. 896/2015, Federal Negarit Gazeta article 4, (Page 4962- 4975), 15th Year No. 63, Addis Ababa, 2009.

Advisory Committee Establishment Council of Ministers Regulation No. 411/2017". Based on the Proclamation`s article 25 the Environment Forest and Climate Change Commission issued directive no.4/2018 to establish major contents of an application for special permit to engage in the transaction of modified organisms for research or teaching; directive no.05/2018 to provide risk assessment parameters for modified organisms; directive no.07/2018 to determine the requirements for transport and storage of modified organisms; directive no.08/2018 to determine the content of an application for undertaking deliberate release of modified organisms; and directive no.09 /2019 to establish institutional biosafety committee.[177]

With regard to biosafety policy frame work, the 1995 Constitution of FDRE provides for general directions and actions relevant to address the problems identified in relation to biosafety.[178] This is because the constitution is both political and legal document. In national policy and objective part under article 92 of the constitution , it regulates about environmental objective that clearly gives a policy direction to have clean and healthy environment, developments should not damage the environment, citizen`s duty and the right to be consulted with regard to environmental protection activities. The Environmental Policy of Ethiopia, which emanated from the Conservation Strategy, addresses biosafety issues. This policy was prepared by the Environmental Protection Authority in April 1997. It was then approved by the Council of Ministers.[179] In addition, the National Science and Technology Policy of Ethiopia provide guidance for the development of science and technology in Ethiopia. The National Biotechnology Policy, the National Biodiversity Conservation and Research Policy and the Agricultural Research Policy are also relevant documents which incorporate elements that can contribute to the biosafety policy of the country. All these policies are necessary to control the importation and export of biotechnology products and to make use of the technology in a safe and responsible way.[180]

[177] EFDR Biosafety proclamation No. 655/2009 as amended by Proclamation No. 896/2015, Federal Negarit Gazeta article 25, (Page 4962- 4975), 15th Year No. 63, Addis Ababa, 2009

[178] EFDR constitution No. 1/1995, Federal Negarit Gazeta (Page 4962- 4975), 1st Year No.1, Addis Ababa, 1995

[179] Environment (n26)

[180] Ibid

3.2. FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA CONSTITUTION

The Constitution of the Federal Democratic Republic of Ethiopia provides the overriding principles and legal provisions for the legislative frameworks in the country.[181] The concepts of sustainable development and environmental protection are enshrined in article 43, article 44 and article 92 of the Constitution that stipulate the rights of peoples in Ethiopia. The incorporation of these provisions in the constitution gives the environmental and health issues a status of one of the primary issues in the country which the government and citizens should adhere when they perform different activities. This adherence is a must because the constitution is supreme law of the land as regulated under article 9 sub article 1. Article 43 which regulates about the Right to Development states that the Peoples of Ethiopia as a whole have the right to improved living standards and to sustainable development. It also guarantees the right of Ethiopian nationals to participate in national development and be consulted with respect to policies and projects that affect their community.[182] Article 44 which regulates Environmental Rights provides all persons the right to live in a clean and healthy environment. This provision also ensures the right to commensurate monetary or alternative means of compensation, including relocation with adequate state assistance, to all persons who have been displaced or whose livelihoods have been adversely affected as a result of state programs.[183] Article 92 which regulates about Environmental Objectives puts an obligation on citizens and the Government to protect the environment. It requires that all design and implementation of programs and projects of development made by the Ethiopian Government should be environment friendly.[184] Article 43 gives citizens the right to full consultation and to the expression of their views in the planning and implementation of environmental policies and projects that affect them directly. These constitutional provisions have served as guiding principles for all activities that are related to policy formulation, strategy development and legislative and institutional frameworks for

[181] Constitution (n175)

[182] Ibid

[183] Ibid

[184] Ibid

environmental protection as well as sustainable development of the country.[185] The above constitutional provisions are in line with technological development and biosafety. They regulate the balanced application of technology and biosafety.

3.3. BIOSAFTY PROCLAMATIONS OF ETHIOPIA

Being one of the parties of CBD and the protocol Ethiopia has developed, in addition to the constitution, a proclamation on biosafety with the objective to protect human and animal health, biological diversity and in general, the environment, local communities and the country at large by preventing or at least managing down the adverse effects of modified organisms to levels of insignificance; and enhance access to and transfer of technologies, including modern biotechnology, that serve for conservation and sustainable use of biological diversity.[186] But there is ambiguity with regard to the interpretation of this objective that the proclamation does not give emphasis to safe development of biotechnology as clearly spelled out in the Preamble of the Protocol stressing the benefits of modern biotechnology.[187] The proclamation mentions the term biotechnology first to define making of modified organism under article 2 sub article 3, second to define modern biotechnology under article 2 sub artice19 and article 4 sub article 2 with relating to access and transfer. More than this the proclamation does not regulate about modern biotechnology to make a balance with its development domestically and environmental and human health while it is the central objective of the Protocol as it has great potential for human wellbeing if developed and used with adequate safety measures for the environment and human health.[188] The proclamation lacks this central objective of the protocol to promote domestic and indigenous research as it is a matchless alternative even for purposes of maintaining existing levels of innovation and further developing biotechnologies which are useful in protecting the environment and human health. Some are calling upon African scientists to develop GM crops themselves rather than adopt those developed in the industrialized world.

[185]Environment (n26)

[186] Biosafety proclamation (n176)

[187] Ibid

[188] Hailemichael Teshome Demissie and Mammo Muchie, Re-inventing the GM Debate: The Ethiopian Biosafety Law and its Implications for Innovation and Knowledge Production on Emerging Technologies Science, Technology & Society 19:1 (2014): 109–125

Removing disincentives for researchers and biotechnology entrepreneurs is a vital measure for national innovation regime to develop emerging and modern biotechnologies.[189]

The proclamation focused on to enhance access to and transfer of technologies with put mentioning development of technologies.[190] It didn't give due care for domestic development of biotechnology by giving more attention to access and transformation of technologies from developed abroad.[191] This can be further supported when we analyze the special permit definition. It says a written permit granted by the Ministry for importation of a modified organism for contained use in research or teaching but not for release into the environment in accordance with this Proclamation.[192] Based on this definition the special permit is given only importation of modified organisms developed abroad. This definition is framed in accordance with the objective of the proclamation which is focused on accesses and transfer of biotechnology. The proclamation doesn't say about the domestically developed modified organism special permit activity, which will needed by other persons for contained use in this country. Based on this it can be said there is problem of striking the right balance between compliance without causing disruptions to the domestic science and technology development endeavours.

The other issue that needs analysis in the proclamation is the scope of application of the proclamation. To have clear understanding of the scope of the proclamation, first it is valued to analysis the scope of application which is regulated under article 3 of the proclamation. The first provision under article 3 says the proclamation shall apply to any transaction. From this provision the determinant term is "transaction" which is defined under article 2 sub-articles 2 as any making or use of any modified organism in teaching, production, import, export, transit, release, contained production, transport, placing on the market, or use as pharmaceutical, as

[189] Hailemichael Teshome 188

[190] Biosafety proclamation 176

[191] Ibid

[192] Ibid art 2/20

food, as feed or for processing.[193] The definition which is given to transaction has to two concepts, "making of modified organisms" and "use of modified organisms". This definition develops two kinds of transactions which are making of modified organism or products, and use of modified organisms or products.

Before analyzing the two transactional activates which are mentioned under article 2 sub-articles 2 it is important to say something about the definition of the phrase "modified organism" which also use to define the term transaction. The proclamation defines the phrase modified organism as any biological entity which has been artificially synthesized, or in which the genetic material or the expression of any of its traits has been changed by the introduction of any foreign gene whether taken from another organism, from a fossil organism or artificially synthesized.[194] The definition of modified organisms in the proclamation is as comprehensive as it can be and its scope is much wider than the Protocol. Modified organisms are not confined to those made using any particular procedure such as the recombinant DNA or gene-splicing method that the Protocol recognises as modern biotechnology.[195]

From the above two concepts regulated under article 2 sub-article 2 of the proclamation, making of modified organism, is defined under article 2 sub-article 3 as the development of a modified organism through modern biotechnology[196] while the proclamation didn't define the term use. So it can be understood that the application of the proclamation with regard to use of modified organism is to all modified organisms by not limiting to modified organisms developed only through modern biotechnology. In the case of "use of modified organisms" the Proclamation's definition of modified organisms has set the scope of the law in such a way as to cover the various emerging technologies that are being introduced as molecular breeding, nano biotechnology and synthetic biology. It could be said the Proclamation has foreseen the arrival of technologies that need to be regulated under the rubric of modified organisms. While the term

[193] Biosafety proclamation (n176) art.2/2

[194] Ibid art.2/1

[195]Hailemichael Teshome (n188)

[196] Biosafety proclamation (n176) art 2/3

the Protocol uses is the narrowly qualified living modified organisms, the Proclamation uses the sweeping expression modified organisms with its broader signification including modified organisms developed through emerging technologies, bulk commodities for direct uses as food, feed and processing.

In case of the first transaction regulated under article 2 sub article 2 and defined under article 2 sub article 3, "making of modified organisms", the proclamation applies to modified organisms developed through modern bio technology. In this kind of transaction of modified organisms, "making", the phrase modern biotechnology is used as defining term. To fully know the scope of application of the proclamation with regard to the "making of modified organisms" which is defined under article 2 sub article 3, analyzing what it means modern biotechnology is mandatory. In the proclamation modern biotechnology is defined as the application of In vitro nucleic acid techniques, including recombinant deoxyribonuclic acid and direct injection of nucleic acid into cells or organelles; and fusion of cells beyond the taxonomic family; that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.[197] It is evident that the definition given for modern biotechnology in the proclamation is the direct copy of the protocol[198]. The definition in Article 2 sub article 19 includes new technological processes not yet identified but which may emerge and give rise to novel combinations of genetic material through the use of modern biotechnology and seeks to reflect the need to cover future techniques, by using the wording "in vitro nucleic acid techniques", giving two existing examples of such techniques, and leaving open whether new techniques will be regarded as "in vitro nucleic acid techniques" or not; and by referring to fusion of cells.

Now it is important to clarify the terms which are used in the definition, nucic acid techniques and fusion of cells, to have clear understanding of what is modern biotechnology. In vitro nucleic acid techniques, a gene has been isolated from a donor organism, it is modified in the laboratory so that it can be inserted effectively into the intended recipient organism. While Cell fusion

[197] Biosafety proclamation 16 art.2/19

[198] Cartagena (n31)

involves cells from two different organisms that are fused resulting in an organism containing the genetic information from both parental cells.[199]

Currently it has witnessed the proliferation of a whole new generation of more efficient and more effective technologies than the modern biotechnology which is regulated both in the protocol and the proclamation.[200] Now molecular breeding technologies, especially the technique known as Marker Assisted Selection, simply speeds and improves traditional plant breeding instead of transferring genes from one species to another which was used in gene-splicing method. In this emerging biotechnology Researchers search through maps of a plant's genome for sequence markers that are consistently associated with desired traits such as improved yield or disease resistance. Those markers can then be used to screen breeding stock and the progeny of traditional crosses even before they are grown or planted in the field.[201]

The other emerging technology is synthetic biology where the aim is no longer modifying existing organisms but creating new organisms from scratch. With synthetic biology instead of transferring genetic material from other organisms, scientists are making artificial DNA and inserting it into the organism removing the entire DNA of the recipient organism. Synthetic biology promises to have organisms with desired traits that may not exist in nature in any form. [202]

Nanotechnology is a general purpose platform technology evolving major biotechnology discipline which enables the atom-by-atom manipulation of biotic matter. The instrumentation and other facilities that have been possible with the help of nanotechnology are changing biotech research for the better. With nanotechnology transforming GM technology, nanotechnology and GM technology are converging and will be wholly intertwined. With new nanoscale techniques

[199] Mackenzie (n 41)

[200] Hailemichael Teshome(n188)

[201]Ibid

[202] Ibid

of mixing and harvesting genes, genetically modified plants become atomically modified plants.[203]

From the above analysis it can be understood in the transaction of "making of modified organisms", the proclamation applies to modified organisms developed through modern bio technology. In this transaction of modified organisms regulated under the proclamation are confined to those made using any particular procedure such as the recombinant DNA or gene-splicing method that the Protocol recognises as modern biotechnology.[204] From cumulative reading and studying of article 3, article 2 sub article 1, 2 sub article 2, 2 sub article 3, and 2 sub article 9 the proclamation do not apply to the making of modified organisms by emerging biotechnology.

The proclamation takes the least arguable Principle, which is central to the Protocol, as its major foundation, the precautionary principle. This precaution is taken when authorized persons take due care and reasonable measures to ensure that all transactions regarding modified organisms and products thereof are carried out in conformity with the provisions of the proclamation. The Proclamation endorses the Precautionary Principle in it and states the need for precaution if there is scientific uncertainty about the risk emanating from modified organisms.[205] The Protocol mentions the Principle in its preamble and in its objective clause article 1, and also in article 10(6) and 11(8), which are more operational provisions, so also the Proclamation places it in the operative clause in Art 10(1) as a risk management principle to guide the making and contained use of modified organisms. [206]

The other important action regulated in the proclamation in relation to any transaction of MOs, except for contained use, or products thereof is obtaining an advance informed agreement (AIA) of the Commission [207] by requests for authorizations regarding any import, export, transit,

[203]Hailemichael Teshome(n 188)

[204]Cartagena (n31) art.3/I

[205] Biosafety proclamation 176 art.5

[206] Ibid art. 9/1

[207]Biosafety proclamation 176 art 9

contained use, release, handling, transport or placing on the market of any MOs or its products whether intended for release into the environment, for use as a pharmaceutical, for food, feed or processing are made by a written application to the Commission.[208] AIA is an explicit written consent granted by the Commission based upon full disclosure of all relevant information regarding the MOs or its products by the applicant seeking authorization to be engaged in any transaction, except contained use, relating to that MOs or any product thereof. To get advance informed agreement the applicant is required to undertake risk assessment to identify any significant risks, specify the means of the prevention or containment of those risks and submit the Commission the risk assessment report together with any other documents determined necessary.[209] Upon receipt of the risk assessment report, the Commission shall disseminate it to experts as well as avail it to the public through appropriate means of communication and solicit comments on it.[210] The risk assessment report is to be evaluated on a case-by-case basis. Expert opinions as well as public comments are also to be solicited regarding the risk assessment report and decision is made accordingly.[211]

The proclamation uses a more environment protective approach than the Protocol by requiring approvals or authorizations from the Commission for all activities relating to all MOs and their derived products on a case by case basis.[212] The Protocol puts less strict requirements for products of LMO for food feed or processing than LMOs.[213] The Proclamation avoids this differential application of the law and brings MOs and modified bulk commodities under the same regime.[214] In all cases except contained use risk assessment should include a cost-benefit or socio-economic analysis with a view to determining the need for MOs and if there are alternative

[208]Ibid art.5

[209] Ibid art.5

[210] Ibid art. 2/19

[211] Ibid art. 2/19

[212]Ibid

[213] Ibid

[214] Biosafety proclamation 176 art 2/19

but appropriate technologies.[215] The Commission should, based on the precautionary principle, assess the risk assessment report submitted to it and grant or refuse authorization to the proponent to be engaged in MOs related activities.[216] Authorization is given only when it is duly determined by the Authority is given only when the conditions for application are fulfilled as per the provision of the proclamation and, that the transaction relating to the MOs or product thereof will benefit the country without causing significant risk to human health, biodiversity or the environment[217], Risk assessment report, and by assessing the adverse impacts on socioeconomic considerations. The decision on approval or rejection of the report should be made within 15 days after receipt of the experts' opinion and public comments by taking in to account the comments made by the public, and in particular by the communities likely to be affected by the transaction.[218] The authorization given may be revoked or subjected to conditions in addition to those originally imposed, if in the opinion of the Commission, new information obtained or a review of existing information about the MOs or product thereof indicates any unacceptable risk.[219] To assure transparency and public participation in decision making the final decision will be posted on the National Biosafety Clearing-House. The National BCH will contain all applications, roaster of experts, list of GMOs that have been approved and rejected for import or export, applicable laws, directives, guidelines concerning the handling, transport, use, transfer and release of GMO and products thereof and the Authority's final decisions. [220]

The Commission is the sole responsibility of authorizing any transactions relating to any MOs or products thereof.[221] Licensing Agencies prior to issuing any type of license to an applicant to be engaged in any transaction relating to a MOs or its product are required to ensure that the

[215] Ibid

[216] Ibid

[217] Ibid art.9

[218] Ibid art 2/19

[219] Ibid

[220] Ibid

[221] Biosafety proclamation (n176) art 2/19

Authority has granted it authorization to do so. These agencies should also cancel or suspend licenses following the final decision of the Authority to that effect.[222]

The Protocol and the international environmental law in general are said to be largely ineffectual in terms of civil and criminal liability [223]and the Proclamation should not mirror this by incorporating penalty provisions.[224] The proclamation contains provisions which impose criminal punishments that are not specifically provided in the Protocol.[225] Contraventions of the provisions of the Proclamation could attract imprisonment of up to fifteen years.[226] In Art 24(1) of the Proclamation it is stipulated that a deliberate transaction with harmful intentions shall be punishable by ten to fifteen years rigorous imprisonment.[227] The more significant value that the Proclamation offers is the deterrent effect of the criminal punishment. The infant infrastructure and the low capacity that the state or civil society can do in Ethiopia, the appropriate warning should be sent to those engaging in biotechnology activities with harmful intentions. Furthermore, in the absence of comprehensive liability regimes in case of damage to biodiversity in international environmental law and the harm done to biodiversity is more likely to be irreversible,[228] the punishment cannot be said too high and the deterrent effect of the punishment is more to be desired than any other intended purpose.

[222] Ibid art 20

[223] Ibid art 2/19

[224] Hailemichael Teshome (n188)

[225] Biosafety proclamation (n176) art 2/19

[226] Ibid

[227]Ibid

[228]Hailemichael Teshome (n188)

3.4. BIOSAFETY DIRECTIVES

The biosafety proclamation under article 25 sub article 2 gives the Commission issue directive to properly implement the proclamation, and regulations issued based on the proclamation.

Directive no.4/2018 issued to establish major contents of an application for special permit to engage in the transaction of modified organisms for research or teaching. It is issued because it is necessary to determine major contents of an application for special permit to engage in the transaction of modified organisms for research or teaching. This directive applies on any application related to modified organisms for contained use or research.[229] Any application on MOs related transactions is required to contain general information related to institutional facilities to conduct the activity, institutional system to conduct risk management and assessment and other additional information required for contained use. The directive in addition regulates about characteristics of parent organisms, characteristics of nucleic acid that affect trait expression, characteristic of the vector, characteristic of modified organism, waste treatment and emergency response plans.[230]

Directive no.02/018 is issued on risk assessment parameters of modified organisms. This Directive is issued to determine risk assessment parameters of MO. The user of the MO or its products shall carry out an assessment prior to the use or release of the GMs or products thereof as regards the risks to human or animal health, biological diversity, the environment or to the socio-economic local communities and the country. The risk assessment, in addition to those stated under the biosafety proclamation, should take the following parameters into consideration. Characteristics of donor and recipient organisms Characteristics of the constructs used vector, promoter, terminator, marker gene, Characteristics of modified organism, Characteristics of resuscitated organism or gene from fossil DNA sequences or synthesized DNA sequences incorporated in the MO Characteristics of any Nano-particle incorporated on its won or as a part

[229] Directive no.4/2018 issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2018)

[230] Ibid

of a DNA or RNA sequence Safety considerations for human and animal health Environmental considerations Socio-economic considerations.[231]

Directive no.07/2018 issued to determine the requirements for the transportation and storage of modified organisms. The Directive is issued to determine the requirements for the transportation and storage of modified organisms. This directive requires a driver who is engaged in the transport of MOs or products thereof to be licensed and certified in accordance with the procedures and requirements to be established by the concerned licensing agency, and approved by the Commission. Any person who wishes to transport any MOs shall apply in writing to the competent agency responsible for transport as well as to Commission. When licensing or registering drivers, the competent authority for transport may require the driver to carry adequate insurance to cover any harm to human health or the environment that may result from an accidental release of any MOs or products thereof, that are being transported by road. However, when the authority believes that a MOs or products thereof cannot cause any risk to human or animal health or the environment, it may exempt any MOs or products thereof, from these procedural requirements on transportation. Any premise or facility in order to store or process MOs or its products should be registered and licensed by Commission in consultation with the agency responsible for health and labor affairs. The person in charge of any premise that is to be used for the storage or processing of any MOs or products thereof shall apply in writing to Commission for permission to use such a premise for such a purpose. Commission, after its receipt of the application, shall inspect the premise to determine if adequate facilities exist for the safe storage or processing of the specified MOs or products thereof, adequate security, segregation and safety measures exists at the premise and employee training in the management of MOs and products thereof has been undertaken. Upon completion of the inspection, Commission may refuse permission for the storage or processing of a MOs or its product or issue permit with condition or without condition or may require additional information. After issuing a permit, Commission should lodge the copy of the permit with the National Biosafety Clearing House. In undertaking the licensing and registration of premises, Commission shall require such

[231] Directive no.5/2018 issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2018)

premises to carry adequate insurance to cover any foreseeable liability for harm to human health or the environment. The Commission may for just cause, at any time, cancel the permit that has been issued if any requirement or condition contained in a permit is not strictly compiled with, or order the immediate cessation of the storage or processing of the MOs or products thereof as may be considered appropriate.[232]

A Directive no.8/2018 is issued to determine the contents of an application for undertake deliberate release genetically modified organisms. This directive is issued to determine the information required for application to authorize the release of MOs to the environment, including import for food, feed or processing, and as a pharmaceutical. Any application on MOs related transactions is required to contain general information related to the MOs or products thereof; Information relating to the conditions of release and the receiving environment ; Information relating to the interactions between the MOs or products thereof and the environment; Information on monitoring, control, waste treatment and emergency response plans and other additional information required in the case of notification for placing a commodity consisting of MOs or products thereof on the market.[233]

[232] Directive no.7/2018 issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2018)

[233] Directive no.8/2018 issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2018)

CHAPTER FOUR

CONCLUSION AND RECOMMONDATIONS

4.1 CONCLUSION

Biotechnology is one of the factors that change and improve the way of life of the world community. But this positive impact is accompanied by the question of safeness of the technology on the environment and human health. To regulate the safeness of the technology and as the same time appreciate its development international legal instruments like Rio declaration, CBD, Cartagena protocol, Africa model law to safety in biotechnology and supplementary protocol was developed. These biosafety international legal instruments primarily deal with LMOs which are the product of modern biotechnology. But now there are existing biotechnologies which are radically novel, uncertain, ambiguous and relatively fast growing that exert a considerable impact on the legal, institutional and socio-economic domains which are involve different actors, called emerging biotechnologies. To mention from many modern biotechnology, synthetic biology and nanotechnology are some examples of emerging biotechnologies which have great benefits and may also have great impact by producing new organisms that disrupt ecosystems, toxic substances that cause cancer or self-replicating robots that cause confusion. The techniques of Marker Assisted Selection (MAS), site directed nucleases (SDN) and oligonucleotide directed mutagenesis (ODM) which are not fall on the scope of modern biotechnology techniques regulated in the Cartagena protocol, and modified organisms which are the result of Nano technology and synthetic biology techniques emerged and produce modified organisms which have impacts on environment and human health.

There are no international multilateral treaties that are developed specifically to emerging biotechnologies. CBD under Article 8(g) of the Convention requires to establish or maintain ways to manage, regulate, or control the risks associated with the use and release of living modified organisms resulting from biotechnology that are likely to have adverse environmental impacts and which could affect the sustainable use and conservation of biological diversity, taking also into account the risks to human health. As it is possible that LMOs resulting from modern biotechnology, synthetic biology and nano technology techniques could cause adverse

effects on the conservation and sustainable use of biological diversity they can be regulated by CBD.

The biosafety regulations incorporating in Cartagena protocol African model law on safety to biotechnology and supplementary protocol to biosafety are focused on LMOs which are the result of modern biotechnology techniques. So they are applied on LMOs which are the result of emerging biotechnologies techniques as much as these are fall under the meaning of modern biotechnology techniques. The damage of LMOs which are the result of emerging biotechnology can be regulated by the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety when the damage falls under the definition set out in Article 2 of the Supplementary Protocol. Generally these legal instruments restrict their selves to providing a framework for LMOs of modern biotechnology, which may do not include emerging biotechnology, from an environmental perspective.

Ethiopia domestic legal instruments are framed by using Cartagena protocol as minimum requirement and, especially based on the principles enshrined under African model law to regulate biotechnology. The two biosafety proclamations, biosafety national committee establishment regulation and the five directives of Ethiopia to greater extent comply with the provisions of the protocol, CBD and African mode law. All these domestic legal instruments are framed in accordance with and without contradiction to the international legal instruments save to party to the supplementary protocol.

The policy frame work of Ethiopia that regulates emerging biotechnology are enshrined under the environmental protection policy and in the constitution that required clean and healthy environment, right to improved living standards and sustainable development and other sector`s policy instruments. This policy instruments gives policy direction to regulate emerging biotechnology.

The biosafety regulatory regime of Ethiopia is now comprehensive with two proclamations, a biosafety committee establishment regulation and five directives which are made to implement the international biosafety legal instruments. Even if there is a gap in the regulation of the domestic making/developments of emerging biotechnologies, the biosafety regulatory regime of

Ethiopia regulates MOs whether they are developed through techniques of modern biotechnology or emerging biotechnologies so long as they have impact o the environment and human health. Therefore, Ethiopia has rectified the flaws in international biosafety regulatory framework with regarded to regulation of LMOs developed through emerging biotechnologies.

4.2. RECOMMENDATIONS

By analyzing of the present biosafety regulatory regime of Ethiopia, the research has identified issues, which should be addressed to comprehensively regulate emerging biotechnologies in Ethiopia as follows:

The existing policies of biosafety are find in different sector`s policy instruments and not enough to comprehensively address the issue of biotechnology. So there should be separate biosafety policy that is framed in the way that balance two interests which are Ethiopia's biotechnology development including emerging biotechnology and protection of environmental and human health concerns from its negative impact.

Ethiopia should amend the existing legislations to fully operationalize the regulation of emerging biotechnologies with regard to the development/making of them domestically by avoiding restrictive terms in the proclamation, as the present biosafety legal regime did not regulate MOs while they are developed domestically by emerging technologies. In addition this, speed up the enactment of the other additional biosafety directives which are necessary to implement the international and national biosafety legal instruments which is necessary for operationalize the biosafety regime.

Ethiopian biosafety regulatory system explicitly includes products of MOs in its regime that needs the approval processes for transaction which requires Advance Informed Consent for a product of MO, or any material derived by processing a GMO. This requires the same procedures, risk assessments, and information for products of MOs like MOs which is not practical and scientific as there may receive much applications from persons and companies who do not know very much about the MO. So it is advisable to amend the legislations to make them require less restrictive application procedure to approval products that derived from the MO.

Ethiopia should ratify the Supplementary Protocol as its entry into force will create an incentive to operators to do their best to ensure safety in the development and handling of living modified organisms. It is expected to be an important additional tool for Ethiopia to fulfill its obligations under the Biosafety Protocol to ensure the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

Bibliography

1. Books

1. Mackenzie R., Burhenne-Guilmin, & La vina, An Explanatory Guide to the Cartagena Protocol on Biosafety, IUCN Environmental Law Centre, IUCN, Gland Switzerland and Cambridge, UK, 2003

2. Mugoyu Charles, Resource Book for Implementation of Biosafety in East Africa. BIO-EARN, Sands P, Principles of International Environmental Law, second edition, Cambridge University press, 2003

3. Tewolde Berhan Gebre Egziabher, Balancing Biosafety, Trade, Economic Development Interests in the Implementation of the of the Cartagena Protocol: A Developing Country Perspective, www.cbd.int/doc/publications/bs-brochure-02-en.pdf visited on November 27,2019

4. Gizachew Girma, Zemenu Yesigat, Compatibility of Ethiopia's Import Regulation of Genetically Modified Organisms (GMOs) with WTO Rules. Humanities and Social Sciences, Vol. 3, No. 6, 2015, pp. 286-292. doi: 10.11648/j.hss.20150306.11

5. The Government of the Federal Democratic Republic of Ethiopia environmental protection authority biosafety framework, Addis Ababa, August 2007

6. Daniele Rotolo, Diana Hicks and Ben R. Martin, What Is an Emerging Technology, July 7,2015

7. Sarah Z. Agapito-Tenfen Odd-Gunnar Wikmark , Current status of emerging technologies for plant breeding: Biosafety and knowledge gaps of site directed nucleases and oligonucleotide-directed mutagenesis, (2015)

8. Hailemichael Teshome and Mammo Muchie, Re-inventing the GM Debate: The Ethiopian Biosafety Law and its Implications for Innovation and Knowledge Production on Emerging Technologies Science, Technology & Society 19:1 (2014): 109–125

9. Chairman UK Synthetic Biology Roadmap Coordination Group, synthetic biology road map for UK. July 2012 p.13,18 pages

10. The future of international environmental law, Leary and Pisupati (eds), United Nations University Press, 2010, ISBN 978-92-808-1192-6

11. Gregory N. Mandel, Regulating Emerging Technologies, LEGAL STUDIES RESEARCH PAPER SERIES, No. 2009-18

12. Der-Chin Horng, INTERNATIONAL LAW ON BIOTECHNOLOGY, Institute of European and American Studies, Academia Sinica, Taiwan, R.O.C.

13. Mariam Mayet, why Africa should adopt the OAU Africa mode aw on safety in biotechnology (2003)

14. E Jane Morris, biosafety n Africa; experiences and best practices (2017)

15. Aregay Waktola (PhD) and Bayush Tsegaye, Biotechnology related policy, management and negotiation competence: Case study from Ethiopia, Noragric Agricultural University of Norway, Noragric Report No. 14-B March (2003)

16. Biotechnology related policy, management and negotiation competence: Case study from Ethiopia

2. Laws

1. The Federal Democratic Republic of Ethiopia, 1995, Proclamation No.1, Federal Negarit Gazeta 1 51 Year No.1

2. Cartagena Protocol on Biosafety Ratification Proclamation, 2003, Proclamation No. 362, Federal Negarit Gazeta, 9th Year No. 87

3. The Cartagena protocol on Biosafety to the Convention on Biological Diversity (Montreal) 29 January 2000 came into force II September 2003

4. The Convention on Biological Diversity (Rio de Janeiro) 5 June 1992, come into force 29 December 1993

5. Organization for African Unity, African Model Law on Safety in Biotechnology 2002

6. The United Nations, Rio Declaration on Environment and Development

7. Biosafety proclamation No. 655/2009 as amended by Proclamation No. 896/2015, Federal Negarit Gazeta article 2/19, (Page 4962- 4975), 15th Year No. 63, Addis Ababa, 2009

8. The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety Adopted Nagoya, 15 October 2010

9. Agricultural research policy Environmental policy, 1997

10. The national science and technology policy, 1994

11. The national biodiversity conservation and research policy, 1998

12. Directive no.4/2018 issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2018)

13. Directive no.7/2018 issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2018)

14. Directive no.8/2018 issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2018)

15. Directive no.5/2018 issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2018)

3. Online resources

1. African Journal of Biotechnology Vol. 10(58), pp. 12389-12394, 30 November, 2019 Available online at http://www.academicjournals.org/AJB p.1

2. Convention on Biological Diversity,AD HOC technical expert group on synthetic biology, Montreal, Canada, 5-8 December 2017

3. United Nations Environmental Program, An introduction to Cartagena Protocol to Biosafety, (2003), Available at http: //www. unep.org visited on November 26,2019, p.64