ADDIS ABABA UNIVERSITY

COLLEGE OF LAW AND GOVERNANCE STUDIES

THE ETHIOPIAN BIOSAFETY REGIME ON GMOS AND ITS IMPLEMENTATION IN LIGHT OF CARTAGENA PROTOCOL: FOCUS ON COTTON AND MAIZE GMOS

By

Samuel Alemayehu

Advisor: Biruk Haile (PHD)

A Thesis Submitted to the College of Law and Governance Studies, School of Law in Partial Fulfillment of the Requirements for the Masters of Law (LL.M) in Business Law

July, 2021

Declaration

I, Samuel Alemayehu, hereby declare that this thesis is my original work and has not been submitted to any other institutions before. Further, I confirm that all resources used in writing the research have been dully acknowledged.

Declared by Samuel Alemayehu

July 2021

Approval Sheet by the Board of Examiners

The Ethiopian Biosafety Regime on GMOs and Its Implementation in Light of the Cartagena Protocol: Focus on Cotton and Maize GMOs

Approved by Board of Examiners

----------	----------	----------
Advisor	**Signature**	**Date**
----------	----------	----------
Examiner	**Signature**	**Date**
----------	----------	----------
Examiner	**Signature**	**Date**

Acknowledgement

First of all, I would like to thank my heavenly father for this golden opportunity. There are many people whom I would like to thank for their support during my thesis work. My deep gratitude goes to my advisor Biruk Haile (PhD) for his countless suggestions, and invaluable advice from the conception to the end of the study. I also extend my warmest appreciation to my Family, especially my mom Mekdes Gorfu and my sister Samrawit Alemayehu, had it not been for their support and encouragement, I couldn't finalize this paper. Lastly, I would like to thank my best friends Samuel Abayneh, Yosef Elala, Misganu Degif and Mintesnot Endale for their uplifting in bringing off this paper.

Thank You All!

Table of Contents

Table of Contents **Pages**

Declaration i

Abstract vii

Acronyms viii

Chapter One 1

1.1. Background of the study 1

1.2. Statement of the problem 2

1.3. Research questions 4

1.4. Research objectives 5

1.4.1. Main objective 5

1.4.2. Specific objectives 5

1.5. Literature review 5

1.6. Significance of the study 7

1.7. Methodology 7

1.7.1. Research Method 7

1.7.2. Research instruments 8

1.7.2.1. Interview 8

1.7.2.2. Laws 9

1.7.2.3. Secondary source 9

1.7.3. Method of data analysis 9

1.8. Scope and Limitation of the study 10

1.9. Organization of the study 10

Chapter two 11

2. An Overview of the Cartagena Protocol on Biosafety and Its Supplementary Protocol on Liability and Redress 11

Introduction 11

2.1. The Cartagena Protocol 11

2.1.1. Background and Negotiations of Cartagena Protocol 11

2.1.2. Major negotiating blocks 12

2.1.3. Adoption and Facets of the Protocol 13

2.1.4. Objective and scope 13

2.1.5. The Advanced Informed Agreement Procedure 14
2.1.6. Unintentional and illegal transboundary movement of GMOs 15
2.1.7. Public awareness and participation 16
2.1.8. Risk Assessment and Management 17
2.1.9. Liability and redress issues under the Nagoya Kuala Lumpur supplementary protocol 19
Chapter Three 22
3. An Overview of the Ethiopian Biosafety Regulatory Framework 22
Introduction 22
3.1. Legal Framework 22
3.1.1. FDRE Constitution 22
3.1.2. The biosafety proclamation 22
3.1.3. The biosafety amendment proclamation 24
3.1.4. Biosafety directives 25
A. AIA and special permit application requirements directive 25
B. Risk assessment and risk management directives 25
C. Transportation and storage directives 27
3.2. Institutional framework 27
3.2.1. EEFCCC 27
A. Historical background 27
B. EFCCC powers and duties regarding GMOs 28
3.2.2. National Biosafety Advisory Committee 28
Chapter four 30
4. Critical Analysis on the Legal Gaps and Implementation of the Ethiopian Biosafety Framework and the Cartagena Protocol 30
Introduction 30
4.1. Advanced Informed Agreement and Special Permit 30
4.1.1. Implementation of biosafety laws in granting permit for BT cotton 31
4.1.2. Implementation of biosafety laws in granting permit for GM-maize 32
4.2. Risk Assessment and Management 33
4.2.1. Application of risk assessment procedure up on granting AIA for Bt Cotton 35
4.3. Public Awareness and Participation 35
4.3.1. Public Awareness 35

4.3.2. Public participation 37
4.4. Labeling of GMOs and Consumers' right to know 39
4.5. Intellectual property and agribusiness aspects of GMOs in Ethiopia 41
4.6. Control of Illegal and Unintentional Cross Border Movement 44
4.6. Liability and Redress 46
4.7. The recognition of differential treatment for Gene Editing and Transgene Modification . 49
Chapter Five 52
Conclusion and Recommendation 52
5.1. Conclusion 52
5.2. Recommendation 55
Bibliography 57
International agreements 57
Books, Journal Articles and Other Sources 58
Interviews 60

Abstract

The development of modern biotechnology raise environmental and health related risks. In protecting both the environment and human health states came up with international and national biosafety framework. This study has made a comprehensive assessment on biosafety framework of Ethiopia and its sufficiency in implementing the CPB. The study aimed at assessing whether proper procedures are followed in the approval of Bt Cotton and GM Maize and whether the public awareness, participation, BCH, and risk assessment issues are addressed under the domestic law and being implemented in Ethiopia, among others. The researcher beyond consulting laws and other secondary sources conducted an interview with key informants from different regulatory agencies. Although the Ethiopian biosafety framework is in line with the CPB, it doesn't sufficiently assure proper implementation of the latter. The study has identified legal and implementation gaps concerning biosafety i.e. limited public awareness and participation, weak border control attributed to lack of skilled man power and laboratories, and weak collaboration between the EFCCC and the ECC, and failure to address liability and redress issues due to government's reluctance to adopt a sui generis law. Concerning the practice there were flows in the implementation of AIA, public participation, risk assessment, and BCH in the approval procedures of Bt Cotton and GM maize. Based on its findings, the study recommends straightening the biosafety legal and institutional framework and implementing the CPB and domestic laws properly in the further approval of GMOs.

Keywords: Biotechnology, Biosafety, EFCCC, Cartagena Protocol on Biosafety

Acronyms

AIA	Advance Informed Agreement
AU	African Union
BCH	Biosafety Clearing House
BI	Biotechnology Institute
BSWG	Ad hoc Working Group on Biosafety
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
CEE	Central and Eastern Europe
COP	Conference of Parties
COP/MOP	Conference of the Parties serving as the meeting of the parties
ECC	Ethiopian Custom commission
EU	European Union
EIA	Environmental Impact Assessment
EIAR	Ethiopian Institute of Agricultural Research
EPA	Environmental Protection Authority
GE	Genetically Engineered
GM	Genetically Modified
GMO	Genetically Modified Organisms
IISD	International Institute for Sustainable Development
LMO	Living Modified Organism
LMO-FFPs	Living Modified Organisms Intended for direct use as food or feed, or for Processing
NKSP	Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress
UNEP	United Nations Environment Program

Chapter One

1.1. Background of the study

Biotechnology is the use of technology to use, modify or upgrade the part or whole of biological system for industrial and human welfare. The advancement of modern biotechnology and development of GMOs, though it comes up with solutions that ease human life, it occasionally has an overwhelming risk. There are different GMO-related environmental risks, *inter alia*, genetic contamination/interbreeding, ecosystem impacts, and increased selection pressure on target and non-target organisms. In the same pattern, it also affects human health, WHO, in listing health-related issues of GMO, included, direct health effects (toxicity), tendencies to provoke allergic reaction (allergenicity), specific components thought to have nutritional or toxic properties, and any unintended effects, which could result from the gene insertion.[1]

Thus, in fear of all those risks, biosafety regimes are developed at the international, regional, and national levels. Through Biosafety regulations, states set measures or actions addressing the safety aspects related to the application of biotechnology and the release into the environment of transgenic plants and other organisms.[2] At the Global level, CPB to the CBD is the first international instrument to ensure the safe transfer, handling and use of GMOs.[3] The CPB regulates the AIA Procedures, Risk assessment, Risk management, public awareness and participation, and illegal cross border movement, among others.

Ethiopia has been the leading advocate for anti-GMO movement in Africa. Moreover, the country has negotiated the CPB as a leading figure. After ratifying the protocol in May 2003, it has enacted a biosafety proclamation and six directives on i.e. AIA application procedure, risk assessment, risk management, transportation, storage, and accidental release of GMOs with stringent requirements in 2009.[4] However, this didn't last for longer. In 2015, the parliament –

[1] WHO, 'Health Concerns of GMOs' (Genetic Generation 2015) available at <https://knowgenetics.org/health-concerns-of-gmos/> accessed August 13 2020

[2] US Legal, 'Biosafety law and legal definition' available at < https://definitions.uslegal.com/b/biosafety/> accessed 14 august 2020

[3] Cartagena protocol on Biosafety to the Convention on Biological diversity, (2000) (CPB)

[4] In 2009 Ethiopia enacted a highly restrictive biosafety law that prohibited the deliberate release of GMOs into the environment. By passing this law, Ethiopia proved to itself and crop diversity enthusiasts that it was protecting its uniquely high crop diversity from GMO contamination and genetic erosion.

introduced an amendment proclamation[5] that tries to give space for the development and adoption of GMOs in Ethiopia. Following the amendment, the EFCCC gave permission for the cultivation of BT- cotton and a field trial on GM maize.

This study makes a compressive analysis of the existing biosafety framework. The domestic legislations on biosafety will also be examined as to its sufficiency in implementing the basic principles ensured under the CPB. The preexisting biosafety proclamation and its directives will be assessed in comparison with the amendment proclamation and biosafety directive enacted in 2018. Moreover, the study devotes itself in examining the implementations of the regulatory framework in the approval of BT- cotton, and GM maize for cultivation and field trials, respectively.

1.2. Statement of the problem

Genetically modified organisms come up with environmental and human health-related risks as already mentioned. It has the power to create an economically dependent society in the agriculture sector since a large portion of the land in Ethiopia is under small holding farmers which may not afford to access GMOs patented under multinational companies. Therefore, minimizing all the adverse effects of GMOs need to integrate the legal and institutional framework.

The CPB bestowed minimum standards at the international level to secure biosafety and oblige each party to develop a strong domestic regulatory framework based on their socio-economic and anthropological context. The protocol brings forth a dissimilar standard of treatment through classifying GMOs as GMO seeds for the direct introduction to the environment, GMO-FFPs, and GMOs for contained use.[6] The procedure provided for GMOs for the direct introduction to the environment is more stringent than others. This procedure includes, *inter alia* an advanced informed agreement, proper risk assessment and management, and export documentation.

In the Ethiopian case, the preexisting regulatory framework was very restrictive which was almost closer to a close-door policy. It provides for similar AIA and risk assessment procedures

[5]Advocates of biotech declared that the amendment enables the proclamation to "solve problems that have been faced during implementation, improve research and technology transfer" and enables the country's gain from the technology to be in harmony with the environment.

[6] Cartagena protocol on Biosafety to the Convention on Biological diversity, (Montrial 2000, Entered in to Force , 2003) (CPB)

for all categories of GMOs unlike the case of the Cartagena protocol. All GMO seeds, GMOs for contained use, and GMO FFPs should pass through the procedures under the proclamation and the directives.

On the contrary, the biosafety amendment proclamation has made two significant changes. Firstly, it has incorporated the objective of enhancing access and transfer of technologies, including biotechnology for conservation and sustainable use of biodiversity. This objective is not derived from the CPB and it is not clear how biotech would enhance the sustainable use of biological diversity. Moreover, it is questionable whether the law bestows differential treatment for different technologies in achieving this goal. Secondly, the law put forward a special permit system for the importation and development of GMOs for contained use. GMOs for contained use are exempted from the AIA procedure under the CPB. However, it clearly designates that states can develop other procedures including risk assessment for contained use of GMOs. Nonetheless, the amendment proclamation is not clear as to whether risk assessment is required for contained use of GMOs.

In addition to the loopholes created under the amendment proclamation, the main biosafety proclamation is not without limitations. Among others, the issues of public participation and public awareness, controlling illegal and cross border movement of GMOs, BCH, and liability and redress issues need critical scrutinization as to their compatibility and their sufficiency in implementing the CPB. CPB require states to promote and facilitate public awareness concerning the safe transfer, handling and use of LMOs in relation to the conservation and sustainable use of biological diversity. It also provides for public participation for decision making regarding GMOs. However, the domestic legal framework does not seem to be sufficient in implementing this obligation needs critical assessment.

The other major concern is controlling illegal cross border movement of GMOs. In this regard, the Cartagena protocol impose obligation on a state party to adopt appropriate domestic measure to prevent illegal transboundary movement of GMOs. The domestic legal regime does not provide a detailed procedure for controlling illegal transboundary movement of GMOs. Moreover, the mechanism of disposing illegally entered GMOs without having adverse effect on the environment and human health needs an assessment.

Concerning liability and redress, the NKSP to the CPB addressed liability and redress issues. Although Ethiopia is a signatory, the protocol is not yet ratified. On the top of that, the biosafety proclamation failed to mention the issues of liability and redress for possible damage that may occur by GMOs. Therefore, the compatibility of national biosafety framework with the Cartagena and its supplementary protocol needs critical securitization.

The issues and setbacks of biosafety in Ethiopia get more intricate on the implementation of biosafety laws. As I have discussed in the background, Ethiopia has approved the cultivation of BT cotton and confined field trial of GM- maize. The field trial of BT- cotton has been made in six areas in the country. Nonetheless, it has been made without public consultation and the area of the field trial was not disclosed by the government. Moreover, it's not clear whether the government implemented the precautionary approach, AIA, risk assessment procedures, risk management, BCH in its approval of BT cotton and GM maize.

1.3. Research questions

- Is the current domestic legal framework adequate to implement the Cartagena protocol regarding the illegal cross-border movement of GMOs?
- Is the current domestic legal framework adequate to implement the Cartagena protocol with respect to public awareness and public participation?
- Is the permit system for contained use of GMOs under the amendment proclamation compatible with the Cartagena protocol?
- Did the commission follow proper procedures under the Cartagena protocol and domestic laws in granting a permit for the importation of BT-cotton and GM maize?
- Is there an isolated field for confined field trials of BT-cotton and GM maize?
- Do the Ethiopian biosafety laws recognize technological progress and differential treatment for mutagenesis and transgene modification?
- Whether the Ethiopian biosafety framework addresses liability and redress issues?
- Is EFCCC implementing rules of BCH under the Cartagena protocol?

1.4. Research objectives

1.4.1. Main objective

The main objective of this thesis is to examine the compatibility and adequacy of the biosafety regime with the Cartagena Protocol and its implementation in Ethiopia.

1.4.2. Specific objectives

This thesis specifically aims,

- To examine the adequacy of the domestic legal framework to implement the Cartagena protocol concerning public awareness and public participation.
- To explore the compatibility of the permit system for the contained use of GMOs under the amendment proclamation with the CPB.
- To assess whether proper procedures were followed in granting a permit for the importation of BT cotton and GM maize.
- To explore whether a confined field trial of BT-cotton and GM maize is being made in an isolated field.
- To assess major changes made by the amendment proclamation and its directive and their compatibility with the CPB.
- To explore the recognition of technological progress and differential treatment concerning gene editing and transgene modification.
- To explore the local biosafety framework regarding liability and redress issues.

1.5. Literature review

Different studies have been made on the regulatory framework of the biosafety regime. Among others, a researcher under a thesis topic "legal framework of biosafety in Ethiopia: the relevance of Cartagena protocol"[7] has made a comprehensive analysis on the legal framework of biosafety at the international and national level, and recommended that Ethiopia should develop a strong regulatory framework compatible with the CPB, regional integration with other African countries, and to elaborate public awareness and define biosafety under the domestic laws.[8] The

[7]BillenGirmay, 'Legal Framework of Biosafety in Ethiopia: The Relevance of Cartagena Protocol' (Master's Thesis Addis Ababa University 2009).
[8] Ibid. P. 102-104

recommendation was made based on the existing draft biosafety laws and the Cartagena protocol. However, the writing, as it was conducted before the enactment of the proclamation and its directives, limits itself with analyzing the existing draft national laws and the Cartagena protocol. Moreover, in no case the writer tried to create a link between the legal framework and the existing practice since the research limits itself with document analysis.[9]

There is also an article published post enactment of the proclamation and the directive and advocates for balancing development of biotech and protection of biosafety, entitled "Toward a workable biosafety system for regulating genetically modified organisms in Ethiopia, Balancing conservation and competitiveness".[10]The writer asserts that the Ethiopian biosafety framework is very restrictive and hinders research and development of biotechnology in Ethiopia. Though Ethiopian government wanted BT- cotton field trial and requested US-based private technology provider, Monsanto, yet request decline for restrictive legal framework in Ethiopia.[11]Furthermore, the writer argued that the law-making process was not accompanied by sufficient public participation and other stakeholders, especially advocates of biotech were not in the process. Regarding intuition, on the other hand, ministry of science and technology is a proper authority than environmental protection authority as the writer stated. This article beyond being pro GMO oriented, does not dictate much about the legal framework and its compatibility with the Cartagena protocol. Similarly, it failed to assess the setbacks with the implementation of laws.

The other more recent article entitled "Biosafety Issues of Genetically Modified Crops: Addressing the Potential Risks and the Status of GMO Crops in Ethiopia"[12] tried to address GMO related risks associated to health and environment, on one hand and, economic social and political concerns on the other. While Allergenicity, toxicity, and feed safety for animal are Health related risks, loss of biodiversity due to the preference of GMOs then natural seeds, new weeds and genetic contamination mentioned as environmental risks. However, the writer reveled less about Ethiopia, it only mentions the weakness of the regulatory and institutional framework,

[9] Ibid. P.14
[10], Adane Abraham, 'Toward a workable biosafety system for regulating genetically modified organisms in Ethiopia Balancing conservation and competitiveness' (2013) GM Crops and Food: Biotechnology in Agriculture and the Food Chain, Vol. 1 P. 29
[11] Ibid.
[12]Motbaynor Terefe, 'Biosafety Issues of Genetically Modified Crops: Addressing the Potential Risks and the Status of GMO Crops in Ethiopia' 2018, ClonTransgen, an open access journal, Vol. 7

and lack of public awareness like the case of other developing states. Similarly, there is also an article which tried to assess the status, challenge and opportunities related to GMO in Ethiopia. With respect to regulatory framework stated that "whether Ethiopia wants or not, neighboring countries such as Sudan and Kenya have already started producing GM crops and hence GM seeds can be found in the country as far as there is illegal and noncertified exchange of seeds in the borders." This shows how toothless the regulatory framework is without proper implementation. Nevertheless, like the case of previous writings, the article more concerned with biotechnology technical issues than regulation and implementation of biosafety related laws.

1.6. Significance of the study

This research clarified the existing biosafety legal framework and the gaps under domestic laws which hider proper implementation of the Cartagena protocol. Moreover, it assesses the existing institutional framework, its strength and weakness to carry out its obligation under the law. Thus, it suggests best institutional framework to implement biosafety laws through comparatively assess the experiences of other developing states.

The study may also important to contribute as literature on the subject matter, as the subject matter is not explored well, it may serve as a stepping stone for further and in-depth studies for legal researchers, and it might useful for further legal development.

1.7. Methodology

1.7.1. Research Method

This research is conducted based on a hybrid research approach since achieving the research aim, needs both doctrinal and non-doctrinal research methods. The methods have not been employed in a manner of mutual exclusiveness since the law and the practice is always interrelated. However, principally some of the questions will be addressed through the doctrinal method while others need an empirical inquiry.

The doctrinal aspect addressed questions as to the compatibility and adequacy of the domestic biosafety framework to implement the Cartagena protocol regarding the illegal cross-border movement of GMOs, public awareness and public participation, and permit system for contained use of GMOs. Moreover, concern of labeling and consumer protection, differential treatment for GM technologies and intellectual property aspect of GMOs in Ethiopia will be assessed under

this method. The CPB, NKSP, domestic biosafety proclamation and directives will be major sources under this method.

On the other hand, an empirical research method was employed to address whether EFCCC has a mechanism to control illegal cross-border GMO movements in Ethiopia and exploring whether proper procedures followed concerning the importation of GM maize and BT cotton in Ethiopia.

Moreover, the researcher identified three different approaches to legal research: a qualitative, quantitative, and comparative method based on their general goals and specific research strategies. To attain the intended objectives of the research, the researcher employed a qualitative approach. A qualitative method of data analysis was utilized to analyze, and present data collected through both primary and secondary sources.

1.7.2. Research instruments

1.7.2.1. Interview

This research used instruments available under a mixed approach with a qualitative study. The main instrument of data collection was an interview, since objectives regarding the practice will be addressed through interviewing key personnel from different institutions. These institutions are the most relevant institutions regarding biosafety issues in Ethiopia. Respondents were selected from EFCCC, EIAR, BI, and ECC. Respondents were selected purposively from each institution and respondents more relevant for addressing major practical questions on the implementation of the biosafety regime were included.

- An interview has been conducted with the key personnel within EFCCC. The commission has forest and environmental directorates. Within the environmental wing, there is a biosafety directorate that looks over GMO-related activities in Ethiopia. The interview was conducted with the biosafety directorate director, risk assessment and capacity building expert.
- EIAR officials were other targets for conducting an interview. There are twelve research directorates under the institute. An interview has been conducted with one purposively selected official from the agricultural biotechnology directorate as the major responsibility regarding biotech falls under this directorate.

- An interview has also been conducted with respondents from ECC. It has been conducted with purposively selected officials from two directorates i.e. intelligence and contraband control directorate, and law enforcement directorate. This helps in addressing questions related to the illegal transboundary movement of GMOs.
- The other organization concerning the development and trial of GMOs in Ethiopia is the BI. The institute works on agricultural, medical, environmental, and industrial biotechnology. The respondent was purposively selected agricultural biotechnology sector since the primary responsibility of development and research on GMOs falls within this category.

The researcher used semi-structured interview questions for two major reasons. First, it helps the researcher to jot down the basic questions which will be answered by the interviewee and not to be skeptical. Second, it allows the flow of ideas between the researcher and the respondents, to ask for incidental questions based on the explanation given by the respondent. This method helps to address major questions concerning the practice in implementing biosafety laws.

1.7.2.2. Laws

The other major primary source of data was international and domestic laws that govern the biosafety regime includes, *inter alia*, the biosafety proclamation and its amendment, the six directives, the Cartagena protocol, biodiversity convention. Analysis of the law address issues related to the compatibility of the domestic legal framework with the Cartagena protocol. Moreover, it also helps in assessing the existing institutional capacity of EFCCC.

1.7.2.3. Secondary source

Secondary data was collected from books, published and unpublished materials, cases, and other internet journals and publications. Secondary sources will be employed to supplement primary sources, consequently, to achieve the research goal and objective. More importantly, this source helps to examine the experiences of other states in regulating the biosafety regime.

1.7.3. Method of data analysis

The researcher used the qualitative method of data analysis to analyze and present data, specifically, narrative, and descriptive methods of analysis is utilized. Data collected through interviews is presented objectively and analyzed through narrative and discourse methods of data analysis. The narrative method allows reformulating stories collected from respondents in

different contexts and based on their different experiences. Similarly, through discourse analysis, the researcher refers to the context when interpreting the message as sometimes the same phenomena will be expressed in different ways. The qualitative methods have also been employed to analyze, and present data collected from binding legal instruments at the international and national levels.

1.8. Scope and Limitation of the study

This research limited itself in analyzing the biosafety regime at the international and national levels through document analysis and assessing the practice in implementing the existing biosafety legal framework in Ethiopia. Moreover, it tries to take the best experiences of other developing states in regulating and implementing biosafety-related laws and principles. Nevertheless, the research limits itself from discussing trade aspects of GMOs.

The researcher does not have in-depth knowledge about technical issues regarding biotechnology, as it is a complicated engendering process that needs an advanced study on the field. Therefore, the pros and cons of biotechnology would not have a role except for either justifying or knock back the regulatory framework, and the research limits itself in analyzing the legal framework of biosafety and its implementation in Ethiopia.

1.9. Organization of the study

With a plan to achieve the research aim and objectives, this research is organized under five chapters. The first chapter gives a general introduction about the research and includes, among other, background, statement of the problem, research question and objectives, and methodology. Under chapter two international biosafety frameworks i.e. the Cartagena protocol and its supplementary protocol on liability and redress will be analyzed in detail. Under chapter three the Ethiopian domestic biosafety framework will be overviewed. Chapter four will be devoted to assessing the legal gaps and the existing practice in implementing the legal framework. Lastly, the conclusion and recommendation will be drawn based on the analysis.

Chapter two

2. An Overview of the Cartagena Protocol on Biosafety and Its Supplementary Protocol on Liability and Redress

Introduction

Biosafety has become an environmental concern in the modern world. The evolution of biotechnology has raised different environmental and health-related issues which have led to the initiation of different international and regional instruments governing biosafety issues. At the international level, the Cartagena Protocol on biosafety to convention on biological diversity[13] is the first international instrument tried to regulate the safe movement and handling of GMOs across the border. Under this chapter, the negotiations and provisions of the CPB i.e. scope ad objective, public participation and awareness, illegal cross-border movement, liability and redress, risk assessment and management, and AIA procedures will be assessed in detail.

2.1. The Cartagena Protocol

2.1.1. Background and Negotiations of Cartagena Protocol

The CPB on Biosafety is an additional agreement to the CBD.[14] It aims to ensure the safe transport, handling, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biodiversity, also considering risks to human health. The Protocol establishes procedures for regulating the import and export of LMOs from one country to another.[15]

The elaboration of the CPB was started in 1996 by a decision of the Conference of the Parties to the CBD establishing an open-ended Ad Hoc Working Group on Biosafety to develop a draft text of the Protocol, in pursuance of Article 19(3) of the Convention.[16]

---

[13] The Convention on Biological Diversity (CBD) was adopted in May 1992 in Nairobi and was opened for signature in Rio de Janeiro on 5 June 1992 at the UN Conference on Environment and Development. It entered into force on 29 December 1992, and as of 20 September 2020 has 196 Parties.

[14] Ibid. the convention has clearly stated biosafety issues under article 8(g) which requires Parties to take national measures to ensure safety in respect of harm by LMOs to the environment, health, and biodiversity. Likewise, article 19(3) requires Parties to put in place an internationally binding instrument for biosafety.

[15] Secretariat of the Convention on Biological Diversity, 'The Cartagena Protocol on Biosafety, and its Nagoya—Kuala Lumpur Supplementary Protocol on Liability and Redress' 2020.

[16] Ezra Ricci, 'Biosafety regulation: the Cartagena protocol' Geneva International Academic Network *(GIAN)* (2004) P.12

2.1.2. Major negotiating blocks

CPB has taken four years since divergent interests from different polar has been represented the negotiation process, the groups under the negotiation process majorly classified under five categories i.e. Miami groups, like-minded group, EU, compromise group, and central and eastern European Group.

The Miami group is composed of pro-GMO states, which majorly produce and export GMO products i.e. The USA, Argentina, Australia, Canada, Chile, and Uruguay. The group made its first meeting in Miami in 1998 to discuss trade-related issues of GMOs and the implication of the protocol on the movement and transfer of GMO products.[17] This group advocates for the free transfer of GMO products with limited restrictions and narrowed application of the principle of precaution.

In the other polar most developing states that manly import GMO products advocated for restrictions on the transaction of GMOs, referred to as the likeminded group. This group encompasses most states which do not have either a domestic regulatory framework or enhanced biotechnology institutes. The firm belief on this side restrained market access for LMOs, considering them as specific products that could be carriers of ecological and sanitary hazards that scientific knowledge still cannot fully apprehend.

The other three groups i.e. the European Union, the eastern and central European group and the compromise group hold a position between the two polarized lines. The EU inclined more with the like-minded group advocated for the inclusion of, among others, the precautionary principle, and identification and labeling. The compromise Group, on the other hand, was formed at the end of the negotiation by Japan Mexico Norway, Singapore, South Korea, and Switzerland. Its major aim was to compromise the interests of different groups and come up with an amenable instrument.[18] Lastly, the fifth negotiating block, formed by some members of EU and eastern European states, while the former was more allied with EUs position the latter more inclined with the like-minded group.

[17] Ibid.

[18] For instance, the compromise group supported the comprehensive scope and precautionary principle, but at the same time accepted internal differences about saving clauses.

2.1.3. Adoption and Facets of the Protocol

The first extraordinary meeting of the Conference of the Parties was opened on 22 February 1999, in Cartagena, Colombia. The Conference of the Parties was not able to finalize its work in the time available. As a result, the Conference of the Parties suspended its first extraordinary meeting and agreed that it should be reconvened as soon as possible and, in any event, no later than the fifth meeting of the Conference of the Parties.[19]

After a lengthy debate, the negotiating blocks failed to agree on some issues which majorly revolve around *inter alia*, the scope of application, application of the precautionary approach in decision making, AIA procedures and its scope, the treatment of LMO -FFPs, and the relationship between the protocol and other international trade-related agreements. Later on, the parties tried to compromise their interests, the pro-GMO groups agreed to support the developing states in capacity building for their environmental and health concerns, and the latter to give some space for market access for GMO products.

2.1.4. Objective and scope

The major objective of the protocol is ensuring the safe transfer, handling, and use of LMOs and an adequate level of protection against biotechnologies that may harm conservation and sustainable use of biological diversity.[20]

The intense negotiations resulted in dissimilar regulatory provisions based on whether the type of GMO is being released to the environment, for contained use, or direct use as food feed or to be processed (FFPs). Only minimum standards of regulation for the transboundary movements of LMOs that may harm the conservation and sustainable use of biological diversity are provided in this protocol, while the scope of the AIA is narrowed.[21]

---

[19] Convention on biological diversity, 'About the Protocol' (2012) < https://bch.cbd.int/protocol/background/ > The resumed session took place in Montreal from 24 to 29 January 2000 and was preceded by regional and interregional informal consultations from 20 to 23 January 2000 at the same venue.

[20] UNEP, 'An Introduction to The Cartagena Protocol' (2011) < bch.cbd.int/help/trainingmaterials/En/03)%20Traning%20modules/MO01En.pdf > Accessed on 14 September 2020 P. 5

[21] Lim Tung, 'Transboundary Movements of Genetically Modified Organisms and The Cartagena Protocol: Key Issues and Concerns' 2014, P.E.R, Vol.17 P. 1743 (Lim Tung)

The law has provided general and special conditions in determining whether a given LMO fall under the protocol. Article 4 of the protocol provides two general conditions i.e. transboundary movement and adverse effect on the conservation and sustainable use of biological diversity and/or risks human health. Therefore, primarily, the protocol does not concern itself if the transaction is made within the territory of a given state, even though it affects the environment or human health. Moreover, it excludes LMOs which do not harm the environment or risk to human health.[22] Aside from these general exclusions, the law excludes LMOs i.e. for contained use, in transit, and pharmaceuticals for humans.

The law also classified LMOs under three categories as LMOs to be introduced to the environment, LMOs intended for contained use, and LMOs intended for FFP. The first categories follow the strict AIA procedure the latter governed under lesser requirements for their transaction unless states set some restrictions at the domestic level. [23]

2.1.5. The AIA Procedure

Although it has limited application in terms of scope, the AIA procedure is the backbone of the Cartagena protocol.[24] It provides a stringent procedure for the transfer and movement of GMOs across the border. The central procedural mechanism set out in the Protocol to regulate the transboundary movement of LMOs is the AIA procedure.[25] The AIA procedure is designed to ensure that before an LMO is imported into a country for the first time for intentional introduction into the environment[26], the Party of import, should be notified about the import, receive full information about the LMO, and its intended use and has an opportunity to assess the risks associated with that LMO and to decide on its importation.

The LMO procedure incorporates two major stages i.e. the communication and decision-making stages, while the former indicates that the exporting state shall notify the party of import written

[22] This general exclusion should be interpreted in line with the precautionary approach, unless it is ascertained it does not have any adverse effect, it's presumed otherwise.
[23] CPB (n3), Art. 7 &11
[24] Aaron Cosbey & Stas Burgiel, 'The Cartagena Protocol on Biosafety: An analysis of results, An IISD Briefing Note' (2000) International Institute for Sustainable Development
[25] Mackenzie, & others, *An Explanatory Guide to the Cartagena Protocol on Biosafety* (IUCN Environmental Policy and Law Paper 2003) p. 63 (Mackenzie)
[26] GMOs for introduction to environment among others include, seeds for propagation, seedlings, fish for release, and microorganisms for bioremediation.

information about LMO[27] and its intended use and the party of import to notify receipt within 90 days.[28] Then the decision must be given to the exporter with 270 days,[29] the latter includes risk assessment,[30] socio-economic considerations, and a precautionary approach in the process of decision making either to approve or dismiss an application for importing GMOs. Unlike the simplified procedures for FFPs under article 11, GMOs for direct introduction into the environment, need risk assessment conducted by the exporter in accordance with Annex III.[31]

The AIA procedure applies not for every transaction on LMO, rather it applies for the first transaction as to a specific LMO. Once the country allowed the entrance of a specific LMO it shall apply for all similar LMOs imported into that state.[32] Therefore, the application of AIA rules is narrower since it's only made once for a specific GMO and GMO-FFPs are already excluded in addition to exclusions under the scope of the protocol.

2.1.6. Unintentional and illegal transboundary movement of GMOs

The AIA procedure and the simplified procedure applied for LMOs and LMO-FFPs respectively in the case of intentional transboundary movement. However, in the case when there is an unintentional transboundary movement of LMOs which may harm conservation and sustainable use of biological diversity states should inform other parties of the BCH.[33] The information which should be indicated includes inter alia, quantities, and characteristics of LMOs, the circumstance and estimated date of release, and any possible adverse effect on the environment or human health.[34]

---

[27] CPB (n3) Annex I.

[28] The notification of receipt ascertains whether all required information is included and indicates the next steps in the process whether the state employ AIA procedure or other domestic regulatory framework which is enacted in consistent with the protocol.

[29] UNDP, The Advance Informed Agreement (AIA) procedure LMOs for intentional introduction into the environment, Available at < https://bch.cbd.int/help/topics/en/The_Advance_Informed_Agreement_procedure.html > The decision given here may be approval, disapproval, request for additional information, extending the period within determined period. Unless unconditional consent is given by the importer, it shall attach the reason for reaching any decision.

[30] The primary responsibility to conduct risk assessment is on the importer, yet the importing state may require the exporter to conduct risk assessment and/or bear the cost thereof.

[31] CPB (n3) Annex III

[32] Ibid. Art. 7

[33] CPB (n3) Art. 17(1)

[34] Ibid. Art. 17 (3)

On the other hand, states have the power to take all necessary measures against unlawful transboundary movement of GMOs carried out in contravention of its domestic measures to implement the protocol.[35] Moreover, an affected state could request the party of origin to dispose of the living modified organism in question by repatriation or destruction at its own expense.[36]

There is no clear borderline between the unintentional and illegal transnational movement of GMOs under the CPB. However, some try to differentiate it as

"Illegal transboundary movement is a transboundary movement carried out in contravention of the domestic measures to implement the Protocol that has been adopted by the affected Party."[37]

"Unintentional transboundary movement is a transboundary movement of a living modified organism that has inadvertently crossed the national borders of a Party whereby the living modified organism was released either deliberately or accidentally."[38]

The definitions are not mutually exclusive. Unintentional transboundary movement can be illegal sometimes if it enters a given jurisdiction in contravention with its domestic law. [39] GMOs that are not approved by a state party without prior authorizations are in most cases are illegal transboundary movements. The CPB imposes an obligation on the state which unintentional release has occurred to inform other states and take necessary measures, while it imposes a duty on other states to control illegal transboundary movements under their domestic laws.

2.1.7. Public awareness and participation

State parties are obliged to create public awareness and make public decision-making available regarding the movement and transfer of GMOs. The CPB under article 23 dictates that public awareness and participation shall be promoted and facilitated by states about safe handling, transfer, and use of GMOs.[40]

[35] Ibid. Art. 25 (1)
[36] Ibid. Art. 25(2)
[37] UNEP, 'Unintentional Transboundary Movements and Emergency Measures (Article 17) and the Detection And Identification of Living Modified Organisms' (2016) conference of The Parties To The Convention On Biological Diversity Serving As The Meeting of The Parties To The Cartagena Protocol On Biosafety Eighth meeting Cancun, Mexico.
[38] Ibid.
[39] Ibid.
[40] CPB (n3) Art. 23(1)

Article 23(1) does not expressly require parties to form particular data accessible to the open. The commitment is a few what milder. Parties are required to advance and facilitate open mindfulness, instruction, and are to endeavor to guarantee open awareness and instruction on LMOs which will be imported. Article 23(2) of the protocol lays down certifiable commitments on parties that allude to the public within the choice-making handle with respect to LMOs.[41]

There are diverse degrees of participation. These extend from straightforward information-sharing, a precondition without which none of the higher levels can be accomplished, to discussion, where views are requested but without any commitment to act on them, to joint decision-making and citizen-led activities.[42] Whereas most action within the biosafety area is confined to the primary two levels at the minute, there are also examples of citizen-led initiatives, and these are said within the discourses of setting and devices underneath.[43]

Providing sufficient information regarding the movement, transfer, and use of GMOs is the minimum requirement for securing public participation and awareness. Public participation cannot be achieved unless access to information is sufficiently guaranteed. However, providing information by itself does not secure public participation rather there has to be a further step of public consultation and sometimes citizen-led activities.

There are challenges in implementing rules of public participation and creating public awareness since it is a high science it may not be easily understandable for the public. On one hand, the literacy level of a citizen in understanding science matters, and on the other hand, scientific knowledge shall be presented to the public in a simple and understandable manner.[44]

2.1.8. Risk Assessment and Management

A risk assessment is meant to identify or evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity in the potential receiving environment

[41] Billen Girmay, (n7) P. 39
[42] Toczeck Skarlatakis and Julian Kinderlerer, 'The Importance of Public Participation' (2019) < https://www.cambridge.org/core/terms. > *see also* Christine Dominic Glover & Others, 'Public Participation and the Cartagena Protocol on Biosafety' <http://wedocs.unep.org/bitstream/handle/20.500.11822/9998/Public%20Participation%20and%20CPB_%20A%20Review.pdf?sequence=1&isAllowed=y > p. 3
[43] Ibid.
[44] Ibid. P. 4

also taking into account risks to human health.[45] Risk assessment is one major component of the protocol applied for LMOs pass through the AIA procedure, in some cases even for LMO-FFPs. The major objective of conducting risk assessment is to ascertain the impact of LMOs on conservation and sustainable use of biological diversity in receiving environment and human health in scientifically sound manner.[46] 'Risk assessment is a tool used by authorities to make informed decisions regarding the transboundary movement of living modified organisms.'[47] The importing state has an option to conduct the assessment by itself at its own cost, at the cost of exporter or can request the other state to conduct the assessment. This option seems especially important for developing states since they may not have the appropriate resources to conduct a scientifically sound risk assessment.[48]

The procedure incorporates principles and methodologies of conducting a sound risk assessment. The assessment should be scientifically sound, transparent, based on guidelines set out by relevant international organizations, and based on a case-by-case analysis.[49] The protocol here failed to mention international institutions with the power to set guidelines which in the end leads to controversies among states in applying standards developed by different institutions.

Methodologically, the risk assessment process should only focus on all relevant information about the specific LMO and identifying any new genotypic and phenotypic characteristics which may have adverse effect on the conservation and sustainable use of biodiversity. The likelihood of realization of the adverse effect and its consequences should also be addressed under the risk assessment process. Lastly, it should determine whether the risks are acceptable or manageable through implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.[50]

Risk does always exist when we come to new technologies, yet we apply them believing that potential benefits outweigh. "Risk management is the use or application of procedures and means

[45] Lim Tung, (n21) P. 1759
[46] Christoph Bail, & Others., 'The Cartagena Protocol on Biosafety Reconciling Trade in Biotechnology with Environment and Development?' (2002) The Royal Institute of International Affair, *Earthscan Publications Ltd,* P. 360
[47] Ibid. P. 333
[48] Ibid. P.361, The importing state does also have a power to reject importation if the risk assessment conducted does not sufficiently guarantee that the LMO does not impact conservation sustainable use of biological diversity based on the Precautionary approach.
[49] CPB (n19) Annex III
[50] Ibid.

to reduce the negative consequences of a risk to an acceptable level. The protocol requires each country to manage and control any risks that may be identified by risk assessment."[51] After identification of possible risks through risk assessment, if the risks are found to be manageable the importing state should install all strategies, measures, and mechanisms to minimize risks identified.[52] Moreover, ensuring that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use is another major point considered under the risk management process.[53]

2.1.9. Liability and redress issues under the Nagoya Kuala Lumpur supplementary protocol

The NKSP to the CPB on Biosafety was gotten in Nagoya, Japan on 15 October 2010 serving as the assembly of the gathering to the Protocol.[54] As per article 27 of the biosafety protocol the first meeting was held in Kuala Lumpur in February 2004. The meeting established a BSWG with a responsibility to come up with framework rules regarding liability and redress issues. Later, after intense negotiation, the working group comes up with the NKSP.[55]

Liability and redress issues are one of the contentious concerns during the negotiation of the CPB. Embraced as a supplementary assertion to the CPB, the NKSP points to contribute to the preservation and economically utilize of biodiversity by giving universal rules and strategies within the field of liability and redress relating to LMOs.[56] It requires that response measures are taken within the occasion of damage resulting from LMOs, or where there's the adequate probability that harms will result in case opportune reaction measures are not taken. The Supplementary Convention moreover incorporates arrangements in connection to gracious risk.[57] It also reaffirms the precautionary approach contained in Rule 15 of the Rio

[51] Billen Girmay, (n7) P.35
[52] CPB (n3) Art. 16(1)
[53] Ibid. Art. 16(3)
[54] Hellen Manyara, 'Effectiveness of Kenya's Biosafety Liability and Redress Regime' (University of Nairobi 2016) p. 34
[55] The protocol ratified by 48 states including, *inter alia*, Japan, Italy, France, Togo, Uganda, Mali, Congo, Burkina Faso, and India as of 2020.
[56] 'The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety' < The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (cbd.int) > Convention on Biological Diversity , (NKSP)
[57] Ibid.

Announcement on Environment and Improvement and recognizes the got to give for suitable reaction measures where there's harm or sufficient probability of harm, reliable with the CPB.[58]

NKSP is applicable for all categories of GMOs under transboundary movements.[59] The scope for liability regime is presumed to be the same as the CPB. For instance, LMOs defined under the CPB confined to GMOs which result from modern biotechnology.[60] Liability cannot be imposed on nonparty states under the supplementary protocol. Moreover, the objective of liability and redress must be clear, and the issue of liability arises when there is damage caused by GMOs. In addressing liability and redress issues two cumulative requirements should be fulfilled. Firstly, causation needs to be established both in law[61] and in fact. The claimant should establish that the damage caused by GMOs. Secondly, there should be a person who can be identified as responsible for the harm caused.[62]

The Nagoya protocol though it has left the power to provide for the details regarding liability and redress issues for domestic laws, it has provided response measures that should be taken by operators and /or competent authority in the event of damage caused by GMOs. The operator/operators[63] are required to inform competent authorities, evaluate the damage, and take appropriate response measures in the event of damage.[64] The response measures include *inter alia* prevention, mitigation, avoidance, containment, and/or restoration. When damage occurs on biological diversity the restoration to the condition that existed before the damage occurred, or replacing the loss of biological diversity with other components in the same or some other location is provided under the NKSP.

---

[58] 'Africa Regional Capacity Building Workshop on Nagoya Protocol on Access and Benefit Sharing (ABS), Traditional Knowledge (TK) and Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress of Bio-safety (NKSP)' P. 2

[59]CPB(n3) Art. 3, GMO FFPs, GMOs for contained use and GMOs for direct introduction to environment are incorporated under the liability and redress protocol. It encompasses intentional and unintentional and/or illegal release of GMOs. However, the damage should occur within the national jurisdiction of state parties.

[60] Gurdial Singh &Sarah Lawson *et al*, 'Liability and Redress Under the Cartagena Protocol on Biosafety' (2008) CEBLAW, Vol. 1 P. 43

[61] NKSP (n56) Art. 4, states that each state domestic law determines the causal relationship between GMOs and the damage caused.

[62] Gurdial Singh, 'Liability and Redress for Damage Arising from Genetically Modified Organisms: Law and Policy Options for Developing Countries' 2007, University of Malaya, Kuala Lumpur P. 2

[63] NKSP (n56) Art. 2(2), defined operator as a person who has a direct or indirect control over LMOs as determined under domestic law.

[64] Ibid. Art. 5

Nevertheless, the NKSP protocol left detailed procedures to implement the protocol for state domestic laws. States are expected to provide for rules and procedures to implement it obligation under the protocol. States have options to apply their general civil liability i.e., tort law, enact *sui generis* rules of procedures regarding civil liability, or a combination of both.[65] Under their domestic regulation states should incorporate among others, damage, the standard of liability i.e., fault-based or strict liability, channeling liability, and right to bring claims.[66]

[65] Ibid. Art. 12(2)
[66] Ibid. Art. 12(3)

Chapter Three

3. An Overview of the Ethiopian Biosafety Regulatory Framework

Introduction

Ethiopia has developed a biosafety regulatory framework to protect biological diversity, the environment, and human health. This protection is given under environmental policies, laws, and institutions. Hereafter I have tried to briefly discuss the legal and institutional framework for Biosafety in Ethiopia. Under the legal framework, different biosafety-related laws i.e. the FDRE constitution, the biosafety proclamation and its amendment, and directives are discussed. On the other hand, the institutional framework also assesses the institutions regulating GMO-related activities i.e. EFCCC & NBAC.

3.1. Legal Framework

3.1.1. FDRE Constitution

The FDRE constitution, the supreme law of the land, has provided some provisions regarding environmental protection. The constitution declares that "everyone has the right to a clean and healthy environment".[67] This constitutional right is supported by environmental objectives which oblige both the state and citizens to protect the environment, and all projects and implementation plans to consider environmental concerns.[68] Moreover, the constitution bestows the right to public participation. The government must make full consultation with the public especially concerning environmental policies and implementation plans which affect the people directly.[69] The environmental and health protections bestowed under the constitution apply to biosafety issues since the major aim of biosafety is keeping the safeguarding of environmental biodiversity and human health.

3.1.2. The Biosafety Proclamation

The biosafety proclamation was enacted in 2009 six years after the ratification of the Cartagena protocol. The CPB has provided the minimum standards for the protection of environmental biodiversity and human health, and the power to set up a strong domestic regulatory framework

[67] FDRE Constitution, Proc. No. 1/1995, Art. 44
[68] Ibid. Art. 85 cum Art. 92
[69] Ibid. Art. 92(2)

has been left for each state. The biosafety proclamation is a strong regulatory framework aimed at protecting human and animal health, and biological diversity through preventing or mitigating risks posed by GMOs.[70]

The proclamation has made any transaction[71] regarding GMOs pass through AIA procedures. Anyone interested to engage in any GMO-related activities shall apply for the EECCC (the then authority). Unlike the case of the CPB, which provides a simplified procedure for LMO FFPs, the biosafety proclamation declares all GMO-related transactions to pass through AIA procedures.[72]

After conducting a proper risk assessment, the applicant for AIA shall prepare a detailed report and brief statement summarizing the report in non-technical terms and bear all the costs of conducting a risk assessment report. [73] The proclamation also tried to address the issue of public participation and BCH before granting AIA. The risk assessment report shall be disseminated to the relevant stakeholders through public notices and comments could be given by any interested person within one month.[74] Likewise, article 12 of the proclamation obliges the commission to provide all information,[75] laws, directives, guidelines, and international agreements to the public and international community through BCH.[76]

The commission after carefully considering the application, risk assessment report, and comments of stakeholders may decide either to approve (with or without condition) or dismiss the application. Approval is made when the commission believes that there will be no significant harm or risk arises from the respective GMO. However, the commission reserves the power to revoke the approval once made if new scientific information as to any potential risk arises from the respective modified organism.

---

[70] Biosafety Proclamation, Proc. No. 655/2009, 15th year, No.63 Art. 4 (Biosafety Proclamation)

[71] Ibid. Transaction defined under Article 2(2) of the proclamation 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 food, as feed or for processing."* This definition incorporates all GMO related activities and each activity needs approval from the commission under AIA procedure.

[72] However, this law doesn't last longer since the amendment proclamation come up with a permit system which empowers the commission to grant special permission for contained use of GMOs.

[73] Biosafety Proclamation, Art. 6

[74] Ibid. Art. 11

[75] Ibid.

[76] The commission may keep some information confidential up on the request of the applicant when such information is not essential for biosafety and not related to description of GMO, methods and plans for emergency response and the evaluation of possible risk.

3.1.3. The Biosafety Amendment Proclamation

The amendment proclamation has made significant changes to the biosafety framework. It has tried to open a space for the adoption and use of GMOs in the country by balancing biosafety and the development of biotechnology. This paradigm shift has been incorporated under the objective of the proclamation. Although the main objective of biosafety laws is to protect the environment, human and animal health, and biodiversity, the amendment proclamation incorporated an objective of enhancing access to and transfer of technologies including modern biotechnology that serves for sustainable use of biological diversity.

The other significant change under this proclamation is that it has incorporated a special permit system for a confined field trial of GMOs. Special permit defined under the proclamation as *"Permit granted for the importation of GMOs for contained use in research or teaching but not for release into the environment. (Emphasis added)"*[77] On the other hand, the law has defined contained use in a broader manner by incorporating confined field trials for production, use, and destruction of GMOs including for research and teaching purposes.[78] This shows the permit system might extend to a field trial of GMOs without following the AIA procedures.

The commission before granting a special permit for the contained use of GMO should ascertain the existence of facilities and institutional system required to conduct specified research, the transaction is not destined for environmental release, the qualification of the applicant to conduct research, and standard procedures stated to minimize the risk.[79]

Three years after the approval of the proclamation, the EFCCC brought a directive to govern the contents of an application for the special permit.[80] It obliges the applicant for a special permit to provide general information about the importer, institutional capacity, and necessary facilities for biosafety class cabinet I-III, and institutional system to conduct a risk assessment.[81] Furthermore,

[77] A Proclamation to amend the biosafety proclamation, Proc. No. 896/2015, 21st year, No. 66, Art. 2 (20) (Biosafety Amendment Proclamation)
[78] Ibid. Art.2 (4)
[79] Ibid. Art. 15(4)
[80] Directive to Determine Major Contents of Application for Special Permit for Contained Use Of Modified Organism in Research and Teaching, Directive No. 04/2018, Ministry Of Environment Forest And Climate Change (Special Permit Directive No.4)
[81] Ibid. Art. 3

information about the parental, recipient,[82]and modified organisms,[83] and information related to waste treatment[84] and emergency response should be provided in a detailed manner.[85]

3.1.4. Biosafety directives

Following the enactment of the biosafety proclamation, the then environmental authority came up with six directives to implement the general provisions of the proclamation. The directives govern different issues ranging from application requirements for AIA to measures that should be taken when there is an accidental release of GMOs. Later when the biosafety proclamation is amended the EFCCC bestows a new directive on the requirements of the special permit and made some changes to the previous directives.

A. AIA and special permit application requirements directive

Directive No. one determines the contents of an application for undertaking transactions involving GMOs. All GMO-related activities, except for contained use, should fulfill all the requirements under the directive. The application for AIA should incorporate among others, the characteristics of the proposed GMO, its impact on health and environment, conditions of deliberate release, and emergency response plan.

B. Risk assessment and risk management directives

Directive No two and three have incorporated risk assessment and risk management parameters for GMOs, respectively. The risk assessment should be made to evaluate potential harm to human and animal health, biological diversity, the environment, ethical values or culture or economic norms of local communities, or the economic condition of the country.[86] The risk assessment should incorporate the characteristic of parental organisms, vectors, and GMOs, safety considerations as to human and animal health, environmental considerations, and socio-economic considerations.

---

[82] Ibid Art. 4

[83] Ibid Art. 7, I the information needed about the GMO for confined field trial and research and teaching proposes is different, while the former needs a detailed information about the environmental, and human health impact of the GMO the latter needs only limited information about rDNA molecule needed for the research or teaching purpose.

[84] Ibid. Art. 8

[85] Ibid. Art. 9

[86] Directive on Risk Assessment Parameters for Modified Organisms, Dir. No. 2, Environmental Protection Authority Art. 4 (Risk Assessment Directive No. 2)

These directives as to risk assessment and risk management were amended in 2018. The directive on risk assessment has made three significant changes. Firstly, it declares that the information required for granting special permit and AIA for contained use and environmental release, respectively, might be different and it will be determined based on the decision of the commission.[87] Secondly, unlike the preexisting directive that has given a broader definition for socio-economic considerations and cultural values, the new directive defines it narrowly and excludes cultural values. Moreover, the directive granted discretion for the commission to consider the inclusion of anticipated socio-economic changes under the risk assessment.[88]

On the other hand, regarding risk management, the risk management directive provided the requirement for a confined trial of each activity related to GMOs except for environmental release.[89] It provides the containment requirement for modified organisms i.e. modified animals and plants or modified organisms made locally for pharmaticals for humans and animals health, among others. For instance, the maximum area for modified animal and modified plant to be considered it is confined; it must not exceed 1000 m^2.[90]

The new risk management directive made some changes in risk management issues. It is applicable for any unforeseen deliberate or unintentional release during transport, use and production of GMOs.[91] Furthermore, the directive established an emergency response group under the EFCCC that comprises representatives of institutions capable of undertaking risk management measures.[92] It also provides the duties of the response group.[93]

[87]Directive issued to provide risk assessment parameters for modified organism, Directive No. 5/2018, Art. 3(2) Ministry of Environment Forest and climate Change (Risk Assessment directive No.5)
[88] Ibid. Art. 3 (3)
[89] Directive Issued to Determine The Procedure of Risk Management Strategy for Dealing With Accidents Involving Modified Organism, Dir. No. 3, environmental Protection Authority (Risk Management Directive No.3)
[90] Ibid. Art. 4.8 & 4.9
[91] Directive to establish procedure for management of risk from any transaction involving modified organism Directive No. 6/ 2018 (Risk Management Directive No. 6)
[92] Response group has been established under the accidental release directive no 6. The new directive merged risk management accidental release directive since the response group under directive no 6 is substituted by emergency response group under the new risk management directive with the same objective and duties.
[93] Directive No.6 (n140) Art.4(3)

C. Transportation and storage directives

Transportation of GMOs needs a special license granted by a competent authority or the EFCCC.[94] The person applied for transportation of GMOs must take adequate training regarding GMOs and the driver must provide information to the EFCCC every month about his transportation services. Concerning storage, facilities of storing GMOs should be registered by the EFCCC, and the EFCCC may require the premise to carry adequate insurance to cover liability for any harm to human and animal health or the environment.

3.2. Institutional framework

Proper implementation of laws and policies rests on a strong institutional framework, laws without institutions are like a toothless lion. Although the main responsibility to look after GMO-related activities rests on the EFCCC, there are different institutions directly or indirectly involve in GMO-related activities in Ethiopia. Hereafter I have tried to discuss major institutions established to follow up the implementation of biosafety regulations and involved in GMO-related activities.

3.2.1. EEFCCC

A. Historical background

EPA is the first institution established in 1995 to protect the welfare of human beings and sustainably protect, develop and utilize resources they depend on for survival.[95] EPA has been empowered to manage and administer environmental concerns in general. The EPA later re-established under environmental protection organ proclamation as a body directly responsible for the prime minister and with an objective to avoiding conflict of interest and duplication of power of environmental agencies.[96]

However, EPA doesn't last long; it has been upgraded to an autonomous minister as the ministry of forest and environment. The ministry was established with responsibility, *inter alia* to achieve environmental objectives under the constitution and international agreements, to create an environmental impact assessment system, to negotiate environmental international

[94] Art. 3 (1) new directive on transport and storage , the special license should be renewed every two years. The driver should secure transportation authorization permit to transport GMOs.
[95] Environmental Protection Authority Establishment Proclamation, Proc. No. 9/1995 No.9 Art. 5
[96] Environmental Protection Organs Establishment Proclamation, Proc. No. 295/2002 No. 7, the Preamble

environmental agreements, and to formulate policies, strategies, laws to implement international environmental principles.

The frequent institutional change leads to the establishment of the ministry of forest, climate change, and environment which has succeeded the ministry of forest and environment. The restructure doesn't come up with a substantial shift on the power and duties the new ministry just succeeded the preexisting one.[97] Surprisingly, three years after the reestablishment of the ministry, the new reform has demoted the ministry to a commission directly responsible for the prime minister as Environmental Forest and Climate Change Commission.

B. EFCCC powers and duties regarding GMOs

The Ethiopian biosafety proclamation has designated the then EPA after frequent changes referred to as EFCCC to oversee GMO-related activities. The commission is empowered by granting AIA for interested applicants to appointing inspectors to oversee GMO-related activities in Ethiopia.[98] All the duties under the Cartagena protocol, biosafety proclamation its respective directives rest on the EFCCC. The role of other governmental institutions is to assist the commission in controlling activities related to GMOs.

3.2.2. National Biosafety Advisory Committee

The NBAC was established under the council of minister regulation to advise the government regarding biosafety issues. The committee consults the government on biosafety issues *inter alia* transactions of genetically modified organisms, the issues of national policies and laws of bio-safety, identifying effective methods to create public awareness, and regarding transactions of genetically modified organisms.[99]

The members of the committee should be with relevant specialization, experience, and organizational representations from government bodies, higher education institutions, civil societies, and non-governmental institutions. It needs to be composed of professionals from

[97] A Proclamation to Provide for The Definition of Powers and Duties of The Executive Organs of The Federal Democratic Republic of Ethiopia, Proc. No. 916/2015, No. 12 Art. 2(18) & 30

[98] Granting AIA and special permit, reviewing risk assessment provided by the applicant, establishing emergency response group, following up transportation and storage of GMOs, and controlling unintentional and illegal cross border movement of GMOs are some of the obligations of the EFCCC. However, this couldn't be achieved unless the commission works in collaboration with other regulatory institutions.

[99] National Bio-safety Advisory Committee Establishment Council of Ministers Regulation, Reg. No. 411/2017 No. 83, Art. 4

disciplines of Biotechnology, Genetic Engineering, Biodiversity, Natural Science, Environmental Science, Medical or Health Science, Nutrition Science, Animal Science, Social Science, and other disciplines as appropriate. [100]

[100] Ibid. Art. 6

Chapter four

4. Critical Analysis on the Legal Gaps and Implementation of the Ethiopian Biosafety Framework and the Cartagena Protocol

Introduction

Under the previous chapter, I have tried to give an overview on the Ethiopian biosafety framework (legal and institutional framework). This chapter presents analysis on the existing legal gaps and the implementation of biosafety concerning i.e. the AIA and special permit procedures, risk assessment and management procedures public awareness and participation, labeling and consumer protection, and control of illegal cross border movement, among others.

4.1. Advanced Informed Agreement and Special Permit

The biosafety proclamation has made any transaction regarding GMOs pass through the AIA procedure. On the contrary, the amendment proclamation excludes contained use for teaching and research purposes from application for AIA and designed a special permit system for it. Contained use defined as

> "*any operation as to field trial in which the modified organism are produced, destroyed or used in some other way* ***<u>including for teaching and research</u>*** *isolated by physical and chemical barriers in space not exceeding …" emphasis added.*[101]

A special permit is granted for research and teaching, while contained use defined to include any operation including field trial of GMOs produced, used, or destroyed. Hence, the question is whether a special permit is applicable for all contained use or research and teaching purposes only? The amendment proclamation states that a special permit is granted for contained use for research and teaching purposes.[102] In the same pattern, the special permit directive under its scope declares that its application is limited to contained use for teaching and research purposes.[103] This conveys that contained production and use of GMOs other than for teaching and research purposes should pass through AIA and not a special permit.

[101] Biosafety amendment proclamation, Art. 4 (2)
[102] Ibid. Art. 2(20)
[103] Special Permit Directive No.4, Art. 2

Confined field trial is not mentioned under the definition of a special permit in the amendment proclamation and it's not incorporated within the scope of the directive for a special permit. Nevertheless, the same directive states additional requirements for a confined field trial of GMOs. Although, the law lacks clarity on the scope of application of special permit, the harmonious interpretation of rules leads to a conclusion that special permit is granted for the contained use of GMOs for research and teaching purposes including confined field trials for similar purposes.

The permit system included under the amendment proclamation is in line with the CPB since the protocol has excluded the contained use of GMOs from the ambit of AIA. Nevertheless, the protocol bestows the minimum standard and allows states to come up with a strong domestic legal framework. Specifically, the protocol gives discretion for states to require risk assessment for the contained use of GMOs. The preexisting biosafety proclamation properly exploited the discretion for safeguarding the biosafety. Contrary to this the amendment proclamation allowed for a confined field trial of GMOs without AIA procedures, and the special permit failed to clarify whether risk assessment required.

4.1.1. Implementation of biosafety laws in granting permit for BT cotton

The field trial of Bt-Cotton has commenced in 2015, a year the biosafety proclamation has been amended. The permission has been given even before the approval of the amendment proclamation by the parliament.[104] It is unclear whether the permission has been granted under the then biosafety law or prospective draft amendment law. If the permission was granted under the former one, since special permit wasn't introduced the responsible authority should have employed the AIA procedures. Nevertheless, the AIA procedure under the CPB and domestic laws wasn't followed in the approval of Bt-cotton. The ministry didn't made public hearing and consultation and examine the risk assessment prepared by the developer.[105] Hence, the approval of Bt-cotton wasn't made under the procedures of AIA. To the contrary, if the commission granted special permit based on the draft law it will be against the then biosafety proclamation. The permit has been given based on the letter from

[104] Interview with Mr. Ambaye G/kidan, EFCCC, Biosafety and Invasive Alien Species, Biosafety Advisory Committee Capacity Building Expert, (Addis Ababa April 13, 2021)
[105] Interview with Mr. Awoke Damte, , EFCCC, Biosafety And Invasive Alien Species, Risk Assessment Expert (Addis Ababa April 13, 2021)

the prime minister office to the MFCE (EFCCC) before the approval of the amendment proclamation.[106] This act of both institutions goes against the biosafety law, since the prime minister lacks the power to derogate the law enacted by the parliament through its letter, the latter could refuse to obey the order since it goes against the then biosafety law.

Furthermore, from the institutional perspective the approval has been granted before the establishment of the biosafety directorate within the then MFCE (EFCCC) and the NBAC. While the former established forthwith after the approval of the Bt-cotton, the latter established three years after the approval.[107] Therefore, the approval of Bt-cotton has been granted in violation of the biosafety law. On the top of that, it was given without properly installing the legal and institutional framework in advance.

4.1.2. Implementation of biosafety laws in granting permit for GM-maize

Procedures under the Cartagena protocol and domestic laws had been better adhered by the commission in granting the special permit for a confined trial of GM maize than Bt cotton.[108] Special permission is given for EIAR to conduct a research based on its application.[109]

The EIAR made an application to the commission after assessment made by the IBC within EIAR.[110] The committee reviewed the application internally and recommended the application for a special permit. Based on such recommendation EIAR has made an application for a special permit for research purposes, after incorporating all required information and the comments of the IBC for GM-maize.[111]

The EFCCC led the application to NBAC established under the counsel of ministers' regulation to consult the government regarding biosafety and biotechnology issues. The NBAC includes

[106] Interview with Mr. Ambaye G/kidan, (n104)
[107] Ibid.
[108] Interview with Mr. Assefa Gudina, EFCCC, Biosafety and Invasive Alien Species Regulation Directorate director , January 23,2021 (Interview with Mr. Assefa Gudina)
[109] Ibid.
[110] Neither the proclamation nor its directive obliges institutions to have IBC. The EARI established the committee by its own intention. Yet, the experience of other states i.e. India, Philippines, show that any institution interested to involve on confined field trial of GMOs must establish IBC. For instance, the Philippines guideline for contained use of GMOs declare any institution involve in contained use of GMOs must have IBC. *See*, the Philippines biosafety guideline for contained use of GMOs (2014) Department of Science and Technology
[111]Interview with Dr. Tadesse Daba, Ethiopian Agricultural Research Institute, biotechnology directorate director, (Addis Ababa 28 January 2021) (Interview with Dr. Tadesse Daba)

representatives of different organizations; *inter alia*, EBI, Public Health Institute, civil societies, and Food and Drug Authority.[112] Each representative has made a critical review on the application as to all the potential benefits and risks of GM maize and given its recommendation for the commission. The commission based on the recommendation of NBAC granted special permit for research and confined field trial of GM maize.[113]

Furthermore, the confinement of the area is based on regulatory guidelines and the institute employed the maximum level of confinement.[114] The field trial for GM-maize is being made in a confined area 400 meters away from agricultural land with similar pollen. This aims at avoiding the unintentional release of GMOs through cross-pollination. Moreover, the area is confined to prevent animals from getting into the compound.[115]

4.2. Risk Assessment and Management

Risk assessment was a necessary condition for involving in any GMO transaction. The commission grants AIA after making a review on the risk assessment report submitted by the applicant.[116] The directive on risk assessment also states every transaction on GMO should be preceded by risk assessment,[117] and the maker and user of GMOs carry risk assessment to any transaction to evaluate possible harm on human and animal health, biodiversity, environment, and ethical cultural and economic norms of the local community or economic conditions of the country.[118]

On the other hand, the amendment proclamation classified GMOs as destined for contained use for research and teaching purposes and GMOs for environmental release; while the former needs a special permit the latter demands AIA. However, it has escaped whether the risk assessment should be examined in both cases.

---

[112] Ibid

[113] Interview with Mr. Assefa Gudina (n108) & Interview with Dr. Tadesse Daba (n111), the confined field trial is already made with respect to BT cotton since its allowed for commercial release. On the other hand, GM maize on the stage of field trial that is being made in Bako, Melkasa, and Holeta agricultural research centers, among others.

[114] Interview with Dr. Tadesse Daba (n111), the respondent mentioned that there is regulatory compliance audit, and GM seeds are controlled and stored under FECCC. It will be counted and given for the EARI and any leftover will be burn. Moreover, there is always control when any person enters to and exits from the confided areas.

[115] Ibid.

[116] Biosafety Proclamation, Art. 5 Cum with Art.6

[117] Risk Assessment Directive No. 2, Preamble

[118] Ibid. Art. 4

Article 6 of the biosafety proclamation states that

> *"The applicant shall use a qualified expert to undertake a risk assessment and prepare the report in accordance with regulations and directives issued …" (emphasis added.)*[119]

It can be argued that the applicant for AIA under article 5 must conduct a risk assessment and it is applied for all GMO transactions. Since this provision isn't amended under the new law risk assessment must be conducted for granting both AIA and special permits. Furthermore, if the legislature has an intention to exclude special permits from the ambit of risk assessment it would have amended article 6 of the proclamation. On the contrary, it can also be argued, the literal interpretation of article 6 refers that risk assessment should only be conducted when an application is made for AIA and there is no need for conducting a risk assessment for special permit or contained use of GMOs for research and teaching purposes. Article 6 of the proclamation is impliedly amended when the law classified permissions as AIA and special permits.

The directive on risk assessment enacted following the amendment proclamation more inclined with the first line of argument. The directives under its scope declare it is applicable for any transaction of GMOs that has not been granted AIA and special permit.[120] Even though the extent of information required for contained use and environmental release might be different,[121] conducting risk assessment is a necessary requirement in both cases.

Nevertheless, the practice in the approval of GM maize and BT cotton indicates the contrary. The special permit for research purposes granted for EIAR for GM maize without properly reviewing the risk assessment. In the researcher's view, the EFCCC has the power to limit the information required for the contained use of GMOs concerning risk assessment; yet escaping risk assessment procedure will be against the biosafety proclamation and its directive.[122]

[119] Biosafety Proclamation, Art. 6
[120] Risk Assessment directive No.5, (n118) Art. 2
[121] Ibid. Art. 3(2)
[122] The experiences of other states also show that risk assessment must be conducted before field trial. For instance, the Kenyan biosafety law declares risk assessment must be conducted before permitting contained use of GMOs, and the confinement level will be determined based on the level of risk.

4.2.1. Application of risk assessment procedure up on granting AIA for Bt Cotton

The issue of risk assessment practically rose when an application is made by EIAR for commercial release Bt Cotton. The EIAR after conducting research and assessment on a confined field trial of Bt Cotton applied with a risk assessment document to the EFCCC for AIA.[123] The application is made after a critical review made by the institutional biosafety committee within the EIAR.[124] EIAR used a risk assessment document prepared by USDA that has been approved by both US Food and Drug Authority and Environmental Protection Authority after a critical assessment made for about ten years. The applicant directly employed the risk assessment conducted by USDA and submitted to EFCCC with a summary report.[125]

The EFCCC led the application and risk assessment document to the NBAC for critical assessment. The NBAC after reviewing the risk assessment submitted has made its recommendation to the commission. The EFCCC approved the commercial cultivation of Bt-cotton without requiring additional risk assessment conducted by the user.[126] The commission checks over the risk assessment made by the developer or the importer. The primary responsibility of conducting an assessment rests on the developer of the technology. However, upon field trial, the commission has checked the conformity of risk assessment result with the implication on field trials.[127]

4.3. Public Awareness and Participation

4.3.1. Public Awareness

Public awareness is the public's level of understanding about the significance and implications of GMOs. Raising public awareness isn't the same as telling the public what to do rather it is clarifying issues and spreading information to individuals so that they can make their choices. In a broader sense, public awareness should begin from creating awareness that the public has the right to access to information about activities related to GMOs. It is a prerequisite for public

[123] Interview with Dr. Tadesse Daba (n111)
[124] Ibid.
[125] Ibid.
[126] Ibid.
[127] Interview with Mr. Assefa Gudina (n108)

participation; the society must have basic knowledge about the meaning, benefit, and risks of GMOs. Moreover, it empowers the public and policymakers to make an informed decision.[128]

The CPB foists the commitment of the states to facilitate public awareness, education, and participation concerning the safe transfer, handling, and use of GMOs.[129] The experiences of other states also show authorities try to raise public awareness. Moreover, they conduct a customer awareness[130] and public perception survey to determine the perception of the people about GMOs and incorporate it in their public policymaking.

In the Ethiopian case, neither the biosafety proclamation nor its directives address the issue of public awareness directly. However, one can argue even though public awareness is not divulged clearly, it can be inferred from other regulatory provisions i.e. BCH, labeling, and public participation. BCH is one mechanism to reach the public with information about biosafety issues. Article 12 of the biosafety proclamation declares public shall have access to any record or document under BCH related to GMOs *inter alia* relevant laws, directives guidelines: modified organisms approved, rejected, imported or exported, a roster of experts, applications lodged as per the proclamation and the final decision of the commission on importation and deliberate release. [131]

Although the laws bestow such information to be made accessible for the public, it's not being implemented properly. The BCH website is developed by EFCCC[132], yet it gives a little information about GMO-related activities in Ethiopia. The BCH bring fourth proclamation, regulation, directives, reports, and information required for the permit system. On the contrary, information about applications made, a roster of experts, final decisions made by the commission on importation and release of GMOs, and lists of modified organisms approved and/or rejected

[128] United nation Economic and social council, 'Report on the workshop on public awareness, access to information and public participation regarding living/ genetically modified organisms' 2011, the secretariat of the Convention on Access to Information, P. 5
[129] CPB, (n3), Art. 23
[130] A survey conducted in Kenya has shown that 38% of respondent has heard about GMO through different mediums, the most important source of information on GM crops was the media, especially newspapers, television, and radio followed by schools. Simon Chege, Hugo De Groote *et al.* 'Consumer awareness and attitudes toward GM foods in Kenya' P. 5 similarly, a perception survey in Zimbabwe, showed 60 % of the respondents have poor level of knowledge about GM products. D. Chagwena, B. Sithole *et al*, 'Knowledge, attitudes and perceptions towards genetically modified foods in Zimbabwe' 2019 *African Journal Online*, Vol. 19 P. 8
[131] Biosafety proclamation, Art. 12
[132] Environment forest and climate change commission, Website for biosafety clearing house https://bch.efccc.gov.et/

are missing. The government doesn't deny the non-availability of this information under its report. For almost all questions related to providing information under BCH, the report responded negatively.[133]

In the same pattern, labeling is another requirement for GM products. The biosafety proclamation stated any transaction of GMOs made out of contained use to be labeled as it contains GMOs. Labeling plays a role in creating public awareness and let the public make the right decision. Lastly, public awareness can be inferred from public participation, since participation needs the dissemination of information and awareness creation.

Despite these inferences, public awareness is not clearly addressed in Ethiopia. This legal gap has also been reflected concerning implementation. An interview with Mr. Assefa Gudina, reveals that there are limitations in creating public awareness since there is no law or guideline to regulate the issue. Although the commission is trying to reach the public through preparing broachers and/or flyers, it isn't accessible for the public for different factors. The main factors that makes providing information challenging is the complexity and scientific nature of the issue, and budgetary limitations.[134] On the other hand, the Ethiopian Biotechnology Institute tried to reach to the public through different media outlets i.e. social media, TV programs, and newspapers.[135]

Hence, addressing the issue of public awareness has a paramount significance for the proper implementation of the biosafety regime. The significance can be expressed from different perspectives, among others, to secure public participation, to prepare public-driven policy, to let the public make an informed decision, and to minimize misinformation by interested groups.

4.3.2. Public participation

Public participation is significant for reasonable and acceptable policymaking. It is ensured under the FDRE constitution, the Cartagena Protocol, and the biosafety proclamation. The constitution declares the decision-making of the government regarding environmental policies

[133] Third National Report on the implementation of the Cartagena Protocol on Biosafety, (2016) available at < https://bch.efccc.gov.et/directives/ >
[134] Interview with Mr. Assefa Gudina (n108)
[135] Interview with Mr. Mesay Emana, researcher, Ethiopian Biotechnology Institute, Biosafety and Climate Change Research Team Leader, (Addis Ababa 05 January 2021)

and state programs to be made in consultation with the public. Since biosafety is a major environmental concern, it can be concluded public participation regarding modified organisms is constitutionally ensured in Ethiopia. Similarly, the CPB and the biosafety proclamation states that authorities must consult with the public in the decision-making process regarding GMOs and shall make such decisions accessible for the public.

However, the public participation ensured under the constitution seems broader than the biosafety proclamation, while the scope of the protocol is uncertain whether it includes public participation at the stage of policy and law-making. As per the constitution, public participation shall be ensured both on the law-making stage, and decision making on approval of a specific activity related to GMOs. On the other hand, the biosafety proclamation incorporated public participation only in the decision-making process.

It is not doubtful that public participation should be secured in the law-making process. Yet, the uncertainty of the issue with regard to biosafety has created a gap in implementation. In 2015 the biosafety proclamation has given a space for the development and use of GMOs in the country. This paradigm shift of the law in opening the space for the adoption of GMOs is rebuked to be made without proper public consultation. There was a campaign by civil society organizations and their global allies to ask the government to prohibit field trial or commercial release for GMOs for no less than 5 years until a proper legal and institutional framework is installed and public consultation is made. While the EFCCC kept silent on the issue the biotech institute tried to deny the fact and intimidate adversaries through social media.[136]

The approval of BT-cotton and GM-maize first announced to the public under the USDA report that declare

> *"The Ethiopian government, from the Prime Minister's office on down, has publicly shown their interests in commercializing agricultural biotechnology as a tool to achieve*

[136] Teshome Hunduma 'GMO debate is democratic test for liberalizing Ethiopia' < https://www.ethiopia-insight.com/2020/06/03/gmo-debate-is-democratic-test-for-liberalizing-ethiopia/#:~:text=A%20coalition%20of%20Ethiopian%20Civil,Genetically%20Modified%20Organisms%20in%20Ethiopia.&text=Three%20years%20later%2C%20the%20government,of%20a%20strain%20of%20cotton. > *Ethiopian Insight* (Addis Ababa 2020) *See also,* "ኢትዮጵያ ሰው ሠራሽ የዘረ-መል ለውጥ የተደረገባቸው የእህል ዘሮችን ለማምረትና ለመጠቀም አልተስማማችም" < https://www.bbc.com/amharic/news-52533113 > *BBC News Amharic* (Addis Ababa 2020)

food security in the country. In 2018, the country officially approved its first biotechnology crop (Bacillus thuringiensis) Bt cotton for commercialization and Confined Field Trail (CFT) on drought tolerant and pest resistant WEMA -TELA Maize."[137]

This report indicated the opening of the space for GM crops cultivation in Ethiopia. Latter on the government admitted the approval of Bt-cotton and GM-maize for commercial cultivation and field trial respectively.[138] This has shown clearly the hesitation of the government to make a public debate on the issue with different stakeholders. Moreover, the approval of GMOs has been made without public consultation.[139]

The bone of contention can only be rectified when there is a separate guideline to address issues of public participation and awareness both at the level of law and decision-making. Public participation was escaped not only during the law-making process but also upon approval of BT-cotton, and GM-maize for commercial cultivation and field trials respectively. The respondent from the biosafety directorate asserted that public participation has been made in the process of approving the commercial release of BT- cotton, and GM- maize. However, there were gaps in implementing public participation due to limited knowledge of the society and officials about biosafety and biotechnology.[140] Similarly, the EBI is working on capacity building through creating awareness for different stakeholders.[141] Nevertheless, as already discussed under chapter two, information sharing by itself doesn't guarantee public participation. Rather, there should be either joint or citizen led decision making procedure.

4.4. Labeling of GMOs and Consumers' right to know

Labeling of GMO becomes an important but controversial legal concern nowadays. The role of labeling in sharing information to the customer is being minimized in the modern world of internet and social media, but labeling still plays a pivotal role in customer information about a

[137] Ibid.
[138] USDA, 'Agricultural Biotechnology Annual' Gain Global Agricultural Network, (2020, Annual Report) <https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Addis%20Ababa_Ethiopia_10-20-2019 > p. 1
[139] Interview with Mr. Ambaye G/kidan (n104)
[140] Interview with Mr. Assefa Gudina, (n108)
[141] Interview with Mr. Mesay Emana (n135)

given product.[142] The issue of labeling gets more interdict when it affect the competition regime in the market through granting competitive advantage for non GM producers over GM producing companies. On the top of that, there are claims that GM products are totally segregated from the market due to labeling.

The experience of EU and USA exists in different polar concerning labeling requirements of GMOs. The EU and its fellow states adopted strict process based labeling approach, and if the product contains more than 0.9% GM content, it should be labeled as a GMO.[143] On the other hand, North American states i.e. USA and Canada provide a lenient product based approach towards GM labeling, and labeling is made voluntarily by production companies. The US position on labeling preferred the principle of "substantial equivalence" over the precautionary approach, which declares GM products doesn't differ in their composition from non GM products.[144] While the position of EU majorly justified by consumers' right to know, the US position justified based on keeping GM products in the market through minimizing non GM producers' competitive advantage. South Africa adopted a kind of mixed approach that incorporates both mandatory and voluntary labeling of GMOs in balancing two contending interests of customer right to know and keeping GM products in the market. Moreover, it classifies labeling scheme under three categories both for mandatory and voluntary labeling.[145]

When it comes to Ethiopia, the issues of labeling of GMOs first come to light under the biosafety proclamation. The proclamation, unlike the case of CPB, prohibits unspecified terms like "may contain GMO". This implies GMOs should be labeled as "contains GMOs" before any transaction unless it is for contained use.[146] The law also provides for voluntary labeling for non GM products as "contain no GMOs".[147] Although the law calls for subsidiary regulation, the detail of labeling regime is uncovered. For instance, issues related to the minimum threshold to

[142] The Directorate-General for Health and Consumer Protection 'Labeling, competitiveness and consumer information' EU A DG SANCO Consultative Document, P. 2
[143] Ibid. P. 10
[144] Kent D. Messer, Shawna Bligh *et al* 'Process Labeling of Foods Consumer Behaviors, the Agricultural sector, and Policy Recommendations' CAST Paper 56, P. 9 *see also,* Gary Merchant & Gay Cardineau 'The Labeling Debate in the United states' (2013) *GM Crops and food biotechnology in the agricultural and food chain ,* Vol. 4, *see also* Byrne, Pendell *et al* , 'Labeling of Genetically Modified Foods' (2014) Colorado state University p. 1
[145] Jessica & Obidimma Ezezika 'To label or not to label: balancing the risks, benefits and costs of mandatory labeling of GM food in Africa' (2014) *Agriculture and Food Security,* Vol. 3 P. 4
[146] Biosafety proclamation, Art. 7 (2)
[147] Ibid. Art. 7 (3)

consider a product as a GMO, and a scheme for untraceable products as to their content is not addressed, among others.

Equivalently, the trade competition and consumer protection proclamation sets some labeling requirements, and consumers right to information. The law aims at preventing goods and services that endanger human health, among other. It unequivocally declares that consumers have the right to get sufficient and accurate information as to the quality and type of goods and services, and the right to make their choice without any interference.[148] Moreover, labeling of goods should be accompanied with information inter alia, name, quality, and description of materials used to manufacture the product.[149] Labeling scheme under this proclamation does also apply to GMOs owing to the fact that it falls under the definition of goods, and law governs every transaction of movables.[150] Nevertheless, the consumer protection regime has limited application with respect to GMOs for two major reasons. Firstly, it excludes GM seeds for direct introduction to environment as the protection is only granted for consumers. Secondly, the law failed to govern labeling of GMOs separately, and treats GMOs on similar standard with other goods.

Generally, the labeling of GMOs in Ethiopia regulated based on the precautionary approach. In the same pattern, the consumer protection law clearly designates consumers' right to get information about products including GMOs. Although the production of GMOs in Ethiopia is in infant stage, it could be argued that the strict labeling laws might result a detrimental effect in the market competition between GM producing and non GM producing businesses in the future.

4.5. Intellectual property and agribusiness aspects of GMOs

The other major concern regarding GMOs is the issue of patentability and its effect in the agricultural business. There are long existing debates on patenting GMOs. The proponents IP protection majorly claim that IP protection encourage inventions and technological development in the agricultural sector. Opponents, on the other hand, raise patenting things which exist naturally are unacceptable form ethical, moral and religious perspectives. As once UK Prince

[148] Trade Competition and Consumer Protection Proclamation, Proc. No. 813/2013, 28th year, No. 28, Art. 14 (1) & (2)
[149] Ibid. Art. 16
[150] Ibid. Art. 2(2)

Charles warned scientists "the realms belongs to God and God alone".[151] Moreover, the IP regime creates dependency of the small holding farmers to GM producing giant MNCs.

At the international level the TRIPS agreement declare members may exclude plant and animals other than microorganism, and biological process for their production other than microbiological process. However, states should come up with an alternative *sui generis* law to protect plant developers' right.[152] The UPOV 1978 and 1991 come to light at the global level as a *sui generis* law to protect new plant varieties, and grants exemptions in comparison with the utility patent regime.[153]

The Ethiopian patent law declares patent is granted for inventions in the field of technology.[154] However, plant and animal varieties or the process of producing plant and animal are excluded from patent protection.[155] Unlike the case of the TRIPS agreement which provide exceptions for an exception for microorganism or micro biological process, the proclamation excludes all plant and animal varieties from patent protection. This could be attributed to ethical, moral and economic concerns. Besides, owing the fact that the country's economy is majorly dependent on small holding farm IP protection significantly affect farmers basic rights and make them dependent on seed producing companies.[156] Moreover, the small holding nature of farm results contamination of conventional breeds by GM varieties which leads to unintentional IPR infringement[157] and loss of biodiversity.

On the other hand, the country has adopted a law on PBR which tries to balance the interest of encouraging inventions with farmers and community interest. The law aimed at protecting plant

---

[151] Carlos Lopez 'Intellectual Property Reform for Genetically Modified Crops; A Legal Imperative' (2004) Journal of Contemporary Health Law & Policy , Vol. 20, P. 373

[152] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C to the Agreement establishing the World Trade Organization of April 15, 1994, Art. 27(1)(b)

[153] The UPOV has made exemptions from PBR protection i.e. acts done privately and for non-commercial purposes, acts done for experimental purposes and acts done for the purpose of breeding other varieties.

[154] Proclamation concerning Inventions, minor Inventions and Industrial Design, Proc. No. 123/1995 54th Year, No. 25 Ibid. Art. 2(3)

[155] Ibid. Art. 4(1)(b)

[156] Selamawit Desta 'the Role of Agricultural Biotechnology in Alleviating Food Insecurity in Ethiopia'2009, Kemmage Development Study center, P. 14

[157] The well-known case, *Monsanto Vs. Schemer*, revealed how an innocent infringers could be liable for patent owners. Schemer has been made liable for patent infringement without proof that he has intentionally used roundup ready canola. In our context denial of patent protection for GM seeds is justifiable since cross pollination and unintentional contamination could easily be occurred owing to the fact that our agriculture is based on small holding farm.

breeders without affecting farmers' right and community knowledge. While breeders have exclusive right to sell and/or to produce protected variety or propagating material of the protected variety,[158] farmers have the right of saving, using and exchanging seeds.[159] In addition, the law guarantees protection of community knowledge.[160] The PBR results a win-win solution for plant breeders and the agricultural community. Hence, producers of GM plant varieties could be eligible for protection under PBR.

The emerging practice with respect to commercial Bt-cotton doesn't seem to raise IP concerns in Ethiopia owing to the fact that bollgurd one Bt-cotton already become a patent free GM variety. However, denial of patent protection doesn't guarantee protection of the agricultural business in general and small holding farmers in particular. JK Agri Genetics; an Indian Company is the only provider of the Bt-cotton variety in Ethiopia. In 2018, commercial farmers complained about the price of Bt-cotton, claiming that it is 30 USD per kilo which is very expensive.[161] In the following year Bt-Cotton was imported with the price of 28 USD per kilo, while the price of organic seed per kilo was 45 Birr.[162] However, the productivity of the first Bt-Cotton was below expectation, and discouraged by the result only few farmers ordered Bt-cotton in 2020.[163] Moreover, lack of hard currency has become the main challenge for importers and local companies should be encouraged to involve on modern biotechnology if the plan is to assist the agricultural sector.[164]

[158] Plant breeders right proclamation, Proc. No. 1068/2017 24th year No. 29 Art. 5 The right of breeders might be limited to protect public interest, the environment, food security and biological diversity of the country. Moreover, there is an exception of compulsory license to safeguard public interest.
[159] Ibid. Art. 7
[160] Ibid. Art. 5 (3), In addition to the protection granted here there is a separate legislation on access to genetic resources and community knowledge which grants inalienable right over community knowledge and genetic resources, and no one can accesses those resources without prior informed agreement. Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation Proc. No. 482/2006, 13th year No. 13
[161] Tesfaye Getenet, 'Bt-cotton price to high, company evasive farmers complain' 2018, Capital Newspaper
[162] While Bt-cotton is need 2.5 kilo per hectare, the organic cotton needs 15 kilo per hectare. This makes the difference insignificant.
[163] Ashenafi Endale, 'GMO Cursed Seed?'2020, Ethiopian Business Review, available at < Ethiopianbusinessreview.net > accessed on May 21, 2021, *See also*, African Centre for Biodiversity 'GM Cotton push in Swaziland: Next target for failed Bt-cotton' 2015 African Centre for Biodiversity, this paper reveals how Bt- cotton affected small holding farmers in South Africa and Burkina Faso. The farmers become debtor of the giant MNC, Monsanto. Now, Burkina Faso is going back to the conventional cotton varieties. Ethiopia should take proper lessons from this states and commercial use of Bt cotton should be made with due care.
[164] Interview with Taddesse daba (n111)

4.6. Control of Illegal and Unintentional Cross Border Movement

GMOs should enter the state's border following all the requirements under the Cartagena protocol and/or domestic laws. Illegal cross-border movement of GMOs refers to the entrance of GMOs into a given territory without following proper legal procedure and authorization.

Installing a strong regulatory and institutional framework must be backed by control of the illegal cross-border movement of GMOs. If states don't have a strong border control over GMOs, the whole biosafety system might fail. The EU has the best experience in controlling and dictating illegal GMOs through enacting an independent guideline or directive to govern the dictation of GMOs. The directive has shifted the burden to develop a dictation mechanism from the Government to the importer and the latter must show the method of dictating its GM product.[165]

In Ethiopian case, the biosafety proclamation states that there should be a dictation of GMOs at the point of entry and exit.[166] Anyone who possesses a GMO must notify customs officers on duty upon entry and exit. Similarly, if the custom officer suspects any person in possession of GMOs without AIA, he shall pond it and notifies the commission.[167] The commission should take the sample and examine whether the organism is modified or not, if it has found a modified organism, it will be disposed of unless taken out of the country within 30 days.[168] And the costs of disposal safekeeping and re-export shall be borne by the importer.[169]

Nevertheless, the law doesn't bestow a detailed procedure for the control of the illegal cross-border movement of GMOs. For instance, methods and procedures of taking samples and disposal are not addressed in a detailed manner. The commission is working mainly on GMOs entering the country following proper procedures. There are gaps in controlling illegal cross border movement of GMOs due to different factors i.e. lack of skilled manpower at the port, limited capacity of laboratories, lack of proper procedural guideline, and lack of awareness of

[165] J. Davison & Y. Bertheau 'The Theory and Practice of European Traceability Regulations for GM Food and Feed' 2008, Article in Cereal Foods World institut National de la Recherche Agronomique (INRA) VOL. 53, No. 4 P.188
[166] Biosafety Proclamation, Art.20(1)
[167] Ibid. Art. 20(2)
[168] Ibid. Art. 20(6)
[169] Ibid. Art. 20(9)

officials about GMOs, and weak collaboration between the ECC and the EFCCC.[170] There is a plan to get into a memorandum of understanding with concerned institutions, Custom Commission, Ministry of Trade, Food and Drug Authority, and Ethiopian Airline, among others.[171]

In the same pattern, an interview conducted with two directorates in the custom commission revealed the existing gap in the implementation of the biosafety law regarding illegal cross-border movement. The major duty of the custom commission is controlling import and export commodities based on national and international laws and at the request of different regulatory institutions. Regarding GMOs, the custom commission doesn't have the expertise to control GMOs; moreover, EFCCC has not made any communication with the commission for the control of the illegal entry of GMOs.[172] Custom officers are not well aware of GMOs, since the EFCCC has not given any training about the issue. Moreover, there is no laboratory established for this purpose.[173]

On the other hand, no one can be sure about the illegal entrance of GMOs in Ethiopia. The EIAR took samples to ascertain whether GMOs to be released to the environment entered illegally in the country.[174] With respect to products, Dr. Tadesse argued products with GMO are entering the country without any restrictions. Similarly, concerning GMO seeds to be released to the environment the respondent asserted that BT cotton has entered the country around the ***Humera*** border and they have taken samples from different areas and it is being checked in laboratories.[175] The country doesn't have the machinery and kit to control the illegal entrance of GMOs, although the government has planned to set up laboratories. If the machinery and kits become available, it doesn't need special expertise and custom officers can easily dictate GMOs at the border.[176]

Illegal cross-border movement of GMOs could be minimized to insignificant level through collaborative work both at the national and international level. At the national level, the EFCCC

[170] Interview with Mr. Assefa Gudina (n145)
[171] Ibid.
[172]Mr. Adugna Andualem, Law Enforcement Directorate Consultant, ECC, (Addis Ababa 26 November 2020)
[173] Interview with Mr. Getachew Mihiret, Contraband Control Directorate Director , Custom Commission, November 26, 2020
[174] Interview with Dr. Tadesse Daba (n111)
[175] Ibid
[176] Ibid.

should work in collaboration with the ECC to control the illegal cross-border movement of GMOs. Since dictating GMO needs a skilled manpower custom officer at the point of entry and exist must know about GMOs and their adverse impact on the environment. They need to be equipped with a means to identify GM seeds so they can inform the commission to make a proper examination.

Likewise, at the international level, Ethiopia needs to enter into bilateral and multilateral treaties with neighboring states to control illegal cross-border movement of GMOs. The CBP declares Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms.[177]

Although, the protocol has opened a space for bilateral and multilateral arrangements, most African states don't come up with any biosafety agreement. Ethiopia as a leading figure in the negotiation of the CBP should initiate a bilateral and multilateral arrangement among African states in the protection of biosafety in general and controlling illegal cross-border movement of GMOs in particular. The BCH and reports submitted by Ethiopia to the CBD show the country has not entered into any biosafety agreement on this concern.

4.6. Liability and Redress

Liability and redress issues hadn't been incorporated under the CP. The protocol stipulated that state parties should put forward a legal framework at the national and international level to govern liability and redress issues.[178] Later on, member states to the CP bestowed the Nagoya Kuala Lumpur supplementary protocol on liability and redress.

Developing a national biosafety law regarding liability and redress has paramount importance, *inter alia*, to determine the scope of damage from a biosafety perspective, for valuation of damage, for channeling liability, and to integrate liability with the precautionary approach. Regarding the scope and definition of damage, it should be given the broadest interpretation to incorporate damage that arises from any GMO-related activities, including illegal and unintentional transboundary movement.[179] The valuation of damage that arises from GMOs is

[177] CPB (n3) Art. 14(1)
[178] Ibid. Art. 27
[179] Suman Sahai & Indran Barpujari, 'A Developing Country Perspective on Liability and Redress' Intended For Use of The Fourth Meeting For The Conference of The Parties To The Cartagena Protocol (COP-MOP 4) P. 5

not an easy task due to different factors. Firstly, GMOs might result a long-term setback in the environment, human and animal health, and socio-economic interests. Secondly, evaluation of the damage on financial terms might be difficult, especially concerning environmental damage.[180]

The NKSP has provided different measures for damage caused by GMOs, and left the power for states to bestow remedies under their domestic laws. State parties have been allotted three options i.e. to adopt a *sui generis* law on liability, to apply the general tort law, or a combination of both. Following these different states that ratified the Protocol provide a distinct law on liability that arises from GMOs.[181]

In the Ethiopian case, the liability and redress regime is not sufficiently guaranteed, since the country is neither ratified the NKSP nor adopted a national biosafety law regarding liability. The biosafety proclamation has provided a criminal liability and imprisonment from 10 to 15 years for GM-related transactions conducted to cause harm to human health, biological diversity, environment, or property.[182] Moreover, it states a penalty from birr 4000 to 7000 and/or imprisonment from one to three years for violation of any of the biosafety laws i.e. the proclamation, regulations, and directives.[183] In the case when the offense is committed by a juristic person the penalty will be determined based on article 90 of the criminal code.[184]

Nevertheless, the biosafety proclamation and its directives failed to govern the civil liability that may result from GMO-related activities. It seems that the liability and redress issues are left for the general tort law. The EFCCC pushed for the ratification of the NKSP on liability and redress and it has been led to the ministry of foreign affairs, yet, there is a tendency on the latter's side that the general tort law will govern the issue of liability and redress.[185]

The Ethiopian tort law does have rules for fault-based and strict liability. If the plaintiff can prove the existing fault of the defendant, he can bring an action based on fault-based liability

[180] Ibid. P. 6
[181] The French liability law on GMO declares GMO cultivator will be responsible for non GMO cultivator when there is a damage that may arise from accidental release. Moreover, it obliges all GMO cultivators to obtain liability insurance coverage. *See*, Restrictions on GMOs (n107) P. 87
[182] Biosafety Proclamation, Art. 21(1)
[183] Ibid.
[184] Ibid. Art. 21 (3)
[185] Interview with Mr. Assefa Gudina (n145)

laws.[186] Consequently, anyone who has suffered harm due to GMO-related activities of another can claim damages through showing the existence of either intention or negligence on the defendants' side, and the defendant acted contrary to the law.[187]

It's also possible to bring an action for harm caused due to GMO transactions under strict liability laws. Although it is not mentioned clearly, harms caused by GMO-related activities could be covered under dangerous activities under article 2069. The provision has enumerated dangerous activities as storing and using explosive substance, modifying the natural lie of the land and engaging in exceptionally dangerous industrial activities.[188] It's argumentative whether these lists are exhaustive or illustrative. Yet, it can be argued that GMO-related activities could be incorporated either way, directly in case of the illustrative argument or through interpreting the lists in the exhaustive argument.[189] Hence, the victim has an option to bring legal action against a person who caused damage using GMOs without showing the fault of the latter under strict liability. This shifts the burden of proof from the claimant to the defendant.

In the researcher's view, despite the fact that the general tort law addresses the issue of liability, the ratification of the NKSP and enactment of a *sui generis* law regarding liability and redress is necessary for different reasons. Firstly, as it was stated damage that may come to light from GMOs might have a long-term effect on human and animal health, environment, and property. Secondly, evaluation of damage in financial terms might be difficult and the law must make sure of the availability of other alternative remedies. Thirdly, the liability regime related to GMOs needs to be entertained from the perspective of the precautionary principle. The burden of proof should be on the person who has been involved in GMO-related activities or the defendant must prove that the harm caused is not due to its transaction of GMOs. Fourthly, channeling liability in the case of GMO transactions might be difficult, since different parties from developer to user might be involved. So, determining the liability of each party on a given transaction needs the

[186] The Civil Code of the Empire of Ethiopia, 1960, Art. 2028 (The Civil Code)
[187] Ibid. Art. 2035, the biosafety proclamation provided a criminal liability for anyone who infringes the biosafety law. On the other hand, article 2035 of the civil code states violation of any state laws i.e. proclamations, regulations, and directives results a fault based civil liability. Hence, if the victim can prove that the person involved in GMO related activity acted against the provisions of biosafety laws, he can bring an action based on fault based liability laws.
[188] The Civil Code, Art. 2069
[189] For instance, GMO related activates could be incorporated under the list about modifying the natural lie of the land.

existence of a separate law.[190] Considering the damage to the environment, biodiversity and human health need the involvement of different interested groups to bring an action against persons who caused the damage using GMOs.[191]

4.7. The recognition of differential treatment for Gene Editing and Transgene Modification

The contemporary experience in the world of GE shows the classification of GM as transgene modification and genome editing. And there is a tendency of developing a differential treatment for transgene modification and gene editing (mutagenesis) believing that it is virtually impossible to detect whether the DNA of a plant or animal has been edited or not, because the changes involved are indistinguishable from naturally occurring mutations.[192] The practice in US shows, USDA accepted gene editing should not be considered as genetic modification and products of gene editing should be treated and regulated with lesser standard than genetic modification or GMOs with a firm believe that gene editing is the modern form of breeding.[193]

To the contrary, the EU regulation regulates transgene and gene editing on similar standard as GMOs.[194] The issue has been presented before the EU court of justice in 2018, and the court ruled that gene editing should be regulated under similar standard with genetic modification or GMOs.[195] Nevertheless, the European Academies' Science Advisory Council (EASAC) supported a proposal made by German scientists that has suggested the definition of GMOs should exclude gene editing and alteration that could occur naturally, and separate legal

[190]The African model law on safety in biotechnology, African union institute for sustainable development, 2002 Art. 14(3). The African model law on safety in biotechnology provides that if there are more than one person's liable for the damage caused the parties will have a joint and several liabilities. In Ethiopian case, the issue of channeling liability is not well addressed under the general tort law.

[191] Ibid. Art.14 (8), it states any person, group of persons, government and private organizations could be entitled to bring a claim, when there is a breach on biosafety law. And, it provides that no costs will be awarded against these persons. This protection is granted under the law due to the special nature of the damage that might be caused by GMOs, yet the Ethiopian tort law provisions doesn't guarantee this special nature and persons who could bring an action are only persons with vested interest.

[192] Ignacio Carreño, &Tobias Dolle, 'The Court of Justice of the European Union's Judgment on Mutagenesis and International Trade: A Case of GMO' *Global Trade And Customs Journal*, Vol. 14, P. 97

[193] Michael Helmstetter 'The Promise and Fear Of Gene Editing' < The Promise And Fear Of Gene Editing (forbes.com) > *Forbs (* New York 2020) accessed on 24 May 2021

[194] The Deliberate Release Into The Environment of Genetically Modified Organisms And Repealing, The European Parliament And of The Council, Dir. No. 2001/18/EC

[195] EASAC, 'The Regulation of Genome-Edited Plants In The EU' 2020, European Academies Science Advisory Council P. 2

framework should be designed for governing gene edited product.[196] In Africa also Nigeria and Kenya has already amended their biosafety laws to create differential treatment for gene edited products.[197]

Under the Ethiopian biosafety context, the biosafety amendment proclamation has included an objective of enhancing modern biotechnology.[198] Providing separate regulatory framework for gene editing believed to be one means of achieving this objective. However, the status of gene editing seems unclear under the Ethiopian biosafety framework.

The proclamation defined GM 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 or any other chemical whether taken from another organism, from a fossil organism or artificially synthesized."*[199]

Based on the definition it could be argued that gene editing is excluded from the ambit of biosafety regulation since GMO is formed by the insertion of foreign gene or gene taken from another organism or artificially synthesized. In other words, insertion, deletion and manipulation of genes within the same organism through gene editing doesn't result GMOs. Furthermore, under the directives, gene editing isn't mentioned while transgene is directly referred under different regulatory provisions.[200]

In the other polar, it could be stated that the biosafety law treats mutagenesis and transgene modification on similar standard. Modern biotechnology defined as any reproduction and recombination of barriers and that are not made in traditional breeding and selection.[201] This indicates any modification including gene editing other than traditional breeding fall under modern biotechnology. And, the CPB defined GMO as a result of modern biotechnology.[202]

---

[196] Ibid. P. 5, *see also,* Greg Jaffe 'European Union opinion on gene editing: Insightful or missed opportunity?' 2018, Alliance for science

[197] John Coman, Lena Tripathi, *et al* 'Biosafety Regulatory Reviews and Leeway to Operate: Case Studies From Sub-Sahara Africa' (2020) Policy and Practice Review Article < https://www.frontiersin.org/articles/10.3389/fpls.2020.00130/full > accessed on 24 may 2021

[198] Biosafety Amendment proclamation , Art. 4

[199] Biosafety Amendment proclamation Art.2 (1)

[200] For instance, The Risk Assessment Directive, 2018 Art. 5(2), Art. 6(2), and Risk Management Directive No. 3 Art. 4.5 & 4.6 referred a word transgenes, but gene editing or mutagenesis isn't mentioned in any of the directives.

[201] Biosafety Amendment Proclamation, Art. 2(19) Cum with, CPB Art. 3(i)

[202] CPB (n3) Art. 3(g)

Hence, the broader definition of GMOs under CPB incorporates gene editing and it will be treated as any other GMOs.

Nevertheless, neither of the arguments is beneficial in Ethiopian case. While the former leaves gene editing unregulated, the later treats gene editing on similar standard with transgenic modification. Hence, the issue of gene editing should be clarified under the Ethiopian biosafety law, and through public consultation with different stakeholders the government should bring forth with a separate regulatory framework that will be adopted based on the level of risk that may arise from respective gene edited product. This will play paramount importance in achieving the objective of enhancing access to biotechnology since gene editing is easily adoptable, faster and cheaper than transgene products. This allows the EIAR, EBTI, and other institutions with limited resources to work on gene editing over transgene products developed by MNC. However, the government should work on capacity building, and there should be scientific mechanism to identify gene edited from transgene products to properly implement the proposed differential treatment.

Chapter Five

Conclusion and Recommendation

5.1. Conclusion

At the international level the CPB to the CBD governed the safe transfer and handling of GMOs. It tried to state the agreeable minimum standard for safe use and handling of GMOs. The CPB govern among others, public participation and awareness, BCH, precautionary principle, risk assessment and risk management issues. Ethiopia ratified the CPB in 2003 and developed a strong national biosafety framework in 2009. Later, the biosafety proclamation and its directive were amended in 2015, and 2018 respectively. This paradigm shift in the law results the introduction of GMOs in Ethiopia i.e. Bt-cotton and GM-maize.

The amendment proclamation and its directives have made significant changes on the biosafety framework. Firstly, it incorporated an objective of enhancing biosafety through biotechnology, which is not derived from CPB and it is not clear how biotech would enhance biodiversity. Secondly, it comes up with special permit system for contained use of GMOs. Although the CPB excluded contained use from its ambit of AIA procedure, it has declared that states can have some other special procedure including risk assessment. The previous proclamation has properly exploited the discretion given under the protocol and AIA procedures were applicable for contained use of GMOs. To the contrary, the amendment proclamation and its directive don't assure the proper implementation of the protocol in protecting biosafety. Thirdly, the law lacks clarity whether risk assessment should be conducted in the case of special permit, yet the position of the law more inclined with the fact that risk assessment should be made before granting special permit. This uncertainty of the law leads to a gap in the implementation. In the approval of Bt-cotton and GM- maize for confined field trial neither the EIAR nor the EFCCC conducted a risk assessment. Lastly, the law has narrowed the definition of socio economic impact of GMOs and the power to determine whether the risk assessment should include socio economic concerns left for the EFCCC. Hence, the EFCCC can give special permit without considering socio economic concerns and cultural values and this might go against the obligation under the CPB.

The approval of bt-cotton was made against the provisions of the biosafety proclamation. The approval has been given based on a letter from Prime Minister Office before the biosafety

proclamation was amended. The biosafety law needed AIA for all GMO transactions including contained use. Public participation and risk assessment are an integral part of the AIA procedure. In violation of this rules and the CPB the government allowed confined trial of Bt-cotton in Ethiopia.

Concerning public awareness and participation the biosafety proclamation and its directive failed to address the issue of public awareness and provide tiny about public participation. This doesn't assure the proper implementation of the CPB. Proper procedures aren't installed to create awareness, and the public level of understanding about GMOs is unknown for lack of survey conducted on the issue. Providing all information under the BCH is one minimum requirement to address the public, however, the BCH provided a tiny about GMO related activities in Ethiopia.

Public participation should be secured both at the level of law and decision making as per the constitution yet the biosafety proclamation doesn't assure public participation at the law making stage. The biosafety law was amended in 2015 and 2018 without making proper public consultation. Likewise, public participation hasn't been secured the decision making process for the approval of Bt-cotton and GM-maize due to limited public awareness, the complex nature of biotechnology, and the hesitation of the government to make a public debate on the issue.

Border control of GMOs is very essential for properly implementing biosafety laws. The experience of Brazil and India, despite the fact that they have installed both legal and institutional framework, illegal cross border movement challenged both states due to weak dictation mechanism at the border. On the other hand, Europeans developed a separate directive to govern dictation mechanisms and developed a strong border control. In Ethiopia the mechanisms of controlling illegal cross border movement is unknown. Lack of skilled man power, unavailability of laboratories, lack of procedural guideline, and weak collaboration between the EFCCC and the ECC are some factors for weak border control of GMOs.

Liability and redress is addressed under the biosafety proclamation regarding criminal liability. Nevertheless, the law has escaped civil liability that may arise from damage caused by GMOs. Civil liabilities that may arise from approved GMOs i.e. Bt-cotton and GM maize or other illegally entered GMOs will be entertained under the general tort law. The Ethiopian civil code bestows fault based and strict liability laws that can be adopted for harms caused by GMOs. Howbeit, ratifying the NKP and enacting a *sui generis* law has paramount importance in granting

proper remedy for damage that arise from GMO, *inter alia*, long term effect on environmental and human health, difficulty in evaluation of damage, to incorporate the precautionary approach, channeling liability, and to give *locus standi* for different interested groups. Lastly, from the perspective of recognizing technological advancement the amendment proclamation has an objective of enhancing access to biotechnology. However, in achieving this objective the law doesn't come up with differential treatment for mutagenesis and transgene modification.

5.2. Recommendation

Through a nitty-gritty examination of the current biosafety framework in Ethiopia, the researcher recommends for:

I. The domestic biosafety framework escaped the issue of public awareness, while the CPB oblige states to provide sufficient information about GMOs and create public awareness. In properly implementing the CPB, the domestic law should incorporate rules oblige institutions to participate in creating public awareness. The EFCCC in collaboration with other institutions should conduct public awareness and public perception survey about GMOs. Furthermore, the government should include biotechnology and biosafety concerns under the national educational curriculum to address the larger public with the basics of GMOs.

II. Public participation should be granted both at the stage of developing policy and legal framework, and decision making. The procedure employed at the law making process in the approval of the amendment proclamation and it directives should be assessed especially, concerning public participation, and proper lessons should be taken for further development of biosafety laws. Moreover, at the decision making stage the government should employ proper public consultation through joint or citizen led decision making process.

III. Concerning illegal cross border movement of GMOs, there should a nitty-gritty procedural guideline to govern dictation mechanisms. The EFCCC should enact procedural guideline to control illegal cross border movement. Establishing laboratories to detect illegal entrance of GMOs is necessary. Furthermore, custom officers at border control should be acquainted with proper training regarding GMOs and their mechanism of dictation. On the top of that, the EFCCC should work in collaboration with the ECC.

IV. The government should initiate and enter into bilateral and multilateral treaties with neighboring states to control illegal and unintentional cross border movement of GMOs.

V. The biosafety regime should clearly designate differential treatment for gene editing since it is easily adoptable, faster and cheaper than transgene modification, and encourage biotechnology institutions and local companies to invest on biotechnology.

VI. The government should ratify the NKP on liability and redress and enact *a sui generis* law that considers and directly address the long term effect on environmental and human health, resolve difficulty in evaluation of damage, incorporate the precautionary approach, channeling liability, and give *locus standi* for different interested groups.

VII. The special permit introduced under the amendment proclamation for contained use of GMOs should clearly include the requirement of risk assessment and provide the detailed procedure for approval of GMOs based on the level of risk. Moreover, the EFCCC, unlike the case of Bt-Cotton and GM-Maize, should include the risk assessment procedure up on granting permit for contained use.

VIII. Labeling should be governed in a detailed manner. The minimum threshold to consider a given product as if it contains GMO, and measures which should be taken in case the product couldn't be identified should be addressed, among other.

IX. The EFCCC shall provide all information available regarding activities related to GMOs under BCH.

Bibliography

Laws

A Proclamation to amend the biosafety proclamation, Proc. No. 896/2015, 21st year, No. 66,

A Proclamation to Provide for The Definition of Powers and Duties of The Executive Organs of The Federal Democratic Republic of Ethiopia, Proc. No. 916/2015, No. 12

Biosafety Proclamation, Proc. No. 655/2009, 15th year, No.63

Constitution of FDRE, Proc. No. 1/1995

Directive issued to determine the procedure of risk management strategy for dealing with accidents involving modified organism Directive No. 3, environmental Protection Authority
Directive issued to provide risk assessment parameters for modified organism, Directive No. 5/2018, Ministry of Environment Forest and climate Change

Directive on Risk Assessment Parameters for Modified Organisms, Directive No. 2, Environmental Protection Authority

Directive to determine major contents of application for special permit for contained use of modified organism in research and teaching, directive No. 04/2018, ministry of environment forest and climate change

Directive to establish procedure for management of risk from any transaction involving modified organism Directive No. 6/ 2018

Environmental Protection Authority Establishment Proclamation, Proc. No. 9/1995 No.9
Environmental Protection Organs Establishment Proclamation, Proc. No. 295/2002 No. 7
Ethiopian agricultural research organization proclamation, Proc. No. 79.1997

Ethiopian Biotechnology Council and Biotechnology Institute Establishment Council of Ministers Regulation, Reg. No. 388 /2016
National Bio-safety Advisory Committee Establishment Council of Ministers Regulation, Reg. No. 411/2017 No. 83

International agreements

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

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

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

The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, Convention on Biological Diversity

Books, Journal Articles and Other Sources

Aaron Crosby & Stas Burgiel, *The Cartagena Protocol on Biosafety: An analysis of results, An IISD Briefing Note*, 2000, international institute for sustainable development

Adane Abraham, *Toward a workable biosafety system for regulating genetically modified organisms in Ethiopia Balancing conservation and competitiveness* 2013, GM Crops and Food: Biotechnology in Agriculture and the Food Chain, Vol. 1

Anna M. Zivian et al, *Biosafety Resource Book* 2011, FAO

Billen Girmay, *Legal Framework of Biosafety in Ethiopia: The Relevance of Cartagena Protocol*, 2009, Addis Ababa University.

Birhanu Fikade, *GMO cotton approved for plantations*, 2018, The Reporter, available at<https://www.thereporterethiopia.com/article/gmo-cotton-approved-plantations>

Carl E. Pray, *Costs and enforcement of biosafety regulations in India and* China, 2006, Int. J. Technology and Globalization, Vol. 2

Center of Eco genetics and environmental health, *Fast Facts About Genetically Modified Organisms*, 2013 University of Washington, available at<https://depts.washington.edu/ceeh/downloads/FastFacts_GMOs_FINAL.pdf> accessed on august 13 2020

Chen Zhang *et al, Genetically modified foods: A critical review of their promise and problems* 2016, *journal of food science and human wellness,* vol. 5

Christoph Bail, Robert Falkner *et al Ed., The Cartagena Protocol on Biosafety Reconciling Trade in Biotechnology with Environment and Development?* 2002, the royal institute of international affair, Earthscan Publications Ltd, London

Dominic Glover & James Keeley *et al., Public Participation and the Cartagena Protocol on Biosafety*, available at<http://wedocs.unep.org/bitstream/handle/20.500.11822/9998/Public%20Participation%20and%20CPB_%20A%20Review.pdf?sequence=1&isAllowed=y >

Dr. Tewolde Berhan Gebre Egziabher, *An Open Letter*, 2020 available at <https://www.ethiopiaobserver.com/2020/05/08/an-open-letter-by-dr-tewolde-berhan-gebre-egziabher/ > Ethiopian Observer

Dr. Thirugnanam Senguttuvan, *Use and Regulation Of Genetically Modified Organisms, George B. Fuller, Ed*., 2005 Report Of The Apo Study Meeting On Use And Regulation Of Genetically Modified Organisms held in the Republic of China, 18-23, Asian productivity organization

Eduardo Soares, *Genetically Modified Organisms Restrictions In 23 Countries and The European Union*, Morris Bishop *ed*., Nova publisher

Eduardo Soares, *Restrictions on Genetically Modified Organisms: Brazil,* available at <Restrictions on Genetically Modified Organisms: Brazil | Law Library of Congress (loc.gov)> 2014,

Ezra Ricci, *Biosafety regulation: the Cartagena protocol*, 2004, Geneva International Academic Network (GIAN)

Gurdial Singh &Sarah Lawson *et al*, *Liability and Redress Under the Cartagena Protocol on Biosafety*, 2008 A Record of the Negotiations for Developing International Rules, CEBLAW, Vol. 1

Gurdial Singh, *Liability and Redress for Damage Arising from Genetically Modified Organisms: Law and Policy Options for Developing Countries*, 2007, University of Malaya, Kuala Lumpur

Hanover re, *Genetically Modified Organisms (GMO's*) 2020 available at<https://www.hannover-re.com/180643/genetically-modified-organisms-2020.pdf> accessed on August 17 2020

Hellen Manyara, *Effectiveness of Kenya's Biosafety Liability and Redress Regime*, 2016, University of Nairobi

Kevin Keener *et al*, '*Biotechnology and its Applications'* Available at<https://fbns.ncsu.edu//extension_program/documents/biotech_applications.pdf> accessed on august 14 2020, NC State University

Mackenzie, Ruth, Burhenne-Guilmin, *et al., An Explanatory Guide to the Cartagella Protocol on Biosafety*, 2003, IUCN environmental policy and law paper the world conservation union,

Motbaynor Terefe, *Biosafety Issues of Genetically Modified Crops: Addressing the Potential Risks and the Status of GMO Crops in Ethiopia*, 2018, ClonTransgen, an open access journal, Vol. 7

OJ Lim Tung, *Transboundary Movements of Genetically Modified Organisms and The Cartagena Protocol: Key Issues and Concerns*, 2014, P.E.R, Vol.17

Orlando Cardoso, *An Overview of the Brazilian Biosafety Regulatory System*, available at <www.cnpma.embrapa.br/anais/proceedings_bio/files/2_CTNBio.pdf > CTNbio

Prof. Dorington O. Ogoyi, *The Biosafety Framework in Kenya*, 2013 National Biosafety Authority

Teshome Hunduma, *Commentary: Ethiopia's Acceptance Of GMOs Turns Decades Of Pan-African Environmental Leadership On Its Head*, 2020, Addis Standard, available at<http://addisstandard.com/commentary-ethiopias-acceptance-of-gmos-turns-decades-of-pan-african-environmental-leadership-on-its-head/> accessed on august 10 2020, Addis Standard

UNDP, *The Advance Informed Agreement (AIA) procedure LMOs for intentional introduction into the environment*, Available at < https://bch.cbd.int/help/topics/en/The_Advance_Informed_Agreement_procedure.html >

UNEP, *an introduction to the Cartagena Protocol*, 2011

UNEP, '*Glossary of Terms for Negotiators of Multilateral Environmental Agreements'* 2007, UNEP Division of Environmental Law and Conventions (UNEP, Terms for Negotiators)

UNEP, *Unintentional Transboundary Movements And Emergency Measures (Article 17) And The Detection And Identification Of Living Modified Organisms*, 2016 conference of The Parties To The Convention On Biological Diversity Serving As The Meeting of The Parties To The Cartagena Protocol On Biosafety Eighth meeting Cancun, Mexico,

US Legal, 'Biosafety law and legal definition' available at <https://definitions.uslegal.com/b/biosafety/> accessed on 14 august 2020

USDA, 'Agricultural Biotechnology Annual' 2020, Gain Global Agricultural Network, Annual Report, available athttps://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Addis%20Ababa_Ethiopia_10-20-2019
WHO, *Health Concerns of GMOs*, 2015 genetic generation , available at<https://knowgenetics.org/health-concerns-of-gmos/> accessed on August 13 2020
Zahra Naz, *Introduction to Biotechnology*, 2015 available at<https://www.researchgate.net/publication/284169166_Introduction_to_Biotechnology>
Third National Report on the implementation of the Cartagena Protocol on Biosafety, 2016 available at < https://bch.efccc.gov.et/directives/ >
J. Davison & Y. Bertheau, *The Theory and Practice of European Traceability Regulations for GM Food and Feed*, 2008, Article in Cereal Foods World institut National de la Recherche Agronomique (INRA) VOL. 53, NO. 4
Suman Sahai & Indran Barpujari, *a developing country perspective on liability and redress*, intended for use of the fourth meeting for the conference of the parties to the Cartagena protocol (COP-MOP)

Interviews

Mr. Assefa Gudina, Environmental, Forest And Climate, Change Commission, Biosafety And Invasive Alien Species Regulation Directorate Director , January 23,2021
Dr. Tadesse Daba, Ethiopian Agricultural Research Institute, Biotechnology Directorate Director, January 28,2021
Mr. Mesay Emana, Researcher, Ethiopian Biotechnology Institute, Biosafety And Climate Change Research Team Leader, January 05
Mr. Getachew Mihiret, Contraband Control Directorate Director , Custom Commission, November 26, 2020
Mr. Adugna Andualem, Law Enforcement Directorate Consultant, Custom Commission, November 26, 2020
Mr. Awoke Damte, , Environmental, forest and climate, change commission, biosafety and Invasive Alien Species, risk assessment expert, February 29, 2021
Mr. Ambaye G/kidan, Environmental, Forest And Climate, Change Commission, Biosafety And Invasive Alien Species, National Biosafety Advisory Committee Capacity Building Expert, February 29,2021