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LEGAL FRAMEWORK OF BIOSAFETY IN ETHIOPIA: THE RELEVANCE OF CARTAGENA PROTOCOL

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DECLARATION

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

Declared by Billen Girmay

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ABSTRACT

This study makes a comprehensive analysis of the current biosafety regulatory regime in Ethiopia. A set of common characteristics and components in biosafety regulatory systems with reference to related provisions of the Cartagena Protocol on Biosafety were used. The introduction of genetically modified organisms (GMOs) especially in agriculture has produced a new range of governance challenges in the fields of environmental safety and human health. The regulation of modern biotechnology in Africa is still in its infancy. Despite this, legislation is urgently required to regulate modern biotechnology. The study assessed how the Cartagena Protocol on Biosafety is implemented by Ethiopia.

The study revealed that though the Cartagena Protocol has gone some way in regulating modern biotechnology. On the national level, the study noted that the draft biosafety regulatory regime of Ethiopia does comply with the provisions of the Cartagena Protocol, but it considers the Cartagena protocol as minimum standard rather than maximum standard. This is mainly because each country has taken a different approach in implementing the protocol depending on its domestic priorities, biodiversity, imperatives and position in the global agricultural market. Finally, the study made recommendations on possible ways in which Ethiopia can coordinate and improve its national biosafety regulatory systems. These will enable the draft biosafety regulatory system to become more successful in protecting the environment and human health.

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LIST OF ABBREVIATIONS

AIA	Advance Informed Agreement
AU	African Union
BCH	Biosafety Clearing House
BSWG	Ad hoc Working Group on Biosafety
CBD	Convention on Biological Diversity
CEE	Central and Eastern Europe
COP	Conference of Parties
COP/MOP	Conference of the Parties serving as the meeting of the parties to the protocol
DNA	Deoxyribonucleic Acid
EIA	Environmental Impact Assessment
EU	European Union
ExCOP	First extra ordinary meeting of the conference of the parties
EPA	Environmental Protection Authority
ESTA	The Ethiopian Science and Technology Commission
GATT	General Agreement on Tarrifs and Trade
GE	Genetically Engineered
GEF	Global Environment Facility
GM	Genetically Modified
GMO	Genetically Modified Organisms
IBC	Institute of Biodiversity Conservation
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
IISD	International Institute for Sustainable Development
IPPC	International Plant Protection Convention
LMO	Living Modified Organisms
LMO-FFPs	Living Modified Organisms Intended for direct use as food or feed, or for processing

NGO	Non-governmental organization
SPS	Sanitary and Pyhtosanitary Standards Agreement
TBT	Agreement on Technical Barriers on Trade
TRIPS	The Agreement on trade related aspects of Intellectual Property
UN	United Nations
UNCST	Ugandan National Council of Science and Technology
UNEP	United Nations Environment Programme
WTO	World Trade Organization

CHAPTER ONE

1.1 Background of the Study

Biosafety is the safe development of biotechnology products and their safe application resulting from the existence of effective mechanisms for the safeguard of human and animal health, safe agricultural production, safe industrial production, safeguard of the natural plants and animal species (flora and fauna) and the environment from negative consequences due to the practice and application of biotechnology and its products.[1]

In order to understand and appreciate biosafety concepts, it is necessary to have some appreciation of what biotechnology is. The term biotechnology refers to any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for a specific use.[2] This concept is not new. Farmers have relied on selective breeding and cross fertilization to modify plants and animals and encourage desirable traits that improve food production and other human needs. Artisans have exploited traditional fermentation techniques to transform grains in to bread and beer and milk in to cheese.[3] Such intentional modification of the natural world has contributed enormously to human well being.

Over the past 30 years, the ability to alter life forms has been revolutionized by modern biotechnology. Scientists have learned how to extract and transfer strands of DNA and entire genes which contain the biochemical instructions governing how an organism will develop from one species to another. Using sophisticated techniques, they can precisely manipulate the intricate genetic structure of individual living cells. For example, they can insert genes from a coldwater fish into a tomato to create a frost resistant plant, or use bacterial genes to make herbicide tolerant corn. The results are known as living modified organisms (LMOs) or, more popularly, genetically modified organisms (GMOs).[4] Two

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[1] Frequently asked questions on biosafety Protocol available at http://www.biodiv.org/biosafety/freqs.asp, visited on 1/5/2008 p.1
[2] Convention on Biological diversity,(1992), Article 2
[3] Biosafety and the Environment, available at http://www.biodiv.org visited on 25/04/2008, p. 4
[4] Ibid

extreme positions appear to polarize the debate on biotechnology, extreme pro-genetic engineering and extreme anti-genetic engineering positions.

Proponents argue that biotechnology will boost food security for the world's growing population by raising sustainable food production. It will benefit the environment by reducing the need for more farm-land, irrigation and pesticides. It will also provide better medical treatments and vaccines, new industrial products and improved fibers and fuels. For many people, however, this rapidly advancing science raises a tangle of ethical, environmental, social and health issues. Because modern biotechnology is still so new, they say, much is known not about how its products may behave and evolve, and how they may interact with other species. Could an ability to tolerate herbicides, for example, transfer from GM crops to related wild species? Might plants that have been genetically modified to repel pests also harm beneficial insects? Could the increased competitiveness of a GMO cause it to damage biologically rich ecosystems?[5]

The debate has led to a broad consensus that, while modern biotechnology may have great potential, it must be developed and used with adequate safety measures, particularly for the environment. Countries with strong biotechnology industries do have national legislation and risk-assessment systems in place. However, many developing countries interested in modern biotechnology and its products are still in the process of drafting regulations. And because biotechnology is a global industry, and GMOs are traded across borders, international rules are needed as well.

Ethiopia, being a party to the Cartagena Protocol which is one of the most important international treaties recently adopted and marks the commitment of international community to ensure the safe, transfer, handling and use of LMOs, is in the advance process of preparing its National Biosafety Framework through financial assistance from the Global Environment Facility (GEF). The draft National Biosafety framework includes policy, legal, administrative and technical instruments that have been developed in order to ensure an adequate level of safety in the field of the safe transfer, development, handling and use of living modified organisms (LMOs), also referred as Genetically

[5] Ibid

modified organisms (GMOs) and their product that emanate from modern biotechnology and have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.[6]

This study makes a comprehensive analysis of Biosafety regulatory regime in Ethiopia. This could be done by comparing selected key features in the regulatory system with reference to related provisions of the Cartagena protocol. This study aims at assessing how Cartagena protocol is implemented in Ethiopia and the compliance level of the Biosafety regulatory systems of the country.

1.2 Literature Review

Various Biosafety responses and regulations have been established at international and national level to address Biosafety concerns. The need for Biosafety was demonstrably shown by their development and the production of an international Cartagena Biosafety protocol. An explanatory guide to the Cartagena protocol on Biosafety is a useful reference work for research conducted on the protocol and its implementation.[7]

The particular contribution of the Cartagena protocol to global Biosafety is helping to ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements.[8]

The protocol deals primarily with GMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified farm commodities (such as corn and grain used for food, animal feed or processing). It does not cover pharmaceuticals for humans addressed by other international agreements and

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[6] Environmental Protection Authority, *Biosafety Framework* , (2007), available at http://www.epa.gov.et visited on 26/04/2008 p. 3

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

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

organizations or products derived from GMOs, such as cooking oil from genetically modified corn or paper from GM trees.

To promote the biosafety, the Protocol reflects another fundamental concept known as the precautionary approach. It reaffirms Principe 15 of the 1992 Rio Declaration on the Environment and Development, which states that, where there are threats or serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation.[9] In the case of the biosafety Protocol, this concept means that a government may decide on the basis of precaution not to permit a particular GMO product to be imported across its borders. This is the case even if there is insufficient scientific evidence about the GMOs potential adverse effect. The protocol applies precaution not just to biodiversity, but to potential risks to human health as well. It also gives importing countries the right to take into account socio-economic concerns; provided their actions are consistent with their international obligations. Such concerns could include the risk that import of genetically engineered foods may replace traditional crops, undermine local cultures and traditions or reduce the value of biodiversity to indigenous communities.

The Cartagena protocol promotes biosafety by establishing practical rules and procedure for the safe transfer, handling and use of GMOs, with a specific focus on regulating movements of these organisms across borders, from one country to another. This system features two separate sets of procedures, one for GMOs that are to be intentionally introduced into the environment, and one for GMOs that are to be used directly as food or feed or for processing. Both sets of procedures are designed to ensure that recipient countries are provided with the information they need for making informed decisions about whether or not to accept GMO imports. Governments exchange this information through a Biosafety Clearing House and base their decisions on scientifically sound risk assessments and on the precautionary approach.

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[9] United Nations Environmental Program, *An Introduction to Cartagena Protocol on Biosafety*, (2003), Available at http://www.unep.org visited on 26/4/2008, p.6

When a country decides to allow the import of a GMO, the exporter must ensure that all shipments are accompanied by appropriate documentation. Governments must also adopt measures for managing any risks identified by risk assessments, and they must continue to monitor and control and risks that may emerge in the future. This applies to trade as well domestically produced GMOs. To ensure its own long term effectiveness, the protocol also contains a number of enabling provisions, including capacity building, public awareness and participation and a financial mechanism. These various elements and others will be given a closer look on this study.

An article by Carolina Lasen Diaz entitled "Biotechnology and the Cartagena Protocol", illustrates through a series of examples derived from recent international, regional and national legislation, the increasing number of legislative and policy measures in the field of biosafety that are contributing to the consolidation and relevance of the precautionary principle.[10] The Cartagena protocol and related laws are expected to play an important role in further clarifying the consideration and operationalisation of the precautionary principle in practice. Furthermore, the inter-linkages between national, regional and international measures on biosafety that incorporate the need to address precaution should result in a better understanding of this concept. The next step is to start gathering experience on the practical application of this principle through the implementation of specific legal provisions. The approach to precaution in the area of biotechnology and biosafety reflect the different values perceptions and judgments both on the specific area of the use of modern biotechnology and on the ways different societies relate to uncertainty and deal with risk.

In addition, if the application of the precautionary principle relates to the actions needed to protect the environment, and human health, the decision making process followed to reach and implement those precautionary measures is also crucial. The need to ensure open, transparent, and participatory processes in the assessment and management of risks

[10] Carolinal Lasen Daiz, *Biotechnology and the Cartagena Protocol*, United Nation Environmental program, (2002), P.22

related to biotechnology will be a key in determining the success or failure of applying the precautionary principle to GMOs.[11]

An article written by Tewolde Berhan GebreEgziaher entitled: "Balancing Biosafety, Trade and Economic Development Interest in the Implementation of the Cartagena Protocol: A Developing Countries Perspective", shows the concern of countries like Ethiopia. According to this article, LMOs, by virtue of being new to nature, may create equally new useful promises or hazards to humans and the environment. Their potential usefulness makes them appealing for development. However, their potential ability to cause harm makes the regulation of their development and use as well as international trade in them, absolutely essential.[12] The development of economy and trade in LMOs as well as their regulation is also the interest of developing countries since protection from any serious hazards and their need to catch up with developed countries. The difficulties of developing countries are:[13]

- The amount of money allocated for biosafety is bound to be inadequate, and if the risk occurs, combating it requires financial and technical capacity that the countries do not have;
- Developing countries have more complex environment because in hotter tropical and subtropical environments, microorganism can survive and flourish indefinitely;
- Developing countries have richer biodiversity compared to developed countries. LMOs pose the environmental risk of passing their transgenic (and possibly other genes) to wild species. Therefore, the larger the biodiversity is, the more complex and uncertain become the evaluation of risks posed by LMOs;
- Crops were domesticated and diversified in certain regions of the world and not equally everywhere. Most centers of origin and diversity of crops are in developing countries. It is, therefore, obvious that a mistaken release of and LMO crop variety is more likely to introduce the unwanted gene or genes permanently

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[11] Ibid
[12] Tewolde Berhan Gebre Egziabher, *Balancing Biosafety Trade Economic Development Interests in the Implementation of the of the Cartagena Protocol: A Developing Country Perspective,* http://www.biodiv.org, visited on 27/04/2008, p.33
[13] Ibid

into a developing country crop gene pool than into a gene pool of a developed country. This would jeopardize future prospects for food production in the world;

- To harmonize Trade and Environment is another concern for developing countries. Trade rules favor industrialized countries. The Agreement on Trade-related aspect of intellectual property Rights (TRIPS) is especially problematic for developing countries in the context of modern biotechnology and LMOs. Because TRIPs by its nature protects the interest of developed countries and it is this countries that have the capacity and knowledge to be protected by intellectual property.

Richard Douglas Ballhorn has developed countries' perspective on the Cartagena protocol. The Miami group (as discussed in chapter two); from its inception set out to design a protocol that would both protect the environment and reflect the realities of global trade in agricultural commodities.[14] Developed countries concern relates to the use of precautionary principle, the possibility of an eventual liability protocol, use of socio-economic considerations in decision making and the operation of Biosafety Clearing House. They also wants to ensure that the trade related provisions of the protocol are consistent with WTO Agreements relevant to trade in LMOs, and that rights and obligations under WTO and other relevant international agreements are not changed as a result of the protocol.[15]

The case of Genetic engineering is a new subject for Ethiopia. Ethiopia should be concerned about biosafety because of the unpredictable nature of biotechnology. Among the most controversial issues on genetic engineering is the extent to which biotechnologies pose a threat to the environment. Relatively little is known about their potential impacts, even those arising from the commercial introduction of modified agricultural crops by far the best studied GMOs.[16] Scientists remain concerned that the full impacts of massive introductions of GMO crops may have serious, albeit still

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[14] Richard Douglas Ballhorn, *Balancing Biosafety, Trade and Economic Development Interest in the Implementation of the Cartagena Protocol: A developed Country Perspective*, http://www.biodiv.org visited on 27/04/2008 p. 35

[15] Ibid

[16] David Hunter, *International Environmental Law and Policy*, Third edition, (2007), P. 1059.

uncertain, environmental impacts. Introducing an Ethiopian Biosafety law in place is necessary not only for nationally implementing the Cartagena protocol but also for ensuring national safety from negative impacts of imported GMOs, and the laws of neighboring countries could affect Ethiopia's safety, once released, GMOs, could simply cross borders.

Currently, Ethiopia does not have a specific law that regulates the transboundary movement of GMOs. But this does not mean that it does not have relevant laws. Therefore, the need for the drafting of a new law which strictly governs the movement of GMOs and products there of arises. In line with this, a draft regulatory framework has been developed in Ethiopia to regulate the transboundary movement of GMOs to avert the possible risks of GMOs on biodiversity, human health and the environment.
The main regulatory regime for Biosafety in Ethiopia includes the following documents:[17]

- Biosafety Proclamation (draft);
- A Directive to determine the contents of an application on transactions involving genetically modified organisms and products thereof (draft);
- A directive on risk assessment parameters of genetically modified organisms or their product (draft);
- A Directive for Risk Management Schemes (draft);
- A Directive on application for the transport of GMOs or products there of by road (draft);
- A Directive for the storage of GMOs or products thereof (draft);
- A directive for Emergency Measures for accidental release of GMOs and products there of (draft);

A biosafety policy could stand alone or be a part of a more general policy or a combination of polices, e.g. policy on biodiversity conservation, environmental protection, science and technology and sustainable development. At present there is no stand alone biosafety policy in Ethiopia. But, there are general polices which address the

[17] Supra note 6, pp 20-27

issues of biosafety. The FDRE constitution under article 43, 44 and 92 provides general direction as to how to address the problems on relation to biosafety. The Environmental policy of Ethiopia, which emanates from the conservation strategy, addresses biosafety concerns. Furthermore, The National Science and Technology Policy of Ethiopia, which emanated for the development of science and technology in Ethiopia, The National Biodiversity conservation and Research Policy and the Agricultural Research Policy are also relevant documents which incorporate elements that can contribute to the biosafety policy of the country. All these policies are necessary to control the importation and export of biotechnology product and to make use of the technology in a safe and responsible way.[18]

1.3 Statement of the Problem

The writer will try to address the following problems in the study:-

- Genetically modified organisms are increasingly becoming a source of environmental risk and human health problem. The environmental risks associated with modern biotechnology and GMOs have not yet been scientifically proven as there is still insufficient evidence as to what environmental risks may pose. The debate around GMO food safety has so far mainly focused on three concerned, allergenicity, toxicity, and antibiotic resistance[19]. Another concern or risk and probably an even more serious one than the health risk, the effect of GMO plants on the environment. The first fear is that non-target species could be harmed by crops modified to produce their own pesticides and the second fear is cross pollution.[20] Although scientists differs their views on these risks, they agree that environmental impacts need to be assessed on case by case bases. This led to the adoption of some kind of international regulation of biotechnology such as the Cartagena protocol, and other regional regulations. Though a precautionary approach has been adopted by the protocol and similar approach have been adopted by many other countries, it is said that some countries especially least

[18] Id. P. 7
[19] Supra note 16, p.1160
[20] Ibid

developing countries including Ethiopia do not have the capacity to regulate trade in GMOs due to a number of factors like poverty, corruption, lack of technology, and financial power. This belief has led to fears that least developing countries are fast becoming dumping grounds and testing centers for GMOs and this may be harmful in the long term. The validity of this claim has been assessed in this study.

- Trade in GMOs is mostly carried out between developed and developing countries. This has created the need to protect developing countries from the risks posed by the GMOs since most of them are not in a position to bargain with the more powerful developed countries that export GMOs and the rich multi-national corporations like *Monsanto* that produce GMOs. Though the Cartagena protocol is aimed at addressing the needs and interests of the least developing countries including Ethiopia, countries are still faced with many challenges that they are yet to overcome so as to effectively implement the protocol. This study assesses how the Cartagena protocol on biosafety is implemented by Ethiopia.
- The draft Biosafety regulatory regime in Ethiopia is an illustration of the many hurdles that other developing countries especially African countries are facing in implementing the protocol. Thus, this study will make an analysis of this national biosafety regulatory regime. This is done by examining how Ethiopia has integrated its international obligations under the protocol, in developing biosafety regulatory frameworks that is relevant to Ethiopia and can easily be implemented. How should a country design its legal framework has not been easy, the main challenge was perceived to be establishing an appropriate balance between potential important technological benefits and appropriate environmental and human health safeguards. This is one of the challenges Ethiopia is facing. This is one of the reasons for analyzing the legal framework of Biosafety in Ethiopia.
- The precautionary principle has been a cornerstone principle of environmental law at both the domestic and international level.[21] It is difficult to remedy environmental injury and in many cases the damage is simply irreversible. Even where damage is reparable, the cost of restoration or rehabilitation is often

[21] Id, p. 12

prohibitive. At best, the principle includes use of risk assessment, or environmental impact assessment of the potential effects of the planned activity, followed by a decision to allow it or to prohibit it. Applying preventive measures requires evidence presented in the various assessment processes regarding the consequences of the contemplated action. The question is then, from a policy point of view, whether the risk is considered acceptable and should be taken, or whether it should be prevented. Different attempts are taking place to include the precautionary principle into different legal documents. This paper will examine in what context the principle is incorporated in our laws.

- Another area of dispute is the relationship between the biosafety laws and other relevant provision in the WTO agreement. Ethiopia is in the process of acceding to WTO, therefore, harmonization of WTO rules and Ethiopian environmental laws will be the central issue. Under the Agreements of the WTO, members are bound by certain obligations that limit their right to limit imports. Any country that joins the WTO automatically becomes a party to a package of multilateral trade agreements, including the general agreement on Tariffs and Trade 1994, the Agreement on Application of sanitary and phytosanitary measures (SPS Agreement), Agreement on Technical Barriers to Trade (TBT Agreement) and other related agreements. Thus, to harmonize this international obligation with domestic laws is one of the issues the Ethiopian legislators required to address. This is one of the issues this study has looked at.
- Importing country must base its decision on risk assessment carried out in a scientifically sound manner. Risk assessment must be based at a minimum on information provided in the initial notification, and other available scientific evidence to identify and evaluate possible adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also in to account risks to human health. In reaching a decision on whether to approve the import of a particular LMO, a party of import may also take into account the precautionary principle, and certain socio-economic considerations. Carrying out and/or evaluating a risk assessment on a LMO will require a broad range of technical and scientific expertise. Decision making may require the development or significant

adaptation of domestic institutions in addition to the competent national authority. How is risk assessment conducted in Ethiopia, who is responsible for preparing this assessment and other related issues to this topic will be examined?

1.4. Objective of the Study

The overall aim of this study is to make a comprehensive analysis of the draft regulatory regime of Ethiopia by comparing selected key features with the aim of determining their compliance with related provisions of the protocol. The specific objectives of this study are:

- To give an overview of the international regulation of biotechnology with emphasis on the Cartagena protocol.
- Analyze the contentious issues during the negotiation of Cartagena protocol.
- Analyze the key issues in the biosafety debate of the convention Biological Diversity and the compromise reached.
- Analyze the meaning of biotechnology, and biosafety
- Investigate the interest of developing countries and developed countries in respect to LMOs.
- Discuss the current status of biotechnology in Ethiopia, and its level of spread.
- Identify the most critical capacity building requirements essential for establishing sufficient National Biosafety capacity for implementing the protocol effectively.
- Discuss the current status of Biosafety Framework in Ethiopia. Define National Biosafety Framework and stages critical in establishing such framework.
- Discuss the compatibility of the draft Ethiopian regulatory framework with the Cartagena protocol
- Facilitate an assessment as to what extent the biosafety regulatory of Ethiopia has or will enable it to fulfill its international obligations with regard to biosafety.
- Make some concluding remarks and recommendations from the study.

1.5. Significance of the Study

This research paper is intended to make contribution to the one going debate on as to how to develop a legal framework biosafety law in Ethiopia and it attempts to clarify some of the controversial issues of genetically modified organisms. It also hopes to contribute the raising awareness at to the relationship between trade and environment with emphasis to biotechnology. It also tries to:

- The finding and recommendation of this study will also serve as stepping ground for biosafety law makers and enforcers.
- The finding of this study will contribute as a literature in the nation's document of research works on biosafety.
- Influence on the implementation of the Cartagena protocol.

1.6. Limitation of the Study

This study in the first place focuses on the current status of biosafety framework in Ethiopia. However, this study does have some limitations:-

- It examines draft national Biosafety proclamation, and directives in Ethiopia. Both of these documents are still in draft form. This is because the biosafety drafts has not yet enacted into law. Since the regulatory regime is in draft form, the analysis advanced in relation to Ethiopia may not be relevant if a biosafety law is enacted after the completion of this study.
- It is imperative to note that environmental law is very dynamic discipline and enactment of legislation is a political matter that is often influenced and delayed by politicians due to many factors. This may make some finding of this study inconsistent with the changed circumstances.
- It cannot be claimed that this study is comprehensively exhaustive.
- This study by its nature requires knowledge of technical terms related to chemistry, Biology, and other related fields. Though at most efforts have been made to familiarize these concepts to readers, it cannot be claimed that it is exhaustive.

1.7. Research Methodology

This is largely a desktop based study which includes an analysis of the literature including the relevant primary and secondary sources of data. A comprehensive analysis of the Biosafety laws of Ethiopia will be carried out. This was essential in satisfying the objectives of this study and understanding the details that are generally associated with GMOs and modern biotechnology. Furthermore, it enables an understanding of the specific challenges that are faced by the developing countries including Ethiopia in this regard. The literature study was essential in analyzing the domestic implementation of the Cartagena protocol that will be discussed in the study.

Information will be gathered from books, internet, articles and law journals. In addition, interview with competent personalities will be conducted. And documents published by internal, international organizations and NGOs will be considered.

1.8. Chapter Outline

So as to achieve its aims and objectives, this study consists of six chapters. Chapter one which is the introduction gives the background of biotechnology, statement of the problem, literature review, objectives of the study, significance of the study, limitation of the study, and methodology. Chapter two gives an overview of the Cartagena protocol by examining the provisions of the protocol in more detail. Chapter three deals with African Model law for biosafety, and the experience of other east African countries. Chapter four and five considers the domestic implementation of the Cartagena protocol focusing on biosafety legislation in Ethiopia by carrying out a comprehensive analysis. Related provisions of the protocol are used as the basis of this study. Lastly, chapter six presents the overall conclusion and makes some recommendations.

CHAPTER TWO

2. BIOSAFETY UNDER INTERNATIONAL INSTRUMENTS

2.1. Cartagena Protocol on Biosafety

The issue of biosafety has been a concern at the international and regional levels for some time now. Genetic engineering is a relatively new technology that can provide considerable benefits but also creates uncertainties and raises questions. Biotechnology is expanding through out the world, both in developing and developed countries. Because of this global nature of biotechnology, its potential trans-boundary effects on the environment, trade, and economy, requires to the introduction of safety measures. The Cartagena Protocol is one of the international agreements that have been concluded to regulate the trans-boundary movement of genetically modified organisms (*GMOs*). Selected key provisions of Cartagena Protocol will be examined in the present chapter.

2.1.1. Background on Biosafety and the Cartagena Protocol Negotiations

Uncertainty about the environmental impacts of *GMOs* has lead to different national policy reactions. Various forms of biosafety regulatory frameworks have been or are been developed, though their operational implementation requires a well developed regulatory capacity that so far only few countries can effectively afford. Among the existing regulatory frameworks, two approaches can be broadly delineated, depending on the confidence of consumers with respect to their domestic regulators and on the relative weight given by policy makers on the potential benefits and costs of biotechnology.

On the one hand, countries that consider genetic modification safe and promising tend to set up product based regulations that test and evaluate a genetically modified product according to its characteristics and novel features. Genetically modified products are considered as conventional products and follow the regulations destined to control the

introduction of any novel product. The safety assessment of a novel product looks at the molecular, compositional, toxicological, and nutritional characteristics of the product in comparison with conventional counterpart.[1] The principal focus is the protein expression products of the inserted genes. The inserted genetic material itself is not of concern. Only possible immediate and short term effects of specific genetic manipulations on health and environment are considered making it possible to quantify risks linked to GMOs and to establish a clear decision making process. This operative regulatory system has lead to approval and rapid commercialization of biotechnology products and characterizes the regulatory framework of producing countries of genetically modified products.

On the other hand, many countries advocate for a restrained market access for LMOs or GMOs, considering them as specific products that could be carriers of ecological and sanitary hazards which scientific knowledge still cannot fully apprehend. Therefore these national regulations tend to be process based techniques of genetic modification have to go through a specific approval procedure. Restrictive measures to trade in LMOs under various forms such as labeling norms and temporary bans are applied.[2]

Biosafety related issues were discussed in a number of international forums at the same time and in many instances parallel exercises made a complicated issue even more complicated. The road to the convention on biological diversity is, roughly speaking, characterized by phases containing elements typical for any process leading to an international environmental agreement.

The first phase (1970s and 1980s) can be described as the period when the biotechnology issue emerged. As public concern grew over the implications of GMOs arising from biotechnology, questions arose from various fields. On the scientific front, there was queries regarding the possible harmful effects of GMOs while the environmental discussions focused on whether GMOs would further sustainable development.[3]

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[1] Ezra Ricci, *Biosafety Regulation: The Cartagena Protocol,* (2004) , p. 9
[2] Ibid
[3] Veit Koester, *The History Behind the Protocol on Biosafety and the History of the Cartagena Biosafety Protocol Negotiation Process*, p.6

The second phase (late 1980s and beginning of the 1990s) saw the development of an international framework to address biosafety issues as well as biosafety guidelines. An informal working group on biosafety was created in 1985 and the UNIDO voluntary code of conduct for the release of organisms into the environment (1992) as well as the OECD safety considerations for biotechnology was issued.[4] During the same period, Agenda 21 was adopted (in June 1992) during the UN conference on environment and development, chapter 16, section 4, of Agenda 21 called for the development of compatible safety procedures as a basis for guidelines to be applied on safety in biotechnology, including considerations of the need for and possibility of an international agreement.

The third phase (1988-1992), partly overlapping phase two, can be characterized as the Biodiversity convention (CBD) negotiation process. This process was rather peculiar with regard to the biosafety issue. While biotechnology was at the center of CBD negotiations from the earliest days, biosafety as an international concern only emerged much later in the process. In November 1991, Malaysia tabled a proposal on international safety measures with regard to GMOs.[5] This proposal is the origin of article 19(3) of the CBD and therefore also the origin of the CBD. It contained a core element that prevailed throughout the negotiations and later became a core element of the CBD, although formulated differently. The element was prior informed consent from countries where GMOs are to be introduced.[6]

The adoption and signature of the CBD with its article 19(3) containing a legal obligation for the parties to the CBD to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, Advance Informed Agreement, in the field of the safe handling and use of any LMO that may have adverse effect on the conservation and sustainable use of biodiversity constituted the first turning point. Article 19(3) together with article 8(g) on domestic measures and the same obligations with regard to biosafety contained in article 19(4) provided the basis for the fourth phase. Article 8(g) provides that each contracting part to CBD to establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs

[4] Ibid
[5] Ibid
[6] Ibid

resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

The fourth phase (1992-1995) also partly overlapping the second phase, can be described as the issue definition phase. It covers the period from the adoption and signature of the CBD until and including the Jakarta Mandate. The executive Director of UNEP established a panel of experts to facilitate the consideration of the need for and modalities of a protocol on biosafety. In the course of 1992/93, this panel prepared a report containing recommendations on the elaboration of the protocol as well as on the contents of such a protocol.[7] In May 1995, a panel of experts (Cairo panel) met in order to prepare a report to be included as a basis for the following step, the meeting of an open ending *Ad Hoc Group of Experts*. However, the report of the Cairo Panel did not contain clear recommendations. Finally, at COP 2 in November 1995 in Jakarta, Indonesia, a decision was taken to establish an open ended *Ad Hoc Working Group on Biosafety* to elaborate a protocol on biosafety specifically focusing on trans-boundary movements of LMOs (BSWG). This was the second turning point, which marked the beginning of the actual protocol negotiations.[8]

The final phase (1996-2000) can be defined, broadly speaking, as the negotiation phase, from the first meeting of the BSWG in July 1996 and to the resumed *ExCOP* in the Montreal in January 2000. This phase is the main subject of the study the Cartagena protocol on biosafety. The protocol was opened for signature in May 2000, at the COP to CBD. The required number of fifty parties was attained in June 2003 and, in accordance with the provisions of Article 37 of the protocol entered into force in September 2003.

2.1.2. The Major Negotiation Groups at the Cartagena Meetings

Five major groups had emerged by the final days of the Cartagena meeting. The first group consisted of the Miami Group. The Miami Group represented the major exporters of GMO crops and seeds (comprising Argentina, Australia, Canada, Chile, Uruguay, and

[7] Id. P. 7
[8] Ibid

USA) and came to be known as the Miami group (from the meeting held in that town in July 1998 to deal with the trade implication of the protocol.[9] This group's interest was to enable free trade of such genetically modified products without burdensome bureaucratic approval procedures, and with out allowing room for protectionist trade barriers disguised as environmental protection.[10]

Core concerns of this group were that the protocol should be consistent with WTO rules and based on sound science, that is, scientific evidence. In addition, they claimed that the scope of regulation should be limited to categories of LMOs, which could be judged to pose potential risks to biological diversity. Therefore, they argued in favor of excluding LMOs for food, feed and processing (LMO-FFPs), which are not destined to introduction into the environment, from the strict Advance Informed Agreement (AIA) Procedure. Moreover, they sought to limit the use of the precautionary principle and socio-economic considerations in the decision making on the grounds that this would be open to protectionist abuse. Scientific evidence, as interpreted by the WTO, should constitute the ground for any restrictive measure.

The second group was the 'like minded' group which was the largest negotiating group (measured in terms of the number of countries, population and biodiversity), comprising of countries ranging from those with no domestic regulatory structures, legislation or biotechnology industries to those with fairly developed systems. They supported the protocol, in light of the unknown effects of LMOs on the environment and human health, and given the need to protect countries without adequate regulatory or institutional capacity to effectively handle LMO imports. The Like Minded Group supported a strong statement of the precautionary principle, and was the prime backer of tough and concrete text on liability and redress.[11]

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[9] Ezra Ricci, *Biosafety Regulation: the Cartagena Protocol,* (2004) , p.12

[10] Zarilli S., *International Trade in Genetically Modified Organisms and Multilateral Negotiations: A New Dilemma for Developing Countries*, (2000), pp. 17, available at http://www.unctad.org/en/docs/poditctneddl.en.pdf accessed on 20th July 2008.

[11] Supra note 9, p.13

The third negotiating group was the European Union, which negotiated as alliance throughout the biosafety negotiations.[12] European Union took strong position because of the high pressure from environmental and consumer groups given public outrage over food safety scandals such as mad cow disease or Dixon-tainted chicken. Regarding the scope, the EU had pushed for inclusion of living modified organisms intended for direct use as food or feed, or for processing (LLM-FFPs), while acknowledging that they might merit special treatment under the AIA procedure. They also support the precautionary principle and alternative considerations for contained use, transit and pharmaceuticals for humans.

The fourth group was the 'compromise group" that emerged during the final stage of the Cartagena negotiations. This group consisted of Japan, Mexico, Norway, Singapore, South Korea, Switzerland, and New Zealand. The compromise group's specific intent was to bridge the major gaps between the other negotiating groups by developing compromise positions and alternative formulations.[13] This group included countries with high levels of biodiversity as well as those with advanced biotechnology industries provided additional reserve for addressing the range of concerns of developed and developing countries.

Lastly, the Central and Eastern Europe (CEE) also emerged as a separate negotiating bloc during the final days of the Cartagena and generally reflected a 'middle-of-the-road' position.[14] With general support for including LMO-FFPs, the precautionary principle and references to other international agreements, CEE focused primarily on the practicality and applicability of the various proposals.

2.1.3. The Major Issues of Debate at the Cartagena Negotiations

The negotiation process of the Cartagena protocol can be categorized as a difficult process, because the protocol dealt with issues related to environment and trade. Delegates of different countries mainly disagreed on the following issues:

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[12] Ibid
[13] Aaron C & Stas Burgiel, *The Cartagena protocol on Biosafety: An Analysis of Results*, (2000). P. 6
[14] Ibid

- The domain of application of the protocol and of the Advance informed Agreement procedure;
- The treatment of LMO-FFPs;
- The application of a precautionary approach in decision making;
- The relationship between the protocol and other international agreements, especially regarding trade issues and the WTO rules;
- The setting up information exchange system as well as the institutional and technical capacity building for developing countries;
- Socio-economic considerations.

2.1.4. Features of the Protocol

The Cartagena protocol on biosafety to the convention on Biological Diversity (Cartagena Protocol) was adopted in Montréal after four years of negotiation by 135 present countries on 29 January 2000. It addresses the potential adverse effects on biodiversity, taking also in to account risks to human health, of LMOs, which are defined in the protocol as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. The term LMO is usually considered to be synonymous with GMO or other similar terms, although precise definitions may vary. The protocol focuses particular on transboundary movements and is therefore relevant to international trade in LMOs. This section of the study examines selected key provisions of the Cartagena protocol which includes;

2.1.4.1. Objective

Reflecting the CBD mandate, the objective of the protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and the use of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity with specific reference on transboundary movements in accordance with the precautionary approach contained in principle 15 of the Rio Declaration on the

environment and development.[15] Generally, the purpose of the protocol is to regulate transboudary movements of LMOs with the aim of eliminating or minimizing their adverse effects to the environment and human health.

2.1.4.2. Scope

The protocol derives much of its significance from the fact that it provides the first international standard addressing some environmental and human impacts of genetic engineering. It does soon the basis of the precautionary principle, which provides that conservationist measures can be undertaken even in the absence of complete scientific information regarding the potential adverse effects that they are intended to prevent.
The scope of the Cartagena protocol on biosafety is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also in to account risks of human health, and specifically focusing on transboundary movement.[16] The scope of the protocol proved to be a highly contentious issue during the negotiation process.

It is therefore an environmental and to some extent sanitary agreement that aims to provide safeguards against the potential risks of living organisms created by means of modern biotechnology through the regulation of trade in LMOs. It does not prohibit trade in LMOs but in fact requires that environmental protection measures taken under the protocol should be the least trade restrictive as possible. Therefore, the Cartagena protocol can be summarized as an agreement that supports trade in biotechnology products while at the same time seeking to ensure that such trade is environmentally safe.[17]

In principle the protocol applies to all LMOs. This is, however, qualified by several exceptions concerning the type of LMO, the type of activity, and the type of risk.

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[15] Article 1 of the protocol
[16] Article 4 of the protocol
[17] Mann, H., *The Cartagena Protocol on Biosafety: An analysis*, (2000), available at http://www.isdlaw.com visited on 12/7/2008.

- The scope is limited to LMOs that may have adverse effects on the conservation and sustainable use of biological diversity.
- The procedures outlined in the protocol only apply to the first transboundary movement for intentional introduction into the environment.[18]
- The protocol does not apply to pharmaceuticals for humans that are regulated by other treaties.[19]
- The procedure concerning the first intentional transboundary movement of LMOs does not apply either in case of transit[20] or in cases where LMOs are destined for contained use[21] (for instance national breeding programs and research).
- The other controversial issue was whether the protocol should cover a class of LMOs known as LMO FFPs that are intended for direct use as food or feed, or for processing. In this class fall such widely traded commodities as genetically modified corn, soy, wheat, canola and tomatoes.[22]Those opposed to including commodities in the protocol had argued that commodities, since they are not intended for introduction into the environment, pose no threat to biodiversity and should not be the subject of a protocol to the CBD. LMOs intended for introduction into the environment, on the other hand such as seeds and microorganisms can mutate, migrate and multiply and therefore may pose unexpected threats to native species. Others argued that it was impossible to ensure that LMO-FFPs would not be introduced to the environment, whatever the intent. They also argued that the protocol should take into account the human health risks of LMO-FFPs, which the negotiators seem to have understood to mean human health risks from biodiversity impacts and direct contact rather than risks on food safety grounds. It had been agreed by Cartagena that LMO-FFPs would fall under the protocol's scope. The tough negotiations then concerned whether they would fall under the scope of the protocol's Advance Informed Agreement (AIA) provisions. Those opposed argued that subjecting such a massive volume of traded goods to an AIA procedure would be unworkable.

[18] Articles 7-10 and 18 of the protocol
[19] Article 5 of the protocol
[20] Article 6 of the protocol
[21] Article 6 and 18 of the protocol
[22]Article 11 and 18 of the protocol

On the whole, the protocol distinguishes between three categories of LMOs covered by separate provisions:

- LMOs intended for introduction into the environment (such as transgenic seeds, subject to the AIA procedure, Article 7-10 and Annex I);
- LMOs intended for contained use (research purposes, free trade as far as it follows the importing countries standards, article 6.2);
- LMOs intended for food, feed, or further processing (article 11 and annex II).

2.1.4.3. Advance Informed Agreement (AIA)

The key mechanism and the centerpiece of transparency framework of the Cartagena Protocol is the Advance Informed Agreement (AIA). The AIA requires that before the first intentional transboundary movement of a specific LMO into its jurisdiction, the party of import is notified of the proposed transboundary movement, receives information about the LMO and its proposed use, and is also given an opportunity to decide whether or not to allow the import of the LMO, and upon what conditions if any.[23]

More specifically, the first time that a new GMO variety is exported for intentional introduction into the environment, the exporting country would notify in writing the importing country, before the movement of LMOs takes place.[24] Information requirement for the notification are included in annex I, which notably entails the obligation to provide to importing country and the Biosafety Clearing House (BCH):

- Information about the characteristics of the LMO;
- The size of the shipment ;
- A copy of the risk assessments that was done in the party of export, and;
- Its regulatory status in the exporting country.

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[23] Mackenzie, Ruth, Burhenne-Guilmin, Francoie, La Vina, Antonio G.M and Werksman, Jacob. D. in cooperation with A Scencio, Alfonso, Kinderlerer, Julian, Kummer, Katharina and Tapper, Richard, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, (2003), P.63

[24] Article 8 of the protocol

2.1.4.4. Scope of application of the AIA procedure

The scope of application of the AIA procedure is laid out in Article 7(1) and 7(2). Article 7(1) state that the AIA procedure shall apply prior to the first intentional transboundary movement of LMO for 'intentional introduction into the environment'. This phrase is however not defined in the protocol. However, on the face of article 7(1), it may be some what unclear whether AIA will be required each time a particular LMO is imported into a party for the first time from a new party of export, or whether it only applies the first time a particular LMO is imported into the party of import from any party- after which, assuming the first import is allowed, imports of the same LMO should be allowed under the same conditions from all parties. Instead article 7(2), confusingly specifies that the term 'intentional introduction' does not refer to LMO intended for direct use as food or feed, or for processing.

Article 7(4) contains a different kind of exception regarding LMOs in transit, LMOs destined for contained use and LMOs identified in a collective decision of the COP as being not likely to have adverse effects. The protocol gives no guidance as to what information or evidence might be required to support such a conclusion. Nonetheless, any such decision would need to be made in light of the precautionary principle. So in practical terms the AIA will apply particularly to the growing of agricultural crops, the release of fish and of modified microorganisms.[25]

2.1.4.5. Notification

Article 8 addresses the first step in the AIA procedure, which is the notification of the proposed transboundary movement to the party into which the LMO is to be imported. According to article 8(1), the exporting country or the exporter shall notify the importing country prior to the first intentional transboundary movement of an LMO that fall with in the scope of the AIA procedure under article 7(1). The notification must take place before the first transboundary movement of the LMO into the party of the imported is initiated. The notification shall contain, at the minimum, the information specified in Annex I.

[25] Supra note 23 , p.65

Annex I covers a wide range of information, which may be loosely grouped into three categories: first, is information concerning the LMO itself aimed at providing the importing country with factual information; second, the regulatory status in the exporting party intended to inform the country of import about the cost benefit assessment of the state of origin; and lastly, the suggested methods for the safe handling and use.

Article 8 places the primary obligation regarding notification on the party of export. However, article 8 does not specify in what language the notification should be made whether it is the language of the party of export, the party of import, or some other language. As with other provisions of the protocol, in order to be effective, article 8 will need to be implemented in the domestic law of parties in relation to both exports and imports of LMOs. Article 8(2) obliges the party of import to require the exporter to provide accurate information about the LMO under national law. The information referred to here is that required for the notification, as indicated in annex I. information provided under article 8 may be subject to confidentiality requirements in accordance with article 21.

2.1.4.6. Acknowledgement of Receipt

Article 9 requires the importing state to acknowledge receipt of the information to the notifier with in 90 days of its receipt.[26] The acknowledgement shall include the date of receipt of the notification, information whether to proceed according to the procedure specified in article 10, or in accordance to the domestic regulatory framework of the party of import that shall be consistent with the protocol. The purpose of the acknowledgement of receipt of notification is to confirm receipt to the notifier and to confirm on preliminary bases whether the notification is in order and that it contains the required information. Finally, under article 9(4), if the party of import fails to acknowledge receipt of a notification within 90 day deadline, its consent to the proposed transboundary movement is not automatically implied.

[26] Article 9(1) of the protocol

2.1.4.7. Decision Procedure

Article 10 of the protocol sets out the procedure to be followed by the party of import in reaching its decision, this decision is whether to allow the first transboundary movement of a LMO into its territory. Article 10(1) provides that decisions taken by the importing party shall be in accordance with article 15. The main requirements of article 15(1) is that risk assessment in accordance with Annex III be carried out in a scientifically sound manner and must be aimed at evaluating the possible adverse effects of LMOs. Article 10(2) provides that the importing state shall, together with the acknowledgement of receipt, notify to the exporting state as to whether the transaction shall proceed only after the party of import has given a written consent or after no less than 90 days with out a written consent.

If the importing state opts for a written consent, article 10(3) defines the time limit for an import decision and the possible content of that decision which is 270 days whether or not consent is granted, whether the period 270 days shall be extended, whether additional information is required. Except in case where the consent is unconditional, the importing country shall also disclose the reasons on which its decision was based in accordance with article 10(4). The reasons given for a decision are likely to be important in the event that the notifier wishes to challenge the decision or where the notifier subsequently requests the review of the decision. The negotiators of the Cartagena protocol were faced with a question of which rules to apply, if the importing party fails to communicate its decision.

Article 10(5) states the failure to communicate, 'shall not imply its consent' to the transboundary movement. However, article 15 does not specifically state what rules will apply in this case. From the different wording of the provision, one can conclude that after a comparative analysis of article 11(7), article 10(5) must be read as requiring explicit consent before any transboundary movement can commence. This provision is largely intended to protect countries which may, for whatever reason, have been unable to communicate a response within the 270 day period specified. However, it is not intended to make way for an open ended undue delay.

Lastly, another important aspect that is not specifically provided for in the protocol is the question whether exporting countries are bound to enforce consent requirements, i.e. to allow the export only in cases where written consent has been notified by importing country. The protocol does not contain an explicit obligation by importing country. The protocol does not contain an explicit obligation on his regard. Nevertheless, as one of the main purposes of any procedure of prior informed consent is that exporting countries have to enforce importing countries decisions.

2.1.4.8. Procedure for LMOs Intended for Direct Use as LMO-FFPs

LMO-FFPs are not subject to the AIA procedure that covers other LMOs, but are covered by a separate, less restrictive, procedure outlined in Article 11. These include:

I. Notification of National Regulations

According to article 11(1), a party that makes a final decision regarding domestic use of a LMO-FFP that may be subject to transboundary movement shall inform the parties through the Biosafety Clearing-House (BCH) system with in 15 days of reaching that decision.[27] This notification shall include the information as set out in Annex II[28], and corresponds in large part to the information required in notifications made under article 8 of the protocol, although there are some significant differences.

The purposes of notification to the BCH under article 11(1) are to put other parties on notice that the LMO in question may be exported for food, feed or processing use and to provide relevant information on that LMO that another party can use when deciding whether or not to allow the import of that LMO for food, feed or for processing in its territory.[29] It is therefore essential that all parties have access to this information. Under article 8(2) of the protocol, parties are required to ensure that under their domestic law there is a requirement for accuracy of information provided in relation to LMO-FFP.

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[27] The Biosafety Clearing House is the key mechanism of the Cartagena Protocol for centralized information exchange.
[28] Annex II contains information required concerning LMOs intended for direct use as food or feed, or for processing under article II.
[29] Supra note 23 , p.87

Under article 11(3) any party may request additional information from the authority identified in paragraph (b) of Annex II.

II. Domestic Regulatory Frameworks Regarding Import Decisions

Article 11(4) asserts the right of parties to require prior approval of imports of LMO-FFPs by referring to national decision of imports. Thus, although LMO-FFPs are outside the scope of application of the protocol's AIA procedure, in their domestic regulatory framework parties may choose to require advanced notification and approval of a proposed transboundary movement of a LMO-FFP. In addition the regulatory framework must be consistent with the objective of the protocol. However, article 11(4) does not contain an obligation, but merely asserts a party's right to make a decision for imports of LMO-FFPs under its domestic regulatory framework that is consistent with the objective of the protocol. Furthermore, beyond consistency with the objective of the protocol, article 11 does not specify any particular procedural requirements to be reflected in domestic regulatory frameworks applicable to imports of LMO-FFPs.

Article 11(5) of the protocol intended to promote transparency and predictability, by requiring parties to notify through the BCH relevant national frameworks that they will apply to imports of LMO-FFPs. It requires parties to make such decisions, laws and regulations available to the BCH. However the protocol does not specify in which language or format the information on relevant national regulations is to be made available.

Article 11(6) addresses the specific needs of developing countries or countries that have economies in transition including Ethiopia which do not yet have in place a domestic regulatory framework addressing imports of LMO-FFPs could nonetheless subject such imports to prior notification and approval procedures in a manner consistent with the protocol's objective. Any such party which does not have a domestic regulatory framework for LMO-FFP imports in place, but which wishes to subject such imports to prior assessment and approval, should indicate this to the Biosafety Clearing House, on which information has to be provided under article 11(1), and will be taken according to a

risk assessment in accordance with Annex III and a decision made within predictable time frame not exceeding 270 days.

If one compares the procedure for LMO-FFPs under article 11 to that of LMOs destined for intentional introduction into the environment under the AIA procedure, two main differences can be observed. Firstly, while the protocol itself mandates a specific procedure to be followed for LMOs of the latter category (the AIA procedure), it does not do the same for LMO-FFPs, but only offers developing countries the possibility to declare a specific procedure as applicable under the protocol. So the importing party has to trigger off the procedure by a specific declaration and, thus, carries the relevant burden. Secondly, while the AIA procedure provides for the requirement of consent before a transaction can take place, under article 11(6), exports may also take place without explicit consent of the importing country.

In summary, it can easily be noticed that the procedural protection which is offered especially to developing countries by article 11 is far lower than that presented by the AIA procedure. Lastly, article 11(8) explicitly allows the parties to take a precautionary approach to decision making on imports. In addition, the general rules concerning risk management and socio-economic considerations are also applicable.

2.1.4.9. Handling, Transport, Packaging and Identification

Article 18 addresses the handling; transporting; packaging and identification of LMOs have two functions. First, is to ensure that LMOs are handled and moved safely to avoid adverse effects on biodiversity and human health. Second, is to provide information to those handling LMOs and to the party of import. Article 18(1) imposes a general obligation on each party to the protocol to require safe handling, packaging and transport of LMOs subject to transboundary movement.[30] This provision is linked to more general obligations upon parties to the protocol and to the CBD to regulate, manage and control

[30] Article 18(1) of the protocol

risks associated with LMOs.[31] A number of countries have in place rules and standards that are relevant to ensuring safe handling, packaging and transport of LMOs.

Article 18(2) requires parties to take measures to ensure that LMOs subject to intentional transboundary movement are accompanied by documentation. This documentation should identify the LMOs and provide contact details of the individuals and institutions responsible for the movement of LMOs. The documentation requirements in article 18(2) are a means of identifying and tracking the transboundary movement of LMOs. However, article 18(2) does not specify the language of documentation accompanying LMOs and it also provides vague identification requirements. In case of LMO-FFPs, the documentation accompanying a shipment must clearly indicate that it may contain LMOs and that the commodities are not intended for intentional introduction to the environment.[32] Furthermore, LMOs intended for contained use must identify the shipment as containing LMOs, and must specify any requirements for safe handling, storage, transport and use, and the contact point for further information.

Lastly, article 18(3) states that the conference of parties (COP) shall consider the need for, and modalities of developing standards with regard to identification, handling, transport, and packaging of LMOs products. The Intergovernmental Committee on the Cartagena Protocol (ICCP) has initiated preparatory consideration on this issue. The vagueness of article 18(1) and 18(2) illustrates that the parties could not arrive at greater compromise during negotiations. Instead, they postponed further measures to the COP.[33]

2.1.4.10. The Precautionary Principle in the Protocol

The precautionary principle says that in some cases particularly where the costs of action are low and the risks of inaction are high preventive action should be taken, even without full scientific certainty about the problem being addressed.[34] In practice this gives the

[31] Article 8(g) of CBD, and article 16 of the protocol
[32] Article 18(2) (a) of the protocol
[33] Goldman Karen, Labeling of Genetically Modified Foods: Legal Scientific Issues, *Georgetown international environmental law review,* (2000). P. 717 & 721
[34] Sands P, *Principles of International Environmental Law',* second edition, (2003), p.212

governments a fair amount of discretion in setting environmental policy. They must decide in the face of uncertainty how high the risks are likely to be, how this compare with the costs of action, and what type of actions, if any, are justified. After establishing that parties could take a precautionary approach to deciding what restrictions they might put on the import of LMOs, the real negotiations thrashed out how to operationalize the principle of precaution. Some feared that the precautionary principle could be an excuse to restrict trade in harmless goods, to protect domestic producers. They argue that such restriction should be based on sound science and rigorous risk assessment. Others argued that the sound science argument itself was an excuse to limit the use of established principle of international environmental law.

The precautionary principle has developed rapidly in international environmental law over the past couple of decades. It first emerged in American and German law, was progressively developed in international documents until its inclusion in the Declaration of the 1992 UN Conference on environment and development (Rio Declaration) conferred it a global recognition. Principle 15 of the Rio Declaration reads as follows:

> *In order to protect the environment the precautionary approach shall be widely used by states according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used for postponing cost-effective measures to prevent environmental degradation.*[35]

Principle 15 constitutes a significant step forward in the development of international environmental law principles but it is noteworthy that the opposition of some states to the development of a precautionary principle led to water down precautionary approach. Following the lead provided by the Rio Declaration, the Cartagena protocol also uses the term approach rather than principle.

[35] The United Nations, Rio Declaration on Environment and Development, (1992)

The convention on Biological Diversity of June 1992 also recognizes the important role of precaution in biodiversity related matters, but only in its preamble which does not give precise definition and content to the principle.[36]

The Cartagena protocol goes much further than the convention and gives a central importance to the precautionary approach in the case of biotechnological risks. It not only reaffirms it in its preamble in its objective clause (article I) but also in article 10(6) and 11(8), which are more operational provisions. Article 10(6) which determines the conditions for taking decisions on the first intentional transboundary movements of LMOs states that:

> *Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the party of import, taking also into risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of that living modified organism.*

The central place of the precautionary approach in the protocol is reflected in the fact that the protocol explicitly allows parties to take precautionary measures. The right to set up precautionary measures may nonetheless be limited by the obligation in article 12 on the importing party to review the decision in light of new scientific evidence on request of the exporting party. The protocol binds national regulatory authorities to implement a decision making process ensuring precaution. It obliges states to make an effort in good faith to use the means at its disposal to prevent possible detrimental effect on the environment. It implies however, the need to clarify how a risk based approach can continue to be followed when the scientific uncertainty is such that conventional risk assessment cannot in it self determine the level of risk, and how decisions should be made on appropriate precautionary measures.

[36] Convention on Biological Diversity,(1992), preamble

The importance of the precautionary approach in the Cartagena protocol has been well captured by Robert Falkner who notes that:

> *The Cartagena protocol was negotiated without evidence of concrete environmental damages resulting from the release of GMOs into the environment. What is more, the scientific community was deeply divided over the potential risks involved. Thus the biosafety agreement is a truly precautionary instrument, setting rules for decision making that seek to minimize the risk of future, potential, damage. This precautionary character goes some way in explaining the difficulties encountered in reaching agreement on the protocol. Although most countries accepted the need for precautionary action, some feared that biosafety regime would unnecessary slow down progress in biotechnological development and hamper international trade in biotechnology*[37].

2.1.4.11. Risk Assessment and Management

The objective of risk assessment under the protocol is, to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biodiversity, taking in to account risks to human health. Key elements of effective risk management include monitoring systems, research programs, technical training and improved domestic coordination amongst government agencies and services. The actual process of deciding as such can be characterized as weighing of policy alternatives in light of considering the risk assessment and possibly other factors.

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[37] Bail Christoph, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development,(* 2002), p.4

I. Risk Assessment

Risk assessment is inherently the most critical component of biosafety implementation. In trying to understand general principles regarding the concepts of risk assessment, it is important to consider the definitions perceptions attached to risk and hazard. Risk has been defined as the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequence will occur. Hazard on the other hand has been defined as the potential of an organism to cause harm to human health or environment. Risk assessment therefore is a measure of the probability of its occurrence and the extent of the resulting damage.[38]

Article 15 establishes the basic requirements for risk assessment under the protocol, and refers to Annex III for further guidance. Article 15 and Annex III are, therefore, closely connected. The protocol requires that decisions regarding the import of LMOs for intentional introduction into the environment to be taken in accordance with risk assessment.

Article 15(1) provides that risk assessment must be carried out in a scientifically sound manner and must be aimed at evaluating the possible adverse effects of LMOs. There is no definition of the phrase 'scientifically sound manner' in the protocol.[39] Further more, the protocol does not explain the term 'possible adverse effects'. The possible adverse effects of LMOs that are to be identified and evaluated are those that might affect the conservation and sustainable use of biological diversity, taking also in to account risks to human health.

Article 15(2) places an obligation on parties of import to ensure that risk assessment are the basis for reaching decisions on proposed imports of LMOs that are subject to the protocol's AIA procedure. The party of import may perform the risk assessment, or alternatively, the party of import may require the exporter to carry out risk assessment. In some countries, national authorities perform a risk assessment, on the basis of information provided by applicant.

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[38] Mugoyu Charles, *Resource Book for Implementation of Biosafety in East Africa*, p.15
[39] Supra note 23, p.108

Annex III specifies the modalities of risk assessment. Accordingly risks associated with LMOs should be considered in the context of the risks posed by non-modified recipients. Annex III, further, sets out the methodology for the risk assessment as well as the aspects that have to be taken into account. Thus, Annex III does not only point to the requirement of scientific soundness, but also provides a point of reference for the risk management technique.

The risk assessment involves several steps, including:

- The identification of potential adverse effects;
- An assessment of the likelihood that the potential adverse effects occur;
- An evaluation of the consequences that may arise where these adverse effects come to be realized, and
- An estimation of the overall risk in relation to each adverse effect, based on evaluation of its likelihood and consequences.

Moreover, as part of risk assessment, Annex III provides for recommendation to be made as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to mange these risks. However, risk assessment sometimes cannot provide clear-cut information on which to base decision. Lack of scientific knowledge or scientific consensus should not necessary be interpreted as indicating a particular level of risk, an absence or risk, or an acceptable risk.[40] Therefore, areas where uncertainty remains regarding the level of risk may be addressed by further investigation on the specific issues concern or by implementing appropriated risk management strategies. Besides, monitoring the LMO in the receiving environment would provide further information on the LMO and would enable to institute appropriate risk management measures should any adverse effects be detected. Nevertheless, if there is insufficient information available or an inadequate risk assessment on which to base a decision, the party of import ultimately has the right to refuse the import on a precautionary basis.

[40] Annex III.4 of the protocol

II. Risk Management

No technology or human activity is completely risk free. People accept new technologies because they believe the potential benefits outweigh the potential risks. Risk management is the use or application of procedures and means 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.[41] Article 16(1) deals with management of risks posed by those organisms that fall within the scope of the protocol (i.e. all LMOs covered by article 4) and refer to the provisions of article 8(g) of the CBD. Article 16(1) places an obligation on parties to set up appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provision of the protocol. However, the protocol does not give any specific guidance on how suitable risk management strategies may be identified. In order to manage risk, risk management strategies need to be effective when applied in practice by those who will have the responsibility for implementing them.

Article 16(2) refers to the measures to regulate, manage and control those risks that are identified through the risk assessment provisions of the protocol, as described in article 15(1) and 16(1). However, the protocol does not comprehensively regulate the risk management process, but it deals with three related issues in this context. These include: scientific uncertainty, socio-economic considerations and necessity. The precautionary principle remains within the overall context of the decision making according to scientific criteria. Most developing countries including Ethiopia do not have efficient regulatory systems and agencies to carry out risk management and this frustrates the whole process.

Thus the protocol therefore, requires each party to notify and consult other affected or potentially affected governments when it becomes aware that GMOs under its jurisdiction may cross international borders due to illegal trade or release into the environment. This will enable the parties to pursue emergency measures or other

[41] Biosafety and the Environment: *An Introduction to the Cartagena Protocol on Biosafety*, (2003), available at http://www.biodiv.org visited on 30, June 2008

appropriate action. Government must establish official contact points for emergencies as a way of improving international coordination.

2.1.4.12. Biosafety Clearing House

One of the important functions of the protocol is to foster information exchange among state parties. The main purpose of Biosafety Clearing House is to:

- Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs;
- Gather all national regulations as well as the final decisions, with a summary of risk assessment underlying them.

In practice, governments shall indicate to the BCH one national focal point to be responsible on its behalf for administration liaison with the secretariat of the protocol. Competent national authorities are required to provide the Biosafety Clearing House with information specified in paragraph a-e of article 20(3), in particular:

- Any existing laws, regulations and guidelines for implementation of the protocol, as well as information required by the parties for the AIA procedure;
- Any bilateral, regional and multilateral agreements and arrangements;
- Summaries of risk assessments or environmental reviews of LMOs;
- Final decision regarding the importation or release of LMOs and;
- Reports of monitoring on the implementation of its obligations under the protocol;

The BCH will therefore help parties in fulfilling their obligations by making available useful information for national competent authorities, such as rosters of biosafety experts, risk assessment reports, and national decisions regarding the imports of LMOs. Moreover, it will increase transparency vis-à-vis consumers by facilitating their access to information on biosafety. The effective operation of the BCH will notably depend on the active participation of parties.

2.1.4.13. Public Awareness and Participation

It is clearly important that individual citizens understand and are involved in national decisions on GMOs. The protocol therefore calls for cooperation on promoting public awareness of the safe transfer, handling and use of GMOs. Public awareness and participation is dealt with by article 23 of the protocol. Parties may on a discretionary or mandatory basis under take to provide information on LMOs to the public,[42] include public participation in LMO related decision making process, and provision of information to the public about access to the BCH.

Article 23(1) does not explicitly require parties to make specific information available to the public. The obligation is some what softer. Parties are required to promote and facilitate public awareness, education and awareness regarding LMOs, and are to endeavor to ensure public awareness and education on LMOs that may be imported. Article 23(2) of the protocol lays down affirmative obligations on parties to consult the public in the decision making process regarding LMOs and make results of such decisions available to the public. The obligation to consult the public applies generally to all decision making processes regarding LMOs, including the making of decision on imports of LMOs.

However, Article 23(2) does not provide specific guideline on the public consultation mechanisms to be adopted in decision making processes and how to make results of decisions on LMOs available to the public. This effectively leaves it up to the parties to decide how this obligation should be implemented in their own national context. Under article 23(3) each party shall endeavor to inform its public about the means of public access to the BCH. It further requires the parties to take steps to inform the public about the means of access to information contained in the Biosafety Clearing House. However, the phrase 'shall endeavor' in article 23(3) appears not to create an obligation on the parties to inform the public about the means of information of access.

[42] Article 23(1) of the protocol

Thus the protocol therefore, calls for cooperation on promoting public awareness of the safe transfer, handing and use of GMOs. It specifically highlights the need for education, which will increasingly have to address GMOs as biotechnology becomes more and more a part of our lives. The protocol also calls for the pubic to be actively consulted on GMOs and biosafety. Individuals, communities and non-governmental organizations should remain fully engaged in this complex issue. This will enable the people to contribute to the final decisions taken by governments, thus promoting transparency and informed decision making. However, in many countries especially the developing countries the right of public participation and awareness is included in their biosafety legislation but it is hindered by many factors such as financial constraints, language barriers and high illiteracy levels where by local population does not even know that such a right exists and they are entitled to it.

2.1.4.14. Compatibility of the Protocol with other International Agreements

The Cartagena protocol is not only an environmental agreement but also a trade agreement, since it provides for trade in LMOs regulation. Indeed, besides technical and financial support, as well as information exchange, trade regulation is considered the main and most effective instrument to promote the goal of the protocol. Parties to the protocol are entitled to set up measures, such as bans or notification and labeling requirements, to control international trade in LMOs to safeguard environmental and health concerns. It is worth noting that these trades related environmental measures can be applied for precautionary purpose. Therefore, may be applied without supporting scientific evidence concerning the risks the measures intend to prevent. However, this flexibility is balanced by the requirement that measures may only be imposed to the extent necessary to prevent the adverse effects of LMOs to the conservation of the environment and health.[43] Moreover, decisions can be reviewed on the request by exporting country when new circumstances or information could influence the outcome

[43] Article 16 of the protocol

of the risk assessment upon which the decision was based.[44] These latter provisions clearly aim at ensuring WTO consistency by preventing trade discrimination and unjustified measures, and reflect the endeavors to balance trade interests and environmental protection concerns.

The relationship between the protocol and other international agreements, in particular the WTO agreements, has been one of the difficult issues that negotiators had to address but failed to clearly solve in the end.

The central question is the hierarchy between environmental and trade agreements. Some negotiating parties, especially countries producing LMOs gathered in the Mini Group, wanted to make sure that the protocol would not justify unnecessary protectionism (not fully based on scientific principles) or discriminatory treatments disguised under environmental measures. Others, in particular the EU and the Like Minded Group, wanted to prevent the subordination of the environmental concerns to trade interests, and make sure that any trade related environmental measure they might set up by virtue of the protocol would not be challenged under the WTO. Both claims have been reflected in two separate clauses of the preamble of the protocol.

- The first clause highlights that the protocol does not imply 'a change in the rights and obligations of a party under any existing international agreement'.[45] This is commonly referred to saving clause, which cautions parties to implement the protocol in a manner that is consistent with their other international rights and obligations. It inserted at the request of countries that were worried the protocol might be interpreted as altering the obligations contained in WTO treaties, in particular the non-discriminatory requirements and the requirements that sanitary and phytosanitary measures must be based on scientific principles. In particular, the Miami Group wanted to protect WTO rights and obligations in order to provide sustainable market access for their biotechnology products.

[44] Article 12 of the protocol
[45] The preamble of the protocol

- The second clause emphasizes that the 'the above recital is not intended to subordinate this protocol to other international agreements'. This is meant to highlight that while WTO obligations are not affected by the protocol, the former should not detract any thing from the substance of the new obligations adopted under the protocol, satisfying the claims of the EU and the Like Minded Group.

While the two clauses just mentioned are phrased generically, they appear just after a paragraph recalling that trade and environment should be mutually supportive with a view to achieving sustainable development. The relationship envisaged here thus concerns mainly the interaction between the protocol as the environmental agreement and the WTO agreements as trade agreements. The two clauses inserted in the protocol make the situation inconclusive with regard to the interpretation of environment and trade agreements in the case of conflict between states obligations under the protocol and under WTO agreements. The second clause seems intended to counterweight is the clear scope of the saving clause, as if it aimed at undermining it, which would raise questions.

However, in the absence of a binding dispute settlement mechanism in the context of the Biodiversity Convention,[46] these clauses provide a reminder to any other adjudicative body, such as a WTO Dispute Settlement Body, that obligations under the protocol cannot be sidelined as irrelevant to the solution of a dispute.

2.1.2.15. Liability and Redress

The issues here are straight forward, if hard to settle. The question is whether, and in what from, to create a liability and redress mechanism for any damage resulting from the transboundary movements of LMOs. A consensus could not be reached regarding liability and redress during the negotiation process. Developing countries asked for substantive provisions for a liability regime that would determine the extent to which each actor would be liable for damages, while producing countries wanted no provision at all on liability. Proponents for inclusion of liability and redress clause argued

[46] The Convention provides that disputes between parties should in principle be solved by negotiation, see article 27 for further details.

convincingly that if it were eventually exercised, then by definition there must have been a need for it. If it were never exercised, there would have been no harm done in including it. The questions of whether had more or less been settled by the time of the Montreal Meeting, leaving just the questions of how and when. Finally, the protocol provides that the conference of the parties will have the task of elaborating rules and procedures in this regard with in four years of the protocol entry into force.[47]

2.1.2.16. Socio-economic Considerations

Under article 26 of the protocol, in making import decisions, parties can take into account socio-economic considerations arising from the import of LMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biological diversity to indigenous and local communities. Article 26 addresses the extent to which parties are entitled to take socio-economic considerations into account in reaching decisions on imports of LMOs. Article 26 of the protocol requires that such considerations be taken into account consistent with a party's other international obligations. Finally, it encourages parties to cooperate on research and information exchange on the potential socio-economic impact of LMOs.

This provisions aims at countering the risk of genetically modified seeds replacing traditional ones and affecting local environment, culture, knowledge and tradition. Indeed, developing countries feared that the introduction of LMOs cultures would lead to the displacement of traditional varieties, the substitution of traditional crops by transgenic crops promoted by multinational corporations, and more broadly a weakening of their agricultural exporting sector.

The range of socio-economic considerations contemplated in article 26(1) of the protocol covers only those 'considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities'. This wording clearly indicates

[47] Article 27 of the Cartagena Protocol , the following webpage informs on the ongoing discussion on this topic: http://www.biodiv.org/biosafety/liability/asp visited on 27/12/2008

that not all socio-economic considerations may be taken into account, but rather only those that arise from the impact of LMOs on biological diversity.[48]

2.1.4.17. Supportive Measures

The preamble of the Cartagena protocol acknowledges the need to take into account the limited capacities of some parties especially the developing countries, to cope with the nature and scale of known and potential risks associated with LMOs.[49] The protocol provides for measures aimed at mainly building the capacity of developing countries and economies in transition, in implementing the protocol,[50]ensuring that import decisions are within the context of the AIA procedure, the information sharing and Biosafety Clearing House(BCH) mechanism, and a system of financial resources to facilitate it implementation for developing countries.[51]

The supportive measures of the protocol have to some extent generally addressed the needs of the developing countries including Ethiopia. For example, the Global Environmental Facility (GEF) which is the financial mechanism for the protocol provides funds to ensure that at least a certain level of financial resources is available to developing countries. But there are still some inadequacies that have to be addressed before developing countries can fully benefit from the supportive measures, in particular, it will be noted that many of the provisions that contain supportive measures contain no specific commitments and are couched in soft terms, and framed as mere obligations to co-operate.

2.1.4.18. Monitoring and Enforcement Mechanisms

Monitoring is a process of keeping track of activities so as to determine whether they are in schedule and whether they are meeting the target objectives.[52] The purpose of the monitoring and evaluation is to gather data concerning the modified organism in order to

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[48] Supra note 23, p. 163
[49] Asif H.Qureshi, '*The Cartagena Protocol on Biosafety and WTO –Coexistence or Incoherence'*, p.845
[50] Article 22 of the Protocol
[51] Article 28 of the Protocol
[52] Supra note 38, p.33

assess the extent, to which transgenic have impacted on the environment, and human health. The Cartagena protocol has various institutions and enforcement aspects that are meant to implement the protocol and also ensure compliance as per article 34 of the protocol. First, the protocol establishes the Conference of the Parties (COP) which it shares with CBD and it serves as the conference of the parties to the protocol (COP-MOP).[53] The COP has the powers to make decisions that are necessary to promote effective implementation of the protocol and is also charged with undertaking further work on the issues that were left unresolved by the protocol. Secondly, the protocol establishes subsidiary bodies of the CBD in relation to the protocol.[54] Under article 30 of the protocol, the subsidiary bodies may be asked to provide scientific, technical, or technological advice to COP/MOP of the protocol.

At present there is only one standing subsidiary body established by CBD. This is the subsidiary body on scientific, technical and technological advice, established under article 25 of the CBD. Thirdly, the protocol provides for the secretariat that is established by article 24 of the CBD.[55] One of the main functions of the secretariat is to administer the protocol and to act as day today contact point for the protocol of the parties for parties, international organizations and others. The secretariat also prepares documentation for meetings of the governing and subsidiary bodies of the protocol, and is also in charge of organizing and servicing the meetings. The secretariat also plays an important role in the functioning of the Biosafety Clearing House (BCH). Furthermore, the COP/MOP may assign additional specific functions and tasks to the secretariat.

The protocol also has various enforcement aspects that are meant to ensure compliance with the protocol. Firstly, the protocol relies on the national system for its enforcement by providing for national legislation to penalize transboundary movements in contravention of domestic measures implementing the protocol.[56] Secondly, the protocol sets up a monitoring mechanism where the parties are to individually monitor the implementation of the protocol, and report from time to time to the conference of the parties on 'measures

[53] Article 29 of the Protocol
[54] Article 30 of the protocol
[55] Article 31 of the protocol
[56] Article 25 of the protocol

taken to implement the protocol'.[57] Lastly, the protocol requires that each party shall designate one national focal point and one or more competent national authorities that shall be responsible for performing the administrative functions required by the protocol.[58]

Enforcement provisions of the protocol are necessary for the effectiveness of the protocol since most of the provisions are couched in soft terms and the obligations are too general and not self executing. This suggests that the parties have to enact substantive domestic legislation and also put in place effective monitoring systems. There is also some kind of duplication of the provisions by the protocol as some are already provided for by the CBD.

[57] Article 33 of the protocol
[58] Article 19 of the protocol

CHAPTER THREE

3. AFRICA MODEL LAW ON SAFETY IN BIOTECHNOLOGY

In Africa countries are trying to put in place measures to ensure the necessary capacity is established to enable member countries to reap the possible benefits from modern biotechnology while at the same time, avoiding the possible risks.[1] To address this challenges, the former Organization of African Unity (at present African Union) assembled a group of biosafety experts in June 1999 to draft a comprehensive framework of biosafety regulations that would serve as a model law, designed to protect Africa's biodiversity, environment and the health of its people, from the risk posed by GMOs.[2] This initiative resulted in the African model law on safety in Biotechnology (Model Law), which was finalized in May 2001, in Addis Ababa, Ethiopia, by 89 participants representing 35 African countries.[3]

At its 74 ordinary session convened in Lusaka, Zambia in July 2001, the OAU council of Ministers endorsed the Model Law. The Council furthermore urged its member states to use the Model Law to draft their own national legal instruments in order to create a systematic and Africa wide biosafety regime to regulate the movement, transport, and import into Africa of GMOs. The Model Law has been strongly influenced by the Cartagena Protocol on biosafety.

The model law specifically recognizes that Africa's biodiversity, environment and the health of its people can only be protected if countries in Africa adopt high standards of safety. Furthermore, it seeks to subject the entire spectrum of GMOs, associated products and GMO related activities to rigorous safety assessments. The model law therefore considers the rules established by the biosafety protocol as a floor rather than a ceiling in determining the regulatory framework. In this regard, the model law fully utilizes the

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[1] African strategy on Biosafety, (2006), p. 2 available at http://www.african-union.org visited on 10/11/2008.
[2] Mayer Miriam, *Why African should adopt the African Model Law on Safety in Biotechnology,* available at http://www.biosafetyafrica.org, visited on 22 July 2008.
[3] Ibid

discretion given by the protocol to the parties to adopt more protective measures than the agreed minimum set out in the protocol.

This approach is also in keeping with the need for special measures to be taken to conserve plant diversity and to retain the integrity of centres of origin of major crops. In this regard, the biosafety protocol expressly recognizes the crucial importance to humankind of centres of origin and diversity. The Sub-Saharan savanna belt that stretches from Lake Chad to eastern Sudan is, for example, considered to be the centre of origin of sorghum and pearl millet, Sub-Saharan Africa is also the centre of diversity of cassava while Ethiopia, the Saharan oases and Sudan, are centre of genetic diversity of wheat.[4] These are major source of food for millions of people requiring the highest standards of safety and protection from genetic contamination.

Furthermore, the model law adopted the approach that proper application of the precautionary principle demands through regulation of the series of activities that may be undertaken in respect of a GMO. These activities include the import, transit, contained use, released or placing on the market of a GMO and the product of a GMO.[5]

Finally, the model law strives to provide a holistic and comprehensive set of biosafety rules including those issues that are not dealt with by the biosafety protocol. These include mandatory labeling of GMOs and genetically modified food, and liability and redress for harm caused by GMOs to human health, the environment and for resulting economic loss. African countries have the sovereign right to take such measures, which the biosafety protocol in any event cannot and indeed, does not preclude. A fragmented biosafety system does not allow for the unique risks of GMOs to be fully taken into account and specifically and appropriately regulated. Holistic legislation is necessary to provide consistency and enable streamlined and more transparent decision making.

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[4] Centre of diversity, *Global Heritage of Crop Varieties threatened by Genetic pollution*, Greenpeace Report, (1999), p.56 available at http://www.greenpeace.org/~~geneng , visited on 10/11/2008

[5] Preamble of the model law

3.1. Scope

The model law applies to import, export, contained use, release and placing on the market of any GMO and a product of a GMO, whether it is intended for release into the environment, for use as a pharmaceutical, for food, feed or processing.[6] It establishes uniform provisions that apply to all these activities because it views the risks from all GMOs as being the same, whether they are used in agriculture, medicine or research, and regardless of whether they are classified as seed, or food. In so doing it adopts the principles that inform the AIA procedure of the biosafety Protocol. Whereas the biosafety protocol only requires that the AIA procedure applies outright to the first time a GMO is imported for direct introduction into the environment of the importing party, the Model Law requires that its AIA procedure apply to all categories of GMOs, all its related uses and products of GMOs.

The model law requires the GMO exporter (notifier) to provide information in to the relevant authority regarding the characteristics of the GMO under consideration as well as the information deriving from the risk assessment of the GMO.[7] These provisions are far more comprehensive than that required by the biosafety Protocol. However, it is not only prudent but critically important for a country to know which GMOs are entering the country and for which uses. There should also be a comprehensive assessment of the risks posed by the GMO prior to a decision being taken on its introduction in whatever form.

The model law also deals with products of GMOs and GMOs that are pharmaceuticals in a similar manner. A product of a GMO is defined in the model law as any material derived by processing, or howsoever otherwise, from any GMO or from product of a GMO.[8] As noted elsewhere, a product of a GMO does not fall within the purview of the protocol. However, this does not mean the protocol completely ignores a product of a GMO. In fact, the protocol does introduce an indirect obligation on the exporter to conduct risk assessment in respect of product of the GMO irrespective of whether the

[6] Article 2 of the Model Law
[7] Article 4 of the Model Law
[8] Article 1 of Model Law

GMO in question will be exported for direct introduction into the environment or as direct use as food, feed and processing. The Model Law has in regard to products of GMOs, adopted a precautionary approach inasmuch as such products may have adverse effects on biodiversity, the environment and human health. Moreover, it has built on the indirect regulation of products of GMOs introduced by the protocol and the mandate provided by article 8(g) of the convention on Biological Diversity.

3.2. Decision Making Process and Precautionary Principle

The model adopts a strict interpretation of the precautionary principle when decisions are to be made concerning GMOs and GMO uses. It does not allow approvals to be given unless there is firm and sufficient evidence that GMOs or products of GMOs pose no risk or no significant risk to human health, biodiversity and the environment.[9] This provision is supported by the provision that where a country finds that risks cannot be avoided, approval must be refused.[10] By adopting this interpretation of the precautionary principle, the model law sets the standard for African countries to strive towards. In any event, this interpretation is particularly pertinent when dealing with decisions to release GMOs into the environment for field trials and commercial cultivation. GMOs reproduce, spread and interact with all other life forms in ecosystems and once released they can not be recalled, resulting in far reaching and irreversible consequences. Genetic contamination is not a problem that can be contained.

Article 5(7) of SPS agreement of the WTO allows members to provisionally apply the precautionary principle, where an appreciable threat has been identified within a risk assessment. The SPS agreement does not prescribe a specific safety standard, as every member is free to set its own level of safety as long as this is based on scientific risk assessment. Where there is uncertainty, an importing country may take a decision to ban or restrict a GMO. However, an importing country will be required to provide scientific evidence to justify the ban and restriction. Thus, African countries, when adopting the Model Law should ensure that the burden of proof is shifted onto exporters to

[9] Article 6(7) of the Model Law
[10] Article 8(5) of the Model Law

demonstrate the absence or low levels of harm, and require the insuring of liability for the existing adverse impacts.

3.3. Public Participation and Access to Information

The model law provides for public participation and access to information as important and indispensable components of environment governance. It requires that public be engaged in the decision making process by way of notice and comment procedure[11] and public consultations, at the discretion of the competent authority.[12] The model law gives the competent authority sufficient latitude to decide when the public should be invited to make comments; the only mandatory requirement is that the public be given sufficient notice in order to invoke meaningful public reaction. The competent authority is also given enough room for maneuver to decide when and how public consultation should be affected. These provisions do not require that there be public consultation for every application concerning a GMO or its products.

The model law requires that the information the applicant furnishes when making application for approval, be made available to the public.[13] The model law does however, limit the information that the public may have access to, where such information is deem to be confidential. The model law clearly in accordance with the protocol[14], invites the applicant to consult with the competent authority in order for the applicant and the competent authority to reach mutual agreement as to which information is considered to be confidential nature.[15] However, as a necessary safeguard, the model law does give the competent authority discretionary powers to override considerations of confidentiality in favor of the public interest.[16]

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[11] Article 5(2) of the model law
[12] Article 5(3) of the model law
[13] Article 5(1) of the model law
[14] Article 21 of the protocol
[15] Article 12 of the model law
[16] Ibid

3.4. Labeling and Traceability

A biosafety law is not complete without a comprehensive labeling and identification/ traceability system. Labeling is one tool in a comprehensive traceability system and has a dual function as it provides access to information and functions as a mechanism to manage risks. As an information tool, labeling upholds the consumer's right to know what he or she is purchasing or using. As a risk management tool, the information that labels can provide to end-users can refer to a GMO or GMO product's toxicity or environmental safety. Consequently, with this information, the end user can take appropriate steps to minimize or avoid the risks specified, for example, by following instructions on a label.

Traceability is the ability to track a GMO. The concept behind traceability is to create a system to ensure that information is available on the origin of a GMO as it moves from its point of manufacture or production to the end user. A traceability system will enable African governments to trace a GMO back to those responsible for the import and exports, as well as those responsible for the GMOs original development. This is particularly important in cases where an illegal import or release is suspected and where damage occurs from international and unintentional release.

The model law sets out provisions on labeling and traceability, which African countries should use and build on.[17] However, experience in developing has shown that the process of establishing labeling and identification /traceability systems are often delayed or hamstrung for various reasons. These include vocal opposition by the biotechnology companies and double standards on the part of food producers who label their products in Europe but refuse to do the same in developing countries.

3.5. Liability and Redress

The model law captures extensively, the essential elements for liability and redress regime, which should be incorporated into domestic biosafety legislation.[18] Additionally,

[17] Article 11 of the model law
[18] Article 14 of the model law

the model law contains a critically important provision to ensure that those responsible for environment and other harm will be required to provide adequate resources for redress. It requires that where approval is granted, the applicant must furnish evidence of insurance cover or some other adequate arrangements to meet its obligations under the law.[19]

3.6. GMOs and Food Aid in Africa

The model law recognizes that strict controls are necessary in Africa, where genetically modified food is donated to African countries as food aid. The World Food Programme has admitted that it has since 1996 been delivering food aid that included genetically modified products, without warning the recipient countries. This food aid has been donated by the United States, the world's single largest donor of food aid. During the recent food crisis in Southern Africa, the US provided 60 percent of the total emergency aid to the affected countries in the region. However, much of this in kind aid comprised of genetically modified food, which the US insisted the affected countries must accept. Zambia, as has been well documented,[20]banned GMOs from entering its territory and other countries like Mozambique, Malawi and Zimbabwe requested that the genetically modified be milled prior to its being distributed.

The model law requires its AIA procedure including notification provisions to apply to this category of GMOs. It requires that prior informed consent of the importing country the import is authorized, a risk assessment to be conducted, and the strict interpretation and application of the precautionary principle. However, this is not to say that the model law advocates that food aid as a whole is acceptable, even if the food donated is subject to safety regulations.

Hence, African countries currently receiving genetically modified food aid are even more at risk. First from the risk posed by GMOs to human health, biodiversity and the environment and second, from the negative socio-economic impacts that may derive from receiving the food aid itself.

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[19] Article 6(7) of the model law
[20] Zambia Bars Altered Corn from U.S. Associated Press Lusaka, Zambia, Aug. 17, 2002

3.7. Biosafety Regulatory systems in East Africa

Kenya, Tanzania, and Uganda have interim biosafety regulatory systems as well as proposals to make those systems more comprehensive and complete. The following is the summary of the current status of the biosafety regulatory systems in each country.

3.7.1. Kenya

In Kenya, the National Council for Science and Technology (NCST) is the government agency currently responsible for overseeing the implementation of the biosafety regulatory system. That office issued regulations and Guidelines for biosafety in biotechnology in 1998.[21] Those regulations were issued under the existing Science and technology act of 1980, although that act has no regulatory authorities and no means to enforce compliance with the regulations.[22] The NCST also established the National Biosafety Committee (NBC) to develop the country's biosafety policy and review GMO applications.[23] The membership of the NBC includes representatives from relevant government Ministries as well as representatives from civil society and the national universities.[24]

Under the interim Kenyan biosafety regulatory system, applications to import or release GMOs (including applications for confined field trials) are submitted to the relevant Institutional Biosafety Committee (IBC) where they are reviewed and assessed for compliance with the guidelines before submission to the NBC.[25] Then, those applications are forwarded to the NBC, where those applications are reviewed by NBC and /or technical subcommittee of the NBC. A recommendation is made by NBC and the NCST

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[21] Traynor P., and H.K. Marcharia, *Analysis of the Biosafety System for Biotechnology in Kenya: Application of the conceptual Framework,(* 2003)
[22] Ibid
[23] Harsh, M., Formal and Informal Governance of Agricultural Biotechnology in Kenya: Participation and Accountability in Controversy Surrounding the Draft Biosafety Bill, *Journal of International Development 17*, 2005
[24] Supra note 2
[25] Republic of Kenya, *National Guidelines for the Release of Genetically Modified Organisms into the Environment,* Nairobi, (1998)

secretary decides whether to approve the application.[26] To date, Kenya has approved a number of confined trials.

In July 2002, Kenya began working on number legal documents to turn its interim biosafety regulatory system into a permanent and comprehensive system. Those documents included revised regulations, a biosafety law, and a national biotechnology and biosafety policy. Although those documents have progressed in the last few years, none have been finalized. The most recent version of the biosafety law is the biosafety bill of 2005.[27]

3.7.2. Tanzania

The structure of Tanzania's biosafety regulatory system is described in its National Biosafety Framework (NBF) issued in March 2005.[28] In that system, the National Biosafety Focal Point (NBFP), who is responsible for review and approving applications and overseeing the implementation of biosafety issues, is the Ministry responsible for environment.[29] The NBFP gets advice on technical and policy issues from the National Biosafety Committee, comprised of government and non-governmental organizations, as well as the Competent Authorities, which are other agencies with areas of relevant expertise within the government. The NBF also discusses institutional Biosafety Committee, who perform biosafety functions within any Institution conducting genetic engineering.

The regulation that establish Tanzania's biosafety system will be promulgated under authority recently established in the Tanzanian Environmental Management Act of 2004 (EMA), which was signed by the president of the republic on 1 July 2005.[30] That law provides the legal authority for the Ministry of Environment to regulate genetic

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[26] Supra note 21
[27] Republic of Kenya, *Draft Biosafety Bill 2005*, Nairobi, (2005)
[28] United Republic of Tanzania, *The National Biosafety Framework for Tanzania*,(2005)
[29] Ibid
[30] United Republic of Tanzania, *The Environmental Management Act, 2004,* parliament of the Republic of Tanzania

engineering organisms. The NBFP is now working on the regulations to implement the biosafety provisions of the Act and to establish the procedures identified in the NBF.

Tanzania also has established a specific interim biosafety regulatory process for permitting small scale confined field trials of plants and plant products. Under the authority of the plant production act, the Ministry of Agriculture and Food Security promulgated schedule 18.[31] That document puts in place a review and approval process for all small scale confined field trials involving GE plants. It requires the completion of a detailed application which is reviewed by the Agricultural Biosafety Advisory Committee (ABSAC), a technical advisory committee which is competent Authority of the Ministry of Agriculture and Food Security (MAFS). The application is also reviewed by the National Biotechnology Advisory Committee (NBAC), which is a national committee on biotechnology issues based under the Ministry of Science Technology and Higher Education (MSTHE). With the advice of the ABSAC and the NBAC, the minister then decides whether to allow the field trial and issue a permit.[32] Schedule 18 also gives the Tropical Pesticides Research Institute (TPRI), which is a plant Biosafety Office consisting of biosafety inspectors, the ability to require risk management measures to ensure that field trial does not affect the environment or human health.

3.7.3. Uganda

The interim biosafety regulatory system in Uganda is coordinated by the Uganda National Council for Science and Technology (UNCST). That office established in 1995 the National Biotechnology Committee (NBC) made up of representatives from the government agencies and civil society.[33] The NBC is the national administrative arm on matters concerning biosafety. The main function of the NBC is technical advice on biosafety issues, including the assessment of individual applications for activities with GE organisms.

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[31] United Republic of Tanzania, *Schedule 18: Requirements for the conduct of confined field trials of Genetically Engineered plants in Tanzania* , Ministry of Agriculture and Food Security
[32] Ibid
[33] Nampala, P.,C. Mugoya, and T. Sengooba, *Biosafety Regulatory System in Uganda*, Uganda

The NBC has been responsible for writing the draft National Biotechnology and Biosafety policy,[34]draft National Biosafety Regulations, Guidelines on biosafety in biotechnology for Uganda, and a number of draft manuals addressing specific issues surrounding biosafety regulation, such as a confidential business information. These documents set forth the current and proposed biosafety regulatory framework for Uganda. Under the biosafety system identified in those documents, the UNSCT will be the competent authority to carry out biosafety regulation. It will be advised on policy matters by the National Biotechnology Advisory Committee (NBAC), which is an inter-ministerial committee, and the NBC.

[34] Republic of Uganda, *Draft National Biotechnology and Biosafety Policy,* Kampala, Uganda National Council for Science and Technology, (2004a)

CHAPTER FOUR

4. BIOSAFETY POLICY IN ETHIOPIA

4.1. Introduction to Ethiopian Biodiversity

Ethiopia is one of the main centers of origin of crop and wild land biodiversity. It is one of the 8 major centers of crop genetic diversity and is endowed with equally large animal and microbial genetic resources.[1] Some of the important economic plants with high genetic diversity in Ethiopia are wheat, barely, sorghum, finger millet, teff, faba bean, chickpea, field pea, lentil, cowpea, enset, anchote, etc.[2]

The significance of Ethiopia as a source of important plant diversity is evidenced by the flow of crops in and out of the country since historical times.[3] It is reported that farmers in the USA alone benefit by about USD 150 million per year from one barely variety originally collected in Ethiopia and resistant to yellow barely mosaic. Ethiopia recognizes the need to conserve its biodiversity (both wild and cultivated) resources. To this end, Ethiopia is party to various conventions and protocols.

4.2. Ethiopia as a Party to the Protocol

Although the Protocol is related to the CBD, it is a separate international treaty. The Protocol with its adoption did not automatically become binding on the Parties to the Convention. According to Article 34 of the Convention, in order to be binding on states, the Protocol is to be ratified by each state separately. Ethiopia gives serious attention to biosafety concerns. It has actively participated in the negotiations and development of the Convention on Biological Diversity, the Cartagena Protocol on Biosafety and the African Model Law on Safety in Biotechnology. It has ratified the Convention on Biological Diversity (CBD) through proclamation No. 98/1994. It became a signatory of the

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[1] Mugoyu Charles, *Resource Book for Implementation of Biosafety in East Africa,* p. 109
[2] Ibid
[3] Prof. Zerihun W. and Prof. Sebsebe D. , *Baseline Information on Biotechnology and Biosafety*,(2004), p. 14

Cartagena Protocol on Biosafety to the Convention on Biological Diversity on May 24, 2000 and ratified it on September 22, 2003 through proclamation No. 362/2003.

As far as the relationship between international treaties and the national law is concerned, Ethiopia follows dualist approach. It means that international treaties do not automatically become part of the domestic law. An implementing law is needed in order to transform the obligations of treaties into domestic law. Accordingly, if the existing laws are not enough to transform the treaty obligations into domestic law, new laws are to be made. One of the important purposes of this study is to review the existing policies and regulatory regime to see how far these are adequate to implement the Protocol's obligations in Ethiopia.

4.3. Purposes of the National Biosafety Framework

A national biosafety framework (NBF) is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the filed of the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The purpose of analyzing of the NBF is two fold:

- Give an overview what is done in Ethiopia during the NBF Development Project, and what legislation and administrative system are in place in Ethiopia?
- Indicate what still needs to be done in order to complete the NBF (i.e. missing legislation that still needs to be drafted/adopted, gaps in administrative or enforcement systems etc).

4.4. Status of Biotechnology in Ethiopia

Biotechnology is a frontier technology, which may have potential to provide new solutions to the problems of development in Ethiopia. Biotechnology in Ethiopia is considered to be at its infancy taking into account developments in other countries.[4]

[4] Ibid

However there are institutions engaged in activities requiring the application of some aspects of biotechnology in their research work, but uncoordinated and at times duplicated in the various institutions.

The Ethiopian Science and Technology Commission (ESTC) in collaboration with the Institute of Biodiversity Conservation (IBC) made a preliminary assessment of the status of biotechnology in Ethiopia[5] with the aim of identifying the capabilities and requirements while a number of institutions so that collaborative work may be initiated. The report concludes that while a number of institutions have initiated or are engaged in research activities in various aspects of biotechnology, most of them lack the human, financial, technological and infrastructure resources to sustain the research and link them effectively to economic benefits. Institutional cooperation's are missing and often operate in isolation and compete for scarce resources leading to wistfulness. Biological related activities are being carried out in some higher learning institutions and public organizations.[6] These include Addis Ababa University, The National Health and Nutrition Institute, The National Veterinary Institute, Armauer Hansen Research Institute, Institute of Biodiversity Conservation, and the Ethiopian Agricultural Research Organization.

4.5. Environmental Policy: Biosafety Context

At present there is no stand-alone national policy on biosafety in Ethiopia to deal with the issues related to biosafety in general and the Protocol in a comprehensive way. However, there are some existing policies in relevant sectors which reflect on some of the issues in the Protocol in a sporadic way and these are briefly touched upon below.[7] The policies covered in this study include: (i) The Environmental Policy of Ethiopia, (ii) The National Science and Technology Policy of Ethiopia, (iii) The National Biodiversity Conservation and Research Policy, (iv)Agricultural Research Policy. Furthermore, the 1994

[5] Haileselassie Yibrah and Abebe Demissie, *Biotechnology for Conservation and Utilization of Biological Resources*, (1998)
[6] Environmental protection Authority, *Biosafety Framework* , (2007), available at http://www.epa.gov.et visited on 26/04/2008 , p. 7
[7] Ibid

Constitution of the Federal Democratic Republic of Ethiopia provides for general directions and actions relevant to address the problems identified in relation to biosafety.

The success of the policy depends on the political will, committed leadership and the active participation of all parties across all sectors of the community. To stimulate this, it is vital that everyone first recognizes, upholds and promotes the core values and guiding principles established about actions are required to address identified issues.[8] In the development of national policy for biosafety, the following practices must be taken into account:

- The approach to policy development must be holistic and inclusive;
- Political will is an essential pre-requisite;
- Policy must be developed through consultation and consensus;
- Policy should take of best practice initiatives elsewhere, but it must be tailor made for the national environment into which it is to be absorbed;
- All stakeholders must be given opportunity and encouragement to participate within an integrated, and coordinated framework;
- And to be effective, policy must make specific provision for activities under the themes of education, prevention, and enforcement;

4.5.1. FDRE Constitution: Environmental Policy Context

A general guiding principle to develop policy and legal framework for the environment is incorporated in the constitution. The concern of the constitution in terms of environmental issues is indicated under fundamental rights and environmental objectives.[9] Article provides the people of Ethiopia have the right to improved living standards and to sustainable development. It also recognizes the right of Ethiopian nationals to participate in national development be consulted with respect to policies and projects that affect their community. Article 44 of the constitution provides all persons right to live in a clean and healthy environment. The provision also ensures the right to

[8] Ibid
[9] FDRE constitution, proc. 1/1995

get compensation, including relocation with adequate state assistance, to all persons who have been displaced or whose live hoods have been adversely affected as a result of state programs.

The other part in the constitution deals with environmental objectives. These objectives must be respected by all organs of the federal and regional governments in implementing the constitution, other laws and public policies.[10] Article 92 puts an obligation on citizens and the government to protect the environment. It requires that all design and implementation of programs and projects of development made by the Ethiopian government be environmentally friendly. In line with article 43, the provision gives citizens the right to full consultation and to the expression of their views in the planning and implementation of environmental policies and projects that affect them directly.

The constitutional provisions (fundamental rights and environmental objectives) have served as guiding principles for all activities that are related to policy formulation strategy development and legislative and institutional frameworks for environmental protection as well as sustainable development of the country.

4.5.2. The Environmental Policy of Ethiopia

General principles and policy provisions related to biosafety are found in different policy documents. The existing policy to the regulatory framework is the Environmental Policy of Ethiopia. This policy is prepared by Environmental Protection Authority on April 2, 1997,[11] in accordance to Proc. No. 9/1995.[12] The policy includes Sectoral and cross Sectoral environmental policy provisions which are set in place to ensure the sound management and use of natural resources and the environment.[13] This environmental policy is based on FDRE constitution, specifically the right to live in a clean environment and sustainable development.

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[10] Id, article 85(1)
[11] Khushal Vibhute, Environmental Policy and Law of Ethiopia, A Policy Perspective, *Journal of Ethiopian law*, XXII, no.1, (2008), p.79
[12] The Environmental Protection Authority establishment , Proclamation No. 9/1995
[13] Environmental protection Authority and Ministry of Economic Development and Cooperation, *Environmental Policy*, (1997)

4.5.2.1. The Policy Goal, Objectives and Guiding Principles

The over all policy goals is to improve and enhance the health and quality of life of all Ethiopian and to promote sustainable social and economic development through sound management and use of natural, human made and cultural resources and the environment as a whole so as to meet the needs of the present generation without comprising the ability of future generations to meet their own needs.

The specific policy objectives of the environmental policy, which set specific policy goals for the environmental law, seek to;

- To ensure that essential ecological processes and life support systems are sustained, biological diversity is preserved and renewable natural resources are used in such a way that their regenerative and productive capabilities are maintained and where possible enhanced so that the satisfaction of the needs of future generations is not compromised;
- To identify and develop natural resources that are current under utilized by finding new technologies, or intensifying existing uses which are not widely applied;
- To ensure the empowerment and participation of the people and their organizations at all levels in environmental management activities;'
- To raise public awareness and promote understanding of the essential linkages between environment and development.

Creating clearly defined guiding principles is considered by the environmental policy as very essential as these principles will shape all policy, strategy and program formulation of their implementation. These guiding principles will be used as checking mechanisms against other Sectoral and Cross Sectoral policy provisions. The following key guiding principles of the environmental policy that are related to biosafety are:

- Every person has the right to live in a healthy environment;

- The development, use and management of renewable resources shall be based on sustainability;
- Appropriate and affordable technologies which use renewable and non-renewable resources efficiently shall be adopted, adapted, developed and disseminated;
- Full environmental and social costs (benefit forgone or lost) that may result through damage to resources or the environment as a result of degradation or pollution shall be incorporated in to public and private sector planning and accounting, and decisions shall be based on minimizing and covering these costs;
- Local, regional and international environmental interdependence shall be recognized;'
- Species and their varieties have the right to continue existing, and are, or may be useful now or for generations to come;

4.5.2.2. Sectoral Environmental Policies

The following Sectoral environmental policy provisions are relevant to biosafety, these are:

(A) Genetic, Species and Ecosystem Biodiversity

For the purpose of conservation of the ecosystem biodiversity, the policy provisions are designed to ensure *in-situ* systems (conservation in a natural reserve, farmer's fields etc) as a means of conserving both wild and domesticated biological diversity, and *ex-situ* systems (conservation outside the original or natural habitat in gene banks, farms, botanical gardens, ranches and zoos) as supplementary to *in-situ* conservation.[14] Thus, the primary target of the policy is to preserve biodiversity in its original status, and to support it by *ex-situ.*

The policy aims to ensure that the importation, exportation and exchange of genetic and species resources is subject to legislation, e.g. to ensure the safeguarding of community

[14] Id , p. 14

and national interests, the fulfilling of international obligation, quarantine, etc.[15] Further more, all biological material which is self regenerative and impossible to control once allowed to get out of control may result in the most insidious and damaging form of pollution, which is biological pollution, thus the importation and use of biological materials including those genetically engineered should be under stringent regulations.[16] It also promotes the involvement of local communities inside and out side protected areas in the planning and management of such areas.[17]

(B) Soil husbandries and Sustainable Agriculture

The 1997 environmental policy outlines the general policies for all relevant sectors including agricultural objectives. For example, in the soil husbandries and sustainable agriculture sector the major policy statements are: (i) all steps taken and technologies adopted for agricultural development and attainment of self-sufficiency in food are to be made environmentally sound; (ii) the application of agro chemicals, artificial materials and inputs which adversely affect the fertility as well as organic properties of soil and also cause adverse impacts on man and animals are to be regulated.[18] The policy provisions are based on use the precautionary principle for assessing potentially damaging impacts when taking decisions that affect social and economic conditions, natural resources and the environment, especially in the pastoral areas, which are perhaps the least studied in the country.

(C) Forest, Woodland and Tree Resources

The policy provisions for forest resources conservation aim to ensure that forestry development strategies integrate the development, management and conservation of forest resources with those of land and water resources, energy resources, ecosystems and genetic resources, as well as with crop and livestock production. Moreover, it aim to promote changes in agricultural and natural resources management systems which will limit the need for free range grazing of animals.

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[15] Ibid
[16] Ibid
[17] Ibid
[18] Ibid

4.5.2.3. Cross-Sectoral Environmental Policies

Cross-Sectoral environmental policies signify the need to tackle, with specific goals, other related sectors, and social as well as economical, to make the environmental policy more effective and holistic.[19]

(A) Public Participation

It is necessary for the country to protect its biodiversity. Ethiopia is one of the world's richest storehouses of genetic diversity. Hence, biosafety issue regarding the use of GMOs is a great concern to environmentalists, consumers and general public. People are concerned about the health hazards originating from plants, animals and other biotechnological sources. Therefore, mechanisms for public awareness, education and public participation in decision making are recognized.

The policy provisions in this regard are to develop effective methods of popular participation in planning and implementation of environmental and resource use and management projects and programs, to develop the necessary legislation, training and financial support to empower local communities so that they may acquire the ability to prevent the manipulated imposition of external decisions in the name of participation, and to ensure genuine grassroots decisions in resources and environmental management.

(B) Environmental Research

Under environmental research, the policies adopted are developed strategic environmental research which aims at identifying the social, economic and technical factors which influence resource management. Funds are to be allocated to support research on appropriate technologies for environmental management and sustainable development through partnership between scientists and potential end users. They also

[19] Supra note 11

aim to co-opt traditional systems of research and learning into a new system which incorporates both modern and traditional components.[20]

(C) Environmental Impact Assessment (EIA)

In the Environmental Impact Assessment the major policy statements relating to biosafety are; (i) environmental impact assessments consider not only physical and biological impacts but also address social, socio-economic, political and cultural conditions;(ii) public and private sector development programs and projects recognize any environmental impacts early and incorporate their containment into the development design process; (iii) to recognize that public consultation is an integral part of EIA ensure that EIA procedures make provision for both an independent review and public comment before consideration by decision makers; (iv) environmental impact statement always includes mitigation plans for environmental management problems and contingency plans in case of accidents.

(D) Environmental Education and Awareness

The 1997 environmental policy gives emphasis the need for creating widespread mass awareness regarding environmental conservation and sustainable utilization of all resources. The need for dissemination of environmental information and public participation is also emphasized in the policy. The policy provisions aim in this regard are considered crucial for the proper implementation of the other policies. The policies related to biosafety are designed to target the public, particularly those involved in public and private sector activities that have significant environmental impacts, for environmental education and awareness programs. These policies recognize the importance role that the mass media play and to effectively use them in creating and promoting environmental awareness in view of the physical problems of access and communications in Ethiopia.[21]

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[20] Supra note 13

[21] Environmental protection Authority, *Biosafety Framework* , (2007), available at http://www.epa.gov.et visited on 26/04/2008

4.5.2.4. Implementation Mechanisms

The policy statements tries to achieve coordination from the federal government down to community level in order to handle the Sectoral and Cross-Sectoral planning and implementation issues identified as the responsibilities of concerned line ministries, commissions authorities and bureaus as capable to the level of organizations, including those of the relevant federal executive organs as well as national and municipal governments, elected councilors, NGOs, community representatives, representatives of professional or other environmental associations and the private sectors. It also encourages or prefers (if possible) to use existing institutional structures.

It identifies the following criteria's for the purpose of determining institutional arrangements[22];

- Conformity with the constitution, especially with respect to the decentralization of power;
- Harmonization of Sectoral interests;
- Integration of environmental planning with development planning;
- Minimization of incremental financial requirements;

The objective is to avoid conflict of interest by assigning responsibilities to separate organizations for environmental and natural resource development and management activities on the one hand, and environmental protection, regulation and monitoring on the other.

The environmental policy aims to ensure that the monitoring the overall impact of the implementation of the environmental policy of the country is consistent with institutional arrangement specified under the conservation strategy of Ethiopia is responsive to popular opinion. The policy gives the responsibility to the Environmental Protection Authority to carry out the overall monitoring of the policy implementation and be responsible for proposing modifications, in consultation with mandated line ministry and regional or lower level bureau is also required to monitor the overall impact of the

[22] Ibid

implementation of the environmental policy on those sectors and elements for which it has legal mandate.

The main rational for introducing a national policy and strategy document on environmental matters was for a determining the objectives and strategies which should be used in order to ensure the respect of environmental values, by taking into account the prevailing economic, social and cultural situations of the country.[23] In this context, with a view to further amplifying the constitutional provisions on environmental protection, the environmental policy and conservation strategy of Ethiopia have been prepared. These policy and strategy document recognized and addressed environmental issues in a holistic manner.

The primary concerns of biosafety strategy plan are creating a coordinating and integrated approach and a participatory decision making culture among resource usurers, and implementing the ideals of the biosafety policy elements. The objective of biosafety planning as indicated by the conservation strategy of Ethiopia, is to materialize the security of tenure on land and the natural resources thereof by supporting sustainability;[24] agricultural development, pastoral development, forestry, fisheries production, and urban development. Thus, the policy statements for the relevant sectors, contained in the 1997 policy, provide adequate basis for the adoption of additional measures to regulate GMOs in environmentally sound way.

4.6. The National Science and Technology Policy

The 1994 science and technology policy, provides direction for the growth and enhancement of science and technology and its utilization in Ethiopia's development. The policy comprises environment and biodiversity objectives to be considered among different sectors and programs that are given priority.[25]

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[23] Id, p. 19
[24] Ibid
[25] The National Science and Technology Policy, 1994

The major objectives of the National Science and Technology policy are;[26] (i) to build national capability; (ii) to generate, select, import, develop, disseminate and apply appropriate technologies for the realization of the country's socio-economic objectives; (iii) to rationally conserve and utilize its natural and manpower and the scientific and technological awareness of the people; (v) to make science and technology activities more productive, efficient and development oriented. Its major elements focus, on collection, conservation, sustainable use of the country's biodiversity and on the promotion of research and publication.

4.7. The National Biodiversity Conservation and Research Policy

The National Biodiversity Conservation and Research Policy were approved in April 1998 by the Council of Ministers.[27] The policy provides a framework for the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources the country.[28] It also ensures that the country's plant, animal and microbial genetic resources and ecosystems as a whole are conserved, developed, managed and sustainably utilized. Furthermore, the policy calls for a legal recognition, fostering and expanding of the indigenous knowledge and methods relevant to conservation, development and sustainable use of biodiversity and the promotion and use of new and emerging technologies such as biotechnology.

4.8. Agricultural Research Policy

The general objective of the agricultural research policy is to give a clear direction and guidance for agricultural research and the application of research results for the development of agricultural science and technology, which makes it relevant in relation to biosafety.[29]

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[26] Ibid
[27] The National Biodiversity Conservation and Research Policy, 1998
[28] Ibid
[29] Agricultural Research Policy

The specific objectives include; (i) to choose and generate agricultural technologies that will improve the productivity of the agricultural sector and that would enable the country to be self-sufficient in food production; (ii) to build capacity, direct and coordinate agricultural research programs so as to solve the major problems and sustainably raise agricultural production and protect environment; (iii) to distribute research results to users thereby contribute to the national economy.

Among the policy statements included, the following statements are relevant in the context of biosafety;[30] (i) to raise the productivity of the agricultural sectors and to be self-sufficient in food production, agricultural research shall focus on generating and choosing technologies that will improve the productivity of the agricultural sector, which constitutes the major part of agricultural production; (ii) the country's natural resource are dwindling with time. Research will conserve, protect and sustainably use the county's agricultural and natural resources; (iii) to resolve urgent problems of the economic sector within a short period of time, agricultural research activities shall focus mainly on applied research and on programs that will bring change within a short period of time. However, research on basic, strategic and new emerging technologies, e.g. biotechnology, will also be under taken as deemed necessary.

The above discussed policies are relevant for the purpose of regulating biotechnology. However, whether Ethiopia needs a separate policy for biosafety is a contentious issue. For example, according to Dr. Tewolde Berhan, Ethiopia does not need a separate national policy on biosafety because; 'the 1997 environmental policy and other Sectoral policies clearly address the issue of biosafety'[31]

But the writer differs with this opinion, and believes Ethiopia needs a separate policy on biosafety. The reasons are; firstly, as examined above Sectoral policies make some references to biosafety issues even though their major thrust is to benefit from the application of modern biotechnology in potential areas like crops, animals, and medical sectors. These policies have their own priorities and in most cases there is no explanation

[30] Ibid
[31] An interview with Dr. Tewolde Berhan , Director of EPA , 24/11/2008

as to how the Sectoral policies be addressed in conformity with the concerns of the Cartagena Protocol, i.e. to ensure adequate level of protection in the field of safe transfer, handling and use of GMOs that have adverse effects on the conservation and sustainable use of biological diversity, taking in to account risks to human health. Thus, a central national biosafety policy can help establish a relationship and coordination between the core themes of the protocol and the policy priorities in all relevant areas of the government.

Secondly, Sectoral policies do not deal with the issues and concerns of the protocol in a comprehensive way. Many important biosafety issues raised in the protocol have been either completely ignored or partially addressed in the Sectoral policies. For example, the vary words genetically modified organisms are missing in almost all policy documents, the need for Advanced Informed Agreement (AIA), the right to know of an importing state, has been completely ignored in these policies. Most of the existing relevant policies have no reference to precautionary approach except the 1997 environmental policy. A separated national policy on biosafety should therefore, be adopted to reflect on the issues and concerns of the protocol in a comprehensive way.

Thirdly, existing of so many related policies on biotechnology and their occasional reference to biosafety might lead to confusion. A central policy on biosafety could provide a comprehensive picture about the country's biosafety objectives and measures. This could help avoid confusion and misunderstanding about the country status on biosafety issues.

Lastly, a separate national biosafety policy is needed for Ethiopia to demonstrate the country's highest level of commitment the biosafety issues. It will affirm that Ethiopia shows adequate respect to the concerns of the international community as expressed in the Cartagena Protocol. This will help improve the country's image in the international community.

CHAPTER FIVE

5. BIOSAFETY REGULATORY SYSTEM IN ETHIOPIA

5.1. Introduction

This chapter deals with the regulatory regime on Biosafety. A regulatory regime on biosafety is comprised of all the legal instruments, such as constitution, proclamations and regulations that are relevant to the regulation of GMOs and the products thereof including the institutional arrangements for implementing those regulations. A regulatory regime is needed in order to ensure adequate level of protection in the field of the safe transfer, handling, and use of GMOs resulting from modern biotechnology that many have adverse effects on the conservation and sustainable use of biodiversity taking into account risks to human health.

As a party to the protocol, Ethiopia is required to implement the obligations of the protocol into its domestic legal system. Article 2(1) of the protocol requires each party 'take necessary and appropriate legal, administrative and other measures to implement its obligations under the protocol.'[1] It is worth mentioning here that at present Ethiopia has a Draft Biosafety proclamation that deals with the use transfer handing and transboundary movement of GMOs as required by the protocol. However, there are good numbers of individual laws that are relevant to Biosafety in Ethiopia. This chapter examines selected key main the draft of law and other individual laws relevant to Biosafety.

5.2. Analysis of Selected Key Provisions

This section of the study makes an analysis of selected key features of the biosafety regulatory system of Ethiopia with reference to related provisions of the Cartagena protocol and the African model law. These include:

[1] Article 2(1) of the protocol

5.2.1 Objective

The objective of the draft biosafety proclamation is to protect human and animal health, biological diversity and the environment at large by preventing or managing down to levels of insignificance the adverse effects of genetically modified organisms and products.[2] The preamble of the draft biosafety law also recognizes the need of biosafety into modern biotechnology. In this regard, the preamble provides for ensuring human and animal health, the safety of the environment and the quality of socio-economic and cultural conditions form the risks arising from GMOs and products thereof fosters the implementation of the environmental rights and obligations enshrined in the constitution of the Federal Democratic Republic of Ethiopia.[3]

The objective of the protocol under article 1 is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movement.

The draft biosafety proclamation fully complies with the protocol. This is because it has clearly outlined objectives under article 4 and the preamble. Furthermore, instead of 'conservation and sustainable use of biological diversity, also taking into account risks to human health'; the draft proclamation use "protect human and animas health, biological diversity and the environment at large…' From this we can conclude in terms of objective the Ethiopian draft proclamation on biosafety is broader than of the Cartagena protocol. The main reason is related to the emphasis given Transboundary movement of LMOs in the Cartagena protocol. Where as, in the draft proclamation it directly addressed the adverse effects of GMOs in general. In the case of the African Model law, the objectives are more illustrative "for protection of biological diversity, human and animal health, socio-economic conditions and ethical values in the making, safe transfer, handling and use of GMOs and products."

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[2] The Draft Biosafety Proclamation, 2007, article 2
[3] Id, Preamble

5.2.2 Precautionary Principle

The precautionary principle represents an important tool for decision making process. The precautionary principle is also international accepted and it is also enshrined in the Rio declaration on Development and the Environment and it postulates, that in cases when serious harm is threatened, positive action to protect the environment should not be delayed until convincing scientific proof of harm is available.[4]

The fact that the precautionary principle is mentioned in numerous conventions does not determine its legal value. No international courts and tribunals have so far taken a position in this regard, be ICJ, the WTO Dispute Settlement Body, or the International Tribunal of the law of Sea.[5] Even if there is no consensus whether it gained the status of customary international law, one should consider it as an emerging customary norm.[6] The precautionary principle is particularly important when dealing with the issues that are presented by GMOs. This is especially so, where the novelty of modern biotechnology and the incredible complexity of the living system of our planet, make it impossible to predict the consequences of the release of GMOs into the environment with any degree of certainty.

Article 5 of the draft proclamation provides for consistence with the precautionary principle when dealing with the potential risks of genetic modification in addressing the risks of GMOs. Article 5 of the draft proclamation states that:

> *Any government organ shall in the implementation of this proclamation, take in to account the need for caution, particularly where there is scientific uncertainty about a risk emanating from any transaction. When faced with any uncertainty in any risk, it shall assume that risk can occur and shall act to prevent or contain it.*[7]

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[4] Rio Declaration, principle 15
[5] Laurence Boisson de chazournes, *The Precautionary Principle*, (2002), p.12
[6] Ibid
[7] Article 5 of the draft proclamation

In general, any government organ or any authorized person shall respect and implement the draft proclamation. When we compare Cartagena Protocol and the draft proclamation, the protocol prefers caution, where as the draft proclamation assumes a risk can occur. Therefore, in terms of expression there is a slight difference, but the approach is the same. It is apparent that the draft proclamation complies with the protocol. However, the standard set by the African model law is very high. Because it stated that unless there is no firm and sufficient evidence that the GMO or products pose no significant risks, the competent authority should not give approval.

5.2.3. Scope

The scope provides parameters within which a biosafety regulatory system functions by identifying aspects that are covered and excluded by the biosafety regulatory system. The goal of Ethiopia's biosafety regulatory regime is to comprehensively address all potential risks that are associated with GMOs. The draft biosafety proclamation of Ethiopia apply to any transaction whether intended for release into the environment, contained use, transit, for use as a pharmaceutical for humans or animals, or for food, feed or processing.[8] Exempted from the scope of the draft proclamation are GMOs that are pharmaceuticals for humans, GMOs that have been determined by the competent authority regulation as not having any adverse effects on human health and the environment. Therefore, Ethiopia's regulatory regime has the ability to address the full range of potential environmental issues that might arise from any type of activity involving a GMO.

While Ethiopia is in the process of establishing a functional and protective biosafety regulatory system, this system continues to evolve and mature. One goal of the regulatory systems is to comprehensively address all potential risks from any genetically modified organisms. The proposed legal framework has definitions that are broad enough to capture different genetically engineered organisms, whether plants animals or microorganism. In addition, those systems do not distinguish generically engineered

[8] Article 3 (1) of the draft proclamation

organisms that are engineered for food or feed use, engineered for industrial purpose, and engineered to produce a pharmaceutical. The main base for this assertion related to article 2 (21) and article 3 of the draft proclamation. The draft proclamation applies to any transaction related to genetically modified organisms. The word transaction means:

> *Any research and development, import, export, transit, handling, release, contained use, transport, placing on the market, use of a pharmaceutical for humans or animals, use of food, feed or for processing of any genetically modified organism or products thereof.*[9]

Further more, the draft proclamation prohibited certain acts. These are:

- Any transaction of a genetically modified organism..... with the intention of causing harm to human health, biological diversity, the environment, or property.... is prohibited;[10]
- Any transaction of a genetically modified organism....with the intention of peaceful application which causes significant risk to human health.... environment which has not been given on Advance Informed Agreement in writing by Environmental protection Authority is prohibited.[11]

In general, any one who wants to engage in any genetically modified organism's related transaction must get authorization. In addition, he/she shall respect the proclamation and other regulations and directives.

To sum up, the draft biosafety proclamation attempt to comply with the provisions of the protocol, though there is difference in terms of approach. The main difference is the draft proclamation does not distinguish GMOs based on their products or their intended purpose. The same is true in the case of African model law, which applies to the making, import, export, transit, contained use, release or place on the market of any GMO or product of GMO. Where as, Cartagena protocol make certain classification based on their intended purpose.

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[9]Article 2(21) of the draft proclamation
[10]Article 6(1) of the draft proclamation
[11]Article 6 (2) of the draft proclamation

5.2.4. The Advance Informed Agreement (AIA)

The Cartagena protocol under article 11(1) provides that, a party that make a final decision regarding domestic use of LMO that may be subjected to transboundary movement shall inform the parties through the Biosafety Clearing House (BCH) system. This shall be with in 15 days of reaching that decision. Article 11(1) function as a means of information sharing with respect to domestic regulations in the field of LMOs. The domestic regulatory framework must be consistent with the objective of the protocol.

As provided for in the protocol, the Advance informed agreement (AIA) is meant to ensure that a party especially that of import is made aware before LMOs/ GMOs is imported so that it can make a decision to import or not to import under draft Biosafety proclamation, there are provisions for AIA. The draft proclamation defines the Advance informed agreement as 'an explicit written consent granted by the authority (EPA) for a transaction.'[12] In case of imported GMOs, the consent shall be based upon the taking of full responsibility by the competent national authority of the exporting country for the complete and accurate disclosure of information. If the GMO is developed in Ethiopia, the consent shall be based upon the taking of full responsibility by the applicant for the complete and accurate disclosure of information.

The AIA is a key mechanism and the centerpiece of transparency of any biosafety regulatory framework. The draft proclamations require that before the first intentional introduction of a GMO or its living product into Ethiopia's jurisdiction the competent authority is notified so that is receives information about the GMO and its proposed use and is also given an opportunity to decide whether or not to allow the import of the GMO and upon what conditions if any.

The draft Biosafety proclamation under Articles 8 to 13 establishes application and approval procedures. Article 8 is a general provision and states that no person shall be involved in research and development import, export, transit, handling, release, contained use, transport, placing on the market, use as a pharmaceutical for human or animals, use

[12] Article 2 (1) of the draft proclamation

as food, feed or for processing of any genetically modified organisms or products thereof without obtaining an Advance informed Agreement from EPA. Furthermore, the following factors will be taken into account:[13]

- The transaction benefit to the country without significant risk;
- The applicant can furnish evidence of insurance cover sufficient to meet his/ her obligation.

Whether, it is possible to furnish insurance cover with out knowing its scientific effect is controversial issue that is faced by EPA to decide.

The application for permit to engage in transaction related to GMOs shall include:[14]

- An assessment report on possible adverse effects caused by the GMOs. Furthermore, the applicant is responsible for preparing the report and for ensuring qualified person prepared the risk assessment;
- Information specified in the draft directive related to application procedure, like;[15]
  - Name and address of the applicant;
  - Information on personnel and training person(s) responsible for planning and carrying out the implementation of the project;
  - Characteristics of the GMOs or products thereof;
  - The impacts of the GMOs on health;
  - Information relating to the conditions of release and the receiving environment (the place where and the purpose for which the GMO and its products shall be used for including detailed instructions for use and detailed labeling and packaging);
  - Information from previous or current transactions of GMO;
  - Its potential environmental impact;
  - Information on monitoring control waste treatment and emergency response plans.

[13] Article 8 of the draft proclamation
[14] Article 9 of the draft proclamation
[15] Draft directive issued to Determine the contents of an application on transactions involving Genetically modified organisms and products thereof, (2007) Articles 3-8

The main mechanisms for the regulation for GMOs under the draft proclamation and directive are authorization from EPA. A permit is required for contained use activities and for deliberate release into the environment. An authorization is also required for import or placing on the market of GMOs under the draft proclamation. And lastly, no approval of a GMO shall be considered and accordingly determined by EPA unless the authority is convinced that the transaction will not cause unacceptable risk; any conditions identified by EPA must be fulfilled by the applicant.[16]

Both the Ethiopia regulatory framework and Cartagena protocol have specific provisions relevant to Advance informed agreement (AIA). However, both biosafety regulatory systems do provide for AIA procedure with in their mechanisms in different ways. This is through the different procedures that are undertaken and the different factors that are put into considerations before an application is approved. The protocol limits its self to the "first intentional transboundary movement". The draft proclamation of Ethiopia related to AIA is broader than the protocol as illustrated by the draft proclamation article 8. Because Advance informed agreement is a necessary requirement for any transaction whether it is intentional transboundary movement, transit, development and other forms of contained use, or placing on the market. The African model law requires consent from the competent authority, for import, export, transit, is undertaken on any GMO or product of a GMO. The model law scope of AIA is broader than the Cartagena protocol.

The Biosafety regulatory system of Ethiopia relies on permit system as the main mechanism for an approval. In Ethiopia approval or authorization is granted by Environmental Protection Authority.[17] With regard to time frame between the time of the receipt of the application and the final decision, the protocol provides for a minimum of 90 days and a maximum of 270 days According to the draft biosafety proclamation, EPA must make its decision whether to reject the application or to give authorization with in two months after it has received an application.[18] Therefore, compared to the protocol Ethiopia regulatory framework requires less time frame, which is 60 days.

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[16] Article 16 (4) of the draft proclamation
[17] Ibid
[18] Ibid

It is apparent that the biosafety regulatory framework of Ethiopia more or less complies with the AIA procedure that is provided for by the protocol, though the Ethiopian regulatory framework is strict than of the protocol in case of AIA.

5.2.5. Risk Assessment

The protocol provides that, before any GMO is released (as discussed in chapter 2) an evaluation of the impacts and risks posed to human health and the environment by the release should be carried out. This is meant to identify it there are any hazard posed by the GMO to human health or the environment, the magnitude of the harm, and what the risks are if the hazards are released. Once the risks have been estimated, the assessment should identify whether or not any management procedures are required to control the risks and prevent or minimize damage to the environment or whether or not monitoring is required to determine that any risk control measure is effective.

The draft biosafety regulatory regime of Ethiopia establishes mechanisms for risk assessment in addition to fundamental steps in risk assessment. The draft biosafety proclamation provides for risk assessment under article 14, 15 and 16. One of the essential parts of any application for permit includes a risk assessment report undertaking a risk assessment to identify potential risks, specify the means of prevention or containment of the identified risks, and submit to the authority (EPA) the risk assessment report, together with any other documents determined as necessary by the Authority.

Article 16 (1) of the draft proclamation provides that a risk assessment of any transaction shall be carried out on a case by case basis.[19] The same provision further provides that EPA shall verify the information presented by the applicant or found in the Biosafety Clearing House (BCH). Before EPA makes its final decision, it may take into account expert opinions and public comments. This illustrates Ethiopia's commitment to develop public participatory legal framework for biosafety.

[19] Article 16 (1) the draft proclamation

According to the draft directive, risk assessment shall take the following parameters into consideration:[20]

- Characteristics of donor and recipient organisms or parental organisms
- Characteristics of the constructs used vector, promoter, terminator, marker gene
- Characteristics of Genetically modified organism
- Safety considerations for human and animal health
- Environmental considerations
- Socio- economic consideration

5.2.6. Risk Management

Risk management under the protocol as discussed in chapter two, refers to means by which a user applies certain control measures to an operation in order to keep the risks to an acceptable level. Having identified and assessed the risk the next step is to consider how the risk can be minimized and best managed. The type of risk management to be applied depends on the novel organism on the particular application. Risk management measures that are used to keep risks at a minimum include containment of biosafety levels.[21]

The draft Biosafety proclamation provide for risk management under article 22. Article 9 provides that the competent authority shall impose such measures upon approval, as may be necessary, to avoid any adverse effects on the environment, biological diversity and human health. Risk management measures that are provided for by article 22(4) include:

- Periodic observation of the GMO or product thereof with its life-cycle, at cost of the applicant before or after it is put to its intended use;[22]
- Order for the cessation of any activity that contains characteristics or specific traits which pose risks;[23]

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[20] Draft Directive issued to determine risk assessment parameters of GMOs and products thereof (2007)
[21] Kinderlerer J., *Regulation of Biotechnology: Needs and burdens for developing countries,* (2002) available at http://www.csd/org/pdf/ Biosafetyscopingstudy.Pdf visited on 18th December 2008
[22] Article 22(4) (a) of the draft proclamation
[23] Article 22(4) (b) of the draft proclamation

- Order for the cessation of any activity that is under taken in violation of the provisions of the proclamation directives or terms or condition of an authorization;[24]
- Require person responsible for any activity to undertake such measures as may be necessary to prevent or limit any harm to human health, biological diversity, the environment, or socio-economic conditions, or cultural norms of local communities, or the economic condition of the country or to restore the environment to its previous state;[25]
- Undertake or initiate safety measures, as necessary at the cost of the person responsible, in the event that the person responsible fails to undertake those measures;[26]
- Take measures as necessary in the case of imminent or serious danger to human health, biological diversity, environment, socio-economic conditions, cultural norms, of local communities or the economic condition of the country caused by a GMO or its product at the cost of the person responsible for causing such danger;[27]
- Require the authorized person to submit reports periodically in respect of the monitoring and evaluation of the risks carried out when the transaction is taking place.[28]

The provision (article 22) as stated above related to risk management in the draft biosafety proclamation of Ethiopia illustrates that many principles of environmental management are considered. These include the polluter pay principle, the preventive principle, and the precautionary principle. Article 22 further provides for monitoring and evaluation report that are submitted periodically by the applicant even though the GMO has already been approved by EPA. The regulatory system of Ethiopia also sets out the principles or parameters of the risk management by draft directive.[29]

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[24]Article 22(4)(c) of the draft proclamation
[25]article 22 (4)(d) of the draft proclamation
[26] Article 22(4)(e) of the draft proclamation
[27] Article 22 (4)(f) of the draft proclamation
[28] Article 22 (4)(g) of the draft proclamation
[29] Draft directive issued to determine the procedures for risk management, (2007)

With regard to risk management, Article 22 of the draft Biosafety proclamation of Ethiopia requires EPA to impose such measures up on approval, as may be may be necessary, to avoid adverse effects on the environment, biological diversity and human health, including socio-economic considerations arising from the GMO or its products. The draft biosafety proclamation of Ethiopia also provide for a range of other risk management measures that include: periodic observation, ordering for cessation of the activity in case it violates provisions of the proclamation and directive and others. The writer believes that the biosafety regulatory system of Ethiopia to a greater extent complies with the Cartagena protocol as far as risk assessment and management are concerned. Similar concepts are incorporated in the African model law.

5.2.7. Identification and Labeling

Identification and labeling of genetically modified organisms especially foods, serves as an important function of providing the public and consumers with information regarding GMOs. However, its value also lies in its biosafety function regarding the traceability of a GMO, risk management and monitoring of the impacts of the GMO.

The Cartagena protocol under article 18 contains a number of labeling requirements in respect of GMOs. For example, Article 18(2) (a) requires each party to provide for documentation accompanying GMOs for direct use as food, feed or processing to be clearly identified as 'may contain' GMOs. Compared to the protocol, the model law provides strong obligation in case of identification and labeling. It calls for GMO and products to be clearly identified and labeled.

The draft biosafety proclamation has provisions for identification and labeling of GMOs under article 23. The draft biosafety proclamation provides that any GMO or its products in storage or transport shall be clearly identified and labeled in both Amharic and English.[30] It shall also specify the scientific name, the common name when available, the unique identifier and the transformation event, and relevant traits and characteristics

[30] Article 23 (1) of the draft proclamation

given in sufficient detail for purposes of traceability.[31] Furthermore, any GMO being transported shall include the full addresses of both the sender and receiver.[32] The specific parameters for transportation of GMOs or products are set in the directive issued by EPA.[33]

As discussed above, the draft biosafety regulatory regime of Ethiopia gives consumers an opportunity to decide on what they want i.e. whether to consume GMO products or not to do so. This is because it provides for the manufactures to clearly label their products for easy identification. In case a particular GMO or its products causes a negative impact on the environment or to human health it can easily be traced back to the producer or the manufacturer. The draft biosafety proclamation of Ethiopia to a greater extent comply with the provisions of Article 18 of the Cartagena protocol that require each party to provide for documentation accompanying GMOs for direct use as food, feed or processing to be clearly identified as may contain GMOs. This is because Article 23 of the draft biosafety proclamation expressly provides for mandatory labeling and identification of GMOs. The draft regulatory framework goes a step further by specifying the parameters by a directive.

5.2.8. Public Participation

Public participation in a biosafety regulatory system usually involves two separate components. First, is the pubic being given opportunity to provide comments and opinions on the laws, regulations, and policies before they are adopted? Secondly, the opportunity to provide comments before an application for GMOs is approved by the competent authority. Public participation is different from public awareness, where the government educates and informs the public about biosafety, biotechnology, and the regulatory process.

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[31] Ibid

[32] Article 23 (2) of the draft proclamation

[33] Draft Directive issued to determine the procedures for they application of the transport genetically modified organisms or products there of, 2007

The draft biosafety regulatory regime of Ethiopia provide for public participation in explicit manner, where as public awareness is impliedly included. The draft biosafety proclamation article 15, 24, and 25 provide for public awareness and participation. Article 15(2) states that public shall be availed with information by EPA with two weeks upon receipt of such information and the public and solicit comments on it for a period of not more than one month.

Furthermore, the public may make comments at the time of notification, where the competent authority arranges for a public consultation. The draft proclamation further provide that a date of public participation and consultation is announced through appropriate means of communication, at least before the decision is made.[34] The competent authority in reviewing its decision shall take into account the views and concerns of he public expressed.[35] The draft proclamation under article 25 provide for establishment of a National Biosafety Clearing-House, in order to facilitate the exchange of scientific, technical, environmental and legal information on and experience with, genetically modified organisms and products there of:[36]

The National Biosafety Clearing-House contains information on:[37]

- A list of names and other relevant information on experts in GMOs or products thereof, risk management and assessment;
- A List of GMOs or products thereof that have been approved and/or rejected for import or export;
- Applications lodged in accordance to the proclamation;
- Applicable guidelines and codes of practice concerning GMOs or products thereof;
- Any national emergency response plan to manage the accidental release of GMOs;
- Any existing laws, regulations and directives for the implementation Ethiopia of the Cartagena Protocol on biosafety; and AIA procedure;

[34] Article 15 (3) of the draft proclamation
[35] Article3 24 (3) of the draft proclamation
[36] Article 25(1) of the draft proclamation
[37] Article 25(2) of the draft proclamation

- Any relevant bilateral, regional and multilateral agreements and arrangements;
- The authority's final decisions regarding the importation or release of GMOs or products there of;
- Other information relevant to the proclamation;

All the above listed information filed in the National Biosafety Clearing House shall be accessable to the public. The proclamation shall not prejudice the right to confidential information.[38] With the above provisions, Ethiopian decision maker may feel more compelled to consider public comments before a GMO release can be approved. Public awareness and participation is an important aspect of the environmental procedural rights in Ethiopia.

Transparency is a very important aspect of any biosafety regulatory system as it creates public confidence in decision taken.[39] The draft biosafety regulatory regime of Ethiopia has provisions that ensure that the system of Ethiopia has provisions that ensure that the systems are transparent. The draft biosafety proclamation under article 24(4) specifically states that EPA will make available to the public information on any transaction, which has been granted or denied authorization. The draft Biosafety proclamation of Ethiopia under Article 25 and 26 also balance the rights of the public to information with the right of the developer or applicant to protect confidential information.

These provisions not only protect confidential information but they also ensure that the public receives at least a minimum amount of information about the GMO that cannot be claimed to confidential.[40] These provisions are consistent with the Cartagena protocol on Biosafety which promotes transparency but allows for the protection of confidential information.

The draft Biosafety proclamation of Ethiopia complies with the provisions of Article 23 of the Cartagena protocol on Biosafety. Under Article 23 of the protocol the parties are

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[38] Article 26 of the draft proclamation
[39] Pew initiative on food and Biotechnology, *Issues in the Rgulation of Gnetically Egineered Pants and Aimals* (2004) available at http://www.pewtrusts.org visited on 20th July 2008
[40] Article 26 (3) of the draft proclamation

required to promote and facilitate public awareness and education on LMOs that may be imported. The Cartagena protocol further calls for the parties to consult the public in the decision making process and make the results of such decisions available to the public.[41] The draft Biosafety proclamation of Ethiopia under Article 24 provide for public awareness and participation where the public is notified by the competent authority, the public makes comments, comments of the public are taken into account by EPA before decision is reached and confidential information is also taken into account. The African model law also recognizes public participation and awareness as essential elements of GMO regulatory system.

However, the draft biosafety proclamation is weak in terms of explicitly including provision for public awareness, rather than including it impliedly. It is a fact that there is limited public awareness and a lot of misinformation with the respect to the techniques, basic applications, opportunities, utility and safety of modern biotechnology and GMOs. The knowledge of modern biotechnology and its full implication for development are still confined to a few individuals and certain categories of Ethiopian society. As a means of stimulating public participation, public awareness is a very important component that should not be over looked.

According to Ato Belete, in Ethiopia public awareness campaigns have taken the form of sensitization workshops, development of a web site by EPA, translation of the biosafety features to Amharic, dissemination of best practices in biotechnology and biosafety to target institutions, dissemination of information in the electronic media e.g. FM radio and TV programmes.[42] The writer believes Ethiopia need to include biotechnology and biosafety in development of a curriculum for schools and colleges. All the above measures are meant to ensure that the Ethiopia public is fully aware of the events takes place in the field of biosafety and biotechnology so that than can effectively participate in the decision making process fully aware of their role. However, like in many developing countries, the public awareness campaigns in Ethiopia also do not have the desired

[41] Article 26 (3) of the draft proclamation
[42] . An interview with Ato Belete, Biosafety expert in EPA, 28/12/2008

impact on the target groups and these campaigns at times only appear on paper do not actually take place.

5.2.9. Socio-Economic Consideration

Consideration of socio-economic impacts and issues during the decision making process is an important aspect of sustainable development and intergenerational equity. Taking into account socio-economic consideration in decision making ensures that proposed projects are in harmony with the social well being of the people concerned and the surrounding environment.

While making decisions it is essential for the decision makers to taken into account socio-economic considerations. The Cartagena protocol has provisions on socio-economic considerations under Article 26 as discussed in chapter two, through its wording 'may take into account' does not create obligations to the parties to take them into account.[43] The African model law defined, social and economic conditions as a means the economic, social and cultural conditions, live hoods, knowledge, innovations, practices and technologies of indigenous and local communities including the national economy. In addition, when the competent authority makes a decision whether to approve or reject application, it takes into account whether the application have adverse socio-economic impacts.

The draft biosafety proclamation does not have specific provision for socio-economic consideration in decision making. However, the preamble of the draft proclamation takes about 'the quality of socio-economic and cultural conditions from the risks...'[44] which can lead us to conclude in decision making socio-economic consideration are taken into account. In addition, article 2(20) of the draft proclamation defines socio-economic impact as direct or indirect effect of a GMO or products there of on social and cultural

[43] .Kalibwani, F, Mugwagwa J, Chon J, *GoverningBiotechnology in Africa: Toward Cnsensus on Ky Isues in Bosafety*,(2004) available at http://www.ifpri.org/pubs/books/oc46.pdf. Visited on 22 July 2008
[44] Preamble second paragraph of the draft proclamation

conditions, the livelihood or indigenous knowledge systems or technologies of a local community, including on the economy of the country.[45]

Generally, the draft biosafety proclamation of Ethiopia recognizes the need to address socio-economic considerations that may arise from GMOs. However, the proclamation does not elaborate on what ways socio-economic considerations will be considered, how they will be analyzed, and how they will be factored into the decision making process. For biosafety regulatory system to be fair, predictable and transparent, the details surrounding the inclusion of Socio-economic consideration in the decision making process should be spelled out in more detail than is currently available in the draft biosafety proclamation. Without sufficient details the system could be perceived as unfair to the applicants and the public who may not know how specific application will be judged in this area.

Risk assessment report is one of the fundamental factors that will be taken into account in decision making process, according to the draft directive on risk assessment parameters of GMOs, socio-economic considerations in one of the factors; anticipated changes in the existing social and economic patterns resulting from the introduction of GMOs include:[46]

- Possible threats to biological diversity, traditional crops or other products and, in particular, farmers, varieties and sustainable agriculture;
- Impact likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies with the GMOs;
- Anticipated social and economic costs due to loss of genetic diversity employment, market opportunities and, in general, means of livelihood of the communities likely to be affected;
- Possible countries and/or communities out side of Ethiopia to be affected in terms of disruptions to their social and welfare;
- Possible effects with in Ethiopia in the other neighboring countries which are contrary to the social cultural ethical and religious values of communities.

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[45] Article 2(20) of the draft proclamation

[46] Draft Directive issued to determine risk assessment parameters of GMOs and products thereof (2007), article 3(7)

Plain language of Article 26 of the practical does not allow all socio-economic considerations of LMOs to be considered, but only those that arise from the impact of LMOs on the conservation and sustainable use of biological diversity especially with regard to the value of biological diversity, to the indigenous and local communities.[47] Some stakeholders believe, however, the socio-economic impacts of GMOs are much broader and could include concerns such as impacts on farmers incomes and welfare, cultural practices, community well being, traditional crops and varieties, domestics science and technology, rural employment, indigenous peoples , food security, ethics and religion, consumer benefits, and ideas about agriculture, technology and society.[48]

The draft biosafety proclamation do not have specific provisions for taking into account socio-economic considerations, but Ethiopia have differently attempted to comply with Article 26 of the protocol in the approval procedures. The wording of Article 26 of the protocol clearly indicates that not all socioeconomic considerations may be taken into account, but the draft directive on risk assessment provides for much broader socio-economic considerations (as discussed above) to be taken into accounts in decision making process.

5.2.10. Liability and Redress

The Cartagena negotiations were not able to address all the key unsolved issues that had not been conclusively agreed up on by the parties by the end of the negotiations. These key unresolved issues included liability and redress. As a result these key issues were not and still remain unresolved but were left at the discretion of individual's states. The African model law provides extensive provision on liability and redress.

As a consequence of disagreements during the negotiation of the protocol, Article 27 of the protocol is a compromise which provides an enabling provision for a process to

[47]Secretariats of the CBD, (2000) available at http://www.boidiv.org , visited on 24 July 2008.
[48] La Vina A., and L. Fransen, *Integration of Socio-economic Considerations into Biosafety Decision; the challenge for Asia,* (2004), available at http://www.pdf.wri.org/lavina_fransen_socioeconomics.pdf, visited on 25 July 2008.

consider the issue of liability and redress, but leaves all substantive discussions on liability and redress to the COP/MOP of the protocol.[49]

The draft biosafety proclamation contains a specific provision for liability and redress. According to Article 29 of the draft proclamation a person who is engaged in any transaction shall be strictly liable for any harm caused by such a GMO or product thereof, i.e. the party would have been held liable for any damages caused by GMOs, even he/she was not at fault. This position (strict liability) was the position of African countries during the negotiation of the protocol. The other core issue commonly addressed in liability and redress regime is scope of article 29. The scope of article 29 is very broad because it applies to "any transaction, which means research and development, import, export, transit, handling, contained use, transport, placing on the market, use as a pharmaceutical for humans or animals, use as food, or for processor of any GMOs or products thereof.

Who would liable for damage? The person responsible for the transaction, the provider, supplier or developer of the GMOs will be liable for any damage or injury or loss.[50] In case of more than one person responsible for the damages, the liability shall be jointly and several.[51]

Who would be entitled to bring clams? Any person, group of persons, or any private or state organization is entitled to bring a claim and seek redress in respect of the breach or threatened breach of any provision on the proclamation, including to damage to human health, biological diversity, environments, or socio-economic or cultural conditions of local communities or to the economy of the country.[52] What kind of damage would be compensated according to the draft proclamation? Possible categories of damage will be considered as follows:

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[49] Article 27 of the protocol
[50] Article 29(4) of the draft proclamation
[51] Article 29(5) of the draft proclamation
[52] Article 29(10) of the draft proclamation

a) In case of harm to the environment or biological diversity, compensation shall include:[53]

- The cost of reinstatement;
- Rehabilitation or clean-up measures which actually are being incurred and;
- Where applicable, the costs of preventive measures

b) In the case of harm to human health, compensation shall include:[54]

- All cost and expenses incurred in getting the necessary medical treatment:
- Compensation for any disability suffered, and for diminished quality of life, and for all costs and expenses incurred in reinstating, as far as possible, the quality of life enjoyed by the person before harm was suffered;
- Compensation for loss of life and all costs and expenses incurred for funeral and other related expenses;

C. Liability shall also extend to damage caused directly or indirectly by GMOs to:[55]

- The livelihood knowledge systems of local communities;
- Technologies of a community;
- Damage arising from incidences of public disorder triggered by GMO or products thereof;
- Disruption to production or agricultural system;
- Soil contamination;
- Reduction in yields
- Damages to the biological diversity
- Damage to the economy of a community;
- Any other consequential economic, social and cultural damages.

The possible circumstances that would lead to exoneration of liability include:[56]

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[53] Article 29(6) of the draft proclamation
[54] Article 29(7) of the draft proclamation
[55] Article 29(8) of the draft proclamation

- If it is verified that it is the victim himself that has caused the damage: or;
- If it is verified that a third party has caused the damage in question.

However, approval for any transaction by EPA does not exonerate the applicant from liability.[57] As discussed above, the Ethiopia regulatory regime for biosafety is very broad and specific in relation to liability and redress. Where as, the Cartagena protocol failed to resolve this complex issue. The African model law incorporates similar provision to that of the draft biosafety proclamation (article 29).

5.2.11. Monitoring and Compliance

Institutional frameworks and regulatory provisions are important in the supervision, enforcement and administration of biosafety regulatory system as this ensures compliance. In Ethiopia a number of bodies are involved in the various aspects of regulating modern biotechnology.

The first regulating to be carried out by the applicant and is part of the application for authorization of GMO related activities as clearly stipulated under the Ethiopia biosafety law. As discussed above, any person who wishes to carry out any transaction in relation with GMO or products thereof shall submit an application in writing to the EPA.[58] The application, among other issues, include a clear and sequential description of the steps to be taken in the implementation of the project,[59] which uses GMOs or products thereof intended for import, and the monitoring and evaluation that will be made at the end of each step, and method of disposing of any waste.[60] In addition, a risk assessment report including the effects of unintentional release and emergency response plans to address the problem.[61] The applicant is required to develop, maintain and implement a risk management strategy to protect human or animal's health and the environment.[62]

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[56] Article 29(3) of the draft proclamation
[57] Article 29(1) of the draft proclamation
[58] Article 10(1) of the draft proclamation
[59] Article 10(2) (g) of the draft proclamation
[60] Ibid
[61] Article (2) (c) of the draft proclamation
[62] Article 19(5) of the draft proclamation

Moreover, after the authorization is granted, the authorized person should maintain a register to record the type, quantity, country of origin and transaction or of any GMO or its products and other information required by EPA.[63] An authorized person is also required to submit EPA, every three moths, a written report regarding the transactions involving any GMO or product thereof that is under his custody.[64] Furthermore, where there is any significant threat related to GMO, the owner or the person in change must immediately report the matter to EPA.[65] To sum up, to draft biosafety proclamation impose a duty of monitoring on the applicant as part of the conditions during the application procedure.

Secondly, the draft proclamation gives the responsibility of exercising of exercising monitoring function to inspectors, which are appointed by Environmental protection Authority.[66] An inspector has the power to:[67]

- To enter any place in respect of which she/he has reason to believe that a infringement of any provision of the proclamation;
- Inspect and order the taking of any corrective measures on any transaction carried out in the place or facility;
- Request or obtain information form any person carrying out or in changes of any transaction.
- Size any application, books, statement or other document which appear to provide proof of infringement of any provision or of the proclamation.
- Take samples of any material or substances as required and carry out or cause to be carried out tests he/she considers appropriate; with out any need for prior notice or court order.

Thirdly, as discussed above, EPA as per proclamation no. 362/2003 is assigned as an institution or government body, which is responsible for the enforcement of Cartagena protocol, in Ethiopia. Cartagena protocol can be enforced in Ethiopia by respecting and

[63] Article 19(2) of the draft proclamation
[64] Article 19(6) of the draft proclamation
[65] Article 19(7) of the draft proclamation
[66] Article 21(1) of the draft proclamation
[67] Article 21(4) (a-e) of the draft proclamation

implementing it. Or it can be enforced by adopting and regulating domestic laws relevant to the protocol. This regulatory framework is part of this process. Therefore, EPA is the central body which gives permit for any transaction, and may also withdraw the authorization or the cessation of any transaction relating to the GMO, in the case of imminent and serious danger to human or animal health, biodiversity, the environment or socio-economic conditions and when the transaction has been under taken in violation of any of the provisions of the draft biosafety proclamation.

Fourthly, the customs officer is also responsible for ensuring compliance of the regulatory regime. Any person in possession of any GMO or its products is obliged to declare such a possession to the customs officer on duty at the port of entry or exit up on arrival or departure.[68] If a customs officer suspects that any person is in possession of a GMO or product thereof for which there no valid authorization, the officer may require the said person to surrender the GMO or its product which will immediately be sent to EPA.[69]The authority may then dispose the seized organism or its product. The authority may charge the attendant costs of disposal, housing or re-export to the owner or the person who had possession of the GMO or its product.[70] However, if the organism surrendered to customs officer or inspector is determined by the authority not to be a GMO, it will be returned to the person who surrounded the sample.[71]

Under article 33 of the Cartagena protocol calls up on each party to monitor the implementation of its obligations under the protocol. Article 33 further provides that, each party shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the parties to this protocol, report to the conference of the parties on measures that it has taken to implement the protocol. Article 33 imposes two obligations on Ethiopia. The first obligation is to monitor their implementation of the protocol and secondary, to report on measures that they have taken to implement the protocol.

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[68] Article 27(1) of the draft proclamation
[69] Article 27(2) of the draft proclamation
[70] Article 28(7) of the draft proclamation
[71] Article 27(4) of the draft proclamation

Article 19 of the protocol requires the parties to designate National Focal Points (NFP) and Competent National Authorities to perform functions relating to the protocol. The biosafety regulatory system of Ethiopia does comply with the Cartagena protocol. The National Focal Point is the primary contact point between a party and the Secretariat to the protocol. For the purpose of Ethiopia the national contact person is Dr. Tewolde Berhan G/Egziabher, Director General of EPA. The functions of the Competent National Authority are quite different to those of the National Focus Point. The Competent National Authority is responsible for exercising the administrative functions required by the protocol, and must be authorized by a party to act on its in relation to these functions. In effect, the functions of the Competent National Authority are spelled out in the AIA and other provisions of the protocol. The draft Biosafety proclamation of Ethiopia establishes Environmental protection Authority as Competent National Authority.

Lastly, as per the memorandum of understanding between EPA and UNEP, EPA has established a National Biosafety Clearing House (NBCH) task force with members draw form key stakeholders institution to assist in the implementation of the national biosafety Framework devolvement project at the national level.[72] Furthermore, any licensing agencies shall, prior to issuing any type of license to any applicant to be engaged in any transaction, ensure that EPA has granted the applicant an authorization to do so. Therefore, there is cross-checking process among different agencies and government bodies in relations to any GMOs or products thereof.

[72]Environmental protection Authority, *Biosafety Framework* , (2007), available at http://www.epa.gov.et visited on 26/04/2008 , p.35

CHAPTER SIX

6. CONCLUSION AND RECOMMENDATION

6.1. Conclusion

The Cartagena protocol can only ensure that the global use of biotechnology is safe if each and every country actively promotes biosafety at the national level. National policy makers and legislators have a vital role to play in establishing and strengthening laws and standards for reducing the potential risks of GMOs. Under the protocol, it is governments that are ultimately responsible for preventing illegal shipments and accidental releases, managing any risks or emergencies and regulating national biotechnology industries. From environmental point of view, one of the highlights of the protocol is the precautionary principle. Because modern biotechnology is such a revolutionary science, and has produced such a powerful industry, it has great potential to reshape the world around us. It is already changing agriculture and the food we eat. Given the complexities and the high stakes, it is reassuring that the global community has already agreed on a regulatory safeguard at this early stage in the development of modern biotechnology. There can be no doubt that biosafety will remain at the top of the international environmental agenda for many years to come.

The protocol constitutes an important treaty because it is the first binding international legal instrument addressing some environmental and health impacts of modern biotechnology. However, the protocol remains limited in scope, both with regard to the coverage of LMOs and the kind of activities it seeks to regulate. In effect, the protocol restricts itself to providing a framework for trade in LMOs from an environmental perspective. It generally seeks to facilitate trade in LMOs by laying down certain obligations for exporters and importers and therefore creating clear rules for transboundary movements LMOs. This implies, for instance, that importers must undertake risk assessment in what is recognized as a scientifically sound manner. The protocol, however, goes much further than its WTO equivalent, the SPS agreement, and

establishes a procedure which not only gives the importing state the final say in a decision on a transboundary movement but it is also based on the precautionary principle, which permits importing states to put restrictions on imports even in the absence of scientific certainty with regard to the potential adverse effects of LMOs on the environment.

In other words, in so far as the biosafety protocol tackles a trade issue from an environmental perspective, it is a successful treaty whose conclusion was helped in large part by the failure of WTO to do the same.

Africa has adopted the African Model Law on safety in biotechnology in May 2001. The OAU Council of Ministries urged African states to use the Model Law to draft their national legal framework for biosafety, which adheres to a broader and unified continental framework. This Model Law utilizes the discretion given by Cartagena Protocol on biosafety for countries to adopt more protective measures than the agreed minimum set out in the protocol. The African Model Law provisions are therefore more comprehensive that required by the biosafety protocol and seek to give recognition to the importance of African as both a centre of origin and centre of diversity with regard to food and other crops. The Model Law embraces the precautionary principle and recognizes the sovereign right of every country to require a rigorous risk assessment of any GMO for any use before any decision regarding the GMO is made. It captures extensively the essential elements for liability and redress regime, which should be incorporated in to domestic biosafety legislation.

The implementation of biosafety leans heavily on government policy. Biosafety decisions are taken by weighing risks and benefits and evaluating the over all impact of a proposed activity with GMOs on the environment, including human health. This decision need the support of clear national policy on what is and is not acceptable and important principles guide decision making. National policies establish the need and scope of biosafety and guides the format legislation will take. Policy is linked to government commitment to implement and should cover the financial, institutional and human resources that will be needed and supplied to ensure competent implementation.

At present there is no stand-alone national on biosafety in Ethiopia to deal with the issues related biosafety in general and the protocol in a comprehensive way. However, there are binding policies in different sectors, which reflect on some of the issues on biosafety. Among this guiding principles to develop policy on biosafety are incorporated in the FDRE constitution. Especially the following rights are the guiding principles for any environmental policy including biosafety:

- The right of Ethiopian nationals to participate in national development be consulted with respect to policies and projects that affect their community. In other words, public participation and awareness.
- All people's right to live in a clean and healthy environment.
- The right to improved living standards and sustainable development.

The environmental policy of Ethiopia is the relevant document for biosafety. Because it contains policy statements related to biosafety. Other policies which are relevant to biosafety include: (i) The National Science and Technology policy of Ethiopia, (ii) The National Biodiversity Conservation and Research Policy, (iii) Agricultural Research Policy. However, the writer believes the above policies are not enough and strongly recommends a separate policy for biosafety to be introduced. The reasons are:

- These policies have their own priorities other than biosafety;
- Sectoral policies failed to deal with the issues and concerns of GMOs in comprehensive way;
- The existence of so many policies on biotechnology and their occasional reference to biosafety might lead to confusion;
- Separate policy is needed to demonstrate Ethiopia's commitment to the biosafety issue.

Implementation of the protocol in Ethiopia is still young. The draft biosafety regulatory regime of Ethiopia is still a draft mode of regulating biosafety as Ethiopia has not yet enacted the biosafety proclamation of 2007 in to laws. The draft biosafety proclamation and the six directives of Ethiopia to greater extent comply with the provisions of the

protocol. The writer further argues that the content of the draft proclamation more comprehensive and broader in scope to that of the protocol.

Ethiopia has recognized the benefits and potential risks posed by modern biotechnology, and has to be differing extents, implemented legislation and directives that have attempted to strike a balance ensuring the development of biotechnology and safeguarding the interests of the consumers and the environment. The Cartagena protocol has, nonetheless, influenced policy debates and regulatory and institutional developments in Ethiopia. Ethiopia has been working the past few years to establish a national biosafety regulatory system so that GMOs may safely be introduced in the agricultural and other sectors. At the time of writing the biosafety regulatory regime of Ethiopia comprised of the draft biosafety proclamation, directives and policies. Therefore, Ethiopia has an opportunity to rectify the flaws in its biosafety regulatory framework since its still in draft form.

The prospects for Ethiopia to choose its own path in biosafety policy will to a large extent be shaped by its domestic priorities and imperatives. This is also keeping with original intent of the Cartagena protocol, which is to empower the GMO importing countries to make informed judgment about the impact of transgenic crops on its domestic ecological, health and agricultural system. The biosafety regulatory regime of Ethiopia has followed a precautionary approach which has also been taken by bodies such as the European Union (EU).

The absence of a shared global approach to GMO regulation, combined with disunity among leading agricultural trading partners in the developed countries, has the potential to open the policy space for autonomous decision-making in the developing countries. This is partly because such conflicts will enable countries that desire to engage in trade with such countries to simultaneously combine openness and precaution towards transgenic in their domestic policies.

In interpreting global biosafety rules such as the Cartagena protocol, in many developing countries such as Ethiopia, where trade, market access and competitiveness are not

deriving the directions of biosafety policy, in so far as visibility to biosafety concerns is concerned. Not with standing the protocol, the controversies around the global and domestic regulation of biotechnology especially between the proponents and opponents of GMOs are unlikely to diminish in the near future, and instead look to escalate especially as the WTO weighs in to the global debate. Critics of stringent and tough biosafety regulatory frameworks argue that these rigid biosafety frameworks may interfere with free trade, while others argue that free trade should not be interpreted to mean unlimited hazards to the environment and human health. However, this study supports the view that globalization of modern biotechnology currently co-exists with regulatory diversity in the national biosafety policies of developing countries. This is because such globalization and associated global regulation itself remains diverse.

6.2. Recommendations

Through a detailed analysis of the current regulatory system in Ethiopia, the study has identified a number of issues, that if addressed could improve the system. Some of the major recommendations from the study are as follows:

1. The regulatory framework for biosafety requires specific or separate policy. The existing policies are not enough to comprehensively address the issue of biotechnology. The objective of this separate policy must be to balance two interests. These are Ethiopia's need for economic development by using biotechnology and protection of environmental and human health concerns.

2. Ethiopia should enact legislations that will fully operationalise the draft biosafety proclamation and the six draft directives and biosafety policy. This is because at present the biosafety regulatory regime of Ethiopia is a combination of draft laws and to limited extent binding laws. This may expose the biosafety regulatory framework and all institutions established there under to legal challenges in the courts of law since it does not have legislation established it. Alternatively, Ethiopia could speed up the enactment of the biosafety proclamation.

3. Ethiopia should work towards strengthening and consolidating the already existing regional approaches, in regulating modern biotechnology. The approach taken must also be in compliance with the African Model Law and the Cartagena protocol on biosafety. This will enable the country to form collective approaches in regulating biotechnology and GMOs, since no single country can regulate GMOs without cooperating or getting assistance from other countries. This will enable countries such as Ethiopia that do not yet have substantive GMO legislation to enact uniform and more practical biosafety regulatory frameworks.

4. As the national competent authority, the Environmental Protection Authority (EPA) should also be given a more clear definition of roles in relation to other institutions or administrative bodies. EPA should also consider establishing the office of substantive administrative officer (for example registrar or permanent committee). This permanent committee should be independent and constituted in a more all encompassing manner. This includes representative of all the interested parties such as the civil organizations and non governmental organizations. There is also need to include other professionals like economists, lawyers, anthropologists, environmentalists and sociologists so that the composition of the decision making bodies is not scientifically skewed.

5. The draft biosafety proclamation of Ethiopia should adopt more elaborate and meaningful provisions on public awareness. Furthermore, more time should be allocated for the public to make comment.

6. The draft biosafety proclamation should adopt clear approach of taking into consideration socio-economic factors more especially in the decision making process.

7. The draft regulatory framework of Ethiopia failed to define biosafety. Thus, the regulatory system needs to take a clear stand in defining the very title of the law, 'Biosafety Proclamation'.

8. Biosafety regulatory systems usually establish safety standards for their approval process. The safety sets forth what level of protection must be satisfied to approve an application and what factors the government will consider before making an approval decision, including the baseline for any risk analysis. The safety standard guides the government on how to use its legal authority to regulate GMOs. The standard also identifies whether the benefits from GMO or the opportunity costs of not introducing the organism will be considered. In a functional protective system, all interested parties know and understand beforehand and government decisions apply that standard in a uniform and fair manner. The Ethiopian regulatory system provides some criteria or benchmarks established by six directives or what they mean is not discussed any where in any other documents that establish Ethiopia's biosafety regulatory system. Thus, without a more through explanation or the release of GMOs can meet those benchmarks. Therefore, EPA is expected to adopt this benchmark either as guidelines or any other form.

9. Biosafety regulatory systems look at each application individually and assess any potential risks to human health and the environment through a scientific risk based analysis. The system usually has the flexibility to treat products differently depending on the potential risks and concerned raised. It prioritized applications its reviewed based on the potential risks and give the most scrutiny to products with the most relative risk while allocating less resources and time to products that rise less concerned. The proposed Ethiopia biosafety regulatory system failed to incorporate this principle. The draft biosafety regulatory system does not mention that different activities with a GMO have different relative risks. Application for contained use, confined field trials, and commercial release are treated the same, requiring the same procedures, data and risk assessment. This is one of the main weaknesses of the draft regulatory system and needs reconsideration.

10. Ethiopian biosafety regulatory system explicitly includes products of GMOs in its regime. The scope of the draft proclamation states that the biosafety regulatory

system includes products of GMOs and the approval processes it describes require Advance Informed Consent for GMO, a product of GMO, or any material derived by processing a GMO. Thus, risk assessment will take place on both GMOs and their products. If Ethiopia biosafety system is supposed to approve each product of a GMO using the same procedures, risk assessments, and information requirements as would be done for a GMO, the system could receive thousands of applications from persons and companies who do not know very much about the GMO. For example, GMO tree could be used to make dozens of different products including paper, wood furniture, and wood picture frames. Is it anticipated that under the Ethiopian biosafety regulatory system, papers would require an approval if they were made from a GMO? Thus, from a practical and scientific view point, it may make sense to consider less restrictive application procedure to approval products that derived from the GMO.

To achieve the recommendations outlined above, it is important that stakeholders from all spheres of influence in Ethiopia build alliances to establish effective legislation by lobbying and establishing consumer advocacy programmes at national, regional and international levels.

6.3. Future Perspectives

The field of modern biotechnology and GMOs is a wide and complex one that involves many challenging aspects. Modern biotechnology is still a new face in Africa and it leaves a lot unresolved and unanswered questions. The present study has revealed that in the field of modern biotechnology as in most other cases of potential risks and threats to the environment, international biosafety obligations (like the Cartagena protocol on biosafety) which imposes restriction on the domestic management and implementation have been globally acceptable. This is because the use of modern biotechnology in one country is perceived to have a possible effect to global commons or territory of other states.

Initially, during the Cartagena negotiations there was a wide spread assumption by the negotiators that the adverse effects of LMOs could only affect other states through trade. As a result, only trade regulations seemed politically agreeable as they do not affect the sovereignty of states with regard to domestic management of GMOs, but rather seek to enable importing developing countries such as Ethiopia to effectively exercise their existing sovereignty.

From an environmental point of view, and taking also in to account approaches existing in the field of human rights law, this tendency as such may be criticized. However, even if one accepts it as a fact, one may criticize the limitation of the Cartagena protocol on trade, as there are many other aspects of international dimensions, which all reach beyond trade such as biotechnology. And one may doubt whether the effects of growing GMOs especially as food may, in the long run, be locally limitable in the developing countries. The Cartagena protocol therefore, constitutes an important recognition of the responsibility of the developed countries in terms of trade with developing countries. It however, seems that the international regulation of biotechnology and GMOs will, in the long run, be insufficient to cope with the various kinds of transboundary environmental and health problems which biotechnology and GMOs pose.

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