EFFECTIVENESS OF KENYA'S BIOSAFETY LIABILITY AND REDRESS REGIME

BY

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DECLARATION

This thesis is my original work and has not been submitted for award of degree or diploma in any other institution.

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APPROVAL

This thesis has been submitted and accepted by the school for execution with approval of my supervisor.

Name: Dr. Collins Odote.

Signed_____Date_____

DEDICATION

To my parents, Mr. Joseph Onkwani and the late Yunuke Kemunto, you supported me through and through, may God bless you abudantly. This is in your honour.

ACKNOWLEDGEMENT

"And he saw them toiling in rowing; for the wind was contrary unto them; and about the fourth watch of the night he cometh unto them, walking upon the sea, and would have passed by them." Mark 6:48. I give thanks to God almighty for he did not pass by me.

To my supervisor, Dr. Collins Odote, you were very patient with me, your diligence and thoroughness is appreciated. To my family: Mum though gone too soon I know you are watching over me and this was your desire I will go all the way. Dad you are my best friend and pillar, without you I wouldn't have achieved this. Thanks for believing in me. To my sons Sidney and Stanley, you mum has been away for too long but it was for a worthy cause, one day you will appreciate. To all my siblings, your prayers, support and encouragement even when I was at my lowest is much appreciated. To all my friends especially Gladys and Agnes thank you for the support. LLM class of 2010, I made best friends Vivian and Rael, thank you for being there for me and to all my year mates you were the best, God bless you all.

ABBREVIATIONS

AIA	Informed advance agreements
AUC	African Union Commission
CBD	Convention on Biological Diversity
CPB	Cartagena protocol on Biosafety
FIS	Fauna Impact Statement
GMO	Genetically Modified Organisms
KARI	Kenya Agricultural Research Institute
LMO	Living Modified Organisms
OECD	Organization for Economic Co-Operation and Development
OAU	Organization of African Unity
UNEP	United Nations Environmental Programme
UNCHE	United Nation Conference on the Human Environment
WHO	World Health Organization

LIST OF STATUTES
KENYA

Agricultural Production (Export) Act, Cap 245

Agricultural, Fisheries and Food Authority Act, No.13 of 2013

Biosafety Act No. 2 of 2009

Constitution of Kenya, 2010

Crop Production and Livestock Act, Cap 318

Dangerous Drug Act, Cap 242

Environmental Management and Coordination Act, 1999

Food Drugs and Chemical Substances Act, Cap 254

Narcotic Drugs and Psychotropic Substances Act, Cap 245

Pest Control Products Act, Cap 346

Public Health Act, Cap 242

Plant Protection Act, Cap 324

Seeds and Plant Varieties Act, Cap 326

Use of Poisonous Substances Act, Cap 231

INTERNATIONAL STATUTES

Biodiversity Convention, 5 June 1992

Basel Protocol on Liability and Compensation for Damage Resulting from Trans boundary Movements of Hazardous Wastes and Their Disposal, Dec 10, 1999

Convention on Biological Diversity, 5 June 1992

Convention on Civil Liability for Oil Pollution Resulting From Exploration of the Exploitation of Sea Bed Mineral Resources 1977

Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 20 January 2000

IMO Protocol to Amend the International Convention on Civil Liability for Oil Pollution, 1969

International Convention on Civil Liability for Oil Pollution Damage 1969 (The Oil Pollution Convention)

International Convention on the Establishment of an International Fund for Compensation for Oil Pollution 1977 (The Oil Fund Convention)

Kuwait Regional Convention for Cooperation on the Protection of the Marine Environment 1977

Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, June 21, 1993

Organization of African Unity

The Brussels Supplementary Convention on Third Party Liability in the Field of Nuclear Energy (The Brussels Supplementary Convention)

The Convention on Third Party Liability in the Field of Nuclear Energy, Adopted In Paris on 29th July, 1960

The Convention Relating To Liability In The Field Of Maritime Carriage Of Nuclear Material (The 1971 Brussels Convention)

The Nagoya Kuala-Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

The Vienna Convention on Civil Liability for Nuclear Damage (The Vienna Convention)

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ABSTRACT

Biotechnology's impact on human health and environment is unknown. The main product of biotechnology is genetically modified organisms (GMO).There are various benefits of GMO's especially for developing countries like Kenya where food scarcity is a perennial problem. The benefits of biotechnology and GMO's therefore, have to be weighed against the risks likely to occur. This calls for striking a balance in order to ensure that biotechnology does not result in harm to the consumers of the various products. It's upon this premise that an established liability and redress mechanism comes in handy to ensure that biotechnology does not result in harm to the consumers. Kenya is a party to the Convention on Biological Diversity and the Cartagena Protocol. In the year 2011, Kenya opened up to Genetically Modified crops after approving laws to allow production and importation. Kenya's commitment to liability and redress was put into question in November 2012, when the president banned the importation of GM foods and the Ministry of Public Health ordered public health officials to remove GM foods from the market and enforce the ban. This put Kenya's legal and regulatory framework in doubt. The work of National Biosafety Authority was also put into jeopardy by this lack of political good will. The big gap between what the law provides on biosafety and the practical reality led to this research. The research has adopted a secondary approach in addressing the legal aspects of assessing the effectiveness of Kenya's liability and redress regime. The research found that there is first, the need for political good will to ensure that institutions tasked with the formulation and review of laws and policies play their roles well. The mandates of various institutions to be clearly defined in law, so as to have a coordinated approach in biosafety regulation in the country and reduce duplication of functions among institutions. The current biotechnology framework is not specific in addressing liability and redress and it needs to be relooked into and be cast in a manner specifically to address liability and redress in biosafety. Public participation was also found to be key in all the processes.

CHAPTER ONE

EFFECTIVENESS OF KENYA'S BIOSAFETY LIABILITY AND REDRESS REGIME

1.1. Introduction

Biotechnology is characterized by the Convention on Biological Diversity as "any mechanical application that utilizations natural frameworks, living beings or subordinates thereof, to make or alter items or procedures for particular employments." The development in biotechnology through the control of organic assets has come about into the generation of items whose effect on human wellbeing and the earth is obscure. One such item is hereditarily adjusted life forms (GMO), which is a novel mix of hereditary material acquired using advanced biotechnology procedures.

This raises the issue of biosafety which imagines "the evasion of hazard to human wellbeing and security to the protection of nature, as an aftereffect of the utilization of research and trade of hereditarily altered life forms." Kenya's Biosafety Act characterizes it as "purposeful presentation into the earth" implies any ponder utilization of genetically modified organisms other than not contained use". According to the World Health Organization (WHO) Laboratory Biosafety Manual (LBM), biosafety is the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release. It can therefore be said that biosafety involves the application of safety principles to liability practices were potentially hazardous biological material or organisms are manipulated. But the question to be asked is what would happen if human beings or the environment were to be injured through the use of these materials?

1.1.1. Benefits of Biotechnology

The benefits Kenya could get from GMO include increased profitability through improved yields, quality and increased tolerance to stress levels and new value addition that offers new opportunities. There could also be a substantial reduction in manual labour for the rural farmers, reduced pressure to till marginal land, fragile ecosystems, support for farming that involves pest management with a higher potential for improving agricultural sustainability. Benefits could also accrue to consumers through availability of food even in adverse weather conditions, lower food prices, and better food security for farmers who form a larger segment of Kenya's rural population.

Biotechnology has the potential of tremendously increasing agricultural, production in Kenya which would deal with problems associated with food insecurity while enhancing sustainable development in natural resources. There is, however, a need to ensure that a balance is struck in order to ensure that biotechnology does not result in harm to the consumers of the various products. Advancements in technology have been seen in certain cases to be accompanied with increased potential for harm and damage. This has therefore necessitated the establishment of a liability mechanism. In order to establish a liability mechanism, certain factors must be taken into account, these are; that a certain action is in contravention of the established legal rules, as a result of that damage has been occasioned, and there is a causal connection between the activity and the harm, and that responsibility for the damage is attributable to the legal entity. These cumulatively warrant the imposition of liability.

1.1.2. Risks Related to the Use of Biotechnology products

The benefits of biotechnology and GMO have to be weighed against the risks that are likely to occur. Biotechnology products pause enormous risks to public health and the environment, due

to “the application of genetic engineering, dubbed modern biotechnology” to modify or manipulate living organisms, in addition to risks to socio-economic and ethical aspects. For example the use of genetically modified (GM) herbicide tolerant crops could produce weeds that are difficult to control and destroy biodiversity. This could as well damage the food chain that depends solely on non-toxic wild plants. Already due to the continued use of biotechnology products in Europe, many countries have experienced massive decline in the bird population some of which are threatened with extinction.

Biotechnology has led to the production of GMO food, although scientific knowledge is not conclusive on whether or not GMO food is good or bad, concerns have been raised about the dangers of allergenicity and toxicity due to the transfer of genes between species. This could be risky to health thus raising the need for testing risks of allergy and toxicity before such products are taken to the market. The development of genetically modified (GMO) foods will facilitate the erosion of genetic base, due to the replacement of local varieties with GMOs, erosion occurs when the new GMO do not contain genes and genetic varieties found in the old farmers varieties.

GMOs have socio-economic effects where the rich are able to benefit from biotechnology as they are able to commercialize these products. The poor farmers on the other hand lack access markets, agricultural infrastructure and extension services. Therefore the need for equity in accessing GMO technology has never been more urgent.

The use of biotechnology in agriculture has a number of risks that are social economic in nature, social ethical, health and environmental related. Social economic impact will involve GMO technologies impacting negatively on the livelihoods of local farmers. The new varieties produced could mean over dependence on external seeds thus becoming more vulnerable. There

is the risk associated with socio-ethics, where in an effort to access genetic information may lead to the violation of privacy and acceptability where genetic materials are introduced from some animals. GMO may as well lead to transfer of genes to populations to the wild other than there agricultural environment. Others may develop resistance and possible creation of super-weeds. In addition, in Kenya, there is the possibility of negative impact of GMO on biodiversity due to cross-pollination which could lead to contamination.

It is upon this that there has been established a liability and redress mechanism to ensure that biotechnology do not result in harm to consumers and where such happens, redress is offered. The establishment of liability and redress mechanisms will serve many functions as an important instrument in the promotion of consistence with universal standards in the usage of the preparatory guideline and counteractive action rule. The danger of obligation and weight of review, goes about as discouragement for shirking of hazard and harm. Besides, obligation moves the expenses of natural hazard and harm far from society to the individuals who make harm the earth and wellbeing. In the allotment of duty regarding repair to harm, an obligation and review structure is a stage towards actualizing the polluter pays guideline. For the creator of ecological mischief, a change office is discouragement for exercises that are naturally unsafe as well as prompt to interest in preventive measures.

1.1.3. Liability and Redress under the International Law

The improvement of worldwide structures for obligation and review identifying with trans-limit harm to wellbeing and property is by and large all around created at the global level however there is no relating administration for trans-limit harm to the earth. Existing obligation and change instruments identify with atomic materials and oil contamination. The improvement of a biosafety administration is a critical system for the authorization of natural approaches and

benchmarks that have been built up through settlements. The consultations since the 1972 Stockholm Conference on Human Environment and the Rio Declaration in 1992 to create law on liability and redress framework has only met limited success and generally postponed for future implementation.

It was noted that there was need of ensuring safety in the use of biotechnology and the development of a liability and redress framework was therefore imperative, this began with deliberations leading to the Convention on Biodiversity (CBD) where biotechnology was at the centre of discussions.

The Cartagena Protocol in Biosafety, which was signed in 2000, was a move towards establishing an international framework in liability and redress. However the protocol experienced major disagreements between the member countries. The gist of the disagreements consisted of four issues; first is the scope of the Protocol and wether member countries would allow various categories of living modified organisms (LMOs) in the Protocol's AIA method? Furthermore, individuals couldn't concur on the relationship between the Protocol and other universal foundations primarily the World Trade Organization (WTO) and the dread that inability to put in place a liability and redress framework could act as a non-tariff barrier (NTB) when trading with nonmembers. The third disagreement related to manner and criteria of decision making within the protocol especially over the inclusion of the precautionary principle and how to treat socio-economic effects of GMOs. The fourth and final disagreement concerned the responsibilities of the exporter and liability regarding the documentation and identification of shipments of LMOs and the improvement of a risk and review system. Considerations on the last were delayed in accordance with Article 27 of the convention:

The Conference of the Parties serving as the meeting of the Parties to this Protocol might, at its initially meeting, embrace a procedure as for the suitable elaboration of universal guidelines and systems in the field of risk and review for harm coming about because of trans-limit developments of living altered living beings, breaking down and assessing the progressing forms in worldwide law on these matters, and should attempt to finish this procedure inside four years.

The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress is a supplementary protocol to the Cartagena Protocol on Biosafety. Parties to the protocol took 6 years and 10 sessions in addition to other preparatory meetings to reach a consensus. It showed the urgency of having an international substantive liability and redress mechanism to address damage that would arise from GMO. It was noted that the development of GMOs may be hazardous to the environment and human health. It was therefore imperative that a risk-assessment mechanism be established in order to identify and assess any risks for the environment and human health that may be caused by these organisms. This particularly became key in relation to transboundary movement of the GMOs where it became necessary that a civil liability mechanism be established.

A feature of the discussions at Nagoya was the conflict between countries that were concerned about risks and the adverse effects of GMO and those that downplayed the impact of the risks. The origin of the disagreement was that some of the countries opposed to an international liability and redress framework were either exporters of GMO or aspired to be exporters so they pushed for a compromised structure.

African countries were major proponents of a substantial liability and redress framework from as early as the Cartagena Protocol on Biosafety. Developing countries and a few developed countries such as Norway wanted a binding international regime that would establish substantive rules on civil liability. This would help those injured by GMO to use national courts for redress. Instead the Protocol adopted an administrative approach. The problem with such an approach was that it gave the owner of the GMO or competent authorities the leeway to determine measures to be taken to limit damage. The folly with such an approach is that it only covers situations where damage has either occurred or is likely to occur.

1.2. Historical evolution of the Biosafety regime in Kenya

Prior the enactment of the Biosafety Act in 2009, Kenya's biotechnology was regulated under diverse statutes in agriculture and public health and welfare. This was notwithstanding the growth in the amount of biotechnology products as evidenced by the sharp increase in transgenic crops from zero in 1995 to about 39.9 million hectares in 1999. This has been enhanced by the adoption of such crops increasing by 23 times between 1996 to1999. Although these developments occurred in countries that were more industrialized than Kenya such as (Argentina, China, Mexico and South Africa), numerous African nations were quick to get these innovations. To do as such anyway, they should be guided by "sound instruments for evaluating dangers and advantages" to empower them settle on smart decisions in receiving the advancements.

In 1987, the Government through the then Ministry of Research Science and Technology set up an advisory group under the National Council for Science and Technology (NCST), to decide the needs for research in biotechnology. The panel known as the National Advisory Committee on Biotechnology Advances and their Applications (NACBAA) made the principal reference to the

requirement for a strategy on biosafety. The board of trustees, comprising of the chiefs of Research Institutes, created a report which suggested that the NCST builds up an arrangement on biohazards and morals in biotechnology.

In 1994, the Kenya National Environment and Action Plan which was affirmed by Cabinet, made the accompanying suggestions relating to biosafety: Establish a National Commission on biotechnology and biosafety. Define a logical criteria for the sheltered utilize hereditarily altered life forms including strategies for risk distinguishing proof and introduction appraisal before GMOs are discharged into nature furthermore configuration measures for organic and Physical regulation of GMOs and components to screen the creatures, hereditary material and procedures presented to GMOs. Make Prior Informed Consent a Pre-imperative for all field-testing. Plan a biosafety strategy and controls. In 1997, The Kenya Agricultural Research Institute created Biosafety Guidelines and shaped the Institutional Biosafety Committee.

In 1998, the National Council for Science and Technology created the directions and rules for wellbeing in biotechnology which gave a base to the foundation of the National Biosafety Committee (NBC) and Institutional Biosafety Committees and in addition recognizing the able power as the National Council for Science and Technology. In 1999, under the structure of the UNEP/GEF Biosafety Enabling Activity, a National Biosafety Framework was created in light of an appraisal of the status of biotechnology and biosafety in the nation. A draft Biosafety Law was likewise arranged and it is at present under amendment for accommodation to the dominant presences in control. In 2000, the National Biodiversity Strategies and Action Plans (NBSAP), distributed by the Ministry of Environment and Natural Resources, distinguished biosafety as an

essential region that required support for its headway. On fifteenth May, 2000, amid the Fifth Conference of Parties to the CBD, the President of Kenya marked the Cartagena Protocol on Biosafety. Kenya was the main nation to sign the Protocol.

In 2011 Kenya become the fourth country in Africa to open up to genetically modified (GM) crops after approving laws to allow their production and importation. The adoption of the GMO technology has been dogged by controversy over safety concerns. In Kenya there is controversy between those for and against trade in GMOs owing to the debate that is centered on intergenerational equity. This controversy is among legislators, scientists, business community and the civil society and focuses on vested interests and non-involvement of all the key stakeholders and lack of full scientific certainty on the effects of GMOs. Lack of information by the public in general and the local communities in particular to enable them make informed choices is also a major problem. As an illustration of the confusion and contradiction involving GMOs, after passing the Biosafety Act in 2009, Kenya banned the importation and consumption of the GMO products in December 2011 pending investigations into safety issues.

1.3. Statement of the problem

Article 27 of the convention requires the Conference of the Parties serving as the meeting of the Parties to this Protocol at its initially meeting to embrace a procedure as for the proper elaboration of universal principles and systems in the field of risk and review for harm coming about because of trans-limit developments of living altered creatures, dissecting and assessing the continuous procedures in global law on these matters, and to attempt to finish the procedure inside four years.

On paper Kenya has for the most part consented to the arrangements of Article 27 of Cartagena Protocol by passing the Biosafety Act, No. 2 of 2009 to regulate biotechnology. However on 8 November 2012, the Cabinet convinced the President to ban the importation of GMO food into the country. On 21 November 2011, a Presidential decree banned the importation of GMO and pursuant to this decree, the Ministry of Public Health (MOPH) ordered public health officials to remove all GM foods on the market and enforce the ban.

The effect of the ban put Kenya's legal and regulatory system in agricultural biotechnology in doubt. The ban also put into jeopardy all measures that are aimed at evaluating the safety of GM products. Thus the ability of the National Biosafety Authority to effect research into the management of risk arising from biotechnology has been severely hampered. This has weakened Kenya's legislative process and regulatory frameworks. Moreover by usurping Kenya's agricultural biotechnology law, regulation and institutional authority charged with addressing safety of GM foods, the ban clearly demonstrates the absence of political will. There is therefore a big gap in terms of what the law provides on biosafety and the practical reality and this has largely been occasioned by lack of political goodwill to ensure that Kenya lives up to her international obligations. Proper safeguards are therefore required in order to ensure that the biosafety regime in the country is clearly developed and enforced.

1.4 Objectives of the study

1. To analyze the extent to which the Biosafety Act No. 2 of 2009 complies with the Cartagena Protocol
2. To investigate international best practices in liability and redress in biosafety
3. To make recommendations on the best practices that can be adopted by Kenya in establishing a liability and redress mechanism on biosafety

1.5 Research Questions

1. To what extent has the Biosafety Act of Kenya complied with Article 27 of the Cartagena Protocol?
2. How effective is Kenya's legal framework on liability and redress in biotechnology?
3. What are the international best practices on liability and redress in biosafety and what lessons can Kenya learn?

1.6 Hypothesis

The legal system on liability and redress in biosafety in Kenya largely complies with the Cartagena Protocol on Biosafety. This is illustrated by the enactment of the Biosafety Act, No. 2 of 2009 which was meant to comply with Article 27 of the Protocol. However the subsequent banning of the importation of GMO products into the country by a Presidential decree demonstrates that the country is not ready to embrace biotechnology in full. There whatever exists in the Act are mere paper rights that cannot be enforced.

1.7 Literature review

Whereas a lot of attention has been given to the legal regulation of biotechnology and biosafety by various scholars, little research has been done on liability and redress in biosafety. Different scholars have taken different approaches towards the subject; Mugo, takes a scientific and therefore narrow approach towards regulation, development and testing of BT maize, which is of minimal value in a legal discourse. The analysis of Kameri-Mbote in both documents is based on a period before the enactment of the Biosafety Act, No. 2 of 2009.While Kangiri, views liability and redress in biosafety as a contested field owing to the varied interpretations on how it can be established.

1.7.1. Kenya's problem in adopting a liability and redress system

The accomplishment of obligation and review component in biosafety relies on upon transnational harmonization of biosafety administration at the global level. This is on the grounds that cross outskirt development of transgenic substances does not regard universal fringes. It was trusted that the arrangement of the African Regional Biosafety Focal Point in 1993, in Harare, Zimbabwe, would help but it has experienced limited success in developing a regulatory regime in the region. This is mainly due to financial constraints and different levels of economic development of African countries. This is in addition to lack of awareness, standards, plans and programmes that would enable the flow of information. There is as well a shortage or absence of technical expertise to do the management and risk assessment throughout Africa and a notable absence of public participation.

Kenya's approach to liability and redress in biosafety has been precautionary as reflected in the National Biotechnology Development and Biosafety Act, No. 2 of 2009. It is meant to govern resources and application of modern technology to food products. This is after a realization that agricultural biotechnology has the capacity to reverse the diminishing food security and nourishment, cultivate wages, revive agro-industry and diminish the adverse effects of environmental degradation.

The challenges of regulating biosafety and the measures to establish an agreeable liability and redress mechanism have been described by the author as being inadequate. This is variously caused by an inadequate legislation, absence of capacity to handle the many facets of biosafety namely the governance and assessment of risk attached to biotechnology. However the article was written before the passage of the Biosafety Act which has addressed a number of the concerns. Thus its contribution is limited to historical facts and background information on the

subject matter. However it also has insights on the structure and nature of the envisaged legislation.

In the opinion of Kingiri, advantages of new developments in farming biotechnology may not be acknowledged without suitable biosafety administrative systems. The weaknesses of these systems regarding risk and change incorporate insufficient and unequal institutional and specialized limit. The consequence is that much of the genetic engineering activities are carried out within the precinct of KARI. There has also been unsustainable subsidizing for research and administrative procedures because of a declining government use on innovative work. To wrap things up is the absence of agreement on approach and system which vanquishes the underlying target of commercializing biotechnology products in Kenya. This hampers the efforts to convince the public and increase awareness on 'real and demonstrable' technology thereby reduce the negative perception of GMOs.

This is however made worse by the administration of life sciences which is viewed as intricate inferable from the disparity of perspectives connected to the instability and impression of hazard and the worldwide way of related issues. On the flipside are many scholars with a conviction of the capacity of such innovations that have the capacity to answer questions of world food and resource challenges. The whole discourse has also placed governments in a duality of capacities as promoters and regulators of biosafety. With regard to life sciences, it is regarded as mode 2 sciences, unlike other sciences and technologies; it demands new ways of research owing to their nature reflected in their increased trans-disciplinary, multi-functionality and highly integrated nature. The result is that it makes biosafety a highly contested field. However these works only evaluate the overall regulation of the biotechnology industry and GMO industry but do not specifically deal with liability and redress thus leaving a gap in the area. The necessity for a

liability legal regime becomes much more important considering the fact that scientific innovations is making it possible for the release of transgenic substances that have possible negative impact on the environment, biodiversity and human health.

1.7.2. Kenya's international governance obligations in liability and redress

The state has a very important role to play in establishing a biosafety regime as a facilitator for private gatherings to seek after their cases. In doing so, the state should negotiate in creating mechanisms for that particular purpose without necessarily being a litigant. The exception to this is when a state claims compensation to redress damage to its interests. According to Gurdial, there are three prospective options for a liability and compensation regime namely: transitional prepare administration arranged worldwide private law administration and universal arbitral administration.

A trans-national regime would be a process whose aim is to build up substantive measures to be connected by national courts. This would have the effect of not only strengthening local remedies but also reduce the effect that relates to issues of subject matter, jurisdiction, forum shopping, the applicable law and how to enforce judgments. This will be in addition to the establishment of an international fund specifically for plaintiffs who have limited resources to pursue their claims.

An arranged universal private law administration will include the foundation of an agreement that specifies a body of liability law that is capable of enforcements in domestic courts against private individuals. This format allows parties to the protocol to enact laws on national liability that incorporates components determined in the worldwide understandings marked. These understandings ought to have ward over outside people and authorization of cases unmistakably

set out in worldwide obligation guidelines. The components of such a framework would incorporate ability to sue, the nature of risk, weight of confirmation, quantum of harms, limits on recovery, compulsory insurance and international fund referred to above. The acceptance of such a liability protocol would then make it part of the domestic law.

As part of the international arbitral regime, the government would be a claimant and defendant through a kind of inter-governmental dispute resolution mechanism. This could be modeled on the 1972 Tradition on International Liability for Damage Caused by Space Objects, where the state is "held obligated for exercises which could have been attempted by people or elements." The dependability of such an administration for biosafety would imply that "an express whose environment or nationals endure hurtful impacts of GMO could bring a claim against the state where the GMO began."

Selcan, in his assessment of the Cartagena Protocol which went into force in 2003, views it as being controversial even among the member states. Accordingly difficulties are conspicuous in three critical areas, risk assessment on biodiversity and human health, disparities in institutional capacities and what constitutes obligation and change for harm emerging from cross limit development of living altered living beings (LMOs). Further he argues on the relevance of having an agreement that combines environmental principles and trade rules and regulations. This is in addition to the fact that nonparties, producers and exporters of LMOs may use the protocol as a nontariff barrier (NTB).

The author however softens his stance after the adoption of the Supplementary Protocol on Liability and Redress as part of the international legal regime. The gist of the protocol being that international governance of biosafety will still be based on a hybrid approach between

environmental conservation and trade related issues. Biotechnology companies will play a leading role and in essence an acceptance of biotechnology and the need for an international, regional and national regime of regulation. This gives an overview of challenges attending to liability and redress in biosafety that countries bent on regulation is prone to face. These are the challenges that the Biosafety Act No. 2 of 2009 has to contend with.

1.7.3. International best practices for liability and redress

Whereas there is no international obligation administration for risk in biosafety, the fruitful usage of the Cartagena Protocol will rely on upon the elaboration of such an administration. Subsequently the technique for connecting GMO's to risk and change is still a test for reasons explained previously. Article 27 of the Cartagena Protocol is enlightening for it starts a talk on the way toward creating global standards on risk and change in biosafety. The order of the Protocol towards this heading is as per the following:

> ...the Conference of the Parties serving as the meeting of the Parties to this Protocol might, at its initially meeting, embrace a procedure as for the fitting elaboration of worldwide standards and methodology in the field of obligation and change for harm coming about because of trans-limit developments of living altered creatures, examining and assessing the continuous procedures in universal law on these matters, and should attempt to finish this procedure inside four years.

Philipe has outlined options available in the absence of international regulation in liability and redress of biosafety. He has cited Canada and the USA which have followed a common approach, and divided liability into three thus: civil, administrative and criminal liability. This study has chosen a comparative approach in chapter 3, for purposes of showing how Kenya can get it right in terms of liability and redress in biosafety.

Civil liability in the two countries involves a plaintiff, bringing an action against the defendant claiming a remedy (compensation or an injunction) for the loss suffered. Thus in these

jurisdictions, a plaintiff could institute a private suit against a company or farmer who introduced a transgenic plant that has brought harm to the plaintiff's body, land or crop. Four other causes of action are available to redress liability in biosafety namely an action in negligence, trespass, annoyance and strict risk.

Aside from common risk which includes a common suit asserting private rights, regulatory obligation emerges from control enactments. The way of these statutes is to delegate obligations, for example, authorization to a particular organization. Regulatory risk could run as one with private residents initiating suits to implement consistence with the statutory arrangement. By and large terms, authoritative obligation is an open risk against infringement of administrative laws whose implementation operator happens to be an administration foundation.

The significance of criminal risk is that the charged individual has either carried out an offense or damaged open reformatory laws. In the event that indicted, the blamed people could either be fined or detained. Such authorizes are not accommodated by regulatory statutes particular to people who make, offer or utilize transgenic crops. However in the two purviews, criminal risk is not a favored type of obligation in biosafety attributable to the challenges in demonstrating the expectation (mensrea) of the charged individual.

1.8 Conceptual framework

Biosafety is a concept that refers to measures put in place to mitigate or protect human health and the environment from possible adverse effects of the products of modern biotechnology. The Cartagena Protocol on Biosafety provides a comprehensive and holistic regime designed to ensure that the development, handling, transport and use of products of modern biotechnology are undertaken in a manner that maximizes benefits while preventing or reducing risks to the

environment and human health. The Protocol is a subsidiary agreement to the UN Convention on Biological Diversity (CBD).

Kenya signed the Biosafety Protocol in 2000 and fulfilled the ratification requirements in 2003. One of the key obligations expected from the Parties to the Protocol is promotion and facilitation of public awareness, education and participation in biosafety activities as stipulated in article 23. The National Council for Science and Technology (NCST) established under the Science and Technology Act, Cap 250, Laws of Kenya under the Ministry of Higher Education, Science and Technology is the designated authority that co-ordinates all matters pertaining to biosafety in Kenya. The National Biosafety Committee (NBC) is the technical arm of the Council charged with the mandates of overseeing coordination and implementation of biosafety issues. The multiple roles of NBC include receiving, reviewing and making approval or rejection decisions on applications to introduce biotechnology products for research or commercial purposes into the country. The NBC platform is a broad one with multi-stakeholder representation. The Kenya Bureau of Standards (KEBS), the National Environment Management Authority (NEMA), the Department of Veterinary Services (DVS), the Kenya Plant Health Inspectorate Services (KEPHIS), the Pest Control Products Board (PCPB) and the Public Health Department are among the key biosafety regulatory agencies represented on the NBC.

1.9 Research methodology

This study has adopted a secondary approach to research in addressing the legal aspects of assessing the effectiveness of Kenya's liability and redress regime. Through this method, the researcher believes that correct data has been collected and analyzed to enable a better understanding of the issues at hand. According to Mugenda, this method is best suited for

sustainable solutions to social, political and economic development problems in most poor countries of Africa and particularly suited for this study.

1.9.1 Data Collection

The research instruments that will be used to collect the necessary information will be the questionnaire and interview. The instrument will be key in addressing specific objectives of the research, research question and the hypothesis of the study. Various data sources will be relied upon both primary and secondary sources of information. Secondary sources will include textbooks, journal articles, online sources, reports and conference papers as secondary sources especially recent publications in the area of biosafety given that this is an emerging area will be heavily relied upon. Primary sources of information namely, treaties, conventions, protocols, declarations, international and regional resolutions will be examined. The following statutory and policy documents will form the basis of the analysis; Tradition on Biological differences 1992, Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, Cartagena convention on biosafety, the Biosafety Act No. 2 of 2009, the National Council for Science and Technology Act (Cap 250), Environmental administration and coordination Act and the Kenyan constitution 2010. This will be in addition to articles by authoritative writers that are either published not. Papers and discussions in various national, regional and international fora where implementation of the Cartagena protocol has been discussed will be referred to as well.

For purposes of clarity and in search of legal and scientific reasoning in the implementation of the biosafety protocol I intend to interview persons and institutions concerned with biosafety such as scientists at the National Biosafety and those from the ministry of environment and natural resources among others.

Libraries will be germane in the research process, the libraries of the faculty of law, university of Nairobi, the United Nations Environmental Programme (UNEP), and the British council library.

1.9.2. Data Analysis

Data analysis in this study is meant to bring order, structure and meaning to the information collected. Having identified the themes, categories and patterns, the data will be evaluated and analyzed to determine its credibility, usefulness and consistency.

CHAPTER TWO

INTERNATIONAL FRAMEWORK FOR LIABILITY AND REDRESS IN BIOSAFETY

2.1. Introduction

The coming into force of the Cartagena Protocol on Biosafety (CPB) is highly credited for being the trailblazer in the growth and development of biotechnology and more particularly biosafety. However, the protocol came into force due to efforts carried out earlier in the Convention on Biological Diversity (CBD). All these efforts aimed at regulating biotechnology were timely owing to an increase in production and trans-boundary movement of GMO's that began in 1970s. Many institutions (private and public) got involved in research and development of biotechnology products at the international and regional level. This period also saw an upsurge in private investments towards research and design in biotechnology. According to Ernest and Young, in 1997, US companies invested $9.4 billion dollars and employed 140,000 people and in the same year total revenues from biotechnology rose to $18 billion. Increased interest in Europe saw over 2000 companies working in biotechnology, with 39000 people directly employed and revenues of over $3.1 billion with a further investment of $2.2 billion.

Developing countries were not left far behind either, in 2004, 35% of GM crops grew outside the developed countries. Nations, for example, India, China, South Africa and Columbia among others were growing GM plants in large quantities. With a truly international presence, regulation of the risk assessment, management and flow of information in biotechnology became very necessary.

The rise in the manipulation of biological resources by human beings to produce biotechnology products became a definite concern for the international community. The concern was not an idle one because the development posed definite danger to the environment and human health.

The Biosafety Protocol was meant to minimize risks from Living Modified Organisms to Biodiversity and thus provide the first concrete international agreement to implement aspects of the CBD. Controversial issues under the CBD that needed to be addressed were the extent to which technologies involving release of genetically modified organisms pose a threat to the environment and to human health. Little was known of potential impact of modified commercial crops and there was concern that release could have serious though uncertain impact on the environment.

Lack of evidence of negative effects of foods derived from genetically modified crops did not eliminate risk and there was not enough known of long term effects of transgenic crops. The main food safety concerns associated with transgenic products related to possibility of increased allergies, toxins or other harmful compounds, horizontal gene transfer and particularly antibiotic resistant genes. The field of GMO crops showed a lot of growth globally in the late 1990's and its use expanded between 1996 -2005. The number of acres under biotechnology crops worldwide grew from 7 million to over 220 million, acres with the United States having 60%, Argentina 20%, Brazil China & S.A with the rest.

This chapter discusses the international approach to ameliorate liability and redress due to the possibility of harm arising from growth in biotechnology products. Focus will be placed on the assessment of the CBD, Cartagena Protocol on Biosafety and the Nagoya–Kuala Lumpur

Supplementary Protocol on Liability and Redress. The three frameworks proceed on the basis of precautionary principle.

2.2. Precautionary Principle: A Basis for Biosafety Regulations

The precautionary principle is an important contribution by the CBD to liability and redress in biosafety with regard to the assessment of risks, management of risk and information sharing. The primary foundations of the precautionary principle, and globally accepted definitions, results from the work of the CBD in 1992 and encapsulated in Guideline 15 of the CBD which expresses that:

With a specific end goal to ensure the earth, the preparatory approach might be broadly connected by States as per their abilities. Where there are dangers of genuine or irreversible harm, absence of full logical conviction should not be utilized as a purpose behind deferring savvy measures to counteract natural debasement.

Developing Nations as major recipients of biotechnology products were more concerned during the negotiations of the convention, with the inadequacy of science to predict with certainty the adverse effects of biotechnology products. The fear was that they weren't sure how much harm would be done to biodiversity by biotechnology and LMOs. These attributes guided the establishment of a biotechnology protocol which proceeded on the principle of precaution. The gist of this principle was that "vulnerability with respect to genuine potential natural mischief is not a substantial ground for shunning preventive measures." This guideline is additionally cherished in Article 15 of the Rio Declaration and arranged in its Preamble and Article 1 of the Biosafety Protocol.

Reactions have, be that as it may, been leveled against the way in which this standard has been systematized in Article 15 of the Cartagena Protocol. It has been noticed that as indicated by this arrangement, references to 'accessible logical confirmation' and 'deductively stable way' are believed to be foreordained terms. In such manner, the weight of setting up the logical proof is too high and the by all appearances supposition is that the GMO make hurt wellbeing and nature. This occasions an ambiguity in the provisions of the Protocol hence making compliance with these provisions difficult especially to developed countries who are largely the producers of GMOs.

The essence of this principle is its application anytime if a situation arises where dangers of damage to nature and human wellbeing exist and in addition instability in logical learning. On account of Leatch v. National Parks and Wildlife Service and Shoalhhaven City Council, The court held in this manner:

> "Taking after an examination of the proof, I am not fulfilled that a permit under s120 of the National Parks and Wildlife Act to take or execute imperiled fauna ought to be allowed to the Council. Notwithstanding, it ought to be stressed that refusal of this permit application ought not really be thought to be an end of the proposition. Additional data on imperiled fauna and advances in logical information may imply that a permit could be allowed later on. Likewise, changes in the proposition and ameliorative measures may prompt to an alternate evaluation. This case has been resolved, as it must, on the confirmation delivered to the Court at the hearing and the Court can't conjecture with regards to what's to come".

The brief certainties of the case were that Shoalhaven City Council (the Council) connected to the Director-General of the National Parks and Wildlife Service (the Service) for a permit to take or execute imperiled fauna. The requirement for a permit emerged from the allowing of advancement assent by the Council to its own proposition to build a connection street through North Nowra to the Princes Highway. In support of its application for a permit the Council presented a Fauna Impact Statement (FIS) to the Service in accordance with s 92B (2) of the Act.

The FIS was promoted in February 1993 and various entries, including one from the candidate, were gotten by the Service. After thought of the permit application the Service looked for additional data from the Council. The National Parks and Wildlife Act was widely revised as far as its fauna security arrangements by the authorization of the Endangered Fauna (Interim Protection) Act 1991. The revising enactment was to some degree a reaction to the choice of the Court in Corkill v Forestry Commission (1991) 73 LGRA 126, insisted in the Court of Appeal (1991) 73 LGRA 247. Segment 92 makes the Director-General (the DG) the power "for the security and care of fauna". A Scientific Committee was designated in accordance with s92A to survey and keep on reviewing Schedule 12 of the Act, which gives a rundown of jeopardized fauna. Areas 92A(5) and (6) individually determine matters which the Committee must have respect to in choosing to place types of fauna on the Schedule as Threatened (Part 1) or Vulnerable and Rare (Part 2). Just the DG may issue a permit to take or slaughter jeopardized fauna [s 92B].

Two entries brought up the issue of the use of the 'prudent guideline' whether, the standard was pertinent, and would be brought up in the interest. It was held that, the consolidation of universal law into local law appeared to be pointless in the level headed discussion and in the judge's sentiment the prudent standard was an announcement of sound judgment and had as of now been connected by leaders in fitting conditions preceding the rule being spelt out. The decision was attempted regardless of the endeavors by Australia which had sanctioned the Endangered Species Protection Act 1992 which made arrangement under s175 to offer impact to worldwide understandings determined in Schedule 4 of the Act which did exclude the 1992 Convention on Biological Diversity. Be that as it may, the preparatory rule had been joined in the Commonwealth Strategies on Endangered Species and Biological Diversity and, all the more for

the most part, in the 1992 Intergovernmental Agreement on the Environment (IGAE), and in addition state enactment, for example, the NSW Protection of the Environment Administration Act 1991.

The principle has been criticized first, for being ambiguous in its scientific prescriptions and a pessimistic approach to risk assessment and uncertainty in biotechnology products. Moreover the principle does not specify criteria for ascertaining the attributes of 'serious', 'irreversible' and 'full scientific certainty' prescribed in Article 15 of the Rio Declaration.

The principle says that now and again; especially where the expenses of activity are low and the dangers of inaction are high; preventive move ought to be made, even without full logical conviction about the issue being tended to. By and by this gives governments a decent lot of prudence in setting natural approach. Some expected that the preparatory rule could be a reason to limit exchange safe products to ensure residential makers. They contended that such limitations must be founded on sound science and thorough hazard evaluation. Nonetheless, others contended that the sound-science contention itself was a reason to constrain the utilization of a set up rule of worldwide natural law. Notwithstanding, the guideline has given part expresses the circumspection to make laws in biotechnology and biosafety that could either be tolerant or confined.

2.3. Challenges Addressed by the Convention on Biological Diversity

The CBD is an international treaty that binds member states for the sake of sustainable development. The CBD has been described as the main document on sustainable development.

Lack of evidence of negative effects of foods derived from genetically modified crops does not eliminate risk. Not much is known as regards the long term effects of transgenic crops. The main

food safety concerns associated with transgenic products related to possibility of increased allergies, toxins or other harmful compounds, horizontal gene transfer and particularly antibiotic resistant genes. The field of GMO crops showed a lot of growth globally in the late 1990's and its use expanded between 1996 -2005. The number of acres under biotechnology crops worldwide grew from 7 million to over 220 million acres with the United States having 60%, Argentina 20%, Brazil China & S.A with the rest.

Article 28 of the CBD orders Parties to collaborate in the detailing and appropriation of Protocols and together with Article 19 (3), the Conference of Parties of the CBD set up an Open-finished Ad Hoc Working Group on Biosafety to build up a Draft Protocol on Biosafety. The Working Group was to concentrate particularly on transboundary development of any living altered living being coming about because of advanced biotechnology that may effectsly affect the preservation and practical utilization of natural assorted qualities.

The Cartagena Protocol on Biosafety was received in January 2000 as an understanding under the protection of the Convention on Biological Diversity (CBD). In 1995 the gatherings to the tradition approved a specially appointed working gathering to start arrangement on a biosafety convention. Arrangements were very antagonistic with creating nations dreading they were being utilized as research facilities for arrival of Genetically Modified Organisms (GMOs) into nature without legitimate testing, notice or effect appraisal. European nations, creating nations and tree huggers summoned the prudent guideline in overseeing, exchange, transfer utilize and treatment of GMOS. Among issues they needed tended to were frameworks for guaranteeing; earlier educated assent before GMOS are discharged or exchanged to another nation, obligation and pay for harm from discharge and ecological and chance evaluation. Then again the United States and

different nations that exchange biotechnology contradicted the issue of risk and pay for harm and looked to confine the extent of the convention.

2.3.1 What issues does the protocol address?

The Cartagena Protocol on Biosafety discusses three issues namely: chance appraisal, hazard administration and the correspondence of hazard data. These are not diverse issues but rather frame a continuum and also having necessary impact in comprehension the extent of the convention.

2.3.1.1 Risk Assessment

Chance appraisal is characterized "as the ID of potential natural unfavorable impacts and deciding when a danger is recognized the likelihood of it happening." This is covered in Article 16 of the protocol which envisages the establishment of a regime that would regulate manages and control risks that accompany GMOs. The risks that need to be assessed under this rubric include: the risks of spreading herbicide resistance that arise from GMOs and harm that would be caused to biodiversity as a result of using GM crops.

The Protocol stresses the fact that absence of logical sureness because of lacking data accessible about the potential negative impacts of LMOs on biodiversity, including considering dangers to human wellbeing, won't keep the bringing in/accepting state from taking choices in regard of LMOs so as to dodge or minimize potential unfriendly impacts. Such appraisal is to be done as per hazard evaluation techniques accommodated under Article 15 and Annex III

The Protocol additionally gives that the financial effect of LMOs on biodiversity, particularly its esteem to indigenous and nearby groups, may likewise be considered by contracting parties, however again to the degree reliable with their other worldwide law. This provision was

especially supported by the developing countries who felt that importation of LMOs may have negative effects on indigenous local communities and on agriculture.

On the other hand, the countries that trade in LMOs were of the view that the incorporation of such matters as financial effect was empowering masked limitations on exchange. This gathering additionally supported a moderate (and less expensive) way to deal with the documentation and naming prerequisites of the Protocol. A contradicting view by the creating states considered logical information alone to be lacking to evaluate the full scope of conceivable effects on preservation and manageable utilization of organic assorted qualities, financial components, and dangers to horticulture and to human wellbeing. This more extensive approach required a multidisciplinary way to deal with hazard appraisal, the execution of which requires a case by case approach. This sort of multidisciplinary approach is what is accommodated in the convention. It grants assessing the worries of indigenous and nearby groups. Yet, it is clear toward the day's end that choice –making with respect to LMOs must be grounded in 'sound science' and that non-logical variables alone-for instance a summed up buyer concerns in regards to hereditarily adjusted foodstuff won't give unchallengeable grounds to refusal to import LMOs under the Protocol.

2.3.1.2 Risk Management

Risk management is the procedure to be used to minimize the harm that has been isolated during risk assessment. Risk assessment is the recognizable proof of potential ecological unfavorable impacts and deciding when a danger is distinguished the likelihood of it happening. A portion of the techniques utilized as a part of hazard administration incorporate binding the utilization of GMO items, limited use, use of GMO under direction, arrangements for specialized and counseling administrations and additionally precise record keeping.

During the time spent hazard evaluation and administration pharmaceutical items are exempted on the grounds that they are directed by other universal legitimate administrations, for example, WHO. The way of the exceptions is: "without preference to one side of a gathering to subject all living altered creatures to hazard appraisal preceding the settling on of choices on import" Article 6, further exempts' biotechnology products that are in transit or those meant for contained use according to advanced informed agreement (AIA) procedure. Parties who transport LMOs are not regulated in the manner they would evaluate risk assessment. The only duty for importing parties is to set standards for LMOs meant for contained use so long as it is used within its jurisdiction. It is under this rubric that Kenya and Zimbabwe have established standards for this specific purpose.

2.3.1.3 Obligation of Exporters

AIA is a procedure that is considered a cornerstone of the protocol and is the chief regulatory technique employed. It requires that before the intentional transboundary movement of living modified organisms for the intentional introduction into the environment, the Party of Import must be notified of the proposed transboundary movement. The AIA Procedure enables a Party of Import to consent or reject the transboundary movement for the intentional release into the environment after assessing the potential risk to the environment.

AIA is designed to ensure that Contracting Parties are provided with the information necessary to make informed decisions before agreeing to the import of LMOs into their territory. AIA marks the Protocol out from the 'prior informed consent' procedures of the 1989 Basel and 1998 Rotterdam Conventions. The Primary purpose of the Cartagena Protocol is to facilitate early assessment by each Contracting Party of the potential risks in accordance with Protocol

According to Patricia Birnie, Boyle and Redgwell AIA establishes principles and procedures to guide national decision-making based on risk assessment and risk management, without mandating a particular outcome. Further the AIA procedures must be read with the risk-management provisions for the safe use, handling, and transboundary movement of LMOs. Other issues that are to be considered as precautionary and that are provided for under the protocol are emergency measures to be taken in the event of unintentional release of LMOs and provision on handling, transport packaging, and identification. Illegal transboundary movements are regulated by Article 25, which includes a 'take –back; provision where the country of origin may be requested to dispose of the LMO at its own expense. Monitoring and reporting is also required under the Protocol.

The procedure for AIA is covered under Articles 7 to 10 and 12; and requires that a Party of Export shall notify in writing to a competent national authority of the Party of Import of an intentional transboundary movement for the intentional release into the environment; the Party of Import must acknowledge receipt in writing to the notifier (Party of export)

Article 12 of the Protocol allows a Party to review its decision at any time in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity regarding an intentional transboundary movement. The Article further allows a Party of Export or notifier to request for a review of decision where a change in circumstances has occurred that may influence an outcome of a risk assessment that was the basis of the decision.

Article 7 (3) further exempts the transboundary movement of living modified organisms intended for direct use as food or feed or processing from the AIA procedure. Article 7 (4) provides that

AIA Procedure shall also not apply to living modified organisms that have been identified by the Conference of the Parties as being likely not to have adverse effects on the conservation and sustainable use of biological diversity.

The protocol also allows that a Party of Import to opt to use a simple notification procedure in the case of intentional transboundary movement of LMOs provided that the Party ensures that adequate measures are applied in accordance with the objectives of the Protocol as per Art. 13.1 (a). A Party of Import may also exempt imports of living modified organisms from the AIA Procedure as per Article. 13.1(b).

The Party of Import still retains the right to subject the LMOs destined for contained use to risk assessment and to set the standards and requisite regulations. Thus each Party should ensure that it has adequate standards and regulations to ensure the safe handling of LMOs destined for contained use and for LMOs in transit as the Protocol has left the regulation of these to the discretion of the Parties. The right of the Party of Import to regulate could include an appropriate notification, transportation and handling procedures. However it is not clear why this issue of risk assessment is left to the discretion of the parties considering how important the issue is.

2.3.1.4 Obligation of Importers

The protocol is clear that all importers of GMOs must be notified of the possible risks through a simplified process. This would facilitate export of LMOs without a permit. The effect of this is to reduce the effect of AIA process on assessment of the accuracy by the exporter alluded to above. Importers are required under Article 10 (3) to inform the exporters of details of how future imports with the importing party fixing any extension of time pursuant to AIA procedure.

The protocol further establishes the Biosafety Clearing-House (BCH) as a component through which logical, specialized, ecological and legitimate data on LMOs could be traded identifying with the execution of the convention:

> "A Biosafety Clearing-House is thus settled as a major aspect of the clearing house instrument under Article 18, section 3, of the Convention , keeping in mind the end goal to: (a) Facilitate the trading of logical, specialized , natural and legitimate data on, and involvement with, living adjusted life forms; and (b) Assist Parties to execute the Pro t o c o l , considering the unique needs of creating nation Parties , specifically the minimum created and little island creating States among them, and nations with economies on the move and also nations that are focuses of source and focuses of hereditary assorted qualities."

The protocol views capacity building as key to implementing AIA process through technical assistance and training of personnel capable of either undertaking or verifying risk assessment and management especially for developing countries that lack this capacity.

2.3.1.5 Criticisms of the obligations

These provisions are skewed against poor countries that do not have capacity to adequately undertake risk assessment and management. In this regard, it may take long for a poor country to conduct the necessary investigations and make a decision .This arises from the fact that these countries may not have adequate resources to conduct these assessments. For example, exporting countries have no obligation to assist poor countries built capacity. The import of Article 15 (2) that: "The Gathering of import should guarantee that hazard appraisals are done for choices taken under Article 10. It might require the exporter to complete the hazard evaluation" is illustrative for it allows exporters carry out risk assessment at own cost. Due to this requirement African countries may not be able to develop indigenous capacity in risk assessment. It is therefore imperative that provisions are put in place to ensure that developing

countries are able to progressively comply with AIA provisions and technical assistance should also be extended to these countries.

The possibility that the accuracy of the risk assessment by the exporter may be tainted by self-interest is real. This could work against the interest of poor countries by exposing them to unnecessary harm. Third and much more importantly, the arrangement complicates the development of a liability and redress system which would be based on the exporters' assessment and not the importers. Consequently, any issues that arise from these transactions or litigation have to take place within the jurisdiction of the exporting party (developed countries) which makes poor states by standers in the GMO discourse.

2.4 Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress

The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was received in Nagoya, Japan on 15 October 2010 at the fifth meeting of the Conference of the Parties serving as the meeting of the gatherings to the Protocol. The foundation of the Protocol embraced a regulatory view to harm that strikes the earth radiating from LMO through the development of these items crosswise over limits. The convention serves two capacities: first as a preventive instrument against harm and also as a certainty sponsor for the improvement of advanced biotechnology.

Pursuant to Article 27 of Biosafety Convention the initially meeting of state gatherings was held in Kuala Lumpur, from 23-27, February 2004. The gathering built up an Ad hoc Open finished Working Group of Legal and Technical Experts on obligation and change with regards to the Cartagena Protocol.

The advancement of an obligation and review administration under the convention was not imagined in a vacuum. It took after other sectoral ecological risk administrations embraced previously. The convention consequently draws from these prior encounters. Its order is particular to the investigation of issues, elaboration of choices and makes recommendations on global tenets and strategies towards an obligation and review system. The brainchild of this Working Group was the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress. This convention simply like others before it (Tradition on Biological Diversity and the Cartagena Protocol) relies on upon the judicious and polluter pays rule.

The Cartagena Protocol, counseled under Article 19 of the Convention on Biological Diversity, focused on "safe trade, dealing with and usage of any living changed living thing occurring in view of biotechnology that may have antagonistic effect on the protection and sensible use of normal varying qualities." While the Cartagena Protocol was counseled to beat any issues between budgetary needs of the biotech endeavors and natural stresses of States, the Nagoya-Kuala Lumpur Supplementary Protocol is wanted to vanquish any prevention between the money related requirements of industry and the stress of States to consider biotech associations in charge of damage achieved by the ponder or inadvertent presentation of living modified life shapes into the earth.

Drafters of the Cartagena Protocol exhibited frameworks for particular groupings of LMOs requiring "Advanced Informed Agreements" among States and remote biotech ventures. As orchestrated, these understandings require exporters of LMOs to enlighten getting countries of their plan to convey and to hold up until they have motivated endorsement to make the shipments. Regardless, not every biotech organization is required to go into these understandings. They are not requested by the Cartagena Protocol when a LMO is not "at risk to

effectsly influence the conservation and practical use of normal contrasts, considering perils to human prosperity." Instead exporters can simply instruct States of their motivation to bring into the market a given LMO through the Biosafety Clearinghouse. Unequivocal exceptions have moreover been made to the before taught consent framework for LMOs "proposed for direct use as sustenance or maintain, or for taking care of." Under the Cartagena Protocol, States have the benefit to hone the judicious approach and reduction the importation of a LMO thing especially where there are winning "money related considerations

> . . . especially concerning the estimation of natural arranged qualities to indigenous and neighborhood bunches."

Despite when States rehearse the preliminary approach, States may bumble. The Cartagena Protocol, in Article 27, saw that the general legitimate organization for LMOs may achieve damage to a State's biodiversity. Article 27 gave that States would make a strategy for "the fitting elaboration of worldwide gauges and techniques in the field of hazard and audit for damage coming to fruition due to transboundary advancements of living modified life shapes." The method was begun in 2004 with the creation by the Conference of Parties to the Protocol of an Open-completed Ad Hoc Working Group of Legal and Technical Experts.

2.4.1 Highlights of the Nagoya-Kuala Lumpur Supplementary Protocol

Parties arranged and received, on October 15, 2010, the Nagoya-Kuala Lumpur Supplementary Protocol to blend the global legitimate standards pertinent to ecological and human wellbeing hazard from living altered life forms. As an augmentation of the Cartagena Protocol, the Supplementary Protocol expands on existing global ecological law standards. Specifically, the preface of the Supplementary Protocol makes reference to Principle 13 of the Rio Declaration asking States to both "create national law with respect to obligation and remuneration for the

casualties of . . . other natural harm" and "to grow facilitate worldwide law in regards to risk and remuneration for unfavorable impacts of ecological harm brought on by exercises inside their ward or control to territories past their locale." The Supplementary Protocol additionally emphasizes the dedication to the preparatory approach as explained in Principle 15 of the Rio Declaration and the introduction of the Cartagena Protocol.

For the motivations behind the Supplementary Protocol, a gathering bringing a claim for obligation or change must show that: 1) there has been an unfavorable impact on preservation or maintainable utilization of organic differing qualities or dangers to human wellbeing; 2) the impact is quantifiable or perceptible for the reasons for attribution of effects; and 3) the antagonistic impact is huge.

The key on-screen characters who may possibly trigger a claim under the Supplementary Protocol are the "administrators" who incorporate any individual in "immediate or roundabout control" of a LMO. Similarly as the International Convention on Civil Liability for Compensation for Oil Pollution Damage was consulted to apply to private performing artists, the expression "proprietor" in the Supplementary Protocol was characterized comprehensively to incorporate non-state on-screen characters, incorporating any gathering in the chain of guardianship of LMOs.

A noteworthy wellspring of conflict was whether the content would cover not simply LMOs but rather "items thereof, (for example, tofu created from transgenic soybeans). A few States contended that the dialect "items thereof" would extend the Supplementary Protocol past the extent of the Cartagena Protocol. The dialect was at last expelled from the content, yet the Parties concurred that States could apply the Supplementary Protocol to harm created by prepared

materials from LMOs the length of a causal connection is built up. Applying local law on causation, a petitioner must exhibit a causal connection between the asserted harm and the presentation of a LMO over a limit.

Where there is a harm guarantee ready for arbitration, petitioners might be qualified for "reaction measures," including measures to "counteract, minimize, contain, relieve, or generally keep away from harm" and in addition activities to reestablish organic assorted qualities either "to the condition that existed before the harm happened or its closest comparable." When in situ reclamation is unimaginable, administrators are required to supplant natural differences with species and hereditary material that is practically comparative either at where the harm happened or "as proper, at an option area."

The prerequisite in Article 5 for States to outline a residential legitimate structure to give "reaction measures" to address transboundary natural harm by LMOs is the essential new commitment of the Supplementary Protocol. To address worries that the "skilled power" could practice shameful ultra vires controls over private administrators, the arranging Parties concurred that administrators must have admittance to authoritative or legal survey of reaction measures under residential law.

While a few partners in the arranging procedure contended for particular worldwide directions to be consulted inside the Supplementary Protocol, the archive as embraced clears up that there are no globally settled upon substantive standards or controls on the transboundary exchange of LMOs. Or maybe, Parties will concede to the astuteness and limit of States working under their local law. For instance, many States and common society partner bunches contended for money related ensures, for example, required protection for administrators, or a store. These

recommendations were with regards to the global structure for risk for oil contamination found in the International Convention on the Establishment of an International Fund for Oil Pollution Damage. These endeavors to look for globally based money related security for the development of any LMOs at last were vanquished in view of worries by industry that these systems would bring about higher costs for hereditarily adjusted yields and creatures. Rather, States were given the choice of whether to require monetary security through their local law.

In about 10 years of transactions paving the way to the Supplementary Protocol, a few creating States, working in conjunction with natural and human wellbeing non-administrative associations, trusted that strict obligation would be forced as the global risk standard in light of the strict obligation principles gave under various settlements including dangerous exercises, including atomic vitality bargains, space arrangements, marine bargains, and risky waste bargains. The territorial Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment forces strict obligation, including risk for harm created by living altered living beings. While there was State and open enthusiasm for setting a strict obligation standard for transboundary hurt brought on by LMOs, the issue was dropped in the last transactions.

The desires for aggregate State activity to lessen harm from LMOs are not sure. Rather, the Supplementary Protocol mostly obliges States to "give, in their residential law, for tenets and techniques that address harm" by giving "reaction measures" either from their current common obligation law or through new law. It was concurred that new thoughtful risk laws to address transboundary LMOs ought to incorporate "as suitable" harm, principles of obligation, directing of risk, and standing concerns.

What the particular LMO common risk administrations will look like stays obscure. While draft rules on common obligation and change had been flowed to Protocol individuals with expectations of giving models to States with no risk administration for LMOs, all references to these draft rules were expelled from the received content.

The Supplementary Protocol gives a generous amount of space to States to inside arrange which obligation and change bits of the Supplementary Protocol will be converted into local law. Article 6 furnishes States with the sweeping special case that Parties "may give, in their local law, for whatever other exceptions or alleviations as they may consider fit." This opens up the likelihood that non-State Parties occupied with exchange LMOs could put weight on Parties to make exclusions in their local law in regards to, for instance, particular LMOs subject to the Supplementary Protocol. This segment may have been politically fundamental on the grounds that the Supplementary Protocol does not take into account any arrangement reservations.

Like the Cartagena Protocol, the Secretariat for the Convention on Biological Diversity in Montreal, Canada will direct the Supplementary Protocol.

2.4.2 The Scope of the Supplementary Protocol

Unlike the CBD where LMOs were treated differently, the scope of the Supplementary Protocol is enough to include all LMOs in general included are those for direct use for food, feed or processing, for contained use or those intentionally introduced into the environment. The justification for this is that the protocol seeks to remedy for damage caused by LMOs. However those relating to human pharmaceuticals are left out because they are regulated by different international regimes such as the WHO. It generally deals with trans-boundary movement that is intentional, unintentional and illegal ones. The parties are free to set criteria that would address damage. Article 2.7 mandates domestic liability and redress regimes be extended to apply to damage from LMOs from parties that do not belong to the protocol.

2.4.3 Nature and Assessment of Damage

The goal of the convention is twofold: to avert and cure harm to biodiversity brought about by LMOs that have their birthplace in a trans-limit development. This is refined by embracing a two dimensional approach: authoritative and common risk. Detailed and thorough arrangements are set out as to the previous; the last is managed by a solitary article that basically obliges gatherings to apply or adjust their current national common obligation law or establish a particular law on the matter. It is a change from prior structures as it has tried to clear up before terms that were poorly characterized, for example, to what constituted 'harm'. Harm is characterized as:

> "… an unfavorable impact on the preservation and maintainable utilization of organic assorted qualities, considering dangers to human wellbeing, that: Is quantifiable or generally discernible considering, wherever accessible, logically settled baselines perceived by a skillful power that considers whatever other human initiated variety and normal variety."

The criteria for evaluating harm must be discernible, quantifiable and essentially distinguished by a skillful body. This basis subsequently prohibits the stringent logical prerequisites based proof of harm typified in past instruments. Article 3 qualifies the essentialness to mean:

> "The long haul or perpetual change, to be comprehended as change that won't be reviewed through characteristic recuperation inside a sensible timeframe; the degree of the subjective or quantitative changes that unfavorably influence the segments of natural differing qualities; the diminishment in the capacity of parts of organic differences to give products and enterprises and the degree of any unfriendly impacts on human wellbeing with regards to the Protocol"

This definition by the convention has given clarity for harm to nature. Article 4 has secured and included conventional harm, which had been prohibited by before biosafety instruments. The convention has embraced two ways to deal with manage harm emerging from LMOs. To start with is a managerial approach and second is the foundation of a common risk system by each part state.

2.4.4 Administrative measures

The protocol requires state parties to ensure that operators make a move in two regards: First where there is adequate probability of harm and also where the harm really happens. Article 5.1 answers the first situation where the operator is required to take action that would avoid the occurrence of harm. In the same vein, the authority out of its own motion can take action to mitigate the damage that could occur. Where the operator cannot be found, the operator is compelled to pay the costs. All these measures are made according to the demands of domestic law.

2.4.5 Response Measures

Article 2 of the protocol envisages certain “reasonable actions” that range from preventive to restorative measures meant reduce environmental damage. These measures are meant to “Avert,

minimize, contain, alleviate, or generally stay away from harm, as suitable; Restore organic assorted qualities" The target of these measures is to reestablish natural biodiversity to its unique condition before the harm happened, and where this is impractical "different parts of natural biodiversity for the same or for another kind of utilization either as the same or, as estimated, at an option area".

The reaction measures should however be grounded on the standards of decency. In this way the administrator must be informed before responsive measures are taken, he/she should be advised of the reasons, accessible cures in residential law and conceivable plan of action to the lawful framework. However gatherings are given sure exclusions that would pardon the offended party from obligation, the push of Article 6 is that a gathering should be exempted from risk if verification is accessible to demonstrate that the harm was either a 'Demonstration of God or constrain majeur'e or 'Demonstration of war or common distress.' Parties are additionally offered breathing space to settle on time restrains, money related breaking points for recuperation of expenses and costs, budgetary security for expenses under local law. In conclusion Article 10 anticipates that part states will choose who the "suitable" administrator would be under residential law. For instance it could be the allow holder, engineer, maker, notifier, exporter, shipper, or provider relying upon the verifiable circumstance.

2.4.5 Establishment of Civil Liability Framework

Common risk in the Supplementary Protocol is given in Article 12. State gatherings are permitted to train principles and laws that address harm as conceived in the convention. They have three alternatives: First is through the use of existing law that ought to include general

standards and method on common obligation. Such a law ought to not particularly manage harm to LMOs. The second alternative is to apply existing law on harm LMOs and on the off chance that it is non-existent one ought to be built up. The third alternative is to create general and particular guidelines and methodology to manage harm brought on by LMOs.

The commitment to submit to these arrangements is guided by Article 26 of the Vienna Convention on the Law of Treaties. Gatherings to a bargain in universal law have a commitment to act in accordance with some basic honesty under the standard of pacta sunt servanda. The minimum requirement of a law to deal with damage must address the following issues: damage, standards of liability (strict or fault based), the bearer of liability and who has a right to bring a claim.

The protocol does not however solve the conundrum of establishing an international framework on liability and redress but instead empowers domestic legal mechanisms to implement its own provisions. Article 12, promotes the principle of civil liability under a domestic legal regime. Finally, liability under the protocol falls under strict liability and fault based liability.

The Supplementary Protocol gives a generous amount of room to States to inside arrange which obligation and review bits of the Supplementary Protocol will be converted into household law. Article 6 gives States the sweeping special case that Parties "may give, in their household law, for whatever other exclusions or alleviations as they may consider fit." This opens up the likelihood that non-State Parties occupied with exchange LMOs could put weight on Parties to make exceptions in their residential law in regards to, for instance, particular LMOs subject to the Supplementary Protocol. This segment may have been politically vital in light of the fact that the Supplementary Protocol does not take into account any bargain reservations. From the above

investigation the inability to draw in sanctions from significant biotech delivering States brings up issues about the authenticity of the Supplementary Protocol as an instrument for guaranteeing fitting risk and review for biological harm and effects on human wellbeing. As noted in the Conference of Parties Decision BS-V/11, the private division has embraced a few activities to guarantee plan of action in case of ecological harm brought about by LMOs. Some contend that it was the authority from the private biotech part, by consenting to subject its industry to common obligation to guarantee a for the most part changed market in LMOs that made it workable for States to acknowledge the present draft of the Supplementary Protocol. State parties have a commitment to make laws or apply existing laws and arrangements in the execution of the convention individually. Secondly, a national law may not necessarily be specific to liability and redress in LMOs. As such parties are free to choose from one of the options enumerated in above which does not establish an international standard for liability and redress regime? Finally developing countries that had pushed hard for a liability regime at international level to protect traditional and socio-economic damage were disappointed after 6 years of negotiation.

CHAPTER THREE

INTERNATIONAL BEST PRACTICES IN ADDRESSING LIABILITY AND REDRESS IN BIOSAFETY

3.1 Introduction

This chapter investigates the main thrust of international best practices in liability and redress frameworks. It makes a comparative study of biosafety legal regimes namely: the African Model law[1] and the Switzerland Gene Technology Act.[2] These are among the very few options available for a country that desires to establish a liability and redress framework as they are related to liability and redress. The Supplementary Protocol to the Cartagena Protocol[3] is the specific international frame work dealing with liability and redress. A detailed discussion of the precautionary principle plays a central role in the establishment of a liability and redress framework. What the African Model law[4] and the Switzerland Gene Technology models depict is that there is absence of an internationally acceptable framework to regulate matters dealing with liability and redress in biosafety.[5]

Many attempts have been made at international level to come up with such a regime but they have come a cropper due to the challenges encountered in linking LMOs to liability and redress.[6] That notwithstanding the release of such substances has the propensity to injure humans and the environment. This raises fundamental questions of risk in the domain of private and open law.

[1] Organization for African Unity (OAU), *African Model Law on Safety in Biotechnology* (OAU: Addis Ababa, 2002) (Hereinafter African Model Law).
[2] Federal Law relating to Non-human Gene Technology (Gene Technology Law, GTL) of 21 March 2003.
[3] The Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, in volume 50, International Legal Materials, (2011)
[4] Organization for African Unity (OAU), *African Model Law on Safety in Biotechnology* (OAU: Addis Ababa, 2002) (Hereinafter African Model Law).
[5] Philippe Cullet, 'Domestic Policy Options: International Trends in Liability and Redress', (2007) 9 (3) *Asian Biotechnology and Development Review* 1 at 2.
[6] Ibid.

This exchange is generally restricted to legitimate commitments and the probability of natural harm.

The coming into drive of the Cartagena Protocol on Biosafety in accordance with the Convention on Biological Diversity changed the account on a very basic level and dialogs started on the foundation of worldwide tenets. The convention enabled part nations to think on a suitable system of guidelines and methods in obligation and review. The command for such a system depended on the arrangements of Article 27 of the convention which gives that:

> *The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from trans-boundary movements of living modified organisms, analyzing and taking due account of ongoing processes in international law on these matters, and shall endeavor to complete this process within four years.*[7]

Best practices under the Cartagena Protocol are based on safe transfer, handling and use of living modified organisms with a focus on trans-boundary movement.[8] The question as to whether it is necessary to develop a separate liability and redress mechanism in biosafety is a pertinent one. This is in part made necessary by the fact that the introduction of transgenic substances into the environment could have undesirable repercussions that have not yet been experienced with previous liability regimes.[9] This explains why the precautionary principle is central to that debate as it influences the direction of a liability and redress regime. Further the definition of damage that arises from introduction of LMO's into the environment challenges the traditional discussion that has not yet occurred. Moreover other issues and classes of damage to be investigated have

[7] Articla 27, Cartagena
[8] Excerpt from UNEP/CBD/ICCP/2/3, prepared for the Second Meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, 2000.
[9] Cullet *supra* note…at 2.

arisen which include but not limited to socio-economic damage and patent liability.[10] Current frameworks work on the assumption that domestic frameworks should be empowered to deal with liability matters within the states borders and do not mind those LMOs that can damage environment in areas that do not fall within any states' boundary.[11]

The limitations observed above (at international level) are equally reflected at the domestic front. This is illustrated by the weaknesses of domestic legal regimes reminiscent of the international frameworks.[12] Besides, if a liability and redress framework is established at international level, it would affect the legal provisions at the national level. Last and more importantly, the composition of a liability and redress mechanism as a whole is inadequate to deal with modern challenges brought about by the introduction of transgenic products.[13]

As was discussed in chapter two, the precautionary principle is an important contribution by the Convention on Biological Diversity to liability and redress in biosafety with regard to the assessment of risks, management of risk and information sharing.[14] The precautionary principle and approach states that if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful falls on those taking an act.[15] This principle is at the core of all liability and redress framework under the CBD and the Cartagena Protocol.

[10] Ibid.
[11] Ibid.
[12] Cullet *supra* note…at 3.
[13] Ibid.
[14] African Union Commission, *Biosafety: Risk Assessment* (AUC: Addis Ababa, 2009) at 18.
[15] Section 2, Environmental Management and Co-ordination Act, 8 of 1999

The precautionary principle was incorporated in the Cartagena Protocol on Biosafety.[16] This inclusion sought to reinforce focus by the Protocol on the principle pursuant to principle 15 of the Rio Summit. Secondly, it was to put into effect and uphold the criteria in Article 10 (6)[17] that concerns the procedure of decision making and Article 11 (8), which makes reference to LMOs that are meant to be used for food, animal feed or for purposes of food processing.

The principle is used as part of the process of guiding decision making and therefore not a compulsory requirement.[18] The principle is informed by the potential harm that could be derived from using transgenic products where scientific assessment has been insufficient in determining its capacity to harm human health.[19] However, the context in which it is used by the Cartagena Protocol is much broader than the traditional one (damage caused or scientific uncertainty). The precautionary principle as used in the Cartagena Protocol encompasses broader damages not to the environment but social and economic in nature.[20] The principle goes further in looking for substitution or other options to innovations that can possibly be risky. For those substances proposing or wanting to present such advances, an extra duty is given to them of noting all

[16] Centre of International Development, Harvard University. *Conferencia Internacional: la Biotecnología en la economía global: la ciencia y el principio precautorio*, 22nd and 23rd of September, 2000

[17] 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 account risks to human health, shall not prevent that Party from taking a decision, as
appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

[18] Chávez, Juanita. *El Protocolo de Cartagena sobre Bioseguridad de la Biotecnología.* Work presented in the International Public Forum: Impact of the Transgenic Organisms, The Bogotá Council Ombudsman, 22nd of June 2000.

[19] Juan Carlos Carullo, *The Cartagena Protocol Adaptation by Countries: Latin-American Examples* (Regional Network on Biosafety (RNBio): Tokyo, Japan, 2002) at 8.

[20] Article 26, Cartagena Protocol, on Socio-Economic considerations
1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. 2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

inquiries concerning wellbeing and illuminating the decency in their choice to deliver the innovation being referred to.

The European Union (EU) has utilized the prudent rule to fortify its position in the Health Agreement amid the Uruguay Round of the WTO. Point 6 of the record sets up the 'logical guideline' confines the application and impediment in exchange that is not bolstered on grounds of logical premise. Consequently exporters should demonstrate the nearness or nonappearance of transgenic items and in this manner it goes about as a non-duty boundary (NTB). Governments then again will have the slack to either permit or deny the importation of LMOs relying upon the hazard appraisal made above. Different elements considered by the Protocol that worry the rule incorporate financial elements, the estimation of natural differences and the enthusiasm of the nearby and ethnic groups on how the choice to import transgenic substances was landed at.

The improvement of an obligation and change administration under the Cartagena Protocol on Biosafety was not considered in a vacuum. It took after other sectoral natural obligation administrations received previously. The convention in this manner draws from these prior encounters. Its order is particular to the examination of issues, elaboration of choices and makes suggestions on worldwide standards and systems towards a risk and review component. The brainchild of this Working Group was the Nagoya-Kuala Lumber Supplementary Protocol on Liability and Redress. This convention simply like others before it (Convention on Biological Diversity and the Cartagena Protocol) depends on the safety measure and polluter pays guideline.

The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress goal "is to add to the preservation and reasonable utilization of natural assorted qualities, considering dangers to

human wellbeing, by giving global guidelines and techniques in the field of obligation and change identifying with the utilization of living adjusted creatures." It is a change from prior systems as it has endeavored to clear up before terms that were not well characterized, for example, to what constituted 'harm'. Harm is characterized as:

> … an unfavorable impact on the preservation and supportable utilization of organic assorted qualities, considering dangers to human wellbeing, that: Is quantifiable or generally noticeable considering, wherever accessible, logically settled baselines perceived by an equipped power that considers whatever other human incited variety and common variety.

The convention does not however settle the problem of building up a universal structure on obligation and change yet rather enables local law to execute its arrangements. Article 12, advances the standard of common risk under a household lawful administration. At long last, obligation under the convention falls under strict risk and blame based risk. In any case, the push of Article 6 is that a gathering might be exempted from risk if evidence is accessible to demonstrate that the harm was either a 'Demonstration of God or compel majeur'e or 'Demonstration of war or common turmoil.'

3.2 Models of liability and redress frameworks

Although there are no internationally recognized frameworks that apply to liability in biosafety, the issues that arise are not necessarily new. Some states have appropriately responded to them previously by developing international and national frameworks designed to prevent harm to human and the environment.[21] States have been encouraged by the protocol to put together civil liability regimes whose aim is to harmonize rules on liability and redress. The responses have

[21] Cullet supra note…at 4.

included treaty based frameworks on hazardous waste (nuclear waste and pollution).[22] Despite the fact that these treaties emanate from different backgrounds they are similar.

Treaty based liability and redress regimes share a number of characteristics. First, they adopt strict liability as a strategy to push liability towards the precincts of the promoter or operator who cause harm to the environment or to humans.[23] This is supplemented by a fault based system for persons who cause damage through negligence. In the latter case, if damage is caused to land, tabulation of compensation would include an estimation of damages to the person and property.[24] Modern frameworks have included elements of preventive measures, costs of restoration and restoration of degraded environment. The treaties being signed currently are not taking into account compensation for non-economic aspects of the environment.

3.2.1 Treaty based regimes: The Lugano Convention

On top of the current universal common risk administrations, the Council of Europe has added to the appropriation of the Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment (Lugano Convention) June 1993. In any case, despite the fact that the Convention is just a territorial structure, some of its arrangements could be received in building up a risk administration for transgenic items at the global level. The concentration of the Convention is to guarantee pay regarding harm to the earth. A portion of the fascinating components of the Lugano Convention is that it perceives among risky exercises the generation, refined, taking care of, capacity, utilize, decimation, transfer, discharge or some other operation

[22] *See for example*, Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Basel, 10 December 1999, UN doc. UNEP/CHW.5/29, Annex III (1999), Convention on Civil Liability for Nuclear Damage, Vienna, 21 May 1963 as amended by the Protocol of 12 September 1997 and International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage, London, 27 November 1992.
[23] Cullet supra note…at 4.
[24] Ibid.

managing GMOs 'which as a consequence of the properties of the living being, the hereditary change and the conditions under which the operation is worked out, represent a critical hazard for man, the earth or property'.

The Lugano Convention re-imagined the importance of harm which it proposed ought to incorporate not just disability of the earth (which was constrained to the expenses and measures of reestablishment really to be attempted) additionally to expenses of preventive measures and any misfortune or harm brought about by preventive measures.

The Convention has however been reprimanded by the individuals who saw it to have neglected to give a hearty premise to a group obligation administration. Faultfinders have likewise observed the Convention to be dubious in the exercises which it tries to cover and it is additionally observed to be ambiguous as far as the definitions that it has. The Lugano Convention additionally has confinements on where a man may bring an activity for pay. It is subsequently given in Article 19 passage 1 that; 'Activities for remuneration under this Convention may just be brought inside a Party at the court of the place: (a) where the harm was endured; (b) where the perilous action was led; or (c) where the respondent has his continual living arrangement' this arrangement is however observed to be prohibitive as it doesn't accommodate change where a mischief has come about because of roundabout acts and thusly no purview has been given where cases emerging from backhanded damage can be taken.

The Convention apparently provides strict risk for harm that is occasioned by exercises perilous to nature. The Lugano Convention in Article 2 attributes risk on the administrator of an action, such an administrator can either be a private substance or an open element. Article 13-16

promote accommodates an intricate arrangement of guidelines which empower access to data held by both private substances and open powers.

The Convention advance accommodates the different sorts of harms that a violator can be made at risk to pay. Article 2 gives that preventive measures can likewise be attempted by a man to minimize the misfortune that is probably going to be occasioned. This apparently is in accordance with the need to guarantee that prudent steps are taken to guarantee counteractive action of mischief on the earth.

To guarantee that a far reaching insurance administration is set up, the Convention has given a wide meaning of the term 'environment'. In such manner, Article 2 accommodates what might constitute the earth and in such manner, social legacy is likewise taken to be in this class.

This approach, if embraced by Kenya, will be believed to go far in ensuring the respectability of nature and guaranteeing most extreme insurance of the earth.

In this manner, without a similar biosafety obligation and review instrument, the Biosafety Protocol could get from a portion of the current universal biotechnology and natural risk administrations that are indicated below.

3.3 Organization of African Union (OAU) Model Law on Safety and Biotechnology

The African Model Law speaks to the African state's position as exhibited to the Biosafety Protocol. The African position supported a stringent risk and review administration during the time spent operationalizing the Protocol. Article 14 of the Model Law is particular to matters of obligation and change, it gives that:

A man who imports, masterminds travel, makes contained utilization of, discharges or places available a hereditarily adjusted living being or a result of a hereditarily changed creature should be entirely at risk for any mischief brought about by such a hereditarily altered life form or a result of a hereditarily altered living being. The mischief might be completely adjusted. Obligation should connect to the individual in charge of the movement which brings about the harm, damage or misfortune and to the supplier, provider or designer of the hereditarily changed living being or of the result of a hereditarily adjusted life form. In the event that there is more than one individual in charge of the harm, damage or misfortune, then the risk might be joint and a few. On account of damage to nature or organic differing qualities, remuneration should incorporate the expenses of reestablishment, recovery or tidy up measures which really are being caused and, where appropriate, the expenses of preventive measures.

The model law has forced strict risk for mischief brought on by GMO items that are either foreign made, made in contained utilize, discharged or discharged to the market. Risk additionally connects to the supplier, provider or engineer and to any individual's exercises that prompt to hurt. On the off chance that the mischief is brought about by numerous people, risk appends to every one of them independently and severally.

Ecological harm is the subject of Article 14. The model law embraced the arrangements of the Lugano Convention that remuneration must incorporate the expenses of restoration of nature, recovery or tidy up measures. Where costs have been acquired simultaneously, that too must be in any way adjusted, "On account of damage to nature or organic differing qualities, pay should incorporate the expenses of reestablishment, restoration or tidy up measures which really are being brought about and, where pertinent, the expenses of preventive measures."

A noteworthy commitment of the model law identifies with financial intercessions. The law has extended limits of risk to incorporate harm to the economy, social harm, and social harm, harm to jobs, indigenous information and related advancements. Article 14 of the African model law gives that:

> On account of mischief to human wellbeing, remuneration might include: all expenses and costs brought about in looking for and acquiring the fundamental and proper restorative treatment; pay for any handicap endured, for decreased personal satisfaction, and for all expenses and costs acquired in reestablishing, beyond what many would consider possible, the personal satisfaction delighted in by the individual before the mischief was endured; pay for death toll and all expenses and costs acquired for memorial service and other related costs; Liability should likewise reach out to mischief or harm created specifically or in a roundabout way by the hereditarily changed living being or result of the hereditarily adjusted living being to financial, social or social conditions; including negatives impacts on the employment or indigenous information frameworks or advancements of a group or groups, or harm or annihilation emerging from occurrence of open issue activated by the hereditarily altered life form or the result of a hereditarily altered living being, interruption or harm to generation or horticultural frameworks, diminishment in yields, soil pollution, harm to the natural differences, harm to the economy of a zone or group, and some other noteworthy harm.

The risk visualized under this rubric incorporates interruption to or harm to horticultural frameworks, diminishment in yields and harm to the nearby economy. The African Model law not at all like the Swiss law as examined beneath does not have a confinement period inside which to establish a case for risk, such a right exists at whatever time hurt shows itself.

The privilege to get any affable activity regard of mischief brought about by a hereditarily altered life form or a result of a hereditarily changed life form might, having due respect to the laws on constraints of rights start from the date on which the influenced person(s) or the group, or groups could sensibly be relied upon to have educated of the damage, assessing: the time the damage may take to show itself; and the time that it might sensibly take to correspond the

mischief with the hereditarily adjusted living being or the result of the hereditarily adjusted creature, mulling over the circumstance or situation of the person(s) or group or groups influenced.

Advance, Article 15 of the African Model Law accommodates obligation under criminal law and could come about into criminal indictment. Criminal obligation will append to any individual who imports GMOs without appropriate approval, discharges it on to the market without endorsement of the skillful power. False deceptive or misleading data to secure an endorsement and where such discharge is in accordance with endorsement necessities may prompt to criminal approvals if observed to be valid. Inability to mark, distinguish or utilization of misdirecting recognizable proof could likewise prompt to criminal approvals. Criminal endorses under Article 15 incorporate detainment, installments of a fine and restriction of further inclusion in GMO related matters. These arrangements give an unmistakable guide to African states in enacting national laws to manage obligation and change.

3.3.1 The Swiss Gene Technology Law

The Gene Technology Legislation goes for the insurance of people, creatures and nature from the misuse of quality innovation.[25]

> The reason for this law is: to secure people, creatures and the earth from misuse of quality innovation; to serve the welfare of people, creatures and the earth in the utilization of quality innovation. Specifically, it might: secure the wellbeing and security of people, creatures and the earth; preserve organic differing qualities and the fruitfulness of the dirt for all time; guarantee regard for the poise of living creatures; empower opportunity of decision for purchasers; anticipate item extortion; advance open data; consider the criticalness of logical research on quality innovation for people, creatures and the earth.

[25] Article 1, Federal Law Relating to Non-Human Gene Technology (Gene Technology Law, GTL) of 21 March 2003.

It must be borne at the top of the priority list that the Swiss law, much the same as the other natural obligation systems depend on the preparatory and polluter pays standards.

One imperative component of the Swiss law is that it has received strict risk paying little respect to whether the harm is coordinated at the buyer or an agriculturist.

> The individual subject to approval is exclusively at risk for harm that jumps out at agrarian or ranger service ventures or to purchasers of results of these endeavors through the allowed advertising of hereditarily changed living beings that is a consequence of the alteration of the hereditary material.

Item risk is a one of a kind component of the Swiss law where a man who is approved to bring GMO into the earth is obligated for any deformities.

> Any individual subject to the notice or approval necessity, who handles hereditarily altered life forms in contained frameworks, discharges such living beings for test purposes or markets them without consent, is at risk for harm that happens amid this taking care of that is a consequence of the hereditary adjustment. The individual subject to approval is exclusively at risk for harm that jumps out at farming or ranger service endeavors or to customers of results of these undertakings through the allowed advertising of hereditarily changed life forms, that is a consequence of the adjustment of the hereditary material, if the life forms: are contained in rural or ranger service added substances; or originate from such added substances..

The import of the above stipulation is that the subject of power is permitted to make a move against anyone who took care of the life forms in an unseemly way or by and large added to the harm.

> The obligation to repay natural mischief lies on the client of the GMO item. Such a man should likewise repay the expenses brought about and any measures that are taken in repairing any harm to the earth or supplant it with actualizes of practically identical esteem. As far as possible for obligation under the Act is 30 years. This is in acknowledgment of the way that it is practically difficult to gauge at the correct time that harm would initiate. The edge of 30 years is just a rule

restricted to when the occasion or the date when the GMO item was put out to the market.

Different matters tended to by the Swiss law identify with issues of harm to basic land. Regular land (a typical) is land claimed altogether or by one individual, however over which other individuals have certain conventional rights, for example, those that permit their domesticated animals to brush upon it, to gather kindling, or to cut turf for fuel. The law clears up that any individual who is obligated to reestablish or repair the earth and does not do as such, the group is engaged to look for review in an official courtroom. This is a territory that the worldwide group must consider up important particularly as to territories that don't fall under national power.

The method of asserting change is that the weight of evidence is on the individual guaranteeing harms to demonstrate causation. Nonetheless, the judge under this enactment has some prudence in deciding it inasmuch as there is 'overpowering likelihood' and where the evidence is not sure. As far as motivating forces, the law has accommodated the Central Government to encourage in giving ensures that would cover any potential obligation for any Swiss national who wishes to market GM The Swiss Gene Technology Law delineates Switzerland as one of the not very many nations to thoroughly enact on matters of hereditary building and received a biosafety structure with inclination on a risk administration. The fascinating viewpoint about the Swiss enactment is that it is firmly impacted by the biotechnology business campaign bunches. In this manner the agreement landed at constitutes a tradeoff of the considerable number of players in the field (biotechnology industry and the NGOs who are for the most part contradicted to the presentation of GMOs).[26]

[26] Ibid.

3.4 Conclusion

From the foregoing discussions, it can be seen that various best practices can be derived from the various Conventions discussed in the preceding sections and these can inform the biosafety regime in Kenya. One such example is the African Model Law on Safety in Biotechnology. This Convention has established a rigorous process through which GMOs must go through before a product is approved. The Model Law is also clear on public participation requirements. In this regard, the public is to be involved in the decision-making process and notice is to be sent to the members of the public inviting them to the public participation sessions.

This relates to the Advance Informed Agreement (AIA) provided for by the Cartagena Convention which requires that information that is relevant for countries to be able to make informed decisions is disclosed to these countries. Public participation is an element that has further been emphasized in this Convention and parties are at all times required to disclose the relevant information to the members of the public.

The absence of an internationally recognized legal framework on liability and redress in biosafety threatens the protection of human health and the environment as a result of abuse by the introduction of LMOs. This is because existing frameworks are specific to either regions (the African Model Law), or are treaty based (Lugano Convention) or to specific states (Swiss Biotechnology Law). This means that states that are outside these classifications lack protection from the introduction of LMOs. Besides they deal with traditional perceptions of damage to the environment that disregards damage to the economy, society and indigenous knowledge. These are issues that an international framework should deal with by broadening and redefining the limits of harm to humans and the environment.

Article 27 of the Cartagena Protocol ordered part states to think on an obligation and review framework. Resulting endeavors that finished in the Supplementary Protocol to the Cartagena Protocol on Biosafety wound up supporting residential systems and commanded them to outline a risk and review administration.

The various models that are available, be they treaty based, regional or domestic share one characteristic of always proceeding with caution especially where risk assessment of the LMO is not backed by proper scientific proof. This in part explains why the precaution and polluter principles dominate liability regimes. The regimes also combine strict liability and fault based liability including time limitations as to when and at what stage liability should attach. Criminal liability for all frameworks attaches liability for misleading information, labeling and failure to get approvals in marketing of GMOs. The Swiss Gene legislation is particularly innovative for establishing liability for harm to common lands that have been left out by existing frameworks.

The convention on nuclear liability although not related to the topic under discussion, offers a good example on the determination of the applicable law in case conflict. The main difference between the nuclear convention regime and autonomous national solutions is that to a large extent, the conventions contain uniform substantive law on liability and compensation, and need to refer to national law only for a relatively few residual questions. Even in respect of those residual questions, the applicable national law is generally clear. Further the nuclear liability regime ensures that judgments rendered in one Convention State are recognized and can be enforced in all other convention States. Outside the nuclear liability regime, it is uncertain whether a judgement for compensation of nuclear damage will be recognized and can be enforced outside the country where the judgement was rendered. It is clearly advantageous for

victims if they can trust that a judgement rendered in one country will be recognized and enforced in others.[27]

An international liability framework in biosafety is still necessary to deal with continuous innovations in the production of transgenic products and the protection of human health and the environment.

[27] http://ola.iaea.org/ola/treaties/documents/liability_regime.pdf- accessed on 15/09/2014

CHAPTER FOUR

CRITICAL ANALYSIS OF KENYA'S LEGAL FRAMEWORK ON LIABILITY AND REDRESS FOR BIOSAFETY

4.1 Introduction

The significant role played by technology in improving agriculture production globally, regionally and nationally has necessitated the development of a liability and redress mechanism in biosafety to deal with the risks associated with LMO's.[28] Main concern arising from the adoption of biotechnology lies on human health, animal health and biotic environment.[29] Biotechnology has been seen to be of much importance in Africa's development [30] and as such protection and regulation of these products have been witnessed in many countries. This is in recognition of the fact that modern technology in agriculture is the answer to alleviating food shortages and the numerous effects of poor agricultural production and remedying the food situation in Africa. In addition, enhanced agricultural production through technology has been identified as a key pillar of Kenya's vision 2030.[31]

In an effort to address the trans-boundary harm brought about by risks in the application of new technology, the Government of Kenya has come up with a raft of policy and legal measures.[32] The government has in these legal and policy instruments committed to undertake several steps to encourage the application of biotechnology in Kenya. In this regard, the government

[28] M.G. Kinyua, W. Tonui, D.O. Ogoyi, Biosafety frame work in Kenya and its impact on application of GM technology
[29] Godliving Mtui, 'Biosafety systems in Eastern and Central Africa' (2012) 6(2) African Journal of Environmental Science and Technology, 80-93
[30] http://www.agbioworld.org/biotech-info/topics/dev-world/benefits.html accessed on 10/7/2014
[31] Government of Kenya, *Kenya Vision 2030: The Popular Version*, p.13
[32] The Biosafety (Contained Use) Regulations, 2011, The Biosafety (Environmental Release) Regulations, 2011, The Biosafety (Import, Export and Transit) Regulations, 2011 and the biosafety (labeling) regulations,20102

commits[33] to support the application of modern biotechnology to improve agricultural production and has implemented among others a National Biotechnology Development Policy[34]and the Biosafety Act No.2 of 2009 to govern research, development and deployment of modern biotechnology products. The policy provides that the legislature will embrace efficiency improving horticultural biotechnologies that can significantly invert the quick breaking down nourishment security and sustenance, cultivate wages, bring forth the agro-business, and lessen ecological debasement.[35]

In Kenya, laws and policies dealing with biosafety usually go hand in hand with those enacted to govern agriculture, health, trade and the environment. These laws and policies have further been enacted to ensure that the government meets its international obligations on biosafety. Furthermore, certain considerations had to be taken into account in the enactment of these laws. One such consideration was the need to ensure that the traditional nature of most Kenyan societies is taken into account. There was need therefore, to ensure that the traditional crops that are grown by farmers in the country are also able to access markets, both locally and internationally. Secondly, and much more importantly, having the largest concentration of GMO institutions, Kenya is considered regionally as a model in matters related to liability and biosafety and therefore the duty of care should be much higher.[36]

This chapter examines Kenya's legal framework on liability and redress in biosafety with a focus on the Constitution, legislation and common law, the adequacy and relevance of the liability and

[33] Deputy presidents commitment in the month of August to lift the ban on GMO in the next three months, Daily Nation, Monday August 17,2015.
[34] National Biotechnology Development Policy, 2006.
[35] Mission report on Biosafety and Germplasm exchange: Kenya and Zambia Jeudi, 28 Juin 2012 15:59 - Mis à jour Vendredi, 06 Juillet 2012 15:15
[36] Patricia Kameri-Mbote, Regulation of GMO Crops and Foods: Kenya Case Study available at www.law.nyu.edu/%20idcplg?IdcService=GET_FILE...ECM, accessed on 5 July 2013 (Hereinafter Kameri-Mbote *Regulation of GMO*) 8

redress mechanisms for harm that arises from trans-boundary use and movement of LMO and it also examines the best practices that can be adopted in order to fill in the gaps identified in the existing legislation. The starting point will be an examination of the gist of constitutional provisions on liability and redress followed by the Environmental Management and Coordination Act, the biosafety national legislation, common law and lastly weaknesses and shortcomings of the current legal framework. The chapter will however not examine the broad legal framework on liability and redress encapsulated in the Cartagena Protocol which forms part of chapter 3.

4.2 Broad legal provisions regulating biosafety in Kenya

Kenya's broad legal framework on liability and redress consists of four broad areas namely: the Constitution of Kenya, Environmental Management and Coordination Act (EMCA)[37], the national legislation on biosafety[38] Agricultural[39] and Public Health [40] legislations, and liability under the law of tort.[41]

4.2.1 The Constitution foundation of a liability and redress regime in biosafety in Kenya

The Constitution of Kenya is the supreme law of the country and binds all persons and state organs.[42] The constitution under article 2(4)[43] recognizes the supremacy of the constitution as against any other laws. Article 2(5) and 2 (6)[44] further recognizes international laws which Kenya has ratified to be part of Kenyan laws. Articles 2 (5 and 6) of the Constitution

[37] Act No. 8 of 1999
[38] Biosafety Act, No. 2 of 2009
[39] Agriculture, Fisheries and Food Authority Act, No.13 of 2013.
[40] Public Health Act, Cap 242 Laws of Kenya
[41] Kameri Mbote 2004 *ALJ* 119.
[42] Article 2 (1), Constitution of Kenya 2010.
[43] Article 2(4) provides that: "Any law, including customary law that is inconsistent with this Constitution is void to the extent of the inconsistency, and any act or omission in contravention of this Constitution is invalid."
[44] Section 2(5) The general rules of international law shall form part of the law of Kenya; (6) Any treaty or convention ratified by Kenya shall form part of the law of Kenya under this Constitution

domesticates international law especially covenants (treaties) that Kenya has ratified. This means therefore that Kenya having ratified the Cartagena Protocol in the year 2000 is bound by the provisions of Article 27 of the protocol that relate to the establishment of a liability and redress system.[45]

The Kenyan constitution comprises a whole chapter on fundamental rights and freedoms; of paramount importance is the right to life. As the origin of all fundamental rights and freedoms, it contemplates that all citizens have a right to life.[46] This right as succinctly addressed includes the right to clean air, water and food, an expanded right to life must of necessity include the three rights. There is no doubt that the right to quality life includes right to a clean and healthy environment.[47]

The use of the term 'person' is broadly conceptualized in this study to mean a human being or a corporate body.[48] However, the Constitution expressly provides in article 42 the right to a clean and healthy environment.[49] A constitution protects human rights, sets forth the obligations of the state, and restricts government power. This therefore means that, the state owes its citizens a duty of enacting laws and putting in place measures for the realization of this fundamental right. The

[45] The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. 2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

[46] ACTS et al, *East African Environmental Laws*, Volume 1, Materials Prepared for Workshop on Access to Environment Justice, Jinja Nile Resort 18-21, June 2000.

[47] G M Wamukoya and F D Situma eds, *A Guide to the Environmental Management and Coordination Act* (Centre for Research and Education in Environmental Law: Nairobi, 2000) at 17.

[48] Article 260, Constitution of Kenya 2010, provides: ""person" includes a company, association or other body of persons whether incorporated or unincorporated".

[49] Article 42, Constitution of Kenya 2010, provides: Every person has the right to a clean and healthy environment, which includes the right— (*a*) to have the environment protected for the benefit of present and future generations through legislative and other measures, particularly those contemplated in Article 69; and (*b*) to have obligations relating to the environment fulfilled under Article 70".

state has taken measures by putting in place a biosafety framework. The biosafety framework has generally been outlined into nine parts. The first part provides for the conceptual framework which outlines among others the objectives, justification, scope and key elements of the legislation: the second part of the biosafety framework provides a review of the national policies related to biosafety: the third part deals with the development of national biosafety policies and guidelines: the framework further provides for the development of biosafety administration systems and broad existing biosafety related legislations and mechanisms: it further takes into account institutional arrangements, open mindfulness, training and investment techniques; social and financial and moral contemplations that should be tended to.

This is unmistakably buttressed under article 69 of the constitution, which accommodates the commitments of the state and the obligation of each native to secure and moderate the earth and to collaborate with the state. This article likewise makes a commitment on the State to guarantee maintainable abuse, usage and protection of the earth and normal assets. Compensation for violating this right is available any time the right is either violated, being violated or about to be violated within the context of the principle of sustainable development. This principle is however underpinned by the principle of public participation in developing policies, plans and all processes relating to environmental management.[50]

Article 70 (1) of the Constitution comes closer to addressing the liability and redress challenges under the Kenyan biosafety regime as it provides for the enforcement of environmental rights.[51] It further grants the High Court the mandate to make orders in the spirit of protecting the

[50] Ibid. section 3 (3).
[51] (1) If a person alleges that a right to a clean and healthy environment recognized and protected under Article 42 has been, is being or is likely to be, denied, violated, infringed or threatened, the person may apply to a court for redress in addition to any other legal remedies that are available in respect to the same matter."

environment.[52] This is in addition to taking positive measures that are meant to protect the environment.[53] A compensation mechanism has also been provided for any person who alleges that his rights to a healthy and clean environment have been breached so long as proof is provided that he/she has suffered loss.[54]In this case therefore, upon successful proof that harm was occasioned by an individual, the court can impose a penalty to ensure restitution of the person who has been harmed.

Ledidi Ole Tauta & Others v Attorney General & 2 others[55], the court referred extensively to section 42, 69 and 70 of the constitution and it had this to say: "**Article 10 (1) of the Constitution binds all state organs, state officers, public officers and all persons to observe the national values and principles of governance when applying or interpreting the Constitution; enacting, applying or interpreting any law; or implementing public policy decisions. Article 10(2) sets out the national values and principles of governance and sustainable development is among the principles enumerated. Although enacted before the Constitution, the Environmental Management and Co-ordination Act defines sustainable development at section 2 as development that meets the needs of the present generation without compromising the ability of future generations to meet their needs by maintaining the carrying capacity of the supporting ecosystems. Protection and conservation of forests and the environment in general are therefore at the core of sustainable development."**

[52] (2) On application under clause (1), the court may make any order, or give any directions, it considers appropriate—(*a*) to prevent, stop or discontinue any act or omission that is harmful to the environment;
[53] (*b*) to compel any public officer to take measures to prevent or discontinue any act or omission that is harmful to the environment".
[54] Article 70 2 (*c*) and 3: "to provide compensation for any victim of a violation of the right to a clean and healthy environment. (3) For the purposes of this Article, an applicant does not have to demonstrate that any person has incurred loss or suffered injury".
[55] Ledidi Ole Tauta & Others v Attorney General & 2 others [2015] eKLR,

The court went further to state that: "**Article 69(2) obligates each individual to co-work with State organs and different people to secure and preserve the earth and guarantee environmentally reasonable improvement and utilization of regular assets. In the ruling delivered in this matter by Mumbi Ngugi, J on 27th January 2012 the Court stated that the decision reached in this suit is bound to have far reaching consequences in view of the fact that there are many other communities in Kenya with similar historical claims which may now be vested in the public. The Petition if allowed would only benefit the Petitioners at the expense of the wider public who benefit from the forest."**

Prior to constitution of Kenya 2010, the courts experienced challenges in making decisions on the true finding on the true limitations of the precautionary principle[56]. This was so because of the absence of clear guidelines on the application of the principle.[57] There now exist a number of decided and reported cases from the land and environmental court on the precautionary principle. In other jurisdictions as early as 1994 decisions had been made regarding the precautionary principle. In the Pakistan Supreme Court in the ***Sheila Zea and others v. Wapda*** **Case**[58] , the plaintiff was opposed to the construction of a grid system by the national authority. The opposition was grounded on the fact that the health of those near the grid would be adversely influenced by the introduction to the colossal electromagnetic field from the lattice station. In their suit, they conjured Articles 4, 9 and 184 of the Pakistan Constitution which given to insurance by the law from being uncovered from risks which might be because of establishment and development of any lattice station, any production line, control station or such establishment. What was not being referred to for this situation was the probability of unfavorable impacts of

[56] Patricia Kameri Mbote, 'Towards a Liability and Redress System under the Cartagena Protocol on Biosafety: A Review of the Kenyan National Legislation System', (2004) 1 *East African Law Journey* at 8.
[57] Ibid.
[58] PLD 1994 Supreme Court 693.

the venture, yet that despite the court decided that "the welfare of, monetary success of the nation and if there were dangers of genuine harm, powerful measures ought to be taken to control and on the off chance that it ought not be delayed simply on the grounds of the logical research and studies were uncertain."

Kenyan courts have taken after the prudent guideline on the Sheila case, for example on account of, Satrose Ayuma and 11 Others v the Attorney General and 2 Others, at 22 - "The ache for the new Constitution in this nation was driven by individuals' desires of better lives in each perspective, change of their expectations for everyday comforts and just treatment that promises them human poise, flexibility and a measure of uniformity".

John Kabui Mwai and Others v the Attorney General and 2 Others, at 6 went further to express that – "In our view, the incorporation of [SERs] in the Constitution is gone for propelling the financial needs of the general population of Kenya, including the individuals who are poor, with a specific end goal to elevate their human poise. The assurance of these rights means that the way that the Constitution's transformative motivation looks past simply ensuring unique uniformity. There is a pledge to change Kenya from a general public in light of financial hardship to one in view of equivalent and fair dissemination of assets".

The legal indifference can be found in the generally dynamic judgment of the High Court of Kenya in the John Kabui Mwai and Others v Kenya National Examination Council and Others [2011] where the Court expressed as takes after: "Financial rights are by their exceptionally nature ideologically stacked. The acknowledgment of these rights includes the making of ideological difficulties which, among others, affect on the way of the nation's monetary framework. This is on account of these rights cause positive commitments and have budgetary

ramifications which require settling on political decisions. In our view, an open body ought to be given proper slack in deciding the most ideal method for meeting its protected commitments".

These protected arrangements are operationalized through the Environmental Management Coordination Act as examined beneath.

4.2.2. Environmental Management and Coordination Act (EMCA)

The Environmental Management and Coordination Act, is the head enactment for the assurance of the privilege to a perfect and solid environment. The commitment to ensure the earth is offered on each native who has the locus standi to acquire a suit the High Court to authorize the privilege to a spotless and solid environment.

Ecological matters have been effectively taken care of in Kenya by the courts and this is obvious from the choices that have been rendered by the courts. On account of Waweru v Republic the Court avowed the position of Section 3 of Environment (Management and Conservation) Act 1999 (EMCA) which requires that courts consider certain all-inclusive standards while deciding environment cases. It likewise went further to express that separated from the EMCA it was of the view that the standards set out in area 3 do constitute a portion of worldwide standard law and the courts should take cognizance of them in all the important circumstances. It in this way had a part in advancing feasible advancement. For this situation, the Court was to manage four standards which it considered straightforwardly significant to the current matter which were: Sustainable advancement; Precautionary guideline; Polluter pays; and Public trust. As to trust, the Court expressed that the embodiment of people in general trust is that the state, as trustee, is under a guardian obligation to manage the trust property, being the regular characteristic assets, in a way that is in light of a legitimate concern for the overall population. The Court likewise

expressed that natural wrongdoings under the Water Act, Public Health Act and EMCA cover the whole scope of obligation including strict risk and total risk and should be extremely rebuffed on the grounds that the test of the rebuilding of the earth must be handled from all sides and by each man and lady. Courts in this way play a vital and key part in accomplishing maintainable advancement which implies clashes must be managed viably.

The National Environmental Tribunal has likewise assumed a key part in guaranteeing consistence with shields that have been set up. The Tribunal has after some time settled various debate identifying with the earth and it has incredibly added to the protection of nature. On account of Peter Mugoya and another v Director General, National Environment Management Authority (NEMA) and 2 others Tribunal Appeal No. 99 of 2012, which concerned a question identifying with the development of a Church expanding on a group backwoods arrive, the Tribunal wiped out the EIA License that had been conceded to the Church furthermore denied NEMA's letter of improvement endorsement that had been issued to the Church. The Church was further coordinated to reestablish the land to the condition it was in before their entrance.

These cases show the way in which the courts and tribunals have been proactive in guaranteeing the insurance of the earth by ensuring that the shields that have been set up are agreed to. The choices of these legal bodies have been enter in ensuring that the obligation and change frameworks that are set up are utilized to uphold ecological rules that are set up.

Under EMCA there is Environmental Impact Assessment which implies a precise examination directed to figure out if or not a program, action or venture will have any unfavorable effects on nature" The EMCA requires that an ecological effect appraisal ought to be completed for activities that go under the second calendar. Biotechnology and all ventures that present and test

GMO fall under this timetable. This has the impact of defeating the confinements of locus standi. Therefore no individual need demonstrate any uncommon harm past that endured by people in general. The outcome is that everybody has a privilege to secure the earth which as a result advances open interest in ecological insurance.

Each advocate of a venture is required to embrace EIA under supervision of the National Environmental Management Authority (NEMA). The Act orders NEMA to set up a specialized consultative board of trustees to guidance on natural appraisal (EA). At NEMA's ask for, these offices which involve associations and establishments which furnish NEMA with natural appraisal in consistence with progress educated assertion method that accommodated under the Cartagena convention.

Open cooperation is a critical element of the EIA forms. The reports are submitted to NEMA for audit, if the report demonstrates significant natural effect, an EIA should be attempted. On effective fulfillment, a permit is issued by the Director General of NEMA.

Open interest is elevated to the individuals who are probably going to be unfavorably influenced and who must be told of the need to complete an EIA. The substance of the notice incorporate a brief outline of the venture, the area and where the report can be normal. The general population is given 60 days inside which to make their remarks which might be broadened when the need emerges. Individuals from general society can likewise assess the enroll of the EIA specialists on installment of an endorsed expense. The precision and ampleness of the reports is ensured by the Act through the strengthening of NEMA to set up specialized consultative boards of trustees on EIA that require the engineer to give extra data.

NEMA may allow an EIA permit for the venture insofar as it is happy with the survey. The permit may likewise be restrictive on the measures to be taken by the designer to be taken with a specific end goal to fit the bill for finish permit. Albeit open interest is ensured through open investigation, the installment of a charge may hinder as opposed to empower open support particularly if general society can't raise the expense. Segment 53 of the EMCA Act, gives a premise to declaring a biosafety directions. As talked about in the previous areas, an administrative structure has been set up to manage biosafety issues in the nation and this contains directions on; taking care of, hazard evaluation, offenses and punishments and basic leadership on biosafety issues.

The polluter pays standard, preparatory guideline and the between generational and intra-generational value which are enter standards in ecological assurance are typified in the EMCA Act. This is notwithstanding thoughtful and criminal law solutions for wounds that are brought on by biotechnology. The High Court under the Act has arrangements for reviewing biotechnology exercises through ecological reclamation arranges, whose impact is to force those in charge of natural corruption to reestablish the debased environment beyond what many would consider possible to its prompt condition before the harm.

Other essential parts of EMCA include: Inspection which is accommodated under part VIII of EMCA. A norms and requirement audit board of trustees is built up to be a piece of the power. The board of trustees is led by the perpetual secretary in the service. The command of the council is given under area.

Part IX accommodate natural reclamation orders, ecological protection orders and natural easements. PART X accommodates examination, investigation and records. The Director-

General is ordered under the demonstration to designate properly qualified people as overseers. The monitors have powers with the composed endorsement of the Director-General request the quick conclusion of any assembling plant or other foundation or undertaking which dirties or is probably going to contaminate nature in spite of the arrangements of this Act and to require the proprietor or administrator of such foundation or undertaking to actualize any medicinal measures that the ecological investigator may coordinate in the notice. Subject to the Constitution and the bearings and control of the Attorney-General, an ecological overseer may, regardless in which he thinks of it as attractive so to do:- (an) establishment and embrace criminal procedures against any individual under the steady gaze of a court of able ward (other than a court-military) in regard any offense charged to have been carried out by that individual under this Act; and (b) cease at any phase with the endorsement of the Attorney-General, before judgment is conveyed any such procedures founded or attempted without anyone else.

Natural examiner might: - (a) screen consistence with the ecological benchmarks built up under this Act; (b) screen the exercises of other area particular natural inspectorates; (c) screen the example of utilization of natural assets; (d) lead ecological reviews; and (e) perform such different capacities as might be required under this Act or under the Gazette Notice designating him.

Natural offenses are given under part XIII. This part accommodates offenses identifying with review , natural effect appraisal , records , norms , offenses identifying with perilous squanders, materials chemicals and radioactive substances ,contamination and offenses identifying with ecological reclamation requests, easements and protection orders (area 143). Of much significance is that the punishments are not sufficiently reformatory considering the damage to the environment that can influence numerous eras. For example a man who declines to oversee

unsafe squanders is at risk to a fine of at least one million shillings or detainment to a term of at the very least two years or both.

4.2.3. Biosafety Act

The biosafety framework in Kenya has developed to react to circumstances and difficulties from advances in the field of biotechnology inside the nation and past. Under the Science and Technology Act of 1980, the National Council for Science and Technology (NCST) is commanded to organize, guide, and counsel and advance the utilization of science and innovation and advancement for financial improvement. In 1996, the NCST started the advancement of rules on taking care of solicitations including Genetically Modified Organisms (GMOs) in Kenya that was distributed in May, 2006. The fruition of rules prompted to the foundation of the National Biosafety Committee (NBC) to organize and execute Biosafety issues inside NCST. A biotechnology and biosafety strategy was received in Kenya in 2006.

The arrangement of the National Committee on Biosafety by the legislature proclaimed another period in biosafety control in Kenya. Propels in innovation and its application in the 1990's were gone for starting dialog and assessment of biotechnology. In 1991, an infection safe sweet potato research was begun at the Kenya Agricultural and Livestock Research Organization In 1993, the DDIS Netherlands Program was established and started the Kenya Agricultural Biotechnology Platform. Rules for biosafety were distributed by the National Council of Science and Technology (NCST) in 1999. This finished into Biosafety Framework built up around the same time through the UNEP-GEF extend, which was gone before by Insect Resistance Maize for Africa Research which was started (CIMMYT, KARI and Novartis).

Vigorously, cutting edge control of biosafety started in the year 2000 with worldwide mediation through the marking of the Cartagena Protocol on Biosafety by the Kenya Government. This was nearly trailed by foundation of a National Biosafety Committee (NBC) in 2003 which affirmed inquire about and contained trials on BT cotton and infection safe cassava. Around the same time, a draft Biosafety Bill was drawn up. The National Biosafety Policy was endorsed by the Cabinet in the year 2003. In 2006, a private movement financed by the USAID/IFRI that restricted the presentation of the Biosafety Bill was presented in Parliament. It campaigned for and against the Biosafety Bill inside and without Parliament. In spite of the restriction, the bill got to be law in the year 2009 when it got presidential consent. This was in the blink of an eye took after by the production of controls and foundations of National Biosafety Authority (NBA).

In Kenya, there exists a lawful and strategy structure controlling biosafety. This comprises of laws established in Kenya furthermore global tradition that have been received by Kenya to give direction on biosafety. In such manner, the National Biosafety Act and the National Biosafety Development Policy are a portion of the appropriate laws that have been instituted to oversee biosafety in Kenya. A portion of the prominent elements of the Biosafety Act incorporate; the forbiddance of the managing GMOs unless authorized by the National Biosafety Authority for the contained utilize; the setting up of the National Biosafety Authority as the point of convergence for Biosafety issues in the nation and; the foundation of the NBA board.[59]

The lawful system on biosafety in Kenya additionally comprises of directions which have been received to control the way in which biosafety concerns are to be taken care of. The administrative structure that has been received manages; the way in which people are to handle GMOs; the way in which the potential dangers postured by GMOs are to be surveyed; basic

[59] Biosafety Act, No.2 of 2009, Preamble

leadership in light of the hazard appraisal that has been done; audit and interest of the decision(s) that have been made and; offenses and punishments to be forced on violators.

The Biosafety Regulations, 2011, is one of the lawful instruments that has been received to guide biosafety in the nation. These controls are intended to fortify the arrangements of the Biosafety Act 2009. In such manner, 4 controls have been gazetted, directions for; Contained Use (2011), Environmental Release (2011), Import, Export and Transit (2011) and Regulations for Labeling (2012).

The goal of the Contained Use Regulations (2011) is to guarantee that the potential unfriendly impacts of hereditarily altered creatures are tended to ensure human wellbeing and the earth when leading contained utilize. In such manner, these controls are intended to provide food for exercises including GMOs. The Biosafety (Environmental Release) Regulations then again are intended to guarantee that potential antagonistic impacts of hereditarily adjusted living beings are tended to secure human wellbeing and the earth when directing natural discharge. In like manner, these controls are intended to cover exercises including arrival of GMOs into the earth and putting them available. Certain criteria have been built up under the Biosafety Act before an individual discharges GMOs into the market. The Biosafety (Import, Export and Transit) Regulations is intended to guarantee safe development of hereditarily changed creatures into and out of Kenya while securing human wellbeing and the earth. The exercises which go under the extent of these controls incorporate the importation into, exportation out of and development of GMOs through Kenya. The Labeling Regulations, 2012, then again are intended to guarantee that customers know about the parts of the items they buy with a specific end goal to guarantee that they settle on decisions from educated perspectives. This is likewise observed to be in accordance with the Constitutional assurance of the privilege to data for all Kenyans.

It is important that the administrative system on biosafety in Kenya is educated by the standard of investment of individuals from people in general in the definition of these structures and thusly the general population is to be included in the administrative procedures built up. Ecological assurance standards have additionally been contemplated and all things considered the standards of precautionary measure, earlier interview and open cooperation in natural matters have been considered.

The appropriation of a legitimate and strategy structure is additionally observed to go far in guaranteeing that advancement is encouraged since mechanical development supposedly is an essential apparatus intended to encourage improvement.

Every one of these improvements come against the background of a past administration where biosafety concerns were not a major issue of concern and in that capacity very little direction was set up. Past administrations have seen the advancement of lawful instruments that have to a great extent been coordinated towards the assurance of specific environments, species and assets. The appropriation of a lawful structure to oversee biosafety is however observed to be a stage in the right course since it offers a thorough system for the insurance against mischief in the utilization of biotechnology. Constraints significantly emerged when it went to the implementation of the biosafety controls that were set up and this significantly identified with the limit of the National Biosafety Committee (NBC), which was the body entrusted with biosafety direction advancement and to handle biosafety matters. In such manner, there was have to guarantee that directions are set up to guarantee that the potential unfavorable impacts of GMOs were managed henceforth guaranteeing insurance of human wellbeing.

Benchmarks for surveying risk have been set via Cartagena Protocol. Appropriately, its fundamental target:

> Is to contribute towards guaranteeing a sufficient level of assurance in the fields of safe exchange, taking care of and utilization of LMO's subsequent from current biotechnology that may effectsly affect the preservation and manageable utilization of differences considering dangers to human wellbeing and particularly concentrating on trans-limit development.[60]

The main focus of the Protocol is safe handling, transportation and release of LMO's into the environment. This comes with the realization that even under the best of circumstances, damage does occur anytime LMO's are released to the market.[61] This is beside the fact that LMO's intended for use in one country may cross over the neighboring country unintentionally largely because the effects of LMO's do not respect national boundaries that cannot be closed.[62] The issue of liability and the standard to be used is a critical problem in the absence of clear legal provisions. This will be made clearer when an analysis is made of the constitutional and legislative provisions relating to adverse effects to the environment in addition to civil liability under the law of torts.[63]

As noted in the previous sections, the evolution of agricultural practices in the country and the development of technology in agriculture warranted the enactment of a legislation to govern the biosafety regime in Kenya. Furthermore, Kenya has obligations on biosafety which arise from the Conventions that have been ratified by the country. In line with county's international obligations under Article 27 of the Cartagena Protocol, Kenya promulgated the Biosafety Act,

[60] Art 1, Cartagena Protocol.
[61] Patricia Kameri Mbote, 'Towards a Liability and Redress System under the Cartagena Protocol on Biosafety: A Review of the Kenyan National Legislation System', (2004) 1 *East African Law Journey* at 8. (Hereinafter Kameri Mbote *EALJ*).
[62] Ibid.
[63] Ibid.

No. 2 of 2009. The objective of the legislation as set out in the preamble is "an act of Parliament to regulate activities in genetically modified organisms, to establish the National Biosafety Authority, and for connected purposes."[64]

The Biosafety Act established the National Biosafety Authority (NBA) in 2010 that replaced NBC with responsibility to supervise and control the use, handling and transfer of GMOs for research and commercial activities in Kenya. The NBA works in consultation with eight regulatory agencies established by law namely Department of Public Health, Department of Veterinary Services, Kenya Bureau of Standards, Kenya Plant Health Inspectorate Services, Kenya Industrial Property Institute, Kenya Wildlife Service, Pest Control Products Board and National Environment Management Authority).[65]

The NBA is managed by a board that comprises a Chairman (who must be a scientist), Permanent Secretary for Science and Technology, Permanent Secretary in the Ministry of Finance, Permanent Secretary in the Ministry of Agriculture and the Director General of NEMA.[66] The main mandate of the Authority is to approve or reject applications for contained use and undertake risk assessment for purposes of approvals of contained use of GMO.[67] Accordingly, under section 19 of the Act, any introduction of GMO, importation[68] and marketing must have a written approval by the Authority.

Where the application for approval is satisfactory, the authority is mandated to undertake a risk assessment. After which the authority can either offer an unconditional approval that would be

[64] Preamble, Biosafety Act, No. 2 of 2009.
[65] Ibid. Fifth Schedule
[66] Ibid. Section 6, Biosafety Act.
[67] Ibid. Part III, Section 18
[68] Ibid. Section 20.

specific to the activity.[69] A conditional approval could also be given under section 30 (2) (b) or the application can be rejected up on which the authority has to justify the rejection.[70]

A review and appeal mechanism exists under the act. The board may review a decision pursuant to Section 29 where there is proof that either new scientific information relating to biosafety has come to light.[71] The Appeal Board consists of the Chairperson who is an advocate and four other members who are experts in environmental matters or social sciences and who must be appointed by the Minister.[72]

The authority is also empowered to issue the orders of environmental restoration and cessation relating to GMO.[73] The appointment of biosafety inspectors under section 43 (Pt VII), enables the authority to monitor compliance with biosafety standards, undertake inspections and submit reports and do other such functions that are authorized by the board.

The Act however has three major deficiencies that make it unsuitable as a liability and redress legal framework in biosafety. The act is set out as an administrative statute with the infrastructure to manage GMO's rather than a legal framework for providing compensation for those harmed by GMOs.[74] This is notable from a reading of Section 4 which provides for the objects of the Act. It is worth noting that this section does not provide that one of the objects of the Act is to provide redress for those who have been harmed by GMO's. A reading of the objects of this statute further indicate that the statute is majorly driven at addressing procedural matters in relation to GMO's. The act also restricts the capacity of individuals to institute

[69] Ibid. Section 30 (2)(a).
[70] Ibid. Section 30 (3).
[71] Ibid. Section 33
[72] Ibid. Section 35 (1)
[73] Ibid. Section 40 (1)
[74] Ibid. Section 16 and 17.

criminal proceedings against a developer, which instead should be done by the AG.[75] This has the effect of limiting the capacity of the public to be pro-active in protecting the harmful effects of GMO. These technicalities set out by the Act are further seen to limit the Constitutional guarantees on the enforcement of environmental rights by individuals. Third, and most importantly, public participation is not given a lot of prominence. It would be expected that as a major stakeholder and victims of the harm done by GMOs, the public need to play a leading role before these substances are introduced.

As has it has been noted in the previous sections, the establishment of proper risk assessment safeguard is of key importance in any biosafety regulatory framework. Article 16 of the Cartagena Protocol on Biosafety is thus clear on this and it requires that parties establish proper domestic mechanisms to be used in the regulation, management and control of risks associated with LMOs. It is however clear from the assessment done in this study that Kenya lacks a proper framework on liability and redress and the institutional capacity on this is also weak. It is therefore imperative that the institutions in existence are to be strengthened in order to ensure that risk assessment safeguards in place are effective.

The Cartagena Protocol has established best practices that are based on safe exchange, taking care of and utilization of LMOs and center has likewise been put on trans-limit development. The legitimate administration in Kenya can get from this in setting up structures on risk for damage emerging outside the outskirts of the state.

On risk and review, different classifications have been recognized by, for instance, the Organization of African Union (OAU) Model Law on Safety and Biotechnology which in Article

[75] Ibid. Section 53

14 has imagined such activities as interruption to or harm to farming frameworks, diminishment in yields and harm to the nearby economy to warrant liability. Criminal sanctions have also been seen to be applicable for certain actions

4.2.3.1. The Biosafety (Contained Use) Regulations, 2011

Sections 51 of the Biosafety Act,[76] empowers the Minister for Higher Education, Science and Technology to make the Biosafety (Contained Use) Regulations, 2011. The main objective of the regulation is: "to ensure that potential adverse effects of genetically modified organism are addressed to protect human health and the environment when conducting contained use."[77] The regulations are meant to facilitate the safe handling of GMO materials or what is known as contained measures.[78]

The regulations require that every research institution that undertakes contained use of GMO materials should establish an Institutional Biosafety Committee (IBC),[79] consisting of a biosafety officer who will be a scientist in the respective field, a representative of technical staff, representative of laboratory management, a representative from the community and a representative of the relevant regulatory authority. The function of the Institute of Biosafety Committee is to prepare applications for contained use activities and refer them to the National Biosafety Authority. The IBC also gives advice to research institutions on biosafety, assist in the establishment of monitoring systems for purposes of risk assessment, review and ascertain the suitability of physical and biological containment and control measures. In addition to the above, the committee advices relevant institutions and investigators on how to limit harm that could

[76] Ibid. Section 51: "T h e Minister may, in consultation with the Authority, make regulations for the better carrying into effect the provisions of this Act, and in particular for prescribing—(a) anything required by this Act to be prescribed; (b) procedures for conducting contained use activities involving genetically modified organisms".
[77] Section 3, The Biosafety (Contained Use) Regulations, 2011.
[78] Ibid. Section 5 (1).
[79] Ibid. Section 6 (1).

likely occur during accidents. Like the Biosafety Act, the Biosafety (contained use) regulations largely deal with procedural related issues and no provisions on liability and redress have been enshrined in the regulations. Penalties have been provided for in Section 20 of the Regulations but these penalties deal with violations arising from the procedural requirements in the Regulations.

4.2.4 Agricultural and Public Health Legislation Regulations

Agricultural technology has been seen in certain instances to pose risks to the consumers of these products and as such the Kenyan legislature had to adopt measures to ensure the protection of consumers of these products. Therefore the tremendous increase in the use of technology in agricultural production had the effect of increasing the vigilance in the need to bring about national biosafety guidelines and regulations.[80] In this regard, regulations have been adopted in the country which is enforceable by the institutions established under the various laws. Kenya's approach has been to make regulations that target safety in different sectors of agricultural production.[81] These are divided into two: agricultural safety regulations and public health and welfare regimes.[82] Agricultural safety regulations are encapsulated in the following legislations: Seeds and Plant Varieties (Amendment) Act, 2012,[83] Crop Production and Livestock Act,[84] Plant Protection Act,[85] Agriculture Produce (Export) Act,[86] and the Agriculture, Fisheries and Food Authority Act The public health and welfare safety regulations include: the Food, Drugs and Chemical Substances Act,[87] Dangerous Drugs Act,[88] Public Health Act,[89] Radiation Protection

[80] G N W Thitai, 'Existing Biosafety Regulations in Kenya', (1995) 3 (3) *African Crop Science Journal* 273 at 275.
[81] J S Wafula, 'State of the Art Biotechnology and Biosafety in Kenya', (1995) 3 *African Crop Science* 277 at 280.
[82] Ibid. at 275.
[83] Chapter 326 of the Laws of Kenya
[84] Chapter 321 of the Laws of Kenya (Repealed)
[85] Chapter 324 of the Laws of Kenya
[86] Chapter 319 of the Laws of Kenya (Repealed)
[87] Chapter 254 of the Laws of Kenya

Act,[90] use of Poisonous Substances Act[91] and Narcotics Drugs Act.[92] These outlined laws mentioned above deal with general aspects of safety but not necessarily genetic engineering involving DNA. This makes the necessity for a liability and redress legal regime even more urgent.

The public Health Act[93] is an act of parliament to make provision for securing ad maintaining health. The important segment of the act relevant to our study is on the management of vessels entering Kenya and the powers bestowed upon the port officers. Port officers have been granted powers to inspect any part of the vessel and anything therein.[94] The act provides further for the powers of the minister to declare any port in Kenya to be a first port of entry for all or for any particular class or description of overseas vessel from a proclaimed place.[95] This regulation is important in biosafety because it will help in the screening of GMO substances entering through the ports or any material that is on transit to avoid international liability. The act bestows an obligation on the master of vessels to take precautionary measures.[96] If precautionary measures

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[88] Chapter 244 of the Laws of Kenya
[89] Chapter 242 of the Laws of Kenya (Rev. 2002)
[90] Chapter 244 of the Laws of Kenya
[91] Chapter 247 of the Laws of Kenya
[92] Chapter 245 of the Laws of Kenya
[93] The Public Health Act, Cap 242
[94] Section 60 ,Public Health Act, Cap 242: (1)The port health officer may at any time board any vessel and inspect any part thereof or anything therein, and may medically examine any person on board and require any such person to answer any question for the purpose of ascertaining whether or not infection exists or has recently existed on board.(2)Any person who refuses to allow any such officer to board any vessel or to make any inspection or medical examination as aforesaid, or otherwise obstructs or hinders any such officer in the execution of his duty, or who fails or refuses to give any information which he may lawfully be required to give, or who gives false or misleading information to any such officer knowing it to be false or misleading, shall be guilty of an offence and liable to a fine not exceeding two thousand shillings.
[95]Section 63 of the Public Health Act: Declaration of infected places, ports of entry, etc. (1) The Minister may, by order (b) declare any port in Kenya to be a first port of entry for all or for any particular class or description of overseas vessels coming from a proclaimed place, and require masters of such vessels bound for Kenya to enter a port so declared before entering any other port of Kenya, except in case of danger or for other sufficient reason;
[96] Section 64 of the public health act 64: Master of vessel from proclaimed place to take precautionary measures (1) The master of any vessel bound for any port or place in Kenya which comes from or calls or touches at any proclaimed place shall, while his vessel is at that place and during the voyage to Kenya, take in respect of the vessel and her crew, passengers and cargo all such precautionary measures as may be prescribed by the order.

are not taken then the owner of the vessel is liable under the Kenyan laws. The owner of the vessel is also to pay for any inspection to be conducted.

Section 72[97] is important to our study where the act provides for agreements with other governments regarding reciprocal notification of outbreaks. This is in compliance with the biosafety laws where states are to give relevant information to other states to ensure safety of substances on transit. This is an important safeguard to states to avoid risks of unknown substances that may cause harm. Under the act the minister has power to make rules[98]. These rules are rules in regard to safety of substances leaving the country. The government is protected from liability under the act on any orders issued by the minister or other officer in accordance with the rules, provided that due care and reasonable precautions were undertaken to avoid any unnecessary delays and damage or destruction then the government will not be liable to pay compensation.[99]The local authorities are under duty to maintain cleanliness and prevent nuisances.[100]

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(2) Any master of a vessel failing so to do and thereafter entering any port of Kenya shall, unless he satisfies the court that he was unaware of the measures required to be taken by him and that he took all reasonable means to ascertain whether it was his duty to take any such measures, be guilty of an offence and liable to a fine not exceeding two thousand shillings.(3) Where a vessel has arrived from a proclaimed place and the prescribed precautionary measures have not been taken, any measures considered necessary by the port health officer, acting on the instructions of the Director of Medical Services, may be carried out with respect to the vessel and her crew, passengers and cargo, at the expense of the owner of the vessel.

[97] Section 72 of the public health act: Agreements with either governments regarding reciprocal notification of outbreaks (1) The Minister may enter into agreements with the Government of any foreign country, providing for the reciprocal notification of outbreaks of any formidable epidemic or other disease of any other matter affecting the public health relations of Kenya with other countries. (2) The terms or a summary of every such agreement shall be notified in the Gazette.

[98] Section 73 of the Public Health Act: Rules concerning port health matters: The Minister may make rules—(g) requiring the disinfection of any article or thing contaminated, or believed to be contaminated, with the infection of any infectious disease, on board of or landed from any vessel, or, if such article or thing is of such a nature that it cannot be so disinfected, prohibiting the landing or providing for the destruction thereof; (l) as to the exportation or removal from Kenya, whether by land or sea, of any article or thing considered likely to convey the infection of any infectious disease, and the examination, detention, disinfection or otherwise of any such article;

[99] Section 75 of the public health Act. Protection of Government Wherever under this Part powers are exercised by the Minister or other officer in accordance therewith and with the rules, and by reason of the exercise of such powers(a) any vessel, person, article or thing is delayed or removed or detained; or (b) any article or thing is damaged or destroyed; or (c) any person is deprived of the use of any article or thing, the Government shall not be

Section 118 of the public Health Act gives an elaborate description of what constitutes a nuisance under the act. Penalties in respect to nuisances are provided for under section 121[101].

The Agriculture, Fisheries and Food Authority Act[102] on the other hand, is an Act of Parliament to provide for the consolidation of the laws on the regulation and promotion of agriculture generally, to provide for the establishment of the Agriculture, Fisheries and Food Authority, to make provision for the respective roles of the national and county governments in agriculture excluding livestock and related matters in furtherance of the relevant provisions of the Fourth Schedule to the Constitution and for connected purposes. This act is important to our study because the whole essence of introduction of GMO's is to alleviate food scarcity though modern methods of food production. Under the constitution of Kenya 2010, the county governments have a responsibility to look for innovative ways of improving agriculture. With the improvement in biotechnology county governments will go a long way in improving food production in their respective counties, given the recent good will from the government. Section 29 of the act provides for respective roles of national and county governments, each county government shall within its area of jurisdiction be responsible, for agricultural matters in

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liable to pay compensation, provided due care and reasonable precautions have been taken to avoid unnecessary delay or damage or destruction.

[100] Section 116 Public Health Act: Local authorities to maintain cleanliness and prevent nuisances It shall be the duty of every local authority to take all lawful, necessary and reasonably practicable measures for maintaining its district at all times in clean and sanitary condition, and for preventing the occurrence therein of, or for remedying or causing to be remedied, any nuisance or condition liable to be injurious or dangerous to health, and to take proceedings at law against any person causing or responsible for the continuance of any such nuisance or condition.

[101] Section 121 of the Public Health Act.: Penalty respecting nuisances (1) Any person who fails to obey an order to comply with the requirements of the medical officer of health or otherwise to remove the nuisance shall, unless he satisfies the court that he has used all diligence to carry out such order, be guilty of an offence and liable to a fine not exceeding one thousand five hundred shillings for every day during which the default continues; and any person willfully acting in contravention of a closing order issued under section 120 shall be guilty of an offence and liable to a fine not exceeding one thousand five hundred shillings for every day during which the contravention continues. (2) The medical officer of health may in such case enter the premises to which any such order relates, and remove the nuisance and do whatever may be necessary in the execution of such order, and recover in any competent court the expenses incurred from the person on whom the order is made.

[102] Agriculture, Fisheries And Food Authority Act,No.13 of 2013

accordance with Part 2 of Fourth Schedule to the Constitution[103]. The national government shall, in accordance with Part 1 of section 29 of the Fourth Schedule to the Constitution, be responsible for agricultural policy and for assisting the county governments on agricultural matters. Each county government shall, for purposes of ensuring uniformity and national standards in the agricultural sector, through its legislation and administrative action, implement and act in accordance with the national policy guidelines issued by the Cabinet Secretary on the advice of the authority under this Act.

Section 22[104] of the Act is important to our study, as it provides for rules on utilization and development of agricultural land. The cabinet secretary is to consult with the national land commission and guide on how land is to be, managed. This includes on the kind of crops to cultivate on the land. This is a cushion to the indigenous farmers who will want to preserve their traditional methods of farming. The owners of agricultural land are able to make informed decisions from such advice. This will go a long way in enhancing food production. Further an owner of agricultural land shall be deemed to fulfill his or her responsibilities to manage it in accordance with the rules of good estate management if, having regard to the character and situation of the land and other relevant circumstances, it enables an occupier of the land

[103] Constitution of Kenya, 2010, fourth schedule part 2.

[104] Rules on preservation, utilization and development of agricultural land (1) The Cabinet Secretary shall, on the advice of the Authority, and in consultation with the National Land Commission, make general rules for the preservation, utilization and development of agricultural land and aquatic resources, either in Kenya generally or in any particular part thereof. (2) Without prejudice to the generality of subsection (1), rules made there under may— (a) prescribe the manner in which owners (whether or not also occupiers) shall manage their land in accordance with rules of good estate management; (b) prescribe the manner in which occupiers shall farm their land in accordance with the rules of good husbandry: (c) advise on the control or prohibition of the cultivation of land or the keeping of stock or any particular kind of stock thereon; (d) advise on the kinds of crops which may be grown on land; (e) provide for controlling the erection of buildings and other works on agricultural land; (f) provide for such exemptions or conditional exemptions from the provisions thereof as may be desirable or necessary; (g) provide for ex situ fish breeding to supplement in situ fish breeding and thereby outlaw seasonal bans on fishing; (h) provide for efficient and effective fishing methods that are sensitive to the social-economic status of local communities; and (i) provide for technical and other assistance to fishing communities to enhance their socio-economic development, especially that of vulnerable groups, including women.

reasonably skilled in husbandry to maintain efficient production as respects both the kind of produce and the quality and quantity. The occupier of agricultural land shall be deemed to fulfill his or her responsibilities to farm it in accordance with the rules of good husbandry if the occupier is maintaining a reasonable standard of efficient production, as respects both the kind of produce and the quality and quantity thereof, while keeping the land in a condition to enable such a standard to be maintained in the future.[105]

County government officers have been empowered to enter into any land and remove any noxious substances. Any owner of the land who obstructs such an officer commits an offence. This therefore means that no owner of land will introduce any sub stances harmful to the land that may harm the neighbours. The state has taken measure to ensure that such harmful toxins are removed from the land. This is a precaution taken by the government to cushion farmers against any harmful invasion.[106] A person who contravenes or fails to comply with the terms of a land development order commits an offence and shall be liable, on conviction, to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding three years, or both, and in the case of a continuing offence to a fine not exceeding fifty thousand shillings for every day of which the offence continues.[107] Under section 40 of the act, participation of farmers is embraced. This is to ensure effective participation of farmers in the governance of the agricultural sector in Kenya. There shall be close consultation with all registered farmers' organizations in the development of policies or regulations and before the making of any major

[105] Section 22(3) (a) and (b)
[106] Section26 Agriculture, Fisheries And Food Authority Act: Power of county government officer to enter land (1) An officer of the county government authorized for that purpose may at all reasonable times enter upon land situated in an area in respect of which he or she is authorized for the purpose of ascertaining whether any noxious or invasive weed exists thereon. (2) A person who obstructs or attempts to obstruct or hinder an officer of the county government in the exercise of his or her duties under this Act commits an offence.
[107] Section 30 of Agriculture, Fisheries And Food Authority Act:

decision that has effect on the agricultural sector. This is a major step towards public participation which is an important aspect in biosafety regulation in the country.

4.3 Liability under tort law

The desire to actualize Article 27 of the Cartagena Protocol[108] by member states found a natural ally in the law of tort. The law of torts generally provides the basic infrastructure for building up a liability and redress system.[109] Since environmental damage is a civil wrong, its redress is found under tortuous liability. The essence of liability in tort is that it arises from a breach by law whose remedy is redressed by an action for unliquidated damages.[110] The law of tort generally expects people to have certain obligations towards others and avoid activities that are likely to harm them. This is known as the neighbor principle which envisages that any breach of this obligation must be compensated by the defendant.[111] The challenge for the law of tort as applied in environmental law is the determination of who's responsible or who bears the relevant loss, is it the manufacturer, importer, purchaser or the distributer or is the nexus too remote? These are some of the questions that will be answered in this section.

It has to be recognized that most actions under the law of tort derive from the common law. Common law for the purpose of this study will be comprised of rules of English customary law that were crystallized by English courts under the principle of *stare decisis/*precedent.[112] The common law found its way into Kenya as a result of colonization and after independence through

[108] Article 27: "The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from trans-boundary movements of living modified organisms, analyzing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years."
[109]Kameri-Mbote 2004 *EALJ* 128.
[110] John William Salmond, *Salmond on the law of Torts 12th ed.* (Sweet and Maxwell: London, 1957) at 15. (Salmond *Salmond on the law of Torts*).
[111] Ibid.
[112] Salmond *Salmond on the law of Torts* 26.

the reception clause of the Judicature Act.[113] As a consequence, the common law is ranked very high as a source of law more so where legislation is lacking.[114] The torts that have been found relevant in a liability and redress system in biosafety are negligence, nuisance and the rule in *Ryland v. Fletcher*.[115] All these have been taken into account by the biosafety regulations that have been adopted which have provisions on liability and redress.

Common law recognized that a private individual may bring a suit in his name on the basis of an interference with a public right in two situations: where the interference with the public right also interferes with some private right of the person concerned or where, in the absence of any interference with a private right, the person concerned has suffered damage peculiar to himself, which is additional to that suffered by the rest of the public.[116]

In Kenya as well as many other common law jurisdictions, this restriction on suits by private individuals has been removed by statutory intervention. The constitution for instance under article 69 and 70 is clear. Section 3(3) EMCA stipulates that "a person proceeding under subsection 3

> ….shall have the capacity to bring an action notwithstanding that such a person cannot show that the defendants act or omission has caused or is likely to cause him any personal loss or injury…."

[113] Section 3 (1) (c), Judicature Act (Chapter 8 of the Laws of Kenya): "Subject thereto and so far as those written laws do not extend or apply, the substance of the common law, the doctrines of equity and the statutes of general application in force in England on the 12 August, 1897, and the procedure and practice observed in courts of justice in England at that date; but the common law, doctrines of equity and statutes of general application shall apply so far only as the circumstances of Kenya and its inhabitants permit and subject to such qualifications as those circumstances may render necessary."

[114] Migai Akech, Common Law Approach to Liability and Redress and Its Application to East African Countries. Paper presented at the International Environmental Law Research Centre Workshop held on 22-26 September 2003, Mombasa.

[115] *Ryland v. Fletcher* (1868), 3 HL 330.

[116] Section 3 of the Interpretation and General Provisions Act, chapter 2 defines "public body " to mean; (a) the government….or any department institution or undertaking thereof; or c) local authority)any authority, board, commission, or other body, whether paid or unpaid, which is invested with or is performing, whether permanently or temporarily, functions of a public nature.

this statutory provision therefore eliminates the common law requirement that the plaintiff demonstrates *locus standi* to sue.

Kenya has utilized the criminal law sanctions to enforce environmental management over the years, without necessarily terming it as environmental criminal law. EMCA makes provisions for both substantive and administrative offences. Substantive offences are provided for under sections 72,82,87,93, and 98. Administrative offences are provided for under section 87 and 91.

Part XIII of EMCA includes provisions on additional environmental offences. These include offences relating to inspection(section 137), offences relating to environmental impact assessment (section 138), offences relating to records (section 139),offences relating to standards (section 140), offences relating to hazardous wastes, materials chemicals and radioactive substances (section 141), offences relating to pollution (section 142), and offences relating to environmental restoration orders, easements and conservation orders (section 143).

EMCA also provides for offences relating to corporations under section 145[117]. Imputing liability on the part of directors and officers of the body corporate makes the put in place mechanisms for environmental compliance and forestall the possibility of passing the cost of non-compliance to consumers.

[117] Section 145 EMCA, when an offence against the Act is committed by a body corporate, the body corporate and every director or officer of the body corporate who had knowledge or who should have had knowledge of the commission of the offence and who did not exercise due diligence, efficiency and economy to ensure compliance with this Act, shall be guilty of an offence."

The act also makes it an offence for anyone to violate a provision of the Act or regulation under the Act, and for this a general penalty of either up to 18 months jail term, a fine of up to ksh 350,000 or both is provided for under section 144.

Environmental offences under EMCA are strict liability offences. The prosecution does not have to establish the defendant's state of mind as an element of the offence. Proof of *actus reus* of the offence will suffice. EMCA provides for fines and imprisonment and also innovative punishments such as; payments of the cost of cleaning the polluted environment and removing the cause of pollution[118], forfeiture of the substance or equipment used to commit the offence to the state, cancellation of licence, payment of the cost of disposal of substance or equipment forfeited to the state, and restoration of the environment.

The tort of negligence has been known to protect interests in physical and mental health, reputation, property interests, economic relations and other public rights. The proof of the existence of negligence is a five tier process that involves whether or not there was a "duty of care," for example does the law attach some duty to the developer of the LMO product (or the defendant)?

The case of *Donoghue v. Stevenson,*[119] illustrates the scope of the duty of care. Lord Atkin said that:

> You must take reasonable care to avoid acts or omissions which you can reasonably foresee would likely injure your neighbor. Who then in law is your neighbor? The answer seems to be persons who are closely and directly affected by my act that I ought to

[118] EMCA section 142(2)(a)
[119] [*1932*] AC 562.

reasonably put them in my contemplation, as being affected, when I am directing my mind to acts or omissions which are called into question.[120]

Secondly, the defendant must be in breach of that duty in either engaging in the activity he did or failing to act. In other word the defendant failed to meet the minimum standards envisaged under the law. Thirdly, out of the action or omission, the plaintiff suffered harm/injury or damage to his body or property. Fourthly, there must have been in existence a causal nexus between the defendant and the careless conduct or omission and the harm complained of. Fifthly, is whether the damage was foreseeable or it was too remote to contemplate.[121]

Be that as it may, the use of the tort of negligence in a liability and redress mechanism in biosafety presents certain difficulties owing to the requirements of *locus standi.*[122] Moreover, the time limitation under the Law of Limitation Act[123] may not be suitable since harm to the environment could take many years for effects to show.[124]

Nuisance is defined as: "an unlawful interference with a person's use or enjoyment of land or some right over or in connection with it."[125] The essence of nuisance is doing something unjustifiable which interferes with the use or enjoyment of another's land. The tort of nuisance is classified into private and public nuisance. Whereas public nuisance is actionable at the instigation of the Attorney General, private nuisance consists of using one's own land in such an unreasonable manner as to interfere with another's use and enjoyment of his own land. Section

[120] Ibid.
[121] W.V.H. Rogers, *Winfield and Jolowicz on Tort* 18th ed. (Sweet and Maxwell: London, 2010) at 167.
[122] Ibid.
[123] Chapter 22, Laws of Kenya
[124] Supra note 78.
[125] Ashiq Hussain, *General Principles and Commercial Law of Kenya* (East African Publishers: Nairobi, 1978) at 90.

61 (1) of the Civil Procedure Code thus provides for the manner in which public nuisance is to be dealt with in Kenya.

The rule in *Ryland v. Fletcher*[126] applies to anything that is brought on land in the course of its natural use that is likely to do mischief when it escapes.[127] Under this rule, damage and escape need not be reasonably foreseeable. Biosafety regulations that have formulated and adopted a liability mechanism that seeks to ensure that whoever is responsible for releasing GMOs in to the market or the environment without approval from the Authority shall be responsible for an offence under the Act. The Act has specified in section 52 that for liability to attach, the actions have to be directly imputed to an individual. This is a departure from the common law position stated in *Ryland* where liability can attach without fault.

At the practical level, it is important to synchronize penalties under EMCA with penalties under sectoral laws to ensure consistency in sentencing and alignment of penal provisions with the changing trends and developments in environmental law. There is also need for training and sensitization of law enforcement officers to ensure that environmental crimes are competently dealt with despite challenges of proof beyond reasonable doubt in criminal cases which has been a challenge in environmental law.

4.4 Weaknesses and shortcomings of the current legal framework

For a long time there has been lack of political good will in the implementation of the existing biosafety laws. This started with the ban of GMO's for a period of three years. Currently there is

[126] 3 H. & C. 774, 159 Eng Rep 737 (Ex. 1865).
[127] Supra note 83 at 203.

a major breakthrough for scientists and GMO's proponents' by the open declaration by the Deputy President of the Republic of Kenya, promising to lift the ban on GMO's to ensure food security in the country. This resolve has been positively welcome although there is some opposition from other quarters who are skeptical of the introduction of GMO's due to unfounded fear of the harmful effects GMO's can cause to the health of humans and the environment. Political good will is key in legislative process and policy implementation.

The weaknesses clearly evident is the main biosafety law, that make it unsuitable as a liability and redress framework include among others; First, the statute is an administrative in nature with the infrastructure to manage GMO's rather than a legal framework for providing compensation for those harmed by GMO's. Section 4 of the act provides for the objects of the act, this section does not provide that one of the objects of the act is to provide for redress for those harmed by GMO's. The act is driven at addressing procedural matters in relation to GMO's. Secondly, the Act restricts the capacity of individuals to institute criminal proceedings against a developer, the institution of proceedings is instead to be done by the attorney general as provided for under section 53.This has the effect of limiting the capacity of the public in being proactive in protecting themselves against any harm arising from the introduction of GMO's. These technicalities' limit the constitutional guarantees on the enforcement of environmental rights as provided for under section 69 and 70 of the constitution by individuals.

Thirdly, the statute does not put serious emphasis on public participation which is not only constitutional right but a key aspect in matters dealing with liability and redress in biosafety. The public and major stakeholders are expected to be involved in every step and to play a major role before the introduction of GMO's. This was a major oversight in the biosafety Act that needs to be addressed as a matter of urgency.

Some of the major shortcomings of the biosafety framework include; lack of technical capacity, weak legal and institutional framework, weak regulatory framework that deals only with procedural issues with no clear substantive provisions in relation to issues of risk assessment.

In order for Kenya to comply with article 16 of the Cartagena protocol on biosafety it needs to establish a proper domestic mechanism to be used in regulating and managing and controlling risks associated with LMO's, it is clear from the analysis that Kenya's framework on liability and redress and institutional capacity is weak. Institutions in existence need to be strengthened in order to ensure that risk assessment safeguards in place are effective. Best practices can be borrowed from OAU Model Law on Safety and Biotechnology discussed in chapter three.

4.4 Discussions and analysis

4.4.1 Type of activities or situations that should be covered under the Kenyan's Biosafety liability and redress regime

The scope of a Biosafety Liability and redress regime in Kenya should cover damage that results during transboundary movements. Transboundary movements should be defined to include after-care of disposal, that is, introduction to the environment of the importing State. In particular, the scope of a Biosafety Liability and redress regime should be extended to cover damage to the environment and to plant, animal and human life and health and to biodiversity by the introduction (export) of the GMO into the environment of the country of import over time. The Cartagena Protocol on Biosafety envisages providing against harm on the conservation and

sustainable use of biodiversity and to human health. Hence, risk assessment measurers require the identification and the evaluation of the possible adverse effects. This harm would occur not during the transboundary movement as such (like an oil spill or a falling space object), but by the introduction of the GMOs into the environment of the country of import and its continued presence in the place of disposal.

4.4.2 Type of damage resulting from transboundary movements that should be compensated

Damage to life and property and personal injury should clearly be made recoverable. Impairment of health should also be expressly provided for as the potential for the Convention on Biological Diversity, and the Cartagena Protocol on Biosafety. The damage recoverable should extend to cover the actual costs of reinstating the environment provided these measures are reasonable, the costs of any preventive measures as well as any damage resulting from the taking of these measures.

Also recoverable should be the loss of profits from a damaged environment. Losses attributed to the impairment of any economic interest derived from the environment is expressly provided for in the Basel Liability Protocol as well as other economic losses that reflect proximate or adequate causality – proving that the damage flowed directly from, and was integrally related to, the incident.

The liability and compensation regimes should be put in place in Kenya not only to provide compensation for the restoration of the environment but also to compensate those who suffer economic loss, in particular, farmers and the local populace, until the environment has been restored to its condition before the incident.

4.4.3 Channeling the liability for damage

The claim should be made to the person who breached the obligation. It is important to note that if the illegal act creates an irreversible situation and it is not possible to restore the position to that obtaining before the breach by reparation, then reparation should take some other form. If individuals or entities suffer damage, then the notifier State and the exporter should be liable for all such damage.

If private individuals or entities suffer damage, then there are three options as to the person to be fixed with liability. Firstly, liability could be 'channeled' to any one person to the exclusion of many others who could be responsible. These persons could include the generator or manufacturer, the exporter, the exporting State, the notifier the carrier, the importer or the importing State. Secondly, liability could be imposed primarily on one entity in the chain and secondarily on another. Thirdly, all those in the chain could be made jointly and severally liable for the damage.

4.4.4 The standard of liability for damage resulting from biosafety

Many multilateral conventions impose strict liability. There is a two-tier approach: it is implicit in the provisions that strict liability is for those activities that are deemed to be ultra-hazardous and in respect of damage that is *nonvolenti* – where the victim has not agreed to risk the injury by his own conduct. Ultra-hazardous Activity also incorporates those situations where the probability of the incidence occurring may be low but the magnitude of the harm huge.

Strict liability will deter reckless behavior. Therefore, for all the reasons, liability should be strict. Strict liability may also be one way of operationalizing the Precautionary Principle, which governs the key elements of the Cartagena Protocol on Biosafety.

Fault-based liability is only confined to the limited situations where the activity is either less hazardous or the person has volunteered to run the risk. Farmers affected by the contamination of their fields and crops by horizontal gene transfer, for example, have never volunteered to assume the attendant damage. A two-tier approach to the standard of liability for a Biosafety Liability and redress regime in Kenya is, therefore, appropriate.

4.4.5 Circumstances where liability should be exempted

It should be accepted under Biosafety Liability and redress regime in Kenya to exonerate a party from strict liability in certain circumstances. These include assumption by the injured of the risk of harm, intentional suffering or infliction of harm by the injured, the intervening acts of a stranger that causes the harm, *force majeur* and acts of God.

In respect of transnational cases, however, multilateral conventions restrict the categories of circumstances for which liability can be avoided. *Force majeur* is limited to an act of armed conflict, invasion (or hostilities), civil war, insurrection or a grave natural disaster of an exceptional character (inevitable, unforeseeable, and irresistible). An assumption of the risk is limited to the site of the abnormally dangerous activity (place of launch for space objects, for example). An intervening act of a stranger is an absolving circumstance only under the CLC. In the Space Objects Liability Convention, the only Convention that places direct responsibility on the State, only the act, omission or gross negligence of the victim exonerates blame. The Organization of European Economic Community Convention (OEECC) does not extend the exoneration for operators to States on the ground that all such *force majeur* matters (such as armed conflict, invasion, etc.) are the responsibility of the nation as a whole. The Basel Liability Protocol adds an additional ground for exoneration: that the damage was wholly the result of

compliance with a compulsory measure of a public authority of the State where the damage occurred.

Form the discussions; it is important to highlight two observations. Firstly, exoneration is granted in some situations where the ground specified is the exclusive cause; and in some others, where it could be a parallel, cumulative or complementary cause. It is preferable for exoneration only for any effective cause for the damage. Secondly, exoneration may be proportionate to the extent that it is responsible for the damage. This is the position under the Space Objects Liability Convention. It contemplates degrees of exoneration. This may be a useful compromise between allowing exoneration for any one of several causes for the damage – no matter how negligible and, refusing exoneration unless it is the exclusive cause.

4.4.6 Time limitation for liability

Many people have been grappling with the question whether liability should be limited in time, and if so, what period? Form the discussions; it is the position of majority of individuals that there should be no time limit. This is the position Kenya should take as well in its Biosafety Liability and redress regime.

4.4.7 Amount limit for liability

Concerning a Biosafety Liability Protocol, two aspects in particular bear on the choice of the applicable law. The first is a concern that a person should be adequately compensated so that he or she is restored to the position before the injury. The other is that he or she should not unjustly be enriched. Perhaps the best solution is to adopt the position under the Space Objects Liability Convention – that is, to take into consideration all relevant factors and the fundamental principles of international law.

4.4.8 Establishment of financial security to compensate for damage

A supplemental compensation fund should be established within the Biosafety Liability and redress regime in Kenya. The biotechnology industry in the country and/or their host countries could share the burden; while importing States are assured that the confidence projected by the industry and exporting States in their declarations of the complete safety of the technology is more than a public relations exercise and backed by an unequivocal financial commitment. The funds must be met by the industry and/or those developed industrialized countries which, by their own account, are engaged in the multi-billion dollar trade.

4.4.9 Courts and/or tribunals that have jurisdiction to adjudicate claims for damage

The Basel Liability Protocol gives three options. By Article 17, the competent court is where either:

a. The damage was suffered; or

b. The incident occurred; or

c. The defendant has his/her habitual residence or has his/her principal place of business.

It is suggested that the options in the Basel Liability Protocol should be adopted for the Biosafety Liability and redress regime in Kenya and that contamination of any center of biodiversity is considered a crime against humanity and adjudicated by the International Criminal Court.

4.4.10 Locus standi

Any person who suffers damage should have the right to bring claims. This would cover individuals, entities and the State itself.

4.5 Conclusion

In conclusion, the effectiveness and efficiency of a liability and redress legal mechanism depends on the capacity of the country to undertake scientific risk assessment and management of LMOs. This is because any potential hazard or adverse effects on the environment can only be identified through risk assessment and management. Kenya is deficient in this respect owing to its lack of technical capacity. This is also reflected in its legal framework which does not adequately deal with the key issues of biosafety. The regulatory framework that is established is also seen to largely deal with procedural issues and lacks clear substantive provisions in relation to issues like risk assessment.

Be that as it may, the country has shown that it has the rudiments of a mechanism that can be improved up on to deal with issues relating to biosafety. For example, the Constitution empowers every citizen to sue for the purpose of protecting the environment. The law of tort or tortuous liability provides a useful framework up on which to launch a liability and redress system in biosafety. While the Biosafety Act and guidelines provide an administrative procedure for risk assessment and management for LMOs.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

The constantly increasing population in Kenya translates into increased demands for food. This has necessitated the adoption of technology in order to ensure that the demands are met. Biotechnology has thus been adopted in Kenya and this comes with a number of challenges. Concerns have been raised in relation to the potential effects of the adoption of biotechnology on human health, animal health and the abiotic environment. Despite these challenges that are identifiable with the adoption of biotechnology, what remains clear is the fact that it can be used as a tool to eliminate the numerous food challenges that plague the African continent. A biosafety framework which seeks to deal with the challenges arising from the adoption of technology in the production of food has been established. These frameworks have established a liability and redress regime where such tools like Environmental Impact Assessment and redress mechanisms under civil law and tort law have been established. Under the latter, individuals can file claims under the tort of negligence or nuisance to complain of an alleged wrongful act by another. Despite these efforts, various challenges have been identified in the biosafety regime in the country which demands for solutions.

From the foregoing discussions, it is evident that the liability framework on biosafety is deficient in Kenya due to lack of technical capacity. This clearly comes out in the legal framework on biosafety that has been established in the country. The framework is seen to be deficient in addressing the key issues relating to biosafety. What is seen is a system that is rudimentary in nature and not focusing on the key issues on biosafety. This chapter concludes the study and

several recommendations postulated on the changes that need to be made to the Kenyan biosafety regime.

The country has enacted several legislations that seek to guide the biosafety sector and various institutions have also been established. These institutions have been tasked with ensuring the regulation of biosafety in the country due to growth in biotechnology in the country which has been adopted in both crop and animal production. Kenya has further adopted various international legal instruments both at the regional and international level which seek to guide biosafety.

Despite these initiatives that have been undertaken towards regulation of biosafety in the country, more needs to be done especially in relation to the establishment of a proper framework which is backed by a political will to enable effective regulation of biosafety in the country. The enactment of the Biosafety Act, No.2 of 2009 was the first step towards the adoption of a biosafety regulatory framework in the country. The steps that have been undertaken so far have been watered down by lack of political will to implement these regulations and the lack of proper institutional framework. What is clear is the fact that a majority of the legislation in place to govern biosafety is largely procedural and does not deal substantively with such issues like risk assessment.

This poses negative effects on the biosafety regime in the country due to lack of a proper framework to ensure assessment of products, hence a likelihood of potential harm to consumers. This is further complicated by the fact that there are massive transborder movements of substances across borders and members of the public lack awareness on the need to ensure that they protect themselves from potentially harmful substances. It has also been established in the

study that Kenya is deficient of technical expertise to conduct assessment and the government has also not devoted enough funding to this sector. This poses possible negative impact on the environment, biodiversity and human health.

At the international level, the Cartagena Protocol on Biosafety is seen to have played a big role in facilitating the growth and development of biosafety. This Protocol was adopted upon the realization that there were increased transboundary movements in GMOs and that there was an increase in the number of institutions undertaking research in biotechnology. It was thus of necessity that an international framework on the regulation of biotechnology be adopted and the Protocol sought to minimize the potential effects of these products on both human and animal health.

The precautionary principle is the principle that has largely informed the adoption of an international biosafety regime. This has been so in order to ensure the elimination of potential harmful elements to the environment and to human health. This has further been adopted in the establishment of municipal biosafety regimes. The international biosafety regime requires of states to share information which will enable the reduction of risks posed by biotechnology. Therefore, cooperation among states has been seen to be of particular importance in ensuring that harmful substances are not transported into another country without consent. At the international level, the Cartagena Convention has been seen to address various biosafety concerns which include assessment of risks, management of risks and communication of information relating to biotechnology. It has however been noted that despite the provisions outlined in the international legal instruments, developing countries have not been able to meet some of these provisions since they lack adequate risk assessment and management mechanisms. This particularly relates

to the provision of Article 15 (2) of the Cartagena Protocol which requires of state parties to ensure that risk assessments are undertaken at their own cost.

At the national level, Kenya is seen to have taken several initiatives towards the establishment of a biosafety regime in the country. The biosafety regulatory regime in the county has evolved over time due to the challenges that have arisen and also to ensure that it is in compliance with global requirements. Kenya has been a leader at the regional level in the biosafety field since it has adopted the Cartagena Protocol on Biosafety.

Some of the challenges that have been witnessed at the national biosafety platform include; the long time taken for decisions relating to biosafety to be made; lack of enforcement authority to the guidelines developed under the science and technology Act; lack of transparency and autonomy by the institutions developed under the Act due to lack of financial independence. The biosafety regime in the country has further been considered to be weak as a result of lack of general awareness by members of the public on biosafety and also as a result of failure by the institutions tasked with biosafety management to harmonize their activities. These institutions also lack the requisite capacity to deal with the numerous challenges that arise in the biosafety sector.

Various initiatives have been put in place to harmonize the biosafety regimes in the country. Some of the notable initiatives include; attempts to establish a comprehensive biosafety system and attempts to harmonize the existing legislation and regulations on biosafety. What still lacks is clear guidance on the particular institutions that are to be tasked with the carrying out of certain functions like ensuring the food safety of GMOs and clarity on what legal authority is to be relied on by these institutions in carrying out their functions. It is therefore necessary that

mechanisms are identified to ensure that concerns on food safety issues are addressed. The other important consideration that has been taken into account by the Kenyan biosafety regime is the recognition of public participation by key stakeholders. Members of the public are key in the protection of the environment from harm. It has therefore been recognized that, it is important to involve all relevant stakeholders in the development of the biosafety framework for the country. The stakeholders that are key in this process include farmers, academia, the government and players in the legal fraternity. These stakeholders have an interest in the formulation of the biosafety framework.

The sectoral approach adopted in the regulation of biotechnology in the country has resulted to an inefficient enforcement mechanism and this poses potential harm to consumers. The legislation governing biotechnology in the country is scattered in various legislations and policy. This poses challenges in the implementation of these legislations. Further there has not been much cooperation at the regional level in ensuring enforcement of laws on biosafety and this makes it difficult for countries to solely implement these laws due to shortages in technical capacity.

5.2 Recommendations

From the foregoing, several recommendations are proposed which the biosafety regime in the country can borrow from. Firstly, the Biosafety Act was developed through a participatory process where the stakeholders were involved in the process and were also educated on the process. Stakeholder trust was gained during the formulation of the Act and hence eliminating potential conflicts as the stakeholders felt a sense of ownership of the process and the output of the process, which is the Act.

It is however worth noting that, more effort should be geared towards implementing the biosafety regulation regime in the country. One such recommendation relates to the biosafety legislation development process. It is thus important that there is developed a political goodwill to ensure that the institutions tasked with the formulation of laws and policies play their roles well and ensure that there is consensus building among stakeholders involved in the formulation of these laws and policies. Further the government is to play a key role in ensuring that there are continuous dialogues with stakeholders even after the enactment of the law and policies and this is to ensure that there is proper implementation of these and that stakeholders are further involved in the amendment of these legislations and policies. In order to establish a comprehensive biosafety framework, it is important that adequate time is accorded for the participation of the stakeholders and the provision of adequate time also ensures that trust is built among the stakeholders. Proper planning is therefore imperative and this is to ensure that all the stakeholders, especially members of the public are given ample time to be able to familiarize themselves with the process and make themselves aware of the expected outcomes. There is further need to ensure that the system that has been established is also comprehensive enough to capture all the genetically engineered organisms whether plants or animals. The involvement of stakeholders should further be done in a manner that is sustainable in the long term so as to ensure that there are continuous engagements with the stakeholders in order to ensure that any future developments are taken care of. In this regard, there needs to be established mechanisms to ensure effective communication among the stakeholders so that constant dialogues on biosafety are encouraged. This initiative should bear in mind that biotechnology is always in a state of flux and that the law in most cases works to catch-up with the developments that have occurred in the area of biosafety.

The ideology informing the adoption of a framework for biosafety should be that of promoting and accommodating biotechnology rather than the adoption of a prohibitory approach in the development of a biosafety framework. In this sense, effort should be put in facilitating the introduction of safe practices in biotechnology rather than prohibition of acts. The government is to play a major role in the promotion of safe practices and further in providing incentives for private entities to practice safety in the adoption of biotechnology.

Since the introduction of regulatory mechanisms there has been a rise in challenges in their implementation. Many a times there have been overlapping mandates by various institutions and this leads to poor implementation of the legislations, policies and international legal instruments that have been put in place to govern biosafety in the country. It therefore follows that there is need to ensure that the mandates of the various institutions are clearly defined in the law.

More particularly, it is necessary that the country is able to establish effective mechanisms to be used in that systems for assessment are established within the country. Further, the assessment mechanisms that have been adopted are to ensure that research and development is encouraged in order to ensure that biotechnology substances are subjected to proper assessment with mechanisms that are up-to-date.

There is need to ensure that biosafety regulation in the country is coordinated in order to reduce the duplication of functions among the institutions. Further, coordination of activities that are to be undertaken is to be done at both the national and international level. This is meant to ensure that there is no duplication of roles and further to help in the cutting down costs. Implementation of the framework is majorly a task that is bestowed upon the government. The government is therefore required to ensure that there is regular review of the existing policy on biosafety laws

and policies in order to ensure that the existing legal framework is in line with the demands that have been established in the international frameworks.

A proper biotechnology framework should have an efficient liability and redress in biosafety. The current framework is not specific in addressing liability and redress in biosafety, it is a general framework. There is need to relook into the current framework and cast it specifically to deal with liability and redress in biosafety. This can be achieved through addressing the establishment of a framework that not only expands the capacity of individuals to institute proceedings but also ensuring that appropriate remedies to the claims are established and that the redress process is accessible to those who have incurred harm. Further, the public is to be informed of these processes and they should be aware of the platforms that they have to raise concerns on biosafety issues.

It is imperative therefore, that requisite steps be undertaken for one to raise a complaint for redress through a summarized and accessible manner to members of the society. Legislation guiding the biosafety framework should also be clear and outline among other things, the objectives, justification and elements of such legislation. In addition such legislation is to ensure that there is a policy framework that guides legislation in this sector and that the law in place clearly provides for the various institutions to be established and their various roles. It is also imperative that the legislation dealing with biosafety regulation are harmonized to avoid overlaps from occurring and also to facilitate the establishment of institutions with properly defined mandates.

Biosafety frameworks are further required to be abreast with the socioeconomic conditions of the country. There needs to be an assessment of the potential impacts that the framework may have

on social, economic and cultural practices and more particularly the potential impacts that the frameworks may have on indigenous knowledge or indigenous technologies that exist in the country. Further, in order to accommodate socioeconomic considerations, it is important that the biosafety systems adopted are fair and transparent and this is to ensure that the system is just to citizens who are to be served by the institutions that have been established.

The adoption of a proper biotechnology framework is seen to be important in ensuring the safety of consumers of products in the country and also ensuring that agricultural production is improved with the use of technology. Further, it is imperative that all the stakeholders are involved in the biosafety implementation programmes and this particularly calls for the adoption of a clear institutional framework that is able to ensure that an integrated approach is adopted to provide for biotechnology in the country. The government is also to ensure effective participation of members of the public in the management of the biosafety frameworks established and further ensure that the needs of communities in embracing biotechnology are taken into account.

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ANNEXURE 1: QUESTIONNAIRE

QUESTIONNAIRE

I am a final year student at the University of Nairobi, and I am currently working on my thesis. I am keen to assess the effectiveness of Kenya's biosafety liability redress regime as a thesis to be submitted in partial fulfilment of the requirements for the award of the degree of masters of laws in environmental law. All information gathered will be anonymous and treated confidentially.

PART A: PERSONAL INFORMATION

1. Name: …… (optional)

2. Date: ……..

3. Organization: ……..

4. Profession: ……..

5. Level of education: ……..

6. Phone number:

7. E-mail:

8. What gender are you?

Female

Male

9. What age group do you belong to?

17-27 28-38 29-39 40-50 51-61 62+

PART B: INTERVIEW QUESTIONS

10. What types of activities or situations should be covered under the Kenyan's Biosafety liability and redress regime?

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11. What types of activities or situations should be covered under the international rules and procedures for liability and redress in biosafety?

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12. What types of damage resulting from biosafety should be compensated?

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13. How should the concept of "damage to biological diversity" be defined, valued and classified, and should this be different from the definition, valuation and classification of this concept in the International framework for liability and redress in Biosafety?

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14. To whom should liability for damage be channelled?

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15. What should be the standard of liability for damage resulting from biosafety, i.e., should it be fault-based, strict or absolute?

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16. In what circumstances should the liability be exempted?

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17. Should the liability be limited in time, and if so, what period?

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18. Should the liability be limited in amount, and if so, to what amount?

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19. Should financial security be established to compensate for? If so, what should be the appropriate mechanism(s)?

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12. Which courts and/or tribunals should have jurisdiction to adjudicate claims for damage?

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13. Who should have the right to bring claims of damage?

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PART C: ANY OTHER IMPORTANT INFORMATION

Do you have any other important information regarding the topic of the study not covered in Part B or any other point you would like to expound? If yes give the details below.

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I have read the above questions carefully and certify that the information provided is correct.

_____ Signature