AN ANALYSIS OF THE BIOSAFETY ACT AS A DOMESTICATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY
CASE STUDY: KENYA

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JUNE 2010

CERTIFICATION

The undersigned certifies that, he has read and hereby recommends for acceptance by the Kampala International University a dissertation titled An Analysis of the Biosafety Act as a domestication of Cartagena Protocol on Biosafety: Case Study Kenya, in partial fulfillment of the requirement for the Degree of Bachelor of Laws.

SIGNED

..... 23.06.10

MR. JEFFREY ATWINE (SUPERVISOR) DATE

DECLARATION

I, Lucy A. Onam, do hereby declare that the work presented in this dissertation is my own, except where acknowledged, and it has never been submitted or examined in any university as an academic requirement for any award.

SIGNED

Onam 23rd June 2010.

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DEDICATION

For my fabulous and humble mom,

and my beautiful Leon Mwangi,

a little angel who will forever live in my heart.

Lucy Onam

JUNE 2010

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The inscription of this paper and my education as a whole made a considerable demand on different and various people that I am more than obligated to extend my very appreciation for each and everyone's contribution of any kind given unto me. However, I am limited of my ability to mention everyone individually thus extend my sincere thanks to everyone who assisted me in every sphere of life regardless of its antiquity.

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Any errors, weaknesses or shortcomings found in this work are entirely mine for which I assume all responsibilities.

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LIST OF INTERNATIONAL INTRUMENTS

The Cartagena Protocol of Biosafety

The Codex Alimentarius

The Convention on Biological Diversity

The International Convention for the Protection of New Varieties of Plants

The International Plants Protection Convention

The Office International Des Epizooties

WTO Agreement on Trade Related Aspects of Intellectual Property Rights

United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, public Participation in Decision-Making and Access to justice in Environmental Matters (Aarhus Convention)

The Vienna Convention on the Law of Treaties

ABBREVIATIONS

AIA	Advanced Informed Agreement
BCH	Biosafety Clearing House
BSWG	Ad Hoc Group on Biosafety
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CGRFA	Commission on Genetic Resources for Food and Agriculture
CHM	Clearing House Mechanism
COP	Conference of Parties to the convention on Biological Diversity
COPMOP	Conference of Parties serving as the meeting of Parties to the Protocol
CPB	Cartagena Protocol on Biosafety
EMCA	Environmental Management and Co-ordination Act
ExCOP	First Extraordinary meeting of the Conference of Parties
EU	European Union
FAO	Food and Agricultural organization of the United Nations
GEF	Global Environment Facility
GMOs	Genetically Modified organisms
ICCP	Intergovernmental Committee for the Cartagena protocol
IPPC	International Plant Protection Convention
IPR	Intellectual Property Rights
ITPGR	International Treaty on Plant Genetic Resources for Food and Agriculture
KARI	Kenya Agricultural Research Institute
KBS	Kenya Bureau of Standards
LMOs	Living Modified Organisms
LMO-FFPs	Living Modified Organisms intended for direct use as Food, Feed or for Processing

MFN	Most-Favoured-Nation
MLS	Multilateral System
NBA	National Biosafety Authority
NBC	National Biosafety Committee
NCST	National Council for Science and Technology
OIE	The Office International Des Epizooties
SPS	Sanitary and Phytosanitary Standards
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UNDP	United Nation Development Programme
UPOV	Union for the Protection of New Varieties of Plants
UNEP	United Nations Environmental Programme
WHO	World Health Organisation
WTO	World Trade Organisation

CHAPTER ONE
SCOPE OF THE STUDY

1.1 BACKGROUND

This dissertation deals with the Biosafety Act which is a domestication of the Cartagena Protocol on Biosafety (CPB).[1] The Biosafety Act has been drafted to regulate biotechnology and biosafety matters. The Act seeks to incorporate terms and requirements under the Cartagena Protocol into national laws. It will provide the legal and institutional framework for the development of biotechnology applications and biosafety standards.

The need for such a law stems from the increased use of biotechnology since the development of the first genetically modified crop, the *Flav Savr* tomato in the United States in 1994[2], which decayed at a much slower pace than ordinary tomatoes. Since then the number of genetically modified agricultural products has steadily risen to include crops such as corn, cotton, soybeans, papaya, potatoes and squash. Genetically modified crops have been favoured for their potentially higher yields, longer shelf life and stronger resistance to diseases and insects.[3]

In recent years, African countries have shown an increasing interest in biotechnology.[4] This interest has been enhanced by the growth in awareness of the subject generated through the negotiations for the Convention on Biological Diversity (CBD). Biotechnology has been viewed largely as a technical issue. As biotechnology is being

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[1] It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003. (http://www.cbd.int/biosafety/about.shtml) (accessed on 15 November 2009)
[2] (http://en.wikipediaa.org/wiki/Flavr_Savr) (accessed on 20 November 2009) also see, Flavr Savr tomato & GM tomato puree: The failure of the first GM foods Article from the Soil Association
[3] www.fftc.agnet.org(accessed on 15 November 2009) Regulatory Framework for Genetically Modified Agricultural Products in Korea
[4] Juma C, Mugabe, J ^ Kameri-Mbote, p, eds, "*Coming to Life: Biotechnology in African Economic Recovery*" (London: Zed Books and Nairobi Acts Press, 1994) Pg 71

introduced, it has the prospect of not only changing the way in which crops are grown, but also the food that we eat. Plants are currently being developed with enhanced nutritional value, with the ability to clean up toxic metals, or that contain vaccines and other drugs for human diseases.[5]

Other applications of agricultural biotechnology include crops with the ability to grow in harsher environments and with the inherent ability to resist pests. The use of genetically engineered pest-resistant plants may lead to a reduction in the use of harmful chemical pesticides.

In addition to plant biotechnology, genetically-engineered livestock are being developed for pharmaceutical development, enhanced meat quality, and waste reduction. Likewise, agricultural applications for genetically-engineered fish, insects, and micro organisms are being explored. The field of biotechnology is rapidly developing, and there is no doubt that it will create new opportunities in agriculture that we cannot even conceive of today.

However the ability of African countries to derive significant benefits from biotechnology will depend largely on the degree to which they reform their national policies to facilitate the acquisition and adoption of capabilities associated with biotechnology.[6]

Kenya was the first country to sign the Cartagena Protocol in May 2000. Resulting from five years of international negotiations, the Protocol offers a set of guidelines regarding the safe transfer, handling and use of living Modified Organisms (LMOs). It also requires

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[5] As one example, a new variety of rice has recently been developed containing genes for production of Vitamin A and higher levels of iron. Vitamin A deficiency affects approximately 300 million people worldwide. Therefore, such rice may help dramatically improve public health in developing countries. (http://www7.nationalacademies.org/ocga/testimony/Biotechnology_Issues.asp) (accessed on 19 November 2009)

[6] Juma C & Mugabe, J "*Public Policy and New Generic Technologies: The Case of Biotechnology in Sub-Saharan Africa*"

that signatory States develop a regulatory framework and capacity, in terms of people, expertise and knowledge to undertake risk assessments. Capacity building and competence in biosafety are thus strategically important for signatory countries both in meeting obligations under the Protocol and in advancing the successful integration of biotechnology into agricultural research and production.[7]

Kenya has also given its consent to the use of genetically modified food in the country. At the Kenya Agricultural Research Institute (KARI) there is a Level 2 Biosafety Greenhouse complex, which is used for biotechnology research. The facility allows Kenya to conduct biotechnology research that conforms to international biosafety standards.[8]

Biosafety as a concept refers to the need to protect human health and the environment from possible adverse effects of the products of modern biotechnology.[9] While it is recognized that modern biotechnology has the potential to contribute towards the improvement of human well-being particularly in enhancing food production and health care, there is growing public concern over the potential adverse affects of the technology and its products to human health and the environment.

These concerns stem from uncertainties about the actual behavior of genetically modified organisms in the natural environment. Issues such as the possibility of horizontal gene transfer of organisms in the natural environment occurring and leading to serious adverse effects on the environment and associated risks to human health, use of modern biotechnology and its products for antisocial purposes, such as production of biological weapons; and the right of individuals to know and decide on the use of the products of

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[7] Traynor PL & Macharia KH "*Analysis of the Biosafety System for Biotechnology in Kenya: Application for a Conceptual Framework*" Pg 1
[8] Crop Biotech Net [knowledge centre@isaaa.org] (accessed on 19 Novemeber 2009)
[9] http://en.wikipedia.org/wiki/Biosafety (accessed on 19 Novemeber 2009)

modern biotechnology, have necessitated the need for the institution of safety measures in the development and application of modern biotechnology and the commercialization of its products.

1.2 STATEMENT OF THE PROBLEM

Biological diversity[10] is pertinent for the survival of mankind. Diversity of agricultural production-comprising cultivated and gathered products such as fruits, vegetables, and multiple varieties of rice- is important to ensure food security. Homestead food production focused on a wide variety of fruits and vegetables and integrated with animal husbandry enables households to diversify and increase the quality of their diet.

Man is able to fashion his material culture from biodiversity as they provide raw materials for our clothing, shelter, and industries.

Genetic Engineering to produce superior quality of plants and animals to forestall crop failure is made possible with biotechnology. Biodiversity helps to maintain ecological processes; plants act as carbon sink and maintaining Greenhouse Effect through carbon sequestration.

Ecotourism is the major stay of several economies. In fact, biodiversity offers aesthetics in nature and earns man some psychological satisfaction.[11]

Modern biotechnology has brought about changes that adversely affect biodiversity hence there is a need to check these effects. Kenya as a recipient of foreign agricultural products

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[10] "Biodiversity" was coined as a contraction of "biological diversity" in 1985, but the new term arguably has taken on a meaning and import of its own. Biodiversity is the variation of life forms within a given ecosystem, biome, or on the entire earth. It is often used as a measure of the health of biological systems http://en.wikipedia.org/wiki/Biodiversity (accessed on 15 May 2010)

[11] *Rapid Decline in Biodiversity: A Threat to Survival of Humankind,* Dr. Prince Chinedu Mmom, Coutesy of University of Port Harcourt, Choba Port Harcourt, Nigeria

and foodstuffs needs to be aware of the consequences of these actions. There is also research in genetically modified agricultural products going on in the country. All these activities have to be controlled through law.

There have been international treaties and conventions where States come together and agree to regulate the use of genetic resources. Examples of such Treaties and Conventions are; The Convention on Biological Diversity, commonly referred to as the Biodiversity Convention, The International Plant Protection Convention, The Rotterdam Convention, The Commission on Genetic Resources for Food and Agriculture, The International Rice Commission and The International Treaty on Plant Genetic Resources for Food and Agriculture.

In Kenya there is also domestic legislation which tries, though not exclusively, to manage and control genetic resources. This has led to the need to come up with legislation that exclusively deals with the safe transfer, handling and use of GMOs, hence the drafting of the Biosafety Act has been drafted and is awaiting consideration by parliament. The Biosafety Act is a domestication of the Cartagena Protocol, which requires State parties to implement national biosafety systems.

The major concern therefore is whether the Biosafety Act provides an adequate legal framework to control risks associated with modern biotechnology. Further it needs to be determined whether the Act has an adequate regulatory capacity to enforce sanctions and punish offenders.

1.3 JUSTIFICATION FOR THE STUDY

A time has come when GMOs are slowly finding their way into our lives and impacting on our environment and health. As a country, we should be adequately prepared to deal with the effects of GMOs whether negative or positive. Such a study is necessary because

a sound biotechnology policy is vital to provide a framework for safe development and application of modern technology in Kenya. It is necessary to prevent any adverse effects of modern biotechnology on human beings and the environment, through a proper control mechanism enforced through law. The Protocol also provides for the implementation of a national biosafety system in developing countries by availing financial and technological resources. Kenya is eligible to benefit from such assistance. Kenya's biosafety system has numerous laws[12] relating to genetic resources culminating with the Biosafety Act. The Biosafety Act needs to be analyzed to ensure the objectives of the protocol are encompassed in the Act to ensure the interests of all Kenyans are met.

1.4 OBJECTIVES

The objectives of the study are to:

- Critically analyze the international instruments relating to Biosafety.
- Examine domestic legislation relating to Biosafety.
- Examine impact of the provisions of the Biosafety Act.
- Suggest any provisions in the Biosafety Act that need amendment to be in line with the Cartagena Protocol.
- Determine the factors that may hamper effective implementation of the Biosafety Act and give recommendations on how to solve these problems.

1.5 HYPOTHESIS

This study will test the following hypotheses:

- That the Biosafety Act is wholly and completely based on the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and does not take into account Kenya's needs and requirements.

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[12] An example is the Program for Biosafety Systems (PBS) which was approved in 2007 and aims to implement a functional national Biosafety system by building capacity and streamlining regulatory processes.

- That the current laws in Kenya are not only inadequate but also procedurally ill suited to deal with the introduction of Genetically Modified Organisms.

1.6 RESEARCH QUESTIONS

The research questions to be answered include;

- What are the international legal instruments relating to biosafety?
- What are the laws relating to biosafety in Kenya?
- To what extent can the Biosafety Act regulate modern biotechnology and biosafety issues?
- What are the factors that thwart the effective implementation of the Biosafety Act and what are the solutions for these hindrances?

1.7 METHODOLOGY

This study is largely theoretical. This is because the national biosafety system is still in its infant stages, as independent and relevant statute law which has just been recently enacted.

Information has been collected from individuals working with the relevant institutions including the National Council for Science and Technology, Kenya Agricultural Research Institute and Biotechnology Trust Africa.

The internet also has a lot of information from sites dealing with biotechnology.

Primary documents to be used are international conventions on biosafety which include the Convention on Biological Diversity, the Cartagena Protocol on Biosafety, the International Plant protection Convention among others.

The Codex Alimentarius which is a collection of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety will also be used.

There is also domestic legislation relating to genetic resources for example the Environmental Management and Coordination Act, the Wildlife (Conservation and Management) Act, the Forests Act and the Biosafety Act, which has just been enacted.

My study is descriptive, analytical and prescriptive. It is descriptive because it defines the current laws relating to the use, transfer and handling of GMOs. it is analytical as it examines the Biosafety Act in line with the Cartagena protocol. It is also prescriptive as it gives recommendations in any area where change is necessary to meet our biotechnology needs.

1.8 LITERATURE REVIEW

For the purpose of this study several texts shall be relied upon; the most important issue at the heart of this study is the analysis of the Biosafety Act in comparison to the Cartagena Protocol. A text that is of fundamental value is. 'An Explanatory Guide to the Cartagena Protocol on Biosafety.'[13] The main objective of this guide is to facilitate the understanding of the legal obligations of the parties under the CPB. It attempts to provide an information basis on the content and origin of the provisions of the Protocol. Ruth Mackenzie has also written and contributed to several articles stated in the bibliography, noteworthy of which is 'The 2000 Cartagena Protocol on Biosafety, Legal and Political dimensions' by peter Newell and Ruth Mackenzie.

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[13] Ruth Mackenzie, *An Explanatory Guide to the Cartagena Protocol on Biosafety* (2003) Union Internationale Pour la Conservation de la Nature et de ses Ressources, Switzerland

'*The Cartagena Protocol on Biosafety; Reconciling Trade in Biotechnology With Environment and Development* by Christoph Bail Robert Falkner and Helen Marquard' which talks about the background and the road to the Cartagena Protocol, negotiating the Protocol and the international process o adoption is also another relevant work of literature shall apply.

Another relevant text is Malcolm Shaw's '*International Law*'[14] which is a book on the principles of international law generally. Of particular interest to this study was the chapter on Law of Treaties, which is an interpretation of the 1969 Vienna Convention on the Law of Treaties. This was pertinent in understanding the Convention on Biological Diversity and the Cartagena protocol on Biosafety and how they relate to the Biosafety Act.

Another important work of literature that reference will be sought is the *Institutional Capacity Building for Intellectual Property Management: A Review of Uganda's Intellectual Property Policies and Legislation*[15]. This publication aims at providing an insight into the current international and national intellectual property laws and policies in place and their administration and enforcement. It also seeks to identify the issues and challenges of Intellectual Property (IP) management in and hence propose interventions.
It proposes the need for government to evolve a clear policy on IP that harmonizes the various pieces of legislation and recognizes all the Conventions that have so far been ratified, such a policy should establish a clear mechanism for the implementation of these Conventions, look into the need for capacity enhancement programmes for management and the need to sensitize the general public about IPRs and related legislation.

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[14] Cambridge, Grotius Publications (1991)
[15] The *National Intellectual Property Team*: David Bakibinga, Fiona Bayiga, Charles Mugoya, Julius Ecuru, John Bananuka, Ismail Barugahara, Jeffrey Atwine, Kampala, Uganda - August, 2005 www.bio-earn.org/Content/Downloads/IP/2005-IP_Report.pdf (accessed on 20 May 2010)

Categories of intellectual property which remain unprotected under the law need to be considered by formulating appropriate laws and policies to cater for them.

Reference will also be made to Dr. John Mugabe's work. His research interests include technology policy and institutional issues related to environmental management in general, and the conservation of biological diversity in particular.[16] His books Environmental Adjustment in Kenya: Emerging Opportunities and Challenges[17] and Governing Agricultural Biotechnology in Africa: Building Public Confidence and Capacity for Policy-Making[18] have vast research on the implications of pursuing biotechnology in Kenya and how such biotechnology can be realized.

Worth of mention is Patricia Kameri-Mbote's publication, '*Towards a Liability and Redress System under the Cartagena Protocol on Biosafety: A Review of the Kenya National Legal System*'[19]which talks about the liabilities and responsibilities of the Kenyan state under the available law in regards to biosafety.

Patricia Kameri-Mbote & Philippe Cullet also published a paper titled 'Biological Diversity Management in Africa: Policy Perspectives' for a workshop on *The Handbook on Implementation of Conventions Related to Biological Diversity* for the UNEP/UNDP/DUTCH Joint Project on Environmental Law and Institutions in Africa'[20] which talked about the authority of national laws to allow the implementation of International Conventions.

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[16] http://www.wipo.int/tk/en/hr/paneldiscussion/biographies/mugabe.html (accessed on 20 May 2010)
[17] Dr. John Mugabe, Norman Clark &Frances Seymour, *Environmental Adjustment in Kenya: Emerging Opportunities and Challenges* (1995) ACTS Press, African Centre for Technology Studies
[18] Dr. John Mugabe ,*Governing Agricultural Biotechnology in Africa: Building Public Confidence and Capacity for Policy-Making, (*2005) ACTS Press, African Centre for Technology Studies
[19] Patricia Kameri-Mbote, *Towards a Liability and Redress System under the Cartagena Protocol on Biosafety: A Review of the Kenya National Legal System'* (2004), East African Law Journal
[20] Held at UNEP on 11-14 October 1999 (Published as an International Environmental Law Research Centre Working Paper)

The rest of the material was acquired through numerous articles dealing with GMOs and their effects, analysis of the implementation of the Biosafety Protocol and recommendations for sound biosafety systems. The internet was a major source of these articles.

CHAPTER BREAKDOWN

Chapter one- scope of the study

This is an introduction into the extent of the study by providing; The Background, Statement of the Problem, Justification of the Study, Objectives, Hypotheses, Research Questions, Methodology, Literature Review and Chapter Breakdown.

Chapter Two- international Legal Instruments dealing with biosafety

The definition of biological diversity is provided with its value and loss. There is also the definition and scope of modern biotechnology with its benefits and adverse effects. An introduction to biosafety is given. International legal instruments relating to biosafety are analyzed, with emphasis on the CPB.

Chapter Three- Laws relating to Biosafety in Kenya

The concept of the domestication of treaty law is provided to show how international laws are made into domestic laws. The domestic laws relating to biosafety are analyzed to determine their adequacy in dealing with biosafety issues. A background to the Biosafety Act, 2003 is given.

Chapter Four- Analysing the Biosafety Act in light of the Cartagena Protocol

This is the analysis of the Biosafety Act as a domestication of the Cartagena Protocol. This is to determine the effectiveness of the provisions of the Biosafety Act as adopted from the CPB. Any shortcomings of the Act will also be determined in order to recommend the necessary amendments.

Chapter Five- Implementation of the Biosafety Act

This Chapter gives the factors that may hinder the effective implementation of the Biosafety Act. Recommendations are given to prevent these problems for taking root and preventing the implementation of the Biosafety Act.

CHAPTER TWO

INTERNATIONAL LEGAL INSTRUMENTS DEALING WITH BIOSAFETY

This Chapter sets the scene that leads to the introduction of international legal instruments that enhance the preservation of biological diversity for the benefit of mankind through biosafety. There is a definition of the term biological diversity and modern biotechnology with their values and likely adverse effects to the environment and human beings. This to know exactly what is being dealt with in the different legal instruments. There is an introduction into the concept of Biosafety.

An overview is given of the different international legal instruments giving details of their establishment and what biosafety issues they cover. Emphasis is laid on the Cartagena Protocol because the Biosafety Act is a domestication of this Protocol. This gives a hint of what kind of environment led to the adaptation of the Protocol and what it stands for as a compromise of the different interest groups.

2.1 DEFINITION OF BIOLOGICAL DIVERSITY

Biological diversity or biodiversity[21] is the term given to the variety of life on earth and the natural patterns it forms.[22]

The biodiversity we see today is the fruit of billions of years of evolution, shaped by natural processes and increasingly, by the influence of humans who's increased use has

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[21] The word biodiversity is a neologism from biology and diversity and was first coined by the entomologist E.O. Wilson in 1986. The term biological diversity was coined by Thomas Lovejoy, in 1980

[22] **The Convention on Biological Diversity** under **Article2** defines biological diversity to mean the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. http://www.cbd.int/convention/articles.shtml?a=cbd-02 (accessed on 18 January 2010)

led to environmental degradation leading to declines in local economies and the societies they supported.[23]

Biological diversity is often understood in terms of the wide variety of plants, animals and micro-organisms. Chromosomes, genes and deoxyribonucleic acid (DNA), the building blocks of life, determine the uniqueness of each individual and species. There is also the variety of ecosystems like mountains, lakes and agricultural landscapes, where humans form a community, interacting with one another and with the air, water and soil around them

2.1.1 The value and loss of biological diversity

Protecting biodiversity is in our self-interest. Biological resources are the pillars upon which we build civilizations. Nature's products support such diverse industries as agriculture, cosmetics, pharmaceuticals, pulp and paper, horticulture, construction and waste treatment. The loss of biodiversity threatens our food supplies, opportunities for recreation and tourism and sources of wood, medicines and energy. It also interferes with essential ecological functions reducing the productivity of ecosystems and shrinking nature's resources from which we constantly use.

While loss of species has always occurred as a natural phenomenon, the pace of extinction has been accelerated dramatically as a result of human activity. Ecosystems are being fragmented or eliminated and innumerable species are on the decline or already extinct. It is reckless if not downright dangerous to keep chipping away at our life support system. It is unethical to drive other forms of life to extinction and thereby deprive

[23] www.biodiv.org (accessed on 18 January 2010) sustaining Life on Earth. How the Convention on Biological Diversity promotes nature and human well being. *The web of life*

present and future generations of options for their survival and development. It was therefore imperative to come up with a law to curb the depletion of biological diversity.[24]

2.2 DEFINITION AND SCOPE OF MODERN BIOTECHNOLOGY

The term 'biotechnology'[25] refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use. It is an applied biology, which puts biological knowledge to work. It is the use of living organisms or parts of living organisms to produce goods or services. Biotechnology has been around for years and traditional biotechnology was used in processes such as sewerage and composting in the home and industry, for food in bread, cheese, wine and beer making and for medicinal plants and vaccines. It was also applicable in animal and plant breeding techniques.[26]

Modern biotechnology includes the application of:

- In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- Fusion of cells beyond the taxonomic family.[27]

These techniques overcome natural physiological reproductive or recombination barriers that have limited traditional breeding and selection.[28]

However in modern biotechnology it is now possible to take a single gene from a plant or animal cell and insert it in to another plant or animal cell to give it a desired characteristic, such as a plant that is resistant to a specific pest or disease. Advances in

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[24] *Ibid*
[25] Also known as Molecular Biotechnology, Genetic Modification (GM) and Genetic Engineering.
[26] *Biotechnology and GMOs* – An Overview paper by Biotechnology Trust Africa Secretariat (unpublished)
[27] http://www.greenfacts.org/en/agriculture-iaastd/l-2/3-biotechnology-for-development.htm (accessed on 20 may 2010)
[28] Supra note 25, Pg 30

biotechnology techniques have enabled us to cross the species barrier by transferring genes from one species to another. This has new found benefit to genetic engineering promises remarkable advances in medicine, agriculture, and other fields.[29] Despite the benefits, there are also concerns, which are both discussed below.

2.2.1 Benefits of Modern Biotechnology

Agenda 21,[30] adopted at the 1992 UN Conference on Environment and Development states that modern biotechnology "promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices. Improved supplies of portable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes".[31]

The benefits include among others:

- Foods of better quality and higher quantity are produced from which allergenic or toxic substances have been removed. There is *Bt Cotton,* an insect resistant transgenic crop, which has a gene from the bacterium, Bacillus thuringiensis that produces a protein that makes caterpillars ill, increasing *Bt Cotton* yields with much less pesticide use.
- Renewable energy crops are grown for conversion to energy for example willow, which can replace fossil fuels and mineral oils thus these resources are not completely depleted and can be used by future generations.

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[29] http://www.freshplaza.com/news_detail.asp?id=1804 (accessed on 20 may 2010)
[30] Agenda 21 adopted by the United Nations Conference on Environment and Development at Rio de Janeiro on 14 June 1992 is the framework for activity into the 21st century addressing the combined issues of environment protections and fair and equitable development for all. Agenda 21 provides a specific framework for many aspects of the UNEP programme. The agenda comprises 40 chapters each addressing specific aspects of these issues.
[31] www.iucn.org (accessed on 18 January 2010)

- Crops can be engineered to directly clean up environmental problems. For example GM plants can be used for bioremediation, where crops can be made to selectively absorb various metals and metal complexes like aluminium, copper and cadmium from contaminated soils. Such plants could be used for instance to detoxify the soil methyl mercury from soil, thereby removing it from the food chain.
- Better health care possibilities where new pharmaceuticals which are better targeted towards particular diseases are produced, such as the cloning of the human insulin gene into a bacterium that multiplies and produces a lot of human insulin which is purified and sold.[32]

2.2.2 Adverse effects of Modern Biotechnology

Despite these benefits there are also concerns which are heightened by the relatively small amount of experience related to the application of the technology to date and the fact that any adverse effects may only be manifested over the long term. Some individuals for example Scientists like Prince Charles, Richard Dawkins and Lewis Wolpert believe that modern biotechnology transcends that which humans should be doing[33], there is currently little evidence to support the claim of increased agricultural yield, many widely promoted examples of GM applications have failed due to the limitations inherent in the technology and the complexity of the problems tackled, for example the production of allergen-free rice, fast growing pigs with additional hormone genes and micro-organisms designed to digest soil contaminants and so on.

The concerns about gene transfer fall into four categories, which are:[34]

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[32] http://www.freshplaza.com/news_detail.asp?id=1804 (accessed on 20 may 2010)
[33] http://www.kenanmalik.com/essays/natural.html (accessed on 20 may 2010)
[34] Mackenzie, R (2003) "*An Explanatory Guide to the Cartagena Protocol on Biosafety*" IUCN Environment Policy and Law Paper No. 46, Pg 8

2.2.2.1 Environmental Concerns

The environmental consequences of the release of GMOs into the environment are likely to be significant, in particular the simplification of the agricultural ecosystem, decreasing biodiversity. GM crops designed to be resistant to pests and tolerant to herbicides may cause the target pests to become resistant to toxins produced by these crops.

There are the unintended changes in the competitiveness, virulence or other characteristics of the target species, the possibility of adverse impacts on non-target species such as beneficial insects and ecosystems, the potential for 'weediness' in genetically modified crops[35] and the stability of inserted genes.[36]

"Weediness" potential is a measure of a plant's ability to successfully colonize an ecosystem, especially when it may also lead to the displacement of other species. Weediness depends on the selective advantage of many genes functioning in combination, which are unrelated to the genes usually introduced for agronomic reasons.[37]

2.2.2.2 Health (Food) Concerns

There is currently insufficient information regarding toxicity, allergenicity and nutritional changes of food products derived from GMOs. In this regard, individuals should be cautious when handling such products because the new genes inserted into GM plants could be incorporated into a consumer's genetic makeup, though there is no evidence of transfer to humans through food and drink. There is also the issue of antibiotic resistant 'marker' genes that are used to identify whether a gene has been successfully

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[35] *Ibid*, where a plant becomes more invasive than the original, perhaps by transferring its genes to wild relatives.
[36] The possibility that a gene will lose its effectiveness or will be re-transferred to another
[37] http://www.agbios.com/cstudies.php?book=ESA&ev=MON810&chapter=Weediness&lang= (accessed on 19 May 2010)

incorporated into a plant which could through consumption of the antibiotics by humans accelerate the trend towards antibiotic resistance though this may be minimal.[38]

2.2.2.3 Economic Concerns

There is globalization and multinational control of food production where there is the displacement of cash crops or traditional crops and disruption of small scale farming systems that are prevalent in developing countries, there is also the introduction of a number of companies involved in agricultural biotechnology and the grouping of seed stock and chemical control agents, which negatively affects small-scale farmers. There is the issue of patents on living organisms, genes and/or genetic resources, which leads to trade wars due to intellectual property rights.

2.2.2.4 Social Concerns

These include dietary and taste preferences of individuals. There are ethical considerations of genetically modified products and their effects. There is the keeping of seeds and organic farming and what effect this shall have on human beings. There is also the issue of labeling so that parties can make informed choices in their purchases.

2.3 BIOSAFETY

Biosafety describes the recognized procedures and policies in ensuring safe application of modern biotechnology and use of its products. This is expected to protect human health and environment from possible adverse effects of modern biotechnology. As it has been observed above modern biotechnology has the potential to contribute towards the improvement of human well-being, particularly in enhancing food production and health

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[38] This is in comparison to use of antibiotics in feed for livestock and overuse as human medicine. (The Royal Society , GM Plants; Food and Agricultural Organization/ World Health Organization, Biotechnology and Food Safety Special Issues, Report of a Joint FAO/WHO Consultation, Rome, 30 September – 4 October 1996)
www.fao.org/waicent/faoinfo/economic/esn/biotech/six.htm (accessed on 18 January 2010)

care, there is growing public concern over the potential adverse effects of the technology and its products to human health and the environment.

The need for adequate biosafety measures to protect the environment stems from the fact that the genetic modification technology is a relatively new technology which raises questions about potential risks to the environment and human health. The limited experience with biotechnology calls for efforts to apply the technology in the most judicious way so as to reduce the risks of any potential adverse effects on the environment and human health.[39] Biosafety covers food safety, plant life and health, animal life and health and the environment, including the introduction and release of GMOs and their products. Increase in trade and travel internationally expands the variety of imported products and the growing number of nations that these products originate, this creates more pathways to spread pests. Diseases and other hazards moving further between and within nations.

This has led to the creation of international treaties between state parties who agree on certain terms and provisions as to the conservation of the environment for both present and future generations. There are sanctions put in place to ensure that parties follow these laws. There are a number of international agreements for the regulation of biosafety and they will be discussed below.

2.4 THE CONVENTION ON BIOLOGICAL DIVERSITY

In 1992, at the Earth Summit which took place at the United Nations Conference on Environment and Development in Rio de Janeiro, Brazil, world leaders agreed on a comprehensive strategy for "sustainable development", meeting our needs while ensuring that we live in a healthy and viable world for future generations. This is termed as inter-

[39] Mayr J, *Cartagena Protocol on Biosafety: From Negotiation to Implementation "Doing the Impossible: The Final Negotiations of the Cartagena Protocol"*

generational equity where the present generation should ensure that in exercising its right to beneficial use of the environment, health, diversity and productivity of the environment is maintained for the benefit of future generations.[40]

They adopted the Convention on Biological Diversity, the first global agreement on the conservation and sustainable use of biological diversity. The biodiversity treaty gained rapid and widespread acceptance. It recognized for the first time that the conservation of biological diversity is "a common concern of humankind" and is an integral part of the development process, as shown in its preamble. The agreement covers all ecosystems, species, and genetic resources.[41]

The Convention on Biological Diversity was adopted in May 1992 in Nairobi and was opened for signature in Rio de Janeiro on 5 June 1992 at the UN Conference on Environment and Development. It entered into force on 29 December 1992. The treaty is a landmark in the field of environment and development. It takes a comprehensive, rather than sectoral approach to the conservation of the biological diversity of the planet and the sustainable use of biological resources. It also encompasses related socio-economic issues, such as the sharing of benefits from the use of genetic resources and access to technology, including biotechnology, public education and awareness, exchange of information, technical and scientific cooperation and access to and transfers of technology.

The Convention has three main goals namely:

- The conservation of biodiversity
- Sustainable use of the components of biodiversity

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[40] Hunter D, Salzman J & Zaelke D (1998) *International Environment Law and Policy:* University Casebook Series: Pg 171
[41] www.biodiv.org, (accessed on 18 January 2010)Sustaining Life on Earth: How the Convention on Biological Diversity promotes nature and human well being; An Agreement for Action

- Sharing the benefits arising from the commercial and other utilization of genetic resources in a fair and equitable way

As a forerunner to the Cartagena Protocol the CBD contains three provisions directly related to living modified organisms (LMOs). Firstly, Article 19(3) generated negotiations of the Cartagena Protocol.[42] Secondly, Article 8(g) requires parties to regulate, manage or control risks associated with LMOs resulting from biotechnology which are likely to have impacts on the conservation and sustainable use of biological diversity, taking into account the risks to human health. Thirdly, Article 19(4) considers transfers of LMOs from one party to another. It requires each party to provide information about the use and safety regulations to the other party, as well as any available information on the adverse effects, which the introduction of LMOs may have for this party. Further, Article 8(g) and 19(4) contain obligations applicable to all parties to the CBD independently of their becoming parties to the Protocol. The provisions of the CBD will apply to the protocol and they should not be contravened.

2.5 CARTAGENA PROTOCOL ON BIOSAFETY

The introduction of the Cartagena Protocol to the Convention on Biological Diversity can be attributed to the enabling provision, Article 28 of the CBD, which mandates parties to cooperate in the formulation and adoption of Protocols, which gives the basic rules for their adoption and consideration, The Conference of Parties decides on the subject of a Protocol, which would be useful in the attainment of the objectives of the CBD. Pursuant to Article 19(3) of the Convention on Biological Diversity, the Conference of the Parties, by its decision II/5, established an Open-ended Ad Hoc Working Group on Biosafety[43] to develop a draft Protocol on biosafety, specifically focusing on transboundary movement

[42] The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, and in particular, advanced informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.
[43] This means that it is open to all parties to the Convention on Biological Diversity and to observers.

of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.[44]

The Conference of Parties held several meetings as they considered the Protocol and these took place as follows:

In 1994, there was the first meeting of the Conference of the Parties to the CBD in Nassau, Bahamas. Thereafter two meetings were authorized to consider the need for and the modalities of a protocol on biosafety. Accordingly, a panel of experts met in Cairo in May 1995, and it was followed by open-ended Ad Hoc Group of Experts on Biosafety, which met in Madrid in July 1995. The large majority of delegates present at the Madrid meeting favoured the development of a Protocol on biosafety.

At its second meeting in 1995 in Jakarta, Indonesia they considered the results of the experts' work. After lengthy debate, the Conference of Parties decided to establish an open-ended Ad Hoc Working Group on Biosafety (BSWG) to elaborate a Protocol on biosafety for consideration by the COP, (Decision II/5). The Ad Hoc Working Group on Biosafety was chaired by Veit Koester of Denmark, the person hailed as 'the father of the Protocol'[45]. They held six meetings between July 1996 and February 1999.

On this basis the sixth and final meeting of the BSWG was held in Cartagena, Columbia in February 1999, followed immediately by the first extraordinary meeting of the Conference of Parties (ExCOP) to the CBD[46]. During the negotiations there were five distinct groups who were The Miami Group[47] and The Like-minded Group,[48] The

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[44] http://www.biodiv.org/biosafety/background.asp (accessed on 19 January 2010)
[45] *Supra* note 33, Pg 4
[46] Newell P & Mackenzie R, *"The 2000 Cartagena Protocol on Biosafety: Legal and Political Dimensions"* IUCN- The World Conservation Union
[47] A coalition of agricultural commodity = exporting countries including Argentina, Australia, Canada, Chile, Uruguay, USA.

European Union, The Central and Eastern Europe Group, The Compromise Group.[49] The Miami Group argued that the Protocol should protect trade in products of modern biotechnology. They resisted lengthy approval procedures and argued against the incorporation of the precautionary principle and socio-economic considerations into decision making the LMO imports as it would be open to protectionist abuse. On the other hand the Like Minded Group who advocated for the right to refuse GM imports sought to protect those countries without adequate regulatory or institutional capacity to handle LMO imports, demanding the inclusion of precautionary principle in decision making and including the socio-economic considerations and liability and redress mechanisms. The European Group called for the inclusion of the Precautionary Principle, identification and labeling requirements and the reflection of potential risks to human health in the Protocol. The Compromise Group's objective was to bridge the gap between the other negotiating blocks by elaborating the compromise stances. They sought to find a compromise on the contentious issues, but this failed thus the Extraordinary Meeting of the Conference of Parties was suspended.[50]

This being the case, two informal meetings took place in Vienna in September 1999 and Montreal in January 2000. These negotiations focused on the remaining core issues, which were crucial to the overall agreement of the Protocol. At this stage, these core issues were, the scope of the Protocol, LMOs intended for direct use as food or feed, or for processing (LMO-FFPs), the precautionary principle, identification and documentation requirements and the relationship between the Protocol and other international agreements, notably the World Trade Organization (WHO) Agreements. The other aspects of the Protocol remained untouched after BSWG6. The final

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[48] The G77 countries (less the three members in the Miami Group)
[49] Japan, Korea, Mexico, Norway and Switzerland, later joined by Singapore and New Zealand
[50] Decision EM-1/1, UNEP/CBD/ExCOP/1/3,Annex 1. The Conference of the Parties suspended its first extraordinary meeting and agreed that it should be reconvened as soon as possible and in any event no later than the fifth meeting of the Conference of the Parties. http://bch.cbd.int/protocol/ (accessed on 19 May 2010)

negotiation of these core issues took place at the resumed session of the ExCOP, which immediately followed the January 2000 informal meeting in Montreal. The final compromise on core issues was struck during the night of 28/29 January 2000. The Protocol was adopted at 5a.m on 29th January 2000.[51]

In accordance with its Article 36, the Protocol was opened for signature at the fifth meeting of the CBD COP in Nairobi, Kenya from 15 to 26 May 2000 and 68 parties to the CBD signed. Thereafter, the Protocol was open for signature at UN Headquarters in New York from June 2000 until June 2001. By that date the Protocol had 103 parties who had signed the Protocol. Thus a State Party regards itself as having given its consent to the text of the Protocol and they are willing to apply it into their national laws.[52] The Protocol entered into force on 11 September 2003, ninety days after receipt of the 50th instrument of ratification.[53] Parties to the CBD who have not yet signed the Protocol may accede to it.[54] States that are not parties to the Convention cannot be parties to the Protocol[55]. Only the states that have ratified the Convention may be bound by it[56]. There are currently 195 states who have ratified this Protocol[57]. It has been provided that no reservation may be made to the Convention and Protocol. This means that a State Party cannot make a unilateral statement, however phrased or named, when signing, ratifying, accepting, approving or acceding to the convention or treaty, whereby it purported to exclude or modify the legal effect of certain provisions in their application.[58]

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[51] For further information on the negotiations, see for example Earth Negotiations Bulletin (http://www.iisd.ca/linkages) Bail, C (accessed on 19 January 2010)
[52] Shaw, MN (1991) *International Law*, Cambridge: Grotius Publication 638, Pg 650
[53] Article 37; Further provided in Article 14 of the 1969 Vienna Convention on the Law of Treaties.
[54] Ibid
[55] Art. 38 (3) of the CBD; If a party withdraws from the Convention they are also considered as having withdrawn from the Protocol
[56] Supra note 50
[57] www.biodiv.org/biosafety/signing list (accessed on 19 January 2010)
[58] Article 2 (1) d of the Vienna Convention on the Law of Treaties

The Protocol, under **Article 6** contains important rights and obligations for its Parties, relating to the transboundary movement, handling and use of LMOs. Its central operational provisions create an Advance Informed Agreement (AIA) procedure, whereby an exporter wishing to export certain categories of LMOs to a country for the first time must notify the Party of import in advance and provide certain information relating to the LMO. The party of import then has an opportunity to examine this information and may decide to accept or reject the import or attach conditions to it, based on a risk assessment. The Protocol also contains provisions on information exchange, capacity-building and financial resources.

The Protocol takes into account the principles enshrined in the Rio Declaration on Environment and Development and in particular, the precautionary approach contained in Principle 15. The Protocol will not exceed the scope of the CBD, it will not override or duplicate any other international legal instrument in this area, it will provide for a review mechanism and be efficient and seek to minimize unnecessary negative impacts on biotechnology research and development and not to hinder unduly access to and transfer of technology.

2.6 THE CODEX ALIMENTARIUS

The Codex Alimentarius is a collection of food standards complied by the Codex Alimentarius Commission (CAC). The CAC is a joint body of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO)[59]. The Codex Alimentarius currently covers 237 food standards and also includes 41 codes of hygiene or codes of practices, limits for pesticide residues and evaluations of additives and

[59] The Eleventh Session of the Conference of FAO in 1961 and the Sixteenth World Health Assembly in 1963 both passed resolutions to establish the Codex Alimentarius Commission, whose legal base for operations is in Codex Alimentarius-Procedural Manual. The two bodies also adopted the Statutes and Rules of Procedure for the Commission. www.fao.org (accessed on 19 January 2010)

veterinary drugs[60]. The main aims of the Codex are to protect the health of consumers and to facilitate the international food trade through harmonization of science based standards[61]. Divergent national food safety laws can impede international trade, thus the need for these standards.

The CAC recognizes future challenges that biotechnology might pose for food safety Principles and Guidelines of Foods Derived from Modern Biotechnology were adopted by the CAC in July 2003. These include the Guidelines for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Micro organisms. The guideline suggests the principle of 'conventional counterpart' be used in safety assessments so that the assessment will show whether the effects of a recombinant DNA organism on human health differ from those of its closest natural relative[62]. Where no close match is found more rigorous safety assessment is suggested. Particular guidance is given to avoid the use of certain genes/combinations of genes. For example antibiotic resistance genes that will be expressed in the end product and genes from known allergic sources are to be avoided (unless their safety has been proven). It is suggested that attention should also be given to issues such as the effects of nutritional modifications on human health, possible immunological effects and whether the gene can be transmitted to human gut bacteria. There is recognition that new genomic knowledge should make the effects of genetic modification easier to predict (Point 20 of the Guidelines), and also that safety assessments may have to be reviewed in light of future scientific knowledge.

Standards are first suggested by member states or by any of the 25 sub-committees of the CAC. Once the CAC accepts that a standard is needed drafts will be drawn up by the relevant sub-committee and distributed to member states in several stages, before a final

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[60] http://www.fao.org/docrep/w9114e02.htm (accessed on 19 January 2010)
[61] http://www.codexalimentarius.net (accessed on 19 January 2010)
[62] Point 5 of the Guidelines, http://www.fao.org/docrep/w9114e02.htm (accessed on 19 January 2010)

draft is handed to the CAC for approval. The Codex Commission with its 171 members encourages States to have national codex points where drafts, new standards and other information can be sent by the CAC and then distributed to relevant groups. Member states can accept standards in one of three ways. The first is full acceptance, the second acceptance with deviations (which must be specified), the third is called free distribution and this is an agreement to allow food meeting the Codex standard to be freely distributed within the country. Acceptances of whichever type must be notified to the CAC and form part of the Codex.

The significance of the food code for consumer health protection was underscored in 1985 by the United Nations Resolution 39/248, whereby guidelines were adopted for use in the elaboration and reinforcement of consumer protection policies. Also the Codex is referred to in the World Trade Organization's (WTO) Sanitary and Phytosanitary Agreement as a basis for acceptable food standards in international trade.[63]

To adopt Codex standards, countries require an adequate food law as well as a technical and administrative infrastructure with the capacity to implement it and ensure compliance. For many years, FAO and WHO have been providing assistance to developing countries to enable them to take full advantage of the Commission's work. This effort has been enhanced to a considerable degree by the financial and technical support received from industrialized countries. They have meetings, workshops and training courses, preparing training manuals and establishing of food control agencies.

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[63] **Annex A(3)(a) of the Sanitary and Phytosanitary Agreement** is to the effect that international standards, guidelines and recommendations for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice shall be applicable under the Agreement. www.wto.org/english/tatop_e/spsagr_e.htm (accessed on 19 January 2010)

2.7 THE INTERNATIONAL PLANT PROTECTION CONVENTION

The Convention was originally signed in 1951 a second text was adopted in 1979; a third revision took place in 1997. The third text is a response to the role given to the International Plant Protection Convention (IPPC) Secretariat set up in 1992 for setting standards for the WTO's SPS agreement[64]. It also formalized the 'Secretariat and established a Commission on Phytosanitary Measures[65]. A revised text was adopted in 1997 to replace the 1952 version but is not yet in force. There are currently 125 state parties. Two-thirds of the states parties must accept the revised text for it to enter into force, so far only 58 have done so. The entry into force of a treaty takes places when parties to it accept to be bound and only then will it be operative.[66]

The International Plant Protection Convention is a creation of the Food and Agriculture Organization, a specialized agency of the United Nations, as this is one of the areas this organization covers. The FAO believes that biotechnology could be very useful in achieving its aims of increasing productivity for enhancing food security. However the FAO also recognizes potential risks to humans, animals, the environment and biodiversity from biotechnological applications[67]. Because of the potential risks the FAO suggests all genetically modified organisms be assessed prior to release and monitored afterwards. FAO also believes that for biotechnology to fulfill its potential in agriculture there must be an increase in technical and financial assistance to developing countries.

This Convention aims to avoid the spread and introduction of plant pests and diseases and promotes international cooperation for this purpose. State parties are required to have National Plant Protection Organization (NPPOs) as a central point for implementing the

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[64] *Ibid*

[65] http://ippc.int (accessed on 19 January 2010) The IPPC Secretariat has recently established a working group on "*Phytosanitary Aspects of Genetically Modified Organisms, Biosafety and Invasive Species*" recognizing their significance to the Convention.

[66] Art 24, of the 1969 Vienna Convention on the Law of Treaties. See also Shaw, MN (1991) *International Law*, Cambridge: Grotius Publication 638, Pg 649

[67] For more information see FAO's Statement on Biotechnology at http://www.fao.org/biotech/stat.asp (accessed on 19 January 2010)

Convention and for reporting the IPPC's secretariat. It provides the responsibilities of the official plant protection organizations[68], the regulated pests[69], requirements as to imports[70] and settlement of disputes[71]. The IPPC's functions include standard setting, facilitation of information exchange and provision of technical assistance. State-parties are obligated to "regulate very strictly import and export of plants and plant products"[72] and also to give reports to the secretariat and to issue Phytosanitary certificates.

The IPPC secretariat also oversees the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement) of the WTO setting and implementing Phytosanitary standards. Regional arrangements are encouraged and the IPPC has a dispute settlement procedure, which although it is non-binding is expected to have "substantial influence."

2.8 THE TADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The TRIPS Agreement is the key international agreement promoting the harmonization of national IPR regimes. TRIPS set minimum standards which individual members may supplement. It covers the areas of copyright, patents, trademarks, geographical indications, industrial designs, integrated circuit designs and trade secrets. TRIPS was established during the Uruguay Round of free trade talks[73] that also established the World Trade Organization.

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[68] Article IV the International Plant Protection Convention
[69] Article VI the International Plant Protection Convention
[70] Article VII the International Plant Protection Convention
[71] Article XIII of the International Plant Protection Convention
[72] http://sedac.ciesin.org/entri/register/reg-009 rrr.htm (accessed on 18 January 2010)
[73] Held between 1986 - 1994

Created within the context of free trade, TRIPS incorporates the general WTO principles of most-most-favoured-nation[74] and national treatment.[75]

All WTO members are involved in the Council on Trade-Related Aspects of Intellectual Property Rights which monitors and reviews the TRIPS agreement. A United Nations body the World Intellectual Property Organization (WIPO), which oversaw the previous intellectual property agreements, helps the WTO to implement TRIPS. WIPO has recently set up a working group on biotechnology, as it recognizes this as a significant issue relating to intellectual property[76]. All WTO members are signed up for TRIPS.

Of particular relevance to the field of biotechnology are the patent rules. Under Trips, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application[77]. It also specifically requires the introduction of plant variety protection but does not impose their protection through patents. Art 27 (3) (b) excludes plant varieties from patentability but provides that parts of plants varieties and products of biotechnology processes are patentable. It imposes the introduction of plant variety protection but does not force member states to introduce patents. It also accommodates the need of developing countries since it provides an exception to the general in subsection 1.

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[74] **Most-favoured-nation (MFN)** treatment means treating one's trading partners equally on the principle of non-discrimination. Under MFN, if a country allows foreign competition in a sector, equal opportunities in that sector should be given to service providers from all other WTO members. (This applies even if the country has made no specific commitment to provide foreign companies access to its markets under the WTO.)

[75] See Articles 3, 4 and 5 include the fundamental rules on national and most-favoured-nation treatment of foreign nationals, which are common to all categories of intellectual property covered by the Agreement. **National treatment** is a principle in customary international law vital to many treaty regimes. It essentially means treating foreigners and locals equally. Under national treatment, if a state grants a particular right, benefit or privilege to its own citizens, it must also grant those advantages to the citizens of other states while they are in that country. http://en.wikipedia.org/wiki/National_treatment (accessed on 19 May 2010)

[76] http://www.wipo.int/globalissues/biotech/ (accessed on 19 January 2010)

[77] Article 27 of TRIPS

Finally the *sui generis* option offered in the case of plant variety could be a model for a number of other areas such as pharmaceuticals, where there is growing dissatisfaction in a number of countries with the regime proposed by the TRIPS agreement at the moment.

Sui generis is a Latin expression, literally meaning *of its own kind genus* or unique in its characteristics. In law, it is a term of art used to identify a legal classification that exists independently of other categorizations because of its singularity or due to the specific creation of an entitlement or obligation. In intellectual property there are rights which are known as being *sui generis* to owners of a small class of works, such as intellectual property rights in mask works, ship hull designs, databases, or plant varieties.[78]

The four eligibility requirements of the UPOV[79] - novelty, distinctiveness, uniformity and stability - have been criticized as unnecessarily rigid, undervaluing plant genetic diversity and precluding Intellectual Property Rights (IPRs) claims by traditional farmers as opposed to commercial breeders. WTO Members need not replicate these problems when designing their *sui generis* legal systems. On the contrary, they are free to improve upon each of the eligibility requirements.

For example, Members may provide protection to plant germplasm that is more heterogeneous than established plant varieties but is nevertheless sufficiently distinct to permit its identification. Extending protection to these heterogeneous varieties would enable farmers and indigenous communities to claim IPR protection in the landraces or plant varieties they have cultivated through traditional farming and breeding methods.
Such protection would address demands for recognition of "farmers' rights" and "traditional knowledge" rights by using IPRs to compensate farmers and local

[78] http://www.upov.int/en/about/pdf/international_harmonization.pdf (accessed on 19 June 2010)
[79] Union for the Protection of New Varieties of Plants

communities for preserving landraces and other traditional cultivated varieties and would provide them with an incentive to continue their preservation activities. It would also prevent third parties (including breeders in other nations) from claiming exclusive rights in the varieties that farmers or indigenous communities have cultivated.

Under the UPOV Convention, all breeders in all members of UPOV enjoy the same level of protection. Enhancing international harmonization is an indispensable tool for the protection of new plant varieties, for international trade and for the transfer of technology. Should a country introduce a system not compatible with the internationally harmonized system based on the UPOV Convention, this might result in barriers to trade and the transfer of technology. Breeders of UPOV members would be hesitant to release their varieties in such a country. This means that farmers in that country would lose the possibility of benefiting from the use of the best varieties. International harmonization in the protection of new varieties of plants is essential. The introduction of a system which differs significantly from the harmonized approach based on the UPOV Convention will raise questions with regard to the implementation of the TRIPS Agreement.

TRIPS constitute the trigger for the development of plant variety protection legislation in most African countries but does not provide precise guidance concerning possible alternative property rights systems that can be developed.

2.9 THE INTERNATIONAL CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

The International Convention for the Protection of New Varieties of Plants is the only international treaty focusing on plant variety protection. It was first adopted in 1961 with

the aim of introducing private property rights on plant varieties[80]. This followed pressure from the private sector arguing that the lack of intellectual property rights in this field threatened industrial innovation. Membership of the UPOV Convention has grown over time but included until recently mainly developed countries. Only a few developing countries mainly from Latin America have joined the UPOV, from Africa only Kenya and South Africa have joined. Kenya became a member of the 1978 Act.

Under this 1978 Act, States parties to both agreements must extend protection to all plant varieties, comply with TRIPs' national rules and adopt effective enforcement measures. They must also comply with all of the other 1978 Act requirements, including its eligibility requirements, terms of protection, exclusive rights and mandatory breeders' exemption. As compared to the 1991 Act, however, breeders' exclusive rights are more limited, terms of protection for varieties are shorter and exceptions and limitations are broader.

To fully comply with TRIPs, member states must modify their national laws to protect the core requirements of **Article 27.3(b) of TRIPS**[81] and they must remove all provisions of their laws which impose a reciprocity requirement as a condition for protecting varieties of foreign breeders. In addition, states in this category may choose to modify their laws to incorporate some or all of the standards found in the 1991 Act without actually becoming a member of that Act. Their refusal to do so, however, does not violate article 27.3(b), inasmuch as the standards found in the 1978 Act satisfy their obligation to protect plant varieties with a *sui generis* IPR.

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[80] International Convention for the Protection of New Varieties of Plants, Paris, 2 December 1961, as revised at Geneva on 10 Nov 1972, 23 October 1978 and March 1991 (Geneva: UPOV,UPOV Doc (E, 1996)

[81] Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

It provides incentives to the private sector to engage in commercial plant breeding through the provision of plant breeder's rights. The Convention recognized the right of farmer's privilege, where farmers were permitted to re-use propagating material from the previous year's harvest and to freely exchange seed of protected varieties with other farmers.

The latest version of the Convention adopted in 1991 has further strengthened the rights of commercial plant breeders. This includes the obligation for member states to provide protection to all plant genera and species. Further it extends the breeder's rights to all seed production of a protected variety even though States can decide otherwise at the national level; in other cases it grants commercial breeder's rights to be harvested material of the protected variety. Plant variety rights have become akin to weak patents and the conceptual distinction between the two is now blurred.

In my view, Kenya would be better off establishing its own *sui generis* regime as under the provisions of the 1978 Act of which it is a Member of , breeders' exclusive rights are more limits breeder's exclusive rights and terms of protection for varieties are short and exceptions and limitations are broader. I recommend a system that takes into consideration farmers' rights, plant breeders' rights, the need for conservation of genetic resources, the protection and utilization of indigenous knowledge and equitable benefit sharing.

2.10 THE INTERNATIONAL TREATY ON PLANT AND GENETIC RESOURCES FOR FOOD AND AGRICULTURE

The International Treaty on Plant Genetic Resources for Food and Agriculture is a comprehensive international agreement in harmony with Convention on Biological Diversity, which aims at guaranteeing food security through the conservation, exchange

and sustainable use of the world's plant genetic resources for food and agriculture, as well as the fair and equitable benefit sharing arising from its use. It also recognizes farmers' rights; to freely access genetic resources, unrestricted by intellectual property rights; to be involved in relevant policy discussions and decision making; and to use, save, sell and exchange seeds, subject to national laws.[82]

The treaty has implemented a Multilateral System (MLS) of access and benefit sharing, among those countries that ratify the treaty, for a list of 64 of the most important food and forage crops essential for food security and interdependence.

The treaty includes, as one of its funding mechanisms, mandatory sharing of benefits arising from the commercial utilization of plant genetic resources for food and agriculture covered by the MLS.

The treaty was nurtured by the Food and Agriculture Organization (FAO) Commission on Genetic Resources for Food and Agriculture (CGRFA), which formed its Interim Governing Body. It now has its own Governing Body under the aegis of the FAO.

The International Treaty on Plant Genetic Resources for Food and Agriculture was open to accession a year after adoption and once closed to signatures[83], that is, on 4 November 2002, 77 countries and the European Union had signed the treaty by that date.

The treaty was under negotiation for 7 years. A previous voluntary agreement, the IU or International Undertaking on Plant Genetic Resources for Food and Agriculture, was adopted in 1983. However, the IU was reliant on the principle of genetic resources being

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[82] http://en.wikipedia.org/wiki/International_Treaty_on_Plant_Genetic_Resources_for_Food_and_Agriculture (accessed on 19 May 2010)
[83] (Article 27)

the common heritage of humanity. The Convention on Biological Diversity (CBD) (1993) brought genetic resources under the jurisdiction and sovereignty of national governments. However, the CBD recognized the special and distinctive nature of agricultural genetic resources: they were international - crossing countries and continents - their conservation and sustainable use requires distinctive solutions and they were important internationally for food security. Subsequently the IU was renegotiated, to bring it in harmony with the CBD, and was renamed as a treaty.[84]

In accordance with Article 28, the treaty entered into force on the ninetieth day after the deposit of the fortieth instrument of ratification, acceptance, approval or accession, provided that at least twenty instruments of ratification, acceptance, approval or accession have been deposited by Members of FAO. Having reached the required number of instruments in order for the treaty to enter into force (40) on 31 March 2004, on which date 13 instruments (including the European Community) were deposited with the Director-General of FAO, the date of entry into force was on 29 June 2004.

2.11 THE OFFICE INTERNATIONAL DES EPIZOOTIES (OIE)

The OIE, the World Organization for Animal Health was established in 1924.
Despite the inevitable slowness of the negotiations undertaken through diplomatic channels, twenty eight states obtained an 'international agreement' on 25 January 1924. The ratification of this 1924 agreement created the OIE based in Paris. The main objectives are to prevent the spread and introduction of animal diseases and harmonize regulations for trade in animals and animal products. The OIE develops standards and guidelines for use by its member countries to protect themselves against incursions of

[84] http://en.wikipedia.org/wiki/International_Treaty_on_Plant_Genetic_Resources_for_Food_and_Agriculture (accessed on 19 June 2010)

diseases or pathogens during trade in animals and animal products while avoiding sanitary barriers.

These standards are developed by experts from member countries and from the OIE's network of Reference Laboratories and Collaborating Centres. Since 1995, the standards developed by the OIE have been formally recognized by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization. The main objective of these standards is to recommend measures that will ensure biosafety and biosecurity. They detail the OIE's requirement to prevent transmission of pathogenic biological agents to animals, humans and the environment.[85]

2.12 CONCLUSION

Biological Diversity is very important for the sustainability of life. Human beings in their very nature would destroy all the natural resources if left unchecked thus the need for the Convention further developed by the Protocol and all other instruments relating to biosafety. The Earth Summit being the birthplace of the notion of the 'common concern for human kind' is where the Convention for Biological Diversity was adopted. The Convention has adequately come up with measures to conserve and sustainably use biodiversity for both the present and future generations.

Modern biotechnology has been found to be quite beneficial despite the numerous uncertainties involved with its application. This complexity was portrayed by the disagreements among the Conference of parties as they attempt to come up with articles to the Cartagena protocol, which were finally resolved through compromise. This means that there are parties whose views were not incorporated into the Protocol, which does

[85] www.oie.int (accessed on 19 January 2010)

not allow for reservations; have to take the Protocol in its entirety when signing it or when it entered into force.

Even with the final draft ratified, changes have been made to the Protocol through the Conference of Parties. This can be seen through the First Meeting of the Parties, serving as the Meeting of Parties. The Protocol permits such changes to be made that will apply to all the parties to the Protocol across the board.

There are also other Conventions which deal with the different aspects of modern biotechnology in relation to biosafety as it has been noted. They cover intellectual property rights of life forms to ensure only the rightful owners benefit from such resources. There are also plant protection rights and protection of new plant varieties. The fair and equitable sharing of benefits arising out of generic resources and public participation in decision making and access to justice in environmental matters ensures parties are always informed where GMOs are involved. Biosafety issues in relations to animals are also covered by international law due to the increased rate of trade.

Due to the fact that the use of genetic resources is a new area of science where the effect of the use of such products is not fully known, caution is very important. Thus the requirement that every encounter with these genetic resources should be controlled by some laws internationally and nationally. Further new discoveries continue to be made in the world of science that needs to be provided for in law because of their unknown consequences on human beings and the environment.

CHAPTER THREE

LAWS RELATING TO BIOSAFETY IN KENYA

This chapter discusses the current legislation which related to genetic resources to determine its effectiveness in dealing with modern biotechnology. These statutes have been amended over time to include provisions on biodiversity and biosafety. They do not deal exclusively with issues on genetic modification. This therefore raises questions as to the effectiveness of these laws. Some of these statutes may be the result of international treaty law or they have been amended to suit the needs of these treaties, an example being the Industrial Property Act.

National laws[86] provide for domestication in order to be applicable as national laws to meet local requirements, hence the requirement of the domestication process. Attention is drawn to this process to see how it is effected and the results in national jurisdictions. This is the background to which the Biosafety Act has been drafted and finally been adopted into an Act.

The need for such laws is because of the biotechnology activities taking place in Kenya in areas such as agriculture, medicine and industry. Biotechnology activities are presently being conducted by individuals both in the private and public sectors, according to their operative research policies. These developments together with the opportunities offered by the introduction into the country of biotechnology products imported from elsewhere, emphasize the need to formulate appropriate biosafety laws.

3.1 THE CONCEPT OF DOMESTICATION OF TREATY LAW

Treaty law represents the consensus of a plurality of parties, and on this account generally provides a standard of broad-based character, in respect of given matter of

[86] www.paclii.org/oldpits/english/domestication.html (accessed on 28 May 2010)

public interest. A treaty once adopted and enters into force, requires the parties to give it fulfillment under their domestic policy, legal and administrative framework. There are two theories on this issue, thought to separate those countries that implement treaty obligations automatically upon ratification, from those that seek to conform these treaties to their domestic law first, before implementing the treaties. The first category of countries would be pursuing the monist[87] tradition and the latter the dualist tradition.[88]

The notion of domestication of treaty law essentially addresses the acceptance of such law and its principles within the policy, legal and administrative structure of a particular jurisdiction. When the discrete elements of the treaty are implanted into the national governance apparatus and the routine motions of regular administration, they are then assured of application, in the same manner as the ordinary law of the land. The treaty law, in this respect undergoes a process of transformation, and is assimilated into the domestic law. Only in this way is it possible to achieve the most effective scheme of implementation for treaty law.

The concept of domestication of treaty law, with regard to the environment in general and to biodiversity in particular, provides a basis for the incorporation of such principle of international environmental law into the scheme of national policy-making, legislation and conduct. Where such incorporation is achieved, enlightened principles of treaty law come to benefit from the implementation and enforcement powers attached to the scheme of national sovereignty and this will provide a real fulfillment to the goals of international law.

The influence of international law's conservation principles upon municipal law will also be strengthened, where states parties are willing and able to apply soft law that is,

[87] http://en.wikipedia.org/wiki/Monism_and_dualism_in_international_law (accessed on 28 May 2010)
[88] http://www.unep.org/padelia/publications/handbook41.htm (accessed 30th November 2009) Paragraph 4.1

principles that are not legally binding, and usually coming from influential international declarations, resolutions and conference documents. Instruments in this category include the Stockholm Declaration 1972, the World Conservation Strategy launched in 1980, the World Charter for Nature 1983, the Rio Declaration and Agenda 21 of 1992. Such instruments have influenced the shaping of national development policies touching upon wild species of flora and fauna and their life support systems.

In the previous chapter we have seen many international instruments in the form of resolutions, declarations and conventions that deal with the subject of biosafety. The conventions create obligations for the parties, and are required to be implemented once they enter into force making them hard law.

Of particular relevance is the Convention on Biological Diversity which seeks to conserve biological diversity, to promote the sustainable use of its components and to encourage equitable sharing of the benefits arising from the utilization of genetic resources (Art. 1).[89] Article 3 of the CBD reaffirms the principle of national sovereignty over natural resources. In the period leading to the Rio Earth Summit there were attempts to characterize biodiversity as the "common heritage of mankind", but these attempts did not succeed. Had they succeeded, these attempts would have qualified national sovereignty over natural resources and implied some kind of collective national ownership of these resources. Instead, the Earth Summit introduced the concept of "common concern of humankind", to underline the significance of the human interest in general without undermining the rights of states over their natural resources. There was a recognition during the negotiation process of the CBD that most biodiversity is in fact

[89] The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. www.cbd.int/doc/legal/cbd-en.pdf (accessed on 28 May 2010)

located under the sovereignty of individual nations; hence the adoption of the expression "common concern", to imply the common responsibility for biodiversity but without detracting from the principle of national sovereignty.[90] The Convention places upon parties the duty to conserve biodiversity within their jurisdictions, as well as outside their jurisdictions in certain cases (Art. 4). States parties are required to undertake co-operative initiatives in respect of areas falling outside their respective jurisdictions (Art. 5). They are charged with responsibility for the formulation and implementation of strategies, plans or programmes for the conservation and sustainable use of biodiversity (Art. 6).

3.1.1 The Domestication Process

Domestication of treaty law essentially means integrating it into the domestic legal - system, so that the regular functioning of day-to-day machinery of governance may assure for it the required implementation.[91] It is recommended that the best way to initiate this process is through constitutional provisions that commit the state to conserve biological diversity, in the interests of present and future generations.[92] The constitution should state the point as a general principle to guide the general conduct of government; and it should commit the legislature to enact statutes giving fulfillment to the principle.[93]

as biodiversity is a broad theme that does not lend in just one statute, or through one apparatus, it is desirable to enact a framework statute. This should establish a coordinating structure for biodiversity management, and should provide for standard setting for environmental issues touching on biodiversity. The statute should leave room

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[90] www.un.org/geninfo/bp/enviro.html (accessed on 28 May 2010)
[91] *Ibid*, Paragraph 6.2.2
[92] Section 2. (5) of the Draft Constitution 2010 provides that 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
[93] In 87 (d) of Wako and in 87 (e) of Bomas Draft Constitution, Principles and Obligations of the State for the Environment, the state shall domesticate international and bilateral agreements and treaties relating to the protection of the environment, to which Kenya is a party; and domesticate international and bilateral agreements and treaties relating to the protection of the environment; http://www.kenyaimagine.com/Legal-and-Constitutional/Proposed-constitution-international-law-and-treaties.html (accessed on 28 May 2010)

for detailed sectoral biodiversity legislation, as well as detailed ministerial rule-making for the fulfillment of conservation functions. The framework statute should carry the general environmental standards to be applied by the environmental agencies. In particular it must provide for environmental impact assessment as a standard procedure to be complied with before projects or policies likely to affect biodiversity are put in place. Below the framework of environmental statute, there should be enacted a number of sectoral statutes dealing with different subject-matter, ranging from species and genetic resources to habitat/ecosystems and indigenous conservation practices. Such statutes should also allow for detailed ministerial rule-making.[94]

Following is a detailed analysis of the laws regulating biosafety in Kenya to see what extent they have fulfilled the above provisions.

3.2 LAWS REGULATING BIOSAFETY

There is a need to implement the Cartagena Protocol at a domestic level. In such a process it is necessary to look at the legal and institutional level, as the two are intertwined. Further the national legislation for biosafety should move in tandem with the modalities for implementation provided for in the international institutions like UNEP/ GEF projects.[95]

The absence of a national biosafety system as in most African countries will impact on the implementation of the Protocol. This is because there is no link between product development and the law that is in place thus the two do not work towards the same goal. Kenya has no specific regulatory regime in place governing access to genetic resources.

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[94] Background paper: Theme 3 Post 2010 vision for The Pan European Region Document prepared by Norway in collaboration with the Friends of the Chair and resource persons for the session http://www.coe.int/t/dg4/cultureheritage/nature/biodiversity/straco2009/STRA-CO_2009_08_Theme3.pdf (accessed on 19 June 2010)

[95] www.UNEP/GEF (accessed 30th November 2009)

Pieces of potential regulatory structure have been put in place, but they are yet to develop into a substantive regime. However there is a range of statutory, regulatory and policy sectoral provisions in place that affect access to genetic resources, whether directly or indirectly.

3.2.1 The Constitution of Kenya (1997)

The Constitution of Kenya does not directly refer to the scientific and commercial fields and only refers to the environment in the context of governmental powers for the purposes of conservation. As a consequence it does not directly refer to the ownership of, access to or benefit sharing of genetic resources. The constitutional provisions may thus have direct and indirect effects; an example being the provisions regarding personal property and trust land. In theory trust land is held for the benefit of its specific traditional occupants and not for the nation as a whole but the fact that the government can extinguish these rights at will would seem to be a precedent that the government has the power to claim authority over land or any rights associated therewith, including rights to control genetic resources.

Section 75 (7) stipulates that any law that provides for compulsory acquisition for the benefit of parastatal institution cannot be held to be unconstitutional. Thus any genetic resources can be seized for use by institutions such as KARI or KEMRI, despite the fact that such institutions have been involved in the commercialization of products, sometimes in partnership with the private sector. Section 75(6)(a) lists a range of situations where a compulsory acquisition by the state should not be held to be in

contravention of the Constitution. Those of relevance to genetic resources are clause (v)[96] and clause (vii)[97]

Kenya has not yet addressed the legal status of genetic resources. Depending upon precise interpretations, in their terrestrial form they could be considered as part of the rights that make up real property, in that they grow or are affixed to land. This is supported by the case of ***Abdikar Sheikh Hassan and 4 others Vs Kenya Wildlife Services***[98]where the High Court held that according to common law and/or customary law of the inhabitants of this country, those entitled to the fruits thereof which include the fauna and flora unless this has been negated by law.

The Draft Constitution in Chapter 8 makes provision for access to genetic resources. It calls for the protection of genetic resources and biological diversity; the enforcement of environmental rights; the protection management, promotion and sustainable development of natural resources and the establishment of a National Environmental Commission.[99] If these provisions are enacted, the protection and access of genetic resources will be better implemented.

3.2.2 The Environmental Management and Coordination Act, 1999

EMCA is Kenya's framework legislation coordinating all management activities in the country. It thus constitutes the primary implementing legislation for the CBD, it is an Act of Parliament to provide for the establishment an appropriate legal and institutional framework for the management of the environment. It was desirable that a framework

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[96] Circumstances where it is necessary to do so because the property is in a dangerous state or injurious to the health of human beings, animal and plants

[97] Failure by the owner of land to carry out conservation activities on the soil and natural resources or work related to agricultural development

[98] Civil Case No. 2959 (High Court of Kenya, 1996)

[99] Articles 87-93 of the Draft Constitution of Kenya

environmental legislation be promulgated as to establish an appropriate legal and institutional framework for the management of the environment.

A number of provisions of the Act have either direct or indirect potential impacts on the issue of access to genetic resources.

The Act defines the terms biological diversity, biological resources, genetic resources, in-situ latter document. The terms are an introduction to the aspect of biosafety in relation to biotechnology issues.

Section 3 entitles every person every person in Kenya to a clean and healthy environment and they have a duty to safeguard and enhance it. This means the use of GMOs should not adversely affect any person and infringe on their above stated right.

Section 42 (3) (j) states that the minister may issue orders for the management, protection and conservation of biological resources.

Section 50 provides for the conservation of biological diversity, through an inventory of biological diversity, determination of endangered biological diversity, potential threats to biological diversity, integration of conservation measures with government activities, national strategies for conservation, protection of indigenous property rights of local communities and measures the value of unexploited national resources. The effective execution of these provisions could create obvious benefits in the field of access to genetic resources significantly assisting any potential applicants for access.

Section 51 deals with the conservation of biological resources in-situ through land use methods, selection and management of protected areas and buffer zones, protection of species, ecosystem and habitats threatened with extinction, prohibition and controlling

the introduction of alien species into natural habitat and integrating traditional knowledge for conservation of biological diversity. Section 52 gives conservation of biological resources ex-situ especially for species threatened with extinction.

In Section 53 the National Environment Management Authority shall issue guidelines and prescribe measures for sustainable management and utilization of genetic resources. Access to genetic resources by non-citizens, regulation of imports and exports of germplasm, benefit sharing, biosafety measures and transfer of biotechnology.

The Act also calls for Environment Impact Assessment in Part VI and Environmental Audits in Part VII.

In exercise of the power conferred by Section 147 of this Act, the Minister made the Environment (Impact Assessment and Audit) Regulations, 2003[100]. The regulations deal with the application for environmental impact assessments, the reports, comments, public hearings and environmental audit study.

3.2.3 The Wildfire (Conservation and Management) ACT

This is an Act of Parliament to consolidate and amend the law relating to the protection, conservation and management of wildlife in Kenya. There are several operative elements of the legislation that either directly or due to interpretation governs the management of genetic resources in protected areas.

Section 3 establishes a department of the government, wildlife conservation and management service, the Kenya Wildlife Service (KWS). KWS has exclusive authority

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[100] Legal Notice No. 101 (Legislative Supplement no. 31)

over the administration of the categories of protected areas. These includes the management of national parks,[101] issuance of licences[102] for hunting.[103]

Section 13.3 (d) prohibits the removal of the plant, animal and microorganism or anything else of value from a protected area. Given that access to genetic resources is almost exclusively sought for some form of scientific purpose and the KWS actively implements the prohibition on removing anything from a national park without authorization, it can be considered to be regulated by this Section.

The process for seeking access to genetic resources under the jurisdiction of KWS is not specific to the field but rather is addressed in the same manner as any form of research and has no specifically iterated and conditions but is rather addressed in an ad hoc basis.

Prior to the introduction of EMCA (1999), the Wildlife (Conservation and Management) Act was the most wide-ranging piece of Kenya legislation of relevance to the governing of the genetic resources.

3.2.4 The Forests Act, Cap 385

This is an Act of Parliament to provide for the establishment, control and regulation of central forests and forest areas in the Nairobi area and in unalienated government land.

The Act allows for the comprehensive regulation of access to genetic resources in forest areas. However to date little has been done in that area and all that is required to obtain access is the issuance of a licence by the Director of Forestry, the only condition being

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[101] Section 9 of the Wildlife (Conservation and Management) Act (1977, as amended 1989)
[102] Section 22 of the Wildlife (Conservation and Management) Act (1977, as amended 1989)
[103] Section 36 & 38 respectively of the Wildlife (Conservation and Management) Act

the payment of an administrative fee and the provision of prima facie evidence that the intended access will not pose a threat to the conservation of any species or ecosystem.

Section 7 and 8 require authorization of the Director of Forestry for a number of activities in forest areas that have an impact on access to genetic resources. In sub section 6 (1) the purpose of a nature reserve is the preservation of the 'natural amenities thereof and the flora and fauna therein' this encompasses any generic resources within the reserves.

Section 15 provides general rule making powers to the minister in areas with potential relevance to access to genetic resources. This relates to matters such as regulating the sale and disposal of produce occupation of land, condition precedent for the issuing of a license, control of entry into the forest, and the prescription of fees and royalties.

There is Kenya Forestry Research Institute (KEFRI) which conducts research into and maintenance of useful tree species. It also carries out the cataloguing and conservation of medical plants, through nurseries. The cataloguing of medical plants has also proved problematic as in the absence of any regime regarding the ownership of this knowledge the catalogue cannot be made public without risking the loss of any intellectual property rights, whether these rights are individual, community or national. These intellectual property rights are owned by the researchers and the implementing institution.[104]

3.2.5 The Crop Production and Livestock Act, Cap 321

This Act provides for the control and improvement of crop production and livestock and the marketing and processing thereof. The Minister has the power to make rules on crops under the Act, method of production of crops, improving the quality of crops to be grown and the destruction of diseased crops and agricultural produce. The improvement of the

[104] http://knowledge.cta.int/en/content/view/full/880 (accessed on 20 June 2010)

quality of crops is through the introduction of genetic material in plants. Also if there are those genetic materials that may have negative impacts these may be destroyed. All this will be essential in the conservation of such crop and livestock.

Of specific relevance to access to genetic resources Section 4 (1) (b) of the Act gives broad powers to the Minister responsible for Agriculture to regulate the methods and for the production of any crop. Section 4 (1)(c) provides powers regarding the improvement of the quality of the quality of any agricultural produce. In Section 4 (1)(d) the minister is empowered to prohibit the cultivation or destruction of 'any kind of crop, tree or plant or variety thereof'. Section 4 (1) (h) allows the minister to regulate license and control trade in any agricultural produce or crop. This Act has not been used significantly to govern access to genetic resources for food, agriculture or research.

3.2.6 Industrial Property Act (2001)

The Industrial Property Act (2001) entered into force in May 2002, upon the issuance of a commencement date order by the Minister for Trade after presidential assent. Kenya as a member of the WTO since 1995 was required to fully comply with TRIPs by January 2000. Although only minor changes to Kenya's 1989 Industrial Property Act were required for compliance, these were only passed by Parliament in mid-2001.

The 2001 Industrial Property Act is substantially clear on the patenting of life forms. Section 26 makes a specific reference to 'plant varieties as provided for in the Seeds and Plant Varieties Act' excluding them from patentability. Thus in the terms of TRIPs Article 27 (3) (b), Kenya has taken the option of recognizing an effective *sui generis* system for plant varieties and to exclude the possibility of patenting.[105]

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[105] An effective *sui generis* system is a system which is designed to encourage the development of new varieties of plants for the benefit of society – which can only be achieved by providing benefits for both breeders and farmers. Also, such a system must include elements for the protection of traditional agricultural knowledge, as well as the inclusion of farmers in decision-making

There are no other specific exclusions relating to life forms, whether addressing plants, animals or humans. Nevertheless, there are two grounds for life forms to be refused patents. The first would be if the granting of such a patent would be considered 'contrary to public order, morality, public health and safety, principles of humanity and environmental consideration'.[106] The second option depends on the interpretation of Section 21 (3) (a), which excludes 'discoveries' from patentability. Discovery is not defined in the Act. Given that a solution to a specific problem could be a discovery; this does not shed much light on the matter.[107] This Act does not directly address the issue, a reasonable interpretation of it will allow for patenting, at a minimum of plant parts, biotechnological products and microorganisms. Plants that do not fit the requirements for recognition as plant varieties, animals and human genetic material are likely to be patented, subject to the limitations set out in Section 26 (b).

3.2.7 The Seeds and Plant Varieties Act, Cap 326

This Act confers power to regulate transactions in seeds, including provision for the testing and certification of seeds, for the establishment of an index of names of plant varieties, to empower the imposition of restriction on the introduction of varieties, to control the importation of seeds, to authorize measures to prevent injurious cross-pollination, to provide for the discovering of new varieties and to establish a tribunal to hear appeals and other proceedings. Section 3 states that the minister has power to make rules for the regulation and control of the production, processing, testing, certification and marketing of seeds.

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and policy-making. Other elements which are relevant to farmers' rights might include the restriction of potentially harmful technologies, and technologies contrary to the maintenance of public order. http://ictsd.org/i/publications/11390/ (accessed on 28 May 2010)

[106] Section 26 (b) The Industrial Property Act (2001)

[107] Lettington R J L, '*Access to Genetic Resources in the Republic of Kenya*'2003, Washington D.C

The Act calls for an index of names for plant varieties, restriction on sale of seeds of unindexed plant variety, seed testing where certificates are issued, prevention of injurious cross-pollination and the grant of plant breeders right.

Plant Breeders' Rights (PBRs) are rights granted by the state to protect the proprietary rights of plant breeders with regard to breeding and discovery of new plant variety.[108] A grant of Plant Breeders' Rights for a new plant variety gives the holder the exclusive right to produce for sale and sell propagating material of the variety. The holders of such rights commonly collect royalties from commercialization of their protected varieties.

Action may also be taken by the holder of rights against someone who sells propagating material of another variety of the same genus or species using the denomination approved for the protected variety. A protected variety with its grant of rights, like other personal property, may be sold, mortgaged or assigned to another person. Consequently, the Plant Breeders Right Office, under the Kenya Plant Health Inspectorate Service, was established to implement the Act and the regulations.

The Plant Breeders' Rights Legislation became operational in 1975 under the Seeds and Plant Varieties Act (Cap 326) of 1972. The Act was revised in 1991 to conform to developments in the liberalized seed industry. The implementing regulations, the plant Breeders Rights Regulations were gazetted on 25 November 1994. Kenya is a member of International Union for Protection of New Plant Varieties (UPOV), 1978 Convention.

The Convention recognizes the right of farmer's privilege, where farmers are permitted to re-use propagating material from the previous year's harvest and to freely exchange seed of protected varieties with other farmers.

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[108] http://en.wikipedia.org/wiki/Plant_breeders'_rights (accessed on 28 May 2010)

This is plant variety protection which dictates the species which may be eligible for the grant of plant protection rights. Any variety that is eligible for plant variety protection is automatically rendered non-patentable. In effect all plant varieties of whatever genera or species are subject to some form of intellectual property rights if they are not subject to plant variety protection then they are subject to patents.

3.2.8 The Science and Technology Act, Cap 250

This Act establishes machinery for making available to the government advice upon all matters relating to the scientific and technological activities and research necessary for the proper development of the Republic and for the coordination of research and experimental development.[109] The Act provides for the establishment of a mechanism to coordinate and advise the government on all matters of science, technology and research related to national development and for the establishment of relevant Research Institute which include the Kenya Agricultural Research Institute, Kenya Industrial Research and Development Institute, Kenya Marine and Fisheries Research Institute, Kenya Medical Research Institute and Kenya Trypanosomiasis Research Institute.[110] The relevant Ministry administers the Act but it does carry the regulatory authority and therefore has no means to enforce compliance with the regulations.[111]

In Part II it establishes the National Council for Science and Technology (NCST). This is the national focal point which deals with all the biosafety matters in the country. Its functions include among others the determination and coordination of scientific and technological activities, playing an advisory role to the government on scientific policies, organizational arrangements and financial requirements and budgets and carrying out surveys and promoting public confidence.

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[109] Section 4 of the Science and Technology Act
[110] Section 12 (1) of the Science and Technology Act, which makes reference to first column of the Fourth Schedule
[111] *Supra* (note 89 above), pg 14

The NCST through the United Nations Environment Project-Global Environment Facility funding has developed various documents hereinafter stated. The intention of the UNEP-GEF project was to promote the harmonization of biosafety instruments at sub regional, regional and global levels, as well as the development of greater awareness of the potential benefits and possible risks resulting from modern biotechnology. Kenya has benefited from its pilot Biosafety Enabling Activity Project, which has assisted 18 countries in preparing national biosafety frameworks.[112]

It drafted the Regulation and Guidelines for Biosafety in Biotechnology, which were issued in 1998, before the Cartagena Protocol was ratified. The regulations and guidelines cover research on recombinant DNA, categorized experiments, plant biosafety, quarantine procedures, containment and field experimentation. The regulations require organizations and persons involved in biotechnology operations to be fully aware of the risks to which biotechnology products expose the society and the environment. This will enable them to make proper judgement on the safety arrangements that must be put in place. They are required through openness to develop a risk assessment and management capability, as a basis for undertaking biotechnology operations. The regulations seek to minimize risk attendant upon the development, importation and release of biotechnology products. They set standards for good laboratory practice and for containment procedures to limit the spread of such products. The regulations in themselves do not provide for punitive measures in case of lack of adherence to its provisions. This makes it difficult to enforce the regulations. This has led to the need for an Act which is legally enforceable.

The Biosafety Act has four broad areas on regulatory matters where it seeks to provide a framework for the proper development of biotechnology, the basic environment for the safe application of GMOs and communicating information to the stakeholders and

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[112] Supra (note 89 above), pg 9

general public on the use of biotechnology to produce food: Research and Development to promote additional research regarding the potential economic and environmental benefits and risks of using biotechnology to produce foods and other products; Production and utilization of seed production, quality control and propagation, trade and commercialization and capacity of building; and coordination and collaboration of transfer of technology internal and international institution collaboration and farmer participation in research.

Further, through the UNEP-GEF funding the NCST has developed the Biosafety Act, which ensures compliance with the regulatory framework. There is also the draft monitoring and inspection protocol, of any GMOs or their respective products.

3.2.8.1 Science and Technology Institutions

3.3.8.1.1 The Kenya Medical Research Institute

The Kenya Medical Research Institute, in particular its Traditional Medicine and Drug Research Centre is involved in applied activities relating to genetic resources. There is research into traditional medicines both for their potential as phytomedical products and as the base for more sophisticated modern pharmaceutical products.

3.2.8.1.2 Kenya Agricultural Research Institute

One of its key roles is in developing new varieties of key staple and commercial crops for the country. In pursuit of this there has been developed an extensive germplasm collection held at the national gene bank. Under Kenyan law, applications for plant variety protection over most of the varieties have been made jointly between KARI and

Kenya Seed Company. Kenya Seed Company is a state corporation[113], thus maintaining ownership of germplasm by the government of Kenya.

3.2.8.1.3 Department of Veterinary Services

Animal health matters are regulated by the Department of Veterinary Services, which is under the Ministry of Agriculture and Livestock. Thus any activities that may be detrimental to animals would be controlled under this department to ensure their good health. An example was the importation in 1994 of a recombitant vaccinia virus-based rinderpest vaccine developed by the US department of Agriculture, which was allowed under a permit from the DVS, which also conducted the testing.[114]

3.2.9 The Agricultural Produce (Export) Act, Cap 319

The Act provides for the grading and inspection of agricultural produce to be exported and generally for the better regulation of the preparation and manufacture thereof.

Section 3 specifies regulation making powers of the Minister. Every occupier or, in the absence of the occupier, every owner of land shall take all such measures as he may be required to take by virtue of any rules made under Section 3, and in addition such other measures as are reasonably necessary for the eradication, reduction or prevention of the spread of any pest or disease which an inspector may by notice in writing order him to take, including the destruction of plants, whether the same are infected with disease or not (sec. 4). Any person who knowingly introduces any pest or disease into any cultivated land shall be guilty of an offence (sec. 7). The Minister may, by order, prohibit, restrict or regulate the importation and exportation of any plants and the soil, packages, coverings or wrappings thereof and of any articles or class of articles, whether of a nature similar to

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[113] Although its ownership is currently under dispute with the revelation that the government's shareholding of 52% held through the Agricultural Development Corporation was diluted to only 40% thereby privatizing the company. The government has failed to recognize the honour the transactions that led to this. www.kenyaseed.com/ (accessed on 28 May 2010)

[114] http://www.kari.org/index.php?q=content/animal-production-research-programme (accessed on 28 May 2010)

plants or not, and to any animals or insects likely to infect any plant with any pest or disease.

Thus any agricultural product will have to undergo grading and inspection so as to determine its merchantable quality especially if it has been genetically modified. This will include any genetically modified agricultural products.

3.2.10 The Suppression of Noxious Weeds Act, Cap 325

The Act aims to provide for the suppression of noxious weeds. The Minister has the power to declare a plant to be a noxious weed. Any person in whose land such a weed is found has a duty to clear it or cause it to be cleared; else they shall be guilty of an offence.

If any plant goes through genetic modification and turns out o be a weed it may be eradicated under the provisions of this Act. This will be viewed under the handling and use of genetically modified products.

3.2.11 The Plant Protection Act, Cap 324

This is an Act of parliament to make better provision for the prevention of the introduction and spread of diseases destructive to plants. The Minister may make rules for the purpose of preventing and controlling attacks by the spread of pests and diseases, the right of entry and destruction of infectious articles.

Any person who knowingly introduces any pest/disease into cultivated land shall be guilty of an offence and is liable to a fine not exceeding Sh 2000 or imprisonment for a term not exceeding 6 months.[115] Section 8 empowers the Minister to order, prohibit,

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[115] Section 7 of the Plant Protection Act.

restrict, regulate the importation and exportation of any plants and the soil, packages, coverings or wrappings of articles/class of article whether of a nature similar to plant or not and of any animal/insect to infect any pest/disease.

3.2.11.1 Phytosanitary Measures

International exchange of germplasm and trade/movement of plants and plant products is crucial in the quest for adequate food production and supply. There is a need to ensure that there is no foreign injurious pests, diseases and noxious weeds which do not exist in Kenya that are introduced in the country. Kenya has a very stringent plant introduction and certification procedures since the 1930's when the plant quarantine services were started in East Africa. In 1996, a state corporation the Kenya Plant Health Inspectorate Service KEPHIS was established to vigilant for the government, business sector, scientists and farmers on all matters related to plant health and quality control of agricultural inputs and produce. Through the activities of KEPHIS, the introduction of plant pests, diseases and noxious weed into Kenya is prevented or delayed.[116] All phytosanitary measures are based on International Plant Protection Convention (IPPC) and World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary (SPS) regulations and guidelines. The Plant Protection Act (Cap 324)/ the Suppression of Noxious Weeds (Cap 325) and Agricultural Produce (Export) Act (Cap 319) provide the legal framework through which the authority carries out phytosanitary regulation services. Plant Protection services ensure that foreign injurious pests, diseases and noxious weeds which are not existent in Kenya are not introduced or spread when importing plant material into the country.

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[116] www.kephis.org/index2.php?option=com_content&do_pdf (accessed on 28 May 2010)

Plant quarantine is important in the plant protection program during the transfer of plant genetic materials by preventing the introduction of plant pests, diseases and noxious weeds. This in turn reduces the chances of introduction of harmful pathogens.

The Grading and Inspection offers regulatory services to imported and exported plant materials at exit/entry points of the country. The plant inspectors ensure that the plant produce being exported or imported into the country is of high quality. Phytosanitary certificates are issued for export consignments meeting the quality standards. Plant materials failing to meet the standards are destroyed or prohibited from leaving the country and that the plant materials meet Kenya's phytosanitary requirements.

Application of importation of genetically modified organisms (GMOs), are considered by Kenya National Biosafety Committee (NBC) which draws experts from National Council of Science and Technology, Ministry of Agriculture, KEPHIS, local universities, environmental pressure groups, local and international research institutes, KEPHIS enforces the regulations and guidelines for safety in biotechnology as stipulated by the NBC.[117]

3.2.12 The Standards Act, Cap 496

The Standards Act promotes the standardization of specification of commodities and codes of practice and established the Kenya Bureau of Standards. The Kenya Bureau of Standards is established as body corporate with perpetual succession with power to sue and be sued and to purchase property and enter into contracts. The National Standards Council oversees the Bureau in financial and advisory matters. The functions of KBS as stated in Section 4 are to promote standardization in industry and commerce, the testing and calibration of precision instruments, carrying out testing, to control the use of

[117] www.kephis.org>(accessed on 20 November 2009)

standardization marks and codes of practice, the education of standards and the declaration of a Kenya standard.

KBS is a member of the NBC handling GMO issues and with its Secretariat at the NCST. It has its mandate under the Act with stakeholders to develop the relevant Kenya Standards covering GMOs including labeling aspects.

The KS 05-40 is the Kenya Standard Labelling of Pre-Packages Foods requires that a declaration be made of each product by its name, identity of the manufacturer, list of ingredients applied in the product, product country of origin, date of manufacture and expiry, as well as instructions of use and storage where applicable should be provided. The Standard was established in line with the requirements stipulated in the Codex standard for food labeling. [118]

Labeling is important as where GMOs have substituted the conventional ingredients or material, consumers and stake holders are entitled to information to be able to make informed choices when purchasing, due to the uncertainties linked with GMOs.[119]

The Protocol in Art 18 (2) stipulates that foods and feeds labeled as LMOs are exported to a country; the importing country through its BCH has the option of following the necessary mechanism of established procedures to establish the status and safety of such LMOs even at the original exporting country.

3.3 THE BIOSAFETY ACT

All the legislation discussed above do not cater exclusively for biotechnology and biosafety issues, these are discussed among other articles in the acts. This system has

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[118] *Safety in Biotechnology of Foods and Feeds: A Kenyan Workshop under the BIO-EARN Programme* , 17-18 October 2000, Pan Afric Hotel, Nairobi, NCST, BIO-EARN, EA; Labelling requirements for GM foods and feeds, By Mrs. C. Rotich, Director, Kenya Bureau of Standards (Presented by Eng. E.L. Songole), Labelling Requirements in Kenya

[119] *Ibid,* Why Label?

been found to be wanting hence the need to draft a specific Act. The proposed Kenya Legal Framework for Safety in Biotechnology is the basis of the Biosafety Act.

There were four versions of the biosafety legislation, which range from April 2003, then August 2003 and November 2003. The first three versions were given to scientists who submitted their comments and inputs, which went to amend each version of the legislation. The fourth version went to peer reviewers. The fifth was the final draft, which was published for discussion as the policy.

The Act establishes, under **Section 7** a competent authority to be known as the National Biosafety Authority, which shall be under the Minister responsible for Science and Technology. The Act lays out the requirements for an applicant to obtain approval from the competent authority in order to handle GMOs. After obtaining approval the applicant shall be given a license/permit by the appropriate regulatory agency. The Act spells out the role of regulatory agencies. It outlines the procedure and requirements for application. It also has a provision for the authority to promote awareness and education of the public. It will also publish notices concerning proposals and decisions on application..

The Act went through the procedure provided for in the Standing Orders.[120] At the time of its consideration in parliament, the legislation was published in the Kenya Gazette at least two weeks before its presentation. In parliament it went through the first reading, which is a formal citation of the legislation's title, by way of notice to the members. At the second reading stage, parliament deliberated upon the motion that the legislation be read a second time. Parliamentarian had the opportunity to accept it. The legislation went on to the committee stage, where it was given detailed clause by clause consideration.

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[120] Republic of Kenya, National Assembly Standing Orders 1983, Parts XXV and XVI. See also Slade H (1969) the Parliament of Kenya (2nd Ed) Nairobi, East African Publishing House Pg. 42-50.

At the report stage, the committee reported its deliberations to the House, where the report was accepted. It was then printed as an Act and then it was sent to the president who assented to it.

3.4 CONCLUSION

Kenya has been very active in the implementation of biosafety laws. Kenya is one of the few African countries who has implemented a national biosafety framework as it has the Biosafety Act. It is encouraging to note that Kenya started such activities even before the ratification of the Cartagena Protocol.

It can be seen that there are gaps identified in the primary legislation, the Constitution as it does not cater for genetically modified organisms and biodiversity. The draft Constitution should include the provisions on biological diversity to be effective in this area. The statute laws that were used for biosafety issues are not exclusive and they are related to other matters such as environmental conservation and management, forest conservation, wildlife and livestock management, agricultural products, and so on. As has been noted the statutes are not in themselves 'LMO issue sensitive' or Cartagena Protocol compliant. Their sections do not express the objectives of the Protocol and Kenya having ratified the Protocol should implement these articles. This reduces efficiency in dealing with biotechnology issues, as the core problems may not be addressed effectively, hence the need for the Biosafety Act. The existing legislation does not have enforcement mandates. This poses a problem in the instance where someone contravenes the provisions of a particular Act. The Biosafety Act should expressly cater for such instances and issues of liability and redress.

The challenge now lies in operationalising these laws due to the sensitivity of the issues involved as any negative effects can be detrimental to biological diversity. The laws have to be relevant to meet our needs as developing country with special consideration in areas

such as capacity building, the biosafety clearing house, decision making and getting support for the Global Environment Fund.

The relevant question that now needs to be addressed is whether the Biosafety Act as a domestication of the Cartagena Protocol is sufficient to cater for Kenya's requirements. This is necessary to ensure that the Act covers all biotechnology and biosafety matters that arise both now and in the future with minimal amendments necessary.

CHAPTER FOUR

ANALYSING THE BIOSAFETY ACT IN LIGHT OF THE CARTAGENA PROTOCOL ON BIOSAFETY

This chapter examines the Biosafety Act as a domestication of the Cartagena Protocol. This is to establish to what the Biosafety Act has met the standards of the CPB, being the minimum standard in the regulation of biosafety.

The Biosafety Act is necessary because as it has been noted in the previous chapter our current legislation is not GMO sensitive and neither is it Cartagena Protocol complaint. Kenya therefore has taken steps to come up with an entirely new legislation to deal with matters on biosafety, hence the Biosafety Act.

The need for the Biosafety Act can also be attributed to the Cartagena Protocol which provides in Art 2 (1) "Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol". This provision is a restatement of a general principle of international treaty law. A State that is a Party to an international treaty is bound by that treaty and must comply with its obligation under the treaty.[121] Kenya is the process of fulfilling its international obligations through the Biosafety Act, as a party to the CBD and the CPB.

The Government also saw the need to institute adequate biosafety measures that would ensure maximization on benefits of the technology while minimizing the risks. A comprehensive biosafety legal framework strikes a balance amongst ensuring the development of biotechnology, protection of the environment and safeguarding the interests of consumers. Potential risks associated with application of modern biotechnology are minimized while facilitating the beneficial application of the

[121] Art. 26 of the Vienna Convention on the Law of Treaties

technology in areas of agriculture, health, environment and industry. The law is vital to deal with transboundary movement of GMOs. For instance, delays caused by judicial and political decisions resulted to an increase in illegal planting of GM soyabean seeds in southern Brazil smuggled across the border from Argentina. Appropriate legislation and a strong regulatory framework are also important in developing public confidence in biotechnology as a technological option.[122]

4.1 ANALYSIS OF THE SPECIFIC SECTIONS

4.1.1 PART I – PRELIMINARY PROVISIONS

The Biosafety Act is defined as an Act of Parliament **to regulate biotechnology and biosafety matters.** The use of the term biotechnology does not effectively capture the regulation of GMOs resulting from the use of genetic engineering technologies. The appropriate word to use would have been modern biotechnology as defined in the Protocol.

The definition of biotechnology is too broad to describe precisely and with legal and scientific certainty, the actual technology being used to produce GMOs. This should be amended to convey the notion that genetic engineering technologies are being addressed which involves modern biotechnology and not biotechnology. The Protocol does not speak of biotechnology but talks of modern biotechnology which is the approach that has been adopted in the Act. The definition of biotechnology in the Act has been adopted from the CBD in Art 2.

The Act in **Section 2** deals with interpretation where it has defined terms such as Authority, Applicant, Biotechnology, Biosafety, Contained use, Genetically modified organism, Genetically modified organism register, Placing on market, Minister and

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[122] http://programs.ifpri.org/pbs/pdf/pbsbriefkenya.pdf. (accessed on 28 May 20101)

regulatory agency. These words are applied in the Act to give it specific meaning and prevent ambiguities. Further interpretation of any terms not defined is through actual analysis of the words in their ordinary meaning. One can also look at the intention of parties who drafted the document and finally, the object and purpose of the document as a whole should be determined.[123]

The only term that is defined both in the Biosafety Act and Cartagena Protocol is 'contained use'. In the Act it is defined as 'any activity undertaken within a facility, installation or other physical structure which involves GMOs that are controlled by specific measures'. On the other hand the Protocol defines it as 'any activity undertaken within a facility, installation or other physical structure which involves GMOs that are controlled by specific measures that effectively limits that contact with and their impact on the external environment". The Act does not mention what these measures are intended to do for contained use making the definition slightly ambiguous.

The Act uses the term Genetically Modified Organism defined as an organism that has been transformed by the insertion of one or more genes. The protocol uses the term Living Modified Organism. LMOs are defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." The term LMO has its origin in the CBD where the term was intended to include genetically engineered organisms resulting from any form of biotechnology.[124]

In everyday usage LMOs are usually considered to be the same as GMOs, but definition and interpretations of the two terms vary widely.[125]

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[123] Shaw, MN (1991) *International Law*, Cambridge; Grotius Publication 638, Pg 655
[124] Article 19 (3) of the CBD
[125] http://en.wikipedia.org/wiki/LMO_(biology) (accessed on 14 January 2010),what is a Living Modified Organism

In the definition of the term biosafety a word appears to be missing after the word 'infectious'. It can be speculated that what is missing in this definition is a reference to the need to avoid adverse social – economic impacts on local communities.[126] An amendment is necessary to include the omitted words seeing as it is a core issue in the Act.

Section 3 covers the Scope of the Act which recognizes the requirements imposed by any other Act. This is relevant because there are other Acts which deal with biotechnology and biosafety issues directly and indirectly. The issue of liability and redress has been referred to other applicable laws[127] which make it relevant to refer to other Acts and laws like civil liability under the law of tort.

In **Section 3 (2)**, the Act does not apply to GMOs that are pharmaceutical for human use.[128] This section disparate to the Protocol does not state that the Pharmaceuticals for humans are addressed by other relevant international agreements or organizations. The Protocol exempts such pharmaceuticals from transboundary movement, thus also exempting it from the AIA procedure. Other provisions of development, transport, use, handling, packaging, labeling, capacity building and public awareness and participation however do apply. The blanket exclusion of the Act means it offers no protection and there can be pharmaceuticals, that are not covered and controlled by international agreements and organizations, which find their way in Kenya. This is a very serious commission, without carrying out any risk assessment in accordance to the detected and prevented going against the objective of the protocol. A control mechanism should be put in place adverse effects of such GMOs, which may be dumped in the country.

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[126] http://www.scidev.net/en/opinions/will-kenyas-biosafety-bill-of-2005-ever-become-la.html (accessed on 14 January 2010)comments on Draft GMO Bill Kenya, Page 4

[127] Section 42 of the Biosafety Act

[128] These are principally genetically engineered vaccines, see Mackenie R., Pg 56

In line with the CPB it can be said that GMOs that do not satisfy these conditions include; GMOs which are not pharmaceuticals and GMOs for human not addressed by relevant international agreements or organizations. The cross border movement of pharmaceuticals for human use in general is governed by the World Health Organization's (WHO) 'Certification Scheme on Pharmaceutical Products Moving in International Commerce'.[129] It is recommended that the Act include such pharmaceuticals within the scope of its ambit as ample room for its regulation exists.

In **Section 4** t he Objectives of the Act are twofold. Firstly, in accordance with the precautionary principle to ensure an adequate level of protection in the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have an adverse effect on the environment and to establish a transparent and predictable process to review and make decisions on such GMOs and related activities. Because of the fact that the precautionary principle has not been defined we refer to the objective of the protocol which refers to the precautionary approach contained in the principle 10 of the Rio Declaration on the Environment and Development which states;

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation.

The Act's use of the word environment encompasses not only biological diversity but also other parts of the environment such as air, water, and soil. This is wider in meaning than the Protocol which refers to biological diversity only.

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[129] WHO, Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving International Commerce http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/ (accessed on 14 January 2010). It was necessary to duplicate efforts. However, it sets standards for human health and does not take into account impacts on the environment and biodiversity. Such standards are usually non-binding and are at best non-binding and are at best mere recommendations.

A reading of the entire Act illustrates that these objectives have been in order to exclude protection of biodiversity and human health from the ambit of the Act completely. It should be questioned why the Biosafety Act has such short sighted objectives which fall far below those enshrined in the Biosafety Protocol.

4.1.2 PART II- ADMINISTRATIVE PROVISIONS

Each country that is a party for the Protocol needs competent national authorities and a national focal point as per Art 19, to perform functions relating to the Protocol. In order to facilitate the work of the ICCP Parties to the CBD were asked to designate focal points for the ICCP, whose function could continue after entry into force of the Protocol.[130] The component national is responsible for exercising the administrative functions required by the Protocol and must be authorize by a party to act on its behalf in relation to those functions. It should be the institution at the domestic level, which has the authority to make decisions on imports of LMOs. The competent national authority must be notified to the secretariat.

Part II provides for the establishment of an Authority, the National Biosafety Authority as a body corporate with perpetual succession, with the power to sue be sued, purchase property and carry out all other lawful functions of a body corporate. This section can be questioned as it is not clear how the minister is to make the appointment.

The duties of the Regulatory Agency are defined in **Section 30.** It is the Agency's duty to monitor an applicant's activities to ensure that they comply with the requirements of the Act.

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[130] Decision EM-1/3

Section 30 (2) caters only for the environment and nothing else. It also provides that that the Authority be informed and the measures to be put in place are to ensure the continued safe use of the GMO. In a biosafety regime where adverse environmental impact may arise why would the remedy be 'continued safe use'? This is clearly a contradiction. The Authority must ask for the activity to be suspended, that a thorough investigation and assessment take place to determine the nature and extent of the adverse impacts. The applicant should be asked to safely dispose of the offending GMO in question and held responsible for the resultant harm.

Part VII deals with the financial matters of the Authority. The Authority's funds comprise of money from Parliament, from the exercise of their powers and other sources lent or donated to the Authority. Investment of their funds is to government services and deposits with any bank quoted on an approved securities exchange in Kenya. It calls for the preparation of annual estimates of revenue and expenditure.[131] **Section 38** calls for proper books and records of account to be submitted to the Auditor General. Accounts should be audited and reported as per **Section 29** and **30A of Exchequer and Audit Act.**[132] There should be regular publications to keep the public informed except for reasons of commercial confidentiality or security justifying exclusion. This limits the extent of public participation and awareness.

The financial mechanism established under the CBD will also be the financial mechanism for the Protocol; this means that financial assistance in relation to the Protocol will be available through the Global Environment Facility (GEF). The GEF was established in 1991 and restructured to the Instrument for the Establishment of the Restructured Global

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[131] This is in Section 37 and includes salaries, allowances, pensions and maintenance costs

[132] These Sections call for the auditing of the Authority's accounts by the Controller and Auditor-General, as it is a state Corporation. The Controller and Auditor General has the powers as the members of the corporation in relation to some tasks. He may also appoint a professional accountant to audit the accounts and report to him. Audit reports are submitted to the Minister responsible then presented to Parliament.

Environment Facility, the Instrument, which lays down the fundamental principles of the operation of the GEF. Its objective is to serve as a mechanism for international co-operation for the purpose of providing new and additional grants and concessional funding to meet agreed global environment needs through the GEF Trust Fund.[133]

Art 28 (a) recognizes that certain groups of Parties may have specific needs in capacity building that need to be reflected in the provision of financial resources for implementation of the Protocol. There is the UNEP – GEF Project on the development of National Biosafety Framework, which helps countries comply with the Protocol. Kenya has been a beneficiary of the UNEP – GEF Project as it has been observed.

4.1.3 PART III – HANDLING REQUEST FOR APPROVAL

Section 14 handles applications for contained use which are conducted with written approval from the Authority. The application contains information from the Third Schedule of the Act, which includes details of the application, the nature of the GMO, the Schedule of the Act, which includes details of the applicant, the nature of the GMO, the purpose of the activity, the containment measures, the potential risk and the remedial measures available. Any additional information deemed necessary to assess potential risk may be included.

Section 14 (2) (b) is dangerous as the principle behind this provision is based on self regulation as to risks. It is not for the applicant to decide what the risks are but for the Authority to make a decision on this very issue. Further more this provision opens the door for the applicant to put information before the Authority of so called 'benefits of GMOs'. This is unacceptable and it should be deleted or amended because this

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[133] Mackenzie R, Pg 175

information is about precautionary measures taken to avoid risks and it is not an opportunity for the applicant to conduct a benefit analysis of its technology.[134]

The protocol in **Art 6 (2)** exempts LMOs for contained use from Advance Informed Agreement procedure. All other provisions of the Protocol remain applicable to such LMOs, for example **Art 18** with rules on the handling, transport, packaging and identification of LMOs. The Authority exercises its right to regulate the entry of such GMOs into their territory. According to the Protocol Parties still have the right to subject all LMOs to risk assessment and to ser standards and regulations for the contained use of LMOS within their territorial jurisdiction. However, there is no specific obligation in the Protocol on the exporter or Party of export to ensure the final use of the LMO in the Party of import conforms to the intended use, in this AIA may be undertaken. The shortcoming of the definition of contained use affects its application and thus applicants may be able to demand for approvals that will not entail strict laboratory use. This will increase risks that the environment, biodiversity and human beings are exposed to, from GMOs that are neither ready for release into the environment nor consumption.

Section 15 states that no person shall introduce into the environment a GMO without having made an application and received a written approval of the Authority. This can be compared to the Protocol which provides under **Art 7** that Advanced Informed Agreement procedure shall apply prior to the first intentional transboundary of LMO for intentional introduction into the environment of the Party of import.

The Fourth Schedule which relates to the information required for application for release, important and placing on the market is similar to Annex I of the Protocol which deals with the AIA procedure.

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[134] *Supra* (note 133 above) Pg 8

Paragraph 6 which deals with centers of origin has omitted the term ' proliferate' which is found in Annex I (f) of the Protocol.

Paragraph 7 loses the core issue of biosafety as in Annex I (g) of the protocol regarding the 'donor organism or organisms related to biosafety'.

Paragraph 10 differs substantially from Annex I (K) as the concept of 'previous risk assessment has been lost.'

Paragraph 11 as compared to the Protocol has lost following 'packaging, labeling, documentation, disposal and contingency, where appropriate' in relation to suggested methods for the safe, handling, storage, transport and use of GMOs.

Paragraph (m)[135] 108 and (n) [136]109 of the Protocol have also been omitted. These two paragraphs hold vital information and should be included. Their purpose is to enable sharing of information on action taken in the Party of export. Parties of import should be aware of any restriction that any countries may have imposed on the use of these GMOs within their territories and reasons for this so that similar considerations may be assessed by the party of import in its risk assessment and decision procedure.[137] This should be provided for in our Act.

Section 17 states that a person intending to export a GMO shall provide the Authority with written advance informed agreement of the competent authority of the importing country. There is no definition in the Act as to what a written advance informed

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[135] Regulatory status of the LMO within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions or whether it has been approved for general release) and, if the LMO is banned in the State of export, the reasons for the ban.
[136] Result and purpose of any notification by the exporter to other states regarding the LMO to be transferred.
[137] Mackenzie R, Pg 214

agreement entail, this should be included. Reference will thus have to be made to the CPB. This evidence that the importing country has been notified of the proposed transboundary movement and it has given its approval based on whatever conditions it finds necessary. In the CPB, AIA procedure is provided for in Arts 7, 8, 9, 10 and 12 setting out the application for the AIA Procedure, which entail notification, acknowledgement of receipt of notification, decision procedures and review of decisions.

In Section 18, a person transporting GMOs through Kenya which are not destined for use in Kenya shall get written approval from the Authority, to ensure GMOs are properly packaged and transported in accordance to regulation and international standards, such transit shall prescribe in the regulations. While Art 6 (1) exempts LMOs in transit from AIA procedure, there is nothing in the Protocol which prohibits Parties from imposing such regulatory and safety rules as they deem necessary which the Biosafety Act has done by requiring proper packaging and transportation according to the regulations and international standards such transit information should be given to the Biosafety Clearing House.

Article 25 is on illegal transboundary movement where each Party should adopt appropriate domestic measures to prevent and penalize illegal tranboundary movement while **Article 25 (2)** deals with the Party of origin disposing of LMOs at its own expense by repatriation or destruction. The Protocol is silent on whether the Party of origin must comply with the request of the affected Party to dispose of the LMO or if it is subject to agreement between the two. Where non–parties are involved customary international law[138] is used or a separate agreement. The Act is silent on this matter and an amendment is necessary to prevent confusion.

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[138] Principle 2 of the 1992 Rio Declaration places an obligation on states to ensure that activities carried out under its national jurisdiction do not cause damage to the environment of other states or to the global environment.

Section 19 deals with confidential information where the Authority shall allow an applicant to identify information as confidential, decide whether it shall accept this and if on withdrawal of such an application it shall maintain the status of confidential information. The Protocol has similar provisions in Art 21 as to information that is to be treated as confidential after consultations with the 'notifier'. Confidential information received in the context of the AIA shall be protected in a manner no less favorable than that relating with the domestically produced LMOs. Unlike the Act the Protocol specifies confidential information as 'commercial and industrial information, including research and development information.' While the Act only states information generally.

Section 22 relates to risk assessment and risk management. On screening an application which is found complete, risk assessment shall be undertaken as per the fifth Schedule.

Art 15 deals with risks assessment, which subject to the AIA procedure is based on information on notification and available scientific evidence. This should be done in a 'scientifically sound manner', which is not expressed defined. This is to evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity and human health. [139]

Risk management is explained in Art 16 which provides for the management of risks of all LMOs according to the scope of the CPB in Art. 16 also refers to Art 8 (g) of CBD, which requires parties to the CBD to;

> Establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse

[139] For example Report to the Working Group on Regulatory Oversight in Biotechnology (to the G8 Heads of States and Government), May 2002, OECD Reference No. C (2000) 86/ADDI

environment impact that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

The Protocol places an obligation on parties to set up appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessment.

Section 22 (2) can be interpreted to refer to human health impact or even the environment exposure. This creates confusion because if it relates to human health impacts, talking of 'any potential exposure to the GMO' seems to be out of place, particularly since the Act does not aim to regulate impacts on health.[140] Therefore this exposure needs to be expounded on to state what it applies to. **Section 22 (4)** is extremely instructive because it is entirely framed in a way that contemplates that the applicant will be granted and not refused their application. This is unacceptable and it should be deleted.

In **Section 23** the Authority may exempt GMOs from certain requirements of Sections 14, 15, 16, where it determines that sufficient experience or information exists to conclude that GMOs or related activities do not pose a significant risk to the environment. This section takes advantage of Art 7 (4) which gives authority to the Conference of Parties serving as the meeting of Parties to provide that the AIA procedure shall not apply to the intentional transboundary movement of LMOs which they have found as not being likely to have adverse effects on human health. The Protocol like the Act gives no guidance as to what information or evidence might be required to support such a conclusion. This section is quite vague and open to abuse. Nonetheless, any such decision would need to be taken considering the precautionary principle approach in Principle 15 of the Rio Declaration which is found in the Protocol

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[140] *Ibid* Pg 14

and Bill's objective. It should be noted that this provision has not yet been implemented as the COP/MOP has taken no such decision and even if they were to take such a decision, then it would be restricted to the intentional transboundary movement of LMOs

In section 24 in reaching a final decision the Authority shall take account; information submitted by the applicant; the risk assessment report; relevant comments submitted by the public; social-economic considerations arising from the impact of GMOs on the environment.

Section 24 (c) contemplates comments submitted by the public, but no mechanism has been created in the Act for the submission of these comments. Subsection (d) makes mention of socio-economic considerations but restricts this only to environmental impact which are far narrower than Article 26.

Article 26 addresses the extent to which Parties are entitled to take socio-economic considerations into account in reaching decisions on imports of LMOs. In the negotiations developing countries emphasized the importance of such considerations which should be the basis for risk assessment, risk management and making decisions on imports of LMOs. Developed countries were against such provisions as they were difficult to quantify for making decisions on imports of LMOs and should be a national domestic concern. For this provision to be included it has to be consistent with existing international obligations. Since such socio-economic consideration are with regard to indigenous and local communities it means that not all socio-economic consideration may be taken to account, but only those that arise from the impact of LMOs on biodiversity.[141]

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[141] Mackenzie R. pg 163 Also refer to Bravo E. "*Socio-Economic Considerations*" in TWN Briefings for MOPI No. 7

In **Section 26** the Authority shall maintain a register which should contain a copy if the application, risk assessment report, decision document, approval and other relevant information. This section should create the responsibility to keep inventories of all GMOs and the locations of sites where releases are authorized or have taken place. This register is what would be submitted to the Biosafety Clearing House.[142] The Act does not expressly provide for the conveyance of information to the BCH.

The BCH is established as part of the Clearing House Mechanism in Art 18 (3) of the CBD to allow exchange of scientific, technical, environmental and legal information and assist Parties in implementation of the Protocol.

4.1.4 PART IV – REVIEW AND APPEALS

In **Section 27** the Authority may review a decision under **Section 24** any time upon obtaining significant new information indicating that GMOs or activities may adversely affect the health of humans, plants and animals or the environment. A regulatory agency[143] or applicant may request a review based on a change of circumstances and additional scientific or technical information. If the authority is satisfied that a change is warranted they shall issue a substitute approval. A decision on review takes 150 days with reasons. The Authority will take immediate action to put measures in place in case of potential risks. This is risk management as shown in Section 22.

Section 28 makes it an offence to withhold information that could change the evaluation of the risk posed by ap plicant's intended activity. An applicant committing such an offence is liable on conviction to fine of two million shillings or imprisonment for ten years.

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[142] Art 20 of the CPB
[143] Given special consideration by the Authority, Section 27 (6) of the Biosafety Act

Section 29 establi shes an Appeal Board consisting of Chairman, an advocate, chief executive and two other persons and they all hold office for three years. A person aggrieved by the refusal to grant an approval, imposition of conditions, revocation/suspension /variation of approval or refusal to treat information as confidential may within 30 days of such a decision appeal to the Appeal Board.

The sections on review are based on **Article 12** dealing with the review of decisions in light of new scientific information on potential adverse effect on conservation and use of biodiversity.

4.1.5 PART IX – MISCELLANEOUS PROVISION

In **Section 39,** the Authority with the Minister's approval may make regulations for better carrying out functions for anything provided in the Act, in particular procedures for contained use activities, release into the environment, importation and transit of GMOs, appeals, application forms and administrative fees.

Section 41 promotes public awareness and education on biosafety mattes though publication of the Act and regulations there under. All notices and final decisions concerning all applications shall be published. This provision is not consistent with the CPB.

Public awareness, education and participation is in Art 23 of the Protocol which is best understood in the context of Principle 10 of the 1992 Rio Declaration on Environment and Development, which states

> Environmental issues are best handled with the participation of all citizens, at the relevant level at the national level. Each individual shall appropriate access to information concerning the environment that is held by public authorities, including information on

hazardous materials and activities in their communities and the opportunity to participate in decision making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy shall be provided.

Article 23 (2) provides that Parties shall in accordance with their respective laws and regulations, consult the public in the decision making process regarding LMOs and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21. This means that the scope, extent and methodologies for public participation are subjected to national laws and regulations governing public participation. The information used for this should not be confidential information. The Protocol does not provide specific guidance on the public consultation mechanisms adopted in decision making processes and how to make results of decisions known. This is left to the Parties to implement in their own national context which Kenya has not effectively undertaken through **Section 41.**

Section 42 on the liability and redress for any damage that occurs as a result of activities subjected to this Act shall be addressed by applicable laws. **Article 27** is concerned with the issue of liability for damage that may result from transboundary movement of LMOs. This issue was complex and could not be resolved during the negotiations. Article 27 thus contains an 'enabling" provision requiring the first meeting of the COP/MOP to establish a process to consider this issue within 4 years. An additional process of relevance for future negations under Article 2 7 is the examination of the question of liability for damage to biodiversity under Article 14 92) of the CBD.[144]

[144]The Conference of Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress including the restoration and compensation for damage to biological diversity except where such liability is a purely internal matter.

The first Meeting of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) was to address the liability and redress issue among others.[145] They established an Open-ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress to carry out the process pursuant to Article 27 of the Protocol. This was done bearing in mind what is going on in the international scene in regard to liability and redress. They analyzed the actual damage caused to biodiversity.[146]

4.2 VITAL PROVISIONS OF THE CARTAGENA PROTOCOL OMITTED FROM THE ACT

There are those Articles in the Protocol which have not been mentioned in the Act but are relevant when it comes to safe transfer, handling and use of GMOs.

4.2.1 Article 11 – Procedure for Living Modified Organism intended for direct use as food, feed or for processing.

There was a lot of argument as to whether LMO-FEPs and not all foods and feeds derived from LMOs should be within the scope of the Protocol. Developing countries wanted LMO-FEPs subject to AIA due to accidental introduction into the environment, while developed countries were opposed to this as they said was meant for direct consumptive use.

It was finally decided that LMO-FEPs would be exempted from AIA procedure. Article 11 provides a special, simple procedure for transboundary movement of LMO-FEPs. Article 11 establishes a multilateral information exchange mechanism for LMO-FEPs, centred on the Biosafety Clearing House. It places the onus on an importing Party to check the BCH for information on new LMO-FEPs which may enter international trade and if it wishes to subject such imports to domestic regulation. Article 11 explicitly

[145] www.iisd.ca/biodiv/cbdintro.html (accessed on 14 January 2010)
[146] http://unfccc.int/meetings/cop_11/items/3394.php (accessed on 14 January 2010) COP/MOP 1 decisions

permits Parties to subject first imports of LMO-FEPs to prior risk assessment and approval.

Since Article 11 does not specify any particular procedural requirements to be reflected in domestic regulatory frameworks applicable to imports of LMO-FEPs, a Party may also be subjected to other relevant international obligations, including those under the WTO Agreement.

The Act should come up with specific provisions on LMO-FEPs to meet the Protocol's standards when it calls for domestic regulations. On the other hand since Kenya is a signatory to the WTO, it can adopt the standards therein.

4.2.2 Article 18-Handling, Transport, Packaging and identification.

This Article covers all LMOs in the Protocol except those meant for pharmaceutical use for human governed by international agreement. Art 18 (1) refers to the international rules and standards which presently govern LMOs on the basis of their characteristics rather than because they are LMOs such as the International Plant Protection Convention by the WHO, UN Recommendation on Transport of Dangerous Goods.[147]

Article 18 (2) requires Parties to take measures to ensure that LMOs for intentional transboundary movement are accompanied by documentation identifying the LMO and providing contact details for those responsible for the movement of LMOs. It calls for specific identification of shipment of LMOs to identify and track tranboundary movement of LMOs. This is so that Parties of import know when they receive these LMOs and in case of accidental release it is known how to deal with them. The ICCP has

[147] ST/SG/AC 10/11/Rev.3.UNEP/CBD/2/12;UNEP/CBD/ICCP/3/7

mandated two expert meetings to consider the need and modalities for developing measures to meet obligations.[148]

The COP/MOP1 has taken measures to urge governments to take steps to require the use of documents to accompany LMO-FFPs, refer to contact points for further information and documentation on the nature of LMOs. There is also provided the establishment of an open-ended technical experts group on identification requirements of LMO-FEPs.[149] The requirement of such documents is missing in the Kenyan Act.

4.3 CONCLUSION

An analysis of the Act has led to my conclusion that it does not in its present form represent an adequate, robust and comprehensive biosafety regime designed to protect the environment, human health and biodiversity from the risks posed by GMOs and its related activities. It is a piece of draft legislation that seeks to put in place, a mere permitting system designed to approve applications for the contained use, import; export, placing on the market and release into the environment of GMOs. The underlying imperative of the Act is the promotion of genetic engineering and not biosafety.

Critically important provisions of the Biosafety Protocol that form the cornerstones of biosafety regulations have been omitted from the Act in their entirety or they have not been adequately catered for. These include LMO-FEPs, the handling, transport, packing and identification, and the BCH. The Biosafety Protocol establishes international rules that are considered to be a "floor" rather than a "ceiling" for the drafting of a regulatory framework. This means, the Rules of the Protocol are the minimum standards for achieving the objectives of the Protocol 9Article 2 (4). It is therefore extremely worrying

[148] Recommendation 3/6 of ICCP
[149] Decision BS-1/6 of the COP/MOP 1

that the Kenyan Act not made an attempt to fully implement the minimum standards established by the Protocol.

The Act restrictively applies only to adverse impacts on the environment. It does not engage at all with biodiversity and human health. Only section 27 refers to human health, plant health and the environment. The rest of the Act only talks of the environment and excludes the protection of biodiversity and human health from the ambit of the Act in its entirety.

Substantial amendments will have to be made to the Act in order for it to comply with the Biosafety Protocol and represent a workable and effective biosafety regime. Attention must also be paid by the Kenyan government to the outcome of the first Meeting of the Parties held in Kuala Lumpur during February 2004 as the Act will thus have to provide for these new measures fully.

There has been controversy as to the implementation of the Act as the farmers feel that they were not consulted during the drafting of the Act. Small scale farmers in Kenya should be included in policy formulation, agriculture research and food security. They want to give their views on the use of GMO seeds. They feel that this new kind of agriculture is expensive and complicated using genetic engineering. Their immediate concern is that the government should concentrate on irrigation, improvement of infrastructure, appropriate technologies, marketing, subsidies, credit, farm inputs and better rangeland management and not GMOs.[150] The agrochemicals associated with GM crops will oblige farmers to pay the high prices set by the livelihoods. This is really short sighted view of the whole process of genetic engineering and even from their arguments it can be noted that their main concern is on the seeds and they are not looking at the

[150] http://www.grain.org/research/contamination.cfm?id=161 (accessed on 14 January 2010), Biosafety Act will not protect Kenya from risk of GMOs.

bigger picture. The problems they are stating can be solved but this should not be a reason to do away with the Biosafety Act at this infant stage before it is enacted and its impact felt in the country. Through public education citizens can be trained on the benefits of GMOs so that they start accepting this new technology which if used wisely will benefit the whole society.

GMOs are a danger to food security and our indigenous gene pool. Patented GMO crop threaten farmers' ability to save and share their indigenous seeds which have stood the test of time. Thus they will reduce our seed security and food security, without the long and short term effects on our health and environment being known. GMOs will hand control of our food systems to the multinational companies, who have created and patented these seeds for financial gain, and not for our need. With the issue of patenting coming to the forefront in Kenya this is a valid argument which the Act fails to address this despite its impact on the farmers. There needs to be an amendment in the Act to cater for this is.

The farmers are also the view that government is being arm twisted to accept GMOs by multinationals, without considering the effect on small scale farmers. The following statement is clear a indication of this,

> We believe that God created life, and no one can own it, not even Monsanto, Syngenta or other multinational companies. We therefore reject all GMOs in agriculture, and call upon the Kenyan government to respect our indigenous expertise. Therefore to be able to fully understand the effects of GMOs on our livelihoods, health and environment, we demand a twenty-year moratorium on GMOs in Kenya.[151]

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[151] *Ibid*

It should be noted however that the actual passing of the Act is in itself a positive step on Kenya's part to try and implement the biosafety laws domestically. Amendments should be made to include the important provisions in the CPB that have been omitted and even to correct the other shortcomings of the Act.

The different groups who are raising their concerns should put forward their views on how best to amend the Act and not to do away with it completely. They should understand that the whole issue of GMOs is a necessary evil which impacts their lives in one way or another and they should try and make an effort to embrace this change gracefully. In line with this they should find ways to integrate these changes in their activities with as little damaging effect as possible.

CHAPTER FIVE

IMPLEMENTATION OF THE BIOSAFETY ACT

This Chapter looks at the requirements for efficient implementation of the Biosafety Act. The Biosafety laws cannot be applied in a vacuum; there are those resources that are needed to implement it. Kenya as a developing country does not have all the necessary resources to carry out the required activities. These shortcomings have to be identified in order to find solutions for them. Solutions to these problems may be found in the recommendations to be enumerated. These recommendations will ensure effective implementation of the Biosafety Act as a domestication of the Cartagena Protocol Biosafety.

5.1 CHALLENGES IN IMPLEMENTING THE BIOSAFETY ACT

Once a Bill has been made into law in the country there needs to be the process of implementation where the provisions of the Act are executed. The actual establishment of the Authority has to take place and panels of experts to carry out their duties. This section aims to anticipate what challenges will be met in the execution of the Act and they are as follows;

5.1.1 Limited access to relevant information

The availability of dependable, unbiased information is the key to making responsible science-based decisions. Yet the serious deficiency in available information may be quite difficult to remedy. Even when such information is freely available, it will be critically important to develop institutional capacity to understand and assess it and thus to apply it to policy development and decision on GMO-related proposals. There is also the problem of determining whether there is sufficient information available to support a final decision or even where policy decisions have to be made before sufficient information is

available.[152] Decisions have to be made with all these issues and even with the limited exchange of information among persons qualified in scientific and technological fields and the end users. Further despite the research being undertaken by scientists, the end users of this technology being farmers, fishing communities and direct consumers do not get to know the latest developments and how they can exploit them.

5.1.2 Liability and redress

Legal systems addressing liability for failed or damage-causing GMO introductions may be the most important tool for encouraging proponents of GMOs to act responsibly. However, liability depends on the ability to obtain evidence, not only of the damage caused, but of the source of the material or organism that are causing it. In this connection, traceability is seen as an emerging risk management tool within the biosafety and food safety areas. By and large, specific tracing techniques do not currently exist that would allow identification of the source of a particular GMO problem, but they are reportedly in development.[153] In the meantime, compilation of information regarding GMO behavior may provide a basis for reasonable regarding liability for harm.

5.1.3 Large Volumes of Goods

Another area of concern is whether a developing country such as Kenya would be able to apply the AIA procedure to large quantities of traded goods. Kenya may not have the capacity to subject massive volumes of commodities to the AIA procedures. Yet in the spirit of the Protocol that capacity limitation should not subordinate safety interests to trade pursuit, thus AIA procedures should be fallowed.[154]

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[152] Young T. *Genetically Modified Organisms and Biosafety: A Background Paper for the Decision makers and others to assist in consideration of GMO issues.* IUCN-The World Conservation Union

[153] Genetically modified *organisms and biosafety: a background paper for decision-makers and others to assist in consideration of GMO issues*, Tomme R. Young, IUCN Policy and Global Change Group, IUCN, 2004

[154] Mugabe J, From Cartagena to Nairobi: *Towards an African Agenda on the Biosafety Protocol, Background paper for the panel discussion at the Fifth Conference of Parties to the Convention on Biological Diversity* (Nairobi, 10 May 2000)

5.1.4 Capacity Building

Article 19 of the Protocol is on capacity building which is designed to address needs in a particular area. National capacity building is one of the critical tools in implementing AIA procedures. National capacity building is one of the critical tools in implementing AIA procedures. Articles 19 and 20 make provisions for technical assistance in the Protocol's implementation to developing countries. The Global Environment Facility has also put in place mechanisms to assist countries in meeting obligations under the Protocol Capacity building can be looked at from the following areas;

5.1.4.1 Limited Experts

There is a dirth of human resource capabilities to expeditious handle application coming before the NBC especially in view of the fact that the applicants are in many instances members of the NBC. This leads to a backlog of applications hindering trade leading to huge losses on the parties concerned. Kenya does not have a mass of expertise in issues of GMOs. This is because this is a relatively new field of research and individuals have not embarked on undertaking the relevant training. There is a problem in the harnessing of this expertise and strengthening of institutional structures so that are suitable for the implementation of a comprehensive biotechnology regime.

5.1.4.2 Dissemination of information

The Biosafety Act does not articulate explicitly the issue of dissemination of information regarding biotechnology risks and benefits. Mechanisms of information gathering and information exchange, including access to databases and knowledge of global developments is not provided. It should be realized that the public controls the fate of biotechnology in willingness or refusal to accept products produced through genetic engineering thus it is essential to inform the public about all aspects of biotechnology.

5.1.4.3 Intellectual Property Rights

There is the issue of lack of protection intellectual property rights that hampers the development of new technologies. Most of the products coming in are already patented and they cannot be exploited by Kenyans who are the source of raw materials in the first instance. Institutions that safeguard IPR in technological innovations are larger and stronger than those that protect interests of local communities in conservation efforts. Harmonizing the rights of the State, the institutions and the local people will be difficult to achieve.[155]

5.2 RECOMMENDATIONS FOR EFFECTIVE IMPLEMENTATION OF THE BIOSAFETY ACT

African States must ensure that their national laws have high standards. However this does not mean that countries should establish rigid regimes to implement the Protocol. Such measures could be anti-biotechnology in nature and tantamount to voluntary exclusion from the main stream of biotechnology development. The pathways of reasonable flexibility appear to be the best approach to national regimes regarding the issue of AIA.[156] Kenya's law should maintain this standard by ensuring the following.

5.2.1 Capacity Building

Capacity in Kenya to implement biosafety regulations must be built. This includes putting in place procedures and institutions for the management of compliance problems as well as means to enable Kenya to comply with obligations. It has been shown that non-compliance in the environment arena is primarily due to lack of institutional capacity and also due to bad faith on the part of the implementors.[157] This means intent to deceive, the act of intentionally trying to deceive or mislead another in order to gain some

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[155] *Supra* (note 4 above) Pg 69
[156] *Supra* (note 144 above).,Pg 66
[157] D. Hunter et al., *International Environmental Law and Policy* (Foundation Press, 1998)

advantage.[158] This is why the Authority should be established immediately to carry the statutory functions provided for it.

5.2.2 Political Will

The success of the implementation of a sound biotechnology policy depends on the nature of the political system in place. A favorable political system should allow and guide a harmonious interaction between the scientific and technological activities and institutions on the one hand and the regulatory system on the other. Political space, broadly speaking is required if coherent scientific and technological policies are to be formulated and implemented. Unfortunately the bureaucratic nature of most African political regimes, of which Kenya is included, have divorced science and technology from national development activities. Parliament should be encouraged to develop and implement a strategic plan for communication and outreach that engages diverse stakeholders and the general public.

5.2.3 Regional Biosafety Standards

There have been attempts to establish harmonious regional biosafety standards in East, Central and South Africa since 1993. Although some of the efforts have finally led to the establishment of regional focal points, the development of a harmonized regional biosafety structure has not materialized, a factor attributed to countries in the region being at different levels of development of their national biosafety guidelines.[159] These efforts should be strengthened as neighboring countries are likely to face similar problems and it would be easier to deal with them as a region.

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[158] http://www.duhaime.org/LegalDictionary/B/BadFaith.aspx (accessed on 28 May 2010)

[159] Keizire BB, et al; *Agricultural Biotechnology Assessment in Sub-Saharan African: Country Specific study- Uganda* (August 2000)., ACTS and Rockfeller, Pg 4-5

5.2.4 Public Knowledge and Participation

Public knowledge and participation are vital to ensure that biotechnology and biosafety policies do not conflict with religious and cultural beliefs in society. The public can only make informed decisions if it is well equipped with information. The public need to clearly understand how these policies will be made and that the decision making procedure is rigorously and publicly followed. There should be possibility for members of the public to comment at different stages of risk assessment together with documents describing workshops. Public access to information can also be enhanced by organizing workshops, symposia, seminars and other forms of dialogue among the scientific and civic society on specific biosafety themes, making full use of the existing scientific and technological expertise in the country.[160]

New or revised laws should make provision for the public access to information with regard to release and commercialization of GMOs. There is also a need to create advisory bodies for GMOs, which should include all stakeholders and representatives of scientific and technological institutions, national academies of sciences, industry and representatives of public interests groups concerned with the protection of public health and the environment. It is also important for scientists to strive to raise awareness among decision makers like Parliament by organizing public awareness courses and exchange information with the media and disseminate information to government bodies and legislators.[161]

5.2.5 Transparency

Given the breadth of options on GMOs, ranging from beliefs that they are inherently dangerous to beliefs that they are the best hope for continued human survival, it seems that the government with the help of the civil society through non-governmental

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[160] *Supra (*note 144 above), pg 67
[161] *Ibid*

organizations can ensure transparency through public participation and freely available scientific and statistical information in the application of the decision making procedures. The civil society can play a great role by keeping checks and balances on the relevant authority. It is important to ensure maximum transparency, receptiveness and procedural rigour in all decisions involving GMO policy application for GMO use.

5.2.6 Accountability

In all situations that require legal framework implementation, it is essential also to ensure greater accountability in the decision making process. Greater account can be supported clarifying the specific responsibility of particular officials with regard to permit decisions and oversight; specify criteria for decision-making; requiring public disclosure of the rationales underlying each decision taken; providing a right for affected members of the public (in addition to the proponents themselves) to seek judicial or administrative review of decisions.[162]

5.2.7 International, Intergovernmental and Non-governmental support and assistance.

The role of national and international assistance, including specifically on-governmental organizations and international/intergovernmental organization in filling the current information and capacity gaps, by promoting and developing the level of understanding and non-biased scientific capacity need in order to responsibly address these issues can be through; assisting with the development of national and regional frameworks to address biosafety and GMO related issues; promoting *in-situ* conservation of genetic resources; increasing awareness in local communities; building capacity in scientific and administrative departments; developing data and case studies; promoting research and funding in biosafety; and collecting and disseminating information.

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[162] Supra (note 144 above)Pg 37

5.2.8 Creation and Use of Institutional and Legal Frameworks

In light of the fact that the GMO issue is relatively new, there is a need for a broader level of institutional controls to address issues that have not arisen yet, but will arise in the future. In the national legislative arena, there are five key policy venues in which choices made can have a significant impact on the various opportunities and can be incentives for the development, marketing and use of GM crops and other GMOs. They include laws and policies in national biosafety; national trade; national intellectual property rights; food safety, health and consumer choice; and public research. Awareness of the manner in which each of these can be address GMO issue will be a key type of capacity building and help assure responsible decision making and informed public participation.[163]

5.3 CONCLUSION

In sum, the field of biosafety is an area in which much activity is ongoing, even though it is extremely controversial. Proponents identify possible benefits of GMOs that are enormous, including possibilities such as hunger alleviation, and universally available medical care, within our lifetimes. Counter-arguments identify a level of possible risks well beyond anything that has ever been deemed 'acceptable' in the past.[164]

It is essential that decision-makers demonstrate a strong commitment to the position that, in the absence of sufficient certainty surrounding the commercial application of modern biotechnology, preventive and precautionary measures based on risk assessment and management are called for at all international and national levels to ensure biosafety. As Kenya endeavors to undertake in biotechnology and biosafety issue, the bottom line must

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[163] *Ibid*

[164] Bjom Lomborg (a non-scientist statistician, who achieved fame by publishing his belief that the concerns of modern environmentalists are generally spurious) has suggested the need for more information and a regulatory framework for GMOs noting that "choosing sensibility in the GM debate requires us to see the risks but also to compare them thoughtfully with all other risks...it is only with this information that we can weigh the risks and benefits in order to make an informed decision" Lomborg B. '*The Skeptical Environmentalist*" (Cambridge University Press, 2001) Pg. 346

remain the protection of the environment and human health and the promotion of biotechnology research and development.

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