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TOWARDS AN INTEGRATED REGULATORY FRAMEWORK FOR GENETICALLY MODIFIED ORGANISMS IN KENYA

BY

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STUDENT'S DECLARATION

I, the undersigned, declare that this is my original work and has not been submitted to any other college, institution or university other than the University of Nairobi for academic credit.

Signed: _____ Date: 30/11/07.

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This project paper has been presented for examination with my approval as the appointed Supervisor.

Signed: _____ Date: 30/11/07

Prof. Patricia Kameri-Mbote

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DEDICATION

I dedicate this work to my loving family.

ABBREVIATIONS

ABSP	Agricultural Biotechnology Support Project
Bt	Bacillus thuringiensis
CMD	Cassava mosaic disease
CAC	Codex Alimentarius Commission
CBA	Cost Benefit Analysis
CPLA	Crop Production and Livestock Act
DNA	Deoxyribonucleic Acid
DVS	Department of Veterinary Services
EIA	Environmental Impact Assessments
EMCA	Environmental Management and Coordination Act
FDCSA	Food, Drugs and Chemical Substances Act
FEWS-NET	Famine Early Warning Systems Network
GM	Genetic Modification / Genetically Modified
GMOs	Genetically Modified Organisms
IRMA	Insect Resistant Maize for Africa Project
IBC	Institutional Biosafety Committee
CIAT	International Centre of Tropical Agriculture
CIMMYT	International Maize and Wheat Improvement Centre
IPPC	International Plant Protection Convention
ISAAA	International Service for the Acquisition of Agri-biotech Applications
KARI	Kenya Agricultural Research Institute
KBC	Kenya Biodiversity Coalition
KEBS	Kenya Bureau of Standards
KEPHIS	Kenya Plant Health Inspectorate Service
KESSFF	Kenya Small Scale Farmers Forum
LMOs	Living Modified Organisms
MSTQ	Metrology, Standards, Testing and Quality Management
NBA	National Biosafety Authority

NBC	National Biosafety Committee
NCC	National Codex Committee
NCST	National Council for Science and Technology
NEMA	National Environment and Management Authority
OQS	Open Quarantine Site
PPA	Plant Protection Act
R&D	Research and Development
SEA	Strategic Environmental Assessments
SPFMV	Sweet Potato Feathery Mottle Virus
SPS	Sanitary and Phytosanitary Measures
SPVA	Seeds and Plant Varieties Act
UNCTAD	UN Conference and Trade and Development
UNDP	United Nations Development Programme
VR	Virus-Resistant
WTO	World Trade Organization

1.0 CHAPTER ONE

1.1 BACKGROUND TO THE PROBLEM

The objective of this research is to analyse the regulatory framework governing genetically modified organisms (GMOs) in Kenya. This chapter will set out the parameters that guide the subsequent research into the adequacy of the regulatory framework governing biotechnology in Kenya and specifically the aspect of GMOs in agriculture and the attempt to make recommendations for an integrated framework.

Biotechnology refers to 'an emerging knowledge intensive field' which 'is a set of enabling techniques for bringing about specific man-made changes in deoxyribonucleic acid (DNA) or genetic material in plants, animals and microbial systems leading to useful products and technologies'.[1] Genetic Modification (GM)[2], a subset of biotechnology, is a special set of technologies that alter the genetic makeup of such living organisms as animals, plants, or bacteria. Combining genes from different organisms is known as recombinant DNA technology, and the resulting organism is said to be "genetically modified," "genetically engineered," or "transgenic."[3]

GM Technology is distinguished from conventional plant breeding, in that it provides a more efficient means of isolating genes. Further, it involves the transfer of the isolated and cloned genes into the DNA, usually the chromosomal DNA, of another organism which need not belong to the same species as the organism from which the genes are

[1] United Nations, *Agenda 21*, Preamble to Chapter 16, <http://www.igc.org/habitat/agenda21> 1992 (accessed 20 May 2007).
[2] The abbreviation GM in this study is also used to mean genetically modified depending on the context
[3] US Government, Department of Energy, Office of Science <http://www.ornl.gov/sci/techresources/Human_Genome/elsi/gmfood.shtml> (accessed 16 May 2007).

drawn. For instance, genetic material of bacteria and viruses is transferred into the genetic makeup of crop plants such as maize and cotton.

GM is regarded as a potential revolutionary tool in the development of nations.[4] At the Rio de Janeiro Conference on Environment and Development in 1992, its potential benefits particularly for developing countries were recognized as including:

a. Increasing the availability of food, feed and renewable raw materials;
b. Improving human health;
c. Enhancing protection of the environment;
d. Its capacity to act as a vehicle for achieving national development[5]

There is currently no scientific consensus on the adverse effects of GMOs. However, scientific evidence points conclusively to uncertainty in the long term effects of GMOs to human and animal health and on the environment.[6] Some of the potential risks of GM include:

- The danger of unintentionally introducing allergens and other anti-nutrition factors in foods
- The likelihood of transgenes escaping from cultivated crops into wild relatives
- The potential for pests to evolve resistance to the toxins produced by GM crops
- The risk of these toxins affecting non-target organisms[7]

Kenya is among several other African countries currently undertaking GM research activity. Field trials on a GM maize strain resistant to the stem borer pest are at an

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[4] United Nations Conference and Trade and Development (UNCTAD), *The Biotechnology Promise: Capacity Building for Participation by Developing Countries in the Bio-economy*, United Nations, New York and Geneva, 2004 p.16.

[5] Ibid p xi

[6] International Council for Science (ICS), *Report on Genetically Modified Organisms* <http://www.icsu.org/1_icsuinscience/GMO/PDF/ICSU%2003%20Full%20Report.pdf> 2003 (accessed 14 November 2007)

[7] Government of Singapore, 'Genetically Modified Organisms', *Genetic Modification Advisory Committee (GMAC) Report* <http://www.gmac.gov.sg/faq/gmo.html> (accessed 14 November 2007).

advanced stage.[8] There is also GM research activity taking place with respect to other crops such as the sweet potato, cassava and cotton[9]. Apart from this GM research activity, GM foods have found their way into Kenya through food aid and food imports.

Despite the presence of GM research activity and food with GM content, there is currently no Act of Parliament in Kenya that explicitly deals with the regulation of GM crop technology. The Biosafety Bill 2007 is the closest attempt at an explicit legislation to govern GM issues.[10] Nevertheless, the Bill which, has been debated since 2003 is yet to become law.

Regulation presently is achieved though the use of legislative Acts that implicitly refer to GM technology such as the Science and Technology Act, the Standards Act, and the Food, Drugs and Chemical Substances Act. A set of administrative guidelines are the primary instrument used in the regulation of the ongoing GM research. In September 2006, the government of Kenya approved a national policy intended to guide the research and development in modern biotechnology products in various fields such as agriculture, environment, human health, trade and industry.[11]

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[8] Mary Onsongo, 'Kenya Biotechnology Report 2006', *Global Agriculture Information Network (GAIN) Report*, No. KE6006, 2006, p.3<http://www.fas.usda.gov/gainfiles/200608/146208638.pdf.> (accessed 20 September 2007).

[9] Wiley, Verlag, GmbH & Co., KGaA, Weinheim, 'Biotech Status in Africa', Biotechnology Journal, 2, 2007 p 22 <http://www3.interscience.wiley.com/cgi-bin/fulltext/114066373/PDFSTART> (accessed 19 November 2007)

[10] Government of Kenya, *The Biosafety Bill 2007*, Memorandum of Objects and Reasons, p 47 <http://www.kenyalaw.org/Downloads/Bills/Biosafety%20Bill%202007%20(Revised).pdf> (accessed 21October 2007)

[11] Government of Kenya, The Kenya National Biotechnology Policy 2006

In the face of the potential benefits of GM crop technology and the likely adverse effects, governments all over the world recognize the need to regulate GM technology to minimise negative impacts and maximise potential gains to be drawn from the new technology. There is a need for Kenya to develop an integrated regulatory framework to achieve this goal.

1.2 STATEMENT OF THE PROBLEM

This research project investigates the adequacy and appropriateness of the existing legislative and institutional framework as well as the proposed Biosafety Bill in governing the use and commercialization of GMOs in Kenya. It will also evaluate the capacity of the framework to ensure GM technology meets Kenya's developmental needs.

1.3 LITERATURE REVIEW

The establishment of regulatory frameworks is a challenge that legislators all over the world have to contend with. Mandel points to some of the difficulties that the law has in adapting to biotechnology advances.[12] It is interesting to note that even in the United States the regulatory system governing biotechnology advances is still highly fractured and inefficient. Appreciation of their experiences provides useful insight, albeit the distinct circumstances, for developing countries such as Kenya who are in the process of creating regulatory systems for biotechnology *de novo*.

Some work has been done in the field of biotechnology regulatory frameworks for developing countries. Kinderlerer discusses the needs and burdens for developing

[12] Gregory Mandel, 'Gaps, Inexperience, Inconsistencies and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals', *45 WM. & Mary L. Rev.* 2167, 2004, p 2191

countries.[13] He points out that a GMO regulatory framework does not necessarily imply the need for new explicit laws. There may well be legal systems in place that address or have the potential to address GMOs. The present research appreciates this and seeks to evaluate the adequacy of such a system in balancing the environmental concern with the development agenda.

Clark et al expound on the execution of public policy towards the agricultural biotechnology for human development and food security in Africa.[14] The monograph is based on an empirical investigation of biotechnology and biosafety policy issues in Kenya, Uganda and South Africa. The work studies the status of food security in the three African countries and in this context discusses the need for a facilitative biotechnology policy environment. This project recognises the existence of a biotechnology policy in Kenya and so seeks to evaluate the regulatory framework in place to determine if it is capable of tackling issues of environmental concern while solving the problem of food security as anticipated in the biotechnology policy.

Research has been undertaken on the development of biosafety regulation in Africa with a view to determining the compliance of national laws with the International Biosafety Protocol. Kameri-Mbote analyzes the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and identifies its implications on the domestic laws of African

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[13] Julian Kinderlerer, 'Regulation of Biotechnology: Needs and Burdens for Developing Countries' 2002 <http://www.unep.ch/biosafety/development/devdocuments/BTregulationJK.pdf> (accessed 17 May 2007)

[14] Norman Clark, John Mugabe and James Smith, *Governing Agricultural Biotechnology in Africa*, (Africa Centre for Technology Studies (ACTS) Nairobi, Kenya 2005) <http://www.acts.or.ke/pubs/books/docs/MacAthur%20Book.pdf> (accessed 7 September 2007)

countries.[15] She analyses the extent to which African biotechnology laws incorporate the biosafety provisions made in the Protocol and makes recommendations for the improvement of the legal and administrative frameworks for biotechnology in developing countries. The current research moves this discussion from the general African level to the Kenyan situation.

Wakhungu et al lay the foundations for the analytical exposition carried out in this work regarding the socio-economic impacts of agricultural biotechnology.[16] Their work seeks to highlight the need for fair and equitable distribution of the benefits of development in this sector. They propose a conceptual framework that ought to guide policy makers in the establishment of regulatory frameworks to govern Bt Cotton introduction in Kenya. The study is driven by the premise that the policy, institutional and regulatory context in which Bt cotton has been introduced is extremely fundamental and will to a large extent determine whether cotton farmers will reap the benefits or not. This project paper has a wider scope in that it is not limited to Bt cotton but rather analyses the adequacy and appropriateness of the regulatory system for Bt cotton GM maize as well as other future GM crops.

Kameri-Mbote carries out an analysis of the regulation of GMO crops and food using Kenya as a case study.[17] This work constitutes a comprehensive report on the status of

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[15] Patricia Kameri-Mbote, 'The Development of Biosafety Regulation in Africa in the Context of the Cartagena Protocol: Legal and Administrative Issues', *RECIEL* 11(1) 2002

[16] Judi Wakhungu and David K Wafula, *Introducing Bt Cotton Policy Lessons for Smallholder Farmers in Kenya* (Africa Centre for Technology Studies, Nairobi, Kenya 2004)

[17] Patricia Kameri-Mbote, 'Regulation of GMO Crops and Foods: Kenya Case Study 2005', <www.law.nyu.edu/centers/elc/programs/Kenya%20GMO%20220805.DOC> (accessed 25 August 2007)

GMO regulation in Kenya as at 2005. A summary of the status of GMO activity in the agricultural sector as at 2005 is given. The current works incorporates new developments in the realm of GM activity and regulation since 2005. Further, this work constitutes an evaluation of the existing regulatory framework on the basis of identified standards.

Andanda evaluates the attempts that have been made to develop legal regulatory frameworks for modern biotechnology in South Africa and Kenya.[18] She sets as the benchmark for this analysis the international regime. In the paper, the law governing GMO technology is evaluated from public policy and legal perspectives. She proposes important factors that ought to be considered in developing appropriate regulatory frameworks for biotechnology. She concludes that a holistic approach should be used in addressing the pressing issues that are raised by biotechnology generally and GMOs in particular. The present work builds on this idea of a holistic approach and seeks to evaluate the existing regulatory framework in Kenya to determine if it meets specific parameters proposed in this work as the marks of a good biotechnology law.

Harsh concludes from his research into agricultural biotechnology in Kenya, that formal governance in the form of national institutional and policy developments has been loosely coordinated and largely reactive, both in terms of bio-safety and in terms of setting national priorities.[19] He observes that modern biotechnology developments in the country

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[18] Pamela Andanda, 'Developing Legal Regulatory Frameworks for Modern Biotechnology: The Possibilities and Limits in the Case of GMOs', *African Journal of Biotechnology* Vol. 5 (15), 2006 pp. 1360-1369,

[19] Matthews Harsh, 'Formal and Informal Governance of Agricultural Biotechnology in Kenya: Participation and Accountability in Controversy Surrounding the Draft Biosafety Bill', (John Wiley & Sons, Ltd. Edinburgh, UK 2005)

have been driven primarily by public-private partnerships. He argues there is a vacuum in the formal state mechanisms for governance of biotechnology. The author analyses the Kenya Biosafety Bill 2005, and its potential to result in increased accountability and open participation of farmers and the public. This research appreciates the importance of public participation and uses it as a benchmark to determine the adequacy of the regulatory framework for GMOs.

This research, as evidenced from the foregoing review, is distinguished from other literature on the subject by virtue of its being a specific study on the Kenyan regulatory framework governing GM crop technology as at 2007. Biotechnology and in particular GM technology is a fast progressing science. As a result, there have been significant changes in GM crop research and in the regulatory structures since 2005 when a comprehensive analysis of the Kenyan regulatory system on GMOs was conducted by Kameri-Mbote.[20]

More importantly, this research is distinguished from other researches in the area on the basis of the perspective adopted. This paper sets out to analyze the regulatory framework governing GMOs in Kenya using a unique methodology. The methodology adopted for the analysis is the determination of the adequacy and appropriateness of the framework using specific criteria identified as mandatory for a good GMO law. Most of the work done on the regulatory framework has been premised on the implicit idea that the true mark of a good GMO framework is its embodiment of the principles set out in the international laws on biosafety to which Kenya is a signatory and more particularly to the

[20] Kameri-Mbote 2005 above note 16

Cartagena Protocol. This paper recognizes the importance of the incorporation of the international biosafety law principles and in fact uses the precautionary principle the main tenet of the Cartagena Protocol as a criterion for evaluation of the GMO framework.

The novelty in approach lies in the use of an additional and more encompassing criterion for purposes of evaluating the Kenya GMO regulatory framework. The developmental potential of the framework is counter-balanced with the precautionary principle as proposed by the concept of sustainable development. This attempt at integrating the precautionary principle in the context of the sustainable development agenda distinguishes it from the literature analyzed in the foregoing.

1.4 OBJECTIVES OF THE RESEARCH

1.4.1 General Objective:

- Determine the adequacy and appropriateness of the regulatory framework governing the use and commercialization of GM crop technology in Kenya.

1.4.2 Specific Objectives:

a. Identify the existing legislative and institutional framework governing the use of GMOs in Kenya and determine if this is adequate in so far as the requirements of the precautionary principle are concerned

b. Determine if the existing legislative and institutional framework governing the use of GM crop technology is appropriate in so far as it facilitates the achievement of Kenya's developmental needs

c. Determine if the proposed Biosafety Bill adds value to the existing framework

d. Make recommendations if necessary for an integrated regulatory framework that is in keeping with Kenya's developmental needs

1.5 BROAD ARGUMENT STRUCTURE

An ideal biotechnology regulatory framework is one that balances the competing concerns of environmental protection, economic development and social development. Such a framework must integrate the precautionary principle so as to adequately protect human and animal health and the environment while facilitating the use of GM technology to contribute to sustainable development of the particular country. The existing framework and proposed legislation in the form of a Bill are evaluated to determine if they constitute an appropriate and adequate framework for the regulation of GM crop technology in this context.

1.6 ASSUMPTIONS OR HYPOTHESES

1. The current framework is inadequate in regulating GMO use and commercialization in so far as it does not adequately incorporate principles of the precautionary approach
2. The existing framework is inappropriate for ensuring that GM crop technology contributes to Kenya's developmental needs in so far as it is not integrative
3. The National Biosafety Bill 2007 forms the basis upon which the future legislation on GMOs will be enacted
4. The proposed framework envisaged by the Bill does not adequately address the issues of protection of the environment and does not ensure that GM technology will contribute to sustainable development in Kenya.

1.7 RESEARCH QUESTIONS

1. Does the current framework used to govern the use and commercialization of GMOs effectively incorporate the precautionary principle?
2. How effective is the framework in ensuring that GMOs contribute to sustainable development in Kenya?
3. Is there an effective institutional mechanism to enforce the legislation governing GMOs?
4. Is the proposed regulatory framework more adequate and appropriate than the existing framework?

1.8 METHODOLOGY

This research involved two main research methodologies that is literature review and field study. The field research took the form of informal interviews of different players in the biotechnology sector in Kenya particularly scientists involved in biotechnology and representatives from government agencies involved in the regulation of GMOs.

The literature review was sourced from:

- Library research
- Internet searches
- Analysis of archived data

1.9 CHAPTER BREAKDOWN

1. Introduction

2. A Conceptual Framework for Regulation of GMOs
   2.1. Overview of Regulation
   2.2. Regulating for Sustainable Development
   2.3. The Regulatory Framework Development Process

2.0 A CONCEPTUAL FRAMEWORK FOR REGULATION OF GMOs

2.1 OVERVIEW OF REGULATION

One of the primary roles of present day government is regulation. Regulation refers to the subset of governance that is about steering the flow of events and behavior.[21] This stewardship by government over particular activities is geared towards the achievement of particular goals deemed to be paramount to the public good. The goals are achieved through the establishment of regulatory frameworks. A regulatory framework comprises of an institutional structure as well as the rules prescribing certain behaviours or outcomes.[22]

Regulation has been classified into three main types: economic, social and process regulation.[23] Economic regulation refers to the process by which the government seeks to govern entries into the market through for instance, the restriction on prices or quantities. Process regulation refers to the government's management of the operation of the public and private sector. Social regulation, the ambit within which GMO regulation is situated, is the regulation affecting a wide array of areas including the environment, safety and public health.[24]

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[21] Editor's Introduction, 'Can Regulation and Governance Make a Difference?' *Regulation and Governance Journal* 2007,No. 1 p.3

[22] Peter J. May, 'Regulatory Regimes and Accountability' Regulation and Governance Journal No.1 2007 p 8

[23] J. Luis Guasch and Robert W. Hahn, 'Costs and Benefits of Regulation: Some Implications for Developing Countries', World Bank Policy Research Working Paper No. 1773, March 1997 <http://ssrn.com/abstract=615039> (accessed 27 November 2007)

[24] ibid

The last three decades have been characterized by a rise in regulation related to the environment, public health and safety. In an era where legal economists have advocated for the deregulation of various sectors of the economy, the suitability of such regulation may be called into question. Various arguments may be put forward to justify government regulation. In the realm of economics, regulation has been encouraged as the means to rectify market failures. The primary argument in favour of environmental regulation is that the environmental realm is characterized by externalities and thus individuals and firms are unlikely to take into account the full social costs of their actions in this area without the intervention of the government.[25] This justifies government involvement and explains the tendency of governments to develop regulatory frameworks in a bid to protect the environment.

Government regulation must nevertheless be subject to evaluation. For just as the market is prone to numerous instances of market failure, there is also the risk of 'government failure'.[26] Regulation must thus be evaluated to determine its adequacy and appropriateness in meeting the objectives it set out to achieve in the course of its establishment. An evaluation of a GMO regulatory framework entails the determination of the objective sought by the regulation and the regulation's efficiency in attaining this objective. An adequate and appropriate framework is one that facilitates the achievement of the objective sought by the policy makers in its development.

[25] Guasch & Hahn, above note 22
[26] ibid

2.2 REGULATING FOR SUSTAINABLE DEVELOPMENT

At the root of the controversy surrounding the use and commercialization of biotechnology and in particular GMOs in agriculture, are two important concerns. Firstly, the ecological and human health risks posed by the planting of GM crops are not definitively known.[27] This has led to a general suspicion of GMOs leading to their description particularly by anti-GMO activists as "Genetically Mistrusted Organisms".

Secondly, and in contrast, the prohibition or restricting of genetically modified crops creates its own significant risks including hunger and starvation, or at the very least the loss of a developmental opportunity. [28] This is because GM crop technology has an undeniable potential in reducing the losses in production yield caused by pesticides, and increasing production through the development of stronger crop varieties. There is the further apprehension that the benefits accruing from GM technology may not be equitably distributed among its potential beneficiaries such as the research companies involved in the development of GM seeds, the subsistence farmers, and the general public.[29]

These concerns demonstrate the need to establish a balance between development and environmental conservation through regulation a task that environmental legislators have been battling with over the years. The Brundtland Commission is credited as having made a significant contribution to the resolution of this problem through its

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[27] Mandel 2004 above note 11

[28] Robert Paarlberg, The Politics of Precaution: Genetically Modified Crops in Developing Countries, (Baltimore: John Hopkins University Press, 2000)

29 Concerns raised in the Declaration by Kenya Small Scale Farmers Forum on August 20, 2004 <http://biotech.indymedia.org/or/2004/08/3316.shtml> (accessed 20 May 2007)

popularisation of the concept of sustainable development.[30] Sustainable development is a dynamic concept that has evolved significantly from its nascent formulation; a development that "meets the needs of the present generation without compromising the ability of future generations to meet their own needs".[31]

Presently, the concept of sustainable development embraces the main concerns illustrated in the GM debate; environmental protection, economic development and social development.[32] These concerns have become constituent parts of the concept and are regarded as its reinforcing pillars. The new paradigm of sustainable development establishes linkages across developmental needs such as poverty alleviation, food security, and environmental concerns including the preservation of the environment and the sustainable use of natural resources. It also seeks to ensure a better quality of life for everyone not only at present but for the future generations too.[33]

The World Summit on Sustainable Development in Johannesburg, in 2002, not only reiterated this wider concept of sustainable development but also recognised the obligation on the part of policy makers at the international, regional and local level to use this concept as the foundation of policy making.[34] Despite this political commitment, the incorporation of the concept into policy continues to be a challenge to many policy

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[30] United Nations, 'Our Common Future', *Report of the World Commission on Environment and Development,* Annex to General Assembly document A/42/427<http://www.un-documents.net/ocf-02.htm#I,> 1987 (accessed 16 November 2007)
[31] Ibid
[32] United Nations, Johannesburg Declaration on Sustainable Development, (2002) A/CONF.199/L.6/Rev.2 <http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/POI_PD.htm> (accessed 16 November 2007)
[33] United Nations, 'What is Sustainable Development', <http://www.unesco.org/education/tlsf/TLSF/decade/uncomESDt04.htm> (accessed 16 November 2007)
[34] ibid

makers, as not only is it difficult to anticipate the needs of future generations but even within the present generation it is often not easy to achieve equitable development across the social structure of a nation or region. The problem for policy makers is further compounded where the decisions sought to be made involve novel and complex technologies such as GM.[35] The policymakers have to contend in such circumstances with differing opinions ranging from those averse to the use of the new technologies due to the risks associated with it, and those who regard such aversion as the sure recipe for losing the developmental opportunity created by GM technology.

Despite the efforts by policy makers to integrate the sustainable development concept into policy making, it is argued that there continues to be a clear inconsistency between the central ethic of sustainable development, as espoused in many government policy statements and the means to achieve sustainable development such as regulatory frameworks governing biotechnology.[36] Biotechnology issues are of a complex nature in so far as they affect the environment where an intricate interplay of factors and interactions occur. This results in difficulties in establishing criteria and mechanisms for decision-making.

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[35] John Patterson, 'Sustainable Development, Sustainable Decisions and the Precautionary Principle', *Journal of the International Society for the Prevention and Mitigation of Natural Hazards*, <http://www.springerlink.com/content/n2xu545621643th5/fulltext.html>2007 (accessed 16 November 2007)

[36] See for example Sharon Beder, 'Costing the Earth: Equity, Sustainable Development and Environmental Economics', *New Zealand Journal of Environmental Law*, 4, 2000, pp. 227-243.

In the face of such difficulties, governments are advised to employ the precautionary principle as the driving vehicle for achieving sustainable development.[37] The precautionary principle can be a valuable aid to sustainable development.[38] It facilitates the integration of the environmental concerns with the development process where there is inadequate scientific evidence. Where there is uncertainty, the principle forbids states to use lack of full scientific evidence to postpone their obligation to take cost effective measures to mitigate the risks. It thus balances the need to protect the environment with the avoidance of expensive measures, which can become an unbearable burden particularly to developing countries.[39]

The use of the precautionary principle as a tool for achieving sustainable development raises several issues. Firstly, the principle suffers from definitional problems. Secondly, its suitability as a decision-making tool is disputed.[40] In order to make the case for the precautionary principle as the measure of a GMO law, these issues must first be addressed.

The definition of the precautionary principle is problematic. The principle has taken various forms as elucidated by Sunstein one of its strongest critics.[41] In its weakest form, the precautionary principle would result in a policy providing, that lack of decisive evidence of harm should not be ground for refusing to regulate. Such a weak construction

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[37] UN, Rio Declaration on Environment and Development, *Report of the UN Conference on Environment and Development*, A/CONF.151/26 (vol. I); 31 ILM 874, 1992, Principle 15

[38] UN, Bergen Ministerial Declaration on Sustainable Development in the ECE Region, (1990) Doc. A/CONF.151/PC/10,

[39] Sumudu Atapattu, 'Evolution and Status of the Precautionary Principle in International Law', *The American Journal of International Law*, Vol. 96, American Society of International Law, 2002 p 1016

[40] Cass Sunstein, *Laws of Fear: Beyond the Precautionary Principle*, (Cambridge University Press 2005)

[41] ibid

is likely to be empty and thus useless in establishing a standard of protection. In contrast a strong precautionary principle is demonstrated for example by a proposition that action should be taken to correct a problem as soon as there is evidence that harm may occur, not after the harm has already occurred. An extreme approach such as this one would have the effect of halting all progress in technology. In this research I adapt the Wingspread definition of the concept, which definition states that: 'when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.'[42]

In so far as it is proffered as a tool for decision-making by policy makers, the precautionary principle is often pitted against the Cost Benefit Analysis (CBA) tool.[43] Mandel et al in reviewing Sunstein's book on the issue of CBA recognize the interesting and innovative arguments he makes for the CBA approach. Sunstein argues that weak forms of the precautionary principle are tautological, and that strong forms offer no guidance because they caution against risk, but risk is usually present on all sides of responses to threats.[44] However, the CBA is not the ideal substitute for the precautionary principle. It has inherent attributes that render it ill suited for acting as a benchmark in determining the approach to take in cases of scientific uncertainty of the effect of certain

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[42] Greenspeace and Others, 'Wingspread Statement on the Precautionary Principle', *Science and Environmental Health Network Report* <http://archive.greenpeace.org/toxics/reports/gopher-reports/precaut.txt> (accessed 17 November 2007)

[43] Gregory Mandel and James Gathii, 'Cost Benefit Analysis versus the Precautionary Principle: Beyond Cass Sunstein's Laws of Fear', *University of Illinois Law Review*, Vol. 2006

[44] ibid p1038

activities on the environment.[45] CBA lays emphasis on tangible costs and benefits and fails to recognize the importance of the intangible variables. In the face of the uncertainties present in case of environmental issues, it could not be a successful tool because the issue of our responsibility to present and future generations is too poorly understood and too little accommodated in the current economic theory. Further, the precautionary principle is better suited in so far as it includes the concept of equity into development by cautioning against the postponing of costs to forestall adverse effects in future.

Having clarified the nature of the precautionary principle, the need for its application to decision making at the policy level becomes less contentious. As all governments face the dilemma of uncertainty, the focus ceases to be whether precautionary measures are being taken but rather shifts to what issues, on what basis, and with what safeguards the principle should be incorporated into regulation to avoid arbitrary action.[46]

2.3 THE REGULATORY FRAMEWORK DEVELOPMENT PROCESS

One of the fundamental considerations in the evaluation of regulation is the degree and quality of the public's involvement in the process of its development.[47] Regulatory reform efforts tend to lay great emphasis on public participation in the process of formation of regulatory frameworks. Increased participation of the public is viewed as a

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[45] Gary Bryner, 'Beyond Cost Benefit Analysis, Promoting Ecological Sustainability in Natural Resource and Environmental Agencies in the United States', *in Proceedings of the Berlin Conference on Human Dimensions of Global Environmental Change*, November 2006, <http://web.fu-berlin.de/ffu/akumwelt/bc2006/papers/Bryner_Beyond.pdf> (accessed 31 October 2007)

[46] Centre for International Sustainable Development Law (CISDL), 'Precaution in International Sustainable Development Law', *Legal Brief for the World Summit on Sustainable Development*, 2002

[47] Steven J. Balla and Benjamin M. Daniels, 'Information Technology and Public Commenting on Agency Regulations' *Regulation and Governance Journal*, No.1 2007 p. 46

demonstration of democracy and a means of improving the quality of decision making. The public in this context includes; the multinational biotechnology companies who have a direct economic interest in GM activity, farmers; both large scale and small scale subsistent farmers affected by the introduction of GM crop activities, reputable non governmental organisations (NGOs) which advocate for ecological interests, and the media in its role as the fourth estate and shaper of public opinion.

However, political theorists have over the years pointed out that there are instances where the participation of the public does not always serve the interests of the public good.[48] Plato, for instance, referring to political governance recommended that a select elite should govern in view of the monopoly of skills and knowledge they enjoy.[49] Plato's views gain credence in cases where the public are ignorant or misinformed regarding the subject matter of the regulation, as is the case with GMOs.

In the context of Plato's argument and the regulation of GMOs, the precautionary principle has been indicted for its holding science "hostage to interest group politics".[50] This struggle between science and other 'interest groups' is particularly manifest in the proliferation of non governmental organizations, and lobby groups against GMOs.[51] These lobby groups frequently use the precautionary principle as the weapon of attack. Scientists argue that by their very nature, scientific approaches never claim certainty and

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[48] Jim Rossi, 'Participation Run Amok: The Costs of Mass Participation for Deliberative Agency Decision Making', *Northwestern University Law Review*, Vol. 92 No.1 1997 p 177

[49] Plato, The Republic, cited in Rossi, J ibid

[50] G Charnley, Donald Elliott E, 'Risk Versus Precaution: Environmental Law and Public Health Protection', *Environmental Law Report*, 32(2), 2002 pp 10363–10366

[51] In Kenya these groups are organized under a coalition referred to as the Kenya GMO Concern (KEGCO)

therefore it would be fatal to postpone all scientific progress pending full scientific evidence. They thus urge policy makers to ignore such views and base decision making and regulation on scientific views.

Apart from the politics of interest groups, scientists also accuse policy actors of hijacking the agenda of science, through the manipulation of the precautionary principle.[52] This perceived manipulation by the law of science has led to the questioning of the place of law in the science and technology realm, bringing into focus the question of the nexus between law, science and technology.

According to Majone the European Commission (EC) is the best example of a policy maker guilty of manipulating the precautionary principle at the expense of unscientific pressures.[53] He argues that the EC has used the precautionary principle in its dealings with the World Trade Organisation (WTO) to frustrate scientific progress. This in his view is a clear case in which the EC has bowed to political pressures of its member states and citizenry who are undoubtedly against GMOs at the expense of science. The accusation formed the subject of a WTO's dispute panel ruling in 2006. A complaint was brought by the USA, Argentina and Canada on the EC's moratorium on approval of GMOs and member state bans on certain GMOs. The moratorium it was argued was a misapplication of the precautionary principle in a bid to bar trade.[54]

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[52] Sandin et al above note 40

[53] G Majone, 'What price safety? The precautionary principle and its policy implications', *Journal of Common Market Studies* 40(1), 2002, pp 89–109 cited in Sandin (2002)

[54] Gene Watch, Briefing Note on Report of the Dispute <www.genewatch.org> (accessed 20 September 2007) gives a comprehensive explanation of the result of the Panel's ruling.

The influence of 'biopolitics'[55] in the development of biotechnology regulatory frameworks in the EU and other countries is undeniable. The current distinction between EU regulations and the US regulations on GMOs is to a large extent a manifestation of this fact. The overall public opinion of GMOs in the EU is perceived as negative explaining the stringent regulations over GMOs. This is not only not undesirable but is in fact a manifestation of a good regulatory framework in so far as it reflects a functioning democracy, in which public perceptions affect public policy processes including the development of regulatory frameworks.

Further as Sandin et al point out a distinction must be made between 'unscientific' and non-scientific.[56] The fact that a policy decision is based on non-scientific considerations does not qualify it as 'unscientific' or irrational. The concept of sustainable development depends for its successful achievement on an integrative decision making process that involves all considerations impacting on GMOs including those of a non scientific nature. The precautionary principle is thus an ideal tool for ensuring that the regulatory formation process is participatory and integrative.

This paper will thus seek to analyze the process by which the regulatory framework governing GMOs in Kenya has been developed to determine if it is participatory and thus integrative of the concept of sustainable development.

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[55] SH Morris and CC Adley, 'Evolving European GM regulations: An Example of Biopolitics at Work', *Trends in Biotechnology* 2000, 18:325-326. They define the term as a catch phrase defined as the politicization of modern biotechnology issues within the political stream, which can influence public policy at local, national, and international levels

[56] Sandin et al 2002 above note 40

2.3.1 Law and Policy

A regulatory system for biotechnology needs to have sufficient legal authority to ensure that its legitimacy particularly, in enforcing precautionary measures is not challenged.[57] This legitimacy is granted by the source of the legislation which could be Parliament in the case of statutes or the enabling Act in the case of delegated legislation. The regulatory framework is dependent for its efficient functioning on the institutions mandated to enforce it.[58] The legitimacy of the enforcement role of such institutions is founded on the parent statute that establishes the institution.

The term 'policy' must be distinguished from law understood as a binding legislative norm. The term policy refers to a design or scheme. In the context of regulatory frameworks, policy refers to the structure upon which legislation on a particular matter will be developed.

Strictly speaking policy statements have no binding force in law and should therefore not be regarded as part of the content and structure of a regulatory framework. However, policy has acquired great importance in so far as it constitutes a transition mode of rule-making. In the absence of clear and explicit legislation on a subject matter, policy statements form the basis of determining the direction the development of the regulatory framework is likely to take.[59] The use of policy statements as guidelines for developing regulatory frameworks is particularly useful where the subject matter in question involves

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[57] Pew Initiative on Food and Biotechnology: *Issues in the Regulation of Genetically Engineered Plants and Animals*, (Washington, D.C 2004)

[58] Mancur Olson Jr, 'Big Bills Left on the Side Walk: Why Some Nations are Rich and Others Poor', *Journal of Economic Perspectives*, Volume 10, No 2-S/m*nq 1996, pp 3-24

[59] U Mörth, ed, *Soft Law in Governance and Regulation: An Interdisciplinary Analysis*, (Cheltenham, 2004)

complex and diverse problems aggravated by uncertainty.[60] A national biosafety framework[61] therefore includes policy instruments.[62]

An ideal GMO regulatory framework ought therefore to be in congruence with the country's broader biotechnology policy. The biotechnology policy sets the broad objectives of the regulatory regime in place to govern GMOs.[63]

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[60] ibid
[61] Biosafety frameworks focus on GMOs
[62] United Nations Environment Programme-Global Environment Facility (UNEP-GEF), 'UNEP-GEF Projects on Implementation of National Biosafety Frameworks', *Guidance Document*, 2003
[63] ibid

3.0 CHAPTER THREE: GMOs IN KENYA

GMOs have already found their way into the Kenyan scene through two main avenues; firstly, through the unplanned exposure to GM content in food aid and food imports and secondly, through GM crop technology research being undertaken in the country with the objective of improving food security in the country.

3.1 GMOs AND FOOD SECURITY

Proponents of GM crop technology have termed it as revolutionary and absolutely necessary in so far as feeding the growing world population is concerned. An agricultural renaissance in Africa along the lines of Norman Borlaug's 1950s Green Revolution is envisaged. [64]

This concern with feeding a growing population is undoubtedly more acute in Africa. In June 2004, at an international food conference in Ethiopia just prior to an African Union summit meeting, the then UN Secretary-General Kofi Annan observed that roughly one third of all adults in sub-Saharan Africa are currently malnourished.[65] Closer home around 11 million people across East Africa are facing a serious food crisis. The potential value of modern biotechnology, and in particular of gene technology, in helping to achieve Africa's development and food security goals has led some scientists to glorify Crop Biotechnology as the African Green Revolution that Africa has been pinning for.

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[64] Norman Bourlag Nobel Prize Winner, cited in J Greenwood, 'Testimony Regarding Benefits and Future Developments in Agriculture and Food Biotechnology' 2005 <http://www.bio.org/foodag/action/20050614.asp> (accessed 1 November 2007)

[65] Quoted in Robert Paalberg, 'Africa's Food Crisis: Are Genetically Modified (GM) Crops Part of the Answer?' 2007. <http://www.umass.edu/tei/TEI_2005/PDF/PaarlbergGMOarticle.pdf> (accessed 20 October 2007)

An examination of GM crop biotechnology in other countries seems to have indeed revolutionalized agriculture. Many developed countries have recorded great success where farmers have been permitted to plant these first generation GM crops.[66]

Kenya is yet to achieve physical, social and economic access to sufficient, safe, and nutritious foods in a sustainable manner. Top on the list of Kenya's food balance sheet deficit are cereals. Cereals constitute the highest percentage of key food sources for the country. The country's production of cereals is insufficient to meet its food requirements. As a result Kenya's total imports of cereals are relatively high as shown in Table 2 below.

Table 2: Estimated Cereal Import Requirements of East African Countries in 2005/6 (000 tonnes) (Source: FAO/GIEWS)

Country	Marketing year	Commercial purchases	Food aid	Total Commercial and aid	Total import requirements (excl. re-exports)
Kenya	Oct. /Sept.	1 139.6	230.7 1	1 370.3 1	1 182.0
United Republic of Tanzania	Oct. /Sept.	743.8	33.9	777.7	612.3
Uganda	Oct. /Sept.	126.7	243.2	116.5	207.0

As at October 2007, Kenya is among the countries identified by the Food Agricultural Organization as being in crisis in terms of food security and thus requiring external

[66] ibid

assistance.[67] This means that Kenya is likely to continue supplementing its food deficit with food imports and in some cases food aid well into 2008 and beyond.

Given the food security situation, Kenya has embarked on GM crop technology research on some of its major food crops in a bid to boost the production yields of such crops.

3.2 STATUS OF GM CROP TECHNOLOGY IN KENYA

According to the latest report on the global status of GMOs, Kenya is still not among the top 14 mega biotechnology countries.[68] However, the ISAAA report indicates that:

> "10.3 million farmers from 22 countries planted biotech crops in 2006, up from 8.5 million farmers in 2005. Of the 10.3 million, 90% or 9.3 million (up significantly from 7.7 million in 2005) were small, resource-poor farmers from developing countries."[69]

This upward trend of developing country involvement in GM agriculture coupled with the current government support for GM research in Kenya may be a sign that Kenya could well be on its way to joining the ranks of countries growing GM crops over large areas. In the last decade, GM crop technology has been on the rise in the Kenyan agricultural scene. Kenya has in fact become a biotechnology role model in Africa second to South Africa and Nigeria. See Table 3.

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[67] FAO 2007<http://www.fao.org> (accessed 20 October 2007)
[68] Clive James, 'Global Status of Commercialized Biotech/GM Crops: 2006' <http://www.isaaa.org/resources/publications/briefs/35/executivesummary/default.html> (accessed 20 October 2007)
[69] Ibid

Table 3: Biotechnology research projects in selected sub-Saharan African countries (Source GLOVER (2007) [70]

Country	Key institutes with agri-biotech research capacity	Biotech research projects/programmes					
		Total	Type of technology		Area of application		
			GMO	Non-GM	Crop	Livestock	Forestry
South Africa	10	92	42	50	58	8	26
Nigeria	7	72	5	67	72	0	0
Kenya	6	36	10	26	31	1	4
Zimbabwe	6	29	2	27	27	2	0
Ghana	6	28	1	27	25	0	3
Uganda	4	25	3	22	21	3	1
Ethiopia	4	22	0	22	9	6	7
Tanzania	4	22	1	21	13	8	1
DR Congo	2	11	0	11	6	1	4
Malawi	4	10	1	9	9	0	1
Namibia	3	2	0	2	2	0	0

As evidenced from the table above, Kenya is actively involved in several biotechnology research projects. Biotechnology research has been going on for more than a decade now.[71] Most of this research has been undertaken by research institutes in Kenya in collaboration with transnational research giants and with the support of multiple donor agencies.[72] Of these biotechnology projects, there are several GM crop research projects as evidenced by table 4.

[70] Dominic Glover, 'Agri-biotech in Sub-Saharan Africa: Facts and Figures', <http://www.scidev.net/dossiers/indexicfm?fuseaction=specifictopics&dossier=6&topic=190> (accessed 20 October 2007)
[71] Harsh 2005, above note 18, p 662
[72] ibid

Table 4: Biotechnology Status in Kenya as at 2007 (Source: Biotechnology Journal, 2, 2007)

GMO RESEARCH INSTITUTES	HAS LEVEL II BIOSAFETY GREENH HOUSE
R&D on Crops	Gene transformation in tobacco and tomato
	GM Sweet Potato
	GM Cassava
	Extension of GM R&D to Bean Varieties
	BT Cotton
	Bt maize resistant to stem borers

3.2.1 Sweet Potato

The first crop biotechnology to be developed in Kenya was a genetically modified (GM), virus-resistant (VR) sweet potato. This was in 1991 and was the result of the conclusion that a biotechnology approach to virus resistance was the most promising long-term solution for the disease caused by Sweet Potato Feathery Mottle Virus (SPFMV) which is the primary contributor of the loss in sweet potato yield. The project was developed and financially brokered by the International Service for the Acquisition of Agri-biotech Applications (ISAAA). Current research efforts aim to produce a second-generation GM sweet potato variety that is equipped with double protection (*Cp gene* and its *replicase gene*).[73]

3.2.2 GM Cassava

It is estimated that on average 30% of the Cassava harvest in Africa is destroyed by Cassava mosaic disease (CMD). During the 1990s a pandemic of an unusually severe

[73] Africa Harvest Biotech Foundation International (AHBFI), Press Release of 8 March 2004, <http://www.ahbfi.org/sweetpress1.htm> (accessed on 25 August 2007)

form of CMD found its way into East Africa. In Kenya the western region was the worst hit.[74] The Danforth Centre, a not for profit research institute based in the United States, began working to develop and deliver disease-resistant cassava to Africa through four separately funded projects. In 2006, the Danforth Centre released an elaborate programme in which the disease resistant varieties would be rolled out across East Africa, starting with the distribution of the region's most popular cassava variety – Ebwanatareka. However, controversy has surrounded the project following press reports that researchers had admitted that varieties of the GM cassava that they had declared to be disease-resistant were actually vulnerable to the devastating cassava mosaic disease.[75] Despite the negative press reports the project continues.

3.2.3 Improved Bean Varieties

Research on bean varieties has as its objective the combinations of genes geared at managing major bean diseases and insect pests determined and deployed in improved varieties. New varieties of climbing beans, adopted in many African countries, have been developed through gene combinations. Research in this area is mainly undertaken in collaboration with the International Centre of Tropical Agriculture (CIAT).

3.2.4 Bt Cotton

The Cotton Board of Kenya estimates that 350,000 hectares of land countrywide are suitable for rain fed production of cotton with a potential to produce 260,000 bales of lint annually. Current estimates place the production at an embarrassing 20,000 bales

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[74] G.W Otim-Nape. A Bua., Y Baguma, S Ogwal, G.N Semakula, G Acola, B Byabakama, A Martin, 'Cassava Mosaic Virus Disease in Uganda: The Current Pandemic and Approaches to Control' Natural Resources Institute (NRI) (Chatham GB, 1997)

[75] Dagi Kimani, East African Magazine, September 11, 2006

annually.[76] The decline in production and difference in actual production and estimates has been attributed to an array of factors including the high incidence of pests and diseases.[77] KARI has been at the helm of activities aimed at revamping cotton production in the country. In 2004, KARI decided to attempt Bt Cotton research. *Bacillus thuringiensis* (Bt) is a naturally occurring bacterium common in soils throughout the world. Several strains can infect and kill insects. Due to this property, Bt has been developed for insect control.Bt. cotton is a pest resistant variety of cotton that is genetically engineered. Monsanto holds the patent for the Bollgard variety of Bt. cotton. This variety has a gene of resistance against the bollworm, the most destructive and acute cotton pest. The Bt. gene works by secreting a protein that kills the bollworms. KEPHIS granted KARI a permit to introduce the seeds.

The trials began at KARI fibre research station in Mwea Tabere after the biosafety facilities had been inspected and approved by KEPHIS on behalf of the NBC. This year, the field trials on a new genetically engineered cotton variety meant to be pest-resistant and higher yielding than traditional type was approved by the NBC. The NBC in conjunction with the KARI has recommended the introduction of Bollgard II, an enhanced earlier type called Bollgard I that was tested between 2003 and 2005. The new variety is also offered by Monsanto. The results of the project are yet to be seen.

3.2.5 Bt Maize

The most advanced crop technology project in Kenya is the Bt Maize project. The IRMA project was launched in 1999 by the CIMMYT and the KARI, with financial support

[76] Export Processing Zones Authority (EPZA) Kenya 2005 estimates
[77] J Wakhungu et al 2004 above note 15

from the Syngenta Foundation for Sustainable Agriculture. The project is aimed at producing maize that is adapted to various Kenyan agro-ecological zones and is also resistant to key insect pests, primarily stem borers.[78]

The objective of the trials is to inject the bacteria Bt into a variety of local maize strains. Introduction of the Bt maize technology in Kenya started with the introduction of leaf tissue in 2001 continued with testing in the biosafety greenhouse complex in 2004. A confined field trial was initiated in May 2005 to test the efficacy of nine Bt maize events carrying particular genes[79] against major stem borers in Kenya including *Chilo partellus, Eldana saccharina, Sesamia calamistis, and Busseola fusca.*

The GM maize trials are now in their second phase though their trajectory has not been a smooth one. The field trials almost ended prematurely in August 2005 when it was announced that the trials had been halted by Kenyan regulatory authorities. In the first trial at the Kiboko Open Quarantine Site (OQS), scientists were testing nine different Bt events when a broad spectrum systemic pesticide called *Furadam* was accidentally applied into the soil. [80] This incident would have greatly impaired any results obtained. On 8 September 2005, the NBC gave its permission for replanting the trial and communicated this to KEPHIS on 21 September 2005, who, in turn, developed a new set of phytosanitary conditions to govern the new trials. Latest reports by IRMA indicate that six maize varieties developed for the drylands by the IRMA project won farmers'

[78] Information on IRMA website <http://www.cimmyt.cgiar.org/english/wpp/gen_res/irma.htm> (accessed 7 September 2007)
[79] cry1Ab and cry1Ba Bt genes
[80] IRMA Updates Vol. 6 Issue 3 2005

approval in participatory evaluations conducted at Kiboko, Kampi ya Mawe, and Katumani in Kenya in August 2006.[81]

Given the high level of activity in the area of GM crop research there is a need to evaluate the regulatory framework within which such activity is occurring to determine if the regulation in place will facilitate Kenya's use of GM technology to attain sustainable development.

4.0 EXISTING REGULATORY FRAMEWORK FOR GMOs IN KENYA

4.1 GMO REGULATION IN KENYA

There are several legislative Acts in the country with implicit provisions that may serve as the basis for regulation of GMOs. The Environmental Management and Coordination Act for instance, extends to GMOs in so far as it regulates all biotechnological projects and developments that are likely to have adverse impacts on the environment. The Science and Technology Act also contains provisions that implicitly regulate the use of GM technology in Kenya in so far as the Act extends to all scientific and technological research undertaken in the Republic.[82]

In terms of explicit laws, as already seen, there is at present no single legislative Act specifically governing the legal and technical issues pertaining to GMOs. The only explicit legislation is a set of administrative guidelines on biosafety developed by the

[81] IRMA Updates Vol. 7 issue 3 2006
[82] Government of Kenya, *Science and Technology Act*, Long Title

National Council for Science and Technology (NCST) in 1998. The proposed legislative Act of Parliament on biosafety, the Biosafety Bill 2007, has been debated in Parliament but is yet to be passed as law.

By signing the Cartagena Protocol, and subsequently ratifying it in 2003, Kenya committed itself to establish a biosafety legislative framework that mirrors the spirit of the Protocol. An analysis of the Protocol reveals the main requirements for regulation of GMOs as; risk assessment, risk management and risk communication all of which are means of implementing the precautionary principle. It is therefore expected that state parties to the Protocol will establish national legislative and administrative mechanisms which incorporate the precautionary principle. The requirements made in the Protocol with regard to the precautionary principle translate into specific national commitments for state parties dependent on the domestication of the provisions of the Protocol in accordance with national legal procedures.

Kenya's law allows for two ways in which an international instrument once ratified can be domesticated so as to form part of national laws. Parliament may decide to adopt the law substantially or in its entirety in which case this must be stated in the preamble or in the long title of the statute.[83] Alternatively Parliament would establish new legislation on the subject which is consistent with the main provisions of the domesticated international instrument. Parliament as we have seen is yet to pass the Biosafety Bill as law. In the absence of an Act of Parliament we must then determine if the current legislative

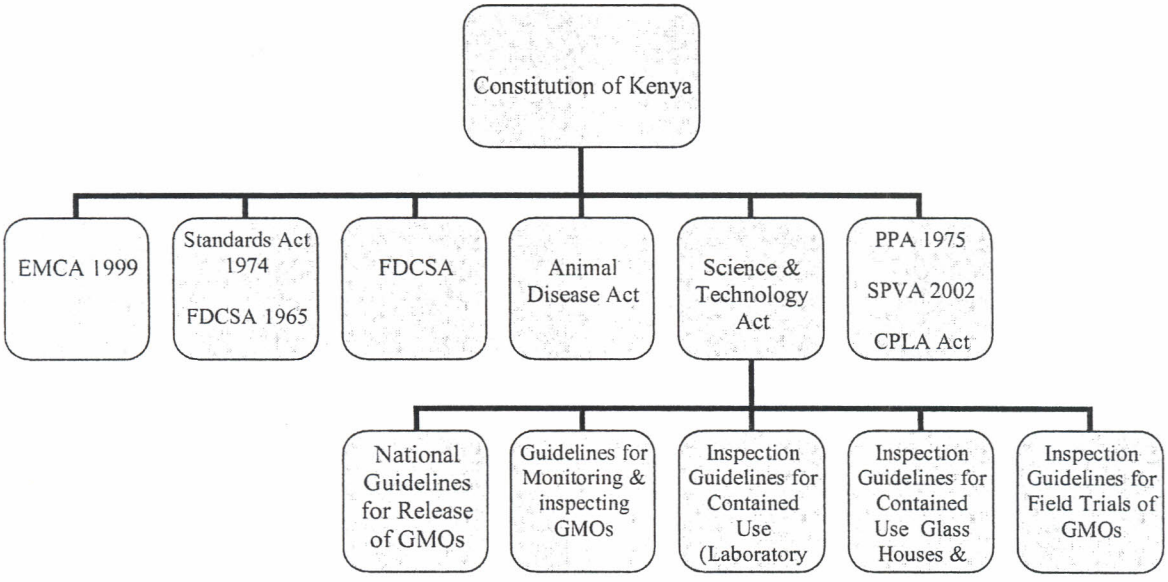
[83] See for example: Government of Kenya, International Monetary Fund Act Cap 467

framework governing GMOs is adequate in so far as the requirements of the precautionary principle as expounded in the Cartagena Protocol are concerned.

4.1.1 Existing Legislative Framework

In the absence of a specific legislative Act, GMOs in Kenya can be regulated using existing statutes though in a fragmented fashion. The organizational chart below shows some of these Acts as well as the hierarchical position of the current set of guidelines used to govern GMOs:

Organizational Chart 1: Legislative Framework within which GMOs operate in Kenya [Source HARSH (2005) with modification]



Key for acronyms used in the figure

1. EMCA: Environmental Management and Coordination Act
2. FDCSA: Food, Drugs and Chemical Substances Act
3. PPA: Plant Protection Act
4. SPVA: Seeds and Plant Varieties Act
5. CPLA: Crop Production and Livestock Act

EMCA[84] was enacted as a regulatory framework for the regulation of all aspects of the environment. One of the key tools of environmental management provided for in NEMA is the Environmental Impact Assessments (EIA). Under Section 58 of EMCA all proponents of a development project of a listed kind must provide a project report to NEMA. The Second Schedule to the Act lists the type of projects requiring submission of a project report. The list includes major developments in biotechnology including the introduction and testing of genetically modified organisms. Once the project report is submitted the authority then decides whether the proponent should then undertake an EIA study.

The Standards Act is the legal instrument used to protect consumers from contaminated goods or substances harmful to human health.[85] In 2005, the Act was amended and 'Verification of Conformity', a system for administration of quality control checks was introduced. This service was contracted out to ensure that goods being imported into the country conformed to national or international quality and standards and that they are correctly specified in the import declaration forms. These provisions provide the Kenya Bureau of Standards (KEBS) with the legislative basis for checking goods for GM content and enforcing regulations governing GMOs.

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[84] Government of Kenya, The Environment Management and Coordination Act, Cap 8 of 1999
[85] Government of Kenya, Standards Act, Cap 496

The FDCSA prohibits *inter alia* the labelling, packaging, sale, treatment and processing of food that is presented to the public in a false or deceptive manner or that does not meet a prescribed standard.[86] This FDCSA has provisions governing the labelling and packaging of foodstuffs. The Act also confers powers on the Director of Agriculture to request sampling of any products covered by this Act appearing to him or her to affect the general interests of agriculture in Kenya. The provisions of the Act highlighted provide a legislative basis by which government authorities can regulate food with GM content.

The PPA, SPVA and the CPLA also contain provisions, which allow the relevant authorities established under the respective Acts to regulate food safety issues in the country.[87] The PPA refers particularly to fruits and vegetables, while the SPVA governs imported seeds or seed crops with potential to grow when planted. Under the CPLA the Minister has wide-ranging powers for the objective of promoting quality in agriculture. The wide scope of application provides a legislative base for regulating GM crop activity using these Acts.

Currently GMO regulation is specifically provided for under a set of guidelines published by the NBC, a government agency established under the Science and Technology Act. The objective of the guidelines is to address issues of risk assessment and safe handling of GM products. Under the Guidelines, a researcher intending to introduce and/or release GMOs must fill in a set of application forms. The application forms are first submitted to an Institutional Biosafety Committee (IBC). This IBC makes a recommendation to the

[86] Government of Kenya, Food, Drugs and Chemical Substances Act, Cap 254
[87] Government of Kenya, Plant Protection Act, Cap 324, Seed and Plant Varieties Act, Cap 326, and Crop Production and Livestock Act, Cap 321 respectively

NBC, which puts together a full recommendation that it submits to the NCST, who take the final decision. Various safety considerations are specified in the various guidelines as set out in the organisational chart above.

4.1.2 Current Institutional Framework

The legislative framework set out above depends for its enforcement on various institutions to varying degrees. The table below identifies the main institutions involved in the regulation of GMOs:

Table 1: Institutional Framework Governing Biotechnology in Agriculture [Source: HARSH (2005) with modification]

Government Agency	Area of GMO competency
NEMA	Implements environmental law and thus monitors the environmental impact of GMOs
KEB S	Monitors and implements standards of goods; thus implements the standards applicable to food and food products including foods with GM content
KEPHIS	Implements plant related regulation; implements guidelines governing GM crop release and research
PHD	Identifies risks to public health and would thus be justified in checking for GM content and its effect on human health
NCST	Advisory role on the development of GM policy and crop research
NBC	Formulation and implementation of biosafety regulations to govern all aspects of GMOs

Key for acronyms used in the figure:

1. NEMA: National Environment Management Authority,
2. KEBS: Kenya Bureau of Standards
3. KEPHIS: Kenya Plant Health Inspectorate Service
4. PHD: Public Health Department
5. NCST: National Council for Science & Technology
6. NBC: National Biosafety Committee

The above scenario of multiple institutions charged with the enforcement of the various aspects of GMOs leads one to wonder whether we can speak of an institutional framework governing GMOs in Kenya in the absence of cohesion in the functioning of

these agencies. It would appear more accurate, in the present scenario, to speak of institutional frameworks.

The NCST is a government agency within the Ministry of Education, Science and Technology and established by the Science and Technology Act. The NCST is mandated with advising all government departments on issues of science and technology. The NCST in Kenya has been charged with overseeing biotechnology and biosafety issues affecting the country. Pursuant to this role the NCST established the guidelines currently in place for governing GMOs, the NBC, and has recently published the National Biosafety Bill 2007.

The NBC has the specific task of overseeing the implementation of biosafety guidelines and regulations that govern the conduct of institutions and individuals involved in biotechnology research and development. The NBC formulates guidelines and conditions for activities involving GMOs in conformance with provisions of the Cartagena Protocol on Biosafety. The NBC is composed of various representatives from government regulators, academic scientists, ministry representatives, the office of the president, scientists from research institutes, non-governmental organizations, NCST and agricultural organizations.

The current guidelines governing various aspects of GMOs stipulate that the NBC is the authority charged with coordinating all biosafety efforts and regulation, including approval of all biosafety applications for biotechnologies to be developed in Kenya.

Administratively, the NBC falls under the NCST, a fact, which we shall see raises problems of legitimacy of mandate.

NEMA is the authority charged with the implementation of policies regarding environmental management. NEMA was established under EMCA, a framework law, which ideally ought to oversee all environmental management in the country. NEMA has the mandate to govern biotechnology developments through the EIA licence requirement provided in EMCA. This implies that NEMA is charged with the responsibility of considering the environmental impacts of any GM activity proposed in Kenya. NEMA's presence in the biotechnology projects developed in Kenya has not been evident. This is perhaps due to constraints faced by the fairly young agency in terms of technical expertise.[88]

KEBS is a government agency established by the Ministry of Trade and Industry. The institution is charged with providing trade facilitation services in Metrology, Standards, Testing and Quality Management (MSTQ). The standards developed by KEBS include food safety standards. KEBS would thus be the agency responsible for developing standards to regulate food with GM content. KEBS currently uses international standards, in particular those created by the *Codex Alimentarius* Commission (CAC) and under the Cartagena Protocol on Biosafety to govern GM content in food. It would appear that the practice is to require food importers whose products are suspected to have GM content to

[88] Information obtained from advocate working from NEMA: The current organizational structure reflects a lean top and heavy bottom. There are very few highly trained experts and many junior unskilled staff. Financial constraints have prevented the Agency from building capacity of this heavy bottom.

obtain certification from internationally accredited laboratories at their own cost.[89] KEBS thus stipulates that imported GMO foods be accompanied with a certificate of analysis. KEBS will in future be required to incorporate the guidelines governing GMO use to check GM quality levels of food products in the country.

Kenya recently launched a regional body for setting standards. The National Codex Committee (NCC) is expected to promote establishment of definitions and requirements for food standards and help national producers access and maintain markets locally and internationally.[90] This may facilitate the setting of standards relevant to the needs and situation of the country, including in the area of GMOs.

The PHD of the Ministry of Health is the department charged with the responsibility for providing essential preventive and promotive health services to the people of Kenya.[91] One of the core functions of the Department is to enforce food safety regulations. The PHD therefore ought to ensure that the food consumed in the country is not hazardous to public health due to the GM content in it. Currently, the institution has not extended its mandate to GMOs but it is hoped that as GMOs extend to pharmaceutical products and health the PHD will implement GMO guidelines with respect to health.

KEPHIS is responsible for monitoring implementation and enforcement of the biosafety guidelines with respect to plants and seeds. It is located in the Ministry of Agriculture and

[89] Interview with Ann Muigai, Director of the Institute of Biotechnology Research (IBR) Jomo Kenyatta University of Agricultural Sciences and Technology (JKUAT), (Juja August 2007)
[90] Philip Wahome, 'Standards Body Launched', The Daily Nation, 27 September 2007
[91] Government of Kenya, Ministry of Health Official Website

is currently mandated to implement the guidelines in place for the regulation of GM crops. Apart from implementing the Guidelines, KEPHIS has put in place an interim mechanism to regulate GM crop activity through the use of phytosanitary measures. According to KEPHIS all phytosanitary measures used in Kenya are based on international standards as provided in the International Plant Protection Convention (IPPC) and the World Trade Organization's (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS). Apart from the phytosanitary measures, KEPHIS uses the legal framework set out in other Acts on Agriculture such as the Plant Protection Act (CAP 324), the suppression of Noxious Weeds (Cap 325) and the Agricultural Produce (Export) Act (Cap 319). KEPHIS thus has sufficient legal leeway to effectively regulate GMOs in the realm of agriculture.

KEPHIS has introduced what they describe as stringent plant introduction and certification procedures. The Plant Protection Service Department is charged with these operations, which are undertaken at three main points; the Plant Health Clinics located at KEPHIS Headquarters, the Plant Quarantine Station in Muguga and the Grading and Inspection points, which are scattered over various points of entry such as airports and the borders. KEPHIS requires additional declaration in phytosanitary certificates stating the GM status of the product.

There are various institutions with the capacity to regulate GMOs, however, there are inadequate mechanisms to facilitate the coordination of GMO regulation by these agencies.

4.1.3 Biotechnology Policy

Apart from the legislative Acts, the Government of Kenya has recently published the National Biotechnology Policy 2006. The Policy demonstrates Kenya's proposed course of action with respect to biotechnology. The document recognizes the potential role of biotechnology in poverty reduction, enhancing food security and conservation of the environment and biodiversity. The policy addresses the issue of public participation in biotechnology by highlighting the need for transmission of useful information to the public.[92]

With regard to precautionary measures the Policy outlines the safety procedures for biotechnology in the context of research development, technology transfer and commercialization of products.[93] It includes provisions intended to safeguard citizens and the environment against the development or introduction of harmful organisms. The policy also outlaws on the basis of ethical considerations human cloning and terminator technologies.[94] Terminator technologies would ensure that seed farmers have to purchase seeds every year as it ensures that seeds cannot be saved and reused in the following harvest.

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[92] Highlights of the National Biotechnology Development Policy <http://www.biosafetykenya.co.ke/legislation.php> (accessed 21 October 2007)

[93] Ochieng Ogodo, 'Kenya Approves a National Policy on Biotechnology', Scidev.Net News October 24, 2006

[94] This is a form of Gene Use Restriction Technology (GURT). It involves the production of transgenic plants that make lethal proteins late in seed development, which ensures that the seed cannot be germinated, at least not without application of a proprietary chemical stimulus

4.2 ANALYSIS OF THE LEGISLATIVE AND INSTITUTIONAL FRAMEWORK GOVERNING GMOs IN KENYA

An analysis of the legislative and institutional framework governing GMOs in Kenya will now be undertaken to determine if it integrates the precautionary principle and in so doing facilitates the use of GM technology to contribute to sustainable development.

4.2.1 Participatory Development Process

As observed earlier, an ideal regulatory framework must be the result of a democratic process. GM activity in Kenya, as in other countries has been characterised by controversy and consequently attempts at regulation have been the subject of heated debate. However, given the technical nature of the subject of GMOs, the debate surrounding the issue has, in reality, been limited to a small section of Kenya's population. An unpublished survey conducted by science students of the University of Nairobi, on the level of public awareness of GM technology revealed that a great percentage of the public have very little knowledge of the real issues of biotechnology and any knowledge they have is sourced from the media.[95] This greatly undermines the capacity of the public to introduce objective contributions to the suitability or otherwise of GM crop technology. Policy makers have not fared any better in so far as understanding of GMOs is concerned. [96] The above situation has given rise to the

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[95] Statement by Maria Goretti Onyango, University of Nairobi MSc Student, (Personal communication April 2006)

[96] Some Parliamentarians, in the course of debate, confessed their ignorance of GMOs and their association of GMOs with devil worship. See Leakey Sonkoyo, 'Kenyan Parliamentarians could pass Biosafety Bill', <http://africasciencenews.org/asns/index.php?option=com_content&task=view&id=33&Itemid=1> (accessed 20 October 2007)

manipulation of the different participants of the debate by external pressure groups in their bid to further their agenda. Media reports in Kenya have alleged that our Members of Parliament have been hoodwinked by the big biotechnology multinationals. An article in the East African claimed that the entire process of drafting the Biosafety Bill was bankrolled by the external agencies affiliated to giant biotechnology multinationals who also organised an all-expenses paid trip for several MPs to South Africa early last year. [97]

4.2.2 Legitimacy of the Regulatory Framework

As evidenced from our discussion of regulatory frameworks one of the important benchmarks for a good GMO law is the backing of a legitimate authority. An analysis of the current framework raises serious doubts about the actual existence of a regulatory framework governing GMOs. The ongoing GM activity in this country is taking place in a 'legislative vacuum.[98] This is because the biosafety guidelines and the NBC were all created by the NCST under the legal authority of the Science and Technology Act of 1980. This parent Act gives the NCST authority to advise the government on science and technology issues. There is no provision in the Act granting regulatory authority to the NCST or NBC over biosafety or GMOs. This means that the NCST and NBC's current regulation of GM activity has no basis in law. Further, the attempt by the NCST to have KEPHIS, NBC and other government agencies enforce the guidelines is irregular as these agencies have been established under other legislative Acts which Acts determine their mandate.

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[97] The East African July 10, 2007

[98] J Wakhungu et al 2004, above note 15

4.2.3 Relation of Law and Policy

In Kenya, the development of biotechnology law and biotechnological research activity, have been happening concurrently. In fact the ordinary sequence of events has been reversed. The first large-scale GM project, the Virus Resistant Sweet Potato project began in 1991 long before the current biosafety guidelines were developed. The government biotechnology policy was approved in 2006.

Such an approach to legislative development is far from ideal in so far as the resultant legislation is often not reflective of the developmental needs of the country in question. A reactionary law is often formulated in haste. Given the urgency involved in such ventures there is frequently little or no time to coordinate such regulations with the existing framework. This increases the risk of overlaps, conflicts and duplication of functions among government departments, as happens in the current framework.

4.2.4 Institutional Weaknesses

This system of organization of institutions responsible for the enforcement of GMO regulation is the result of the larger governance structure in the country. Kenya's system of government is organized along the structure of line ministries which operate on the basis of subject specific mandates. The rationale for such an organizational structure is the age old belief that specialization leads to greater efficiency. However, the inherent danger in such systems is the fragmentation of mandates of the regulatory institutions. This could contribute to overlapping of jurisdictions or gaps where the institutions fail to recognize certain matters falling within their purview. This hinders the efficiency of the GMO legislation.

The successful implementation and enforcement of a biotechnology law is dependent to a large extent on the availability of a critical mass of experts in science and technology and other related fields, such as law. Risk assessment, the fundamental application of the precautionary principle, requires that the authorities charged with responsibility have the relevant capacity to evaluate the biotechnological projects. This has been a major challenge in Kenya. The root of the problem according to investigation by the author is not a shortage of local expertise but rather the inability of national public institutions to retain highly trained and experienced scientists in their employment. Despite government efforts to build capacity of these institutions, there is still shortage of expertise. This is because most highly trained Kenyan scientists are working in the Diaspora where remuneration is more competitive and facilities are more advanced.

The effectiveness of institutions involved in the implementation and enforcement of GMO laws is also greatly undermined by fiscal restraints. The technologies required for risk assessment and management are costly. Despite the current government's commitment to biotechnology research and development, the funding directed to this sector is still relatively inadequate. The restraints in the national budget mean that apparently substantial percentage allocation to science and technology results in very little funding in reality.

4.2.5 Precautionary Measures

As demonstrated earlier, one of the means of ensuring that a regulatory framework achieves sustainable development is through its incorporation of the precautionary principle. The primary application of the precautionary principle involves risk

assessment. Risk assessment should be conducted for three specific types of treatment with GMOs; contained use of GMOs, introduction of GMOs into the environment, and placing of GMOs and products on the market. The administrative guidelines governing GMOs include risk assessment provisions but only with respect to contained use and introduction of GMOs into the environment. [99] However, no provisions are included for risk assessment with respect to placing of GMOs on the market.

A clear procedure for assessing the potential impacts of by products with GM content does not exist in the current framework. As more and more countries use GM corn, food products and derivatives from corn are likely to have traces of GM material. GM maize may be used to make maize oil, maize starch, and maize syrup and could be found in Coke, Fanta, Pepsi, Corn Flakes and many other products. The current GMO framework does not have clear procedures to cover the regulation of such products.

Comprehensive regulatory systems for GMOs ought to cover not just engineered plants used for food or feed but also plants engineered to produce non-food substances, non-food crops such as trees, and engineered animals. The current guidelines still have a long way to go before they can be described as adequate in this regard.

The administrative guidelines in place lay emphasis on risk assessment and risk communication while paying no heed to risk management.[100] Risk management decisions

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[99] Ref. Government of Kenya, National Guidelines Governing GMOs <http://www.biosafetykenya.co.ke/legislation.php> (accessed 21 October 2007)

[100] Risk Management has been defined as: "The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors

typically consider not only the scientific evidence as presented in the risk assessment, but also incorporate, social, cultural and financial factors in establishing policy. Article 16 of the Cartagena Protocol requires parties to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment associated with the use, handling and transboundary movement of GMOs.

A manifestation of the lack of provisions on risk management is the guideline's silence on labelling and traceability[101] measures. The objective of labelling and traceability provisions in law is to ensure the monitoring of the potential effects on the environment and human health of targeted products. Such measures would also allow regulatory authorities to withdraw products containing GMOs and that result in unforeseen harmful effects. Labelling requirements would also ensure that consumers are only exposed to GM products through choice.

4.2.6 Facilitation of Sustainable Development

Within the current framework there are no provisions in place to protect the interests of subsistence farmers. As observed the current legislative framework has been largely reactionary and driven by the research corporations as a consequence the emphasis has been on approval standards and procedures by scientists. The socio-economic aspects of GMOs have yet to be addressed. Under the Industrial Properties Act 2001, patents are

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relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options." Ref. Codex Alimentarius Commission Procedural Manual, Fourteenth Edition 2004 <http://www.fao.org/docrep/007/y5817e/y5817e00.htm> (accessed 1 November 2007)

[101] Traceability can be defined as the ability to trace products through the productions and distribution line.

available for invention in all fields of technology and are the principle for protecting ownership of any device, substance, method of process, which is new, or inventive. GM technologies thus have a potential of obtaining a 20 year protection subject to renewal.

Despite the well developed provisions protecting industrial technology under the current regime, there is no protection afforded to traditional indigenous knowledge which is many times at the heart of the subsequently developed GM technology. This current industrial property regimes favour the transnational companies with the necessary resources to engage in scientific research while failing to take into consideration the interests of the indigenous farmers whose biodiversity resources may have formed the raw material of the protected inventions.

4.3 INADEQUACY AND INAPPROPRIATENESS OF CURRENT REGULATORY FRAMEWORK: CASE STUDY OF THE VR SWEET POTATO

The development of the first biotechnology project, the VR sweet potato demonstrates to a large extent the inadequacies and inappropriateness of the current framework for the regulation of GMOs in Kenya.[102]

The Kenyan phase of the project was part of the larger Agricultural Biotechnology for Sustainable Productivity (ABSP) project and was to be carried out by KARI in collaboration with Monsanto. The project began in 1991 long before the development of the biosafety guidelines that today govern the release and introduction into the environment of GMOs in Kenya.

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[102] Hannington Odame, Patricia Kameri-Mbote, D Wafula, 'Innovation and Policy Process: The Case of Transgenic Sweet Potato in Kenya', African Centre for Technology Studies: Nairobi. 2003

In the absence of the biosafety guidelines, the implicit provisions contained in the Acts identified in the foregoing section on the existing regulatory framework ought to have been sufficient to govern the sweet potato project. However, the project was unable to proceed until the establishment of explicit guidelines on GMOs. This indicates that the implicit laws are inadequate for purposes of regulating GMOs.

The absence of an explicit regulatory framework to govern the issues arsing in the course of the research led to unprecedented delays. For instance, the actual transfer of the recombinant sweet potato technology from the Monsanto to KARI did not take place until 2000. The actual process of transfer took a period of three years as it coincided with the development of the biosafety guidelines and the establishment of the NBC.

The process of developing the guidelines did not count on public participation. It was financed by international research institutes involved in the GM technology research.[103] The guidelines were thus designed with great urgency and in a manner to ensure approval of the transgenic sweet potato project and other GM projects. This explains why the scope of the guidelines was limited to contained use and introduction of GMOs into the environment, the preoccupation of the project's proponents at the time.

One of the strongest arguments in favour of the introduction of GM crops is their potential to boost food security. At the time of the initiation of the project there was no national biosafety or biotechnology policy. However, there were broad policy

[103] The International Service for Acquisition of Agbiotech Applications (ISAAA) a pro GMO institute supported a number of researchers from KARI to travel to USA for short-term capacity building courses.

statements indicating the government's priorities in so far as food security in the country was concerned. The choice of the sweet potato as the pioneering GM project was not reflective of these policy goals which identified cereals such as maize as the priority crops for boosting food security. [104] The choice of the sweet potato was based on the preferences of the biotech corporations behind the research.

The VR sweet potato trials were characterised by irregularities which manifested the institutional weaknesses present in the existing regulatory framework. Conflicts and disagreements between KARI and the NBC emanated in the course of the project demonstrating the lack of clear mandate and overlaps in jurisdiction of the institutions responsible for enforcing GMO laws. The lack of scientific expertise and capacity in the NCST and the NBC and inadequate funding caused delays and undermined the risk assessment capacity of the regulating agencies. Inadequate funding forced the NCST to rely on the sponsorship of international institutions engaged in GM research for capacity building for its staff. This greatly undermined the objectivity and impartiality of the regulating agencies.

The VR sweet potato project did not involve farmers as there are no provisions in the current regulatory framework to involve farmers in the setting of research agendas. While the scientists concentrated on virus-resistant sweet potatoes to increase yields, the farmers were more concerned with the existing constraints to utilization and marketing of sweet potato. The result was the project's failure to contribute to sustainable

[104] Government of Kenya, Sessional Paper number 1 of 1986 on Economic Management for Renewed Growth and Sessional Paper number 2 of 1994 on Food Policy

development. The project has had little effect in contributing to food security in the country. The experience is demonstrative of the inadequacies and inappropriateness of the current regulatory framework and the need for a more integrated framework.

4.4 ANALYSIS OF THE FUTURE LEGISLATIVE AND INSTITUTIONAL FRAMEWORK

The Biosafety Bill published in June 2007 is intended to constitute the regulatory framework for governing all aspects of GMOs in the country in future.[105] It seeks to regulate all biotechnology and biosafety issues in the country. The following section analyzes the Biosafety Bill 2007 to determine whether it fills the gaps identified in the current regulatory framework.

4.4.1 Participatory Development Process

The development of the Biosafety Bill 2007 has been a more inclusive exercise in so far as public participation is concerned. Various stakeholders including farmers, scientists, consumers and legislators have contributed to the Bill and the debate surrounding the Bill. Public awareness on GMOs is still limited. However, the increase of public participation in debates in the media indicates an increasing understanding of the nature of GMOs.

4.4.2 Legitimacy of the Regulatory Framework

The proposed legislative Act would definitely provide the legal basis that we observed is lacking in the current state of affairs. A legislative Act dealing specifically with biosafety provides the opportunity for legislators to unify the regulatory environment for biotechnology. The Act would also constitute the enabling statute for the legitimate

[105] Government of Kenya, The Biosafety Bill 2007, Memorandum of Objects and Reasons, <http://www.kenyalaw.org/Downloads/Bills/Biosafety%20Bill%202007%20(Revised).pdf> (accessed 21 October 2007)

establishment of the National Biosafety Authority (NBA), an agency mandated by an Act of Parliament to address all matters related to biosafety and biotechnology.[106]

4.4.2 Relation of Law and Policy

The 2007 Bill has the advantage of having been revised after the National Policy on Biosafety had been deliberated and approved. There are marked improvements in the congruence between law and policy in the 2007 Bill, a goal which the legislators consciously sought to achieve.[107] Section 29 for instance attempts to introduce socio-economic considerations in decision-making in accordance with the spirit of the National Policy, and makes it mandatory for the NBA to take socio economic impacts into account. In our view such a provision though a welcome step does not per se guarantee that such considerations will be taken into account.

4.4.3 Institutional Weaknesses

The Kenya Biosafety Bill creates a new agency the NBA managed by a Board from a number of government agencies. The institution is mandated with the governance of GMOs. The Bill is silent on the relation of this Authority with the NBC.[108] It is unclear whether that authority will make use of the existing expertise from the NCST and the NBC. To this extent, the Bill contributes to further confusion in the institutional chaos by adding yet another institution regulating GMOs. Should the NBA replace the NCST and NBC, any experience gained from by the agencies so far is likely to be lost. This we believe is a clear case of an attempt to 'reinvent the wheel'. However, the composition of the authority is a commendable attempt at coordinating the various institutions involved

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[106] Biosafety Bill 2007 s5
[107] Biosafety Bill 2007, Memorandum of Objects
[108] Biosafety Bill 2007, s56 on transitional provisions does not explicitly indicate if the NBA replaces the NBC

in the regulation of GMOs.[109] By co-opting the permanent secretaries of the various line ministries, the NBA may be better placed to adopt and effectively pursue a uniform GM agenda.

There is a provision for inclusion of experts from biological, environmental and social sciences which is a step in the right direction in so far as inter-disciplinarity is concerned.[110] The NBA thus constituted would be a good platform from which to achieve a balance between the different scientific disciplines involved in GM technology. However, as observed before, the problem of inadequate expertise is not purely a regulatory problem and thus cannot be resolved by the mere enactment of a legislative Act. Nevertheless such a good law can create an environment that would facilitate the resolution of this problem.

The Bill does not include explicit provisions that could prevent the NBA from facing fiscal restraints similar to those faced by the NCST. Nevertheless there are provisions indicating that the Authority shall with the approval of the Minister determine the remuneration due to board members. There is a further provision granting the Minister the powers to draw up a schedule of fees chargeable for application and making of notices. The Minister could make regulations setting fees at a level guaranteed to generate revenue for the NBA. Experience may be borrowed from NEMA which fixes the licence fees at 0.1% of project costs. Nevertheless, the fees must be well thought so as not to discourage prospective developers of GM technology. The presence of the

[109] ibid, s6(1)
[110] ibid, s6(1) k(i)

permanent secretary of finance in the NBA may also help the Authority to lobby for a sufficient allocation of funds to it in the budget.

4.4.4 Precautionary Measures

The Bill extends beyond the introduction and or release of GMOs into the environment by including provisions on applications for importation or placing of GMOs in the market.[111] In accordance with the provisions of the Cartagena Protocol, the Bill also has provisions on export of GMOs[112] as well as provisions dealing with GMOs in transit.[113] To this extent the Bill fills in the gaps present in the current guidelines governing GMOs. Nevertheless, the provisions made in the Bill are very general and effective implementation is dependent upon the promulgation by the Minister of supporting regulations. Section 51 of the Bill, gives the Minister responsible for science and technology matters, in consultation with the NBA, the power to make regulations necessary to bring into effect the provisions of the Bill.

The Bill makes general recommendations to the NBA on risk assessment and risk management measures.[114] The recommendations made are very general and supporting subsidiary legislation would be needed to concretize the responsibilities of the NBA with respect to risk assessment and risk management. Section 3(b) is a controversial provision similar to a provision that has been included in the GMO law of South Africa. The section provides: "Scientific knowledge or scientific consensus shall not necessarily be interpreted to indicate a particular level of risk, an absence of risk or an acceptable risk."

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[111] ibid s21
[112] ibid s23
[113] ibid s22
[114] ibid 5th Schedule

The import of this clause is unclear. There are fears that the clause could be interpreted in a manner to negate the precautionary principle.[115] These fears are not without basis, the premise on which the precautionary principle is based is scientific evidence. Scientific evidence is the foundation for decision-making in the risk assessment process. By asserting that scientific knowledge or consensus is not conclusive evidence of risk, the provision introduces an element of ambiguity. In future such a provision may be interpreted to disregard scientific consensus and place a higher risk measure or vice versa.

The Bill explicitly excludes GMOs in pharmaceuticals used for human consumption.[116] However it makes no reference to the use of gene therapy and germ line therapy. This explicit exclusion may be interpreted to mean that what the legislators wish to exclude from the Act is limited to what they have explicitly excluded. Such an interpretation could lead to the deduction that such gene therapies are included in the scope of the Act whereas this does not seem to be the intention of the legislators. The exclusion of GMOs in pharmaceuticals raises questions on whether a further legislative Act will be passed to specifically deal with these issues.

The provisions for procedures for contained use, environmental release of GMOs, their import and export of GMOs, as well as transit of GMOs depend for their efficacy on the

[115] African Centre for Biosafety, 'Comments on the Republic of Kenya's Biosafety Bill' 22 June 2007 p10
[116] Biosafety Bill 2007 s3(2)

establishment of supporting regulatory guidelines. It is expedient that the Minister in consultation with the NBA make the necessary regulations.

The Bill contains a provision allowing the authority to exempt certain GMO applications from the risk assessment provisions "where it determines that sufficient experience or information exists to conclude that the genetically modified organisms or activities do not pose a significant risk to the environment."[117] Such a provision is dangerous as it is likely to be subject to abuse. However, the rationale behind the inclusion of this clause may be cost considerations. Risk assessment procedures are costly and time consuming and it may be justifiable to grant the NBA some flexibility in determining GM projects to be submitted to the risk assessment procedure. Further, the provision may be particularly useful in the present regional cooperation arrangement. In order to reduce on costs the East African countries could exempt from the risk assessment procedure, projects which have been subjected to the procedure in any of the other countries in the region. In order for this to work, Kenya, Uganda and Tanzania would need to harmonize their biotechnology and biosafety laws and policies.

The issue of labelling which had been omitted in previous drafts of the Bill is now included in Section 50 of the Biosafety Bill 2007. The Bill requires any person manufacturing or importing any GMO to package and label GMOs in the prescribed manner. The effectiveness of this provision in protecting the interests of the Kenyan public is questionable. The use of labelling presumes a sensitized public that read labels and has sufficient information on GMOs to make informed choices. The level of GM

[117] ibid s28

knowledge in Kenya is low and thus the efficacy of a labelling regime depends on a complementary awareness campaign to educate the public.

There is no mention of traceability in the 2007 Bill. Traceability as we have seen is an important measure of risk management. Like the current guidelines the Biosafety Bill does not contain provisions on liability and redress that may arise as a result of any activity conducted with a GMO, where State liability does not arise on the part of the Authority. In a country such as Kenya where the bulk of GMO research is driven by multinational research companies whose interests may not always coincide with those of the population, such a provision may be well worth considering. The provision need not attempt to establish a detailed mechanism for determination of liability and redress but rather should merely recognize the spirit of the polluter pays principle. With such a provision aggrieved parties can then use existing civil law mechanisms for redress.

4.4.5 Facilitation of Sustainable Development

The initial drafts of the Bill did not include provisions permitting the participation of small scale farmers in decision-making related to GMOs. As a consequence they expressed disapproval of the initial Bill. KESSFF issued a strong declaration against the Bill in 2004.[118] They faulted the Biosafety Bill 2003 for being skewed in favour of international corporations and insensitive to the interests of the small scale farmers. The composition of the Board governing the NBA has since been revised to include one

[118] Kenya Small Scale Farmers Forum (KESSFF), Declaration 20 August 2004 <http://biotech.indymedia.org/or/2004/08/3316.shtml> (accessed 20 May 2007)

representative from consumer groups and the other from farmer organizations.[119] This is a welcome change though small scale farmers continue to oppose the 2007 Bill.

The Bill requires that an application for environmental release be subject to notification of the public. Applicants would be required to publish a notice of the intended release in the Kenya Gazette and 2 newspapers circulating nationwide.[120] The publication of this notice is designed to solicit public input. This may provide an opportunity for small scale farmers to lobby for the protection of their interests. Such public participation will ensure that all stakeholder interests are considered in the decision making. The challenge is that the nature of GM projects is that they are highly technical and thus out of the reach of majority of the public. Guidelines to the Act should require that project reports avoid technical jargon and remain simple and concise enough to be comprehensible to the general public.

The Bill does not include any express provisions on the transfer of technology and benefit sharing. It may be argued that the place for such provisions is not a Biosafety Bill. Nevertheless, given the special needs of Kenya and the nature of GM research activity it may be worthwhile to consider the inclusion of framework type provisions recognizing the importance of these two issues and giving the Minister power to make regulations to effect the provisions.

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[119] Biosafety Bill s6(1) (K)
[120] ibid s19

In light of the foregoing analysis, we conclude that the proposed Biosafety Bill 2007 makes commendable progress in establishing an adequate and appropriate legislative and institutional framework for GMOs in Kenya. However, much ground still needs to be covered before the current framework can ensure Kenya achieves sustainable development. In our view despite the shortcomings highlighted, the proposed Kenya Biosafety Bill 2007 is redeemable and much better than the current system.

5.0 TOWARDS AN INTEGRATED FRAMEWORK FOR THE REGULATION OF GMOs IN KENYA

This research paper set out to determine the adequacy and appropriateness of the regulatory framework governing the use of GM crop technology and proposed commercialization of GMOs in Kenya. This study posits that an ideal biotechnology regulatory framework is one that encompasses three pillars of sustainable development; environmental protection, economic development and social development. These three concerns are integrated into a regulatory framework using the precautionary principle.

5.1 RESEARCH FINDINGS

The research questions that this paper set out to answer were firstly, whether the current framework used to govern the use and commercialization of GMOs effectively incorporates the precautionary principle. The study has shown that the explicit legislative framework in the form of guidelines incorporate some mechanisms of risk assessment particularly for introduction, release and confined use of GMOs in the country. However the mechanisms in place are not comprehensive as they do not include all the necessary precautionary measures. As observed they do not extend for example to placing on the market. The guidelines are also inadequate in so far as they do not legislate on labelling and traceability.

Secondly, the research sought to determine how effective the current framework is in ensuring Kenya achieves sustainable development. The present regulatory framework governing GMOs is inadequate in so far as it lacks a legitimate authority. The absence of a legislative basis undermines the capacity of implementation and enforcement of any

precautionary provisions set out in the present guidelines. The analysis shows that the National Biotechnology and Development Policy is effective in so far as it identifies the potential of GMOs for achieving Kenya's developmental needs through GMOs contribution to poverty reduction and food security. However the current framework is not in congruence with the National Policy and is thus inappropriate for tapping the developmental potential of GMOs.

Thirdly, the research paper set out to determine if there is an effective mechanism for the implementation of these guidelines. An analysis of the current institutional framework demonstrates that this question cannot be answered in the affirmative. The legal basis on which the NBC is established has been challenged. The mandate and role of other agencies such as KEPHIS, DVS, the PHD and KEBS is unclear. Further there is no clear hierarchical structure within the current setup.

Finally, the paper set out to check if the proposed regulatory framework as enshrined in the Biosafety Bill 2007 is more adequate and appropriate than the existing guidelines. An analysis of the Kenya Biosafety Bill 2007 demonstrates that the proposed legislative framework is more adequate and appropriate than the existing guidelines. However, the Bill contains some weaknesses discussed in the analysis.

5.2 RECOMMENDATIONS

The above findings confirm that the current framework for the regulation of GMOs is inadequate. The research reveals that the proposed framework enunciated in the Kenya Biosafety Bill 2007 is more appropriate and adequate albeit its weaknesses.

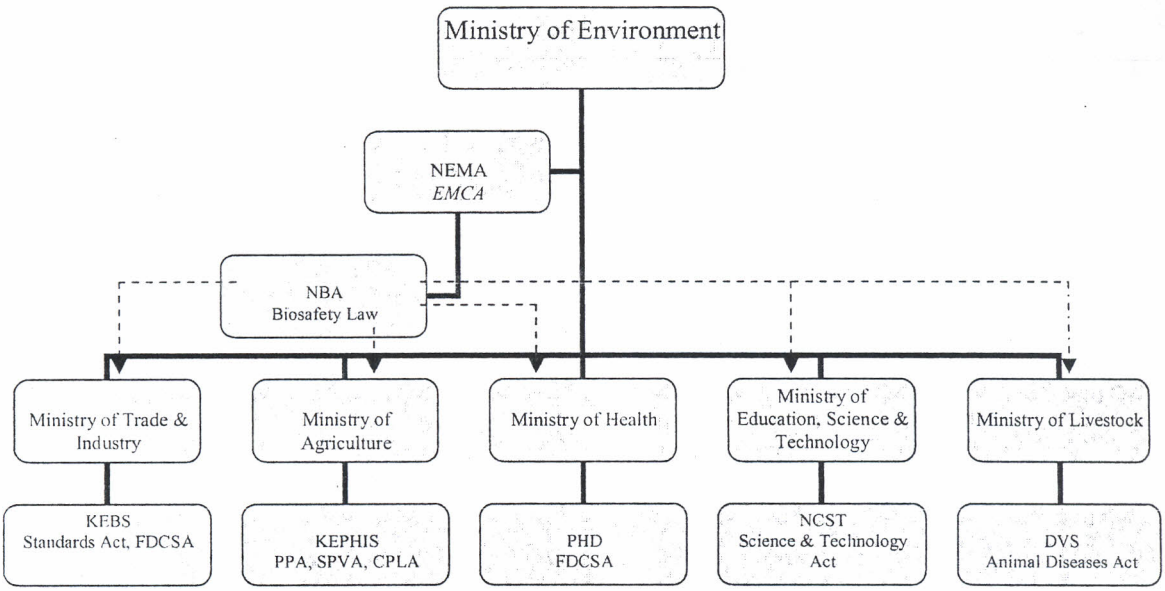
The results of the analysis undertaken by this research lead to the conclusion that the weaknesses identified in the proposed framework can be remedied. We are of the view that reorganization of the governmental structure relating to environmental legislation and institutions as well as amendments to the Biosafety Bill could result in an integrated regulatory framework.

5.2.1 Integrated Regulatory Framework for GMOs

As evidenced from the analysis undertaken one of the greatest drawbacks to the current framework is its fragmented nature which has contributed to the lack of coordination and the overlap in mandates making it inadequate to facilitate sustainable development in GM technology. In our view there is a need to strategically position the proposed Biosafety Bill within the existing structures as a means of avoiding overlaps and facilitating coordination.

The organizational chart below demonstrates a proposal for the reorganization of the institutional framework governing environmental law. Such reorganization is a necessary step towards the reorganization of the institutional framework governing GMOs.

Organizational Chart 2: Proposed Hierarchical Structure for Regulatory Framework on GMOs [Source HARSH (2005) incorporating author's recommendations]



Under such a structure the Ministry of Environment would have supervisory functions over all other ministries with respect to matters related to the environment. The Ministry would carry out its enforcement and regulatory functions through NEMA. NEMA would be the ultimate agency granting approval for biotechnology projects through Strategic Environmental Assessments (SEA). SEA has been defined as

> "a systematic process for evaluating the environmental consequences of proposed policy, plans and programmes initiatives in order to ensure they are fully included and appropriately addressed at the earliest appropriate stage of decision-making on par with economic and social considerations"[121]

Considerations for granting an SEA could include socio-economic factors such as to the impact of introduction and release of GM plant material on food security and on the

[121] B Sadler, and R. Verheem, 'Strategic Environmental Assessment: Status, Challenges and Future Directions', *Report Ministry of Housing, Spatial Planning and the Environment of the Netherlands* No. 53. 1996

livelihoods of small scale farmers. They could also take into account the country's research priorities and need for technology transfer in approving biotechnology projects.

The NBA would be housed under the Ministry of Environment as opposed to the current position of the NBC in the Ministry of Education, Science and Technology. The NBA would be mandated with the task of coordinating and supervising all regulations governing GMOs in the country. Applications made to NEMA for SEA licences for projects involving biotechnology would be referred to NBA by NEMA. NBA would make recommendations on the basis of the provisions in the biosafety legislative Act. The ultimate decision would lie with NEMA which would be required to incorporate socio-economic considerations in evaluating the proposed projects.

The other agencies established under the line ministries would be responsible for implementation and enforcement of the provisions of environmental law and biosafety pertaining to their particular sector.

Table 8: Proposed Functions of the Institutions dealing with GMOs [Source HARSH (2005) incorporating authors proposals]

Authority	*Mandate*
NCST	Advise all government agencies on matters related to GM technology
NBA	Implementation of biosafety and biotechnology laws, Supervisory functions of implementation of these laws by other government agencies
KEBS	Implementation and enforcement of biosafety laws on food, feed and other non food substances with GM content
KEPHIS	Implementation and enforcement of biosafety laws on GM activity related to plants
PHD	Implementation and enforcement of biosafety laws on GM activity involving human beings including medical products, use of gene therapy treatment
NEMA	Overall implementation of environmental management provisions through SEA

Under the proposed structure the source of harmonization of the various sectors would be NEMA the regulatory authority governing environmental management in general. All development projects likely to have an impact on the environment including those involving GMOs would have to be preceded by an SEA. NEMA would use the NBA to evaluate GMO related projects.

The NBA would be responsible for the making of regulations to be used by the various agencies including KEBS, KEPHIS, DVS, and PHD, which agencies may in the course of the discharge of their duties deal with GMOs or products containing GMOs. The regulations would be in keeping with the Biosafety Framework Law.

The NCST would advise all government departments on issues of GM technology. The agency would also be responsible for proposing research priority areas and coordinating any research activity relating to GMOs. The NCST would also advise NEMA on the impact of proposed GM technologies on the environment, on the basis of scientific evidence, as a means of providing NEMA with a base line to be used in the risk assessment and risk management procedure for granting SEA licences.

The other agencies would also advise NEMA on the effects of the new technologies on organic agriculture, the effect on subsistence of local farmers, the socio-economic effects of the introduction of new technologies, their impact on human and animal health as well as on the environment.

5.2.2 Proposed Amendments to the Bill

Apart from structural reorganisation, some amendments could be made to the Kenya Biosafety Bill 2007 to make it more integrative and thus facilitative of the attainment of sustainable development.

5.2.2 1 Framework Law and Supporting Regulations

The Kenya Biosafety Bill should be redesigned to act as a framework law on all biosafety and biotechnology issues in Kenya. The enactment of the Bill would then be accompanied by complementary regulations concretizing the general precautionary provisions included in the Bill. For instance guidelines on the mode of implementing and enforcing the measures of risk assessment, risk communication and risk management. The regulations would also deal with sector specific aspects of GMOs such as GM content in food and feed, GM content in non food substances, medical products containing GMOs, use of GM technologies in the health care industry, use of GM and technology in agriculture in plant and animal farming.

5.2.2.2 Increased Scope

The proposed Biosafety Bill should be amended to increase its scope. In order to constitute an integrated biosafety and biotechnology law, the Bill should address all GMO issues including use of GMOs in pharmaceuticals, the potential future use in human health care, the regulation of GM content in food imports and food aid, regulation of GM content in non food substances. As seen above the Bill would not need to contain comprehensive provisions on each of these issues but could be structured as a framework that would then form the basis for making more specific regulations to deal with the different aspects of GMO use. The Bill could also dedicate some provisions to the ethical

dimensions of GM research in accord with the principles outlined in the National Biotechnology Policy.

5.2.2.3 Balance between Precaution and Development

Risk assessment, one of the essential elements of a biosafety framework can be a costly venture for developing countries. A balance must be stuck between the need to guard against potential environmental and health risks and the need to economise on resources necessary for the risk assessment procedure. One of the ways in which the costs of risk assessment can be reduced is through regional cooperation. An East African Risk Assessment Body could be used to grant approvals to projects within East Africa. Clear provisions on the operation of such a system should be developed.

5.2.2.4 Funding

The Bill should include provisions indicating how the NBA is to obtain its funding. Some proposals on sources of funding include; a provision requiring a proportion of the SEA licence fee to be allocated to NBA to enable it meet the necessary administrative costs. Another proposal would be to have a percentage of all revenue generated by the other agencies from fines imposed for non compliance with GMO regulations to be remitted to the NBA.

5.2.2.5 GM Free Zones

Considering that Kenya is still a major producer of organic agricultural produce which is marketable particularly in European countries that are opposed to GM foods and feed, the Bill should empower the Minister to declare certain agricultural zones as 'GM free' and ban the use of GM crop technologies in such zones. This would ensure that a balance is maintained between organic agriculture and GM crop agriculture. GM free zones would

be the source of organic foods both for the local and export markets that prefer organic products. The determination of such zones would to be made by the Minister of Environment in consultation with the Minister for Trade, the Minister for Agriculture, the NBA, and the NCST. Considerations that could lead to declaration of a zone as GM free could include the protection of the livelihood of small scale farmers and preservation of genetic biodiversity.

5.3 CONCLUSION

Kenya needs to develop an integrated GMO regulatory system in order to ensure that the new technology contributes to sustainable development.

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