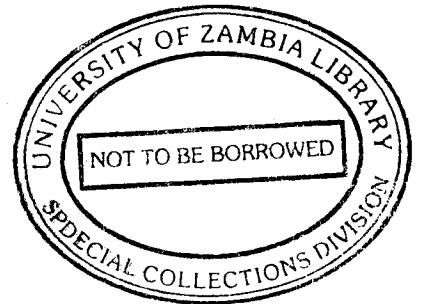


SHOULD ZAMBIA HAVE A LAW ON GMOs?

**THE NEED TO HAVE A LEGAL NATIONAL BIOSAFETY
FRAMEWORK**



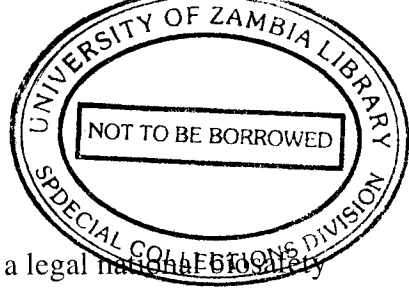
BY

KAOMA CHILESHE MATLDA

**UNZA
LUSAKA**

JANUARY, 2007

Obligatory Essay on



Should Zambia have a law on GMOs? The need to have a legal national Biosafety framework.

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Computer No.: 21077479

Submitted to the University of Zambia in Partial fulfillment of the requirements of Bachelor of Laws (LL.B) Degree Programme.

School of Law
University of Zambia
January, 2007

**The University of Zambia
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I recommend that the Obligatory Essay was prepared under my supervision by Kaoma Chileshe Matilda.

Entitled: **Should Zambia have a Law on GMO? The Need to have a Legal National Biosafety Framework.**

Be accepted for examination I have checked it carefully and I am satisfied that it fulfils requirements relating to format and laid down procedures governing obligatory essays.

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DECLARATION

I **Kaoma Chileshe Matilda**, do hereby declare that this dissertation is my authentic work and that to the best of my knowledge, information and belief, no similar piece of work has been previously produced at the University of Zambia or any other institution for the award of a Bachelor of Laws degree. All other books referred to in this dissertation have been duly acknowledged.

Made on this ...^{12th}.....day of...^{January}.....2007 by the said
Kaoma Chileshe Matilda.

.....^{Kaoma}.....

Signed

DEDICATION

This research paper is especially dedicated to my loving parents, the late **Richard Kaoma** and **Bwalya Crelity**. **Daddy** I would have loved you to see how far your efforts have gone, its sad you cannot. And to my **Mother** thank you for having carried on the good work of raising me all on your own. You have given your all that I can reach this far.

May the Almighty God continue to richly bless you.

ACKNOWLEDGEMENT

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I would like to convey gratitude to my supervisor **Dr. Matibini** for his assistance, patience and help given during my research. I never thought I would successfully complete this research, but his help and confidence made me go through.

ABBREVIATIONS

AIA	-	Advanced Information Agreement
CBD	-	Convention on Biological Diversity
EU	-	European Union
GE	-	Genetic Engineering
GM	-	Genetically Modified
GMO	-	Genetically Modified Organism
LMO	-	Living Modified Organisms
UNEP	-	United Nations Environmental Programme

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CHAPTER ONE

1.1 INTRODUCTION

Genetic modification, which is also known as 'genetic engineering' or recombinant DNA technology, was first used in the 1970s. It is one of the newest methods of introducing novel traits to micro-organisms, plants and animals. As application of modern technology, this technique allows selected individual genes to be transferred from one organism to another. This also is done between non – related species. Genetically modified organisms (GMOs) are a result of this technology. GMOs have been defined as organisms whose genetic material has been deliberately altered in a way that does not occur naturally by mating or recombination.¹ Recombinant DNA technology makes it possible to transfer genetic material through biochemical organisms. The most common types of GMOs that have been developed and commercialized are generally modified crop plant species such as genetically modified maize, soybean, oil – seed rape and cotton varieties. The varieties, have in the main, been genetically modified to provide resistance to certain insect pests and tolerance to total herbicides. The development of insect- resistant plants (such as cotton BT) reduces the use of harmful insecticides needed to control certain insect pests in crops. The use of plants tolerant to herbicide allows the use of this herbicide to be used to destroy a range of super weeds in the crop without destroying the genetically modified plant.

¹ Gundling, Williams N, (2000), A guide to designing Legal Institutional Frameworks on Alien Invasive species , IUCN p1

There are other types of GMOs which have direct implication on the characteristics of foodstuffs. For instance, by introducing a particular gene into a plant, fruit with delayed ripening is changed to early ripening. Animal such as fish (salmon) can be genetically modified to enhance their quality and accentuate certain characteristics like resistance to cold.² A genetically modified food is a food product containing some quantity of any GMO as ingredient. Although the term 'biotechnology' and 'genetic modification' (GM) are used interchangeably, GM is a special set of technologies that alter the genetic make up of such living organisms as plants, animals or bacteria. Biotechnology is a more general term and refers to the use of living organisms or their components, such as enzymes to make products that include wine, cheese, beer and yoghurt. Combining genes from different organisms are known as DNA technology and the resulting organisms are said to be genetically modified, genetically engineered or transgenic. GM products include medicines and vaccines, food and food ingredients, feed and fiber.

Gomes are alien in so far as they have no normal distribution and occur nowhere in the natural environment until released. As with all alien species that have become invasive, it is possible that the release or escape of transgenic or novel DNA might have severe and irreversible effects on the environment's safety. Like

² Ibid

alien species, GMOs have the potential to disrupt national biodiversity, natural resources and ecological processes unless appropriately assessed, regulated and managed. On the other hand, like many intentionally introduced species, GMOs may have potential to deliver economic and food security benefits.

1.2 CONTROVERSIES OVER GENETIC MODIFICATION

Genetic modification is a subject of controversy in its own right. This has led to much debate in the recent years as it poses risks both known and unknown. Some people view the science as intolerable meddling with the 'natural order'. Others would like to see it banned. Zambia, for instance, banned the importation of genetically modified food from the United States in 2005. Others would simply push for required labeling of GM food. Other controversies include the definition of patent and property pertaining to products of modified organism proliferating. In some countries like the United States, the practice of genetic modification as a scientific technique is not restricted. Some countries, however, especially in Europe, have taken the opposite side stating that genetic modification has not yet been proven safe, and, therefore, must not be accepted. This issue has been brought before the World Trade Organization (WTO), which determined that not allowing GM foods in a country creates an unnecessary obstacle to international trade.

1.3 RISKS AND BENEFITS

Benefits and risks of GMOs are assessed through comparison of the new organism in relation to its conventional counterpart (variety of food) and associated techniques (like pest management or food processing techniques).

Heffner P. observed that 'inputs traits, in general, allow lower use of pesticides and as a consequence, they benefit the environment and improve farmers' revenue. Among other specific benefits, insect-resistant varieties limit post harvest losses (insects are responsible of up to 50 percent of losses of harvested products in developing countries) and production of mycotoxins (responsible for serious health problems), and herbicide tolerant varieties contribute to soil erosion. Output traits will be of considerable benefit to the consumers through access to healthier food. Therefore, farmers, the environment and consumers benefit for the development of GMOs.³ This benefit will increase with the release of GMOs combining input traits and output traits.

Despite the fact that approximately 80million hectares have been grown with GMO crops worldwide from 1995 to 1999, and that billions of people have eaten GM foods without any documented harmful effect on human health or the environment, we have to be aware that GMOs, as any new product, may be associated with some risks which may be of various kinds. For instance, the use of herbicide tolerance genes could result in the production of super weeds that would be resistant to total herbicides. Also the introduction of a gene from a

³ Heffer P, Biotechnology: a modern tool for food production improvement, Switzerland

species that is known to be allergenic could result in the introduction of allergens in the novel food.

In 2000, the Food and Agriculture Organization (FAO) adopted a statement on biotechnology. This statement recognizes that biotechnology provides powerful tools for sustainable development and can be of significant assistance to increased agricultural production and productivity crucial to meeting the needs of an expanding population. It acknowledges that biotechnology could lead to higher yields on marginal lands, improve food quality and the health of many low income communities. In parallel, the FAO recognizes the potential risks to human health. Thus, caution must be exercised in order to reduce the risks.

The potential benefits can be summarized as follows:

On crops:

- (i) Enhanced quality and taste;
- (ii) Reduced maturation time;
- (iii) Increased nutrient, yields and stress tolerance;
- (iv) Increased resistance to disease, pests and herbicides; and
- (v) New products and growing techniques

On animals:

- (i) Increased resistance, productivity, hardiness and feed efficiency;
- (ii) Better yields of meat, eggs and milk;
- (iii) Improved animal health and diagnostic methods

On the environment:

- (i) Friendly bio-herbicides and bio-insecticides;
- (ii) Conservation of soil, water and energy;
- (iii) Bioprocessing for forestry products; and
- (iv) Better natural waste management.

On Society:

- (i) Increased food security for growing population;

The risks of GM products include the following:

On safety:

- (i) Potential human health impact; allergens, transfer of antibiotic resistance markers and several unknown effects;
- (ii) Potential environmental impact; unintended transfer of transgenes through cross pollination and loss of flora and fauna biodiversity; and
- (iii) Negative impact on wildlife.

On access and Intellectual Property;

- (i) Domination of world food production by few companies;
- (ii) Increasing dependence on Industrialized nations by developing nations;
and
- (iii) Bio-piracy: foreign exploitation of natural and genetic resources

On ethics:

- (i) Violation of natural organisms' intrinsic value;
- (ii) Tampering with nature by mixing genes among species;
- (iii) Objectives to consuming animal genes in plants and vice versa; and

(iv) Stressing of animals

On society:

(i) New advances may be skewed only to the interests of rich people.

Critics of GM foods contend that there is strong evidence that the cultivation of genetically modified plants may lead to environmental changes. However, whether a genetically modified plant itself can harm the environment is still a matter of controversy among scientists? Despite the fact that no scientific study has yet shown GM food to be harmful to humans, a 2003 survey by Pew Research Centre found that the majority of people in countries surveyed felt that GM foods were “bad”. Even though there are claims that GM foods may be safer than their conventional counterparts, many consumers especially in Europe are demanding that their “right to know” the origin and content of the food they consume be respected. During the crisis in Southern Africa, in 2002 -2003, the United States provided 60 percent of the total emergency aid to the affected countries in the region. Being aware of the risks of GMOs, the affected countries were reluctant to receive the aid. Mozambique, Malawi and Zimbabwe requested that the GM food be milled prior to it being distributed. This was after the World Food Program admitted that it has, since 1996 been, delivering food aid that included GM products without warning the recipient countries.⁴

⁴ Pierce F, 19 September 2002 “New Scientist” UN Shipping Modified Food Aid.

The risks of GMOs are a more source of concern than the benefits. This can be noted especially from how the European Union has responded to the use of GM products. European Union officials have put in place regulations to restore consumer confidence in technology. The regulations require strict labeling and traceability of all food and animal feed containing more than 0.5 percent GM ingredients. This will enable regulators to identify contaminated crops, food or feed and withdraw them from the food chain, thus preventing problems from arising. The US contends these regulations will violate free trade agreements. Despite such opposition several other countries feel that biosafety rules should be put in place. For instance, China, a producer of GM cotton has put in place biosafety rules that demand strict labeling and extensive documentation and Government approval for food shipments. Japan, also maintains labeling of GM food products. There is currently lack of knowledge concerning GMOs. It is imperative therefore, that the Zambian government educates the sensitizes the people on the nature of GMOs, the controversies that surround them and their risks and benefits.

CHAPTER TWO

THE INTERNATIONAL LEGAL FRAMEWORK

As the world must feed an increasing human population, agricultural producers and researchers need all available technologies including the rapidly developing modern biotechnologies. However, like all new technologies, there are uncertainties and potential risks associated with the use of biotechnology, which are addressed through the concept of biosafety. As such the international community developed international legal instruments to ensure that the testing, release, use and cross- border movements are properly managed and regulated.

2.1 NATURE OF INTERNATIONAL INSTRUMENTS

Several inter-governmental organizations have adopted international instruments addressing the issue of biotechnology and more specially the GMO issue. Trade in biotechnology is currently regulated within international rules and standards at the international level. Internationally agreed instruments may be binding or non-binding. Binding instruments are agreed between states, and have a mandatory character. They must be observed and their obligations performed in good faith. Non -binding instruments, sometimes referred to as 'soft law' are resolutions adopted by inter-governmental institutions, which are accepted by states concerned as guidelines for future action, though not mandatory.

There a number of international instruments that examine biotechnology and GMOs. These instruments provide a source of inspiration for developing national instruments. Some of the relevant ones are analyzed below.

2.1.1 THE CARTAGENA PROTOCOL ON BIOSAFETY (BIOSAFTEY PROTOCOL)

This Biosafety Protocol was adopted in Montreal in 2000 and came into effect on 11th September 2003. It is the first international law to specifically regulate genetic engineering, reflecting a global climate of concern about the safety, health and ecological risks of genetically modified organisms and wider political and socio-economic implications of corporate – driven science and technology. The Cartagena Protocol regulates genetic engineering biotechnology and not biotechnology in general. It covers living modified organisms (LMOs). This term (LMOs) is said to exclude non-living modified organisms which may potentially exclude all GMOs except those intended for growing in fields, GM animals and GM micro organisms. Therefore, countries should formulate natural laws where the term used, whether GMO or LMO, should be clearly defined. The Protocol addresses the fact that GMOs may have adverse effects on the conservation and sustainable use of biodiversity and also on human health. For the first time in international law, GMOs are recognized as inherently different, carrying special risks and hazards and hence need to regulate them internationally. The protocol

establishes the foundations of international law on the regulation primarily of the trans-boundary movement of GMOs.

The protocol sets minimum standards for the regulation of GMOs. Parties may take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the protocol. The objective of the protocol is to contribute to ensuring adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology and may have adverse which also effects on biodiversity conservation accounting for risks to human health. It does not apply to the transboundary movement of LMOs that are pharmaceuticals for human use addressed by other relevant international agreements. It is critical that national governments and developing countries in particular formulate domestic biosafety laws that improve on the scope and standards set by protocol.

At the heart of the Biosafety Protocol is a process of Advanced Informed Agreement (AIA). The process requires risk assessments and approval by an importing country before any LMO can be shipped to that country. The risk assessments and procedures are intended to identify and minimize the potential threat of a given LMO to the environment of the importing country. The protocol does not restrict the right of a party to take action that is more protective than it provides.

Each party to the protocol is to take the necessary and appropriate legal, administrative and other measures to implement the protocol obligations and to ensure that the development, handling transport, use, transfer and release of GMOs is undertaken in a manner that prevents or reduces risks to biosafety⁵. The most significant provisions of the biosafety protocol focus on the evaluation and notification between parties for LMOs stated for export and subsequent import. For LMOs intended for direct use as food or feed for processing, the contracting party that makes a final decision for domestic use must notify the biosafety clearing house created under the protocol when the LMO could find its way into international trade.⁶ The notification, at minimum, must contain information required under annex II. Most developing countries have no laws or regulations on biosafety and lack the capacity and technological and financial resources to regulate genetic engineering. Where it lacks a domestic regulatory framework, a developing country contracting party, or a party with a transition economy, can declare through the biosafety clearing house that its decision on the first import of an LMO for direct use as food, feed or processing will be pursuant to risk assessment. The protocol contains explicit public participation provisions. Contracting parties shall promote and facilitate public awareness, education and participation concerning safe transfer, handling and use of biosafety, conservation and sustainable use taking into consideration risks to human health.

⁵ Article 2 (1 and 2)

⁶ Article 11

2.1.2 CONVENTION ON BIOLOGICAL DIVERSITY – CBD

The Convention on Biological Diversity (CBD) addresses biosafety in two articles: Article 8 (g) and Article 19 (3) and (4). Under this Convention each contracting party is required to domestically regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity. Risks to health are also taken into account. The Convention places a general obligation on the parties to transfer environmentally sound technology relevant to the conservation and sustainable use of biodiversity. Under the CBD, there are several general requirements that provide important indicators for planning tools and co-operative approaches that should underpin the design of legal frameworks. There is also specific guidance on the introduction to marine and coastal ecosystems developed in accordance with Jakarta Mandate on Marine and Coastal Biological diversity.

2.1.3 THE CODEX ALIMENTARIUS

The Codex Alimentarius is a collection of internationally adopted food standards presented in a uniform manner. Codex standards ensure that consumers receive products that meet internationally accepted minimum quality levels which are safe and do not present a health hazard.⁷ The highest priority of the codex is to

⁷ FAO/WHO 1999

protect the health of consumers and to ensure fair practices in food trade.⁸ Codex standards, guidelines and recommendations are based on current scientific knowledge including assessment of risk to human health. The range of standards developed by the Codex commission covers all foods whether processed, semi processed or raw, intended for sale to consumer or for intermediate processing. The Codex Guidelines for the production, processing, labeling and marketing of organically produced foods provide an internationally agreed approach to produce, label and make claims about organically produced foods. The general aims of the guidelines include, inter alia, protecting consumers against deception and fraud, to protect organic producers against misrepresentation of other agricultural products as organic. Codex standards, guidelines and other recommendations are not binding on member States, but are of a point of reference in international law. They can also form the basis for national legislation on food control.

2.1.4 AGENDA 21

Agenda 21 addresses the environmentally sound management of biotechnology in chapter 16. The programme assists to foster the application of internationally agreed principles to ensure environmentally sound management, to engender

⁸ Article 1

public trust and confidence, to promote development of sustainable biotechnological applications and to establish appropriate enabling mechanisms.⁹

Agenda 21 sets out a five point programme which includes:

- (i) Increasing the availability of food, feed and renewable raw materials;
- (ii) Improving human health;
- (iii) Enhancing environmental protection;
- (iv) Enhancing safety and developing international mechanisms for co-operation, and
- (v) Establishing enabling mechanisms to develop and apply biotechnology in an environmentally friendly sound manner

Programme area (i) puts into perspective the need not just to increase food supply through biotechnology, but also to improve food distribution and putting agriculture on a more sustainable footing. It highlights that productivity gains have only benefited industrialized countries where biotechnology has been concentrated and that this imbalance needs to be specified. For example, Governments are called on to improve plant and animal breeding and micro-organisms through traditional and modern biotechnologies. But this should be

⁹ Paragraph 16.1

undertaken, taking into account the needs of farmers, as well as socio-economic, cultural and environmental impacts.¹⁰

2.1.5 THE WORLD TRADE ORGANISATION (WTO) AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES (SPS AGREEMENT)

The WTO oversees the implementation of the Agreement on Application of Sanitary and Phytosanitary Measures (SPS Agreement).

The SPS Agreement applies to all sanitary and phytosanitary measures which may directly or indirectly affect international trade. The SPS Agreement does not explicitly mention GMOs. However, when GMOs are in international trade, and may pose a threat to human, animal or plant life or health in an importing country, the SPS Agreement would apply to national sanitary or phytosanitary measures (SPMs) designed to address the threats prior to import. In general, the SPS Agreement provides a multi lateral framework of rules to guide development, adoption, and enforcement of sanitary and phytosanitary measures to minimize their negative impacts. SPMs are necessary to protect human, animal, plant life or health, provided these measures are not consistent with the SPS Agreement.

¹⁰ Paragraph 16.4

2.1.6 THE WTO AGREEMENT ON TECHNICAL BARRIERS TO TRADE

The WTO oversees the implementation of the Agreement on Technical Barriers to Trade (TBT Agreement). The TBT Agreement is relevant to biotechnology products because it generally applies to technical regulations and standards, including packaging, marking and labeling requirements. It also applies to conformity assessments procedures. The TBT Agreement recognizes that no country should be prevented from taking measures necessary to ensure the quality of its exports; to protect human, animal or plant life or health, or the environment, or prevent deceptive practices. The TBT Agreement applies to all products. It does not apply to phytosanitary measures. Therefore, the SPS Agreement would not apply where a biotechnological product is the object of measures to prevent a risk to human, plant or animal health. The TBT Agreement would apply where, for example, a product is merely labeled as containing GMOs. In general, imported products are to be accorded national treatment.

2.2 STATE RESPONSIBILITY UNDER INTERNATIONAL LAW.

In international law, States have a general responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or to areas beyond the limits of national jurisdiction. Charles Riemenschneider, Director of the FAO in North America, observes that at

present, public international law on liability is underdeveloped. Such questions of liability raise complex questions of how different sets of international rules (biodiversity, biosafety, quarantine and trade) fit together in the current state of international law. Thus, it is imperative that countries assess whether or not they have adequate national legislation to protect the environment, biodiversity and human health. Countries are called upon to set up procedures to develop liability rules.

Biodiversity related instruments are essentially silent on this question. At the current time, the Berne Convention (not discussed above) seems to be the only treaty under which a formal recommendation covering liability has been adopted.¹¹ Zambia is party to all the international instruments that have been discussed in this chapter. However, these international instruments do not adequately cover liability. For instance where a specie is introduced into a territory of a state and spreads to other states or the region, causing damage to the environment, no liability can be placed on the state from which it originated. Most of the laws developed internationally on biosafety are not binding on the countries or States that are party. As such, states are under no legal obligation to observe and implement their provisions. It is important therefore that countries have in place their own legislation that will ensure strict observance of biosafety regulations.

¹¹ The non-binding recommendation on the education of non-native Terrestrial Vertebrates (No. 77, 1999) adopted by the Standing Committee to the Convention, provides that where a species is introduced into the territory state spreads to neighboring states or entire regions and damages the environment; this should give rise to the liability of the state from which it originated.

Zambia is a developing country with limited scientific capability to assess the risks of GMOs. In fact, it is more expensive for farmers to grow GM crops and this allows corporations to have greater control over the farmers' income. This is an issue not adequately addressed by international instruments. These loopholes or flaws of international law make it necessary for countries to develop national legislation that will adequately cover their problem. The following chapter will therefore examine some countries that have already developed their own legislation and compare them to Zambia which has a national policy on Biosafety and is yet to have a law that addresses biosafety.

CHAPTER THREE

3.0 REGIONAL LEGAL AND POLICY BIOSAFETY FRAMEWORKS

Genetic engineering brings with it a wide range of biosafety concerns and broader socio-economic impacts. Genetic engineering and GMOs have an impact on several fundamental human rights, including the right to nutrition, safe and culturally acceptable food. It also raises far reaching ethical concerns for those that adhere to value systems underpinned by communal, spiritually concerning life and food. Biosafety refers to the need to protect human health and the environment from the possible effects of products of modern technology. Thus there is a pertinent need to promote safe adoption of biotechnology through national legislation.

In the previous chapter a number of international instruments dealing with and addressing GMOs were discussed. These, however, cannot and do not take into account the differing legal structures and traditions, the varying environmental conditions and concerns and the societal and cultural uniqueness of each country. The need for national legislations that impose stringent biosafety measures is well recognized under international law. Most regions in the world have put in place legal and policy biosafety frameworks on which most of the states within those regions base their legal biosafety frameworks

3.1 EUROPEAN UNION (EU)

A report compiled by experts in Europe indicates that over the past four years the European Union has put in place a stringent system to regulate genetically modified food, feed and crops.¹² The authorization procedure under this new system ensures that only GMOs which are safe for human and animal consumption and for release into the environment can be placed on the European market. Clear labeling rules allow farmers, other users and consumers to choose whether or not to purchase such products. A GMO or a genetically modified food, feed or products can only be put in the market on the EU after it has been authorized on the basis of detailed procedure which provides the basis for a scientific assessment of the risks to human health and the environment.

OVERVIEW OF THE EU LEGISLATION

The EU legislation on GMOs has been in place since the early 1990s. This legislation has two main objectives which are ÷

- (i) To protect human health and the environment; and
- (ii) To ensure the free movement of the same GM products in the EU market.

¹²

The entire corpus of GMO legislation was recently amended leading to the creation of two main legal instruments. These are Directive 2001/18/EC and Directive 90/219/EC. Directive 2001/18/EC applies to the deliberate release of GMOs into the environment. This includes the experimental release of GMOs into the environment and the placing on the market of GMO feed food and products. Directive 90/219/EC as amended by Directive 98/81/EC regulates research and industrial work activities involving genetically modified organisms. In general, the European Union legislation introduces a number of issues. These can be seen in part C of Directive 2001/18/EC and they include the following:-

- (i) Principles for environment risk assessment;
- (ii) Mandatory post-market monitoring requirement, including the long term effects associated with the interaction of other GMOs and the environment;
- (iii) Mandatory information to the public;
- (iv) A requirement for member states to ensure labeling;
- (v) Allow the identification and detection of GMOs to facilitate post-market; inspection and control; and
- (vi) An obligation to consult the European Parliament on decisions to authorize release of GMOs

The EU legislation takes into account the EUs international trade commitments and requirements of the Cartagena Protocol on Biosafety, specifically as obligations on importers in products on the EU and obligations on exporters of products to third countries. The EUs regulatory system for authorizing GMOs is deemed to be in line with the World Trade Organization (WTO)'s rules.

3.2 AFRICAN NATIONS

In June 1999, the African Union (then the Organization of African Unity), engaged a team of biosafety experts to prepare a framework of biosafety regulations that would operate as a model law for African countries. The model law was designed to protect Africa's biodiversity environment and the health of its people from risks posed by GMOs. The African model law on safety and biotechnology was finalized in Ethiopia, in May 2001, and endorsed by the Council of Ministers in Zambia in July 2001. Although the model law is not legally binding; it facilitates the harmonization of existing legislation in the area of biosafety that would ensure the adoption of unified legislation in Africa. The model law has been strongly influenced by the Cartagena Protocol on Biosafety. The protocol provides a legally binding framework of rules to be applied to the import, export, transit and other activities related to the use of GMOs in order to protect biodiversity, the environment and the human health from risks posed by GMOs.¹³ The model law seeks to introduce such measures. It specifically

¹³ Art 4 of Biosafety Protocol.

recognizes that Africa's diversity, environment and the health of its people can only be protected if countries on the continent adopt high standards of safety. The model law deals with some issues that are not dealt with by the biosafety protocol. These include mandatory labeling of GMOs and GM food, the liability and redress for harm caused by GMOs to human health, the environment and for the resultant economic loss. African countries have the sovereign right to take such measures which the Biosafety Protocol does not preclude. The model recognizes that strict controls are necessary in Africa where genetically modified food is just donated as food aid. It recognizes the sovereign right of every country to require a rigorous risk assessment regarding the issue of any GMO for use before it makes decisions.

3.3 SCOPE OF THE MODEL LAW

The model law applies to the import, export, transit contained use, release and placing on the market of any GMOs and products of GMOs, whether it is intended for release into the environment, for use as the pharmaceutical, for food, feed and processing. It establishes uniform provisions that apply to all these activities because it views the risks from all GMOs as being the same, whether they are used in agriculture, medicine, or research, and regardless of whether they are classified as feed or food.

The model law recognizes the sovereign right of every country to require a rigorous risk assessment regarding the use of GMO for any purpose before it

makes a decision. It also deals with products of GMOs and GMOs that are classified as pharmaceuticals in a similar manner. The model law with regard to products of GMOs adopted a precautionary approach in as much as such products may have adverse effects on biodiversity, the environment and human health. The model law provides for public participation and access to information as important and indispensable components of environmental governance. In so doing, it expressly takes into account Article 23 of the Biosafety Protocol which obliges parties to consult the public in the decision making process by the way of notice and comment procedure.¹⁴

A biosafety law is not complete without a comprehensive labeling and traceability system. Article 11 of the model law sets out provisions on labeling and traceability which African countries should build on. Miriam Mayet, an expert on GMOs, stated that traceability, is the ability to track a GMO back to those responsible for the GMOs original development and those responsible for import and export. This is particularly important where an illegal import or release is suspected and where damage occurs from intentional and unintentional releases. It has been observed however, that developing countries delay the process of establishing labeling and traceability or identification systems. The Model Law has provided an opportunity for Governments in Africa to introduce national biosafety regulations that adhere to a broader and unified continental framework. African countries are urged to adopt the model law and subscribe to common environmental standards and protective measures established by it. In so doing,

¹⁴ Article 5(2) of the Model Law

African countries will demonstrate to their citizens and the international community that they are committed to protecting Africa's people, environment and biodiversity.

3.4 SELECTED NATIONAL BIOSAFETY FRAMEWORKS IN AFRICA

Putting in place a national legislation enables a country to desist from being used by the powerful biotechnological industry as experimental and dumping grounds for its products. As each country has sovereign rights over its resources, it is imperative that there is legislation that protects its resources from exploitation and negative impacts of GMOs. Most of the African countries receive food and which is mostly genetically modified as such these countries have put in place legal biosafety frameworks that will safeguard human and animal health and the environment. Zambia is yet to respond to this new technology in terms of enacting a law. Today there is the National Biotechnology and Biosafety Policy that was adopted in 2003.

From the several African countries that have national biosafety frameworks, Malawi, Kenya, Tanzania and South Africa will be discussed.

3.4.1 KENYA

In 2004, the Director of the African Centre for Biosafety critically analyzed the Kenyan Biosafety Bill (which is now law) and noted the following:

In general, the Bill does not in its present form represent an adequate, robust and comprehensive biosafety regime designed to protect the environment human health and biodiversity from the risks posed by GMOs and its related activities. It is a draft legislation that seeks to put in a place a mere system designed to approve applications for the contained use; import, export and placing on the market and release into the environment of GMOs. The underlying imperative of the Bill was the promotion of genetic engineering and not biosafety. Critically important provisions of the Biosafety Protocol that form the cornerstones of biosafety regulation have been omitted from the Bill in its entirety. Further, the Bill restrictively applied only to adverse impacts on the environment. It did not engage with biodiversity and human health. It failed to deal with traceability and labeling and liability and redress. In this regard, the African Model Law on Safety in Biotechnology was not used for drafting the Bill. This was critical to the decision of the heads of state of the African Union in July 2003, which urged member states to use the model law as the basis for their biosafety regulatory framework.

Kenya needs a comprehensive biosafety framework that will adequately protect the environment human and animal health and biosafety from the risk posed by GMOs.

3.4.2 TANZANIA

Tanzania like Zambia has no legislation on Biosafety and related activities. It has National Biosafety Guidelines that were prepared in June 2004, under the United Nations Environmental Programme (UNEP) Biosafety Capacity Building Project.

The salient features of the guidelines are that they facilitate the importation and use of GMOs and their products in Tanzania. The scope is broad enough to apply all the relevant activities related to GMOs and include import, export, and experimentation and so on. They contain good provisions on liability and redress inspired by the model law. They reflect a commitment to involving a wide range of stake holders, through a consultative process in order to promote and facilitate public awareness and participation.

These guidelines have shortcomings to the extent that they are not legally binding. As they are a voluntary framework for the introduction of GMOs, they lack the force for compliance and enforcement and are hence a poor substitute for a legally binding biosafety regime. As they are not enforceable in the art of law, they cannot act as deterrent for the introduction of risky GMOs in Tanzania.

The guidelines emphasize field trials and neglect adequate biosafety regulation for commercial releases and imports of GMOs as food aid, and processing. A legally binding biosafety regime is indispensable. Every effort should be made to put in place such a regime in Tanzania. As the guidelines lack the force of law they should be discouraged. The Government should aim to have a sound biosafety regulatory framework in place.

3.4.3 MALAWI

The Government of Malawi published its biosafety draft regulations in 2002, when there was extreme food aid controversy. Malawi is not yet party to the Cartagena Protocol on Biosafety. It however participated in a United States Agency for International Development (USAID) funded biosafety capacity building project, the Southern African Regional Biotechnology Program (SARB).

Miriam Mayet, Director of African Centre for Biosafety made the following remarks over Malawi's Biosafety law 'Malawi's biosafety law is unspeakably appalling, displaying and contemptuous disregard for biosafety. It is the only biosafety law that deals with the issue of risks posed by GMOs to human health and the environment in its preamble only and not in its operational provisions. The biodiversity law makes a mockery of the biosafety protocol hard fought by the African Group of countries.'¹⁵

¹⁵ Mayet M, (2004) Analysis of Malawi 's Biodiversity Legislation

Malawi is the first African country to allow gene therapy for humans to be regulated allowed in a biosafety legislation. Malawi has produced a biosafety legislation that has absolutely nothing at to do with biosafety. This is because the imperatives that underpin the law include;

- (i) Ensuring that research experiments of GMOs can take place with minimum or no biosafety restriction being imposed by creating a special permit system;¹⁶
- (ii) Genetically modified food aid is accepted without any restrictions or receipt of such food. GMOs and their products may be imported into Malawi without any restriction;
- (iii) Establishing a licensing system. This is provided in section 19 of the Biosafety law. This system however, does not encompass, any biosafety measures such as risk assessment, risk management, social-economic impacts and so on; and
- (iv) The law excludes the public from participating in the regulation and decision making process concerning GMOs and their products. All decision making powers are rested in the Minister of Environment who is not obliged to consult with any scientific or expert institution.

The biosafety law of Malawi has been said to be a bad piece of legislation in that it does not address biosafety in its entirety. After all the efforts by the African Union to put in place a model law which acts as a guide for the African countries, Malawi was influenced by the United States.

¹⁶ 5.Art.18 of Of Biosafety Law of Malawi.

3.4.4 SOUTH AFRICA

South Africa's Genetically Modified Organism Act (Act No.15 of 1997) came into effect on 1st December 1999. This "GMO Act" is riddled with fundamental flaws, when compared, in particular, to a number of international biosafety regimes. It does not in its present form constitute an adequate biosafety regime that ensures GMOs are appropriate and do not cause harm to the environment, or to human and animal health. The preamble of the GMOs Act, 1997, states that it is an Act to provide for measures to promote the responsible development, production, use and application of GMOs; and to ensure that all activities involving the use of GMOs shall be carried out in such a way as to limit possible harmful consequences to the environment. The Act applies only to viable living organisms and not to the products derived from GMO products. Products of GMOs per se, are not regulated by any specific legislation, so they are not subject to specially tailored testing. Public participation is not adequately provided for. This is inconsistent with tenets upon which South Africa's democracy has been built. The only opportunity for public participation is by way of notice and comment procedure linked to permit application for environmental releases. With regards to access information, the Act provides only for the right of access only to information regarding the foreseeable impact of GMOs, in particular any pathogenic or ecological disruptive impacts. The Act in so providing has precluded from gaining access to information on the potential or

likely impacts and the risks posed by the GMOs concerned to human and animal health, biological diversity and the environment.

Adoption of a national biosafety regulatory framework is essential in order for government to respond to the challenges posed by the rapid growing technology. A number of African countries including the selected ones discussed above are responding. Their biosafety frameworks, however, have serious shortcomings and as such do not adequately address biosafety. It is imperative for the African countries to base their national biosafety frameworks on the model law because it is a comprehensive tool for biosafety. To subscribe to other regional biosafety regimes would not protect African countries as the continent is being used by the powerful biotechnology industry as experimental and dumping grounds for its products.

CHAPTER FOUR

ZAMBIA'S RESPONSE TO GMOs

4.1 NATIONAL BIOTECHNOLOGY AND BIOSAFETY POLICY

Zambia has contributed enormously to the debate regarding the risks posed by GMOs to human health, the environment and biodiversity on the African continent generally, and in Southern Africa in particular when it banned the import of genetically modified (GM) food from the United States.¹⁷ The Zambian government under the Ministry of Science and Technology in response to the problem of GMOs developed the National Biotechnology and Biosafety Policy in 2003. Zambia, along with other African countries, took on negotiations that led to development of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity. Zambia signed the Convention on Biological Diversity on June 11, 1992 and ratified it on May 28, 1993. It took ten years however, to fulfill some of the obligations of the CBD when it implemented the Biosafety Policy. The United Nations Environment Program UNEP/GEF Project made it possible to initiate the process of developing the policy.

Biotechnology and its products can contribute significantly to economic development of Zambia, especially in the areas of agriculture, health-care, environment as well as industry. However, maximal benefits from modern

¹⁷ Mayet Mirriam, (2004) comments on the Zambian Draft National Biosafety Framework.

biotechnology can only be realized if it is applied judiciously and in a sustainable manner. Although there a number of international instruments and agreements that address the use of biosafety, they are limited in scope and/or do not adequately address cross-border movement and handling of GMOs. Zambia therefore, adopted the Biosafety Policy in an attempt to adequately address the use, and release into the environment and movement of GMOs.

The mission of the Biotechnology and Biosafety policy is to guide the judicious use and regulation of modern biotechnology for the sustainable development of the nation, with minimum risks to human and animal health, as well as the environment, including Zambia's biological diversity. The objectives are to support the development of research and industrial capacity to safely apply biotechnology techniques for the enhancement of Zambia's socio-economic and environmental well being. The guiding principles of the Biosafety Policy include; the precautionary principles, advanced information agreement, risk assessment, socio-economic impact, public participation liability and redress, recognition of possible conflict between conservation of biodiversity and trade, as well as recognition of rights of both developers and innovators over genetic resources and technologies.

The Precautionary Principle

No approval for transfer, use and release of GMOs shall be given unless there is firm and sufficient evidence that the GMOs or products thereby pose no risk to

human and animal health or the environment. Approval shall not be given where there is reason to believe that harm or damage may result, even when there is lack of scientific evidence or certainty.¹⁸

Advance Informed Agreement

Any person who intends to conduct research, develop, apply, release and commercialise GMOs and products thereof shall submit an application in writing for authorisation. There shall be no research, development, application, release and commercialisation of GMOs, combinations of GMOs and products thereof without the prior approval of the National Biosafety Authority (NBA) to be created under the Biosafety Act.¹⁹

Risk Assessment

No research, development, application, release and commercialization of GMOs and products thereof shall be taken without a risk report. It is the responsibility of an applicant to conduct and/or have an assessment of the impacts and risks posed by GMOs and products thereof to human and animal health, the environment and biological diversity under the supervision of the NBA.²⁰

¹⁸ National Biotechnology and Biosafety Policy (2003) p.7.

¹⁹ Ibid.

²⁰ National Biosafety Policy, August 2003, page 8.

Socio-economic Impact

The risk assessment report shall include the direct or indirect effects to the economy, social or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies as a result of the import, contained use, deliberate release or placing on the market of GMOs or products.²¹

Public Participation

As regards public participation, the National Biosafety Policy (2003) provides that the NBA shall make available to the public information pertaining to applications for the research, development, use and commercialisation of GMO(s), and products. The public may make comments within such period as may be specified by the NBA.

4.2 SCOPE OF THE BIOTECHNOLOGY AND BIOSAFETY POLICY

The Biotechnology and Biosafety policy shall apply to:

- (a) The research, development, application, release and commercialization of GMOs, combinations of GMO(s) and products thereof;
 - (b) Occupational safety at work places where biotechnology procedures are used or products handled;
 - (c) Labeling of GMOs and products developed in or imported in Zambia;
- and

²¹ Ibid.

(d) Any other resources deemed necessary to ensure protection of human and animal health as well as the environment with respect to the use of Biotechnology in Zambia.

4.3 IMPLEMENTATION OF THE POLICY

Biotechnology and Biosafety policy will be implemented through the NBA. The regulatory and administrative processes will include notification, information transfer and review, risk assessment and management, research and development activities, field release procedures including handling, containment, monitoring agreed disposal and contingency plans for spillage or accidental release. The Biotechnology and Biosafety policy is not sufficient to regulate and address the use of GMOs and its products. There is need for enacting supporting legislation. The policy constantly refers to the National Biosafety Authority (NBA) which will only be established upon enactment of the legislation. This makes implementation of the policy almost non-achievable.

4.4 LEGAL FRAMEWORK

There is no law in the existing Zambian statutes that provides for biosafety. That is to say, there is no Zambian statute that protects human and animal health as well as the environment, including biological diversity from potential risks posed by GMOs. The only laws that are there basically deal with the transfer, handling, release and use of animals and plants. There are no laws which deal specifically with the transfer, handling and use of micro organisations. Some laws cover the

quality of food and other foodstuffs and pharmaceutical products whereas the other laws are concerned with protecting the general public and the environment from possible negative effects of industrial activities. Some of these laws are:

- CAP 303 - Food and Drug Act
- CAP 231 - Noxious Weeds Act
- CAP 233 - Plant Pest and Disease Act
- CAP 237 - Tobacco Act
- CAP 238 - Cotton Act; and
- CAP 204 - Environment Protection and Pollution Control Act.

There is a pertinent need to amend and/or modify these laws in line with Biosafety. This is so because under the current scenario in Zambia (absence of biosafety legislation) these laws can ensure that biotechnology research, application and commercialization of GMOs is carried out with minimum adverse effects both to human health and the environment.

4.4.1 The Draft National Biosafety Framework of 2004

Introduction of GMOs into the environment may be harmful and dangerous to the environment. Similarly, handling of pathogenic or micro organisms can be dangerous. The chemicals that are used in these manipulations may be harmful to life. To protect human and animal health and the environment from these possible dangers, the Ministry responsible for science and technology is making

every effort to put in place a National Biosafety Framework. This initiative dates back to 2002, yet to date there has been no enactment. There have been drafts made in respect of the Zambian National Biosafety Framework.

In April 2004, Miriam Mayet made some comments on the Zambian Draft Biosafety Framework. The comments were made after the USAID made recommendations to the Republic of Zambia in respect of the National Biosafety Framework. The USAID made extensive comments throughout the text of the draft legislation, urging Zambia to use the specific wording of the Cartagena Protocol on Biosafety in regard to the definitions, socio-economic impacts, risk assessments and so forth. Zambia was intimately involved in the Biosafety Protocol negotiations and thus is aware that every single definition, proposal or annex was strongly contested by genetic engineering industry. Mayet thus observed that there is no need for Zambia to restrict itself to the wording (verbatim) of the Biosafety Protocol.²²

The Biosafety Protocol does not and cannot restrict the sovereign rights of countries to which actions should be taken as regards GMOs. Article 2(4) of the Biosafety Protocol provides that:

“Nothing in this Protocol shall be interpreted as restricting the right of a party to take action that is more protective of the conservation and sustainable use of biosafety diversity...”

²² Mayet M. (2004) comments on the Zambian Draft National Biosafety Framework p.2.

According to the IUCN, this paragraph establishes that the rules contained in the Biosafety Protocol are a 'floor' rather than a 'ceiling', that is, they are the minimum standards for achieving the objective of the protocol.

As regards products of GMOs the Bill included them in the draft legislation. The USAID, however, recommended that all references to products of GMOs be removed from the scope of the legislation, on the grounds that they be regulated in terms of existing legislation dealing with health and safety issues. Mayet recommended on the contrary, that products of GMOs should be covered in the national biosafety framework as they may pose the same risks to biodiversity and the environment as GMOs. There is increasing scientific evidence that points to the adverse effects from products of GMOs on human and animal health and the environment. It has been found that products of certain GMOs may contain recombinant DNA, which may persist and be transferred to the micro flora in the intestinal tracts of humans and animals.²³

The USAID recommended that GMOs imported into Zambia for use as feed, food and processing not be subject to the same regulatory measures and rigor as GMOs imported for the introduction into the environment, since the Biosafety Protocol creates a special mechanism to deal with the former scenario. Although it is true that the Biosafety protocol excludes the so called LMO-FFPs (living modified organism intended for direct use as feed processing), the distinction

²³ Ibid.

between GMOs and LMO-F is one that the Miami Group of countries and industry introduced into the Protocol in order to expedite trade in GMOs and not because it is scientifically justified. Zambia has a sovereign right to require notification before any import of any GMO for any use can take place, and a right to require a risk assessment for any import of any GMO for whatever purpose. Therefore, it is in the interest of good governance for the biosafety legislation not to make the distinction because risks from all GMOs are similar irrespective of whether GMOs are used as seeds, pharmaceuticals food, feed or processing.

In respect of access to information, the USAID recommended that the location sites of releases not be made available to the Zambian public because of the likelihood of vandalism. Mayet stated that there has been no single act of vandalism accruing anywhere in Africa where sites of releases have been established. She further stated that although protest action had taken place in Europe and elsewhere, it had no bearing on Zambia. In any event, it must be borne in mind that parties to the Biosafety Protocol have an obligation to make certain information available, such as decisions which include permits, and information on the location of sites of release.

Biotechnology and Biosafety is an exceptionally expensive and specialised field of technology. The regulation and monitoring of Biotechnology is costly for governments irrespective of their own Biotechnology capacity. Zambia needs to rehabilitate its laboratories to suit accreditation to international standard. To

CHAPTER FIVE

RECOMMENDATIONS AND CONCLUSION

Legally binding biosafety regimes are indispensable and irreplaceable. Every effort must be made by any state to establish a sound and comprehensive framework. The level of protection should not only be confined to those activities that international instruments (e.g. the Biosafety Protocol) regulate. It is imperative that the scope of a national biosafety framework includes what is not addressed in the international instruments.

5.1 RECOMMENDATIONS

In formulating the national legislation, Zambia must ensure that it goes beyond the provisions of the Cartagena Protocol. This is so because some problems are peculiar to Zambia and as such cannot be addressed in an international instrument. The Biosafety framework must not only avoid the adverse effects of GMOs on the environment, but specific reference must be made to human and animal health and Zambia's biodiversity. Biosafety must be the underlying imperative of the law.

Zambia should ensure that important provisions that form the cornerstone of the biosafety regulation are not in any way omitted from the legislation.

These include, inter alia, the precautionary principle and access to information, traceability and labeling and liability and redress for harm caused by GMOs to human health, the environment and resultant economic loss.

The proposed legislation must also cover products of GMOs and GMOs that are pharmaceuticals in a similar manner. Most laws ignore products of GMOs (e.g. the South African GMO Act). The law must also put in place a rigorous risk assessment and risk management system. In so doing, Zambia will have a right to sufficient, as opposed to minimum, information being furnished about the GMO or its' proposed use prior to decision making. It is critically important for a country to know which GMOs are entering the country and for what uses.

As regards definitions, it is recommended that the Zambian legislation should provide more scientifically accurate decisions so as to prevent loopholes in the law. The Biosafety Protocol on which Zambia relies has flaws in some of its definitions. As such, it would be dangerous for Zambia to restrict herself to the definitions provided by the Biosafety Protocol.

It is recommended that the Zambian legislation should not include users of technology and Industry as part of the National Biosafety Authority. Biosafety regulation is about regulation of technology and industry. Industry cannot be part of the decision making apparatus. It has an interest in the promotion of

technology and the commercialization of its products because it stands to profit financially, as such it should not be allowed to participate.

CONCLUSION

Genetic engineering brings with it a wide range of biosafety concerns and broader socio-economic impacts. Genetic engineering and GMOs impact on several fundamental human rights including the rights to nutritious, safe and culturally acceptable food and the right to a safe and healthy environment. GMOs are alien and it is possible that their release or escape might have severe and irreversible effects on environmental safety. GMOs have the potential to disrupt native biodiversity, natural resources and ecological process unless they are properly assessed and managed. GMO applications are encumbered with many uncertainties and as such require a regulatory framework.

A number of international instruments have been established to regulate the release, use and movement of GMOs. These however, do not adequately address some elements that are specific to particular countries. A national binding biosafety framework becomes indispensable as it can be used to respond to the changes in technology and the changes a country will experience socially and economically.

The Zambian Government has responded to this by formulating a national biosafety policy. It has also drafted a new legislation that will, among other things, implement the Cartagena Protocol on Biosafety. The draft legislation is to be submitted to Parliament between January and March 2007. It is hoped that this legislation will help regulate and monitor GMO and enable Government to penalize organizations and companies that do not meet biosafety requirements. The Government needs to make its own decisions based on the needs and opinions of the Zambian people. This can be achieved by having a biosafety law in the Zambian context. A comprehensive biosafety law needs to be adopted to ensure that the Zambian people and the environment are protected from GMO contamination through experimental releases, food, feed or any other means.

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