GMOS FOR FOOD, FEED AND PROCESSING: IS THE LEGAL FRAMEWORK EFFECTIVE?

BY

HUMPHREY MATUTA CHITALU

UNZA 2012

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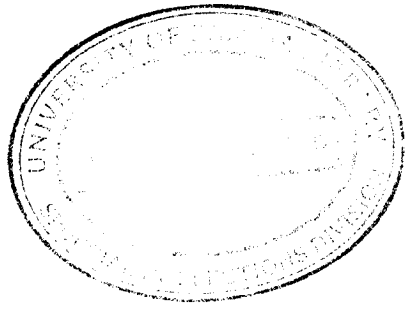

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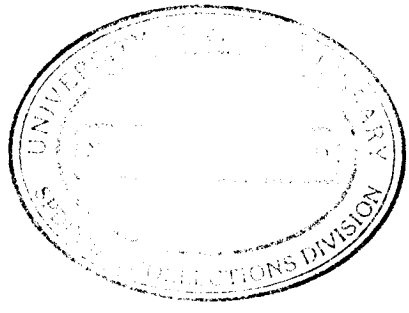

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BY

HUMPHREY MATUTA CHITALU

BEING A PAPER SUBMITTED IN PARTIAL FULFILMENT OF THE EXAMINATION REQUIREMENTS FOR THE AWARD OF THE DEGREE OF BACHELOR OF LAWS OF THE UNIVERSITY OF ZAMBIA

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ABSTRACT

The problem is that biotechnology and its GMOs products has moved at such a dizzying pace that neither the law nor regulating authorities can keep up with it. Researchers warn that there are no long-term, large scale tests to prove the biosafety of the GMOs. GMOs biosafety is a concept that refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. At the same time, modern biotechnology is recognized as having a great potential for the promotion of human wellbeing, particularly in meeting critical needs for food, agriculture and health care.

This study was intended to provide a basic and balanced understanding of the GMO issue, the current debateand the particular issues of regulation and responsible environmental action that arise from it. To achieve this objective, an examination of the national biosafety legal framework was performed in comparison with such similar regional and international frameworks and established that the Zambian system is effective for GMO biosafety regulatory aspects.

It is common ground that harmonization of international, regional and national regulatory frameworks should focus on the issues of strengthening capacities and information sharing for biotechnology safety. Zambia must acquire technology and capacities necessary to sustainably handle the challenges of modern biotechnology.Setting up an effective national regulatory framework demands for harmonization at the national level all the institutions dealing with the regulatory issues.

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I thank my supervisor Dr. Iris Mwanza for getting me started. Her resourceful experience and supervisory guidance enabled me to successfully complete this work.

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To you all, I would like to say, may the Almighty Jehovah God enrich your lives to the fullest.

DEDICATION

This work is dedicated to all who sacrificed for me, both spiritually and financially, especially my wife Dr. Mirriam P. Mtolo and my daughter Faith Chitalu. It has not been an easy journey and without your support, I would not have managed. I thank the Almighty Jehovah God for all of you.

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LIST OF ABBREVIATIONS

CBD: Convention on Biological Diversity

DNA:Deoxyribonucleic Acid

ENVR: Environmental Research Literature Review

FAO: Food Agriculture Organisation

GM: Genetically Modified

GMOS: Genetically Modified Organisms

GBDI:Global Biodiversity Institute

IDS: Institute of Development Studies

ISAAA: International Service for Acquisition of Agri-biotech Applications

IPPC: International Plant Protection Convention

LMOS: Living Modified Organisms

NASIR: National Scientific Institute of Research

NIH: National Institutes of Health

OECD: Organization for Economic Cooperation and Development

SADC: Southern African Development Committee

SPS: Sanitary and Phytosanitary Measures

TBT: Technical Barriers to Trade

TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights

UNEP: United Nations Environmental Programme

WHO: World Health Organisation

WTO: World Trade Organisation

GLOSSARY OF TERMS

As an aid to the reader, an attempt was made to define the meanings of the following terms, as they will be used throughout the text of this document[1].

Advance Informed Agreement: The consent obtained before any activity is undertaken based upon full disclosure of all relevant information and the taking of full responsibility by the supplier of the information for its accuracy and completeness.

Biosafety: A set of measures, policies and procedures used or established for assessing, preventing, monitoring and managing any risk associated with GMOs to human health and safety and to the environment.

Biotechnology: The development of products by exploiting biological processes or substances using intact original or modified organism or by using active cellcomponents.

Control: To examine, regulate, manage or direct any activity within a person's jurisdiction.

Environment: The aggregate of surrounding objects, conditions and influences that influencethe life and habits of man or any other organism or collection of organisms or biodiversity.

Export: The intentional transboundary movement of any GMOs or a product of a GMO from one country to another country.

[1]Biosafty Act, section 2

Exporter: Any legal or natural person who arranges for any GMO or a product of a GMO to be exported.

Genetic Engineering: A technique whereby individual genes can be copied and transferred to another living organism to alter its genetic makeup and thus incorporate or delete specific characteristics into or from the organism. The technology is also referred to as gene splicing, recombinant DNA (rDNA) technology, or genetic modification.

Genetically Modified Organism: Any biological entity, capable of replication or of transferring genetic material or any plant, animal or microorganism, in which the genetic material has been altered through modern biotechnology.

Gene Technology: Any technique that involves the isolation, characterisation, modification and introduction of deoxyribonucleic acid (DNA) into living cells or microorganisms.

Import: The intentional transboundary movement of any GMO or a product of a GMO into one country from another country.

Importer: Any legal or natural person who arranges for any GMO or a product of a GMO to be imported.

Modern Biotechnology: Includes the application of the following techniques:

(a) any recombinant nucleic technique involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism into a virus, bacterium, plasmid or other vector, and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(b) any technique involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; and

(c) any cell fusion, including protoplast fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells.

Notification: Means providing information to and, where appropriate, the lodging or depositing of samples with the Authority.

Organism: A biological entity, cellular or noncellular, capable of metabolism, replication, reproduction or transferring genetic material and includes a microorganism.

Placing on the Market: Includes supplying, selling, advertising, donating or making available to any third party of any GMO or product of a GMO.

Risk Assessment: An evaluation of any direct or indirect, short, medium and long term risk to human or animal health, the environment, biological diversity and to the socio-economic

conditions or ethical values of the people of Zambia arising from the import, transit, contained use, release or placing on the market of a GMOor a product of a GMO.

Risk Management: Measures necessary to prevent and manage adverse effects of any GMO or product of a GMOon human or animal health, non-GM crop, biological diversity, the environment, or socio-economic conditions.

Socio-economic impact: Any direct or indirect effect to the economy, social or cultural practices, livelihoods, indigenous knowledge systems or indigenous technologies as a result of the import, transit, contained use, release or placing on the market of a GMO or a product of a GMO.

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CHAPTER ONE

1.1 INTRODUCTION

Our true challenge today is not debts and deficits or global economic melt-down but the need to find a way to live rich, fulfilling lives without destroying the planet's biosphere, which supports all life. As David Suzuki, a geneticist noted in a *New Scientist* article on April 2, 2000 "*Humanity has never before faced such a threat: the collapse of the very elements that keep us alive*".

It is not uncommon today for one's breakfast, lunch or dinner to be a meal rich in Genetically Modified (GM) food. It might take the form of potatoes with built in repellant or tomatoes that stay firm longer after being picked. In any case, the GM food or ingredient may not have been labeled, and one's palate could hardly distinguish it from the natural one. Such GM crops such as soya beans, rapeseed and potatoes are growing in Argentina, Canada, China, Mexico, South Africa, Western Europe and the United States. According to one report by 1998, 25 percent of maize, 38 percent of soya beans, and 45 percent of cotton grown in the United States were genetically modified, either to make the crops resistant to weed killers or to produce their own pesticides[1].

GM crops appeared for the first time on the market in the USA in 1994. By the end of 2005, an estimated 81.0 million hectares global area of cropland were covered with GM crops in commercial cultivation, though not all of these are food crops[2]. In the same year, GM crops were

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[1] James Clive. *Global Review of Commercialised Transgenic Crops 2001* (New York: ISAAA, 2001 Brief No. 24)
[2] James Clive. *Global Status of Commercialised Biotech/GM Crops 2004* (New York: International Service for Acquisition of Agri-biotech Applications ISAAA Brief No. 32 2004)

grown by 8.25 million farmers worldwide from 17 countries on 6 continents. The global value of GM crops was estimated at 4.7 billion USD that represented 16% of the global seed market for 2005, which shows considerable economic benefits of modern biotechnologies. It is worth to note that 90% of the beneficiaries are the poor farmers from developing countries, whose increased incomes from biotech crops contributed to the alleviation of the poverty. Similar data from these sources shows that Western Europe and the United States have committed an unprecedented percentage of their arable land area to GM crop cultivation.

1.2 HOW IS FOOD GENETICALLY MODIFIED?

The science behind GM food is called biotechnology- the use of modern genetics to improve plants, animals and microorganisms for food production. The beginnings of a major change in this process came into being in the 1950s, when James Watson and Francis Crick discovered the structure of DNA – the double stranded helix of nucleotides. As noted by Dr. Barry Commoner, a geneticist in his research paper[3], "*Biology was once regarded as a languid, largely descriptive discipline, a passive science that was content, for much of its history, merely to observe the natural world, rather than to change it. No longer! Today, biology, armed with the power of genetics, has replaced physics as the activist Science of the Century ..., calling forth artificial forms of life rather than undiscovered elements and sub-atomic particles.*" This modern life science created astounding possibilities whose very novelty and power suggested to some the need to challenge the technology before any other factors were considered. Some commenters' description of genetic manipulation as an exercise of "nearly godlike creative powers" is

[3]McGill School of Environment:ENVR 401: Environmental Research Literature Review: Genetically Modified Plants

evidence of the level of discomfort felt in response to highly publicized achievements such as the production of the cloned sheep, Dolly, by Ian Wilmut of the Roslin.

Of course, the concept of tinkering with living things is almost as old as agriculture itself. The first farmer who bred his best bull with the best cow in his herd to improve the stock, instead of allowing the animals to breed randomly, was implementing biotechnology in a rudimentary sense. The first baker who used yeast enzymes to make bread rise was likewise using a living thing to produce an improved product. The one feature common to these traditional techniques was the use of natural processes to bring about the desired change in the food[4]. Although these methods were traditional, they were forms of biotechnology.

Modern biotechnology emerged in the 1960's with the Green Revolution. The apparent lack of food to feed the increasing global population caused international alarm and action. Modern biotechnology likewise employs living organisms to make or modify products. But unlike traditional methods, modern biotechnology allows for modifying the genetic material of organisms directly and precisely. Therefore, GMOs are organisms produced by transferring very often of one gene encoding a desirable trait in one organism to another, through precise molecular biology technique called genetic modification. It enables the transfer of genes between completely unrelated organisms, allowing for combinations unlikely to occur by conventional means. Breeders can now take qualities from other organisms and put them into the genome of a

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[4] Canadian Food Inspection Authority, *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*,(Regulatory Directive (Dir. 94-08) 1994), accessed on, January, 26, 2012 http://www.inspection.gc.ca/)

plant for instance, frost tolerance from fish, disease resistance from viruses, and insect resistance from soil bacteria.

Suppose that a farmer does not want his potatoes or apples to turn brown when they are cut or bruised. Researchers come to the rescue by removing the gene that is responsible for this browning and replacing it with a modified version that blocks browning. Or let us assume that a beet grower in the USA would like to plant earlier in order to reap a better harvest. Ordinarily he could not because the beets would freeze in the cold weather. Biotechnology comes into play when genes from fish that easily survive in Antarctic polar cold water are transplanted into the beets. The result is a GM beet that can withstand temperatures as low as $-7^{\circ}C$, more than twice the lowest temperature beets can typically withstand.

Therefore, the study of genetics has given rise to a lucrative new industry the so called biotechnology. As the name suggests, it blends biology and modern technology through such techniques as genetic engineering. Some of the new biotech industries as they are called, specialize in agriculture and are working feverishly to patent seeds that give a high yield, that reduce the need for hazardous chemicals[5]. If such goals could be achieved, it would be most beneficial. But critics have raised concerns about genetically engineered crops.

In nature, genetic diversity is created within certain limits. A rose can be crossed with a different kind of rose, but a rose will never cross with a potato. Genetic engineering, on the other hand, usually involves taking genes from one species and inserting them into another in an attempt to transfer a desired trait or character. It is now possible for plants to be engineered with genes from

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[5] George M. Kanja, *Intellectual Property Law:* (Lusaka: UNZA Press,1997)

bacteria, viruses, insects, animals or even human beings. In essence, then, biotechnology allows humans to breach the biological boundaries that separate species.

Is GM food safe for human consumption, feed and processing? Do the scientific techniques used to produce GM crops pose any threat to the environment? Globally, the debate over GM food is heating up. The GMOs biosafety debate is at the forefront of the larger question of how humanity can, in an integrated and harmonious way, address human livelihoods, while at the same time fulfilling its international mandates to conserve and sustainably use the environment. In a world focused on issues such as poverty and food security, as well as species loss and ecosystem destruction, these questions are among the most important and the most difficult on the planet. In this connection, we find many claims about GMOs – that they can be a basis for increasing food production, without the need to convert more land to cultivation, for example. These claims, however, are countered by the claims that GMOs may have a variety of impacts on people and animals, and especially on ecosystems and lands not under cultivation, and concerns about whether and how the benefits of GMOs are actually experienced in developing countries.

1.3 POTENTIAL DANGERS

The problem is that biotechnology has moved at such a dizzying pace that neither the law nor regulating authorities can keep up with it. Research can scarcely begin to prevent unforeseen consequences from arising. A growing chorus of critics warn of unintended results, ranging from severe economic dislocation for the world's farmers to environmental destruction and threats to human health[6]. Researchers warn that there are no long-term, large scale tests to prove the

[6] Second World Conservation Congress: Resolution 2.31 "Genetically Modified Organisms"

biosafety of the GMOs. Theories about the possible effects of GM foods on animals and human health and the environment remain controversial. They point to a number of potential dangers:

1.3.1 Allergic reaction

If a gene producing a protein that causes allergic responses ended up in maize, for instance, people who suffer from allergies could be exposed to grave danger. Despite the fact that food regulating authorities require companies to report whether modified food contains any problem proteins, some researchers fear that unknown allergens could slip through the system. It is also feared that if such scientific techniques fall in the hands of the terrorist organizations it might be used as a chemical and biological warfare.

1.3.2 Increased toxicity

Some experts believe that genetic modification may enhance natural plant toxins in unexpected ways. When a gene is switched on, besides having the desired effect, it may also set off the production of natural toxins.

1.3.3 Resistance to antibiotics

As part of genetic modification of plants, scientists use what are called marker genes to determine if the desired gene has been successfully embedded. As most marker genes provide resistance to antibiotics, critics fear that this could contribute to the growing problem of antibiotic resistance. Other scientists, however, counter that such marker genes are genetically scrambled before use, thus alleviating this danger.

1.3.4 Spread of "superweeds"

One of the biggest fears is that once modified crops are planted, genes will escape via seeds and pollen to weedy relatives, creating "superweeds" that are able to resist herbicides. "*We are flying blindly into a new era of biotechnology with high hopes, few constraints, and little idea of the potential outcomes*," said science writer Jeremy Rifkin.

1.3.5 Harm to other organisms

In May 1999, researchers from Cornell University reported that monarch butterfly caterpillars that ate leaves dusted with pollen from GM maize sickened and died. While some question the validity of this study, there is still some concern that other non-targeted species could be harmed.

1.3.6 Demise of safe pesticides

Among the most successful GM crops are some that contain a gene that produces a protein toxic to insect pests. However, biologists warn that exposing pests to the toxins produced by this gene will help the pests develop resistance and thus render pesticides useless.

There is need for effective biosafety legal frameworks to enable regulating authorities keep up with the pace at which biotechnology has moved and to ensure compliance with international mandates to conserve and sustainably use the environment. Notwithstanding the great benefits this technology could bring to the environment and the society, there is a common understanding within the global community at large that balanced approach of biosafety is needed for evaluating the possible adverse effects from the deliberate release of biotech products into the environment, as well as their use in human and animal diets. The next chapter will discuss this issue at the international level.

CHAPTER TWO

2.0 GMOS BIOSAFETY: INTERNATIONAL LEGAL FRAMEWORKS

GMOs biosafety is a concept that refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology[7]. At the same time, modern biotechnology is recognized as having a great potential for the promotion of human wellbeing, particularly in meeting critical needs for food, agriculture and health care[8].

It is clear to appreciate the question, why do we require effective biosafety legal frameworks at national level as well as coordinated international instruments and guidelines? The answer to this question was enunciated by the United Nations Environmental Programme (UNEP) when it commented, "*because biotechnology is such a revolutionary science, and has spawned such a powerful industry, it has great potential to reshape the world around us. It is already changing agriculture and what many of us eat. Any major mistakes could lead to tragic and perhaps permanent changes in the natural world. For these reasons, future generations are likely to look back to our time and either thank us or curse us for what we do or don't do about GMOs and biosafety. Doing the right thing is not simple*[9]."

The year 1992 witnessed the United Nations Conference on Environment and Development, also known as the Earth Summit, which was held in Rio de Janeiro in Brazil. At this conference, the

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[7]Secretariat of the Convention on Biological Diversity. Introduction to *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes* by the Secretariat of the Convention on Biological Diversity: (Montreal:Secretariat of the Convention on Biological Diversity, 2000), 1

[8] Ibid

[9]CBD, UNEP. *Biosafety and Environment: An introduction to the Catagena Protocol on Biosafety*: (Montreal: Secretariat of the Convention on Biological Diversity, 2000) accessed on, January, 28, 2012 http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt

international community came to agree on many aspects of biosafety which were reflected in the Rio Declaration on Environment and Development and the Convention on Biological Diversity.

The concept of biosafety is based on the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development which deals with the environmentally sound management of biotechnology and recognizes two important facts: (1) the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health, and (2) that modern biotechnology has great potential for human wellbeing if developed and used with adequate safety measures for the environment and human health. These two facts were also reflected in a document called Agenda 21.

With the two facts in mind the GMOs biosafety issues then becomes one of international community responsibility towards a balanced approach to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity. To that end the international community through the auspices of the United Nations has set the stage for the development of international legally binding instruments to address the issue of biosafety. Relevant to this essay are the following international conventions:

2.1 Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (1992) and its Cartagena Protocol on Biosafety (2000) are the main international instruments for addressing biosafety issues. The scope of the Convention and its objectives are the conservation of biological diversity and seeks to ensure:

"*....the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.....*[10]"

It is clear from the onset that the objectives of the CBD are in sharp conflict with Intellectual Property Rights. The CBD promotes equitably shared benefits of biological resources and protection of traditional knowledge[11]; the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) promotes private appropriation of benefits and has no mechanism for acknowledging the role of traditional knowledge in the industrial use of genetic resources[12].

These potential conflicts in the various Coventions relating to biosafety will be addressed when analyses of regional and national regulatory frameworks are considered. However, it is sufficient to state that the conservation of biological diversity highlighted by the CBD is the management of risks associated with living modified organisms (LMOs) commonly known as GMOs resulting from biotechnology[13].

The salient provisions under the Convention relevant to biosafety are in two articles: Article 8(g) and Article 19(3) and (4). Article 8(g) requires each Party "*...to manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology*

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[10]Convention on Biological Diversity, Article 1
[11]Convention on Biological Diversity: Preamble
[12]GBDI and IITA "Report of the Global Biodiversity Institute/International Institute of Tropical Agriculture Training Course on Biodiversity, Biotechnology, and Law. (Ibadan: Global Biodiversity Institute and International Institute of Tropical Agriculture 2000), accessed on January, 28, 2012 http://www.aaas.org/international/africa/gbdi/GBDI-Ibadan.pdf
[13]**Krattinger Henri, Lesser William.** *Biosafety-An Environmental Impact Assessment Tool and the Role of the Convention on Biological Diversity, Widening perspectives on biodiversity:* (Geneva: ICUCN and IAE 1994) 353-366

which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity".

Article 19 (3) requires Parties "*.... to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.*"

From the wording of the above two articles there is no doubt that Article 8(g) deals with measures that Parties should adopt at national level, while Article 19 (3), sets the stage for the development of an international legally binding instrument to address the issue of biosafety.

Some scholars are of the view that the obligations imposed under Articles 8(g) and 19(3) are a good example of the crystallization of customary international law into a Convention. They argue that whether a Party to CBD ratifies or accedes to the Protocol or not, it must still fulfill its obligations to implement Article 8 (g) of the CBD[14]. Where it does not ratify or accede to the protocol, a CBD Party still needs to implement Article 19(4) of the CBD[15].

Article 14 further requires a Party to take environmental impact assessment and minimizing adverse impact on biological diversity[16]. Other obligations under the article include notification and exchange of information among member States where activities in one State Party may

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[14] **Ingrassia Antonella** *International and Regional Regulatory Frameworks relevant to Biosecurity for Food and Agriculture*, FAO consultation paper, 2003
[15] ibid
[16] Convention on Biological Diversity, Article 14 (1) (a)

adversely affect the biodiversity of another State Party or an area beyond the limits of any national jurisdiction.[17] Parties are also required to create emergency response arrangements at national level and joint contingency plans with other States[18].

The Conference of the Parties of the CBD was tasked to consider under Article 19(3) the need for a biosafety protocol. At its second meeting, held in November 1995, the Conference of the Parties to the Convention established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety focusing specifically on transboundary movement of any LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. After several years of negotiations, the Protocol, known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, was finalized and adopted in Montreal on 29 January 2000 at an extraordinary meeting of the Conference of the Parties[19].

Article 19(4) creates an obligation for a CBD Party to provide information on the use and handling of LMOs prior to releasing such organisms to another CBD Party. The Article provides: 19(4) *Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse*

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[17] Convention on Biological Diversity, Article 14 (1)(c and d)
[18] Convention on Biological Diversity, Article 14 (1) (e)
[19] Secretariat of the Convention on Biological Diversity, an introduction to the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes* by the Secretariat of the Convention on Biological Diversity. (Montreal:Secretariat of the Convention on Biological Diversity 2000)

impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

2.2 Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The Protocol was adopted in 2000 and entered into force in September, 2003. It is the first global legally binding instrument focusing on LMOs. The scope and purpose of the Protocol seeks to ensure: "*adequate levels of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health, and specifically focusing on transboundary movements*[20]".

Two key concepts can be distilled from the above provision that is biosafety and precaution, form the basis for the framework developed in the protocol. Biosafety is based on the concept of precaution and implies minimizing risks to human, animal and environmental health. This principle was enshrined at the 1992 Rio Conference on the Environment and Development, during which the Rio Declaration was adopted, whose Principle 15 states that: "*in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*[21]".

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[20] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Articles 1and 4.
[21] Cartagena Protocol on Biosafety to the Convention on Biological Diversity Article11(8)

The Cartagena Protocol applies precaution not just to biodiversity, but to potential risks to human health as well. Additionally it gives importing countries the right to take into account socioeconomic concerns (provided their actions are consistent with their international obligations[22]). Such concerns could include the risk that imports of GM foods may replace traditional crops, undermine local cultures and traditions or reduce the value of biodiversity to indigenous communities.

The Protocol's greatest innovation which is also connected to the precautionary principle is the introduction of an Advance Informed Agreement (AIA). The AIA requires that, prior to the intentional introduction of LMO into the environment of an importing Party there must be a notification of the exporting Party containing certain information relating to the possible adverse effects of the LMO and there must be a written consent of the importing Party.

The other innovation introduced in the Protocol is the creation of a Biosafety Clearing House. The Biosafety Crearing House serves a twofold function: it is intended to address capacity problems of developing countries; and to function as a registry for the exchange of information. It is an international institutional arrangement within the framework of the CBD providing capacity-building and financial resources.

The Protocol provides that the Parties should each have a domestic biosafety regulatory framework to serve as a basis for the national implementation of the Protocol. It is clear from the text of the Protocol that this framework allows a party to implement broader national policy and

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[22]Cartagena Protocol on Biosafety to the Convention on Biological Diversity Article 2 (4)

practice regarding GMOs and biosafety within national jurisdiction. The conclusion of the Biosafety Protocol has been hailed as a significant step forward in that it provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry[23]. The Protocol thus creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health[24].

2.3 Codex Alimetarius

In the food safety and nutrition, the Codex Alimentarius is the primary internationally accepted food standards and as such is of great relevance to biosafety. The Codex has become the global reference point for consumers, food producers and processors, national food control agencies and the international food trade. Among the many aims of the Codex is to give priority to consumer interests in the formulation of the food safety standards. The accepted food standards reflects the emphasis that Codex places on ensuring that consumers receive products that are of acceptable quality, are safe and do not present a health hazard. The Codex Commission is a specialized body responsible for the food safety aspects of GMOs. Food consisting of GMOs or LMOs is a type of novel food that is covered by the Codex.

2.4 International Plant Protection Convention (IPPC)

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[23] Secretariat of the Convention on Biological Diversity. Introduction to *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes* by the Secretariat of the Convention on Biological Diversity: (Montreal:Secretariat of the Convention on Biological Diversity, 2000), 1

[24] ibid

The IPPC came into force in 1952 and has undergone two major amendments ever since. The IPPC controls plant pests. It also regulates any organisms capable of spreading pests that affect plants or plant products[25]. The purpose of regulation is to prevent the spread and introduction of these pests and promoting measures for their control. Pest is broadly defined in the Convention as any species, animal life or any pathogenic agent injurious or potentially injurious to plants or plant products. Therefore, the IPPC's scope of application is broad enough to include GMOs, or LMOs or products of modern biotechnology that may directly or indirectly damage plants.

2.5 World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

The World Trade Organisation oversees the implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement provides for a common approach in relation to biosafety by applying to all sanitary and phytosanitary measures which may directly or indirectly affect international trade[26]. The Agreement allows governments to use measures to maintain national sanitary and phytosanitary protection. This Agreement does not specifically refer to or mention the GMOs or LMOs. However, when such organisms enter international trade their regulation must comply with the provisions of the Agreement. The Agreement requires that sanitary and phytosanitary measures must be applied for no other purpose than that of ensuring food safety and animal and plant health. A member States' sanitary and phytosanitary measures must only be applied to the extent necessary, be based on scientific principles and must not be maintained without sufficient scientific evidence[27]. These measures

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[25]International Plant Protection Convention, Article 1(4)
[26]WTO-SPS Agreement, Article1
[27]TBT Agreement, Article 2(2)

must not be arbitrary or unjustified or applied merely to discriminate between member States and cannot be applied in a manner that would constitute a disguised restriction on international trade[28].

2.6 World Trade Organization-on Technical Barriers to Trade Agreement

The World Trade Organisation also oversees the implementation of the Agreement on Technical Barriers to Trade (**TBT Agreement**). The Agreement ensures that regulations, standards, testing and certification procedures do not create unnecessary obstacles. The TBT Agreement may apply to biosafety because biotechnology products must be subjected to technical regulations and standards, including packaging, marking and labeling requirements. It does not apply to sanitary and phytosanitary measures[29]. Therefore, the SPS Agreement would apply where a product of biotechnology is likely to pose a risk to human, plant or animal health. The TBT Agreement applies where a product is merely labeled as containing GMOs.

The main purpose of the TBT Agreement is to ensure these regulations should not create unnecessary obstacles to international trade and should not be trade-restrictive[30]. The legitimate objectives the regulations must seek to achieve may include: preventing misleading trade practices, protecting human health or safety, animal or plant life or health, or the environment.

Obviously the objects and purposes of the two World Trade Organisation Agreements as they relate to the regulation of the GMOs in international trade may significantly conflict with the

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[28]TBT Agreement, Article 2(3)
[29]TBT Agreement, Article 1(5)
[30]TBT Agreement, Article 2(2)

Convention on Biological Diversity and its Cartagena Protocol on Biosafety. The Convention and its Protocol are based on the precautionary approach and mandates a Party to take protective measures in order to avoid or minimize potential adverse effects of the GMOs even where there is no scientific evidence. The said World Trade Organization Agreements requires that such measures be based on scientific principles and must not be maintained without sufficient scientific evidence otherwise they are perceived to be unnecessary obstacles to international trade. This potential conflict of interest will be demonstrated in chapter three when the European and American regional regulatory systems are considered.

Zambia is a party to all the above international Conventions on biosafety regulations of the GMOs. Typical of international law, there is no international legislature enacting binding rules nor is there an international executive enforcing the said Conventions. It is clear from the above examination of the Conventions that there are no sanctions or penalties for non-compliance with the obligations imposed by the Conventions. The Cartegena protocol on biosafety recognizes the problem of enforcement of international law. It is clear from the text of the Protocol that the legal framework created under the protocol allows a party to implement broader national policy and practice regarding GMOs and biosafety within national jurisdiction. It is the responsibility of each individual Party to formulate and implement positive measures and mechanisms in support of the observance of the provisions of these Agreements. It follows therefore; the crux of this obligatory essay is the question- to what extent has the Zambian Biosafety legislation complied with the international biosafety regulations of the GMOs? This question will become clearer when the national regulations and legislation are examined in the light of the standards set by international law on the subject.

CHAPTER THREE

3.0 GMOS BIOSAFETY: REGIONAL AND SUB-REGIONAL REGULATORY FRAMEWORKS

The debate over GMOs is a household issue across the continent of Africa. The lack of sustainable food security and abject poverty in many parts of Africa has brought biotechnology and its GMOs products to center stage. Drought, poor soils, along with other poor agricultural practices and social factors, account for the many food shortages in many parts of Africa. Some western countries as well as the World Food Programme have on many occasions offered GM crops as food aid. In many cases, the GM food had not been labeled and the recipient countries could hardly distinguish it from the natural ones. This has generated wide spread public concern and debate over the GMOs across the African continent.

In Southern Africa for example, the debate over the GMOs reached its climax point during the devastating drought of 2002 -2003 when various countries expressed concerns about the use of GM crops as food aid, given the lack of certainty about their potential dangers. The drought inflicted severe wide-spread food shortages causing international alarm. Despite this immediate food insecurity and imminent malnutrition of the masses, several African countries opted to reject GM crops as food aid. Among the reasons considered for the rejection of such food aid were: the unclear impacts of GM crops for human, animal and environmental health; also future directions in agriculture; livelihood and development options; ethical issues and rights concerns[31].

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[31] **Mohamed Katerre, University of Sussex.** *Risks and Rights: Challenging Biotechnology Policy in Zimbabwe.* (Sussex: Brighton and the Institute of Development Studies 2003), accessed on, January 28, 2012 http:/www.ids.ac.uk/ids/bookshop/wp/wp204.pdf

Mozambique refused to accept GM maize aid stating biosafety and human health reasons and completely banned its import. Zambia rejected GM food aid in any form; Zimbabwe and Malawi refused to accept GM food aid unless it was milled, this measure was taken as a precaution to avoid any germination of intact grains and to limit impacts on biodiversity; Lesotho and Swaziland authorized the distribution of non-milled GM food, but warned the public that the grain should be used strictly for consumption and not for cultivation; and in 2004, Angola and Sudan introduced restrictions on GM food aid and Ethiopia banned import of GMO food, saying it would undermine farmers who already had their own traditional ways of fighting pests and weeds[32]. Debate continues over whether GMO crops could help the country out of years of serious food shortages such as Ethiopia.

3.1 AFRICAN REGIONAL REGULATORY FRAMEWORK

Against this background it is easy to appreciate the fact that Biotechnology and its GMOs products have posed serious challenges to the African governments and policymakers. Governments have to consider not only the impacts on human health, but also poverty and hunger, livelihoods and food security, international trade and the environmental biodiversity.

These challenges clearly call for effective laws and institutions designed with a goal of striking a reasonable balance between these competing and often conflicting interests. Despite the many challenges faced by the continent, Africa has taken an active role in spearheading measures responding to the challenges brought about by biotechnology and its GMOs products. It has been in the forefront advocating for and supporting measures at the international plane such as the

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[32]Apps,P. "South Africa leads on GMO, other African States wary". *Reuters News Service*, 1 March 2005. http://www.planetark.com/dailynewsstory.cfm/newsid/29768/story.htm

CBD and its Cartagena Protocol. At the regional level, Africa has developed initiatives such as the African Biosafety Model Law and has begun to develop national frameworks for GMO development and biosafety.

3.1.1 The African Biosafety Model Law

The African Biosafety Model Law was adopted by the African Union at its 74th Ordinary Session held in Lusaka, Zambia, in July 2001. Member states were advised to use the African Biosafety Model Law to draft their own national regulatory frameworks. The Model Law is a product of a wide participatory and consultative action involving governments, researchers, and interest groups such as the non-governmental organizations. It represents the African regional biosafety regulatory framework as well as coordinated guidelines based on broad consensus on issues of biotechnology development.

It is important to note that the regulatory framework developed under the African Model Law has taken advantage of the wide discretion permitted by the Cartagena Protocol on Biosafety. The Protocol allows countries to adopt more stringent protective measures than the agreed minimum standards set out in the Protocol. The African Biosafety Model Law makes provision for considering socioeconomic factors in assessing risks and opportunities.

The salient legal principles and approaches incorporated include: The precautionary approach widely applied by States according to their capability. Where there are threats of serious or irreversible damage, states are urged to use cost-effective measures to prevent environmental degradation; The African Model Law further declares that, *it is the sovereign right of every*

country to require a rigorous risk assessment of any GMO for any use before any decision regarding the GMO is made; and a liability and redress regime. The Model Law unlike the Cartagena protocol has liability regime. The law requires companies which export GMOs to pay compensation for accidents involving the biotechnology. A person who imports, releases or places on the market a GMO or product of GMO is strictly liable for any harm that might be caused by such GMO[33].

It appears that the African Biosafety Model Law provides for a set of biosafety rules tailored to the African situation and includes issues that are not dealt with by the Biosafety Protocol. For example, the African regulatory system provides for mandatory labeling and identification or traceability requirements for GMOs and GM food. According to Marriam Mayet, an expert on GMOs, traceability is the ability to track a GMO back to those responsible for its development and those responsible for its import or export. Traceability is crucial under the African Model Law for purposes of liability and redress for harm caused by GMOs to human health and the environment, and for resultant economic loss[34].

3.1.2 Sub-Regional Policy Responses

The Southern African Development Committee (SADC) established an advisory committee on GMOs to develop guidelines and to assist member states in guarding against potential risks in food safety and consumer concerns. The following recommendations were formulated and

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[33]African Biosafety Model Law, Article 4

[34]Mayet Marriam, "Why Africa should adopt the OAU African Model Law on Safety in Biotechnology. African Centre for Biosafety" *African Journal of Biotechnology Vol 5* (2003): accessed on, January 20, 2012 http://www.biosafetyafrica.net/_DOS/CommentBiosafetyModelLaw.pdf

approved by the SADC in August 2003 as interim measures aimed at guiding the region on issues relating to biotechnology and biosafety:

Policy and regulations

All member states are urged to sign and ratify the Cartagena Protocol on Biosafety to the CBD. The interim measures call for the development of harmonized national regulatory systems based on the African Biosafety Model Law and the Cartagena Protocol on Biosafety.

Handling of food aid

Donors providing GM food aid should comply with the notification requirements in accordance with Cartagena Protocol on Biosafety. Food aid in transit that may contain GMOs should be clearly identified and labeled.

Capacity-building

In order to exploit the benefits of biotechnology, it is necessary that member states should develop capacities at national levels. The SADC should encourage member states to institute research on the aspects of biotechnology and biosafety.

Public awareness and participation

Member states should develop public awareness programmes on biotechnology and biosafety involving all stakeholders.

3.2 THE EUROPEAN VERSUS THE AMERICAN REGULATORY FRAMEWORK

The precautionary approach is the foundation of the biosafety regulatory framework created under the European system. Directive 2001/18/EC provides for procedures for the release of GMOs into the environment for experimental and commercial purposes. It also contains provisions for direct use of living modified organisms as food, feed or for processing.

Environmental risk assessment before the release of GMOs is mandatory and is done on a case by case basis. Consultation among member states on ethical and scientific concerns is crucial.

In November 2003, the European Union introduced two new regulations one on GM food and feed known as Regulation 1829/2003, and one on traceability and labeling which is called Regulation 1830/2003. It is a requirement under the European Union regulatory framework that food containing 0.9% or more of GM food must be labeled as being produced from a GMO. By the end of December 2003, the European Union had failed to agree on lifting its five-year-old moratorium on new GM foods.

In sharp contrast to the European Union, the United States has not developed separate biotechnology regulations, but rather has opted for regulating GMOs through existing product legislation. There are no mandatory risk assessment requirements for GMOs, although the proposed Premarket Notice Concerning Bioengineered Foods will require companies to submit information on safety considerations before marketing GM foods.

The European Union moratorium on new GM foods provoked a standoff between the United States and the European Union. The United States, Canada and Argentina referred the matter to a WTO panel against the European Union *Concerning Measures Affecting the Approval and Marketing of Biotech Products.*[35] This is a clear demonstration of the potential conflict between diverse approaches to biosafety, and the competing and often conflicting interests of international trade and biosafety. In this case, the three states alleged that the European Union

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[35] WT/DS291/23, 19 August 2003

moratorium on the approval of LMOs or GMOs poses an unjustifiable trade barrier in violation of the WTO Agreements. The European Union moratorium was imposed in June 1999, when a declaration urging the need for rules on labeling and traceability of GMOs and GMO-derived products was adopted. In the view of the European Union adoption of such rules was in accordance with the preventive and precautionary approaches. The European Commission described the request for WTO panel as "*legally unwarranted, economically unfounded and politically unhelpful*," arguing that the European Union measures were justified under international law, citing the recently adopted Codex Alimentarius principles for risk analysis of GM foods and the precautionary approach provided for in the Cartagena Protocol. Civil society groups also attacked the decision to commence a trade dispute against the European Union accusing the countries concerned of trying to force GM foods onto European consumers[36].

Chapter two dealt with the international biosafety regulatory framework established under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The precautionary principle to biotechnology and biosafety aspects came out strongly as the bedrock for the GMOs international biosafety regulatory framework. It must also be remembered that the Protocol allows countries to adopt more stringent protective measures than the agreed minimum standards set out in the Protocol. This Chapter has explored how the regional systems have taken advantage of this wide discretion and how they have designed regulatory systems tailored to meet their concerns. The African as well the European regional regulatory frameworks have adopted similar approaches in that both systems have designed more stringent protective measures than those contained in the Protocol. Risk assessment, traceability and labeling

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[36] Source: ICTSD 2000, The GM Dispute at the WTO: Forcing GM Foods on Europe @www.genewatch.org

requirements for GMOs are mandatory under the two systems. The African system has gone even a step further than European system by providing for liability and redress for harm caused by GMOs to human health and the environment, and for resultant economic loss. To the contrary, the American system has taken a more commercial and less biosafety approach to biotechnology and its GMOs products. There are no mandatory risk assessment requirements for GMOs in the American biosafety regulatory system.

It must be noted that stringent application of the precautionary approach under the guise of the sovereignty principle may have a negative or chilling effect on other international obligations especially in the areas of agricultural development, international trade and intellectual property rights. This conflict was clearly demonstrated in the trade dispute between the United States and European Union in the matter *Concerning Measures Affecting the Approval and Marketing of Biotech Products.*[37] It appears the precautionary approach entrenched under the African biosafety system is coupled to the sovereignty principle and urge member states to require a rigorous risk assessment of any GMO. Under international law, member states are justified to take more stringent measures than the minimum agreed standards set out in the Protocol. However, this must be cautioned by a reasonable balance that must be had to other equally competing interests. These measures must not be arbitrary or unjustified and should not be applied in a manner that would stifle the development and exploitation of the benefits of biotechnology.

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[37] WT/DS291/23, 19 August 2003

CHAPTER FOUR

4.0 GMOS BIOSAFETY: NATIONAL REGULATOTY FRAMEWORKS

The increasing economical importance of biotechnology industry and its products has led developed and developing countries to institute biosafety policies, procedures and legislation to ensure their safe use. These protective measures are implemented through established or new systems that have been adapted to meet the challenges of the evolving biotechnology industry. For these regulatory systems to function successfully and effectively, they should be flexible to adapt to the evolution of biotechnology industry. This matter is approached by selecting examples of diverse biosafety frameworks from both industrialized and developing countries which reflect different approaches in decision making, regulatory and legislative bases. These approaches include developing new laws dealing with biotechnological environmental and health issues and adapting the existing legislative systems based on guidelines rather than on laws. Among the countries studied include: Australia, Japan, South Africa, the European Union/United Kingdom (chapter three), the United States and Zambia.

4.1 Australia

The Commonwealth Gene Technology Act of 2000 constitutes the key element of the national regulatory framework for GMOs. The Act regulates all dealings with GMOs in Australia, relating to research, manufacture, import, production, propagation, transport and disposal of GMOs. The Act established the position of the Gene Technology Regulator to administer the legislation.

Dealings involving the intentional release of GMOs into the environment are illegal in Australia unless carried out under a licence granted by the Regulator. This applies to both field trials and

commercial scale releases. Before issuing such a licence, the Gene Technology Regulator must prepare a risk assessment and risk management plan that identifies any potential risks to the health and safety of people and the environment posed by biotechnology, and the means of managing those risks.

The Office of the Gene Technology Regulator does not directly regulate the use of GM products. The use of GM products is regulated by other regulatory agencies. For example, the use of GM products in food for human consumption is regulated by Food Standards Australia New Zealand.

The Office of the Gene Technology Regulator maintains a Record of GMO and GM Product Dealings on its website. The GMO Record is a complete list of all GMO dealings approved by the Regulator and of all GM product approvals notified to the Regulator by other product regulators. The purpose of the GMO Record is to provide the Australian public with access to information about GMOs and GM products being used in Australia. Australia is the first country in the world to make such a comprehensive record available to the general community. The GMO Record is a clear demonstration of the openness and transparency of the regulatory system for GMOs operating in Australia.

GM food safety is the responsibility of Food Standard Australia New Zealand. All GM foods or ingredients to be sold in Australia are required to undergo a mandatory pre-market safety assessment to ensure that they are safe for human consumption[38]. In addition, since December 2001, Australia has had in place a mandatory labeling regime that requires all GM food sold in Australia to be labeled as such if novel DNA or protein is present in the final product.

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[38]Standard 1.5.2 of the Australia New Zealand Food Standards Code

Food Standard Australia New Zealand carries out safety assessments on a case by case basis, which means each new genetic modification is assessed individually for its potential impact on the safety of the food. Food Standards Australia New Zealand compares the GM food with a similar, commonly eaten non-GM food from a nutritional and compositional point of view. If the genetic modification causes an adverse effect in the food, such as increasing its allergies or toxicity, it will not be approved.

4.2 Japan

Japan's approach to ensuring the safe use and application of biotechnology has been through a series of voluntary guidelines that are administered by four government agencies[39]. These guidelines cover the application of biotechnology products in confined laboratory settings, the industrial application of GMOs, the environmental release of GMOs, and the safety assessment of genetically engineered foods. The relevant government departments are: Ministry of Science and Technology; Ministry of International Trade and Industry; Ministry of Agriculture, Forestry and Fisheries; and Ministry of Health and Welfare. Each Ministry has produced its own set of guidelines. When safety assessments have been completed in accordance with the relevant guidelines, the developer may request the responsible government minister to approve the safety criteria and procedures used to ensure compliance with the guidelines.

The Japanese government's guidelines or approach on the safe use and application of biotechnology and its products is modeled after the United States National Institutes of Health guidelines. Prior to the commencement of experiments, a safety assessment is performed by the

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[39]Organization for Economic Cooperation and Development, *Compendium of National Food Safety Systems and Activities*,(Paris: OECD 2000), accessed on, February 22, 2012; www.oecd.org/subject/biotech/comp_nfssa.pdf

research institution proposing the work, and the physical and biological controls are selected based on this assessment. A safety committee has to be established at each institution engaged in genetic manipulation work and advise the head of the institution on the acceptability of planned experiments. The guidelines stress individual responsibility and the heads of institutions are held accountable for the work undertaken within their institution, for approving or rejecting plans for experiments, and for ensuring adequate training for staff. The Ministry of Science and Technology has a 15 member advisory committee on Biotechnology activities.

The Minister of Health and Welfare has the authority to establish specifications for food components and standards for manufacturing foods with a view to preserving and promoting public health[40]. If a food contains an organism obtained through biotechnology, the organism must undergo food safety assessment by the Ministry of Health and Welfare.

4.3 South Africa

South Africa was the first country in Africa to have adopted a specific legislation to regulate the development, use and release of GMOs through the South African Genetically Modified Organisms Act of 1997. The Act was amended by Genetically Modified Organisms Amendment Act No. 23 of 2006. The legislative objective of the Act is to ensure that any activity with a GMO in South Africa is conducted so as to limit potential risks to the environment and to human and animal health and take socio- economic considerations into account. Any dealing in any GMO in South Africa involving import, research, general release, field trials and contained use is prohibited unless a permit is issued thereof.

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[40] Food Sanitation Law, article 7

The GMO Act is implemented by the Directorate of Biosafety of the Department of Agriculture, Forestry and Fisheries. The Act establishes the office of Registrar of the GMOs to administer the Act. Two regulatory bodies namely the Executive Council and the Advisory Committee evaluate and decide on applications. The Advisory Committee is composed of eight independent scientists with various scientific backgrounds. This body advises the Executive Council on any risk associated with the dealing in GMOs and whether the permit for that particular activity can be issued. This may include risk management strategies that may need to be implemented should the permit application be approved. The Executive Council is the decision making body made up of representatives from a number of government departments. If the Executive Council is satisfied with the findings of the Advisory Committee and if other issues that may be brought up by the Executive Council are resolved, including for example trade issues or consideration of public comments, a permit for that particular dealing may be issued by the Registrar. Inspectors ensure compliance to permits approved under the GMO Act.

Under the South African regulatory system any dealing in GMOs has to be submitted to Executive Council by way of an application which must be accompanied by public notice, published in at least three daily newspapers from where the activity is to take place[41].

4.4 United States

Regulatory framework of biotechnology has been in place in the United States for longer than in most other parts of the world. The first environmental release of a GMO occurred in 1983 following the approval of the National Institutes of Health (NIH). This approval sparked a heated

[41] **Thomson, J.** "Biosafety regulations in South Africa regarding genetically modified organisms." *SCN News*, February 23rd 2000 20, 33-35

controversy, including several court cases, challenging the NIH decision and questioning the ability of federal agencies to address potential dangers to ecosystems in light of the uncertainties.

In 1984, a White House committee was formed under the support of the Office of Science and Technology Policy to propose a plan for regulating biotechnology. This plan was published in 1986 as the Coordinated Framework for the Regulation of Biotechnology and is still in use today. It is based on the principle that techniques of biotechnology are not inherently risky and that biotechnology should not be regulated as a process, but rather that the products of biotechnology should be regulated in the same way as products of other technologies. The framework outlined roles and policies of the federal agencies and contained the notions that[42]:

1. Existing laws were adequate for regulation of biotechnology products;
2. The products, not the process, would be regulated;
3. GMOs are not fundamentally different from non-modified ones; and
4. Regulatory authority should be exercised only where there is evidence that the risk posed by the introduction is unreasonable.

Three US agencies share responsibility for regulating agricultural biotechnology: the Animal and Plant Health Inspection Service of the United States Department of Agriculture is responsible for ensuring that the growth of GM plants does not harm the agricultural environment; the Environmental Protection Agency is responsible for ensuring the human and environmental safety of pesticides substances engineered into plants and the Food; and Drug Administration is responsible for assuring that foods derived through biotechnology are as safe as their traditional counterparts.

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[42] Coordinated Framework for the Regulation of Biotechnology, Report of 1986

Products are generally regulated according to their intended use, with some products being regulated under more than one agency. Notwithstanding product focus, the cause for regulation with respect to the environmental release of plants derived via biotechnology is the process of biotechnology. The same degree of scrutiny is not applied to these products derived through traditional breeding or selection. Before commercialization, GMOs must conform to standards set by State and Federal marketing statutes such as State seed certification laws, the Federal Food, Drug and Cosmetic Act, the Federal Insecticide, Fungicide, and Rodenticide Act, the Toxic Substances Control Act, and the Federal Plant Pest Act.

4.5 Zambia

The Biosafety Act of 2007 and its Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations of 2010 constitutes the key element of the national regulatory framework for GMOs. This legislation regulates all dealings with GMOs in Zambia involving research, development, application, import, export, release or placing on the market of any GMO whether intended for use as a pharmaceutical, food, feed or processing, or a product of a GMO.

4.5.1 The Biosafety Act, 2007

The Act establishes the office of Registrar of the GMOs to administer the Act. Two regulatory bodies namely the National Biosfety Authority (the Authority) and the Scientific Advisory Committee evaluates and decides on applications. The Authority consists of thirteen part-time members appointed by the Minister which includes the following :*(a)* one representative from the ministries responsible for: science and technology; environment and natural resources; agriculture; health; commerce, trade and industry; information; and justice *(b)* one person from

each of the following groups: consumers; religious; farmers; and traditional authorities and; *(c)* two other persons. The Scientific Advisory Committee is composed of nine part-time scientific experts from relevant fields. This body advises the Authority on any risk associated with the dealing in GMOs and whether the permit for that particular activity can be issued. This may include risk management strategies that may need to be implemented should the permit application be approved.

The following are the salient elements of the national regulatory framework for GMOs in Zambia examined in the light of the international biosafety standards:

4.5.1.1 Institutional biosafety committees[43]

An institution involved in any dealing with any GMO or any product of a GMO is required to register with the Authority and to establish an institutional biosafety committee to institute and control safety mechanisms and approval procedures at the institutional level.

4.5.1.2 Notification procedure[44]

Any dealing with any GMOs or product of any GMO is prohibited in Zambia unless with the approval of the Authority. Inspectors ensure compliance with the Act.

4.5.1.3 Public consultation and participation[45]

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[43] Biosafety Act, section 9
[44] Biosafety Act, section 13
[45] Biosafety Act, section 14

Before the grant of any approval the Authority must consult with any relevant institution responsible for the conservation, management or protection of the environment, human and animal health, and farming local communities. In making its decision regarding any application, the Authority must take into account the views or concerns of the public or any relevant institution. This is in consonant with the standards set in the Convention on Biological Diversity and its Cartagena Protocol. Decision making is a process of accountability and transparency.

4.5.1.4 Criteria for decision making (precautionary approach)[46]

We saw under the international and regional regulatory frameworks that the concept of biosafety is based on the precautionary approach. The Act reflects this by providing that before any approval is given there must be sufficient evidence that the GMO poses minimum risk to human and animal health, non-GM crop, biological diversity or the environment. The lack of scientific evidence cannot be used as a basis for not taking preventive measures where there is reason to suspect threats of any damage to socio-economic conditions, human and animal health, non-GM crop, biological diversity or the environment.

4.5.1.5 Socio-economic considerations[47]

In line with international standards, the Authority cannot grant any approval unless it is satisfied the dealing in any GMO will contribute to sustainable development; not have adverse socio-economic impacts; and accord with the ethical values and concerns of communities and does not undermine community knowledge and technologies. This principle adopted by the Act, is deeply entrenched in the African Biosafety Model Law.

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[46] Biosafety Act, section 18
[47] Biosafety Act, section 19

4.5.1.6 Risk assessment[48]

An applicant is required to carry out an assessment of any risk associated with a GMO or a product of a GMO in respect of which the application is made. The risk assessment must be conducted in a scientifically sound manner, on a case by case basis. The weakness is that we do not have adequate technical staff to confirm or evaluate the risk assessment reports carried out by an applicant. The scientific advisory committee comprising of nine part-time members is dangerously inadequate to effectively meet all the challenges of biotechnology. There is only one biosafety laboratory in the entire country accredited as a referral laboratory.

4.5.1.7 Risk management[49]

The Authority is empowered under the Act to develop, maintain and use as the need arises, a risk management measures for protecting human and animal health, non-GM crop, biological diversity or the environment from accidents related to genetic engineering, the use of any GMO or any product of a GMO. Such measures may include revocation, suspension, cancellation or loss of permit. Risk management may prove to be impractical in Zambia given the inadequate staffing which is poorly equipped with the knowledge of biotechnology and its challenges.

4.5.1.8 Co-existence[50]

A person who cultivates any GM crop must prevent contamination of the GM crop with any non-GM crop. Also a person keeping a GMO livestock must prevent any cross-breeding between the

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[48] Biosafety Act, section 24
[49] Biosafety Act, section 27
[50] Biosafety Act, section 28

GMO and non-GM livestock. There is a penalty for failure to comply with this provision. One wonders how such a provision can be enforced when the technical staff is seriously lacking.

4.5.1.9 Identification and labeling[51]

Any GMO or product of a GMO is required to be clearly identified and labeled as such. The identification required must specify the relevant traits and characteristics given in sufficient detail for purposes of traceability. This is a feature of the African Biosafety Model Law adopted in the Act connected to the liability and redress regime endorsed by the African Union for any harm caused by GMOs to human health and the environment, and for resultant economic loss.

4.5.2.1 Export (Advance Informed Agreement)[52]

A person intending to export a GMO or a product of a GMO is required to provide to the Authority a written advance informed agreement or approval of the competent authority of the importing country. This principle adopted in the Act is related to the precautionary approach and is an innovation created in the Cartagena Protocol to the Convention on Biological Diversity.

4.5.2.2 Requirements for GMOs in transit[53]

In consonant with the international standards, any transboundary movement of GMOs or a product of a GMO is prohibited in Zambia unless with the written consent of the Authority.

4.5.2.3 Liability and redress[54]

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[51] Biosafety Act, section 29
[52] Biosafety Act, section 30
[53] Biosafety Act, section 31

Any person who imports, develops, releases or places on the market a GMO or product of a GMO shall be strictly liable for any harm caused by the GMO or product of the GMO and must compensate any person to whom the harm is caused. This is a feature of the African Biosafety Model Law adopted in the Act. The Zambian regulatory framework has adopted and designed a more stringent protective regulatory framework than that created in the Cartagena Protocol to the Convention on Biological Biodiversity. This stringent precautionary approach implemented at national level is permitted under international law.

4.5.2 The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010 simply referred to in this essay as Biosafety Regulations of 2010 regulates the importation of GMOs for direct use as food, feed or processing. The following are the salient provisions of the said Regulations:

4.5.3.1 Importation of GMOs[55]

The importation of GMOs for direct use as food, feed or processing is prohibited unless: the importation is authorized by the Authority; the GMO is authorized for commercial distribution as food or feed in the country of origin; and if the GMO pose no risk to human or animal health, biological diversity, non-GM crop or the environment.

4.5.3.2 Consideration of application[56]

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[54] Biosafety Act, section 36
[55] Biosafety Regulations of 2010, regulation 3

Application for permit to import GMOs for direct use as food or feed or for processing must be in a prescribed form. The Authority upon being satisfied that the application complies with the Act and the Regulations must forward a copy of the application to the Scientific Advisory Committee. The Scientific Advisory Committee must evaluate the application particularly the risk assessment studies conducted by the relevant authorities in the country of origin and submit its report to the Authority. As already noted the so-called Scientific Advisory Committee rarely performs any additional or confirmatory risk assessments but heavily relies on risk assessment reports submitted by the developers of GMO products. This is a major weakness.

4.5.3.3 Referral to other agencies[57]

The Authority may refer the copies of application to other agencies such as: Plant Quarantine and Phytosanitary service, if the GMO is a raw agricultural commodity intended for direct use as food or processing into food; and veterinary services, if the GMO is intended for direct use as feed or for processing into feed. In practice at each entry port there are Phytosanitary officers from the Ministry of Agriculture stationed to carryout routine checks of any suspected GMOs imported in the country. Where a suspected unauthorized import of a GMO is detected, the case is referred to the National Biosafety Laboratory located at Mount Makulu in Lusaka.

4.5.3.4 Public consultation[58]

An applicant upon the acceptance of the application by the Authority is required to publish a notice in at least two daily newspapers of general circulation in Zambia, inviting interested

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[56] Biosafety Regulations of 2010, regulation 5
[57] Biosafety Regulations of 2010, regulation 6
[58] Biosafety Regulations of 2010, regulation 7

parties to send their comments or objections on the proposed importation of GMO for direct use as food or feed, or for processing to the Authority. This provision ensures transparency and accountability of the decision makers and is in harmony with the international standards.

4.5.4.5 Grant of permit[59]

The Authority upon satisfying itself that the applicant has complied with the Act, the Regulations and that the GMO for food, feed or processing does not pose any significant risk to the environment must approve the application.

5.5.4.6 Permit conditions[60]

The permit holder is required under the regulations to comply with the following conditions: the GMO must be imported solely for direct use as food or feed, or for processing into food or feed, and not for field testing or propagation; the GMO must be maintained and disposed of in such a manner as to prevent risks to human or animal health, biological diversity, non GM crop or the environment; the permit holder must give access to inspectors to the facility where the GMO is located and to any records relating to importation of the GMO; the GMO must be identified with a label showing permit number, name of the GMO and date of importation; in the event of any accident or unauthorized release of the GMO, the permit holder must report immediately to the authority; if new information becomes available indicating that the GMO could pose significant risks to human or animal health, biological diversity, non-GM crop or the environment, the applicant must report to Authority who must take protective measures immediately.

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[59] Biosafety Regulations of 2010, regulation 8
[60] Biosafety Regulations of 2010, regulation 10

5.5.4.8 Suspension, revocation or cancellation of permit[61]

The authority may suspend, revoke or cancel any permit issued if in the opinion of the Authority, any GMO or product of a GMO to which the permit relates poses any risk to human or animal health, non-GM crop, biological diversity or the environment.

5.5.4.9 Traceability[62]

At all stages a person placing on the market of a GMO is required to transmit the information in writing to the person receiving the product that the product contains or consists of GMOs. The person is required to put in place standardized procedures to allow the holding of such information for a period of five years. We saw under the African regional regulatory system that traceability was crucial to the enforcement of the liability and redress regime for any harm caused by the GMO to any person or the environment. The same purpose is envisaged here.

5.5.5.0 Labeling[63]

The person placing on the market of a GMO is required to ensure that pre-packaged products consisting of GMOs the words '*this product contains GMOs*' for non pre-packaged products offered to the final consumer the words '*this product contains GMOs*' must appear on the display of the product. The labeling requirement ensures that accurate information is available to consumers to enable them to exercise their freedom of choice. This is also in accordance with the international standards.

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[61]Biosafety Regulations of 2010, regulation 14
[62]Biosafety Regulations of 2010, regulation 16
[63]Biosafety Regulations of 2010, regulation 17

5.5.5.1 Unique identifier[64]

A producer of a GMO for food or feed must develop a unique identifier for each GMO. Where consent for placing on the market of the GMO has been granted, the Authority is obliged under international law to communicate the said unique identifier for the GMO in writing to the Biosafety Clearing House created under the Convention on Biological Diversity.

The Zambian biosafety regulatory framework approach on the safe use and application of biotechnology and its products is modeled on the Convention on Biological Diversity and its Cartagena Protocol and the African Biosafety Model Law. Under the Act the National Biosafety Authority serves as the National Biosafety Focal Point and receive, process and respond to information and notifications from the Secretariat of the Cartagena Protocol on Biosafety. Among the legal concepts entrenched in the Convention on Biological Diversity and its Cartagena Protocol adopted in the biosafety regulatory framework developed in Zambia are: the precautionary approach; risk assessment; advance informed agreement; and public consultation and participation. The Zambian Biosafety Act of 2007 and its Biosafety Regulations of 2010 has also adopted mandatory identification and labeling of GMOs for purposes of traceability, socio-economic considerations, liability and redress regime espoused in the African Biosafety Model Law. The national biosafety legislation reflects international standards and is largely tailored to suit the African unique situation. The major weakness is poor training and staffing in this field.
It is submitted that the ministries responsible for: science and technology; environment and natural resources; agriculture; health; commerce, trade and industry; information; and justice must embark on staff development in the fields of biosafety and biotechnology.

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[64] Biosafety regulations, regulation 21

CHAPTER FIVE

5.0 GMOS BIOSAFETY: COMPARATIVE ANALYSES OF REGULATORY SYSTEMS STUDIED

In order to give a sound and reasoned comparison of the different regulatory systems considered in this study, the following are the heads under which this comparison is conducted: legislative basis; pre-market notification; philosophical approach/the reason for regulation; research involving genetic manipulation; advance notification and public comment; risk assessment process; source of safety data; benefits assessment; the decision makers and; post-market monitoring. This summary comparison presents a brief description of the significance of each head of comparison in the context of Zambia's regulatory framework for biotechnology and highlights significant similarities and differences with the approaches taken in other countries.

5.1 Legislative basis

In Zambia, biotechnology and its products are regulated nationally by the Biosafety Act of 2007 and its Biosafety Regulations of 2010 modeled on the Convention on Biological Diversity and its Cartegena Protocol and the African Model Law which is a new technology specific legislation. Like Zambia, the regulation of biotechnology and its products in Australia and South Africa is based on specific legislation. Unlike Zambia, the regulation of biotechnology products in the United States and Japan is based on preexisting legislation and voluntary system of guidelines respectively.

5.2 Pre-market notification

Like Zambia, pre-market notification for environmental release and food usage is mandatory in Australia, South Africa and the European Union. This also applies to research on, development, or, import of GMOs. Even though Japan has had a system of voluntary guidelines, and the United States engages in a voluntary consultation process with industry, there has been effective pre-market notification for every product in both countries.

5.3 Philosophical Approach/the reason for regulation

The biosafety legal framework developed in Zambia like Australia, the European Union and South Africa regulates both the process of biotechnology and its products. It is generally acknowledged amongst scientists worldwide that product attributes define the associated risks, each of the other countries included in this comparative study use the process of biotechnology as the *de facto* cause for regulation. The exception is the United States where the products and not the process of biotechnology are regulated in the same way as products of other technologies.

5.4 Research involving genetic manipulation

As a minimum requirement, all countries studied have established specific guidelines for control and regulation relating to health and safety procedures to be followed when undertaking research involving biotechnology.

5.5 Advance notification and public comment

Zambia, like Australia and the United States has implemented product approval systems that require both public notification and a request for public comments prior to the final regulatory decision. Australia's system is more open than the US in a number of areas. Australia has taken

the extra step of publishing draft risk analysis reports and seeking public comment prior to preparation of the final risk assessment report. By comparison, public pre-notification is not a requirement in the case of field trials in the United States.

5.6 Risk assessment process

The United States regulatory frameworks employ an evidence-based approach to risk assessment. In all countries studied the research, risk assessment and testing is the responsibility of the developer. Evaluations by regulatory authorities are based on data supplied and which in turn is examined within the context of an expert knowledge of the relevant scientific discipline. Risk assessments have focused on the defined differences between GM food and existing non-GM foods. Zambia, Australia, the European Union and South Africa have adopted the so-called precautionary principle as an attempt to eliminate risk. Adoption of the precautionary principle is not consistent with existing practice in countries such as Japan and the United States.

5.7 Source of Safety data

Without exception, the developers of GMOs and GM products have been responsible for conducting all of the research, testing, and monitoring necessary to establish the safety of their products. Additional testing of specific products by regulatory authorities has not been implemented in any of the countries examined in this comparative study. In many cases, regulatory authorities have continued to invest in research targeted to address specific issues related to the environmental and food safety of GMOs.

5.8 Benefits assessment

Assessing the potential risks associated with biotech products is by far more straightforward than attempts to evaluate potential benefits. None of the regulatory systems studied have implemented a systematic benefits consideration into their review processes, and there is no international consensus on the best approach.

5.9 The decision makers

In Zambia and the United States the responsibility for product approval lies solely within the institutional structure of the regulatory authority. This is unlike the situation in countries such as Australia and the United Kingdom. In the latter cases, the ultimate decision involves political factors, which in the case of the United Kingdom includes multinational (European Community) agreement.

6.0 Post-market monitoring

There has been no organized post-market monitoring of GMOs in Zambia. This study has revealed that the responsibility for post-market surveillance in many countries is covered by an ongoing duty of care on the part of the developer. The developer is under an obligation to monitor for existing and emerging risks that may be associated with its product and notify the regulatory authorities whenever new information is discovered.

BEST PRACTICES/RECOMMENDATIONS

Each of the countries studied have taken a different approach toward the regulation of biotechnology and its products. This is better illustrated by comparing the United States and the European Union, who have approached the issue from entirely different perspectives. The United

States has adopted an optimistic approach towards biotechnology and its products whereas; the European Union approach is more pessimistic, precautionary and involves trying to predict the unknown. These differences in philosophical approaches have been translated into unique regulatory systems with significant differences in legislative basis and decision-making.

What then are the best practices? Notwithstanding the diverse philosophical or political approach, at technical level, each country asks similar questions when evaluating the potential environmental and human health risks of biotechnology products. For example, in evaluating GM foods each country takes a comparative approach that focuses on the defined differences between the GM food and its traditional counterpart, and the effect these differences have on composition, nutritional quality, toxicity, and potential allergies. In each country, the safety data upon which regulatory decisions are based are produced or supplied by the developer without verification by the regulatory authorities.

From my assessment, I believe that the following approaches or processes represent best practices in the regulation of biotechnology and its products:

1. Zambia's precautionary approach

Since its endorsement by Rio Declaration on Environment and Development in 1992 the concept of biosafety based on precautionary approach has been internationally acclaimed as environmentally sound management of biotechnology. The precautionary approach has been validated by numerous scientific bodies as promoting a balanced approach to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity. Zambia's

approach is not unique, Australia, the European Union, South Africa have taken similar steps and have been truest to the scientific principle that modern biotechnology is recognized as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care.

2. Australia's open and transparent regulatory decision making process

In Australia, applications for any dealing in GMO and food safety evaluation are subject to public notification and request for public comment prior to a final decision. The same approach has been taken by Zambia; prior to any approval of similar applications the regulatory authority must take into account the views or concerns of the public. This is a clear demonstration of the openness and transparency of the regulatory systems for GMOs operating in Australia and Zambia.

3. Evidence based approach to risk assessment free of social or ethical considerations.

Risk assessments are fact based evaluations of the likelihood of certain adverse impacts which are conducted in the absence of perfect information. They depend on available evidence. The precautionary principle on this score must be approached with caution as it tends to bias the process of decision making under uncertainty. Decisions cannot be made in shades of grey. Evaluations of biotechnology products are conducted on a case by case basis, and must not be open to a consideration of broader undefined social or ethical issues in the process.

4. Risk assessments conducted by expert scientists within the regulatory authority.

A number of the countries examined in this study employ advisory committees which are primarily scientific in nature to evaluate the product safety information submitted by developers. This approach may seem to be an attractive alternative to using expertise within the regulatory authority. There are some drawbacks including: committee members are part-time volunteers who cannot devote their full energies to risk assessments. The selection process for committee members may not result in the right combination of scientific expertise and regulatory experience. Product evaluations conducted by competent scientists within the regulatory authority, supplemented by an independent panel of experts may be the best approach. At the heart of the product evaluation process in every country is the scientific peer review process. Risk assessors of GMOs must truly be peers of the academic or industrial scientists that developed these products.

5. Mandatory labeling, liability and redress regime implemented in Zambia

Risk assessment, traceability and labeling requirements for GMOs are mandatory in Zambia, Australia as well the European Union. Zambia has taken a step further by providing for liability and redress for harm caused by GMOs to human health and the environment, and for resultant economic loss. This is a perfect example of statutory codification of the common law general principle of duty of care owed by the manufacturer to the ultimate consumer[65].

CONCLUSION

There is no doubt that the legal framework for biosafety regulatory aspects of GMOs for food, feed and processing in Zambia is effective. There are several models of national regulatory

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[65] *Donoghue v, Stephenson* (1932) AC 562

frameworks studied in this essay that may be effective in building up a workable biosafety system. The model chosen depends on the policy of a given country and should be in accordance with its international and regional obligations. It is common ground that harmonization of international, regional and national regulatory frameworks should focus on the issues of strengthening capacities and information sharing for biotechnology safety. To ensure the best practice of evidence based approach to risk assessment free of social or ethical considerations, Zambia must acquire technology and capacities necessary to sustainably handle the challenges of modern biotechnology. The Scientific Advisory Committee must be comprised of full time scientific experts and more resources must be invested in capacity building. Therefore, public awareness, education, and technology transfer play an important role. A number of international organizations such as FAO, WHO and UNEP as well as regional cooperation are in the position to offer necessary assistance in capacity building and dissemination of information on biosafety. Zambia has setup a modern biosafety laboratory under the National Scientific Institute of Research (NSIR) to detect GMOs entering the country. The goal of this facility is accredited as national referral laboratory that provides research and training in collaboration with the National Biosafety Authority, the University of Zambia and the Norwegian Institute of Gene Ecology[66]. Setting up an effective national regulatory framework demands for harmonization at the national level of all the institutions dealing with the regulatory issues. The ministries responsible for: science and technology; environment and natural resources; agriculture; health; commerce, trade and industry; information; and justice must work together to ensure an effective legislative and institutional national biosafety framework for the regulation and control of GMOs.

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