THE REGULATION OF GENETICALLY MODIFIED ORGANISMS (GMOs). A SOUTH AFRICAN LEGAL ANALYSIS.

By

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Abstract

Genetically Modified Organisms (GMOs) have become a topical issue today. Almost every newspaper in any country carries an article on GMOs at least every week. A global debate on the benefits and costs of GMOs began scaling heights by the beginning of the 21st century, and still rages on today. Proponents of GMOs allege that the modern biotechnology is important for boosting agricultural produce and therefore believe it is a panacea for solving problems of famine and food shortages suffered especially by the drought prone poor nations of the world. Apart from that, they also believe it contributes to an advancement of research in the area of pharmaceuticals.

The debate led the international community to adopt the Cartagena Protocol (which is a creature of the Convention on Biological Convention) to look at the regulation of GMOs so as to minimize the risks posed by the phenomenon, while harnessing the potential benefit, which the world could derive from the modern biotechnology. The Protocol, like the Convention on Biological Diversity (the Convention), which gave rise to it, requires parties to it to strengthen its measures through domestic implementation. South Africa is one the countries which have responded to this call by enacting the Genetically Modified Act 15 of 1997. The Act was drafted mainly on the basis of the Convention. This work will therefore attempt to assess the domestic implementation of the requirements of the Protocol in the light of the standards set by international law, the National Environmental Management Act (NEMA), and the Constitution of South Africa.

To establish the above, this thesis will briefly consider the debate which influenced the international legal framework on GMOs in chapter one. Chapter two will trace the international legal position on GMOs, as enshrined in the Protocol and the Convention. An assessment of the consistence of the South African GMOs Act with standards set by international instruments and national pieces of legislation which impact on environmental management and biodiversity conservation will follow in chapter three. Then finally the curtain will come down in chapter four, which will suggest the way forward for South Africa in form of recommendations and proposals flowing from the analysis of the Act given in chapter three.

DECLARATION

I declare that the whole of this dissertation, save as specifically admitted and acknowledged in the text, is my original work, and has neither been published elsewhere nor submitted in any other University for the same qualification or any other purpose

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Chapter one

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1.1 Introduction

Almost every newspaper in any country today carries at least one article on Genetically Modified Organisms (GMOs) or Genetically Modified Food (GM food) per week.[1] GMOs are a result or a product of modern biotechnology[2], which has been held to hold the key to solving many global environmental and health problems, including the need for sustainable development[3]. A closer look at the newspaper articles referred to above will show that the tone of the article is to either raise concern over the risks of GMOs or the safety and benefits of the GMOs, depending on who is speaking, and with what motives. Caution has been raised on the use of GMOs throughout the world, beginning with the developed world first. It has been argued that it is now difficult to know who exactly is right in the debate surrounding the issue of GMOs due to divergent views on the subject[4].

Proponents for GMOs argue citing the various benefits of the new technology in areas like pharmaceuticals where they advance medical research and in agriculture for boosting agricultural production[5]. Some conservationists also argue that the modern technology enhances biological diversity[6]. One thing stands out in this whole debate, that is the fact that GMOs are here to stay. Equally persuasive arguments have been made for or against

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[1] See the meaning of GMOs under the section on definitions of terms, 1.3 below

[2] See the meaning of the term biotechnology under the definitions section under 1.3 below

[3] Sustainable development has been defined as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs." *Marie-Claire Cordonier Segger; Weaving the Rules for Our Common Future, CISDL, 2002*, definition adapted from the Brundtland Report, 1987

[4] In Britain for example, the Prince of Wales has been vocal about GMOs. He has raised a number of questions around the safety, labeling, suitability of GMOs for the developing world taking into account the costs of scientifically testing them etc. See an *Article by the Prince of Wales*, The Daily Mail (in Britain), *1st June 1999*

[5] Healy.P. Bernadine; New Developments in Biotechnology, Genetic and Ecological Issues, Technomic publishing Co; Lancaster, Basel p33

[6] Ibid

them, but still little remains known about the future consequences of introducing them into the environment. In South Africa, GM food appears to have been widely accepted by consumers. Is it because the government has not fulfilled its role of public education as required by law? Such questions provide an incentive for inquiring into how the legislature has dealt with the consequences of GMOs on the environment using the rich resource of international law.

The issue or problem, which this research identifies and seeks to deal with, can best be located within this global debate or controversy surrounding the issue of GMOs. Development and introduction of GMOs into the environment raises a number of legitimate technical, political, legal and ethical concerns[7]. The most important of these include environmental protection, food safety, and corporate control or monopoly of agriculture by big transnational corporations in the rich North.

On food safety for example, several countries including those in Southern Africa for example, have blocked or attempted to, or severely restricted the importation or use of GM crops or food. Zimbabwe, for example, has for so many months been adamant that no GM food aid would be allowed into the country until the country's scientists have ascertained its safety[8]. Some of these actions are related to fears that the GMOs might contain allergens or other harmful substances, which may impact negatively on human health and the environment where they are introduced. A distinguishing characteristic of many GMOs that causes understandable alarm in the developed or even the developing world is the presence of an anti-biotic resistance marker gene[9]. GMOs are created by linking the target gene, for example for insect resistance, to the gene of an easily identifiable trait. The result is that most GMOs currently available carry an antibiotic resistance gene. The concern therefore is around the possible incorporation of antibiotic resistance in humans, or in the animals that consume GMOs as food or feed[10].

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[7] Genetically Modified Organisms: Issues of the debate in the South; *www.bugwood.org/*asareca
[8] However the Herald in the Friday September 6 issue indicated that the government has given a nod to GM food aid,"---on condition that it will be quarantined to allow Zimbabwe's agricultural scientists to closely monitor its shipment, milling and distribution in the country." See www.herald.co.zw 6 September issue
[9] See note 6 above
[10] Ibid

The greatest challenge facing developing nations is the difficulty of ascertaining the extent of the impact of GMOs on the environment, and this has implications for policy making[11]. Considerably high quality information is required for adequate assessment of GMOs in the South[12], where less is understood about many of the ecologies into which GMOs might be introduced[13]. Such information is costly, and most of the developing countries do not have adequate resources for this purpose. Therefore external funding is needed to support environmental studies, as well as for broader concerns of biological diversity conservation[14].

The other controversy of relevance to Africa is the issue of corporate control of agriculture. It has been pointed out that a global battle is currently raging to determine whether or not private parties will be allowed to own a significant proportion of the economically valuable living organisms of the earth[15]. If they do, then they stand to gain control over most of the food production globally. Such private parties, who are transnational corporations, claim that it is essential that they be granted monopoly rights over genetically modified organisms and other life forms to ensure that they have sufficient incentive to continue to innovate. Farmers and governments of developing countries, as well as other concerned individuals and NGOs heavily criticize this[16]. The basis for their opposition varies from moral, ethical to political objections to the concept of genetic engineering. Other fears raised are that this may represent some form of "neo-colonialism" and may perpetuate dependency of food producers in developing countries of the South on Northern-based transnational corporations[17].

South Africa, despite being a developing nation dependent on agriculture, is held to have advanced technology and scientists who are able to genetically modify organisms. This

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[11] National Research Council; Field Testing Genetically Modified Organisms; National Academy Press, p2
[12] South or the North refer to developing nations and developed nations respectively
[13] Bernadine, op cit p20
[14] See note 6 above
[15] Cormac Cullinan; Assessing the effectiveness of South Africa's legislation around genetically Modified Organisms; www.globesa.org/gmoslecture
[16] Ibid.
[17] Ibid.

factor, plus the geographical location makes South Africa an interesting case study. It is important to point out that SA, unlike some of her neighbours in Southern Africa has a Genetically Modified Organisms Act in place.[18] The Act is meant to regulate the introduction and use of GMOs into the environment. On the other hand, the majority of the African states are united in their opposition to the introduction of GM crops into Africa and the patenting of life forms.[19]

It is in the above context that there are divergent views in SA over GMOs, and their impact on the biodiversity of the country. Some argue that the new technology opens doors for sustainable development, while others argue that it is not in the interest of the majority of South Africans to increase the dependence of small-scale food producers on purchasing relatively expensive seeds and chemical inputs used in conjunction with them.[20]

Questions have been raised in SA regarding risks associated with the use of GMOs. Consequently, the legal regime on the GMOs has come under scrutiny, with queries raised on the legislation's consistence with the constitution and the NEMA, plus its reflection of the current international requirements.[21] Some questions can be asked around the regulation of GMOs. Is there a mechanism for the risk assessment and environmental impact assessments as required by the NEMA? Are the consumers and users of GMOs and their products in a position to make informed decisions about their use and consumption? Is the idea of public participation in decision-making relating to GMOs and the implementation of laws provided? Such questions are a part of the problem for which this work seeks solutions.

[18] GMOs Act 15 of 1997 is discussed in depth in Chapter three paragraph 3.2
[19] See Cullinan op cit n14
[20] Ibid
[21] At international level, an agreement popularly known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was reached in January 2000 in Montreal, and this Protocol was an outgrowth of the Convention.

1.2 Direction of the research

In trying to provide an answer to the various questions, the research will follow the following direction. The work will consider the debate around the issue of genetic modification or GMOs.[22] It is this debate that has influenced the international position regarding the general conservation of biological diversity, and GMOs in particular. The work will look at this debate as the main force underlying the development of international standards on modern biotechnology. This discussion will entail an inquiry into the potential costs and possible benefits which can be derived from the biotechnology. This should pave way for the understanding of the reason why the international community is so much interested in the issue of GMOs.

After looking at the debate surrounding GMOs and the whole concept of genetic modification, this work will trace the international regulation of GMOs. The debate considered above is the main force behind the international framework on GMOs regulation. It is at least known that the Cartagena Protocol on Biosafety to the Convention on Biological Diversity is the main international legal instrument regulating biosafety and related issues. This work will seek to establish the historical foundation of the Protocol, and other international rules and instruments which has influenced it. In tracing the history of the Protocol, the Convention on Biological Diversity will be briefly looked at, as will the Principle 15 of the Rio Declaration and the precautionary principle. All this will be done in Chapter two.

Apart from tracing the international position, this research also seeks to establish what the position is at regional level. The research will not attempt to look at all regions of the world. That is beyond the scope of this work. Attention will be limited to the African Union's position on GMOs. Reference may be made to the European Union by way of comparison. The position of SADC[23] will also be briefly considered.

After tracing the international and regional legal framework for GMOs, attention will be shifted to South Africa, in Chapter three. The Genetically Modified Organisms Act 15 of

[22] See 1.5 below

1997 will be examined in the light of International law, particularly the Cartagena Protocol. The purpose will be to find out how much the South African GMOs Act meets the requirements set by international standards on biosafety. Chapter three will also inquire into the consistence of the Act with the NEMA, which sets standards for environmental management in South Africa, as well as the constitution, which is the supreme law of the land..

The purpose of examining the domestic implementation of the Cartagena Protocol in South African law through the GMOs Act is to pave way for recommendations if the Act is found wanting in meeting South Africa's international obligations on biosafety. This research will show that deficiencies exist in the GMOs Act. Recommendations and proposals will therefore be made accordingly in the concluding chapter four. The conceptual issues, that is the definitions of important terms will be looked at in 1.3 below before we turn to the debate surrounding GMOs in 1.4.

It is important to note that the issue of genetic modification[24] stems from the need to conserve biological diversity. Genetic modification was seen as a way of enhancing biological diversity. For example, in agriculture, genetic modification would result in crops which do not require the spraying of herbicides, thereby eliminating or minimizing the killing of untargeted species of insects, which is one good way of conserving biodiversity.[25] Therefore one can draw an inextricable link between biological diversity and genetic modification. They are complementary, in that the latter enhances the former. We now turn to the meaning and the various forms of biodiversity.

1.3 Definition of the concept of biodiversity

Biodiversity has been described as "an umbrella term for the degree of nature's variety".[26] It has also been described as "the total variety of genetic strains, species and

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[23] SADC is the acronym for Southern African Development Community
[24] See paragraph 1.4 below for the definition of the term genetic modification
[25] Kurt Buechle, *The Great Global Promise of Genetically Modified Organisms: Overcoming fear, Misconceptions, and the Cartagena Protocol o Biosafety*, http://ijgls.indiana.edu/archive/09/01/buechle.shtml
[26] J.A McNeely et al, *Conserving the World's Biological Diversity* (1990) at 17

ecosystems".[27] The Convention on Biological Diversity (CBD) defines biodiversity as "the variability among living organisms from all resources including, *inter alia,* terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part, this includes diversity within species, between species, and ecosystems".[28]

One other interesting definition of biodiversity is given by the White Paper on the Conservation and Sustainable Use of SA's Biological Diversity.[29] The paper describes it as "the number and variety of living organisms on earth, the millions of plants, animals and micro-organisms, the genes they contain, the evolutionary history and potential they encompass, the ecosystems, ecological processes, and landscapes of which they are integral parts. Biodiversity thus refers to the life support systems and natural resources upon which we depend".[30] Through the above definitions, biodiversity is captured as a three-layered concept embracing the following:

(i) Genetic diversity within species

(ii) The diversity of ecosystems; and

(iii) The diversity of species.[31]

1.3.2 *Genetic Diversity*

This literally means or refers to the variation of genes within species, which makes it develop new breeds of crop plants and domestic animals, while allowing species in the wild to adapt to changing conditions.[32] Genes, if they are to be defined, are the biochemical packages that are passed on by parents to their offspring and which determine the physical and biochemical characteristics of the offspring. While diversity of ecosystems may be regarded as a concept commanding the highest respect, genetic diversity is considered to be the most fundamental element. Bowman gives the reason for this as lying in the fact that, it is in the very variety of genetic material existing within and between species, that the raw materials for scientific, industrial and agricultural

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[27] Alan E.Boyle; in *International Law and the Convention on Biological Diversity* at 33-34
[28] Art.2 of the Convention on Biological Diversity.
[29] J.Glazewski; *Environmental Law In South Africa* at 300
[30] See the White Paper as adapted in Glazewski, op cit at 300
[31] M.Bowman, in *International Law and the Conservation of Biological Diversity,* 1996 at 5
[32] Glazewski op cit at 300-301

innovation and development is found. The same applies to the resilience and adaptability which will be needed if the earth's biosphere is to survive in the face of current trends of continuing environmental degradation.[33]

1.3.3 *Diversity of ecosystems*

Of the three elements of diversity outlined above, ecosystem diversity is regarded as a highly important concept.[34]This is so because all living organisms exist and function not in isolation from each other, but as part of a wider environment occupying a particular niche within their appropriate ecosystem. Therefore diversity can be maintained or achieved through the preservation of entire ecosystems as a unit.[35] Ecosystem diversity refers to the variety of ecosystems within a particular region or particular political or geographical boundary. Glazewski[36] defines an ecosystem as a community of plants, animals and microorganisms, and the soil, water and air on which they depend. One important aspect of this definition is that the living organisms are considered together with their physical environment. The interactions of these contribute to life supporting processes like the water cycle, energy flow, soil formation and nutrient cycling among others.

1.3.4 *Species diversity*

The definition of a species is not yet a clearly settled issue. It is however, generally accepted that a species is a population of organisms, which are able to interbreed freely under natural conditions.[37]The term that is usually used to depict the measure of species diversity is 'species richness'. A species represents a group of organisms, which have evolved distinct characteristics or features, and occupies a particular area.[38] Species diversity, in relation to the two other elements of diversity, may be claimed to be the

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[33] Bowman op cit n31
[34]E.O Wilson; *The Diversity of Life* (1992) at 35-45
[35] C.Redgewell and M.Bowman in *International Law and the Conservation of Biological Diversity,* 1996 at
[36] Glazewski, op cit at 301
[37] Ibid
[38] Ibid

central concept, since the species has traditionally been regarded as the taxonomic starting point for the classification of living organisms.[39]

The tree elements of diversity above demonstrate that in simple terms biodiversity is what the White Paper envisages it to be, that is, all living organisms, including fauna and flora and the habitat in which they live. In other words, in a nutshell, it "refers to the life support systems and the natural resources upon which we depend".[40] The drive behind the biodiversity concept is the conservation of natural resources. In 1.3.2 to 1.3.4 above it has been highlighted that each element of diversity has some importance attached to it. It is however not preferable to regard one element as being more important than the other since their focus is one, that is, the protection of the environment. The better view is therefore to regard the three aspects as mutually interdependent, and equally important, so reflecting the symbiotic relationships existing within the biosphere itself.[41]

1.4 The Concept of Genetic modification

The reader shall be introduced to novel scientific terminology, which touches on the concept of genetic modification during the course of this work. The purpose of this section is therefore to lay down a foundation for the conceptual comprehension of the terms that shall be widely employed throughout this work. It should be pointed out that the meaning of these novel terms shall be adapted to suit the environmental law purposes where possible, although some, if not all, may retain their original scientific flavor and meaning.

Before defining the other terms commonly associated with the concept of genetic modification, it is important to gain an understanding of the concept itself. Now, genetic modification can be defined to mean the alteration of the genetic material of a virus, a cellular organelle or an organism by inserting a piece of deoxyribonucleic acid

[39] See note 8 above
[40] Art 9 of the White Paper
[41] Bowman op cit at 6

(DNA),[42]or new genes to an organism.[43] The other terms that are sometimes used interchangeably with genetic modification are genetic engineering and genetic manipulation.

1.4.1 Genetic Engineering (GE)

The Dictionary of Gene Terminology[44] defines the term to mean the in-vitro methodology to change the structure of genes to design new genes, or to construct chimerical genes. This also refers to the technology to transfer these genes into any organisms of choice and to express them in a foreign environment. In basic science, genetic engineering is used to study the gene structure and regulation. In industrial application it serves as a means to provide organisms with new traits to produce more and better chemicals or drugs, or to perform better or additional functions. Genetic engineering is a discipline of ***modern biotechnology***[45] whose definition is closer to that of GE.

1.4.2 Gene manipulation

This refers to the formation of novel combination of heritable material by insertion of DNA[46] molecules, produced outside the cell, into any virus, plasmid or other vector system so as to allow their incorporation into a host organism in which they are capable of continued propagation.[47]

The obvious result of genetic modification is the popular or rather the infamous genetically modified orgasms (GMOs).

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[42] DNA is a nucleotide polymer that carries the genetic information of viruses, bacteria, and all higher organisms. DNA may occur single-stranded (ssDNA, as in some viral genomes) or double-stranded (dsDNA as in organelles and chromosomes of all higher organisms).

[43] See www.foodmarketexchange.com/datacenter/laws/detail/dc_lr_reference_GMOdef.htm

[44] G.Kahl. *The Dictionary of Gene Technology,* 2nd Edition at 330.

[45] Modern biotechnology means the application of in vitro nucleic acid techniques, in
(a) recombinant de-oxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
(b) fusion of cells beyond the taxonomic family

[46] See note 38 above for the meaning of DNA.

[47] Kahl, op cit at 329

1.4.3 Genetically Modified Organisms (GMOs)

In simple terms, a GMO is an organism in which genetic material has been changed through modern biotechnology in a way that does not occur naturally by the multiplication and or natural recombination.[48] The dictionary of Gene Terminology defines a GMO as any organism that contains a foreign gene or promoter, generally DNA, its chromosomes, its organelle genomes, or its plasmids, introduced by direct gene transfer techniques.[49] It has also been briefly defined as an organism, plant or animal that has had a gene from an organism spliced into it through biotechnological means.[50] The EU-Commission Directive 90/220 describes GMOs as biological entities capable of replication or of transferring genetic material through genetic modification.[51]

Some terms which are used alongside GMOs include such terms as ***Living Modified Organisms (LMOs)*** which means any living organism that posses a novel combination of genetic material obtained through the use of modern technology.

Transgenic Organism is another of the terms used as a synonym of GMO. It refers to an organism with a piece of DNA spliced into a chromosome[52] in its cell. This piece of DNA typically contains a gene.

The third term adopted is the term ***Genetically Engineered Organism (GEO).*** This is an organism that has been modified by the application of recombinant DNA technology.[53] This concept of altering an organism's genes for human benefit goes back over 20 000 years with selective breeding of deer, antelope and sheep. About ten thousand years ago

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[48] See *Draft Amendment to The General Standard for The Labeling Of Pre-packaged Foods*: Definitions, www.txinfinet.com/ban-gef

[49] Kahl op cit at 328

[50] See note 48 above

[51] See note 48 above

[52] A chromosome can be defined as:

(a) a circular double-stranded DNA molecule in prokaryotic cells, usually attached to the cell membrane and containing all the genetic information essential for cell life

(b) one of the self-replicating thread or rod-shaped structure within the nuclei of eukaryotic cells that consists of extremely condensed chromatic and contains genetic information for specific functions of the cell. The number of chromosomes per nucleus is characteristic for a given species.

[53] See note 42 above

societies were reportedly modifying strains of wheat for cultivation.[54] Farmers have long crossed plants displaying favorable traits in order to produce an improved hybrid. Consequently, almost all the food that is eaten today is nolonger from genetically pure species.[55] Gene-splicing technology is held to have been developed in the United States of America around 1983.[56] The development of the concept of genetic modification and the biotechnology was to serve in providing advanced pharmaceutical research and boosting agricultural produce.[57] In agriculture for example, the products of the process of gene transfer have been seen as transgenic crops, which may have disease resistant genes inserted. Some of the GM crops also offer herbicide tolerance or insect resistance.[58] Many plant breeders believe that GMOs offer significant opportunities for agriculture including reducing the reliance on dangerous pesticides, promoting soil conservation through the rational use of herbicides, and eventually the development of varieties that can withstand environmental stresses such as drought. The discussion which follows will spell out the risks posed by GMOs as well as the potential benefits which can be derived in more detail in the context of the debate on the matter.

1.5 The Debate around GMOs

GMOs are a highly contested issue at an international plane, and now even in national spheres the debate is heating up. Even at times the issue may provides some politically playing field for nations. Lisa Oladotter, in her unpublished MA thesis, says that USA has accused some European nations of playing politics with the issue of GMOs, when they insisted on mandatory labeling of GMOs, and also imposed a ban on USA exports which contained GMOs.[59] It is sometimes not easy to tell whether the debate started at national levels or at international level. But what is clear is that for most of the developing nations, the debate was picked up from the international scene. The debate is

[54] See www.foodmarketexchange.com/datacenter/laws op cit n43
[55] Ibid
[56] Dr Harry Klee, a professor of horticultural sciences at the University of Florida who does research in genetic modification
[57] See paragraph 1.5 below for the discussion of the debate around GMOs, in which the costs and benefits of GMOs are outlined.
[58] Overseas Development Institute Briefing Paper; *The Debate On Genetically Modified Organisms: Relevance For The South*, www.odi.org.uk/briefing/1_99.html
[59] Lisa Oladotter, see note 61 below

beginning to assume great heights in many countries in the South[60] due to the global debate. It should be pointed out here that it is this global debate which has been responsible for the adoption of international rules and standards in the context of conventions and protocols. The Cartagena Protocol, and the Convention on Biological Diversity which gave birth to it, are the two internationals forums at which the issues of biological conservation and its sister issue of biosafety were negotiated, and binding agreements came out as a result of compromises made on some potentially explosive issues. Some issues are yet to be fully settled though, like the issues of trade in GMOs.[61] Nevertheless the importance of the debate is seen in its products, the achievement of binding international legal instruments impacting on biodiversity conservation, and biosafety in particular.

What made or rather what makes the issue of GMOs so controversial is the fact that GMOs are complex and their regulation can not be easily done on a purely objective and technical basis.[62] The assessment of risk and the interpretation of information will always be affected by values of the regulators and the political and economic pressure exerted on the regulatory process. It is also important to note that social, ethical, moral and environmental factors also inform the debate. This discussion of the debate will be categorized into benefits and costs of GMOs.

(i) Benefits of GMOs

The proponents for GMOs advance their argument in favor of the idea on the basis of its benefits to the human society. These people see more value in the GM plants and food than harm. One of the factors they argue around is the fact that the biotechnology in this respect increases agricultural productivity. The transgenic crops, which are currently being grown, possess character traits, which are designed to increase farm level productivity, either by reducing input use or by raising crop yields. The 1998 trial of

[60] The South and the North are terms, which are used to denote the developing countries and the developed countries respectively.
[61] See Lisa Oladotter Sandblom (Monterey Institute of International Studies), *Genetically Modified Organism;;* http://www.commercialdiplomacy.org/ma_projects/ma_sandblom1.htm

insect resistant cotton in the Makatini Flats of KwaZulu Natal showed a significant decrease in the use of insecticides and an increase in yield of between 18 to 23 percent.[63] The small-scale farmers involved in the trial achieved the highest increase in yield and one woman farmer is reported to have pocketed R30 000 in her bank that she had not expected. Thus it should be noted that productivity can be stepped up and maintained without increasing the acreage of land, thereby creating reasonable space for wildlife or create space for housing and other pressing needs of the people.

The other benefit of the GM crops is that they induce resistance to disease in the crops where they are used, and this reduces the need for chemical pest control.[64] This has also other benefits to the farmer. They will for example, nolonger depend on the weather conditions when deciding when to spray, and will be able to reach to reach parts of the plant traditionally difficult to with sprays. Secondly, farmers will realise great benefit when freed from the many costs involved with spraying. Thirdly a GM crop is also less expensive to develop than a new chemical insecticide. The use of GM crops, which decrease or eliminate insecticide spraying, means more non-target insects will be protected. This is more environmentally friendly. Use of the transgenic crops does not have to mean increased production only, it can also mean maintenance of the current levels while using fewer acres. More efficient use, as has been pointed out in the above paragraph, means more space for nature, and consequently this boosts biodiversity, and even better soil conservation. The other benefit is the reduction of ground water contamination since fewer pesticides will be used.[65]

GMOs have been held by proponents to have health benefits to the human body. Firstly, decreasing the need to spray should definitely mean less danger for spray operators, particularly in the developing world where it is still done manually.[66] Nutritionally, there is enhanced quality. Plant breeders have always endeavored to develop crop varieties

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[62] Overseas Development Briefing Paper, op cit n58
[63] Jennifer A Thompson, Head, Department of Microbiology, UCT, *The Genetically Modified Organisms;* www.uct.ac.za/microbiology/gmos.htm
[64] Buechle op cit n25
[65] Ibid
[66] Ibid

with added vitamins and minerals. Nutritionally fortified crop varieties should prove especially valuable in developing countries, where millions of people suffer from dietary deficiencies and malnutrition. Such nutritionally enhanced crops should also prove attractive in industrialized countries as a means of reducing consumption of oils, proteins and starches. Soybean and canola varieties have already been engineered to produce healthier oils containing reduced levels of fatty acids. It should be noted that nutritionally enhanced GMOs also benefit animals greatly in the same way it does on humans. Some plant varieties will even contain vaccines beneficial to the body's ability to fight disease attack[67]

(ii) Costs of GMOs

Critics of GMOs are eager to shoot them down, basing their arguments on the harms and risks associated with the use of GMOs and their introduction into the environment. Some of the concerns raised about GMOs include environmental, health, ethical and political misgivings of the critics. Among the environmental concerns is the uncertainty as to whether a GM crop would become a weed either by itself or by transferring of modified genes to wild relatives, and even possible effects on the ecosystem in which it might enter.[68]

There are also complaints or concerns about the possible health effects of the GMOs like allergies and anti-biotic resistance.[69] One example of a food that was not allergenic but could be easily made allergenic is the soybean through an allergen from the Brazil nut.[70]Although it may add protein value, the nut however turns to be an allergen when crossbred with soybean. Secondly, many GM crops contain anti-biotic resistance gene in addition to the gene from the protein that a plant breeder wants to produce. Some studies have actually revealed a health risk caused by these crops, in that bacteria living in

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[67] Buechle; op cit n25

[68]Matthew Feldmann et al, *Why so much controversy over genetically modified organisms?Answers to 10 frequently asked about GMOs*; http://www.cimmyt.org/ABC/10-FAQaboutGMOs/htm/10-FAQaboutGMOs.htm

[69] Buechle op cit n67

[70] Ibid

human gut could pick up these antibiotic resistance genes, thus reducing the effectiveness of these antibiotics in our bodies.

The other concerns raised against the increase of GMOs in Africa are of socio-economic and political nature. Fears are raised that this development represents a form of neo-colonialism, which will ultimately increase the dependency of food producers in developing nations of the South on huge Northern, based multinational corporations. It is reported that such trans-national companies today control about 80 percent of business in Africa.[71] Their bid to control and genetically manipulate these organisms through a monopoly of the patent rights over all form of GMOs, is viewed in Africa as a way of establishing the same hegemony once enjoyed by the colonial powers during their times. The only difference, it has been argued, is that theirs is subtler form and is hidden in a beautiful business camouflage. The OAU[72], as it was then, was instrumental in the fight to resist this alleged neo-colonialism through advocating for African countries to adopt legislation, which promotes the protection of the rights of local communities' farmers and breeders. This is based on an approach, which emphasizes community rights over biological resources as a means of countering what is perceived to be a new attempt to "enclose the commons by privatising rights to indigenous knowledge, seeds and plants".[73]

The debate above establishes one thing, that there are strong points for and against GMOs. This is why the debate around GMOs is so hot, broad and far-reaching. The international community realised this, and decided to engage each other in round table negotiations to try and break the impasse which such a broad debate usually results in. The most recent results were the Convention on Biological Diversity and the Cartagena Protocol. The agreements reached at these international negotiations were influenced by the desire to deal with issues raised in this debate. The next chapter will consider the Cartagena Protocol, which was directly influenced by the issues emanating from the debate discussed in this section. The international community realised that the way

[71] Cullinan op cit n15
[72] Now the African Union-AU
[73] See note 71

forward for the world was to find a way to minimise the risks associated with the GMOs, while at the same time preserving and making use of the benefits which can be derived from the modern biotechnology. Hence the calling of the biosafety Protocol which will be discussed in chapter two below.

Chapter two seeks to establish the exact position on the handling of GMOs. To this effect the chapter shall look at the provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD). The chapter will also trace the history of the Protocol, and the international rules and standards which influence the concept of biosafety. This chapter will therefore lay a foundation for analysing South Africa's domestic implementation of the requirements[74] of the Cartagena by establishing what these requirements are, and what they entail. The chapter will also consider the African region's position on GMOs, at a limited scale.

[74] This will be done in Chapter three.

Chapter Two

International and Regional Regulation of Genetic Modification

2.1 Introduction

Genetic modification, or the issue of GMOs is now regulated both at international level, and at domestic level in some countries. Before 2000, the main legal instrument to deal with genetic modification was the Convention on Biological Diversity (the Convention)[1], while plans were underway to come up with a more comprehensive legal instrument to deal with the effects of modern biotechnology on biological diversity[2]. The Cartagena Protocol came into existence in January 2000 as an offshoot of a process set in motion by the Convention[3]. The Protocol is now the most relevant international instrument to deal with genetic modification and its effects on biological diversity. In other words, it is the first internationally binding legal instrument that regulates the handling, use and transboundary movement of genetically modified organisms (GMOs).[4] The Protocol requires national governments to put in place measures, which allow the conservation of biological resources.

Various regions, especially the global economic blocks, also came out in response to the international regulation of genetic modification. The European Union, for example, has a detailed law in place regulating GMOs[5]. Besides tracing the international regulation of GMOs, this chapter also seeks to establish what the African Union, or its predecessor, the OAU's position on genetic modification or GMOs is and how helpful such a legal position is to the continent. The chapter will also trace how genetic modification has been dealt with by the SADC sub-region, and the responses of a few selected SADC countries to the issue of GMOs. The next chapter has been devoted to look into the domestic adaptation of the international regime on GMOs by the South African legal system. The Cartagena Protocol and its background will be dealt with first in this chapter.

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[1] J.Glazewski *Environmental Law in South Africa* at 302
[2] See Cartagena Protocol on Biosafety: About the Protocol; www.biodiv.org/biosafety/background.asp
[3] Ibid
[4] "Cartagena Biosafety Protocol Officially Signed at Convention on Biological Diversity" www.biotech-info.net/Cartagena_protocol_signed.html
[5] EU and UK Regulation of GMOs http: www.ncbe.reading.ac.uk/NCBE/GMFOOD/euregs.html

2.2 The Cartagena Protocol

The Protocol was a supplementary agreement to the Convention, and was adopted by the Conference of the Parties. The Protocol seeks to protect biological diversity from the potential risks posed by Living Modified Organisms (LMOs) resulting from modern biotechnology[6]. The purpose of the Protocol is to advance the aims and objectives of the Convention, which can be summarized as to conserve biological diversity through the preservation of the benefits brought about by modern biotechnology, while minimizing its effects on the environment and human health[7]. The Protocol is a manifestation of the international community's concerns about the impact of biotechnology on the environment.

The Cartagena Protocol is a creature of the Convention. Therefore, for one to fully grasp the essence and the thrust of the Protocol, one needs to understand its history, which is inextricably rooted in the Convention itself. An outline of the background or history of the Protocol to which we now turn will serve to illustrate and demonstrate this point.

2.2.1 History of the Protocol

It should be reiterated here that the history of the Cartagena Protocol is to be found in the Convention on Biological Diversity[8]. However the history of the Protocol cannot be complete without mentioning the other international principles, which have hitherto formed the backbone of international environmental law. Such principles include the precautionary approach[9] and Principle 15 of the Rio Declaration. We will now turn to the above-mentioned principles before we look at the Convention on Biological Diversity.

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[6] See note 2 above
[7] Press Release UNEP/106, www.un.org/News/Press doc/2002/unep106.doc.htm
[8] See article 19(3) of the Convention on Biological Diversity, as quoted in Glazewski op cit at 309

2.2.1.1 *The precautionary approach and Principle 15 of the Rio Declaration*

The definitions of the precautionary principle and Principle 15 of the Rio Declaration are almost identical. It would rather sound more accurate to say that the Rio principle is an adaptation of the precautionary principle. The precautionary principle has been described in the following way:

> Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation[10]

Today, the precautionary principle enjoys currency in many developed countries, particularly in the European Union where it originated in the then West German environmental law and policy[11]. The principle has also been included as Principle 15 of the Rio Declaration, which states:

> In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[12]

It can be noted that the Rio principle 15 includes a cost-benefit element[13]. The precautionary approach as adapted in Principle 15 of the Rio Declaration, provides a paradigm shift in that, in the past, while a project would normally go ahead unless there is evidence of serious environmental consequences, the precautionary principle says that it cannot proceed unless it can be shown that it will not cause serious environmental degradation or pollution[14]. Sands points out that the precautionary principle provides guidance in the development and application of environmental law where there is scientific uncertainty[15].

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[9] Glazewski op cit at 19
[10] Birnie and Boyle, *International Law and the Environment*, 1992 at 97
[11] Von Moltke "*Best Practicable Environment Option" Twelfth Report Royal Commission on Environment Pollution,* HMSO, 1998 at 57
[12] K.Buechle; *The Great Promise Of Genetically Modified Organisms: Overcoming Fear, Misconceptions, and the Cartagena Protocol on Biosafety*: http://ijgls.indiana.edu/archive/09/01/buechle.shtml
[13] Glazewski op cit at 19
[14] Sunkin Ong and Wight; *Sourcebook on Environmental Law,* 1998 at 30
[15] Sands; Principles *of International Law* 1995 at 11

There is a line of caution that runs through the veins of the Cartagena Protocol, as evidenced by articles 10 and 11.[16] The foundation of these articles is laid down by Article 1, which clearly states that the objective of the Protocol is meant to be in line with the "precautionary approach contained in Principe 15 of the Rio Declaration on Environment and Development---".[17] This demonstrates the fact that the history of the Protocol cannot be limited to the Convention, but includes the precautionary approach as contained in the Rio Declaration.

2.2.1.2 *The Convention on Biological Diversity*

As has been pointed out earlier on, the Convention is the immediate parent of the Protocol. The Convention itself was finalized in Nairobi in May 1992 and opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro on 5 June 1992.[18] It entered into force on 29 December 1993. Today the Convention is the main international instrument for addressing biodiversity issues.[19]

The Convention provides a comprehensive and holistic approach to the conservation of biological diversity[20]. The overall objective of the Convention is given as:

> ---the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate transfer of relevant technologies, taking into account all the rights over those resources and to technologies, and by appropriate funding.[21]

The objectives set out above are to be achieved in a variety of ways. One of the ways is contained in the Convention's provision for General Measures for Conservation and Sustainable Use, and requires contracting parties to develop national strategies, plans and programmes for the conservation and sustainable use of biological diversity and to

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[16] Articles 10 and 11 of the Cartagena Protocol to the Convention on Biological Diversity
[17] Article 1 of the Protocol gives the objective of the Protocol, and is in line with the precautionary principle as enshrined in Principle 15 of the Rio Declaration
[18] Convention on Biological Diversity Secretariat: *Cartagena Protocol on Biosafety*; www.biodiv.org/biosafety/background.asp
[19] Glazewski op cit at 302
[20] Ibid
[21] See article 1 of the Convention on Biological Diversity

integrate these as far as possible into relevant sectoral programs[22]. The second other way is found in the articles, which provide for in-situ conservation and ex-situ conservation respectively[23]. The third method is given by articles 15 and 16 which emphasizes one of the main thrusts of the Convention, the issue of access to genetic resources by importing countries while providing returns to the exporting countries in the form of transfer of technology, research methodology and other benefits[24]. The regime contained by the above mentioned articles is such that the developed countries (who are usually the importing countries) would plough back into the developing countries (the exporting countries) through returning benefits like transfer of technology, and even some funding necessary to achieve a high degree of biological conservation in the less developed nations of the world. [25]

2.2.1.3 *Biotechnology and Biosafety*

Biosafety is one of the issues addressed by the Convention. This concept 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 great potential for the promotion of human well being, particularly in meeting critical needs for food, agriculture and health care. The biosafety concept is based on the precautionary approach, whereby the lack of full scientific certainty should not be used, as an excuse to postpone action when there is a threat of serious or irreversible damage[26].

In the context of the safety and ethical concerns about the potential risks to biodiversity and human health posed by genetically modified organisms (GMOs), the British Medical Association has sounded the word of caution when handling biotechnology:

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[22] Article 6 of the Convention
[23] Article 2
[24] The benefits are not only financial in nature, but can be in forms like the exchange in scientific and or technical or technical information, or expertise
[25] See Glazewski op cit at 307
[26] Secretariat of the Convention on Biological Diversity; *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*: *Text and Annexes* http://www.unep.ch/biodiversity/Cartagena-protocol-en.pdf

> ---the best strategy for dealing with environmental risks where we are confronted by profound uncertainties, is to act cautiously, and to embark on a systematic programme of research to improve our understanding; an approach known as the precautionary principle. This principle should be applied for the foreseeable future to GM (genetically modified) crop release and the introduction of GM product into the food chain until the health and the environment impact of GMOs (genetically modified organisms) are fully assessed and in the public domain.[27]

Sands points out that the Convention on Biological Diversity is the first international legal instrument outside the EC to suggest that biotechnology was a matter of concern to the international community[28]. The Convention has a particular measure, which provides that each contracting party shall, as far as possible and as appropriate:

> ---establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.[29]

The issue of regulating living modified organisms (LMOs) or genetically modified organisms (GMOs), their use and release, and minimising the risks associated, were too broad and too technical to be fully dealt with within the text of the Convention. The basis for doing all this was left to be determined by a protocol at a future date. The relevant article provides the following:

> The Parties shall 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 the use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity[30].

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[27] British Medical Association "*The impact of Genetic Modification on Agriculture, Food and Health*" 18 May 1999 in Glazewski at 309
[28] Sands op cit at 479
[29] Article 8(g) of the Convention
[30] Article 19(3)

At its second meeting held in November 1995, the Conference of the Parties to the Convention[31] established an open-ended Ad Hoc working Group on Biosafety to develop a draft protocol on biosafety, focusing specifically on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity[32]. The committee held six meetings between July 1996 and February 1999.At its conclusion, the working Group submitted a draft text of the Protocol, as well as outstanding concerns of the Parties, for consideration by the Conference of the Parties at its first ordinary meeting, convened for the purpose of adopting the Protocol[33].

The Conference of the Parties was opened on 22 February 1999, in Cartagena, Colombia. The Conference was not able to finalize its work in the time available. The reason for the failure of the Conference to finalise its work has been given as the deadlock on key issues which proved to be very contentious. Such issues include the design of the Advance Informed Agreement (AIA).[34] As a result, it suspended its first extraordinary meeting and agreed that it should be reconvened as soon as possible and in any event no later than the fifth meeting of the Conference of the Parties.[35] After these 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, Canada, on 29 January 2000 at an extraordinary meeting of the Parties.[36]

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 the environmental protection with respect to a rapidly growing global industry,

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[31] Conference of the Parties serve as meeting of the Parties under the Protocol, see article 18 (2)(a) of the Protocol
[32] See www.biodiv.org/biosafety/background.asp op cit n18
[33] Ibid
[34] Rafe Pomerance; *Genetically Modified Organisms: Colloquium Article, The Biosafety Protocol: The Cartagena and beyond,* New York University, School Of Law, *Environmental Law Journal, 2000 8 N.Y.U Envtl.L.J.614 at 616*
[35] Ibid
[36] Ibid

the biotechnology industry.[37] 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 minimising the possible risks to the environment and to human health.[38] The Protocol will come into force 90 days after 50 countries have submitted their ratification papers. So far nearly two thirds of the signatories are developing countries. South Africa has not yet ratified the Protocol.[39] The last country to ratify the Protocol (at the time of writing) is Slovenia on the 20th of November 2002; just a month after Mozambique had also ratified the Protocol.[40] We now turn to the body of the Protocol and its provisions.

2.2.2 Structure of the Protocol and what it regulates

The Protocol is made up of at least forty articles[41]. It will not be possible to deal with every article in the Protocol. This section will therefore focus on the main provisions of the Protocol, which clearly bring out its main thrust and purpose. When looking at the main provisions, the section will also consider the institutions created, or tools employed by the Protocol to aid the realization of its objectives. The main elements to be looked into include such provisions which deal with what the protocol specifically covers, information sharing, documentation, capacity building, public awareness, risk assessments, how the issue of the relationship between the protocol and trade (WTO) is dealt with, the tools and institutions created by the protocol like the Advance Informed Agreement (AIA), a Biosafety Clearing House (BCH), and National Focal Points and competent National Authorities. It should be stated that the above is discussed with special attention being drawn to the situation of developing countries and those without regulatory systems.

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[37] It is the author's view that the respective needs of trade and the environment have not been fully reconciled by the agreement at Cartagena. The 'agreement' was and still remains an uneasy settlement or rather compromise. Seeds for future commercial conflicts were sown at Cartagena and Montreal. There is still misunderstanding between the USA, a leading nation in the trade in GMOs, and the European nations who are bent on restricting trade in GMOs and even GMO products. See the article by Pomerance op cit n34.

[38] See note 26 above

[39] Secretariat of the Convention on Biological Diversity; *Signing List: The Cartagena Protocol on Biosafety to the Convention on Biological Diversity* http://www.biodiv.org/biosafety/signinglist.asp

[40] Ibid

[41] The articles are supported by three detailed annexes

2.2.2.1 *What the Protocol specifically covers*

The Protocol addresses the safe transboundary movement, transfer, handling and use of living modified organisms (LMOs)[42] that may have an adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health[43]. However, LMOs that are pharmaceuticals for humans are excluded from the scope of the Protocol if another international agreement or arrangement covers them[44].

While the Protocol regulates LMOs, it treats LMOs differently, that is, depending on their intended use.[45] The different treatment depends on whether the LMOs are destined for introduction into the environment (for example as seed to be used for planting crops), or whether they are meant for direct use as food, animal feed or for processing[46]. It is convenient at this stage to consider these two groups of LMOs in their different categories as they are treated by the Protocol.

(a) LMOs intended for introduction into the environment

The LMOs, which are destined for introduction into the environment, are treated more strictly than the ones intended for direct use as food, feeds or for processing. This treatment makes more sense because the Protocol arose from the Convention (the CBD), and seeds to be planted present the greatest potential danger to the environment[47]. It is the elimination of such danger, which forms the objective of this Protocol.[48] These LMOs are subject to Advance Informed Agreement (AIA)[49], which is a type of prior informed consent under the CBD[50]. Articles 7 through 10 and 12 of the Protocol discuss the AIA procedure.

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[42] The Protocol employs the term Living Modified Organisms (LMOs) instead of the more popular GMOs
[43] Paul E. Hagen and John Barlow Weiner: Symposium Article; *The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms, Georgetown International Law Review, 2000 2 Geo.Int'l Envtl.Lrev 697* at 702. Also see Cartagena Protocol-a summary adapted from www.iisd.ca/linkage/biodiv/cbdintro.html
[44] See article 5 of the Protocol
[45] Buechle op cit n 12.
[46] Ibid.
[47] Ibid.
[48] See article 1 of the Protocol.
[49] Article 7.
[50] See article 19(4) of the Convention.

Article 7 gives a basic overview of the process that a party to the protocol must follow when importing, for the first time, a particular LMO "for intentional introduction into the environment"[51]. A mechanism is provided for exempting certain LMOs from this standard AIA procedure, if the parties agree that they are safe[52]. Article 8 requires an exporting party to notify the country that is to receive the LMO, including at least the information called for by annex 1 of the Protocol[53]. Article 9 requires the importer, within ninety days of receiving notification, to acknowledge the exporting party's notification. Article 10 then explains the guidelines an importer must follow in deciding whether to accept an LMO. These guidelines require the potential importer to give its answer not just to the exporter, but also to the Biosafety Clearing-House (BCH). Article 20 outlines the functions of the BCH[54]. Article 10 also allows for use of the precautionary decision-making, in line with the objective of the Protocol, to treat the dealings with LMOs with caution, for safety purposes.[55] The Protocol, through article 12 provides more clarification on the decision procedure including reference to risk assessment and risk management[56].

(b) *LMOs intended for direct use as food, feed or for processing*

LMOs marked for direct use as food, feed or for processing are subject to AIA, but other rules do apply and are outlined in article 11. It should be pointed out here that these LMOs intended for use in food or feed, or for processing are subject to a less onerous regime than LMOs intended for release into the environment.[57] Rather when a party decides that it will allow the importation of a particular LMO for such a direct use, it must give notice within fifteen days by communicating information in annex 11 to the BCH. Article 11 allows for precautionary decision-making and refers to risk assessment under annex 111. Developing countries are allowed to treat "Article 11 LMOs" under the

[51] Article 7(1).
[52] Article 7(4).
[53] Article 8(1), also see annex 1.
[54] See Buechle op cit at 5.
[55] Ibid.
[56] These are described in articles 15 and 16 respectively. Also see paragraph 2.2.2.4 below on risk assessments.
[57] Hagen and Weiner op cit at 703

more strict AIA procedure[58]. There are also "handling, transport, packaging and identification" rules for these "Article 11 LMOs", outlined in article 18.

2.2.2.2 Information-sharing, technical and scientific co-operation under the clearing-house mechanism

Article 20 of the Protocol establishes a Biosafety clearing-house (BCH) as part of the clearing-house mechanism, which was established by article 18 of the Convention[59]. The purpose of the BCH is to facilitate the exchange of scientific, technical, environmental and legal information on, and the experience with, living modified organisms; and to assist Parties to implement the Protocol.

The basis for this provision in the Protocol is to be found mainly in article 18 of the Convention, but also in other articles of the Convention, namely articles 16 and 17.These provisions (particularly 16&17) relate to the return of benefits to the country from which genetic resources originate.[60] The countries envisaged to benefit most from the return of benefits are "in particular, the least developed and small island developing states among them, and countries with economies in transition---"[61]. This return of benefits, according to article 17 of the Convention, is to be in the form of exchange of information, and this specifically acknowledges the needs of the developing countries[62]. The exchange of information in both the Convention and the Protocol is to include the results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge (which is still limited or even not yet available in developing countries) and indigenous and traditional knowledge[63].

Article 20 (of the Protocol) provides for technical and scientific co-operation between developing and developed countries. This co-operation should ensure that both parties dealing with living modified organisms would share the benefits arising from the trade of

[58] Buechle op cit at 6
[59] See article 20 (1).
[60] See Glazewski op cit at 307.
[61] See article 20 (1)(b).
[62] See note 55 above.
[63] Ibid.

the LMOs or the Genetically Modified Organisms (GMOs), as they are now popularly known. It should be reiterated here that the emphasis of the Protocol is that the technical and scientific co-operation should be done with the view of helping developing countries to improve or develop their national policies and to enhance capacity building[64]. Article 18 of the Convention from which article 20 of the Protocol is derived provides thus:

> Each Contracting Party shall promote technical and scientific co-operation with other Contracting Parties, particular developing countries, in implementing this Convention, *inter alia*, through the development and implementation of national policies. In promoting such co-operation, special attention should be given to the development and strengthening of national capabilities, by means of human resource and institution building.[65]

Therefore in order to realize the objectives of the Protocol, the contracting parties (especially the developed countries) shall take appropriate measures to provide access to and transfer of technologies to countries, which provide genetic resources[66]. Such countries are usually developing countries.

2.2.2.3 *The Advance Informed Procedure (AIA)*

The Protocol prescribes an advance-informed agreement (AIA) that must be followed, prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import[67]. In these cases, the exporter must provide a detailed, written description of the LMO to the importing country in advance of the first shipment[68]. The importer is to acknowledge receipt of this information within 90 days and then explicitly authorize the shipment within 270 days or state its reasons for rejecting it[69]. (However the absence of a response does not imply consent.)[70] The purpose of this procedure is to ensure that the recipient countries have both the opportunity and the capacity to assess risks that may be associated with the LMO before agreeing to its import.

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[64] Secretariat of the Convention On Biological Diversity; *Cartagena Protocol on Biosafety: Frequently Asked Questions about the Cartagena Protocol on Biosafety* www.biodiv.org/biosafety/faqs.asp at 6.
[65] See article 18(2) of the Convention.
[66] See article 16(3) of the Convention.
[67] Article 7(1) of Protocol.
[68] See article 8(1), read with Annex 1.
[69] Article 9(1) of Protocol.
[70] Hagen and Weiner op cit at 704 n43

There are, however, a number of actions involving the movement of LMOs which are excluded from the AIA procedure, including:

- LMOs in transit;
- LMOs destined for contained use;
- LMOs intended for direct use as food or feed or for processing.[71]

The Conference of the Parties to the Protocol may also in future decide to exempt additional LMOs from the AIA procedure. However, while these categories of LMOs are excluded from the Protocol's specific AIA procedure, this does not imply that countries may not regulate their import[72].

For LMOs intended for direct use as feed or food or for processing, the Protocol establishes a special procedure which requires countries to exchange information at an early stage, through the Biosafety Clearing House, such as: to give notice of domestic authorizations of LMOs and to make available copies of national laws and regulations concerning these LMOs[73].

When implementing the AIA procedure, a party may also take into account, "consistent with its international obligations", socio-economic considerations relating to the impact of LMOs on the conservation and sustainable use of its biodiversity. This grants parties of import substantial discretion to regulate trade in LMOs, not only for environmental protection purposes, but also to protect domestic social and economic interest.[74]

2.2.2.4 *Risk assessments*

In line with its adherence to the spirit and the purport of the precautionary approach[75] (as enshrined in the Rio principle 15), which is, to minimize risks and potential adverse

[71] See note 59 above.
[72] Ibid.
[73] See article 20 (3)(a).
[74] Hagen and Weiner op cit at 704 n43.
[75] See article 1.

effects of LMOs, the Protocol provides for the carrying out of risk assessments[76]. To this end, governments will decide whether or not to accept imports of LMOs on the basis of risk assessments[77]. These assessments are to be undertaken in a scientific manner based on recognized risk assessment techniques[78]. However, in case of insufficient relevant scientific information and knowledge, a country may decide to apply the precautionary approach and refuse the import of the LMO into its territory[79]. The Protocol also recognizes the right of importing countries to take into account socio-economic considerations such as the value of biological diversity to its indigenous and local communities in reaching a decision on import of GMOs[80].

2.2.2.5 *Capacity building*

Risk assessments, the AIA procedure, and the Biosafety Clearing House will only be effective if governments are fully equipped to use them[81]. The Protocol therefore promotes international co-operation to help developing countries and countries with economies in transition to build the human resources and institutional capacity that they will need to use biotechnology safely and to regulate it effectively.[82]

Member governments are encouraged to assist with scientific and technical training and to promote the transfer of technology, know-how, and financial resources. Because the Protocol is part of the Convention on Biological Diversity, biosafety activities will be eligible for support from the Convention's "financial mechanism"[83]. Governments are also expected to facilitate greater private-sector involvement in capacity building[84].

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[76] Articles 15 and 16 of the Protocol. These provide for risk assessments and risk management respectively. But for the purposes of this section both will be treated as meaning risk assessments.
[77] See note 59 above.
[78] Article 15(1).
[79] Ibid note 70 above.
[80] See article 26(1) on socio-economic considerations.
[81] Ibid note 59 above.
[82] Ibid.
[83] Ibid.
[84] Ibid.

2.2.2.6 *Public awareness*

While the Protocol concentrates on international action, it recognizes that national measures are vital to making its procedures effective. Member governments therefore commit themselves to promoting public awareness,[85] ensuring public access to information, and consulting the public in decisions about Biosafety[86]. They must also take national measures to prevent illegal shipments and accidental releases of LMOs, and they must notify affected or potentially affected states in case an unintentional movement occurs[87].

2.2.2.7 *National Focal Points (NFPs) and Competent National Authorities (CNAs)*

One of the national measures put in place by the Protocol to ensure effectiveness of its procedures is the provision for the NFPs and CNAs[88]. Each Party designates one national focal point to be responsible on its behalf for liaison with the Secretariat of the Protocol. Each Party also designates one or more competent national authorities, which are responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions of both focal points and competent national authority[89].

2.2.2.8 *The relationship between the Protocol and the World Trade Organisation (WTO)*

The commercialization of biotechnology has spawned multi-billion-dollar industries for foodstuffs and pharmaceuticals that continue to grow at a dramatic pace[90]. Under WTO regulations, that is, under the Agreement on the Application of Sanitary and

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[85] Hagen and Weiner op cit n43

[86] This commitment is through one of the following ways, accepting to be bound by the Protocol through signing it, ratifying it, implementing the Protocol or giving effect to it by including it in national policy or law.

[87] Article 17(1) of Protocol.

[88] Article 19 (1).

[89] Ibid.

Phytosanitary Measures (SPS), regulation of trade must be based on "sound scientific knowledge". Under environmental regimes, the precautionary approach is seen as an indispensable component of sustainable development.[91]

Concerns have been raised on the possible conflicts between the Protocol and the WTO[92]. For example, the WTO does not accept socio-economic concerns, such as the risk that exports of genetically modified crops may replace traditional ones and undermine local cultures; however, this forms part of the risk assessment requirement under the Protocol[93]. This has the potential to sow seeds for future trade wars[94]. The other possible ground for confusion is the language used in the pre-amble to the Protocol. For example, the pre-amble reads: "Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements---". This statement is followed by this: "Understanding that the above recital is not intended to subordinate this Protocol to other international agreements"[95]. The two statements are not easy to reconcile from a trade point of view to ecological or environmental point of view.

Nevertheless there is a link between the Protocol and the WTO emanating even from the pre-amble itself. For example, the Pre-amble:

- Recognizes that trade and environment agreements should be mutually supportive;[96]
- Emphasises that the Protocol does not change the rights and obligations under existing agreements; and
- Understands that the Protocol is not subordinate to other international agreements.[97]

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[90] See Cartagena Protocol on Biosafety: Frequently Asked Questions about the Cartagena Protocol on Biosafety op cit at 7.
[91] Ibid.
[92] Jonathan H.Adler; Symposium Article: *The Cartagena Protocol: Biosafe or Bio-sorry? Georgetown International Environmental Law Review 2000 12 Geo.Int'l Envtl. L.Rev 761 at 772*
[93] See article 15.
[94] Ibid note 84 above.
[95] Ibid.
[96] Hagen and Weiner op cit at 706
[97] Ibid at 28.

2.3 *GMOs in the African context*

There are divergent views over GMOs in Africa. Major disagreements exist between international organizations over whether GM foods are right for Africa. Charities like Oxfan and Action Aid oppose the introduction of GM crops into Africa saying that food shortages result not from a lack of food but from the inability of poor countries to buy it[98]. Action says that if GM seeds are supplied to Africa, "farmers will be caught in a vicious circle, increasingly dependent on a small number of giant multi-nationals"[99]. Africa has been caught up in the web of the wide-ranging debate surrounding GMOs. While opponents of the introduction of GMOs into the environment in Africa argue against the monopoly over the economically viable organisms by the small trans-national companies from the North who wish to gain sole ownership of patenting rights over GMOs, some see hope with the coming of GMOs[100]. These proponents of GMOs in Africa like the consortium called African Biotechnology believe the introduction of GM crops will boost crop yields in Africa[101]. However, many African countries cannot readily accept GMOs. The major reason being to a greater extent the fact that most countries on the continent are ill-prepared to deal with or handle GMOs which require complex scientific knowledge and expertise, which most states lack. Those that have finally accepted GMOs did not do so because they acquired new knowledge which they lacked at the time that they resisted offers of GM food. With their populations starving to death as a result of drought, and shrinking economies, some nations had no choice but to accept the USAID offer of GM food despite the risks associated with the use of the maize for food[102].

2.3.1 *The African Union's position on GMOs*

It is not easy to find a well-documented African Union policy on the hot issue of GMOs. However, back in 1998 at a meeting of the Food and Agriculture Organisation of

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[98] BBC November 14 2002, *Famine and the GM debate*, www.thecampaign.org/News/nov02v.htm

[99] Ibid.

[100] Cormac Cullinan: *Assessing the effectiveness of SA's legislation around Genetically Modified Organisms* http://www.globesa.org/gmoslecture.htm

[101] Ibid 89 above

[102] Zimbabwe is a good example of such African states, as shall be highlighted below.

the UN, all African nations, except South Africa, rejected GM crop offers by US-biotech corporations like Monsanto, saying:

> We strongly object that the image of the poor and the hungry from our countries is being used by giant multinational corporations to push a technology that is neither safe, environmentally friendly, nor economically beneficial to us.[103]

Such sentiments were particularly common during the days of the Organisation of African Union (which is now the African Union-AU). Cormac Cullinan even records that the OAU at some stage called upon African countries to adopt legislation based on a draft model law, which promotes the protection and rights of local communities, farmers and breeders.[104] The draft Model law could be entitled "The African Model Legislation to the Recognition and Protection of the Rights of Local Communities".[105] This is based on an approach which emphasizes community rights over biological resources[106] as a means of countering what is perceived as a new attempt to 'enclose the commons' by privatizing rights to indigenous knowledge, seeds and plants[107]. Perhaps this should explain why the majority of Southern African countries have strongly resisted USAID in form of GM maize despite facing acute food shortages due to drought and famine which have rocked the sub-region.

2.3.2 *Southern Africa*

As famine took hold in Southern Africa, many countries were opposed to GM food supplies. Zimbabwe and Mozambique resisted the food supplies. Mozambique was particularly concerned about the supplies to Zimbabwe being transported across their territory in case seeds would accidentally contaminate her territory[108] (Mozambique is more aware of her rights under the Protocol since she has ratified the Protocol). The major concern of these SADC countries in refusing GM food was the fear that the seeds

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[103] See www.worldpress.org/article_model.cfm
[104] See note 91 above
[105] Glazewski op cit at 313.
[106] Part 1 of the Preamble states that the objective of the legislation is "---to recognize, protect and support the inalienable rights of local communities including farming communities over their biological resources and crop varieties, knowledge and technologies". Also see note 98 above.
[107] Ibid.
[108] See note 89 above

might be planted before the governments had carried out any research or formulated policies on the GM issue.[109]

SADC has been without a clear and harmonized policy on GMOs. Due to the ever-increasing debate on GMOs in the region, the sub-regional body has begun the process of putting in place regional policy on GMOs, whose absence has created "problems with regard to the movement of food items"[110]. All this had been set for the October 2002 SADC conference in Luanda, Angola[111]. The Ministerial committee was scheduled to look into GMO issues such as:

- safety concerns
- the impact of GM food on the environment
- ethical issues
- trade with countries who would not accept GMOs and access to seeds by small-scale farmers.

The main objective of the committee meeting was to set up an advisory committee to help determine the potential effects of GM food on the SADC country populations[112]. Hopefully by the beginning of the year 2003, the SADC policy on GMOs will be fully in force, and the advisory committee will be fully functional.

2.3.2.1 *Zambia*

Zambia became the third country in Southern Africa after Zimbabwe and Mozambique to join the opposition to the introduction of GM food into the region. While countries like Zimbabwe were won over by deals between donors, aid agencies and recipients under which GM maize was to be milled before distribution so that seeds could not be planted,

[109] Most countries in Southern Africa have not yet developed clear policies on GM crops as highlighted by Panos Institute in London, which provides an information service specialising in issues for developing countries-see note 89 above.
[110] This was revealed by the Executive Secretary of the Southern Africa Development Community (SADC) in an interview with the BBC, see note 89 above.
[111] See note 89 above.
[112] Ibid.

Zambia remained adamant. The country has since stopped the World Food Program (WFP) from distributing GM maize in a refuge camp[113].

Before making the decision, Zambia sent a scientific team to the US, South Africa, Britain and Belgium to examine the issue of genetically modified crops. Its report led the government to maintain the ban, with President Mwanawasa calling GM food "poison", a remark that attracted stinging attacks from some sections of the South African press and US media. On the other hand, opponents of GMOs have hailed Zambia's stance as a step in the right direction in terms of conservation of biological diversity.

2.3.2.2 *Zimbabwe*

For some months in 2002, Zimbabwe resisted the offers of GM maize to avert famine in the country. She remained adamant for some time that no GM food would be allowed into the country until the country's scientists have ascertained its safety. Due to persistent negotiations by the WFP and USAID, the country finally agreed to allow GM food "on condition that it will be quarantined to allow Zimbabwe's agricultural scientists to closely monitor its shipment, milling and distribution in the country"[114]. Her position during the months leading to acceptance clearly shows lack of a clear policy on GMOs. However Zimbabwe had no much choice on the matter. The need for food aid to feed a starving population forced her to abandon her initial position. It became a matter of necessity, and not necessarily policy. Zimbabwe is not alone in this dilemma. Many African countries are not prepared to handle GMOs, and are yet to put into place laws regulating the issue of GMOs[115].

2.4 *A comment*

The purpose of this chapter was to trace the international and regional regulation of the GMOs. It has been established that the Cartagena Protocol, which is a product of the Convention on Biological Diversity, became the first internationally binding legal instrument that regulates the handling, use and transboundary movement of GMOs,

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[113] Ibid.
[114] The Herald Reporter, "*State accepts GM maize*", Herald September 6 2002, www.herald.co.zw
[115] See note 98 above.

known as LMOs under the Protocol.[116]The Protocol provides a helpful framework from which national governments can operate to fulfill the objective of "an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms"[117]. This objective can only be possible if the poor and developing countries are empowered and capacitated through technical and scientific co-operation with the developed nations who are better experienced to deal with GMOs. The Protocol places more emphasis on the needs of the developing nations and nations with economies in transition[118].

While the Protocol has been hailed as a milestone in dealing with the issue of genetic modification, it has not been without criticisms levelled against it. Since the Protocol is a result of compromises between the negotiating parties, it was impossible that a documented agreement without gaps could be achieved. The manner in which the Protocol handles the issue of its relationship with the WTO has been criticized as leaving a lot to be desired. The relationship between the two has been hailed to be an uncertain one due to "the conflicting statements in the Protocol's preamble and ambiguous language..." which may create significant confusion regarding priority issues.[119] The Protocol has also come under fire for not clearly dealing with the issue of labeling. What seems to create problems is the "may contain" language on the labeling requirements of the Protocol[120]. Considering that the Protocol adopts a precautionary approach in its handling of the GMOs, one would have expected the issue of labeling to have been made mandatory, or to have been dealt with more adequately, if risks to human health and the environment are to be minimised. It may help to regard the provisions of the Protocol as setting minimum standards to which national biosafety legislation should then step in to fill in the gaps that exist in the Protocol[121].

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[116] See note 4 above.
[117] See article 1 of the Protocol.
[118] See article 1 of Protocol.
[119] Buechle op cit at 10
[120] See article 18.2(a), which prescribes that LMOs intended for direct use as food, feed or for processing, should clearly identify that they may contain LMOs.
[121] See www.biotech-info.net/Cartagena_protocol_signed.html

This chapter has also shown that GMOs are not adequately regulated by the African Union as compared to the European Union, which has a clear position on, and a detailed legislation dealing with GMOs[122]. The policy, which exists, is not clearly spelt out and needs to be re-considered. The same would go for SADC's position. It is reported that a new policy on GMOs is underway, since it was deliberated on, during the last SADC conference held in Angola in October 2002[123]. Many countries in the region also lack a clear policy on GMOs, with the exception of South Africa, which has a GMOs Act in place. In their responses to GM food offers, most countries relied more on political tastes and preferences rather than on laid down principles[124].

In the next chapter we will examine the GMO Act 15 /1997 of the Republic of South Africa in the light of the Cartagena Protocol. It should be noted that this particular Act came into force at least two years before the new international law on the safe handling and release of GMOs came into existence-the Cartagena Protocol. The chapter will therefore examine the consistence of the Act with the Protocol. In South Africa, every law which comes into force should be consistent with the national Constitution[125], and the Act should not be seen to be repugnant with the supreme law of the land, otherwise it will be invalid. The Act will be analysed in the light of the general Constitution and the environmental right in particular[126]. The Act will also be tested against the major environmental legislation in South Africa, the NEMA[127] and sections of other environmental laws that have not yet been repealed by the NEMA. The analysis of the Act should naturally lead to recommendations or the way forward.

[122] See EU Environmental Policy Regulation of GMOs: *Food Safety or Trade Barrier*? www.eurunion.org/legislation/gmoweb.htm
[123] See paragraph 2.3.2 above.
[124] Ibid.
[125] Act 108 of 1996.
[126] Section 24 of the Constitution.

Chapter three

South Africa

3.1 The legal regime: Introduction

In the previous chapter, the regulation of GMOs at international level as well as regional level was examined. It has been established that the Cartagena Protocol is the greatest authority in regulating the safe transfer, handling and use of GMOs resulting from modern biotechnology and the fact that GMOs are not effectively regulated under the African Union legal regime. The purpose of this chapter is to examine how South African law handles the same issue of regulating genetically modified organisms, taking into account her international obligations on the matter. It should be pointed out that South Africa does have a Genetically Modified Organisms Act in place. This Act was enacted in 1997, and came into force late 1999, (I December to be precise), after the promulgation of the Regulations to the Act on November 26 1999.[1] It can be noted that this Act came into existence before negotiations on the Cartagena Protocol were completed in Montreal. This implies, obviously, that the South African legislature relied more on the provisions of the Convention when enacting the Act. Therefore the focus of this chapter, within this context, is to give an overview evaluation of the extent to which the GMOs Act reflects the requirements laid down in the Protocol.

Before looking at the Act, this chapter will also briefly examine some pieces of South African legislation, which impact on biodivesity conservation, particularly the regulation of GMOs. The Act will be tested against the environmental law provisions in the constitution like the environmental clause, provisions relating to access to information and a just administrative clause, and the provision relating to locus standi in terms of environmental issues.[2] The Act should pass this test well, otherwise, it will be declared invalid if found to be inconsistent with the constitution.[3] Other laws to be used as a yardstick in assessing the GMOs Act include the NEMA,[4] which is standards-setting

[1] See paragraph 3.2.10 for more information on regulations.
[2] See the discussion of these provisions under the Constitution and environmental protection in 3.1.2 below
[3] See s172 of the Constitution
[4] See paragraph 3.1.3 for the meaning of the acronym NEMA and more detail on the Act.

legislation for environmental management in the country and the Environmental Impact Assessments of 1997, among others. The aim is to examine the Act's consistence with international standards, as well as standards set by leading national environmental laws.

3.1.2 The Constitution and environmental protection

While South Africa has plenty of environmental laws, it has been short of effective environmental laws[5]. The existing body of environmental legislation is weakly enforced, since whatever deterrents or incentives there may be on the books all too often remain unenforced in practice.[6] As for administration of environmental law, development of the law and improvement in the quality of its enforcement is hampered by lack of clear policy direction by the government.[7]

The national Constitution[8] provides for the regulation of the environment in South Africa. The constitutional right to a healthy environment, and the constitutional duty imposed on the state actively to protect the environment will go some way to re-invigorating South African environmental law[9]. All government action and legislation as well as individual conduct that impacts on the environment must now comply with the constitutional right to a healthy environment. The constitution has various provisions, which can pave way for effective protection of the environment. For example, locus standi (or standing) requirements also facilitate litigation by environment interest groups aimed at enforcement of environmental law. Administrative justice rights compel the government to give reasons or to justify its behavior. A right to information in both the state and private hands will alleviate the absence of information that has hitherto frustrated the conduct of environmental litigation. Those concerned with the environment should exploit this new range of possibilities created by the constitution. Public interest litigation could do much to correct the absence of proper enforcement of environmental controls that has hitherto characterized South African environmental law.[10] The constitutional

[5] J.De Waal et al *The Bill Of Rights Handbook* 402
[6] Ibid
[7] Ibid
[8] Act 108 of 1996, see the *Annotated version*
[9] See s24 (a) and (b)
[10] De Waal et al op cit at 403

provisions outlined above will now be examined as they relate to biodiversity conservation in general, and the impact of GMOs on health and the environment in particular.

3.1.2.1 *Section 24, the right to a healthy environment*

Section 24 of the constitution, generally coined as 'the environment right'[11], is of much relevance to the handling of biotechnology in South Africa. The focus of the right, as shall be shown below, is the protection and enhancement of people's health and well being, and that of their surroundings, which is reminiscent of international trends. The section provides:

> Everyone has the right –
>
> (a) to an environment that is not harmful to their health or well-being; and
>
> (b) to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that;
>
> (i) prevent pollution and ecological degradation;
>
> (ii) promote conservation; and
>
> (iii) secure ecologically sustainable development and use of natural resources while promoting justifiable economic and social development[12]

The above right is a right not to be exposed to an environment that is detrimental to a person's health or well being[13]. Involved in this provision is a public interest right, framed as an individual right. The right is seen as falling within the category of so-called third generation rights[14], yet it has both an individual and collective character-which is the nature of the threats to the environment.[15] They (the threats) tend to affect or have the potential to affect large groups of persons. Hence they give rise to collective and individual rights.

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[11] See note 5 above. See also GE.Devenish-*A Commentary on the South African Bill Of rights* at 332. The Learned Professor points out s24 shows a shift from an environmental right to the right to a healthy and balanced environment, which is a comparatively recent progressive development at international level.

[12] See note 3 above

[13] Liebernberg "Environment" in *Fundamental Rights in the Constitution* (eds) Davis, Cheadle and Haysom 256

[14] See De Waal et al op cit at 403

[15] Ibid note 7 above

The term 'environment' in section 24 is a composite and inclusive notion encompassing issues such as "nature or biodiversity conservation", "protection" and "pollution".[16] It is important to note that the right applies to the 'health' and 'wellbeing' of the bearer or bearers of the right. These are wide and general terms. The term 'wellbeing' covers important concerns of environmental law such as the conservation of fauna and flora or the maintenance of bio-diversity. 'Human health' is also a complex and integrated phenomenon which is a synthesis of physical, emotional and spiritual factors-to be interpreted in a way that promotes "the spirit, purport and objects of the Bill Of Rights".[17]

Since the right to a healthy environment is like any other right in the Bill Of Rights, it is justiciable and, in theory, directly enforceable.[18] Therefore, conduct of the state or a private individual or institution violating that right may now be challenged.[19] Section 24 shows a shift from the interim constitution, which could only be enforced against the state and its departments.[20]According to s24, such collective and individual rights, as the environment one, now apply both vertically and horizontally, that is, against the state and its institutions and against "natural or juristic persons if, and to the extent that it is applicable".[21] Enforcement of the environmental clause has, *inter alia*, been enhanced by the liberalisation of the standing requirements in the new constitution.

3.1.2.2 *Locus standi to enforce 'the environment right'*

A major obstacle to the effective protection of environmental integrity and to the development of environmental law has always been the common law requirement of locus standi.[22] At common law, an individual seeking to protect his or her right must prove a direct, and probably a pecuniary interest in proceedings in order to have the necessary standing to proceed. There are a number of non-governmental environmental and human rights organisations in South Africa,[23] which would be willing to initiate

[16] Devenish op cit at 332
[17] See section 39 (2)
[18] *Ibid note 9 above. Also see s24 (a) which contains an individual right.*
[19] De Waal et al op cit at 403
[20] See s29 of the interim constitution Act 200 of 1993
[21] This has been made possible through the insertion of s8 (2) in the 1996 Constitution.
[22] Ibid note 11 above
[23] A good example is BioWatch SA

litigation on environmental issues against, for example, biotechnology industries, which cause environmental damage, and government agencies which fail to comply with their legal obligations to protect the environment. The *locus standi*, which was an obstacle, which stood in the way of such litigation when enforcing the environmental laws, has been considerably widened by the Constitution, and through the case of *Ferreira v Levin NO.*[24] Applicants should have sufficient interest in obtaining a remedy. They now fall into the following categories as listed in s38:

(a) anyone acting in their own interest;

(b) anyone acting on behalf of another person who cannot act in their own name;

(c) anyone acting as a member of, or in the interest of, a group or a class of persons;

(d) anyone acting in the public interest; and

(e) an association acting in the interests of its members.

This implies an extension of standing to act in any instance where the constitutional right to environmental integrity is at stake.[25] Any person may claim relief, this includes an organisation, and group of persons acting in the interests of any other person or class of persons adversely affected by the infringement. The extension of the standing requirements will also mean that environmental interest groups can now act not only on behalf of the present generation, but also on behalf of the posterity.

Professor Devenish is of the opinion that the liberalisation of locus standi could meaningfully facilitate the vital issue of educating the public on the environment.[26] This accords well with the requirements of public participation and awareness in the Cartagena Protocol, discussed above.[27] This is also an effective tool to ensure participatory democracy in the new constitutional and democratic dispensation and transformation in South Africa. Other provisions which can be used in juxtaposition to s24 and which also promote participatory democracy are the provisions, which ensure access to information and just administrative action.

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[24] *Ferreira v Levin* NO 1996 (1) SA 984 (CC)

[25] Bray "The Liberalisation of *Locus standi* in the Interim Constitution: An Environmental Angle" 1994 THRHR 481 AT 487

[26] Devenish et al op cit at 341

3.1.2.3 *Just administrative action and access to information*

The Promotion of Administrative Justice Act [28] has given effect to section 33 of the constitution which guarantees lawful, reasonable and procedurally fair administrative action, and grants a right to everyone affected by administrative action to be given written reasons for that action. Such principles have made a significant contribution towards ensuring that environmental factors are taken into account in the exercise of administrative discretion. Such a right which also forms part of environmental rights in the constitution, require environmental considerations to be given appropriate recognition and respect in administrative procedures, which implies that the *audi* rule should apply before taking decisions affecting or impacting on the environment.[29]

A right, which flows together with the right to have reasons for administrative decisions, is the right of access to information.[30] The right granted in the Constitution is a blanket right of access to all state information. Section 32(1)(b) sets out a right of access to information in private hands where the information is required for the protection of rights. Taken together with the right to provision of reasons in s33 (2), these rights, as given effect to by the Promotion of Access to Information Act 2 of 2000, will alleviate the absence of information relating to state and private actions that has hitherto frustrated the conduct of environmentally based litigation.[31] There are benefits, which accrue from this right, to the cause of environmental protection. For example, there will be enhancement of accountability by the administrative bodies which make decisions affecting the environment, and transparency will be achieved in the whole process through the requirement to afford an affected person the opportunity to be heard, in accordance with the basic rules of natural justice.

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[27] See chapter two section 2.2.2.6
[28] Act 3 of 2000
[29] See *Director, Mineral Development, Gauteng Region v Save the Vaal Environment* 1999 (2) SA 709 (SCA) para 20
[30] Section 32 of the Constitution
[31] De Waal et al op cit at 407

3.1.3 The NEMA[32]

The NEMA (the Act) is a piece of legislation that provides the legal framework for dealing with matters affecting the environment in South Africa.[33]In other words, the Act provides a framework to set in place much needed environmental norms and standards, and it emphasizes public interest in the environment, based on the global ideal of sustainable development.[34] In determining what sustainable development is, the Act refers to biodiversity in providing that "---the disturbance of ecosystems and loss of biological diversity are avoided or where they can not be altogether avoided, are minimised and remedied".[35]

Of particular relevance to the handling of biotechnology, especially in dealings in or with GMOs, is chapter one of the NEMA. As has been noted in chapter two above,[36] a precautionary approach has to be adopted when dealing with genetically modified organisms, since little is still known about the extent of their harm or risks to both human health and on biological diversity. This is particularly important for developing countries like South Africa where the expertise on issues of biotechnology is still limited. Now, the NEMA incorporates this principle into national law by providing that "---a risk-averse and cautious approach is applied, which takes into account the limits of current knowledge about the consequences of decisions and actions".[37] The Act is also people-centered, as it provides that "environmental management (*in South Africa*[38]) must place people and their needs at the forefront of its concern, and serve their physical, psychological, developmental, cultural and social interests equitably".[39] Therefore the GMOs Act has to be analysed in the light of such legal provisions, which require public

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[32] NEMA is the acronym for National Environment Management Act 107 of 1998
[33] Cormac Cullinan "*Assessing the effectiveness of South Africa's legislation around Genetically Modified Organisms*" http://www.globesa.org/gmoslecture.htm
[34] J.Glazewski *Environmental Law in South Africa* at 166
[35] Glazewski op cit at 315. Also see s2 (4)(a) (i)
[36] See chapter two, sections 2.2.1.1 and 2.2.2.4 for the use of the precautionary principle in international law, with specific reference to the Cartagena Protocol
[37] S 2(4) (a) (vii)
[38] The italicized words are the author's own additions or insertions
[39] S 2(2)

interest (which also includes consumer interests) to be the guiding principle in every decision made by the administration which impacts on the environment in South Africa.

3.1.4 Environmental assessment regulations

The September 1997 environmental assessment regulations[40] under the Environmental Conservation Act 73 of 1989 (ECA), which require the carrying out of environmental assessments, have the potential to affect biodiversity, and the handling of biotechnological processes and its products. Glazewski[41] points out that only two of the various activities listed by the regulations are most relevant to biodiversity. These are item 5, which refers to "---the release of any organism in its natural area of distribution that is to be used for biological pest control---". The most relevant item (6) refers to "---the genetic modification of any organism with the purpose of fundamentally changing the inherent characteristics of that organism".

3.1.5 National Forests Act 84 of 1998

The National Forests Act's relevance to this subject hinges on the fact that it touches on the conservation of biological diversity. Its definition of biodiversity includes "---genetic diversity, species diversity and ecosystem diversity".[42] According to the Act the management of forests should be done in a manner, which promotes the conservation of biological diversity, ecosystems and habitats.[43] It is important to note that the management of forests has the potential to be affected by genetic modification, either detrimentally or beneficially.

3.2 The Genetically Modified Organisms Act 15 of 1997

The Act is a result of the South African legislature's attempt to implement the country's international obligations under the Convention on Biological Diversity, of taking up the biosafety aspects of the Convention into national law. South Africa, as a Party to the

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[40] R1182 to R1184 *IN Government Gazette* No.18261 dated 5 September 1997
[41] Glazewski op cit at 315
[42] See s2 (1) (i)
[43] S 3(3)(a)

Convention[44], has the duty to do the above, which is spelt out in article 8.This requires each contracting party to:

> Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health[45]

Therefore South Africa's response to article 8 of the Convention was the passing of the Genetically Modified Organisms Act 15 of 1997(the Act). The Act came into force on 1 December 1999. It is important to note that the Act was drafted and came into existence at least a year before the Cartagena Protocol was adopted,[46] and was adopted before the NEMA[47] (the Act which provides the legal framework for dealing with matters affecting the environment in South Africa) came into existence.

3.2.1 *Scope and application of the Act*

The Act regulates the responsible development, production and use of GMOs, including all activities associated with such, and the establishment of institutions to oversee the above, in a way that ensures reduction of potential risks to the environment.[48] The Act specifically applies to the following three cases:

- the genetic modification of genetically modified organisms
- the development, production, release, use and application of GMOs (including viruses and bacteriophages); and
- the use of gene therapy.[49]

The scope of the Act however, excludes three techniques:

- techniques involving human cloning[50], which is left to be dealt with by the Human Tissues Act 65 of 1983;[51]
- techniques in which recombinant DNA molecules or GMOs are not employed in:

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[44] South Africa ratified the Convention on 2 November 1995. See Glazewski op cit at 299
[45] S8 (g) of the Convention on Biological Diversity. Also see Chapter two paragraph 2.2.1.3
[46] The Cartagena Protocol is the first and most relevant internationally binding legal instrument that regulates the handling, use and transboundary movement of genetically modified organisms. See section 2.1 of Chapter two.
[47] See note 27 above.
[48] See the pre-amble to the GMOs Act 15 of 1997.
[49] S2 (1) (a)- (c).
[50] The term human gene therapy is adopted in the Act, rather than human cloning.

(i) in *in vitro* fertilisation in humans and animals;

(ii) in conjunction, transduction; transformation, or any other natural process; and

(iii) in any polyploidy induction; and

- techniques in which genetically modified organisms as recipient or parental organisms are not employed-

(i) in mutagenesis;

(ii) in the construction and use of somatic hybridoma cells; and

(iii) in cell fusion (including protoplast fusion) of plant cells.[52]

3.2.2 *Institutions created by the Act*

One of the objectives of the Act as set out in the preamble is "to establish a council for genetically modified organisms" to ensure supervision of the activities regulated under the Act. A council is the main, of the institutions established by the Act. The bulk of the legislation is made up of the work of the institutions in ensuring that the objectives of the Act are realized.[53] There are basically three of these administrative institutions under the Act, which are; the Executive council for Genetically Modified Organisms (the Council), the Registrar and a scientific Advisory Committee. Each one of them will be looked into in the subsequent paragraphs.

3.2.3 *Executive Council for Genetically Modified Organisms*

The Council is the main of the three institutions established by the Act to administer activities regulated by the Act. The other institutions cannot function independent of Council. For example, the Minister, although he seemingly wields a lot of power under the Act, can only appoint the Registrar after consultations with the Council[54], and also appoints the Advisory Committee at the recommendations of the Council.[55] The Council and its sister institutions seem to fall under the purview of the competent national authorities as provided for or proposed by the Cartagena Protocol.[56]

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[51] See Glazewski op cit at 316.
[52] S2 (2) (a)- (c)
[53] See sections 3,5,8 and 10 of the Act.
[54] See s8 (1) (a)
[55] S10 (1)
[56] Article 19(1) of the Protocol. Also see Chapter two paragraph 2.2.2.7

The Council shall consist of not more than eight members, six of whom are to be officers from six national government departments, including the Department of Environmental Affairs and Tourism.[57] This gives an unbalanced picture of representation, since only government departments are represented, but the defect is however almost cured by the requirement that the "Council may co-opt other knowledgeable persons to serve on the Council in order to advise the Council whenever the council deems it necessary".[58] The objectives of the Council are given as to:

> ---advise the Minister on all aspects concerning the development, production, use, application and release of genetically modified organisms, and to ensure that all activities with regard to the development, production, use, application and release of genetically modified organisms are performed in accordance with the provisions of this Act. [59]

This provision further entrenches the fact that the Council is the main executive administrative organ of the Act.

The Act sets out in detail the powers and duties of the Council.[60] These duties and powers evolve around the requirement for a permit to any person who applies to use facilities for the development, production, use and application of the GMOs, or to release such organisms into the environment. The application by such a person has to be done through the Registrar.[61] Another requirement imposed by the Council on the applicant include submission to the Council of an assessment of the risk involved, and an assessment of the impact on the environment of such development, production, use, application or release of the organisms (GMOs), as the case may be.[62] The council may authorize the Registrar to issue a permit after consideration of the risk assessment and, where required, the environmental impact assessment.[63]

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[57] S14. Also see Glazewski op cit at 317
[58] S7 (5)
[59] S4
[60] Glazewski op cit at 317. Also see s5
[61] S5 (a).
[62] Ibid
[63] S5 (g)

The applicant may also be required to notify the Council of any change in the type of activities or nature of release which he may be engaged in, and to be subjected to inspection of the facilities and /or activities he may be engaged in.[64]

One interesting provision, which is reminiscent of the Cartagena Protocol, is the provision requiring the Council to notify any other country of any accident, which may have an impact on its environment,[65] as well as to co-operate or enter into agreements with persons or institutions on such conditions as may be agreed to by Council.[66] Apart from the duty discussed above, the Council is also tasked with the duty to "promote co-operation between the Republic and any other country with regard to research, development and technology transfer in the field of genetic modification of organisms".[67] In light of the Protocol, this provision is particularly important for South Africa as a developing country, since it promotes scientific and technological co-operation between developed countries (who are more experienced in dealing with GMOs) and developing countries who still lack the adequate expertise regarding genetic modification, and how to handle its impact on health and the environment.[68]

Other provisions of the Council include the power of the Council to advise the Minister on a variety of aspects concerning GMOs.[69] According to Glazewski this is one of the remaining powers of the Council, implying that the Council might have been stripped of some of its powers under the Act.[70]

It is important to note that the Council's powers and duties under section 5 reflect the spirit and purport of the Cartagena Protocol, that is, of minimizing the risks to the environment through adopting a cautious approach to the treatment of the issue of GMOs. This is done through the requirement for risk assessments and environmental impact

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[64] *Ibid note 55 above. Also see s5 (d).*
[65] S5 (i). Also see article 17.1 and 4 of the Protocol, http: bic.yu.ac.kr/Regulation/cartagena_e.htm
[66] S5 (i)
[67] S5 (k)
[68] See article 20 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity; http://bic.yu.ac.kr/Regulation_e.htm
[69] S 5 (m)
[70] See Glazewski op cit at 318.

assessments where necessary. The interesting thing is that the Act came into existence before the Protocol was adopted, and relied heavily on the Convention, but was still able to catch up the spirit of caution in the Protocol, which can be traced back to Principle 15 of the Rio de Janeiro Conference.[71]

The Council has been hailed as an independent decision-making body that ensures arm's length regulation of GMOs.[72] It takes into account trade and socio-economic issues when making decisions. The Council's independence as a national body is a welcome development, since it wrestled decision-making from the Department of Agriculture which always had an interest in the decisions it used to make concerning the issue of genetics.[73]

3.2.4 *The Registrar*

The Registrar is the single official who is expected to implement the administrative work that is assigned to him under the Act, and within the context of the conditions laid down for him by the Council.[74] In other words the Registrar is "charged with the administration of this Act".[75]The Minister appoints him after consultations with the Council. This makes the Registrar to work under the supervision and guidance of the Council.[76]

Some of the duties or functions of the Registrar include, *inter alia,* issuing permits as prescribed under the Act, furnish an inspector with a certificate of appointment and to ensure that the legal requirements of the Act are complied with when developing, producing or handling GMOs, so as to protect the environment from hazards.[77] The functions of the Registrar therefore involve a strict monitoring of the legal requirements of the Act. The objective is to protect both the environment and the public, although the Act does not clearly bring out the public protection function of the Registrar.

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[71] See Chapter two paragraph 2.2.2.4
[72] See note 63 above.
[73] Glazewski op cit at 318.
[74] S8 (2) (b)
[75] S8 (2) (a)
[76] S8 (1) (a)

3.2.5 *The Advisory Committee*

The scientific Advisory Committee (the Committee) is the third institution established by the Act.[78] The Committee is to consist of not more than ten persons appointed by the Minister, eight of whom are "---knowledgeable persons in those fields of science applicable to the development and release of GMOs---",[79] and two persons from the public sector who have knowledge of ecological matters and genetically modified organisms. The Committee is an advisory body that will base its decisions on scientific data.[80]

The Act gives a good description of the functions of the Committee in section 11. They include advising the Minister, the Council and appropriate parties on various matters concerning GMOs and to carry out related functions.[81] It replaces the South African Committee for Gene Experimentation (SAGENE), which previously carried out this work, although it did not enjoy any statutory status.[82] One important function of the Committee in the context of international environmental law is its duty to "liaise, through the relevant national departments, with international groups or organizations concerned with biosafety".[83] Seen within the context of the Protocol, the Committee would qualify, as the national focal point, whose duty, is to liaise with the Secretariat of the Protocol.[84]

One other function of the Committee is to advise the Minister, Council and other relevant bodies on proposed regulations and written guidelines. To this end, in March 1999, the Department of Agriculture passed a notice of intention to make proposed regulations under the Act and these were promulgated in November 1999.[85]

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[77] S9 (f)
[78] See s10 of the Act
[79] S10 (1) (a)
[80] See note 66 above
[81] See s11 (1) (i) – (iii)
[82] Glazewski op cit at 318
[83] S11 (1) (c)
[84] See paragraph 2.2.2.7 in chapter two above

3.2.6 *Monitoring and enforcement*

The duty of monitoring is done by the Registrar through the instrumentality of the inspectors. The former appoints the latter, with the approval of the Minister.[86] The inspector can only function after he has been authorized to do so through a certificate issued to him by the Registrar.[87] His duty is therefore to ensure that the provisions of the Act are being complied with. In the execution of their duties, inspectors my even go as far as entering any facility or any other place registered in terms of the Act to check if the activities at the place are in compliance with the Act, even without a warrant, as is required by s15 (4). The constitutional validity of this action remains questionable, though. However any person who will be affected by the action of the inspector, the Registrar, Council or the Minister may seek relief through the appeal provision of the Act.[88]

3.2.7 *Risks and liability*

In terms of risks the Act provides that:

> Users shall ensure that appropriate measures are taken to avoid an adverse impact on the environment, which may arise from the use of genetically modified organisms.[89]

The provision somehow echoes the precautionary principle as it is enshrined in both the Convention and the Protocol[90] in requiring that measures be taken before hand to ensure safety of the environment. Of peculiar interest in this provision is the use of the term 'user'. The Act defines a 'user' as "---any natural or legal person or institution responsible for the use of genetically modified organisms and includes an end user or consumer".[91] It is not clear from this definition whether the definition also includes the developers and producers of GMOs. Not enough information is given to the reader to understand the scope of the term 'user' in this provision.

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[85] R 1420 in Government Gazette No. 20643 dated 26 November 1999.
[86] S15 (1)
[87] S15 (2)
[88] See s19 (1)
[89] S17(1)
[90] See article 1 of the Protocol.
[91] S1 (xxviii)

On liability, the same difficult with the term user is encountered. The Act nevertheless provides:

> The liability for damage caused by the use or release of a genetically modified organism shall be borne by the user concerned: Provided that when such an organism was in the possession of an inspector as set out in section 15 (4), the user concerned at the time of such use or release shall not be held liable for any damage and could or should have prevented the damage but failed to take reasonable action to prevent such damage.[92]

Questions can arise as to whether the term 'user' encompasses developers or producers of the GMOs, the extent to which consumers are liable for damage caused through the use of GMOs and the clarity of the language used in section 17 of the Act.[93]

3.2.8 *Confidentiality*

One surprisingly interesting provision of the Act is section 18, on confidentiality. The section is fashioned almost in the manner of article 21 of the Protocol. It is surprising considering the fact that the Act predates the Protocol. The confidentiality provision prohibits release and disclosure of information by an official under the Act or anyone, except in some circumstances. These include:

> (a) in so far as it is necessary for the proper application of the provisions of this Act
> for the purpose of any legal proceedings under this Act
> (b) for the purposes of any legal proceedings under this Act;
> (c) when ordered to do so by any competent court, or
> (c) if he or she is authorised to do so by the Minister.[94]

Like the Protocol[95], the Act clearly points out that certain information shall not be kept confidential, perhaps in any circumstance. This refers, *inter alia,* to information concerning the description of GMOs, identification of the applicant and purpose of application.[96]

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[92] S17 (2).
[93] See the analysis of the Act below.
[94] S18 (1) (a)- (d)
[95] See article 21 of the Protocol.
[96] S18 (2)

One of the instances when the Council keeps information confidential is, when it is in agreement with the applicant that "certain information should be withheld in order to protect the intellectual property rights of the applicant".[97]

This section and its provisions should be examined in the context of the Access to Information clause in the Constitution and the Promotion of Access to Information Act 2 of 2000.[98] The areas in which the Committee keeps confidentiality are given as three, which includes; co-operation and partnership agreements; detailed molecular data and efficacy data during the developmental stage. It is also pointed out that confidentiality is respected during the developmental stage but becomes unclassified when the product is released on to the market.[99]

3.2.9 *Criminal sanctions*

The Act provides for penalties for the following offences:

(i) failure to comply with the legal requirements of the Act[100]

(ii) hindering access to information through refusal to furnish information to the inspector or answer questions put to them by the inspector to the best of their ability[101]

(iii) fraudulent behavior, misrepresentation of facts and obstructing the inspector from performing his legal duties;[102] and

(iv) impersonification.[103]

If anyone is found guilty of any of the above offences, he will be liable for imprisonment of at most two years, if it is a first offence, but for a second or subsequent conviction, a period not exceeding four years is imposed.[104]

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[97] S18 (3).
[98] See the discussion on the right to just administrative action and access to information paragraph 3.1.2.3 above.
[99] Glazewski op cit at 320.
[100] S21 (1) (a)
[101] S21 (1) (c)
[102] S21 (1) (b)
[103] S21 (1) (d)

3.2.10 *Regulations*

Regulations under the Act have already been made and published under the Act.[105] The regulations introduce for the first time reference to protection of human health in the risk assessment of activities, which the Act had consistently omitted in its provisions. Among other things, the regulations impose a permit requirement in that no person may import, export, develop, produce, use and apply GMOs without authorization.[106] The Regulations exempt GMOs referred to in table 3 of an annexure to the Regulations.[107] There is a requirement for public notification of proposed trial release and general release of genetically modified organisms.[108] Other important provisions in the Regulations include those for; risk assessments,[109] registration and maintenance of records,[110] waste management,[111] accidents,[112] offences and penalties,[113] and others. Regulation 3 is one provision which does not sound compatible with the precautionary approach in dealing with the handling of GMOs[114], as the subsection or regulation "appears to negate the precautionary principle---".[115]

3.3 Analysis of the Act

The purpose of this section of the work is not to give a detailed analysis of the whole Act. Such an in depth evaluation is beyond the scope of this work. Rather, this section attempts to provide an overview analysis of the GMOs Act. In other words, the main objective here is to indicate where the Act complies or does not comply with international law, and the other guiding principles within the national legislation. To this end, the Act will be analyzed in the light of a few selected aspects of the Cartagena Protocol, the NEMA and the national Constitution.

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[104] See s21 (2) (a)-(b) and (3)
[105] R 1420 in Government Gazette No. 20643 dated 26 November 1999.
[106] Reg 2(1)
[107] Reg 2(2)
[108] Reg 6
[109] Reg 3(1)
[110] Reg 4
[111] Reg 8
[112] Reg 7
[113] Reg 10
[114] Reg 3 (2)
[115] See Glazewski op cit at 320.

The author will attempt to give a combined approach in the overview analysis. There are questions, which this analysis attempts to answer. Cullinan has captured them well in his article.[116] Some of these questions are:

- Whether the scope of what is being regulated is sufficiently wide enough to encompass all relevant issues. This would include both what organisms and products are being regulated and the activities being regulated.
- Are the users and consumers of GMOs or products made from GMOs in a position to make informed decisions about their use?
- Whether appropriate mechanisms exist that enable the wider public to be involved in decision-making relating to GMOs as well as rights to participate in decision-making relating to GMOs and the effective implementation of the laws. This touches on access to information concerning GMOs as well as rights to participate in the decision-making processes and to monitor compliance.
- Does the law provide adequate remedies in the case of non-compliance through a clear and effective liability regime and monitoring mechanisms?

The effectiveness of the Act is therefore viewed in the manner in which it deals with aspects raised in the above questions. Before considering these aspects, we will consider some of the good aspects of the Act which any reform, which may be proposed, should build on.

The GMOs Act contains some valuable provisions which can be effectively used for the protection of biodiversity in the country. The functions of some of the institutions reflect the spirit and purport of international law requirements. For example one of the functions of the Council is to ensure safety of the environment in the handling of GMOs. This will be done through the permit requirements of the Act and the requirement to submit risk assessment and environmental impact assessments report to the Council through the Registrar, as a pre-requisite for an application for a permit.[117] This is followed up with rigorous checks of the facilities used for developing or producing GMOs[118] (this may also

[116] Cormac Cullinan; *Assessing the effectiveness of South Africa's legislation around Genetically Modified Organisms*, http://www.globesa.org/gmoslecture.htm
[117] See s5 (a).
[118] S5 (g).

include routine checks by the inspectors[119]), and notification requirements in case of accidents.[120] This is in line with the objective of the Protocol, which is bent on minimising risks to the environment.[121]

One other function of the Council, which reflects the provisions of the Cartagena Protocol,[122] is its duty to promote co-operation between South Africa and other countries in the transfer of scientific and technical knowledge in the field of genetic modification. The Council is also required through section 5 of the Act to inform any other country of any accident in SA that may have an impact on that country's environment.[123] Considering that the Act came into force before the Protocol, the legislature should be commended for a good job in capturing international standards into national law. The succeeding paragraphs will now examine the Act in the light of the selected aspects raised in the questions in the second paragraph of this section. This is basically done by way of critique.

3.3.1 *Scope of the Act*

The Act covers genetically modified organisms, which are meant for introduction into the environment.[124] Although GM food is widely consumed in South Africa, and poses risk to human health and the environment, the Act omits this in its scope. On the other hand, the internationally binding legal instrument, which regulates GMOs, the Cartagena Protocol, takes care of the protection of both the environment and human health.[125] It does this by treating the GMOs[126]differently, depending on whether they are destined for introduction into the environment (for example as seed to be used for planting crops), or whether they are meant for direct use as food, animal feed or for processing.[127] For this

[119] S16. Although the constitutional validity of the inspectors in this case may be doubtful, the provision nevertheless shows an attempt by the legislature to ensure adequate protection of the environment.
[120] S5 (h) (i)
[121] See article 1 of the Protocol
[122] See article 20 of the Protocol
[123] S5 (i). Although the author feels that this function should rather be delegated to the Advisory Committee which has the duty to liaise with the outside world, to avoid duplication of duties, this provision reflects the spirit of the Protocol and makes the Act consistent with it on this aspect.
[124] See s2 and the preamble to the Act.
[125] See Cartagena Protocol-a summary adapted from www.iisd.ca/linkage/biodiv/cbbintro.html
[126] The term Living Modified Organisms (LMOs) is used in the Act
[127] See chapter two paragraph 2.2.2.1

reason, the Protocol adopts a precautionary approach towards the treatment of GMOs to minimise, not only the impact on the physical environment, but also harm on the health of consumers of the products of genetic modification.[128] On this aspect the GMOs Act is not wide enough to cover this important point. The way it also omits health concerns in its scope is a matter of great concern, taking into account that the environment is protected chiefly for enjoyment by human-beings (which the Act ironically captures well in its definition of the term "environment").[129] A closer look at the preamble also shows this omission of public health interests.

The omission of health concerns also makes the Act to be inconsistent with both the Constitution[130] and the NEMA.[131] Section 24 of the Constitution, as seen above, provides for protection of human health, and makes it an enforcible justiciable right in the Bill of Rights.[132] The NEMA, in Chapter one, requires environmental management in South Africa to be people-centered by placing "people and their needs at the forefront of its concern".[133] This disregard of such important human needs in such an important piece of legislation is surely regrettable.

3.3.2 *Pre-cautionary approach in the Act?*

A look at international trends will reveal that authorizations in relation to GMOs must be dealt with on the basis of the "precautionary principle".[134] This principle was expressed as Principle 15 of the "Rio principles" of 1992. According to this principle, which has crystallized into an international rule or standard, lack of full scientific knowledge should not prevent an individual, state or institution from taking decision to prevent environmental degradation.[135] The decision to be taken should be in favor of environmental interests, that is, where such uncertainty exists.

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[128] Articles 1and 4 of the Protocol. Also see note 120 above.
[129] S1(x)
[130] See s24 of Act 108 of 1996
[131] Act 107 of 1998
[132] Liebernberg *"Environment" in Fundamental Rights in Constitution* (eds), Davis, Chide and Haysom
[133] S2 (2) of the NEMA.
[134] Cormarc Cullinan op cit at 4 of 6

The Cartagena Protocol re-affirms the precautionary principle and a precautionary or cautious approach is also enshrined in South African legislation in section 2 of NEMA.[136] This issue is particularly important in dealing with the issues presented by GMOs, where the novelty of the technology, and the incredible complexity of the living systems of the earth, mean that it is currently impossible to determine the consequences of the release of GMOs into the environment with any degree of certainty.[137] In trying to deal with the precautionary principle, the GMOs regulations provide:

> Lack of scientific knowledge or consensus on the safe use of genetically modified organisms shall not be interpreted as indicating a particular level of risk, an acceptable risk, or an absence of risk.[138]

This has been held to mean that a lack of scientific knowledge or consensus is likely to be regarded as neutral and should not be taken into account in risk assessment. This is directly contrary to the spirit of the precautionary principle, which is intended to establish a bias in favour of protecting the environment in situations of scientific uncertainty. Therefore, the Act does not reflect the precautionary principle as is required by the Cartagena Protocol and national legislation in form of the NEMA. To this end, it can never be said that the Act fully protects the public against the risks posed by biotechnology, particularly GMOs, since the ultimate goal of the principle includes public health protection.[139]

3.3.3 *Informed decision-making and consumer protection*

Informed decision-making concerning an aspect affecting one's life is dependent upon the availability of necessary information. This touches on the issue of access to information. The NEMA provides that access to information necessary to protect one's interests or rights should be provided according to law.[140] The law referred to here

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[135] Secretariat of the Convention on Biological Diversity (2000).*Cartagena Protocol on Biosafety to the Convetnion:Text and annexes.Montreal:* http://.yu.ac.kr/Regulation/cartagena_e.htm

[136] See paragraph 3.1.3 above, for the explanation of the use of the precautionary principle in the NEMA chapter one.

[137] Cullinan op cit at 4

[138] Reg.3(2)

[139] See article 1 of the Protocol and s2 (2) and (4)(a)(vii) of the NEMA. In these two instruments, the goal of the principle is given as one to protect the physical, psychological, social and spiritual interests of people, which include protection of their health, well being and even integrity.

[140] S2 (4) (k) of the NEMA.

includes the right which is enshrined in the constitution,[141] and the Promotion of Access to Information Act 2 of 2000 which give an individual the right to access information held either by state departments or by private individuals if it will advance protection of rights.[142] It therefore follows logically that if the public will not get information regarding whether the food they consume contain GMOs or not, they will not be in a position to make informed decisions concerning the protection of their health. The Act does not contain anything pertaining to the labeling or possible labeling of food to show whether it contains GMOs or not. The public in other words has no choice when it comes to what it consumes.

The general public in South Africa may not even be aware that some of the food they consume may contain GMOs, since information about GMOs in South Africa is not readily available to the public.[143] The public is therefore not in a position to make informed decisions about whether or not to consume GM products as they do not have to be labeled as such. This runs counter to the NEMA's requirements of access to information and concern for people's health and well being. The Protocol might have not been clear on the same issue, but at least it contains some "may contain" requirements to allow consumers to have a choice in the matter.[144]The Act is therefore deficient in so far as protection of consumers is concerned.

3.3.4 *Public participation*

For purposes of this section, public participation can be defined to entail giving the general populace the opportunity to contribute to the decision making process regarding issues of their governance, which includes decisions affecting the environment they live in. It is clear from the Constitution and the NEMA that public participation in relation to decisions affecting the environment and the health and well-being of people is now one of the cornerstones of our society.[145] However, some of the provisions of the Act do not reflect this. For example, the Act provides for the establishment of an Executive Council

[141] S32.
[142] See paragraph 3.1.2.3 above.
[143] Cullinan op cit at 5. *www.globesa.org/gmoslecture.htm.*
[144] See chapter two where a comment on the "may contain" provisions of the Cartagena Protocol is given.

for Genetically Modified Organisms and for an Advisory Scientific Committee, but there is no provision for public participation in either body. The Council, in its functions, can co-opt other so-called knowledgeable people to advise it, and invites written comments, also from these "knowledgeable persons".[146] All this excludes the rest of members of the general populace in preference of those that already have knowledge. This is an anomaly considering the fact that the Protocol urges parties to allow for public participation and the raising of public awareness. This can only be achieved if members of the public are allowed to take part in the activities or decision-making process of the institutions created by the Act.

Section 18[147] of the Act restricts access to information concerning GMOs and although subsection 2 specifies certain information that must not be kept confidential, in practice the National Department of Agriculture has not been prepared to release most of this information. Lack of information means no checks on the government actions and those of corporations. Also prospective field trials need only be advertised in local newspapers, and consequently the general public is unaware of where field trials are being undertaken in South Africa.[148] All this points to the poor public participation and awareness mechanisms in the Act. These two tools are meant to be effective tools for participatory democracy in the new constitutional and democratic dispensation in South Africa.

3.3.5 *Risk and environmental impact assessments*

With regard to risk assessments, the GMOs Regulations provide that:

> No person shall undertake any activity involving genetic modification unless a suitable and sufficient assessment of the risks created thereby to the environment and human health has been made.[149]

Although the Regulations at least takes into account health concerns, it is unclear whether this covers, for example, the sale of GMO products or even the release of GMOs.

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[145] See *note 138 above.*
[146] See s7 (5)-(6) of the Act.
[147] S18(1)
[148] Cullinan op cit
[149] Reg.3(1)

Apart from that there are no legally binding requirements regarding how risk assessments in relation to the use of GMOs should be conducted.[150] Cullinan points out that, currently, this is done on the basis of voluntary and incomplete guidelines. Another problem or deficiency is that the Regulations impose very short time limits for the regulators to respond which probably means that they have insufficient time to consider any risk assessments that have been done.[151]

The environmental impact assessment (EIA) regime in relation to the GMOs has been criticised for being wholly inadequate.[152] The EIA provided under the ECA, discussed in 3.1.4 above, has a provision, which is currently not enforced because the requirement to undertake an EIA is triggered by the start of the process of genetic modification, (at which stage the nature of the GMO is not even known) rather than, for example, the proposed release or import of a GMO. It is also lamentable that there is no provision for the exchange of information with other countries with regard to the import and export of GMOs and GMO products, such as the "advance informed agreement" (AIA) system set out in the Cartagena Protocol.[153] As a consequence it is not easy, for example, to assess the extent of the risks associated with the exported rice to South Africa, or maize food aid by the USA to Zimbabwe.

3.3.6 *Liability regime*

One provision of the Act, which strikes the reader with concern, is the liability regime established in Section 17. The section provides:

> The liability for damage caused by the use or release of a genetically modified organism shall be borne by the user concerned.

Problems around the meaning of the term "user" have been highlighted in paragraph 3.2.7 above. The Act establishes that user includes end-user.[154] The consequences of this liability regime are that consumers may be held liable for harm caused by GMO products which they consume. This liability regime is also inappropriate to engender appropriate

[150] The GMOs Regulations does not provide for any. See Reg. 3.
[151] See Table 2 under the annexure to the Regulations.
http://www.nda.agric.za/doc/geneticresources/AnnexureGMO.htm
[152] See note 143.
[153] See article by Cullinan, www.globesa.org/gmoslecture

caution in those who develop GMOs for profit. The Act does not provide for liability of those who develop GMOs, and does not come out clear on civil remedies for those affected by , for example, accidental release of the organisms. This is so despite the fact that the Act contains a provision for criminal sanctions. The omission of a proper provision for remedies does not shield people against the risks posed by the handling of GMOs in the country. This is not helpful to the Act's goal of protecting the environment.

3.3.7 *Summary of the chapter*

The GMOs Act's effectiveness has been tested above in the light of the Cartagena Protocol, the national Constitution, the National Environmental Management Act 107 of 1998, among other pieces of applicable legislation. The Act was drafted mainly using the provisions of the Convention on Biological Diversity which required Parties to the Convention to implement measures agreed upon at the Convention in their domestic laws. Although the Act reflects some of the issues in the Protocol, it lacks on some important issues like on public participation requirements, the precautionary principle is not adequately reflected in the Act, a 'bizarre' liability regime is in place, the scope is not wide enough to cover all important issues like the regulation of GM food, public health and or consumer interests are not protected in accordance with the NEMA and the constitution, among other issues. Therefore important aspects of international standards and national standards are not reflected in the Act. This is what the overview analysis has established.

In the next chapter, the result of the analysis of the GMOs Act 15 of 1997 will be considered. The purpose of chapter three has been to test the effectiveness of the Act in light of international standards, the NEMA and the constitution. In most important respects, the Act has been found wanting. Chapter four will therefore come up with proposals and recommendations emanating from the analysis. It will be recommended that amendments be made to the GMOs Act. The proposed amendments will not seek to make a wholesale change of the GMOs law. Rather, the amendments should introduce the important aspects missing from the Act, like public participation in the decision-

[154] S1 (xxviii).

making process relating to GMOs, informed decision-making regarding GM food[155], widening of the scope to cover all important issues pertaining to the regulation of GMOs in South Africa, taking into account risks to human health, besides the physical environment.

[155] Perhaps the amendments should include a possible labeling of GM food or anything which should enable consumers to make a choice as to what kind of food they should consume-whether it contains GMOs or not.

Chapter Four

Conclusions: Summary, recommendations and proposals for South Africa

4.1 Summary

The purpose of this whole work was set out as to give a South African legal analysis to the regulation of genetic modified organisms. The regulation of GMOs is international in its nature. Therefore for one to fully grasp the concept of GMOs regulation in a particular domestic legal system, reference should be made to international and regional trends.[1] For this reason, this work traced the international position on genetic modification.[2] International trends, which were influenced by adoption of such instruments like the CBD and the Cartagena Protocol, in turn set in motion the development of legislation around GMOs in many countries. For example South Africa responded to the Convention by enacting the GMOs Act 15 of 1997,[3] which has been analyzed in the preceding chapter.

Reference has been given in the first chapter to forces which informed the development of legislation around the conservation of biodiversity (GMOs) at international, regional and national levels. Such forces can be best located within the debate surrounding GMOs.[4] In this debate, opponents of GMOs perceived (and some still do) GMOs and biotechnology in general, as a vehicle for disaster to the environment which should not be allowed access into society. They argue that GMOs pose risks to biodiversity and human health, among other factors. They further argue that the risks posed by GMOs can never be fully known because of the scientific uncertainty associated with this biotechnology.[5] Human beings cannot therefore be sacrificed as guinea pigs by consuming GM products, used as direct food or from meat products coming from animals fed with GM feeds.

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[1] The World Development Movement; Briefing on GMOs: *The Battle for International Rules on GMOs: The Biotech Industry vs. The World's poor;* http://www.wwdm.org.uk/cambriefs/GMOs/battle.htm
[2] See section 2.2 in Chapter two above
[3] Glazewski op cit at 303
[4] Overseas Development Institute Briefing Paper; *The Debate On Genetically Modified Organisms: Relevance to the South;* http://www.odi.org.uk/briefing/_99.html
[5] Ibid

Ranging against them are proponents for GMOs who hail the coming of the modern biotechnology as heralding a bright future for the environment and the agricultural sector.[6] Their line of argument is that, on the contrary, GMOs may enhance biodiversity, and boost agricultural production, and therefore easy food shortages experienced by some developing countries that face perennial famine due to incessant drought.[7] It is on this point that they are accussed of hypocrisy by opponents of GMOs, who hold that seeds from genetic modification will be, on the contrary, more expensive than other seeds.[8] To the opponents of GMOs, genetic modification will result in big transnational corporations from the rich North who will obviously press to patent rights to life forms.[9] The proponents fear that in this way, these companies will therefore, with time, control trade and increase prices for the GMO seeds beyond the rich of the poor citizens of the South.[10]

What this global debate around GMOs and biotechnology in general has established is the fact that there are benefits accruing from modern biotechnology which should be preserved for the benefit of society. These benefits are to be seen in the areas of pharmaceuticals where it has a proven record of providing advance medicines to improve health, and in agriculture.[11] At the same time, it was discovered that the biotechnology also poses serious dangers and risks to the conservation of biodiversity and human health.[12] The desire to minimise the risks while preserving the benefits, led the international community to come together in 1992 to adopt the Convention on Biological Diversity. One of its main thrusts was the issue of biosafety, a term which refers to efforts or the need to protect human health and the environment from the possible adverse

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[6] Jennifer A. Thomson *The Genetically Modified Foods Debate In South Africa*; http://www.uct.ac.za/microbiology/gmos.htm
[7] Overseas Development Institute Briefing Paper op cit, see note 4 above
[8] Cormac Cullinan *Assessing the effectiveness of South Africa's Legislation on Genetically Modified Organisms;* www.globesa.org/gmoslecture.htm
[9] Ibid
[10] Ibid
[11] Overseas Development Institute Briefing Paper op cit, see note 4 above
[12] Matthew Feldmann et al *Why so much controversy over genetically modified organisms? Answers to 10 frequently asked questions*; http://www.cimmyt.org/ABC/10-FAQaboutGMOs/htm/10-FAQabout GMOs.htm

effects of modern biotechnology and its products. The concept of biosafety also acknowledges the potential benefits of the biotechnology.[13]

The Convention could not fully deal with the modalities of biosafety, and left this to be handled by the Protocol.[14] The Cartagena Protocol, as it came to be known, was adopted in 2000, in Montreal. The focus of the Protocol was to address the safe transfer, handling and the use of living modified organisms (LMOs) better known as GMOs. To achieve this the Protocol incorporates the precautionary principle and details information and documentation requirements. The spirit of caution should guide the handling, use and transfer of GMOs among states and other institutions. Some other important provisions of the Protocol include information sharing among nations (which entails scientific and technical co-operation between developed and developing countries to improve the lot of the latter in handling GMOs), capacity building and public participation. One of the main focal points of the Protocol is domestic implementation of standards set in such international instruments. Hence the bulk of the provisions stated above have a bias towards measures to strengthen national legislation in dealing with the technical issues presented by GMOs.[15]

It should be pointed out here that one of the thorny issues which the Protocol had to deal with, which also has national implications, is the issue of labeling.[16] European countries preferred the adoption of mandatory labeling requirements in the Protocol, while the USA and her allies felt that the labeling requirements would unnecessarily demonise GMOs. Finally the two camps had to reach a compromise, and settled for the minimum "may contain" requirements, without prejudicing those who wish to adopt stricter measure to protect their domestic environment and their national citizenry's health.[17] The implication of this on international trade is that it has sown seeds for future trade wars

[13] See 2.2.2.3 in Chapter above.
[14] See explanation of this point in 2.2.2.3 above
[15] See paragraph 2.2 above
[16] Kurt Buechle *The Great Global Promise of Genetically Modified Organisms: Overcoming Fear, Misconceptions, and the Cartagena Protocol on Biosafety* in the Indiana Journal Of Global Legal Studies: http://ijgls.Indiana.edu/archive/0901/buechle.shtml
[17] Ibid

between, for example, the USA and the European Union.[18] Developing nations are also caught up in the 'cross fire'. It is beginning to surface now that one of the reasons why Zimbabwe and Zambia resisted food aid, but especially Zambia, was fear of losing European markets of their agricultural products. Europe will not allow any products which it may suspect of having been contaminated by GMOs, including even meat products.[19]

The regulation of GMOs in the African context was also considered. It has been established that while the European Union has a detailed legislation around GMOs in place, the OAU (now the African Union-AU) only has a draft model in place. This draft model legislation seeks to promote the rights of local communities, farmers and breeders. In a world where every region has a clear position on this hot issue of GMOs, it would be better for the AU to improve the African legislation around GMOs. It should show a clearer legal position for African states than what currently exists. The SADC has reconsidered its position on GMOs.[20] It is yet to be seen how far the revised approach can go in guiding the sub region, but nonetheless, SADC should be commended for taking up measures to improve its position on GMOs.

After looking at the international and regional approaches to GMOs regulation, this work turned to the South African legislation. The GMOs Act 15 of 1997 was considered and analysed in the light of the Cartagena Protocol requirements, and the standards set by the national constitution and the NEMA. It has been established that the Act was basically enacted on the basis of the Convention on Biological Diversity, and not on the basis of the Cartagena Protocol which specifically touches on the safe transfer, handling and use of GMOs.[21] When tested against the Protocol, the Act is seen to be deficient on a number of important respects, (although it has some few good aspects noted in paragraph 3.3 above). The scope of the Act has been criticised for not being wide enough to cover all

[18] Lisa Oladotter Sandblom (Monterey Institute of International Studies) *Genetically Modified Organisms* www.commercialdiplomacy.org/ma_projects/ma_sandblom 1.htm

[19] The Zambian Deputy President commented that the one of the reason for his country's refusal to accept Gumwood/maize aid from USAID was fear of losing its European markets for agricultural products, see article by the Zambian Times reporter, *GMOs Harmful?* www.zamnet.zm/newsys/news/viewnews

[20] See paragraph 2.3.2 in chapter 2 above

important aspects which the Act should have covered. The liability regime of the Act has been criticised for being inappropriately drafted and is riddled with unclear, vague and ambiguous language.

The Act also lacks an important provision allowing for public participation in decision-making processes and in procedures for the approval of field trials and commercial releases (see Press release art.). The precautionary principle is not adequately and appropriately adopted by the Act .The regulations to the Act have also been criticised for the following reasons:

- They negate the very purpose of the law by precluding almost any GM seed, food or animal feed from permitting requirements;
- Another problem is that academic or research facilities are exempt from permitting requirements;
- The permit-granting process provides inadequate means to for the public to be involved in decision making processes and directly and directly affects their daily lives (e.g. food security);
- There is no comprehensive risk assessment procedures in place to deal with the uncertainties in genetic engineering, ie in the widespread experimentation and commerce of GM crops;
- The use of the precautionary principle in the regulation is considered a dangerous interpretation, running in direct conflict with international and national definitions that are enshrined in the biosafety protocol and the NEMA; and
- There is no procedure for following environmental assessments for GM crops, for example the evaluation of impacts on food security and livelihood, among other things.[22]

4.2 Conclusion

The Genetically modified Organisms Act 15 of 1997 was drafted on the basis of the Convention on Biological Diversity, and not on the basis of the Cartagena Protocol,

[21] See paragraph 3.3.7 in chapter above

which is the most relevant and intenationally binding legal instrument around GMOs to date. As a result the Act is deficient on important respects of the Protocol. For example the scope of the Act does not cover all important issues, which are great concerns of international law, that is, the regulation of GM food. The Act also fails to reflect the precautionary principle, which is the backbone to biosafety and the conservation of biological diversity. In an attempt to interpret the principle, the Act unfortunately ran contrary to international and national standards enshrined in the Protocol and the NEMA. The Act does not put public health in the forefront of its concerns as required by the NEMA and the spirit of the constitution which is reflected in section 24.

There is more to be concerned with about the Act than to admire. Whatever the Act attempted to do, it sometimes overdid it. For example in trying to strictly monitor the implementation of the Act, section 16 runs in danger of undermining the very values which the constitution sets out to achieve, by allocating excessive powers to the inspectors, which opens it up for abuse.

There is however need to guard against the proverbial danger of throwing the babe out with bath water. The few good aspects of the Act need to be preserved. The good thing about the Act in this regard, therefore, is that it provides a good basis upon which reform to the regulation of GMOs in South Africa can be ushered in. It is for that reason that the succeeding paragraphs will make recommendations and proposals on the Act for South Africa.

4.3 *Recommendations and proposals for South Africa*

It should be noted that the recommendations and proposals to follow are only given on few selected aspects of the Act. They will include every issue which has been critiqued in section 3.3 above.

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[22] Press Release 28 February 2000, *"Stop the Crop!" Citizens' call to revoke SA's Genetic Engineering Law* www.greenparty.org.za/GE/2000228GMOACT.htm

In the light of the analysis given in section 3.3 above (which has also been highlighted in the preceding paragraph, ie, the last paragraph in 4.1), the following recommendations are made on the GMOs Act 15 of 1997 in form of amendments to the Act:

1. The scope of the Act should be widened to include GM food and animal feed. An amendment is hereby proposed to section 2 of the Act to include the classification of GMOs according to their intended use, that is:

   (ii) Those intended for introduction into environment; and

   (iii) those intended to be used directly as food, so as to factor in GM food into the Act taking into account the importance which such food has now acquired.

   The inclusion of GM food should also enable the Act to reflect more adequately the health concerns of South Africans. To this effect a related amendment will be suggested to the preamble;

2. The preamble, in line with proposal 1 above, should include public health protection, as an addition to the protection to "environment". The preamble should also adequately reflect the precautionary principle by, for example clearly stating that it reaffirms the principle. At the moment the interpretation of the principle in the Regulations does not truly reflect its true meaning as used by the Protocol and the NEMA. The interpretation adopted in the regulations seems to suggest that the use of the principle is not mandatory, and therefore reduces its importance, which should actually favor the protection of the environment in cases of scientific uncertainty. However the interpretation in the Regulations negates the very purpose for which the precautionary approach stands for. A complete overhaul of the adoption of the principle in the Act is therefore proposed.

3. The Act should include public participation in the activities of the Executive Council for Genetically Modified Organisms and the Advisory Committee. To this effect, amendments are therefore proposed to section 7. Members of the general public, who are consumers of GM food should be co-opted by the Council to serve on the Council. Members of the public to be also invited to give comments, whether written or oral to the Council, pertaining genetic modification. The Act should provide for such public participation. An amendment is also proposed to the language of section

10 to clearly state that two persons who shall form the Committee shall come from the public, not from the public sector, as is the current position.

4. Public participation should also be extended to include the permit granting process in s5 of the Act.
5. It is hereby proposed that one institution should do the country's obligation under the Protocol to co-operate with other countries for scientific and technical exchange, and for liaison with the Secretariat of the Protocol, not as it is currently where both the Council and the Committee share the work. Another institution should be created to carry out that function. Or if the financial implications of this may not permit for a new institution, then the whole function should be re-assigned to the Committee, to avoid duplication of functions.
6. Labeling of GM food should be made mandatory to give consumers a choice as to whether they should consume GM food/products or not. A provision should be inserted in the Act to regulate mandatory labeling.
7. The government should step up public awareness efforts to enable the general populace to know about the possible risks of GMOs, including benefits. The Act should clearly provide for such public awareness. So many people in South Africa, especially those in the rural areas who do not have access to the press and media, are unaware of GMOs, that is, what they are and what their possible impact on their health or the environment is.
8. Section 16 of the Act should be removed. The constitutional validity of the Act is doubtful since it allows inspectors to enter premises for search without warrant to search for genetically modified organisms in any premises, and to if activities are not in compliance with the Act. This provision is open to abuse, and does not adequately protect some people against arbitrary action by the inspectors.
9. (i) In terms of liability, section 17 needs complete overhaul. The language should be clearer. The provision should state who is liable and under what circumstances is the person liable. The liability of developers of GMOs should be more clearly provided. The word "user" should be avoided because it causes confusion as to who the user is, since the Act gives a far-reaching meaning of the term user. Simpler and clear terms

like "developers", "producers" and "consumers" should be employed by the Act in place of user.

(ii) The Act should provide for remedies to people who are affected, say, by the accidental or negligent release of GMOs by the producers or developers of GMOs. As it stands, the Act seems to provide liability only for the people vaguely referred to as 'users'. This has the potential of making consumers of GM products liable, while letting negligent developers or producers of the GMOs off the hook. A clear provision for civil remedies to people affected by negligent handling of GMOs by developers or producers will help inculcate a sense of caution in them. This is in line with the spirit of the precautionary principle.

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