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**DOMESTIC IMPLEMENTATION OF THE CARTAGENA PROTOCOL IN  
KENYA AND SOUTH AFRICA: A COMPARATIVE ANALYSIS**

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Research dissertation (24,593 words) presented for the approval of Senate in fulfillment of part of the requirements for a Master of Laws in approved courses and a minor dissertation. The other part of the requirements for this qualification was the completion of a programme of courses.

I do hereby declare that I have read and understood the regulations governing submission of a master of laws dissertation, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation conforms to those regulations.

15<sup>th</sup> February 2007

## **DECLARATION**

I Charles Otuke Moitui, do hereby declare that this minor dissertation submitted for the degree of Master of Laws at the University of Cape Town has not been previously submitted by me at this or any other University, that it is my own work and that all referenced material in it have been duly acknowledged.

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Charles Otuke Moitui

**DEDICATION**

To my dear and beloved wife Marcella and our  
beloved children Edgar, Kenn and Brian, with love and hope.

## ACKNOWLEDGEMENTS

Academic pursuit is intriguing as much as it is challenging. Hence, my efforts though desirable, were neither sufficient nor conclusive, in the completion of this study. The external force of the Almighty God made everything possible. He used people who were willing to assist and these are the people to whom I am greatly indebted. It is difficult, if not impossible, to thank each of them individually. May the Almighty God do His will. On my part, by this passage and, in the absence of any intention to the contrary, I publicly convey my sincere appreciation and request that the sentiments expressed here, be treated as equally applying to each of the above people.

However, I need to make a few specific remarks, beginning with the teaching staff. I lack the words, but in a special way, I sincerely thank my Supervisor Prof. Jan Glazweski. He guided me with ingenuity thereby enabling me to finish in time. Special appreciation to: Prof. Gibson, Prof. Bennett and Sandy. I will always miss their lectures; Sandy again, for the encouragement and for his efforts that enabled me to attend a biopiracy seminar at Johannesburg. Last but important, is Debbie Collier. Though I lack the words, I am sincerely grateful for her guidance and useful comments. I thank the entire staff of the law library: Amanda, Dilshaad, Pamela, Zoelfa, Paul, Wesley, Judy, Raymond and Jasmine. They offered me high quality services that reduced, guess what? Stress. Sincere grateful to Hon Justice Joseph Serгон, my bro. Ezra Okemwa and Ken Nyaundi; Gerrald Ouma, in a special way, for the timely guidance and useful comments and Cina Mosito too; Allan Onsando, Ongwae; Nyamwange and Mary as one; Santosh (Durban), classmates especially Temitope and Joy for treating all interruptions as legitimate!

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## ABSTRACT

This comparative study sought to answer the following key research question: to what extent are current and proposed biosafety legislations in Kenya and South Africa consistent with or at variance with key provisions of the Cartagena Protocol on Biosafety (the Protocol)? The specific objectives of the study were: to provide an overview of international and African regional approaches to regulation of modern biotechnology; to establish the extent to which such legislation is consistent with or at variance with key provisions of the Protocol, and to assess whether the above legislations are relevant and workable domestically. The study utilized the comparative study methodology. Analysis was guided by a conceptual framework which captured variance and consistency of the Kenyan Biosafety Bill 2005 on one hand and the Genetically Modified Organisms Act<sup>1</sup> together with the Genetically Modified Organisms Amendment Bill 2005 on the other hand as against the Protocol.

The study noted that whereas Legal regulation of modern biotechnology is a complex and a sensitive issue globally, translating science into the normative language of law is itself a complex process. The intricacies of legal regulation are exacerbated by the competing and quite often, irreconcilable socio-economic, cultural, ethical and political imperatives that affect biosafety legislation. Biosafety legislation in Africa is at its infancy yet attempts to establish and maintain a balance; grapples with the above competing imperatives thereby raising political questions that leave African states (Kenya and South Africa included) caught up in the genetically modified organisms (GMOs) cold war. In essence, modern biotechnology raises and leaves more questions than can be answered.

The findings of this thesis are threefold: the Protocol is itself inadequate; variance significantly outweighs consistency in attempts to comply with the Protocol by Kenya and South Africa, and establishing relevant and workable biosafety legislations in the two countries is problematic and unforeseeable in the near future if not mired in controversy.

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<sup>1</sup> Republic of south Africa, Act 15 of 1997.

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## LIST OF ABBREVIATIONS

AIA	Advance informed agreement
AU	African Union
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
COP / MOP	The Conference of the parties serving as the meeting of the parties to the
DNA	Recombinant deoxyribonucleic acid
EIA	Environmental Impact Assessment
EU	European Union
GE	Genetically engineered or Genetic Engineering as the case may be.
GM	Genetic Modification or Genetically Modified
GMOs	Genetically modified Organisms
GRAS	Generally regarded as safe
LMO-FFPs	LMOs intended for direct use as food or food or for processing
LMOs	Living Modified Organisms
LMOs	Living Modified Organisms
MCM	Marine and Coastal Management. (South Africa)
NBA	National Biosafety Authority. ( Kenya)
NCST	National Council for Science and Technology (Kenya).
NEMA	National Environmental Management Act 107 of 1998
PAIA	Promotion of Access to Information Act 2 of 2000.
PAJA	Promotion of Administrative Justice Act 3 of 2000.
PIC	Prior Informed Consent

## CHAPTER ONE

### INTRODUCTION TO THE STUDY

*'This we know: the earth does not belong to man: Man belongs to the earth...All things are connected like the blood which unites one family...Whatever befalls the earth, befalls the son of the earth. Man does not weave the web of life; he is merely a strand in it. Whatever he does to the web, he does to himself.'*<sup>2</sup>

#### 1.1 Background

##### 1.1.1 Introduction

Legal regulation of Genetically Modified Organisms (GMOs) is a complex and sensitive issue globally. One of the main reasons of the complexity is because translating science into policy and ultimately law is itself, a complex process.<sup>3</sup> Moreover legal regulation of modern biotechnology creates even greater challenges as it grapples with contradictory and invariably competing and often, irreconcilable interests. As Bauer and Gaskell argue, biotechnology inherently operates within and alongside an interplay of economic, legal, religious, mass media and political environment,<sup>4</sup> each of which has vested interests. It is for these reasons that as Kidd authoritatively states, “environmental issues are prominent in people’s minds and they dominate political agendas”<sup>5</sup> worldwide since, as Glazweski observes, “environmental problems know no political boundaries”.<sup>6</sup>

Whereas some fear that without stringent legislation, genetic engineering and GMOs will lead to a fundamental threat to human health and the balance of ecosystems, others see

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<sup>2</sup> Letter from Chief Seattle, Patriarch of the Duwamish and Squamish Indians of Puget Sound, to the President of the United States, Franklin Pierce in 1955 quoted in Environmental pollution control by J.McLoughlin and E.G. Bellinger. - 1993. pg.157.

<sup>3</sup> Mazzoni C,(Ed.) Ethics and Law in Biological Research, 2002, Martinus NIJHOFF Publishers, The Hague / London / New York, Pg 81. Also my personal interview with MrElpidio Peria of Philippines at Johannesburg during a biopiracy hunters training course I attended from 11<sup>th</sup> to 18<sup>th</sup> November 2006 in which he was a delegate. The interviewee represents Philippines in CBD meetings. He confirmed that that even agreeing on definitions of scientific terminologies in such meetings is problematic. As a result many definitions remain in quotation marks. His Contact is with the writer

<sup>4</sup> Bauer M and Gaskell G, Biotechnology: The Making of a Global Controversy, Cambridge University Press, London, 2002, Pg.4

<sup>5</sup> Kidd Michael, Environmental Law in South Africa, , Juta &Co Ltd, 1997.Pg.1.

<sup>6</sup> Glazweski J, Environmental Law in South Africa, 2<sup>nd</sup> Ed.2005, LexisNexis Butherworths, Durban Pg.29.

any limitation as a hindrance to human development and sound science.<sup>7</sup> Although it has been argued that everything depends on what is considered acceptable,<sup>8</sup> attempts to establish and maintain a balance on what is acceptable among the competing interests, creates legal challenges and political paradigms that are difficult to reconcile when promulgating biosafety legislation. Moreover, the rules which make up environmental law are a consequence of the establishment of political aims and goals and the setting of scientific standards which form a framework of the law.<sup>9</sup>

Efforts to balance the above and other interests in the making of biosafety legislation are further complicated and hardly objective for two reasons. Whereas scientists have vested interests in the scientific inventions associated with genetic engineering, they are often at the center of decision making. Other complications arise due to the fact that science does not have all the answers relating to the risks associated with modern biotechnology.<sup>10</sup> This has led to increased skepticism about the role of science in resolving regulatory controversies.<sup>11</sup> Consequently, modern biotechnology raises and leaves more questions than can be answered as is evident from this comparative study of current and proposed biosafety legislation in Kenya and South Africa.

### **1.1.2 Biotechnology**

Biotechnology is not a new phenomenon in human history. It is defined as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.<sup>12</sup> Essentially it implies the use of microbial, animal or plant cells or enzymes to synthesize, breakdown or transform materials.<sup>13</sup> Biotechnology has been practiced for centuries in baking bread,

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<sup>7</sup> Perrez F, 'GMOs and International Law: The Swiss Example', RECEIL 14 (2) 2005, 161.

<sup>8</sup> Bell S and McGillivray D, Environmental Law, Sixth Ed., Oxford University Press, 2006, Pg.14.

<sup>9</sup> Bell S and McGillivray D, supra, Pg. 48.

<sup>10</sup> Kinderlerer J, Regulation of Biotechnology: Needs and Burdens for developing countries, Available at [www.google.com](http://www.google.com)

<sup>11</sup> Sands P, Nelkin D and Stewart R, 'The international Challenge of GMO Regulation'  
8 N.Y.U.Env'tl L.J 524, 1999 – 2000.

<sup>12</sup> Article. 2 of the Convention.

<sup>13</sup> Smith E, Biotechnology, 4<sup>th</sup> Ed., Cambridge, 2004, Pg. 3

beer, wine and compost.<sup>14</sup> These traditional practices of biotechnology do not appear to have caused any serious problems. It is modern biotechnology that is problematic and controversial as indicated below.

### 1.1.3 Modern Biotechnology

Modern biotechnology was the result of the discovery of the structure of Recombinant deoxyribonucleic acid (DNA) by two scientists Watson and Crick in the 1950s.<sup>15</sup> Genetic modification also referred to as 'genetic engineering', (which developed since the 1970s), with the associated recombinant DNA technology is the new powerful tool for biotechnology.<sup>16</sup> Modern biotechnology is defined as application of in vitro nuclei acid techniques, including DNA and direct injection of nucleic acid into cells or organs or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or combination barriers and that are not techniques used in traditional breeding and selection.<sup>17</sup>

Through genetic modification genes are transferred and modified between different species, and between animals and plants and micro-organisms.<sup>18</sup> Smith asserts that in essence, gene technology is the modification of the genetic properties of an organism by the use of recombinant DNA technology.<sup>19</sup> Consequently, genetic engineering has given mankind the ability to create novel plants, animals and micro-organisms with properties they could never have acquired naturally and new organisms can now be created not in accordance with the natural laws of survival but in accordance with human will<sup>20</sup> thereby raising unresolved ethical moral and other issues.

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<sup>14</sup> Mackenzie, Ruth, Burhehenne-Guilmin and Others (Eds) An Explanatory Guide to the Cartagena Protocol on Biosafety, IUCN, Gland, Switzerland and Cambridge, 2003, Pg. 25. (hereinafter Mackenzie and others ,Explanatory Guide)

<sup>15</sup> Mackenzie and others(Eds), supra, Explanatory Guide, supra, Pg. 6.

<sup>16</sup> Walgate R, Miracle or Menace?: Biotechnology for the third world, , Palmos institute 1990, Pg. 3.

<sup>17</sup> Article .3 Protocol.

<sup>18</sup> Mackenzie and others(Eds), supra, (Explanatory Guide) , supra, Par. 28

<sup>19</sup> Smith E, supra, pp. 42.

<sup>20</sup> Smith E, supra, Pg 3.

### 1.1.3.1 Benefits and Potential risks

Genetically Modified Organisms are said to have benefits yet they are potentially harmful to the environment and humans. It is argued that modern biotechnology can be used to slow environmental degradation due to a decrease in the need for pesticides and herbicides; and weeds.<sup>21</sup> The increase in yields may reduce agricultural clearing and thereby reduce habitat loss and damage to biodiversity.<sup>22</sup> It has been observed that these genetically modified (GM) crops engineered to be resistant to insects, disease, parasites, drought and soil depletion, promise similar benefits for developing countries.<sup>23</sup> Such a promise at times turns into disappointment as in the state of Andhra Pradesh in India where Monsanto Bt cotton has failed and approval withdrawn.<sup>24</sup> It is however argued that these apparent benefits are used as an excuse to protect the commercial and trade interests of the GMO promoters, as what is important depends on the value and priority one gives to it.

There are significant potential environmental risks associated with modern biotechnology. A few examples will suffice. A genetically modified crop may transfer modified genes to wild relatives and potentially create a “super weed” or could itself become a weed potentially threatening biodiversity. It is further argued that the spread of GM traits can threaten valuable wild precursors of crop plants and invade neighbouring organic and other non-genetically modified crops.<sup>25</sup> In *Hoffman v Monsanto*,<sup>26</sup> the plaintiffs claimed damages caused to them by the defendants’ genetically modified (GM) canola on the grounds that the ‘adventitious presence’ of GM canola in fields of organic grain farmers, ‘made it impossible’, for farmers to guarantee that canola grown as organic did not contain traces of GM canola seed. Justice Smith dismissed the plaintiff’s suit, for failure to disclose a reasonable cause of action under the common law rules on

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<sup>21</sup> Schneir D , *supra* , at 386

<sup>22</sup> Adler J H, Cartagena Protocol: Biosafety or Bio-sorry?- 12 Georgetown Int’l Env’tl L.J Rev. 2000, 761 at 772.

<sup>23</sup> Meijer E, and Stewart R, ‘The GM Cold War: How Developing Countries Can go from being Deminos to being Players’ REICEL 13(3) 2004, 250.

<sup>24</sup> ‘Whither Biosafety?’, Grain October 2005 Available at [www.grain.org/articles\\_files/biosafety](http://www.grain.org/articles_files/biosafety)  
Last visited on 8<sup>th</sup> Jan. 2007.

<sup>25</sup> Meijer E and Stewart R, *supra*, 250.

<sup>26</sup> (2005) 7 W.W.R 665. Full text available at [www.canlii.org/sk/cas/skqb/2005/2005skqb225.html](http://www.canlii.org/sk/cas/skqb/2005/2005skqb225.html)

negligence in accordance with *Rylands v Fletcher*,<sup>27</sup> strict liability and trespass.<sup>28</sup> Recently farmers in Girona, Spain burnt their organic corn on learning that it contained GMOs.<sup>29</sup>

The potential risks to human health include allergy and, reduction in the expected levels of nutrients, decreased efficacy of antibiotics, speedier development of antibiotic resistant bacteria and greater human exposure to herbicides.<sup>30</sup> The potential risks have made legal regulation of modern biotechnology imperative.

### 1.1.3.2 International Regulation

International regulation of modern biotechnology (discussed in chapter two) mainly began with the adoption of the Convention on Biological Diversity (CBD, see 2.2) in 1992. The Convention has two important provisions that directly relate to this study. It requires that “each party shall... [D]evelop national strategies, plans or programmes for the conservation and sustainable use of biological diversity...”<sup>31</sup> Glowka observes that strategies, plans or programmes are the mechanisms through which a party can “organize and implement” its approach to biodiversity conservation and the sustainable use of its components. He takes the view that the process of developing them is “as important as their implementation” and that “successful implementation may very much depend on the process leading to their development”.<sup>32</sup> In essence efforts at international regulation of modern biotechnology were necessitated by the need to protect biodiversity from the potential harmful effects of GMOs. Second Article 19(3) of the Convention makes provision urging parties to consider the need for a biosafety Protocol (see 2.2) hence the Cartagena Protocol on Biosafety (the Protocol).

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<sup>27</sup> (1868) L.R 1 Ex.265; L.R. 3 H.L 330.

<sup>28</sup> Ibid Pars. 19, 88-95;341.

<sup>29</sup> Sunday Times, South Africa, 9<sup>th</sup> July 2006.

<sup>30</sup> Mackenzie and others (Eds), (Explanatory Guide) Pg. 8

<sup>31</sup> Article 6(a) CBD.

<sup>32</sup> Glowka, L, et al, 1994, A Guide to the Convention on Biological Diversity, IUCN, Gland Cambridge, Pg.29.

Currently global regulation is essentially through the Protocol<sup>33</sup> (see 2.3). Efforts at adoption of the Protocol, in the late twentieth and the beginning of the twenty first century were resisted and delayed and even negotiations stalled.<sup>34</sup> This resulted in the adoption of a compromise treaty in respect to living modified organisms (LMOs)<sup>35</sup> as opposed to genetically modified organisms (GMOs),<sup>36</sup> which embrace both living and dead organisms. In effect, the Protocol is selective and limited in its application to GMOs. This is why the Protocol lacks a holistic approach biosafety regulation.

Inadequate as it maybe, member states are obligated to take necessary and appropriate legal and administrative and other measures to implement their obligations under the Protocol.<sup>37</sup> The Protocol has significant influence over domestic biosafety and it is regarded as a ‘cornerstone’,<sup>38</sup> which attempts to set forth the scientific and legal boundaries for national biosafety regulatory systems and establish a minimum set of rules and procedures.<sup>39</sup> However, in exercise of their sovereign rights, both in international law and under the Protocol<sup>40</sup> states have a right to adopt more stringent biosafety legislation that fits into their own local circumstances if they have the political will to enable them do so.

### **1.1.3.3 The African Regional approach**

The gaps and inadequacies inherent in the Protocol necessitated the African Union to adopt the African model law in 2001 (discussed in chapter two). Although the African Model law is holistic in its approach and provides for more stringent rules, it has no binding force. Its influence and effect in domestic implementation are yet to be realized.

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<sup>33</sup> Signed in Montreal on 29<sup>th</sup> Jan. 2000 and entered into force on the 11<sup>th</sup> Sept. 2003.

<sup>34</sup> Pomerance R, , ‘The Biosafety Protocol: Cartagena and Beyond, 8 N.Y.Envntal L.J 1999-2000 pp. 614-616

<sup>35</sup> Article. 1 Protocol.

<sup>36</sup> See the Preamble to the African Model Law for a definition and Art. 2 for the Scope thereof.

<sup>37</sup> Article .2 Protocol.

<sup>38</sup> Burgei S, The Cartagena Protocol on Biosafety: Taking the steps from Negotiation to Implementation. Reicel 11(1) 2002, pp.53

<sup>39</sup> Jaffe G, ‘Implementing the Cartagena biosafety Protocol through National Biosafety Regulatory Systems: An Analysis of Key Unresolved Issues’ J.Publ.Aff. 5: 2005, Pg. 299.

<sup>40</sup> Article. 2(4) Prptocol.

Biosafety legislation in Africa is problematic and slow and at its infancy. Yong asserts that issues of biosafety were (and probably are) “completely new” for many countries especially among the developing countries.<sup>41</sup> In such circumstances attempts to regulate Biosafety have been resisted and slow; expensive<sup>42</sup> and invariably cumbersome. At the same time such attempts must grapple with the powerful forces (discussed in chapter two) that influenced the provisions of the Protocol Moreover, Africa has become a target of a GM lobby desperate to open new markets and enhance its public relations with the result that the solidarity and good intentions among African governments are under siege.<sup>43</sup>

Walgate identifies two added complications unique to Africa. Technology is in the hands of strong multinational companies (such as Monsanto) supported by their governments ‘whose motives may be suspected’. Two, lax or non-existent regulations controlling biotechnology releases in the third world attract the multinational companies to test products that cannot be tested in the tougher regulatory regimes of their home country.<sup>44</sup>

#### **1.1.3.4 Domestic Implementation**

Member states are under an obligation to comply with their obligations under the Protocol.<sup>45</sup> One such obligation is to develop regulatory frameworks that are consistent with the Protocol.<sup>46</sup> Kenya and South Africa being member states and the leading promoters of GMOs in Africa<sup>47</sup> have every reason to have biosafety laws in place and in the process or as a consequence, attempt to comply with the Protocol.

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<sup>41</sup> Yong P, From Adoption to Implementation of the Cartagena Protocol: A Review of the Progress Made by the ICCP in Preparing for the first meeting of the COP-MOP pp.38 Available at [www.biodiv.org](http://www.biodiv.org)

<sup>42</sup> Kinderlerer J, Regulation of Biotechnology: *Needs and Burdens for developing countries*, supra, Available at [www.unep.ch/biosafety/development/developments/BTregulationpdf](http://www.unep.ch/biosafety/development/developments/BTregulationpdf) last accessed on 15<sup>th</sup> Dec. 2006.

<sup>43</sup> ‘Whither Biosafety?’ An opinion Paper Published by GRAIN, Oct 2005 available at [www.grain.org/atg/](http://www.grain.org/atg/) last visited on 8<sup>th</sup> Jan. 2007.

<sup>44</sup> Walgate R, supra pp. 172

<sup>45</sup> Article. 2(10) Protocol

<sup>46</sup> Article. 9(3) Protocol

<sup>47</sup> Traynor P and Macharia H, ‘An Analysis of the biosafety System for biotechnology in Kenya: An application of a conceptual framework’ ISNAR Country Report 65, The Hague, Netherlands, 2003.(unpublished).

Falkner and Gupta state that the regulatory process of GMOs in South Africa dates back to the late 1980s when there was no biosafety law in place. At that time research and field testing of transgenics was regulated under the 1983 Agricultural pests Act and a South Africa Committee for genetic experimentation (SAGENE) served as the scientific advisory body on environmental releases of GMOs. The first general release of transgenics occurred in 1997. Subsequently the GMO Act was passed in 1997 and became operational in 1999. The GMO is Act administered by the Ministry of Agriculture and it establishes procedures and an institutional structure for regulating transgenics in South Africa. Currently South Africa is the only country in Africa that grows transgenic crops commercially<sup>48</sup>

The first pilot biosafety project in Kenya started in 1997 after approval by the Global Environmental Facility (GEF) Council. In 1998 the National Council of Science and Technology (NCST) produced the first regulations and guidelines which to date govern GMO activities in the country. Kenya was the first country to sign the Protocol in May 2000. Development of biosafety legislation is in part a UNE/GEF project. Absence of a biosafety Act has made it difficult for transgenics to be released for commercial use.

In an attempt to comply with the Protocol in their domestic legislation, Kenya which has no biosafety Act, drafted the Biosafety Bill 2003 which never saw the light of the day. The same has now been replaced by Biosafety Bill 2005 that is yet to be presented to parliament while South Africa has opted to amend the current GMO Act<sup>49</sup> by filling gaps through the GMO Amendment Bill 2005 (pending before parliament). Biosafety legislation in South Africa and Kenya, present test cases of the challenges facing many African countries in attempts to develop biosafety legislation. Whereas the member states are under an obligation to comply with the provisions of the Protocol in their domestic legislation, these attempts cannot in themselves be tenable. It is imperative that such

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<sup>48</sup> Falkner R and Gupta A, 'The Cartagena Protocol on biosafety and Domestic Implementation: Comparing Mexico, China and South Africa', March 2006, ChathamHouse, Available at [www.chathamhouse.org.uk/eedp](http://www.chathamhouse.org.uk/eedp) last accessed on 6th Dec. 2006.

<sup>49</sup> Act 15 of 1997.

biosafety legislation is ultimately holistic, relevant and workable, if it is to serve any meaningful purpose.

## 1.2 Statement of the Problem

The problems and dilemmas arising from genetic engineering are a reflection of a wider<sup>50</sup> socioeconomic and political global struggle. In that struggle, powerful forces, nations<sup>51</sup> and multinational companies,<sup>52</sup> have vested commercial and political interests in GMOs. In Kenya for instance, the US and some European countries have vested interests in the proposed biosafety law and regulations. It has been claimed that they are trying to influence the government to 'either put or remove' some things in the proposed law to accommodate their interests.<sup>53</sup>

Legal regulation of modern biotechnology must therefore contend with several critical concerns (discussed in 1.3 below) in an attempt to establish and maintain a balance between exploiting and safeguarding the benefits accruing from scientific inventions in modern biotechnology on one hand, and the need to protect the environment and humans from the potential harmful effects of genetic engineering on the other hand. Attempts made to reconcile the competing paradigms and strike a balance have not been possible. Currently, only limited compromises have been achieved in international regulation of modern biotechnology by way of adoption and entry into force of the Cartagena Protocol on biosafety (see 2.3.1).

The approach taken by the Protocol hardly serves the interests of the developing countries particularly in Africa. The Protocol is a compromise treaty which lays minimum requirements yet Africa's rich biodiversity (worldwide), needs stringent rules

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<sup>50</sup> The GMO debate relates to several other emotive and conflicting issues including globalization and global trade that fall outside the scope of this study.

<sup>51</sup> Led by the US (which has refused to ratify the CBD) and Canada. The powerful nations push for GM crops and their governments acquiescence. See 'USAID: making the world hungry for GM crops' available at [www.grain.org/seedling](http://www.grain.org/seedling) last visited on the 15<sup>th</sup> Jan. 2007.

<sup>52</sup> Led by Monsanto, Syngenta, Bayer, Dow and Dupont

<sup>53</sup> Arthur O, 'Kenya Intrigues Behind the Biosafety Bill' 5<sup>th</sup> May, 2006 Available at [www.chechbiotech.org/root/index.cfm?fuseaction=new&doc\\_id=12720&start](http://www.chechbiotech.org/root/index.cfm?fuseaction=new&doc_id=12720&start)

that enhance its protection. Moreover African countries are ‘dumping grounds’<sup>54</sup> of products which have been rejected in Europe or which cannot be tested in their home countries that have more stringent biosafety legislations. This explains why developing countries need more stringent biosafety legislations that fit into and serve their local circumstances

Biosafety legislation in Kenya and South Africa presents test cases of the challenges facing many African countries. Apart from the obligation to implement the Protocol,<sup>55</sup> it is imperative, ultimately, that each of the two countries adopts biosafety legislation that is holistic, relevant and workable, if such legislation is to serve any meaningful purpose domestically.

In essence, this study compares existing and proposed domestic biosafety law in Kenya and South Africa with a view to examine how the respective jurisdictions have grappled (and are grappling) to incorporate the complex issues alluded to above in their existing and proposed domestic law and also to consider the extent to which the resultant legislation is relevant and workable. This arguably constitutes the litmus test and provides a basis for future development of biosafety legislation in Africa as a whole. While this is desirable, several biosafety concerns have caused complications. We now examine some of these concerns.

### **1.3 Key Biosafety Concerns**

Modern biotechnology raises several and intricate biosafety concerns. In this section, we examine four main ones: opposing approaches to issues of biosafety, issues of risk assessment, the changing character of biosafety concerns and ethical issues.

First as Magnonile and Zacher observe: the point at issue in relation to environmental protection is ‘how much and how’?<sup>56</sup> The extent and manner in which international

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<sup>54</sup> Adoption of the 1991 Bamako Convention was intended to ban use of the African countries as dumping grounds for hazardous waste from the developing countries.

<sup>55</sup> Article 2 Protocol

<sup>56</sup> M’gonigle and Zacher, *supra* pp.3;

regulation of biosafety should be permissible have divided the international community to two main competing and opposing camps. Sheldon succinctly states the problem as follows:

there are clearly very distinct differences between the US and EU approaches to regulation of GMOs. The US approach is based on a scientific, risk-based assessment of GMOs, and the principles of substantial equivalence and minimal oversight of food products that are GRAS. The logical conclusion of this approach is that there is no general requirement for labeling of GM foods. In contrast, the EU is adhering to the precautionary principle as they revise and develop their regulatory regime. Specifically the EU believes there is uncertainty about the long-run risk assessments of GMOs, the existing results cannot be treated as conclusive.<sup>57</sup>

Although these opposing approaches have significant effect on regulation of modern biotechnology, the paradigms arising thereof have caused a dilemma that developing countries find difficult to reconcile when developing biosafety legislations. Moreover the US presumes GMOs to be safe until proved otherwise and the burden of prove lies with the consumer!<sup>58</sup> Meijer and Stewart assert that the trade and regulatory GMO conflict between the EU and US has exacerbated existing differences with developing countries caught in the cross-fire of the GM cold war. Consequently, they argue, the GMO cold war has placed immense pressure on developing countries thereby undermining their abilities to make independent judgments and choices. They further argue that developing countries must address two key issues. Whether or how GM biotechnologies fits into their particular circumstances; and the extent to which developing countries may bar or restrict imports of GMOs yet be in compliance with international trade law, is a legal question fraught with political significance, they argue.<sup>59</sup>

Second attempts to balance the potential benefits and potential risks create paradigms which make biosafety regulation especially in Africa, slow, problematic and expensive. For instance if a country must justify restrictions on GM imports on the basis of an

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<sup>57</sup> Sheldon Ian, *Regulation of biotechnology: Will we ever 'freely' trade GMOs?* An paper presented at the 77<sup>th</sup> EAAE Seminar / NJF Seminar No. 325, August 17-18, 2001 Helsinki (unpublished)

<sup>58</sup> Juma C, 'Biotechnology in a Globalizing world: The Coevolution of Technology and Social Institutions' *Bioscience* March 2005, Vol. 55 No. 3 Pg. 268.

<sup>59</sup> Meijer E and Stewart R, 'The GM Cold war: How Developing Countries Can Go from Being Dominos to Being Players', *Reicel* 13 (3) 2004, 247 at 252 - 254.

elaborate risk assessment, many developing countries might have to allow the import of GM products because they lack the ability to conduct such an assessment. Conversely, their own potential GM exports to developed countries might be barred by developed countries that are able to conduct such assessments.<sup>60</sup>

Third, the problems associated with biosafety or genetic engineering increase or change with new scientific inventions. The unpredictable nature of the risks and harmful effects of GMOs on the environment and humans is also closely interlinked with new and even existing inventions. A disturbing aspect arising from this scenario is identified by Kinderlerer who asserts that 'science does not have all the answers' relating to the risks associated with modern biotechnology. As a consequence, he argues, there is disagreement at the scientific level about the manner in which an inserted gene is likely to modify characteristics of the organism or its impact on the environment. This results in incomplete, imprecise or inconclusive scientific evaluation of the risks thereby making it difficult to determine with sufficient certainty what the risks actually are.<sup>61</sup> Second, application of the precautionary principle (discussed in chapter two) has not been accepted in some jurisdictions including the United States the leading promoter of GMOs globally.

Last but important, modern biotechnology raises critical ethical issues one of which is whether creating new organisms according to human will as opposed to natural laws of survival<sup>62</sup> is legitimate? Sterckx asserts that both the scientific community and the general public have missed the mark on ethical issues attributable to genetic engineering. He argues that the public have lost the mark due to ignorance and as a consequence, public opinion is influenced by the media in distinguishing existing social concerns on one hand and specific moral concerns on the other hand. He contends that scientists have missed the point due to their failure to see the moral issues in science and their belief that

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<sup>60</sup> Meijer E and Stewart R, 'The GM Cold war: How Developing Countries Can Go from Being Dominos to Being Players', *Reicel* 13 (3) 2004, 247 at 254.

<sup>61</sup> Kinderlerer J, 'Regulation of Biotechnology: *Needs and Burdens for developing countries*' *supra*.

<sup>62</sup> Walgate R, *supra* Pg. 2

moral issues are nothing more than emotional issues, emotive responses and individual preferences.<sup>63</sup>

The concerns and other paradigms attributable to modern biotechnology have therefore placed South Africa and Kenya (and other African countries) in a delicate position when developing biosafety legislations. The multinational companies supported by their governments notably the US, work “behind the scenes”<sup>64</sup> to ensure that their interests are sufficiently protected before any such legislation is passed. Delay is one of their favourite tools. Second, the Protocol (discussed in chapter two) is itself inadequate yet member states are under an obligation to comply with its provisions<sup>65</sup> subject to retention of sovereign rights to adopt more stringent legislation and other requirements.<sup>66</sup>

Attempts to implement the Protocol in South Africa and Kenya are not sufficient. It is imperative that the resultant legislation must be relevant and workable domestically. This is the litmus test, if such legislation is to be credible.

#### **1.4 Rationale for Regulation**

Regulation of modern biotechnology is intended to provide legal biosafety tools and mechanisms to safeguard the environment and humans from potential harm. Hence, the Protocol is concerned with ‘ensuring an adequate level of protection’ in the field of transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.<sup>67</sup>

Tewolde observes that by virtue of their being new to nature, artificial modifications have potential ability to cause harm. As a result, he argues, regulation of their development

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<sup>63</sup> Sterckx S, *Biotechnology, Patents and Morality*, 1997, Ashgate , pp 114 – 115.

<sup>64</sup> Okwemba A “Kenya: Intrigues behind biosafety bill” 5<sup>th</sup> May, 2006 available at [www.chechbiotech.org](http://www.chechbiotech.org)  
Last accessed on 8<sup>th</sup> Jan. 2007

<sup>65</sup> Art. 2 (1) Protocol.

<sup>66</sup> Art.2 (4) Protocol.

<sup>67</sup> Article. 1 Protocol

and use, as well as international trade in them, are absolutely essential.<sup>68</sup> Kinderlerer argues that regulation is a response to the risks and hazards that come with new technologies, products and services and aims to ‘protect’ consumers and citizens from harm. He takes the view that today; technology requires regulation before it is made available to consumers, rather than permitting the market to decide whether it is acceptable.<sup>69</sup>

Other states saw a biosafety framework as a mechanism of enabling them to develop biotechnology in a sound and sustainable manner.<sup>70</sup> It is also tenable to argue that cultural and ethical concerns and the increasing awareness of the risks associated GMOs have impelled public demands for regulation of modern biotechnology. Whether cultural and ethical considerations are catered for by the Protocol or national legislations is another matter altogether.

Due to need for legal regulation of modern biotechnology, member states are under an international and treaty obligation to comply with the provisions of the Protocol, whether the Protocol is inadequate or not. Also considering that Kenya and South Africa are the leading promoters of GMOs in Africa, yet they must grapple with the competing imperatives that underpin biosafety legislation thereby taking different approaches in attempt to comply with the Protocol, an important research question arises. The question is: *to what extent are current (in the case of South Africa) and proposed biosafety legislations in both countries at variance or consistent with the Protocol?*

## 1.5 Objectives of the Study

Having posed the above question, the main goal of this study is to provide a comparative analysis of the biosafety legislation (current and proposed, as the case may be) in South

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<sup>68</sup> Tewolde Berhan, ‘Balancing Biosafety, Trade and Economic Development interests in the Implementation of the Cartagena Protocol, in Cartagena Protocol on Biosafety from Negotiation to Implementation available at [www.biodiv.org](http://www.biodiv.org), pp.33 last accessed on 14<sup>th</sup> Dec.2006.

<sup>69</sup> Kinderlerer J, ‘Risk and the Law’, Embo Reports 5, Suppl 1 566-570 available at [www.embo.org/](http://www.embo.org/) last accessed on 4<sup>th</sup> Dec. 2006

<sup>70</sup> ‘Comparative Analysis of Experiences and Lessons from the UNEP – GEF Biosafety Project’ (UNEP) Nov. 14, 2006 Available at [www.gefweb.org/document/council\\_documents/](http://www.gefweb.org/document/council_documents/) last visited on 8<sup>th</sup> Jan. 2007.

Africa and Kenya in the context of compliance with the Protocol. A comparison is in itself, not sufficient. Whether the resultant legislation is relevant and workable domestically, provides the litmus test of the effectiveness and credibility of such legislation. In order to achieve these goals, the following specific objectives are addressed:-

- (i) To provide an overview of international and African regional approaches to regulation of modern biotechnology
- (ii) To establish the extent to which current and or proposed domestic biosafety legislations, in South Africa and Kenya are consistent with or at variance with the Protocol.
- (iii) To assess whether the resultant legislation passes the litmus test of being relevant and workable domestically, if such legislation is to be credible.

### **1.6 Significance of the Study**

Kenya and South Africa were chosen for this study by reason of being the leading promoters of GMOs in Africa and also for having pending biosafety Bills<sup>71</sup> which provide comparable variables. The findings and recommendations of this study, if acted upon, will contribute towards improvement of the existing and proposed legislations. Second, the study is intended to assist the two countries share each other's experiences and, where appropriate, replicate the credible aspects of either regime. The findings and recommendations may also assist other African countries which are in the process of or have no biosafety legislation to identify measures and mechanisms that are not workable in Kenya, and or South Africa, and thereby assist them to develop biosafety legislations that may be tenable right from the beginning.

### **1.7 Scope and Limitations**

This is a comparative analysis of regulation of modern biotechnology in agriculture, in Kenya and South Africa, in relation to living modified organisms in the context of the

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<sup>71</sup> Kenya has the Biosafety Bill 2005 and South Africa has the Genetically Modified Amendments Bill 2005

Cartagena Protocol. Transboundary movements of GMOs being an issue of global concern, international and African regional approaches to biosafety are examined so as to place regulation of modern biotechnology in its appropriate context.

This study has some limitations though. It examines the biosafety Bill of Kenya 2005 without policies and regulations which regulations can only be made .after the Act is enacted into law. Draft policies and regulations (if any) have not been published. The arguments advanced in relation to the proposed legislations in both countries, may not be relevant in the event that the proposed legislation, if and when enacted, shall be substantially at variance with the present Bills. Second, inordinate delay in enactment of the Bills occasioned by political or other considerations, may lead to a fundamental change in circumstances that may make the findings of this study inconsistent with or at variance with the changed circumstances. It important to note that environmental law is a political discipline<sup>72</sup> and its issues and priorities change rapidly<sup>73</sup>. Last but important, due to limited space, it cannot be claimed that the discussion in this study is exhaustive.

### **1.8 Outline of the Study**

Chapter Two comprises an overview of the international and Regional approaches to legal regulation of modern biotechnology. The Cartagena Protocol is examined in a little more detail as it constitutes the basis of comparison. The African Model law on biosafety is examined briefly as it sets an example of a viable biosafety regime that can be replicated by the member states of the AU that may have political ability and willingness to do so.

Chapter Three comprises a thematic comparative analysis of the current and proposed (as the case may be) biosafety legislation in Kenya and South Africa in the context of compliance with Protocol by way of the Biosafety Bill of Kenya 2005, GMO Act and the GMO Amendment Bill 2005. The specific key features of the Protocol that form the basis of this study are: the objective and the precautionary principle, scope, institutions,

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<sup>72</sup> Bell and McGillivray, *supra*, Pg. 13

<sup>73</sup> Glazweski J, *Environmental law in South Africa*, 2<sup>nd</sup> Ed, Lexis Nexis, Butherworths, Durban 2005 pp.5.

advance informed agreement, public participation, risk assessment and risk management, socio-economic considerations and monitoring. Chapter Four comprises the conclusions and recommendations.

### **1.9 Design and Methodology**

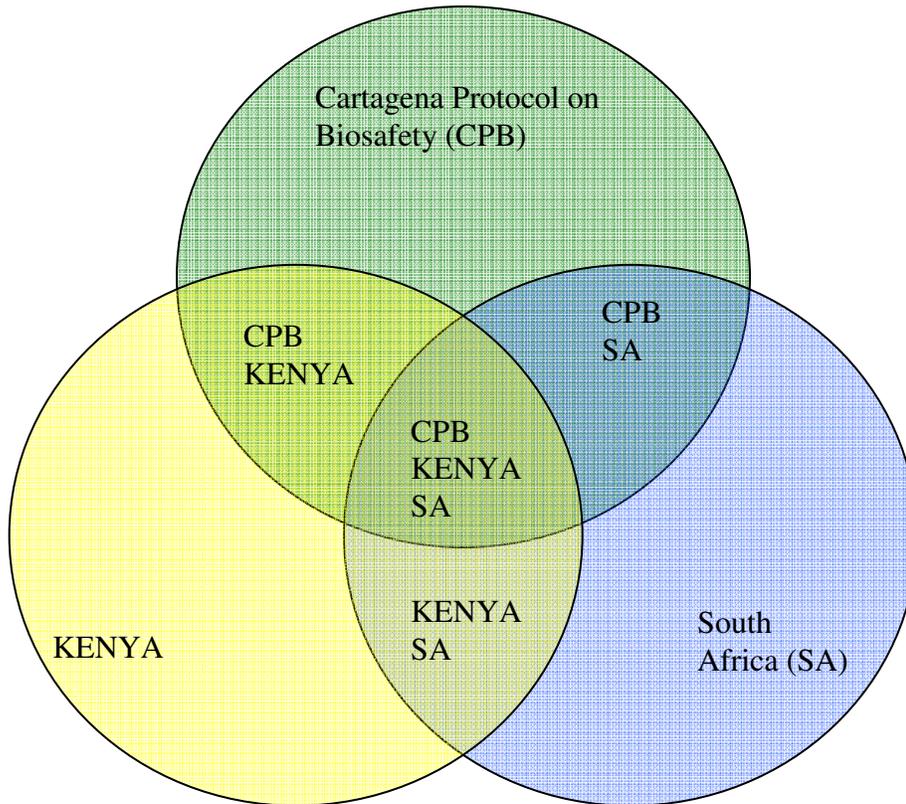
This study is premised on a cross-national comparative study of domestic implementation of the Cartagena Protocol on biosafety in Kenya and South Africa. In order that the overall goal and the specific objectives are achieved, international and the African regional approaches to regulation of modern biotechnology are examined with a view of placing biosafety legislation in its appropriate context. A comparison of domestic implementation of the Protocol in Kenya and South Africa is then addressed. The Biosafety Bill of Kenya 2005 and the Genetically Modified Act<sup>74</sup> together with the Genetically Modified Amendment Bill 2005 provide comparable variables. The conceptual framework illustrated in Figure 1 (page.18) guided this study and it is used as a tool of analysis. Each of the salient features discussed constitutes a theme. In chapter three, the relevant provisions of each theme are examined under the Protocol and under each country followed by a section on a comparative analysis at the end of each theme.

Apart from limited personal oral interviews, this study is desktop based. The primary sources of data include relevant international instruments, applicable (current and proposed) domestic laws and regulations, guidelines and decided cases. Secondary sources include textbooks, journal articles and other relevant materials. Internet resources, newspaper reports and other reports will be used where they provide useful information. The existing laws and intended legislations shall be analyzed and comparisons done with a view of satisfying the objectives of this study. The study uses the strengths of the Protocol as the central point of reference and its weaknesses as part of the challenges to biosafety legislation in the two countries. Decided cases are analyzed where appropriate. A schematic illustration of the conceptual framework of this study follows and after which, international and regional approaches to biosafety are examined in chapter two.

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<sup>74</sup> Republic of South Africa, Act 15 of 1997

Figure 1- A Schematic illustration of the conceptual framework of this study.



Source: Generated by the writer.

The above figure is an illustration of the conceptual frame work of this study. Whereas Kenya intends to comply with the Protocol by drafting the Biosafety Bill 2005, South Africa intends to do so by amending the GMO Act through the GMO Amendment Bill 2005, The intersections “CBP, SA” and “CBP, KENYA” represent anticipated compliance with the Protocol by South Africa and Kenya respectively while the intersections shown as “South Africa (SA)” and “KENYA” represent anticipated variance with the Protocol respectively. The portion shown as “CPB, KENYA, SA” represents compliance with the Protocol by the two countries. The intersection shown as “KENYA, SA” indicates aspects of the two regimes that are consistent with each other (if any) but at variance with the Protocol. Note that at this stage the extents of consistency or variance have not been determined and so the different sizes of the portions and intersections in the above figure are not a representation of the extents of neither consistency nor variance with the Protocol or any other consistency or variance.

## CHAPTER TWO

### INTERNATIONAL AND REGIONAL APPROACHES TO BIOSAFETY

#### 2.1 Introduction

This chapter traces the origins of international regulation of modern biotechnology in the context of the Convention on Biological diversity (CBD) and the Cartagena Protocol (the Protocol). The Protocol is examined in a little more detail as it is the central point of reference in this study. Regional approach is limited to the Africa Model law which is examined briefly towards the end of the chapter.

#### 2.2 Convention on Biological Diversity

Though it is possible to argue that Biosafety has its roots in customary international law, through the principle of harm prevention,<sup>75</sup> international regulation has mainly developed through soft and hard law instruments. The Convention on Biological Diversity was the first international treaty to attempt international regulation of modern biotechnology.<sup>76</sup> Adopted in Nairobi on 22<sup>nd</sup> May 1992 and signed at Rio de Janeiro on 5<sup>th</sup> June 1992, the treaty is significant in the development of an international biosafety regulatory regime in two important ways. By comprehensively addressing biodiversity and recognizing it as a ‘common concern of humankind’ the Convention is a landmark treaty in the environment and development field.<sup>77</sup>

The three main themes<sup>78</sup> of the Convention have been evaluated as: setting out the balance between conservation, sustainable use and sharing of benefits, thereby constituting the ‘the heart of the political agreement’ upon which the Convention is

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<sup>75</sup> Birnie and Boyle, *International Law and the Environment*, 2<sup>nd</sup> Ed. Oxfprd University Press, 2002 Pg. 109.

<sup>76</sup> Sands P, *Principles of International Environmental Law*, 2<sup>nd</sup> Ed. 2003, Cambridge Uni. Press pp. 521.

<sup>77</sup> Glowka L, *A guide to the Convention of Biological Diversity*, IUCN, 1994, pp. 1-3

<sup>78</sup> Article 1 of the CBD sets out the three themes as :the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of genetic resources

founded<sup>79</sup>. Issues concerning sustainable development are particularly critical in biosafety legislation as principle 15 of the Rio declaration puts emphasis on the precautionary approach as one of the key tools of environmental protection. Being a Protocol to the CBD, the Cartagena Protocol is not devoid of the attributes that form part of the legal and political character of the Convention.

Second, the Protocol is only open to member states which are parties to the CBD<sup>80</sup> hence already bound by the provisions of Article 19(3) and (4), articles 8 (g) and 17 of the Convention. These articles arguably constitute an integral basis of the Protocol.<sup>81</sup> Article 19 (3) urges states to consider the need for and modalities of a Protocol setting out appropriate procedures including advance informed agreement(AIA) in relation to LMOs resulting from biotechnology that may cause adverse effect on the conservation and sustainable use of biological diversity. Apart from urging states to adopt a Protocol to specifically deal with safe transfer, handling and use of LMOs, the Convention gives guidance<sup>82</sup> on the issues that ought to be considered by the parties to such a Protocol. The Cartagena Protocol was arguably adopted upon the influence of the provisions of article 19(3) of the Convention on Biological Diversity (the Convention or CBD)

### **2.3 The Cartagena Protocol: An Overview**

The Protocol attempts to set forth the scientific and legal boundaries for national biosafety regulatory systems and establishes a minimum set of rules and procedures.<sup>83</sup> It has also been described as ‘a cornerstone’<sup>84</sup> and a centerpiece of an emerging global architecture designed to govern uptake of genetic engineering in agriculture.<sup>85</sup> These attributes and others make the Protocol an important point of reference in issues of biosafety. Moreover member states are under a binding obligation to implement the

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<sup>79</sup> Glowka L, et al, supra, Pg. 15.

<sup>80</sup> Preamble to the Protocol

<sup>81</sup> Preamble to the Protocol

<sup>82</sup> Glowka et al, supra Pg. 98

<sup>83</sup> Jaffe G, supra, Pg.. 299.

<sup>84</sup> Burgei S, The Cartagena Protocol on Biosafety: Taking the steps from Negotiation to Implementation Reicel 11(1) 2002, pp.53

<sup>85</sup> Falkner R and Gupta A, supra, 2

provisions of the Protocol in their domestic biosafety frameworks.<sup>86</sup> Consequently, any intelligent comparative analysis of biosafety legislation in the two countries under study requires an understanding and balanced assessment of the tools, mechanisms; and the international context within which the Protocol operates<sup>87</sup>.

### 2.3.1 History and Negotiations Prior to Adoption

Although issues of biosafety date back to the 1970s when public concerns grew over the implications of GMOs,<sup>88</sup> Koester<sup>89</sup> argues that the history behind the Protocol and its actual negotiation is rather complicated with a multitude of actors and many different processes involved. He further argues that due to the many processes and the complicated subject matter, it is impossible to outline the history behind the Protocol in ‘a satisfactory manner’.<sup>90</sup> He however identifies five important phases. He terms the period between 1970s and 1980s as problem identification period in which public concerns grew over the implications of GMOs arising from biotechnology; the second phase between late 1980s and early 1990s is regarded as a framework development period. During this period an international framework to address biosafety issues and biosafety guidelines for the release of organisms into the environment developed.<sup>91</sup> The third phase is adoption of the CBD in 1992 which ‘planted the seeds’ of the negotiations on a biosafety Protocol.<sup>92</sup> In particular, article 19(3) of the Convention provides thus:

The parties shall consider the need for and the modalities of a Protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

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<sup>86</sup> Article. 2 Protocol.

<sup>87</sup> Ruth Mackenzie and others(eds.) supra, An Explanatory Guide, Pg.1

<sup>88</sup> Ruth Mackenzie and others (eds) supra, Pg. 6

<sup>89</sup> Koester V, of Denmark chaired the BSWG meetings held between July 1996 and February 1999.

<sup>90</sup> Koester V, ‘The History Behind the Protocol on Biosafety and the history of the Cartagena Protocol Negotiation Process in: *Cartagena Protocol on Biosafety: From Negotiation to Implementation* Available at [www.biodiv.org](http://www.biodiv.org) ( CBD News special Edition) pp. 6 last accessed on the 18<sup>th</sup> Dec. 2006

<sup>91</sup> Koester V, supra pp. 6

<sup>92</sup> Pomerance R, supra, pp. 615.

Although the wording of article 19(3) is persuasive rather than binding, this provision appears to have given impetus to the member states to adopt a biosafety Protocol in respect of modified living organisms.

In November 1995 the second Conference of the Parties (COP 2) to the CBD met at Jakarta (the Jakarta Mandate) with a view of developing a framework for negotiations and to set a timetable and identify the elements to be negotiated.<sup>93</sup> Overall, the Jakarta Mandate established an Open-ended *Ad Hoc* working group on biosafety (BSWG) specifically focusing on the transboundary movements of LMOs. Koester takes the view that this was the second turning point which marked the actual Protocol negotiations.<sup>94</sup>

Three but important phases of the negotiation process followed the Jakarta Mandate. The elements definition phase in which the Ad Hoc Working Group (BSWG) held two meetings in 1996 and 1997; the drafting and negotiation phase spanning from 1997 to 1999 pursuant to which draft articles were drawn and the final negotiation phase 1999-2000.<sup>95</sup> In February 1999 the sixth BSWG meeting of the open-ended *Ad Hoc* was held at Cartagena Columbia with a view of finalizing a text for the Biosafety Protocol to be approved by the first extraordinary meeting of the conference of the parties to the CBD (ExCOP) but this was never to be. According to Mayr, failure by the different negotiating groups, to make concessions in order to reach a consensus led to ‘considerable frustration’ and the ExCOP was suspended.<sup>96</sup> Finally the Cartagena Protocol was adopted in Montreal on the 29 January 2000 and entered into force on 11 September 2003 after its 50<sup>th</sup> ratification. The Protocol has current membership of 134 states.

### **2.3.2 Why Negotiations Stalled**

The negotiations stalled for a number of reasons. Pomerance observes that the wisdom of an international system of advance informed agreements (AIA) for agricultural products was a key issue that emerged at Jakarta which issue continued to hang over the negotiations for the next three years including the meeting at Cartagena. He argues that a

<sup>93</sup> Pomerance R, *supra*, pp. 616.

<sup>94</sup> Koester V, *supra*, Pg. 7.

<sup>95</sup> Mackenzie and others (Eds), *supra*, Pg. 5.

<sup>96</sup> Mayr J, (Cartagena protocol on Biosafety: Negotiation to Implementation) *supra*, Pg.10.

country such as the United States was worried on the trade restrictions imposed by the AIA requirements. The Advanced Informed Agreement (AIA) debate was central to the inability to conclude an agreement at Cartagena as the Miami group would not cede its 'economic interests' to an agreement that was (in its opinion) unworkable. Pomerance further argues that though the USA is not a party to the CBD and hence the Protocol, it had substantial interest in the proceedings because the multilateral Protocol would regulate trade in GMOs a market in which the United States leads the world. Other factors suggested by Pomerance include the fact that no basic issues had been resolved prior to the arrival of delegates in Cartagena; and, the Protocol with potential impacts on trade, agriculture, food safety, science and the environment had to involve more than the representatives of biodiversity and environmental interests and such coordination had not been completely achieved by the time of the Cartagena meeting.<sup>97</sup> It is therefore not surprising that the United States has, to date, not ratified the CBD as doing so is arguably not favourable to its commercial and political interests over GMOs

The expectation that the Cartagena meeting would be the final round of the negotiations proved premature.<sup>98</sup> The negotiating parties had different and opposing views on outstanding core issues.<sup>99</sup> These included the AIA, labeling, and documentation, risk assessment and procedures of management, the treatment of non-parties to the agreement, scope of the Protocol, and the relationship of the Protocol with other International agreements including those under the World Trade Organization

Burgiel identifies five major negotiating groups which emerged at Cartagena. The Miami Group comprising of Argentina, Australia Canada, Chile, Uruguay and USA represented the major actual or potential exporters of LMOs. This group generally supported a protocol limited in scope, based on strictly scientific procedures for risk assessment and as consequence, rejected inclusion of the precautionary principle. The second was the European Union which due to increasing public and political attention on biosafety supported a strong Protocol that embraced the precautionary principle and labeling of

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<sup>97</sup> Pomerance R, supra, Pg. 614-617

<sup>98</sup> Pomerance R, supra, Pg. 616

<sup>99</sup> Mackenzie and others (eds) supra (An Explanatory Guide) Pg. 4

LMOs. The third one was the like minded group which comprised of most developing countries except those in the Miami group. This group argued for an inclusive scope addressing LMO-FFPs, transit, contained use, pharmaceuticals, the precautionary principle, provisions on liability, labeling and socio-economic considerations. The fourth was the compromise group which included Norway, New Zealand Switzerland, Singapore and Mexico. This group generally sought a middle ground. The fifth one was Central and Eastern Europe whose spokespersons were Hungary and Russia. This group generally served as a swing role but frequently supported the final positions taken by the EU and the Compromise Group<sup>100</sup>.

### 2.3.3 Stalled Negotiations: Implications

The stalling of the negotiations has three important implications relevant to this study. It underpins the influence and effect of opposing commercial, political and other interests that member and non-member states strive to safeguard within the areas covered by the Protocol. It also confirms as Tallachini asserts, that translation of science into legislation is ‘a complex process’ which he attributes to many reasons two of which are key. The characteristic effects produced when a scientific proposition is transposed onto the normative language and the dissenting scientific opinions which make it difficult to determine the criteria to be used in evaluating and validating ‘good’ science occasioned by ‘objective’ and ‘subjective’ uncertainties that exist in science.<sup>101</sup> Thirdly, an interplay of the forces, contentious issues and the problems encountered during the negotiations of the Protocol cannot be ignored as they affect domestic implementation of the Protocol not only in South Africa and Kenya but also in many developing countries of Africa.

For instance the United States is a Non-member State yet its participation<sup>102</sup> and influence on the proceedings and the outcome of the negotiations of the Protocol was enormous and cannot be overlooked. Moreover failure of the United States to ratify the

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<sup>100</sup> Burgiel S, *supra*, pp. 55-56.

<sup>101</sup> Tallachini M, ‘*The Epistemic State-The Legal Regulation of Science*’ in *Ethics and Law in Biological Research*, Mazzoni C M *at el*, Martinus Nijhoff Publishers, The Hague / London / New York pp. 81-83.

<sup>102</sup> Redgwell C, ‘*Biotechnology, Biodiversity and International Law*’ In *Current Legal Problems*, 2005 Vol. 18 pp.543 note 47

CBD as a prerequisite of becoming a party to the Protocol while being the greatest global promoter<sup>103</sup> of GMOs arguably hampers and complicates biosafety legislation in the two countries (and other developing countries in Africa).

## **2.4 Salient Features of the Protocol**

The Protocol has tools and mechanisms that essentially determine its content and character. We shall examine the salient features under study with a view of laying a basis to ascertain the extent to which they are reflected in the current and proposed biosafety legislation of the two countries in chapters three of this study.

### **2.4.1 Objective**

The objective of the Protocol is in accordance with the precautionary approach. Article 1 of the Protocol provides thus:

[T]o contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of modified living organisms resulting from modern biotechnology... taking also into account risks to human health, and specifically focusing on transboundary movements<sup>104</sup>

The overall aim of the protocol is to ensure that countries receiving, exporting and using LMOs have the opportunity and capacity to assess possible risks to the environment (taking into account risks to human health) posed by the products of modern biotechnology.<sup>105</sup> The unpredictable nature of the potential risks dictates that precautionary measures are taken so as to avoid or minimize such harm if and when it occurs.

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<sup>103</sup> Eg. Monsanto supported by the government(USA) promotes GMOs in many countries of Africa including South Africa, Kenya and It funds GMO research projects and has invariably influenced domestic legislation.

<sup>104</sup> Article 1. Protocol.

<sup>105</sup> Public Participation and the Cartagena Protocol on Biosafety: A Review for DFID and GEF Part 1: The Main report, January 2003 Available at [www.ids.ac.uk/ids/knots/pdf/NBFreport%20main](http://www.ids.ac.uk/ids/knots/pdf/NBFreport%20main) last Accessed on 24<sup>th</sup> Dec. 2006 pp. 21 (hereinafter: Ids Report, Jan. 2003); Redgwell C, supra, pp. 555.

### 2.4.2 The Precautionary Approach

The precautionary approach is derived from principle 15 Of the Rio Declaration which provides in part that 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”.

Sands argues that although the principle is potentially the most radical and far reaching of the environmental principles, ‘its meaning and effect are unclear and remain mired in controversy.’ He observes that its supporters invoke it to justify pre-emptive international (and national)<sup>106</sup> measures to address potentially catastrophic threats while opponents have decried the principle for allowing overregulation of a range of human activities.<sup>107</sup> Justice Stein argues that while the precautionary principle provides the philosophical authority to take decisions in the face of uncertainty, it will fade as a principle of international law unless given the teeth to enable it to be applied in the reality of a world environment subject to various assaults on all sides.<sup>108</sup> The ‘teeth’ must be provided for in domestic legislation. Whether the proposed biosafety legislations in the two countries do so, is doubtful.

The principle helps to determine whether a risk is sufficiently foreseeable and serious, to require a response though it cannot determine what the response should be.<sup>109</sup> Birnie and Boyle argue that these are policy questions which, in most societies are best answered by politicians and society as a whole rather than by courts or scientists. They observe that in determining whether and how far to apply precautionary measures states are obliged to take into account their own capabilities, economic and social priorities, the cost-

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<sup>106</sup> Birnie and Boyle, *supra*, Pg.117

<sup>107</sup> Sands P, ‘*Environmental Protection in the Twenty-First Century: Sustainable Development and International Law*’ In Revesz R, Sands P, Stewart R, (Eds) *Environmental Law, the Economy and Sustainable development*, Cambridge University Press, 2000 pp. 376  
pp. 375-376

<sup>108</sup> Justice Stein P, A cautious Application of the Precautionary Principle, 2 *Envtl. L. Rev.* 2000 pp. 1-2

<sup>109</sup> Birnie and Boyle, *supra* pp. 120; Sands P, ‘*Environmental Protection in the Twenty-First Century: Sustainable Development and International Law*’ in Revesz R, Sands P, and Stewart R, (Eds) *Environmental Law, The Economy and Sustainable Development*, Cambridge University Press 2000, pp. 375

effectiveness of preventive measures and the nature and degree of the environmental risk in question.<sup>110</sup>

The greatest temptation as Justice Stein observes is that domestic legislation frequently picks up the precautionary principle as an “objective or goal but (possibly deliberately) omits to give it a crucial role in decision making” and relegates it to no more than a guiding principle. He authoritatively asserts that the precautionary principle must be given “specific work to do” and decision makers need to be told “what the role of the principle is and how it should be applied” if the principle is to become operational and inspirational.<sup>111</sup> In the absence of appropriate criteria (as it often happens) the precautionary principle is invariably used to serve political rather than legitimate environmental interests.

### 2.4.3 Scope

Article 4 of the Protocol establishes the general coverage of the Protocol. It provides thus: “the protocol shall apply to the transboundary movement, transit, handling and use” of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into also into account risks to human health. Under the Protocol LMOs are any living organisms(such as seeds trees or fish<sup>112</sup>) that posse a novel combination of genetic material introduced through in vitro nucleic acid techniques including DNA or fusion of cells beyond the taxonomic family.<sup>113</sup>

The Protocol’s AIA procedure is not applicable to LMOs in transit,<sup>114</sup> LMOs destined for contained use in the party of import,<sup>115</sup> LMOs intended for direct use as food or feed or for processing(LMO-FFPs),<sup>116</sup> LMOs identified by COPs as being not likely to have adverse impacts.<sup>117</sup> Also excluded from the Protocol’s provision on transboundary

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<sup>110</sup> Birnie and Boyle, *supra*, pp. 119- 120.

<sup>111</sup> Justice Stein P, *supra* pp. 2.

<sup>112</sup> Jaffe G, *supra* pp. 301.

<sup>113</sup> Article. 3 Protocol.

<sup>114</sup> Article. 6(1) Protocol.

<sup>115</sup> Article 6(2) Protocol.

<sup>116</sup> Article. 7(2) Protocol.

<sup>117</sup> Article. 7(4) Protocol.

movements are pharmaceuticals for humans that are addressed by other international organizations or agreements.<sup>118</sup> It is important to note that even where certain LMOs are excluded from some or all of the Protocol's provisions, a state may in exercise of their sovereign rights subject them to national regulation provided such legislation is consistent with the objective of the Protocol and that state's other obligations under international law.<sup>119</sup> In the case of LMO-FFPs, the provisions of Article 11 (procedure for LMO-FFPs) shall be complied with in addition to the foregoing.

#### **2.4.4 Institutions**

The Protocol essentially shares institutions with the Convention. The CBD Conference of the Parties (COP) shall under article 29 of the Protocol, serve as the meeting of the parties to the Protocol. When the COP to the CBD sits as a meeting of the parties to the Protocol, the body is known by the 'cumbersome' name 'the Conference of the parties serving as a meeting of the parties to the Protocol (COP / MOP) and only parties to the Protocol participate in decision making.<sup>120</sup> The third COP / MOP was held in Curitiba, Brazil in March 2006. This is the principal governing body of the Protocol with a wide range of important functions specified under article 29 which include keeping under review implementation of the Protocol. COP/MOP has the power to make, within its mandate, the decisions necessary to promote effective implementation of the Protocol. Arguably, the COP / MOP is (or ought to be) a powerful body that will play an important role in the 'evolution' of the Protocol as it has the power to undertake further work on some of the areas the Protocol text does not presently provide clear guidance.<sup>121</sup> These include issues such as liability and redress which we shall examine shortly.

Article 19 of the Protocol requires that "each party shall designate one national focal point...also designate one or more competent national authorities...responsible for performing" the administrative functions required by the Protocol. See further discussion at (3.4).

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<sup>118</sup> Article. 5 Protocol.

<sup>119</sup> Article 2(4) Protocol.

<sup>120</sup> Article. 29(2) Protocol.

<sup>121</sup> Mackenzie and others (Eds), *supra*, 9An Explanatory Guide) Pg.. 19.

#### 2.4.5 Advance Informed Agreement

The biosafety Protocol divides LMOs into two groups for purposes of international regulatory action.<sup>122</sup> Those subject to AIA procedure and those are not. Article 7 (1) identifies transboundary movement of LMOs for intentional introduction into the environment which must comply with the AIA procedure specified in articles 7-10, 12 and 15. These require written consent of the importing state.<sup>123</sup> The procedure for AIA involves three key stages. Notification in writing by the party of export,<sup>124</sup> acknowledgement in writing of receipt of notification by the party of import,<sup>125</sup> a decision procedure<sup>126</sup> and provisions for review of decisions in the light of new scientific information<sup>127</sup>

The AIA procedure set out in article 7 has been described as the chief regulatory technique designed to ensure that contracting parties are provided with the information necessary to make informed decisions before agreeing to the import of LMOs into their territory.<sup>128</sup> Under article 7(1) the AIA procedure applies to the first intentional transboundary movement of LMOs for introduction into the environment of the party of import. This excludes LMOs that have previously been introduced into the environment of the importing state under the pretext that the importing state is estopped from laying claims of adverse effects if it never did so before the Protocol entered into force. The requirement for notification (subject to provisions of confidentiality in Article 21) and decision making,<sup>129</sup> arguably buttress the provisions of article of article 7.<sup>130</sup>

The second category of LMOs is FFPs. These do not require AIA and are subject to a simple procedure. Under article 11 a party that makes a decision regarding domestic use of FFPs is only required to inform the parties through the Biosafety Clearing –House, within fifteen days of making that decision, provided the decision is consistent with the

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<sup>122</sup> Birnie and Boyle, *supra*, Pg.. 737

<sup>123</sup> Article 10(2) Protocol.

<sup>124</sup> Art. 8

<sup>125</sup> Art. 9

<sup>126</sup> Art. 10

<sup>127</sup> Art. 12(1)

<sup>128</sup> Redgwell C, *supra*, pp. 555.

<sup>129</sup> Art. 8-10

<sup>130</sup> Redgwell C, *supra* pp. 556

objective of the Protocol and it does not apply to decisions regarding field trials. It is however significant to note that the precautionary approach is applicable to FFPs.<sup>131</sup>

#### **2.4.6 Public Awareness and Participation**

Public participation in the biosafety regulatory process is essential for purposes of consumer trust in that process.<sup>132</sup> It has been recognized that on a general level, public participation consists of “attempts to influence law, policies and individual decisions” made by the government or regulatory bodies.<sup>133</sup> Article 23 of the Protocol does not do more than give guidance to states on issues of public awareness and public participation. International basis of public participation is traceable to the three pillars enunciated in Principle 10 of the Rio declaration. These are the right of citizens to information, the right to participate in environmental decisions that affect them and their access to mechanisms of redress and justice when their rights are violated.

Public awareness and public participation are issues of democratic governance whose quality will arguably largely depend on, though not limited to levels of: literacy, freedom of expression, the right and means of access to information, transparency and accountability, judicial independence and more significantly, the political will to promote and enhance public participation in decision making (both legally and in practice) at the domestic level.

Gregory notes that many countries include, in their biosafety regulatory systems, the ability for the public to comment before a decision is made on a GMO application. However, he argues that making sure that the public is aware of that opportunity and providing the public with the knowledge and tools to make their participation meaningful is much more difficult. He takes the view that in developing countries, financial constraints, language barriers, and the lack of good communication vehicles makes implementing public participation requirements in a meaningful way much more

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<sup>131</sup> Art. 11(8)

<sup>132</sup> Gregory J, Biosafety Regulation in the North and South Available at [www.google.com](http://www.google.com)  
Last accessed on 26<sup>th</sup> Dec. 2006.

<sup>133</sup> Bell S and McGillivray D, *supra*, pp. 338.

difficult.<sup>134</sup> It cannot be denied that these challenges and limitations are typical to both Kenya and South Africa..

#### **2.4.7 Risk Assessment**

Risk assessment under the Protocol is to be carried out in a scientifically sound manner with a view of identifying possible adverse effects in the potential receiving environment taking into account recognized risk assessment techniques.<sup>135</sup> It entails evaluation of the probability of adverse effects occurring and of their consequences.<sup>136</sup> Being an entirely a scientific issue, the quality of risk assessment is largely dependant upon expertise<sup>137</sup> and the resources necessary to achieve objective results. In Kenya and South Africa, this is done by way of environmental impact assessment (EIA) through the relevant laws and regulations.<sup>138</sup> Rules apart, aspects of poor governance and corruption, in some cases, obstruct effectiveness and objectivity of the EIA process.

#### **2.4.8 Risk Management**

Among other things, the Protocol requires member states to “establish and maintain appropriate mechanisms, measures and strategies” to “regulate, manage and control risks” identified in the risk assessments under the protocol.<sup>139</sup> What constitutes appropriate mechanisms, measures and strategies, is for individual states to determine and presumably in accordance to their local circumstances. However, it is apparent that the regulatory system envisaged by Article 16 of the Protocol must be functional and that the strategies must possibly be workable, practicable and reliable. Absence of or inefficient regulatory agencies will arguably frustrate the good intentions of Article 16.

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<sup>134</sup> Gregory J, Biosafety Regulation in the North and south , Available at [www.google.com](http://www.google.com) last Accessed on 26<sup>th</sup> Dec. 2006

<sup>135</sup> Article 15 Protocol.

<sup>136</sup> Mackenzie and others (Eds) supra, (An Explanatory Guide) pp. 108.

<sup>137</sup> Expertise is required inter alia in the fields of: Nucleic acid technology, molecular genetics, Population genetics marine biology, pathology etc See note 57, supra pp. 109.

<sup>138</sup> South Africa –National Env't. Management Act 107 of 1998(chapter. 5), Kenya- Env'tl.Management and Co-ordination Act, 8 of 1999 (Chapter VI)

<sup>139</sup> Article 16 Protocol.

### 2.4.9 Monitoring

Each party is required to “monitor the implementation of its obligations under the Protocol” and to report to the COP/MOP, at intervals to be determined by the COP/MOP on “measures that it has taken to implement the Protocol”.<sup>140</sup> Monitoring is crucial to the effectiveness of the Protocol since most of the obligations are not self executing and thus require “national measures, of a legislative, regulatory and institutional character” to enable their implementation.<sup>141</sup> It has also been stated that “[m]onitoring is a necessary foundation for giving effect to environmental obligations”.<sup>142</sup> It is further argued that in order for the parties to implement these obligations, it will be important to have “access to, or set up, reliable mechanisms of information gathering and data management” at national level.<sup>143</sup> This suggests that a party needs substantive provisions in its domestic legislation relating to monitoring if it is to comply with the requirements of monitoring and reporting under the Protocol. Absence of provisions on monitoring may lead to inferences of bad faith on the party concerned.

### 2.4.10 Key Unresolved Issues

The Protocol has not been able to resolve all key issues and in some cases it does not give clear guidance. Balancing the competing and at times contradictory issues<sup>144</sup> is by no means easy. The signing of the Treaty at Montreal was arguably intended to avoid collapse of the biosafety negotiations. Hence a compromise was necessary. As a result some key issues were not and still remain unresolved. Gregory identifies four of the unresolved issues as: “[w]hat the applicable safety standards should be, how to incorporate socioeconomic considerations, how to address food safety and how to incorporate public participation”. All these were and are still left to individual states’ discretion<sup>145</sup>

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<sup>140</sup> Article 33 Protocol

<sup>141</sup> Mackenzie and others(Eds) (Explanatory Guide), Par.713.

<sup>142</sup> Kiss A and Shelton D, International Environmental law,3<sup>rd</sup> Ed., Transnational Publishers New York Pg. 268.

<sup>143</sup> Mackenzie and others(Eds) (Explanatory Guide) Par. 718

<sup>144</sup> For an excellent and concise summary see Jaffe G, supra, pp.300-301

<sup>145</sup> Jaffe G, supra, pp. 299.

## 2.5 The African Regional approach to Biosafety

The African model law was endorsed by the Organization of African Union Council of Ministers in Lusaka (Zambia) in July 2001. Adoption of the African model law especially after signing of the Protocol is arguably intended to serve four important purposes. It provides a holistic and broader regulatory biosafety regime with a view of filling some of the gaps<sup>146</sup> left by the Protocol. These include provisions for enhanced public participation,<sup>147</sup> clear identification and labeling of GMOs<sup>148</sup> and a liability and redress regime based on strict liability.<sup>149</sup> The scope of the model law is wider as it addresses genetically modified organisms (dead or alive) or a product of a genetically modified organism,<sup>150</sup> with the result that its provisions are likely to prevent or minimize dumping of products that have otherwise been rejected in the exporting countries.

Second, the model law embraces the precautionary ‘principle’ as opposed to the precautionary ‘approach’.<sup>151</sup> Third, the model law establishes ‘uniform provisions’<sup>152</sup> that apply to all types of GMOs whether they are intended for release into the environment for use as pharmaceutical, for food, feed or processing or a product of a genetically modified organism<sup>153</sup>; Four, it can be replicated by African countries that are unable to establish biosafety legislation due to financial or other constraints.

Although the African Model law adopts an approach that avails higher protection against actual and potential risks, it is regrettable that African countries developing biosafety legislation have not significantly adopted the key provisions of the Model law into their municipal law. It is not convincing to attribute such failure to lack of a binding effect on the part of the Model law as much as to the vociferous opposition by the biotechnology

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<sup>146</sup> Article 11 of the African model law

<sup>147</sup> Article 5 of the African Model Law

<sup>148</sup> Article. 11 of the African Model. Law

<sup>149</sup> Article 14 of the African Model Law

<sup>150</sup> Article 2 of the African Model Law.

<sup>151</sup> Birnie and Boyle, *supra*, Pg.. 116.

<sup>152</sup> Mariam Mayet, *Why Africa should adopt the African Model Law on Safety in biotechnology*, (2004) 11 SA J.of Env'tal Law and Policy, pp. 200

<sup>153</sup> Article 2 of the African model Law

industry, and the double standards on the part of food producers who label their products in Europe but refuse to do the same in the developing countries.<sup>154</sup>

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<sup>154</sup> Mariam Mayet, *supra*, note 110 Pg. 210.

## CHAPTER THREE

### IMPLEMENTATION OF THE CARTAGENA PROTOCOL IN KENYA AND SOUTH AFRICA: A COMPARISON

#### 3.1 Introduction

This chapter compares domestic implementation of the Cartagena Protocol (the Protocol) in Kenya and South Africa. Two main objectives are addressed here. The extent to which existing and proposed legislations are consistent with or at variance with the Protocol and, the extent to which such legislation is relevant and workable in each of the two countries. Complying with the provisions of the Protocol in domestic legislation is in itself not sufficient. Whether the regime is relevant and workable domestically provides the litmus test of the effectiveness and credibility of such legislation. Unless the regulatory system is efficient, workable, fair and equitable,<sup>155</sup> it will not serve any meaningful purpose and it is likely to be rejected. It has been argued that efficient regulatory systems minimize costs, functional ones make decisions promptly and fair regulatory systems treat similar products in a similar manner and decisions on similar products are consistent with one another while being fair and equitable to developers, researchers and their products.<sup>156</sup>

The salient features that form the basis of this study were discussed in chapter two. Here we examine their implementation thematically and systematically beginning with the Protocol (in a few cases) Kenya, South Africa followed by a comparison for each of the themes under focus. The selected key themes under study are:, Objectives, Precautionary Approach, Scope, Advances Informed Agreement, Public Participation, Risk Assessment and Risk Management, Monitoring Liability and Redress and. In the case of Kenya the Biosafety Bill 2005 (the Kenyan Bill) is examined and in the case of South Africa, the Amendment Bill 2005 (the GMO Amendment Bill)<sup>157</sup> are examined. Biosafety legislation

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<sup>155</sup> Jaffe G, 'Comparative Analysis of the National Biosafety Regulatory systems In East Africa' Jan [Genetically Modified Organisms \(GMO\) Act<sup>155</sup> and the Genetically Modified Organisms](#). 2006

Pg.9 Available at [www.ifpri.org](http://www.ifpri.org) last accessed on 15<sup>th</sup> Dec. 2006

<sup>156</sup> Jaffe G, supra,(Comparative Analysis) pp. 9

<sup>157</sup> Republic of South Africa, Genetically Modified Organisms Amendment Bill 2005.

But first, an overview of constitutional and other legislative provisions relevant to biosafety in the two countries is necessary.

## 3.2 Constitutional and Legislative Support

### 3.2.1 Kenya

The current Constitution<sup>158</sup> has no provision for an environmental right. However section 70 of the Constitution provides for the protection of the fundamental rights and freedoms of the individual, among them is the right to life. Interpretation from an environmentalist perspective suggests that protection of the environment is desirable in order to realize the right to protection of life. The Environmental Management and Co-ordination Act (EMCA)<sup>159</sup> provides general principles which includes the provision that: “every person in Kenya is entitled to a clean and healthy environment and had the duty to safeguard and enhance the environment”. The Act also provides for environmental impact assessment (EIA), the precautionary principle, and public participation among others. In the absence of an environmental right, these provisions provide some biosafety support. It is hoped that if and when a new constitution is enacted<sup>160</sup>, the environmental right in EMCA shall receive appropriate recognition.

### 3.2.2 South Africa

Section 24 of the Constitution<sup>161</sup> provides thus: “Everyone has the right- to an environment that is not harmful to their health or well-being” and to have the environment “protected for the benefit of present and future generations” through “reasonable legislative and other measures” that prevent pollution and ecological degradation and promotes conservation among other things. In the circumstances, it may be argued that the Constitution provides *the foundation stone* yet it is incumbent upon parliament to ‘lay’ the foundation by way of appropriate legislative and other measures.

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<sup>158</sup> Constitution of Kenya as Adopted in 1963 as Amended in 1999.

<sup>159</sup> Republic of Kenya Act 8 of 1999.

<sup>160</sup> The *Wako* draft constitution 2005 which was rejected in a referendum of that year, provided for an environmental right and there is no evidence that it was one of the contentious issues.

<sup>161</sup> Constitution of the Republic of South Africa, Act 108 of 1996.

Further biosafety legislative support is also available in the provisions of the Promotion of Access to Information Act <sup>162</sup> (PAIA) that makes provision for a right to access to information, the Promotion of Administrative Justice Act<sup>163</sup> (PAJA) that makes provision for the right to administrative justice in the decision making process; and the National Environmental Management Act<sup>164</sup> (NEMA) which provides for the principles that govern “the actions of all organs state that may significantly affect the environment”<sup>165</sup>, the duty of care<sup>166</sup> and environmental impact assessment among other things..<sup>167</sup>

Undoubtedly, South Africa has a strong Constitutional and legislative framework which provides a favourable environment for the development of a holistic biosafety regime if there is political will to do so and the freedom to exercise that will (if any) We now turn to the selected key features.

### **3.3 Selected Key Features: A comparative Analysis**

#### **3.3.1 Objective**

Having discussed the objective of the Protocol in chapter two (2.4.1), it important to note here that stated objective(s) play critical roles in biosafety legislation. Apart from being a mechanism of avoiding or minimizing ambiguities, an objective reflects in clear terms the common purpose and intention of the legislature or the parties to an international treaty such as the Cartagena Protocol. The objective specifies what the parties intend to achieve, and in some cases, provides mechanisms<sup>168</sup> on how to achieve it. In domestic legislation such an objective would arguably serve a significant additional purpose enhancing public confidence in and acceptance of biosafety legislation.

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<sup>162</sup> Republic of South Africa, Act 2 Of 2000.

<sup>163</sup> Republic of South Africa, Act 3 Of 2000.

<sup>164</sup> Republic of South Africa, Act 107 of 1998.

<sup>165</sup> Section 2 NEMA.

<sup>166</sup> Section 28 NEMA

<sup>167</sup> Section 24 NEMA

<sup>168</sup> Art. 1 Protocol; section 4(b) Kenyan Bill

### 3.3.1.1 Kenya

The objectives of the biosafety Bill of Kenya 2005 (Kenyan Bill) have two components. The first one embraces the precautionary principle (discussed in 2.4.2). It Provides thus: “in accordance with the precautionary principle, to ensure an adequate level of protection” in the field of “safe transfer, handling and use” of GMOs “resulting from modern biotechnology that may have an adverse effect on the environment”.<sup>169</sup>

#### 3.3.1.1.1 The Precautionary Principle

Kidd observes that the precautionary principle rests on the need to recognize that harm to the environment can be irreversible and therefore “it is better to avoid any possible harm to the environment than to try to remedy it later”.<sup>170</sup> Considering that science cannot provide all the answers to the problems arising from genetic engineering and that the environment and the public are entitled to protection from the potential risks of GMOs, the precautionary principle arguably provides the only escape route in the event of scientific uncertainty.

Whereas the Protocol provides for the ‘precautionary approach’<sup>171</sup>, the Kenyan Bill provides for the ‘precautionary principle’ as a tool of ensuring an adequate level of protection in the field of safe transfer, handling and use of GMOs. The question that immediately arises is whether the two terminologies are different or mean one and the same thing. It does appear that there is no consensus as to distinction or difference between the two terminologies.

Birnie and Boyle argue that attempts to distinguish the approach from the principle points to the reality that the concept of precaution appears to mean different things in different contexts. They attribute the confusion to failure to distinguish the identification of risk from the entirely separate question of how to respond to that risk. According to the two writers, the precautionary approach (or principle) may mean that when faced with uncertainty states must be more cautious in identifying risks or it may mean that states

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<sup>169</sup> Section 4 (a) Kenyan Bill

<sup>170</sup> Kidd M, *supra*, Pg. 9

<sup>171</sup> Art. 1 Protocol

must be more cautious in taking measures to deal with those risks. However they take the view that developments in international law have adopted the precautionary principle as used in the former sense. Used in that sense, they argue ‘few commentators regard the difference as significant’.<sup>172</sup> Sands contends that although the precautionary principle is potentially the most radical and far-reaching of environmental principles, its meaning and effect are unclear and remain mired in controversy.<sup>173</sup>

The controversy surrounding the meaning and effect of the precautionary principle explains why the Protocol adopts the precautionary approach ‘contained in Principle 15 of the Rio Declaration’ to avoid ambiguity as already discussed in chapter two. That being the case and considering that the EU, Sweden and Germany<sup>174</sup> prefer use of the ‘principle’ rather the ‘approach,’ it tenable to argue that the use of ‘approach’ instead of ‘principle’ was motivated by reason of offering more flexibility and being less restrictive than the ‘principle’<sup>175</sup>. However this does not necessarily solve the problem because “flexibility can create problems of certainty and precision”.<sup>176</sup> Consequently use of ‘principle’ in the Kenyan Bill instead of ‘approach’ used in the Protocol strongly suggests that Kenya has taken a more strict view of protection of the environment than the minimum criteria set out in the Protocol and thereby minimized uncertainty in its objectives. It appears that the Kenyan Bill emulates the position taken by the EU and the African Union (African Model law) as far as the precautionary principle is concerned.

### **3.3.1.1.2 Transparency and Predictability**

The second component relates to transparency and predictability of the process that reviews and makes decisions regarding GMOs. It provides thus:

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<sup>172</sup> Birnie and Boyle, *supra*, Pg.. 116

<sup>173</sup> Sands P, in Revesz, Sands P and Stewart, *supra*, pp. 375-376.

<sup>174</sup> Birnie and Boyle, *supra*, Pg.. 116

<sup>175</sup> Birnie and Boyle, *supra*, Pg.116

<sup>176</sup> Bell S and McGillvray D, *supra*, Pg. 59

to establish a transparent and predictable process to review and and make decisions on such genetically modified organisms and related activities.<sup>177</sup>

This component sets minimum standards on decision making. This implies that the process must be open, and devoid of undue influence from commercial, political and other interests. It also suggests that in order to be predictable, the process must be understood, be popular and consistent in decision making. It has been argued that in “a functional and protective system” all interested parties “know and understand” the safety standard before hand and government decisions apply that standard in “a uniform and fair” manner.<sup>178</sup> A transparent and predictable biosafety regulatory system must provide the public with information that include: a roadmap of the process and what is expected of the applicant, how the agency will conduct its review, where, when and how the public can be involved in the regulatory process.<sup>179</sup> It is hoped that the regulations will shed more light on these imperatives.

By requiring that the process be transparent and predictable the second component of the Bill successfully achieves three goals. It demonstrates that states (and in particular developing countries) are capable of taking action that is more protective than envisaged by Article 2(4) of the Protocol, for the conservation and protection of their biological diversity. Secondly, a transparent and predictable process sets the parameters and a firm legislative foundation of any regulations and guidelines that may be promulgated or approved pursuant to the resultant Act. Thirdly such a process is capable of being replicated in other African countries and thereby increasing the chances of establishing a unified biosafety regime as envisaged by the African Model law. By making provisions relating to transparency and predictability, the Bill goes beyond the minimum criteria set out in the objective of the Protocol.

Although the objectives are clearly stated, achieving them or any part thereof is another matter altogether. As Paterson observes, prescribing and implementing legal doctrine are

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<sup>177</sup> Section 4 Kenyan bill

<sup>178</sup> Jaffe G, supra, (Comparative Analysis).Pg.5.

<sup>179</sup> Jaffe G, supra (Comparative Analysis) Pg.6.

two interrelated yet distinct tasks, the latter frequently proving far more challenging than the former.<sup>180</sup> It is argued that achieving these objectives is largely dependant upon effective implementation and the requisite political will.

### **3.3.1.2 South Africa**

Whereas the Protocol has a clearly stated objective, (and inspite of the critical role it plays) both the GMO Act and the Bill have none. The requirement to comply with the Protocol dictates that the Bill should have a stated objective. It would appear that since the precautionary approach being the central tenet of the objective under the protocol is excluded from the Bill, constructing an objective under the Bill without the 'precautionary approach' would make the inherent inadequacies of the Act and the Bill obvious.

Absence of provisions relating to the precautionary approach in the Bill, strongly suggest that the government has taken a strict view of the consequences of the precautionary approach and thereby ignored it. Considering that South Africa is the sixth in the hierarchy of top growers and promoters of GMOs globally, (and the leading in Africa)<sup>181</sup> it would be reasonable to argue that provisions relating to the precautionary principle may have been seen as unnecessarily prohibiting trade in GMOs. It has also been argued that the broad definitions of the precautionary principle allows for extreme interpretations that are frequently used to 'push a particular political agenda'.<sup>182</sup>

Considering the importance of the precautionary principle in the protection of the environment,<sup>183</sup> and bearing in mind the attention it attracted during the negotiations prior to adoption of the Protocol, its absence in the Bill not only offends Article 1 of the Protocol but it also a matter is of concern domestically and internationally. The immediate consequence of its absence in the Bill is that it defeats rather than enhances

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<sup>180</sup> Paterson A "Fuelling the Sustainable Development Debate in S.Africa" South African Law Journal [2006] [1] 52 at 53

<sup>181</sup> See 'genetically engineered crops: Sacrificing the rights of the future generations' A briefing paper No. 1 available at [www.biowatch.org.za](http://www.biowatch.org.za) last visited on 15<sup>th</sup> Jan. 2007.

<sup>182</sup> 'Public Attitudes towards agricultural Biotechnology in South Africa' Final Report April 2002\*

<sup>183</sup> Principle 15 Rio Declaration

the primary objective of complying with international agreements that the Bill sets out to achieve.<sup>184</sup> It is argued that absence of the precautionary approach will establish a biosafety regime with lower thresholds than those permissible by the Protocol in relation to the safe transfer, handling and use of LMOs since application of the precautionary approach is the minimum criteria set by the Protocol.

In any event, the constitution requires that the environment be protected through ‘reasonable and other measures’ inter alia to prevent ecological degradation and promote conservation.<sup>185</sup> The environmental management principles under NEMA also require 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.<sup>186</sup> As a consequence, absence of provisions relating to the precautionary approach, strongly suggest that the intended amendments are superfluous and can only result into legislation that is not relevant and workable.

By ignoring the precautionary approach, the Bill fails to appreciate the inherent scientific uncertainty of modern biotechnology. Further complications arise as, absence of provisions on the precautionary approach, deprive the Bill of an accepted and recognized key tool and criteria of biosafety legislation, which, has been endorsed by the member states of the Protocol. As a consequence legislation resulting from enactment of the Bill in its present form will not only be inconsistent with the Protocol, but it will lack transparency, predictability and credibility.

### **3.3.1.3 A Comparative Analysis**

The objective contained in section 4(a) of the Kenyan Bill complies with Article 1 of the Protocol but only partially. That objective is lacking in two material ways. First, it ignores the important aspect of conservation of biological diversity and the element of human health. The absence of these two critical elements leaves a lot to be desired.

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<sup>184</sup> Preamble to the GMO Amendment Bill.

<sup>185</sup> S. 24 Constitution of South Africa 1996

<sup>186</sup> S. 2(4)(vi) NEMA

Considering that socio-economic considerations and public participation<sup>187</sup> have been provided for in the Kenyan Bill<sup>188</sup>, it is improbable that protection of biodiversity and humans were intended to be excluded yet it is necessary that specific provision be made in terms of Article 1 of the Protocol. The Kenyan Bill takes an environmentalist perspective (ecocentric approach) which is characterized as placing more weight on the need to protect the environment and “where there is no conflict with such protection, human health”.<sup>189</sup> An anthropocentric approach that places the environment within the sphere of human interests<sup>190</sup> is desirable. Second, the objective contained in section 4(a) Kenyan Bill, is narrow in its application. To the extent that it does not encompass the regulation of import, development, transport, packaging, identification, export, contained use, release or placing on the market, it may be argued that the Kenyan Bill is restrictive save that other than identification and packaging, the other aspects are governed by the AIA procedure (contained in part three) of the Kenyan Bill.

The second element concerns transparency and predictability. This is an important step towards enhancing efficiency, credibility and accountability of the decision making process. It minimizes abuse of the decision making process thereby increasing public confidence in the decision making of the NBA. It is evident that by including this additional yet critical element, the Kenyan Bill goes beyond the minimum criteria set by article 1 of the Protocol.

In the case of South Africa, having ignored the precautionary principle, the GMO Amendment Bill has not made any attempt to comply with Article 1 of the Protocol. The biosafety regime that ensues from the Bill does not provide for the precautionary approach nor is there evidence anywhere in the Bill that the precautionary approach forms part of its regime. The fact that Bill is keen on and repeatedly provides for “scientifically based risk assessment” clearly demonstrates that character of the biosafety regime in South Africa may for along time, be lacking in the relation to the precautionary

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<sup>187</sup> Section 42(1)

<sup>188</sup> Section 24(10 (e), Also see the discussion on socio-economic considerations at (3.3.7)

<sup>189</sup> Bell S and McGillivray D, *supra*, Pg. 55

<sup>190</sup> Bell S and McGillivray D, *supra*, Pg. 55

approach. However the jurisprudence of environmental law in South Africa is taking an admirable trend which in many instances<sup>191</sup> breaches the gaps and cures the inadequacies inherent in the GMO Act (current and proposed). The Constitutional and other legislative support (see 3.2.2 above) provide strong mechanisms that have enhanced environmental protection in South Africa. That being the case, the GMO Act, (together with the GMO Amendment Bill 2005), is left as mere permitting regimes for GMOs. Consequently, it is justifiable to argue that the GMO Act needs ‘overhaul reforms’ if it is to be tenable rather than piecemeal amendments.

### **3.3.2 Scope**

Scope provides the parameters within which a treaty operates. It identifies aspects covered by the treaty and at times those excluded from the treaty. A treaty may also remain silent on some issues. We now examine Scope under the Protocol (briefly in addition to the discussion in (2.4.3) followed by Kenya and South Africa before a comparison is done.

#### **3.3.2.1 The Protocol**

Under the provisions of Article 4, the mandate of the Protocol is limited to living modified organisms as opposed to genetically modified organisms that encompass living and dead organisms. The effect is that in the case of an LMO, whereas a GM seed that falls within the scope of the Protocol is governed by the provisions of the Protocol, its flour or other derivative is not. In the case of a GMO, both the seed and its derivatives are covered under domestic law if the law provide for GMOs.

#### **3.3.2.2 Kenya**

The Bill applies to both living and non-living genetically modified organisms (GMOs). All the relevant sections (especially under part three of the Bill) refer to GMOs. Section 14(1) provides thus: “No person shall conduct...activities involving genetically

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<sup>191</sup> The instances may not be exhausted in this limited scope but this reference is mainly in relation to the provisions of section 24 of the Constitution of S. Africa, PAIA, PAJA and NEMA

modified organisms without the written approval of the authority”. The preamble to the Bill defines GMOs as ‘any living or non-living organism that possesses a novel combination of genetic material...’ The Bill does not apply to GMOs that are pharmaceuticals for human use.<sup>192</sup>

By subjecting all categories of GMOs (covered by the Bill) to its permitting regime, it follows that GMOs intended for direct use as food or feed or for processing are not exempted from the only permitting regime established under the Bill. As a consequence, all food aids that have caused controversy in the past, must comply with the provisions of the Bill. Aid in the form of GMO foods has its own political implications. It is not surprising if these and other provisions that make the Bill appear restrictive, delay or even hinder enactment of the present Bill into law.

However, section 3(1) with the title “scope of Act” is vague and ambiguous. It provides thus: “The requirements of this Act are in addition to the requirements imposed by any other Act”. This provision is superfluous to the extent that it lacks specificity. Those other Acts are not specified nor does the provision adopt the provisions of any of ‘those’ Acts. Section 3(2) is clear. It states thus ‘This Act shall not apply to genetically modified organisms that are pharmaceuticals for human use’. Whether the exclusion of pharmaceuticals is acceptable or not, is another matter altogether, but the provision is clear and unambiguous. One wonders why exclusion is stated unequivocally under section 3(2) of the Kenyan Bill while application of the Act under section 3(1) is elusive.

### **3.3.2.3 South Africa**

Section 2 of the GMO Act states that the Act shall apply to:-

- (a) the genetic modification of organisms
- (b) the development, production, release, use and application of genetically modified organisms(including viruses and bacteriophages); and

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<sup>192</sup> Section 3(2) Kenyan Bill

(c) the use of gene therapy

By making reference to GMOs rather than LMOs as provided by the Protocol, the GMO Act would appear set to cover a wider scope than the Protocol but that was never to be. The scope of the GMO Act has been framed in such a manner that it essentially negates the objective of the Protocol. The Act does not indicate in what manner, and for what purpose the Act applies to “the genetic modification of organisms”.

The Protocol clearly provides that it is concerned with “transboundary movement, transit, handling and use” of GMOs that may have adverse effects on biological diversity, “taking also into account human health”. The GMO Act is silent on these aspects which are otherwise specifically provided for by the Protocol. What is of serious concern is that the GMO Amendment Bill which is specifically intended to make the GMO Act Protocol compliant, has no provisions relating to amendment of section 2 of the GMO Act. The effect is that the even after the GMO Amendment Bill becomes law, the GMO Act shall still remain a regime “skewed in favour of facilitating permits”.<sup>193</sup>

#### **3.3.2.4 A Comparative Analysis**

Article 4 of the Protocol (discussed in chapter two: 2.4.3) has clear provisions relating to the harmful effects of transboundary movement, transit, handling and use of LMOs on biological diversity taking into account human health. However the Kenyan Bill is elusive and escapist in its provisions on scope in section 3(1) of the Bill. Failure to make specific provision leads to confusion and uncertainty. Section 2 (1) of the GMO Act makes provisions relating to scope but the scope is inadequate yet it is clearly intended to promote the development, production, release, use and application of GMOs. As a consequence, both regimes do not comply with the Protocol nor are they relevant and workable as the GMO Amendment Bill is intended to serve political purposes and hence cosmetic.

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<sup>193</sup> Eastwood J, ‘GMO Amendment Bill-Perpetuating the Shortcomings of the GMO Act?’ Available at [www.winstanleycullinan.co.za](http://www.winstanleycullinan.co.za) last accessed on the 20<sup>th</sup> Jan 2007.

### 3.3.3 Institutions

It has been stated that much of environmental law consists of setting out a framework for behaviour. It is concerned with who should make decisions, how they should make those decisions and what procedures must be followed.<sup>194</sup> It is for this reason that institutions are important in the administration and enforcement of biosafety legislation and related matters. Effectiveness of such institutions therefore becomes critical. As discussed in chapter two (2.4.4), Article 19 requires that each party designates a competent national authority to perform the administrative functions required by the Protocol. We now examine the nature and character of the institutions in the two countries.

#### 3.3.3.1 Kenya

Section 5 of the Kenyan Bill establishes the National Biosafety Authority (NBA),<sup>195</sup> a body corporate with perpetual succession capable of suing and being sued.<sup>196</sup> The NBA shall be managed by a statutory board whose membership is drawn from various government ministries and other government agencies. Membership of the board includes three experts from biological, environmental and social sciences.<sup>197</sup> The Act empowers the NBA inter alia, to receive, respond and to make decisions on applications under and in conformity with the Act, keep a record of biotechnology and biosafety activities in Kenya and promote awareness and education among the general public in matters relating to biosafety.<sup>198</sup> The board is empowered to appoint a chief executive officer (CEO)<sup>199</sup> who shall manage the affairs of the authority and shall be the secretary to the board. To the extent that the NBA coordinates all activities of GMOs visa-avis the regulatory agencies,<sup>200</sup> the authority serves as an umbrella institution.

By being a corporate entity, the element of legal competence is satisfied. Although the Bill does not make specific reference to the Protocol it empowers the NBA to coordinate

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<sup>194</sup> Bell S and McGillivray, *supra*, pp. 11

<sup>195</sup> Section 5(1) Kenyan Bill

<sup>196</sup> Section 5 (2) Kenyan Bill

<sup>197</sup> Section 6 Kenyan Bill

<sup>198</sup> Section 7 Kenyan Bill

<sup>199</sup> Section 11 Kenyan Bill

<sup>200</sup> Section 32 Kenyan Bill

all activities involving genetically modified organisms (GMOs),<sup>201</sup> establish contact and maintain liaison with other countries and organizations and also perform such other functions as may be necessary for the proper administration of the Act.<sup>202</sup> The NBA has power to make regulations<sup>203</sup> for the better carrying out of its functions and, it shall be the body responsible for issuing approvals in matters relating to GMOs<sup>204</sup>.. Considering these and other powers and functions of the NBA, an inference can be drawn that the authority acts both as the competent authority and the national focal point envisaged by Article 19 of the Protocol.

### **3.3.3.2 South Africa**

Section 3 of the GMO Act establishes the Executive Council of GMO (the council) as the competent authority<sup>205</sup> whose membership the GMO Amendment Bill increases to ten.<sup>206</sup> An advisory committee<sup>207</sup> of not more than ten persons shall be the national advisory body on all matters concerning or related to GMOs. The registrar appointed pursuant to article 8 of the GMO Act shall inter alia be responsible for communicating to the Biosafety Clearing House of the Protocol.

### **3.3.3.3 A Comparative Analysis**

It has been argued that “in implementing environmental protection policies, regulatory agencies are carrying out a political balancing process”.<sup>208</sup> Bell and McGillivray argue that law in practice is affected by the values and culture of those who make the rules. They argue that values “cover the things which are important to us and the priority we give to them”.<sup>209</sup> In administering biosafety issues, they further argue, regulatory agencies must grapple with “guidance notes, circulars, official policy documents, codes of practice, even politician’s speeches” which have a marked effect upon the way in

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<sup>201</sup> Section 32(1) Kenyan Bill

<sup>202</sup> Section 7 Kenyan Bill

<sup>203</sup> Section 40 Kenyan Bill

<sup>204</sup> Section 24(2) Kenyan Bill

<sup>205</sup> Article 19 Protocol.

<sup>206</sup> Section 2 of the bill

<sup>207</sup> Section 10 of the Act.

<sup>208</sup> Bell S and McGillivray D, *supra*, pp. 14

<sup>209</sup> Bell S and McGillivray D, *supra* pp. 9

which the law operates in practice.<sup>210</sup> For instance, opponents of EIA in the developing countries label it a process that is “anti development, expensive or a mere paper tiger”.<sup>211</sup> Also political statements were made recently equating green laws in South Africa with ‘butterfly eggs’ that slow down economic activity.<sup>212</sup> These are tacit illustrations on how political statements may influence the functioning and effectiveness of regulatory institutions.

Establishment of the NBA in the Kenyan Bill and the council in the GMO Amendment Bill are no doubt consistent with the provisions of Article 19 of the Protocol. However, the extent to which these institutions will be transparent and effective and devoid of political manipulation (domestically) is another matter altogether.

Unlike the NBA which is a body corporate under the Kenyan Bill, the legal status of the Council in the GMO Act is not specified.<sup>213</sup> Section 5(2) Kenyan Bill provides thus: “The authority shall be a body corporate with perpetual succession...capable of suing and being sued”. Section 6 of the Kenyan Bill further provides the chairman “shall be an eminent scientist, appointed by the minister” Section 3(3) of the GMO Act merely provides for the establishment of the Executive Council for GMOs and that the minister “shall designate a chairperson and a deputy chairperson from among the members of the council”. These provisions have two important implications. On the one hand, the Kenyan Bill creates a strong corporate legal entity (NBA) that is accountable as opposed to the GMO Act which is silent on the legal status of the Council. This explains why the registrar is usually sued on behalf of the Council.<sup>214</sup> On the other hand, the Kenyan Bill obligates the minister to appoint “an eminent scientist” as the chairman (though regrettably gender insensitive). Under the GMO Act<sup>215</sup> the minister can, in exercise of his discretion, appoint a person who has no scientific knowledge to be chairperson or

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<sup>210</sup> Bell S and McGillivray D, supra, pp. 9. Also see Notice No. 1046 and 1047 of 2004 (Guideline documents in relation to GMOs S. Africa)

<sup>211</sup> Robinson N A International Trends in Environmental impact Assessment 19 B.C Env'tal. Aff.L.Rev 591 at 595 [1991-1992]

<sup>212</sup> See Fiona Macleod ‘Mbeki joins assault on green laws’ Mail & Guardian August 4 2006

<sup>213</sup> Section 3 GMO Act does not specify the legal status of the Council

<sup>214</sup> See *Trustee Biowatch case op. citation.*

<sup>215</sup> Section 3(3)

deputy chairperson. The framing of the objective and functions of the Council both under the GMO Act and the GMO Amendment Act, arguably create the impression that the Council is a “mere rubber stamp” of the minister. Moreover the functions of the NBA specified in section 7 of the Kenyan Bill that include establishing: administrative mechanisms and a database, keeping a record of biotechnology activities, promoting public awareness and education among the general public, make the NBA a stronger and relevant body than the Council under the GMO Act.

The Kenyan Bill makes provision for the appointment of the chief executive officer (CEO) whose principal function shall be management of the affairs of the authority and being the secretary to the board.<sup>216</sup> Under the Kenyan Bill, the CEO has no substantive statutory powers to exercise in respect of GMOs. Unlike the GMO Amendment Bill which gives the registrar power to communicate with the BCH,<sup>217</sup> the Kenyan Bill does not give the CEO such powers nor does it provide for communication with BCH.

In contrast to the Kenyan Bill, the GMO Amendment Bill gives the registrar immense substantive powers which, unless checked, may be abused. A careful consideration of the powers of the registrar under the Bill suggests that in some instances the registrar exercises unfettered powers. The registrar is empowered to issue an extension permit for an activity in respect of GMOs for which a permit had previously been issued.<sup>218</sup> Exercise of this power *inter alia* offends the Provisions on monitoring (discussed at 2.4.9) envisaged by article 23 of the Protocol. It also implies that the registrar can extend a permit as a matter of routine. This provision is inadequate as it fails to appreciate the changes that may take place relating to the harmful effects of GMOs from the time the permit was issued for the first time to the time of an extension of the permit is sought. The consultation by the council referred to in section 5(2) (d)<sup>219</sup> in respect to application for an extension permit, applies to the committee but, it does not appear to apply to the registrar. Secondly exercise of that power by the registrar implies that a permit can be

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<sup>216</sup> Section 11 Kenyan bill.

<sup>217</sup> Section 9(2) (e) as set out in section 6 of the GMO Bill

<sup>218</sup> Section 9(3) as set out in section 6 of the bill.

<sup>219</sup> As set out in section 4 of the bill.

renewed as many times as possible at the discretion of the registrar as no limit is placed on the number of times the registrar may renew a permit without reference to the Council.

Although legally competent, both the NBA and the Council are agents of and subject to state control. In both institutions of Kenya and South Africa, the minister plays a critical role in two main ways. By appointing the chairman of the board or chairperson of the council, as the case may be, and by approving regulations made under the relevant Acts on biosafety. Section 6(a) of the Kenyan Bill provides that the council shall consist of “a chairman, who shall be an eminent scientist, appointed by the minister”. Similar provisions exist under the provisions of section 3(3) of the GMO Act. Arguably the minister has a political agenda to protect if and when circumstances dictate. This suggests that once the regulatory agency is a tool for political manipulation, that regulatory agency itself becomes the obstacle in achieving its objectives. Political manipulation is not a new phenomenon in the two countries. Within the Marine and Coastal Management (MCM)<sup>220</sup> of South Africa it is claimed that there is an exodus of highly qualified scientists who are unhappy with decisions taken on political rather than scientific grounds.<sup>221</sup> In Kenya, heads of such institutions are sacked usually over the lunch time electronic media news bulletin. Other common factors that hinder effectiveness of the regulatory agencies in the two countries relate to governance,<sup>222</sup> lack of sufficient experts and personnel, insufficient funding and corruption. The values these institutions give priority to and the interests they recognize and promote are critical in determining the success or failure of the biosafety regime of each country.

### **3.3.4 Advance Informed Agreement**

The purpose of Advance Informed Agreement (AIA) is mainly to ensure that a party is aware of the adverse effects of an LMO (or GMO) before making a decision to import or not to import. It has been stated that AIA requires that before the first intentional transboundary of a specific LMO into its jurisdiction, the party of import, is notified of

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<sup>220</sup> Established under Marine Living Resources Act 18 of 1998

<sup>221</sup> Sittert L, Branch G, Hauck M, Sowman M ‘ Benchmarking the first decade of post-apartheid fisheries Reform in south Africa’, Marine Policy 30, 2006 96 at 107

<sup>222</sup> These include co-management and lack of co-operation among government departments

the proposed transboundary movement; receives information about the LMO and its use and is given an opportunity to decide whether or not to allow the import of the LMO and upon what conditions (if any).<sup>223</sup> Kiss and Shelton (in reference to prior informed consent (PIC) often used interchangeably with AIA) state that PIC is a procedural mechanism “utilized in advance of activities” in order to avoid potential conflict and reduce the risks of environmental or social harm.<sup>224</sup> It has correctly been argued that only “transparent and comprehensive domestic regulations and procedures” can assist in clarifying some of the areas left unclear by the Protocol.<sup>225</sup> We now examine AIA in Kenya and South Africa.

#### **3.3.4.1 Kenya**

The Bill does not have a specific heading on advance informed agreement (AIA). Instead, it prohibits dealings in GMO activities including transboundary movement of GMOs, without written approval of the NBA.<sup>226</sup> Part three of the Bill prohibits contained use, introduction into the environment, importation and placing on the market and transboundary movement of GMOs without written approval of the NBA. The Bill provides for making application for each of the categories<sup>227</sup> of activities involving GMOs. Upon receipt of an application the NBA shall within one hundred and fifty days acknowledge receipt of the application. Subject to seeking and considering public comments, carrying out risk assessment, and taking into account socio-economic considerations, the NBA shall communicate its final decision of approval or rejection of the application to the applicant within one hundred and fifty days of receipt of the application. In essence the process of AIA under the Bill takes a total of three hundred days.

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<sup>223</sup> Mackenzie and others (explanatory Guide) supra, Pg. 63.

<sup>224</sup> Kiss A and Shelton D, supra, Pg. 257.

<sup>225</sup> Mackenzie and others (Eds) supra, (Explanatory Guide) Pg. 65.

<sup>226</sup> See part three of the Kenyan Bill

<sup>227</sup> Section 14 contained use, s.15 introduction into the environment, s.16 Importation or placing on the Market, s.17 GMOs in transit.

### 3.3.4.2 South Africa

The AIA is dealt with in two ways: under the Act and under the regulations. Section 4 of the GMO Amendment Bill substitutes section 5 of the principal Act in its entirety. The Bill does not contain a separate section dealing with AIA under the Act. Provisions relating to approval of applications are weaved with the powers and duties of the Council. The Bill makes provision for the procedure to be followed by an applicant and the decision making process. Section 5(1) (a) and (b) states thus: “The Council shall -where an applicant applies in the prescribed manner for a permit...in consultation with the committee, decide whether to approve an application...” The Bill makes provision of the issues to be considered when considering an application. These are (subject to the provisions in the Bill), scientifically based risk assessment and proposed risk management measures, public input, EIA and socio-economic. If the Council is satisfied that the application conforms to the factors in section (1) (c) or paragraph (a) it shall authorize the registrar to issue a permit.

Regulation 5(1) requires that certain activities relating to GMOs can only be conducted under authority of a permit issued by the registrar. These activities are specified as import and exportation, contained use, trial release, gene release and marketing of GMOs. The time frame<sup>228</sup> within which the permit shall be issued is also stated for each of the four categories of activities. In this respect, it appears that the registrar usurps the powers of the council.

### 3.3.4.3 A comparative Analysis

Neither the Kenyan Bill nor GMO Amendment Bill adopts the approach provided for by articles 6, 7 and 11 of the Protocol. The two pieces of intended legislations provide the rules, factors to be considered and the procedures to be complied before an application is approved. None of the two Bills restricts itself to “the first intentional transboundary movement”. Part three of the Kenyan Bill repeatedly provides thus: “No person shall conduct...activities involving genetically modified organisms without the written

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<sup>228</sup> The time frame ranges between 30-180 days See Table 1 of the Annexure to the Regulations.

approval of the authority”. The GMO Amendment Bill is silent on first intentional transboundary movement.

In relation to GMOs in transit, whereas Article 6 of the Protocol provides that AIA procedure does not apply to GMOs in transit, the Kenyan Bill requires written approval from the NBA. Section 17(1) of the Kenyan Bill requires that “A person transporting through Kenya” GMOs “which are not destined for use in Kenya shall apply for written approval”. The Kenyan Bill subjects GMOs in transit to approval, but both the GMO Act and the GMO Amendment Bill are silent on GMOs in transit.

Time frames from notifications to final decision making under the Protocol takes a total of three hundred and sixty days but the Kenyan Bill reduces that period to three hundred days. Under the Protocol notification should be acknowledged within ninety days<sup>229</sup> and a final decision made within two hundred and seventy days.<sup>230</sup> Under the Kenyan Bill notification is acknowledged within one hundred and fifty days and a decision made within a similar period in respect of all categories of GMOs.<sup>231</sup> In effect the Kenyan Bill reduces the total duration by sixty days.

The approach of South Africa is different also. The current GMO regulations (Annexure Table 1) provide different time frames for approval of applications for different activities regarding GMOs. It provides thus: Importation and exportation of GMOs 30 days; contained use 30 days; Trial release 90 days and general release and marketing of GMOs 180 days. The Protocol fixes the minimum period of acknowledging notification to be 90 days and 270 days as the minimum duration of decision making. The duration provided for by the GMO Act is below the expectations of the Protocol.

To the extent that GMO Amendment Bill does not provide for approval of applications for GMOs within a period comparable to that of the Protocol or any other reasonable duration as that provided by the Kenyan Bill, its transparency and credibility are

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<sup>229</sup> Article 9(1) Protocol

<sup>230</sup> Article 10 (3) Protocol

<sup>231</sup> Section 20 (10 as read with section 25 (1) Kenyan Bill.

doubtful. Inclusion of substantive provisions on time frames in the Bill would give the AIA procedure more legal protection as opposed to leaving the procedure within the realm of regulations. The danger of failing to provide substantive provisions in the Act and leaving it to the regulations is that regulations can change from time to time as opposed to the substantive rules that can only be amended by an Act of parliament.

As between Kenya and South Africa, the manner in which the two Bills deal with applications is interesting. Whereas the Kenyan Bill provides for “approval or rejection”<sup>232</sup> of the application by the NBA, the GMO Amendment Bill only empowers the Council to “decide whether to approve”<sup>233</sup> an application. A careful construction of the wording in section 5 of the Act<sup>234</sup> technically suggests that the Council has no specific power to reject an application compared with the Kenyan Bill. Second, The Kenyan Bill makes it mandatory for the NBA to give and communicate to the applicant, the reasons for rejection of the application within one hundred and fifty days.

Although the two countries have taken approaches that are substantially inconsistent with the Protocol in relation to AIA, the Kenyan approach gives sufficient protection to the AIA procedure. The procedure provided is clear and understandable. The approach of South Africa is vague, uncertain and ambiguous.

### **3.3.5 Public Participation**

Public participation has been discussed at (2.4.6) but, three observations need to be made here. First, public participation involves many things including “access to, understand, evaluate, formulate and comment” upon proposals, plan and programmes. It therefore forms an integral part of decision making in environmental issues.<sup>235</sup> It has also been recognized and accepted that public participation improves the quality of decisions, enhances environmental problem solving, promotes environmental citizenship and

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<sup>232</sup> Section 25(1) Kenyan Bill

<sup>233</sup> Section 5(1) (b) as set out in section 4 of the Bill

<sup>234</sup> As set out in section 4 of the Bill

<sup>235</sup> Bell and McGillivray argue that envtal law is a political discipline and the public elects environmental law makers hence the public has aright to democratic accountability, see pp. 13 and 337-338..

improves procedural legitimacy.<sup>236</sup> Third, public participation has many challenges. One such central challenge is “to ensure that the quality of the participation is sufficient” to actively engage the public and that “proper opportunity” is given to respond to any consultation exercise.<sup>237</sup> On this basis, it is pertinent that provisions relating to public participation in biosafety legislation must be geared to achieving specific purposes, the ones identified above included. Under the (1998 UN/ECE) Aarhus Convention<sup>238</sup>, public participation must be timely, effective, adequate and formal and contain information, notification, dialogue, consideration and response. We now examine issues of public participation in Kenya and South Africa.

### 3.3.5.1 Kenya

The Kenyan Bill gives the public an opportunity to participate in process of decision making in two ways: providing an opportunity to respond in relation to each application for the release into the environment of a GMO<sup>239</sup> and partial access to information of portions of the applications that are not regarded as confidential.<sup>240</sup> Section 21 (1) and provide thus: “The Authority shall publish in the Kenya Gazette and in at least two newspapers of nationwide circulation” and section 21(2) provides thus: “The public may, within thirty days...respond to the notice and the Authority shall address appropriately any relevant concerns raised by the public”.

The Bill presumes that advertising in the Kenya Gazette and two newspapers constitutes sufficient notice to interested, affected persons and the public. The immediate question that arises is how accessible these papers are? The Kenya Gazette is an official government document that is printed at the government printers in Nairobi (and sold at a fee) and usually distributed to the judiciary and a few other government offices. In many instances the general public does not know the existence let alone the content of that document. Even if the general public were to know of its existence, many of the people

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<sup>236</sup> Bell S and McGillivray D, *supra*, pp. 318

<sup>237</sup> Bell S and McGillivray, *supra*, pp. 339

<sup>238</sup> Adopted on 25<sup>th</sup> June 1998 and entered into force on 30<sup>th</sup> Oct. 2001.

<sup>239</sup> Section 21(2) Kenyan Bill

<sup>240</sup> Section 21(3) Kenyan Bill

would not afford to purchase a copy. The draft constitution 2005 dubbed the *Wako draft* is the first and only government Gazette document the writer is aware of which was distributed ‘free of charge’ in 2005. The general public had to be taught<sup>241</sup> and guided on its content and effect before the document was rejected in a referendum held towards the end of 2005.

The requirement of two newspapers of nationwide circulation has its own problems. These are newspapers meant for commercial purposes and are mostly available to the elite. In most of the remote agricultural areas where GMOs are likely to be grown, many farmers do not get access to nor can some of them afford to purchase newspapers. The situation gets worse during the long or heavy rains when most of the remote areas are not accessible. In as much as communication through the newspapers may be appropriate though not sufficient, accessibility and literacy levels are some of the barriers to effective communication.

Section 21(3) of the Kenyan Bill makes provision for access to portions of an application that do not qualify as confidential information. This provision enables the general public to get access to some of the information contained in the application which would otherwise not be obtainable in the absence of such a provision. The information contained in any such a portion may assist the members of the public who wish to respond to make reasoned comments.

### **3.3.5.2 South Africa**

The GMO Act has no substantive provisions relating to public participation. Currently public participation is provided for in limited ways in the GMO regulations.<sup>242</sup> The regulations require that “The applicant shall notify the public of any proposed release of genetically modified organisms prior to the application for a permit for such release”.<sup>243</sup>

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<sup>241</sup> The writer participated in the creating awareness exercise at Eldoret Kenya one week before the day of the Referendum. Many of the people did not know nor understand what a government Gazette Notice is nor could they understand the content of document on their own.

<sup>242</sup> Section. 6 GMO Regulations 1999 and the Regulations under NEMA

<sup>243</sup> Section 6(1) GMO regulations.

This is to be done by publishing a notice in at least three newspapers circulating in the area in which the proposed release is to take place.<sup>244</sup>

### 3.3.5.3 A Comparative Analysis

The biosafety Bill of Kenya complies with the provisions of the Article 23 in two important ways. Section 42 (1) of the Bill provides for public awareness and participation. The Bill provides for binding obligations by requiring that “The Authority shall promote public awareness and education concerning biosafety matters”. On access to information section 21(3) provides for access to information that does not qualify as confidential in any application and section 42(2) requires thus: “The Authority shall publish notices of final decisions concerning all applications”.

Although the Kenyan Bill appears promising, it is argued that in the local context, the provisions relating to public participation in decision making are inadequate. Advertisement in the Kenya Gazette and two newspapers cannot of itself avail the transparency and predictability envisaged in the objectives of the Bill. The advertisement provided for does not target large numbers of the public as to enable the NBA to rely on such advertisement alone as a basis of concluding that the public is sufficiently aware of such an application. Moreover, it appears that advertisement is to be done only once.

It is suggested that inclusion of communication through electronic media will enhance communication for purposes of satisfying the requirements of section 21 of the Kenyan Bill. The Bill should take advantage of the increasing electronic media houses in Kenya to achieve that purpose. The period of thirty days within which the general public may make comments also appears inadequate. Activities involving GMOs are intricate even to the experts. Hence reasonable time should be given to the general public to consider the notices and make comments. It is also necessary that provision be made for holding a public meeting (*baraza*)<sup>245</sup> at the intended scene to enable the poor peasants express their views as well.

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<sup>244</sup> Section 6(2) as read with section 6(4) GMO regulations

<sup>245</sup> This a typical name for public meeting among Kenyans

In relation to public participation, South Africa has taken a somewhat different approach. The GMO Act has no provisions relating to public participation (see below). Currently public participation is provided for in limited ways in the GMO regulations.<sup>246</sup> Section 6(4) of the regulations require an applicant for a permit to notify the public of any proposed release of GMOs prior to the application for a permit for such release by publishing a notice “in at least three newspapers circulating in the in which the proposed release is to take place”. There is no requirement to publish any such notice in the government Gazette as in the case of Kenya.<sup>247</sup> Section (6) (6) requires the registrar to refer any comments or objections received from interested parties to the Council. Although the council is required to “consider all the comments and objections” when considering an application for release of GMOs<sup>248</sup> but there is no corresponding duty to publish the decisions concerning applications.

Even in these limited ways the regulations merely offer lip service to public participation. The regulations were made without a biosafety policy in place, (a similar predicament of the Bill). Public participation is apparently directed to a section of the public that has access to the print media only. No provisions are made as to the period within which such comments are to be made and in what manner. It may also be argued that the requirement to ‘consider’ the comments from the public (in granting or refusing an application for a permit by the council) is vague and may not be of any practical value unless the final decisions are published (as provided by S. 25 of the Kenyan Bill). This may reduce the expenses and time involved in seeking judicial remedies.

As indicated above, the Bill also has no substantive provisions on public participation. It provides thus:

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<sup>246</sup> Art. 6 GMO Regulations 1999 and the Regulations under NEMA

<sup>247</sup> Section 21(10) Kenyan Bill

<sup>248</sup> Section 6(7) GMO Regulations, *supra*

The council may before making a decision regarding an application submitted in terms of this section consider the following factors:

- i. public input
- ii. the environmental impact assessment or
- iii. the potential socio-economic impact of such activities<sup>249</sup>

The term public ‘input’ is not defined. In any event public input cannot be a substitute for the public awareness and participation envisaged by the Protocol unless a broader definition is to be provided. Unlike the Biosafety Bill of Kenya<sup>250</sup> which requires the NBA to “promote public awareness and education concerning Biosafety matters”,<sup>251</sup> the GMO Amendment Bill of South Africa does not contain similar provisions. Lack of such or any other similar provisions arguably absolves the government, whether intentionally or not, from its treaty and national responsibility to promote and facilitate these essential tenets of public participation. Moreover the reference to ‘public input’ is only limited to decision making in respect to an application for a permit and the provision to consider public input is discretionary as it uses the word “may” as opposed to the Kenyan mandatory one which uses the word ‘shall’.

Both the GMO Act and the GMO Amendment Bill of South Africa are far from complying with the Protocol insofar as public participation is concerned. On the other hand, by failing to provide for publication of the final decision, the Act is not only inconsistent with Article 23(2) of the Protocol, but it is also inconsistent with section 32 of the Constitution which provides for the right to access to information and the provisions of PAIA. To this extent it is tenable to suggest that issues of public participation ought to be addressed if biosafety legislation of South Africa is to comply with the Protocol and also be acceptable and meaningful domestically. Failure of the Act to provide for public participation can be regarded as fatal to the biosafety legislation of South Africa. The provisions in the GMO Amendment Bill can, in the words of Bell and McGillivray, be regarded as “icing on the cake”.<sup>252</sup> Moreover, information provision and

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<sup>249</sup> Section 5 of the Act as set out in section 4 of the bill

<sup>250</sup> Section 7(i) Kenyan bill

<sup>251</sup> Section 42(1) Kenyan Bill

<sup>252</sup> Bell S and McGillivray D, *supra*, Pg.. 339

the enabling of participation are central to ensuring that biotechnologies become “accepted by a skeptical and worried public”.<sup>253</sup>

In relation to both regimes, whereas under the Kenyan Bill it is the obligation of the NBA to conduct the public participation, under the GMO Act that obligation is imposed on the applicant. The NBA is required to publish the notices in the government Gazette and receive the comments from the public within thirty days and “shall address appropriately” the relevant concerns raised by the public”. In the case of South Africa, the GMO regulations require the applicant to publish the notice in three newspapers circulating in the relevant area and the registrar shall refer the comments or objections to the Council. The Council shall consider “all the comments and objections when considering an application for release”. The Kenyan Bill uses the words “shall address appropriately” the concerns raised whereas the GMO regulations requires the Council to “consider” the comments and objections raised.. The difference between the two terminologies may not be as material as the extent to which the concerns raised are taken into account in the decision making. Since the GMO regulations do not provide for publication of the decision reached by the Council it is difficult to tell whether and the extent to which the comments and concerns raised have been taken into account.

### **3.3.6 Risk Assessment and Risk Management**

The objective of risk assessment is to identify and evaluate the potential adverse effects of LMOs in the likely potential receiving environment taking also into account risks to human health.<sup>254</sup> It has been argued that the nature and extent of risk to the environment and human health is one of the factors placed into a balance in environmental decision making.<sup>255</sup> Risk assessment and risk management are sensitive issues in biosafety legislation. We now compare the approaches of Kenya and South Africa.

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<sup>253</sup> ‘Public participation and the Cartagena Protocol on Biosafety’ January Report 2003, supra, pp. 24

<sup>254</sup> Annex III Protocol

<sup>255</sup> Bell S and McGillivray D, supra, Pg. 53

### 3.3.6.1 Kenya

Risk assessment under the Bill is conducted by the NBA. Section 22(3) provides thus:

The authority shall conduct a risk assessment as required and shall audit risk assessment information submitted by the applicant

The risk assessment shall be undertaken as set out in the fifth schedule of the Bill.<sup>256</sup> The fifth schedule provides the objectives and the general principles governing risk assessment. Whereas the objective of risk assessment under the fifth schedule is to identify and evaluate the potential adverse effects of GMOs on the environment, it also enables the authority make informed decisions. In relation to the general principles, two such principles require special attention. Risk assessment shall be carried out in a scientifically sound and transparent manner. Two lack of scientific knowledge or scientific consensus shall not necessarily be interpreted to indicate a particular level of risk, an absence of risk or an acceptable risk. (See the discussion on these two principles in chapter two).

The NBA has the onerous task of undertaking a transparent risk assessment. Two aspects may enable the NBA to achieve this objective. It has the power to appoint such officers and other staff as are necessary for the proper discharge of its functions.<sup>257</sup> Second, it has the power to either generally or in any particular case, delegate the exercise of any of its powers under the Act to persons including any officer.<sup>258</sup> A combination of these two provisions suggests that the NBA may recruit or contract an expert to carry out the risk assessment or use its own staff.

Whether the risk assessment shall be transparent is a matter of fact that may be deduced from the appeals and judicial challenges that may ensue. In the alternative or in addition, scrutiny by an independent assessor or the public (none of which is provided for) may also provide a test in that regard. Although the NBA is obligated to publish the application for purposes of public comments, there is no provision for publishing the final decision. This means that the public have an opportunity (though limited) to participate in

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<sup>256</sup> The fifth schedule of the Kenyan Bill.

<sup>257</sup> Section 12 Kenyan Bill

<sup>258</sup> Section 9 Kenyan Bill

the process of decision making but they do not have a corresponding opportunity to know the final decision made by NBA. In order for public participation to be meaningful and transparency to be achieved, it is imperative that the final decision of the NBA be published as well. Arguably, publication of the final decision is an essential element of the transparency and predictability envisaged by the objectives of the Bill.

On risk management section 22(4) of the Kenyan Bill imposes an obligation on the NBA to “indicate any measures to be taken to ensure the safe use” of the GMO upon completion of its report on risk assessment, while section 22(5) requires the authority to “liaise” with the appropriate regulatory agency “to ensure that measures are in place to manage and control risks identified during the risk assessment process”. In cases of unintentional release into the environment the regulatory agency “with knowledge” of such unintentional release shall “within twenty-four hours” when the regulatory agency knew of the introduction, report to the NBA.<sup>259</sup> However the Bill does not indicate the manner of reporting such an accident.

### **3.3.6.2 South Africa**

Neither the current GMO Act nor the GMO Amendment Bill contains substantive specific provisions governing risk assessment. The Act merely empowers the council to call for a risk assessment.<sup>260</sup> Section 5(a) of the current Act provides thus: “the council may—require any applicant for a permit... to submit to the Council...an assessment of the risk” Bu the GMO Amendment Bill removes that power and instead provides that “the Council shall-...determine whether the applicant must, in addition to his or her application, submit an assessment of the impact on the environment”.<sup>261</sup>

A careful analysis of these provisions together with the provisions of section 5(2) (a), makes it apparent that EIA is not mandatory under the biosafety regime, (the provisions of NEMA apart). It has been argued that the power to determine provided for in section 5(1) (a) of the Act<sup>262</sup> is of a narrow application as most of the permitted activities do not

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<sup>259</sup> Section 33(1) Kenyan Bill.

<sup>260</sup> Section 5(a) of the Act

<sup>261</sup> Section 5(1)(a) as set out in section 4 of the bill

<sup>262</sup> As set out in section 4 of the GMO Amendment Bill

involve genetic modification, such as import, export or release of a GMO.<sup>263</sup> The problem is exacerbated as GMOs are only subject to a basic assessment<sup>264</sup> as opposed to scoping and EIA.<sup>265</sup> It has authoritatively been stated that EIA is fundamental to any regulatory system which seeks to prevent or minimize environmental harm as it provides decision makers with information about possible environmental effects.<sup>266</sup> By exercising his discretion to subject GMOs to a basic assessment,<sup>267</sup> the minister arguably takes a lesser strict view of the potential harm of GMOs thereby exposing the bias of the Act and the Bill in aggressively promoting GMOs in South Africa rather than taking a holistic approach so as to consider and accommodate all other relevant factors.

Both the Act and the Bill embrace risk assessment carried out in a scientific manner. This is clear as all the relevant sections repeatedly refer to ‘scientifically based risk assessment’.<sup>268</sup> Considering that genetic engineering is scientific in nature, it is only practicable that risk assessment is carried out in a sound and scientific manner. Arguably, that may not be problematic in itself. Problems arise when (as in the present case) decision making is based purely on the scientifically based risk assessment to the exclusion (or inadequate consideration) of other pertinent and relevant factors such as socio economic considerations.

The GMO Amendment Bill empowers the council to take into consideration the scientific based risk assessment and proposed risk management measures in considering an application.<sup>269</sup> Two observations need to be made in respect to this requirement. First it excludes socioeconomic considerations (which are discussed below) when considering an application. Secondly the provision relating to lack of scientific knowledge or scientific consensus having no effect on risk assessment confirms the uncertainty inherent in modern biotechnology. Having recognized so, there is no justification for failure of the

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<sup>263</sup> Eastwood J, *supra*.

<sup>264</sup> NEMA regulations published as LN No. 28753 (Notice No. R 386). of 21<sup>st</sup> April 2006.

<sup>265</sup> NEMA regulations published as LN No. 28753 (Notice No. R387) of 21<sup>st</sup> April 2006.

<sup>266</sup> Birnie and Boyle, *supra*, Pg. 130

<sup>267</sup> Under NEMA regulations

<sup>268</sup> See examples in section 5(c) as set out in section 4 of the bill and section 18(b0 as set out in Section 12 of the bill.

<sup>269</sup> Section 5(c) of the Act as set out in section 4 of the bill.

Bill to make specific provisions for application of the precautionary approach discussed above. However, considering that South Africa is the sixth top grower of GMO crops globally (and the leading in Africa),<sup>270</sup> it is unlikely that a restrictive risk assessment regime will be promoted. In any event there are no provisions for subjecting the risk assessment to an independent assessor (save for the NEMA regulations) or auditing hence raising questions of accuracy and transparency of such assessments.

On risk management, neither the GMO Act nor the GMO Amendment Bill contains provisions on the risk management. Only the regulations make provision for accidents arising from GMOs and require that “the registrar is notified immediately both verbally and in writing” of such an accident.<sup>271</sup> There are no requirements for monitoring an LMO for a period commensurate to its life–circle or any other period before it is introduced to the environment or released for commercial purposes as required by the Protocol.<sup>272</sup> This implies that an LMO can be released so long as the requirements as to risk assessment are complied with for purposes of obtaining a permit. This situation suggests that neither the Act nor the bill is geared towards protection of the environment and human health insofar as risk management is concerned.

### 3.3.6.3 A Comparative Analysis

Although the Protocol adopts a scientific approach and, provides no substantive guidance on scientific uncertainty in relation to risk assessment,<sup>273</sup> it does not inhibit the sovereign right of a state to take action that is more protective of its biological diversity.<sup>274</sup> Moreover the Protocol gives a wide discretion to states to take ‘appropriate legal, administrative and other measures’ in order to comply with their obligations under the Protocol.<sup>275</sup>

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<sup>270</sup> After US, Argentina, Canada, Brazil and China, see ‘Genetically engineered crops: Sacrificing the Rights of future generations’ Briefing Paper No. 1 available at [www.biowatch.org.za](http://www.biowatch.org.za) last visited on the 15<sup>th</sup> Jan 2007.

<sup>271</sup> Section 7 of the Regulations under the GMO Act.

<sup>272</sup> Article 16(4) Protocol

<sup>273</sup> Annex III Protocol.

<sup>274</sup> Art. 2(4) Protocol.

<sup>275</sup> Art.2(1) Protocol.

Whereas risk assessment under the Kenyan Bill is conducted by the NBA, the GMO Act has no specific provision as to who should conduct risk assessment. However from the wording of section 5(1) the applicant shall be required to submit “an assessment on the impact on the environment” if the Council determines that such an assessment needs to be submitted implies that it is the responsibility of the applicant to conduct an assessment, in case it will be needed. As noted above the Kenyan Bill makes specific provision empowering the NBA to conduct a risk assessment.<sup>276</sup> The requirement to “audit risk assessment information” submitted by the applicant would suggest that the applicant must have already done a risk assessment of his own. Otherwise the applicant would hardly provide information on “suggested methods for safe handling, storage, transport and use” required under the fourth schedule of the Kenyan Bill. Auditing the risk assessment information submitted by the applicant is presumably intended to confirm whether the risk information submitted by the applicant is consistent with or at variance with the findings of the risk assessment carried out by the NBA.

The Kenyan Bill is silent on who pays the costs of the risk assessment. However, since the NBA is obligated to carry out risk assessment, a reasonable inference may be drawn that the authority bears the costs. In as much as the NBA may have the expertise and personnel (and this doubtful), lack of funds is likely to be a barrier in some instances. It should be noted that environmental issues compete for funds with critical ministries such as defence, health and education, only to mention a few. There is usually a likelihood of giving environmental issues less attention when it comes to government funding. In such cases, the NBA may lack sufficient funds and thereby do shoddy work (or none at all) thereby affecting the quality of the risk assessment to be carried out.

On risk management section 22(5) of the Kenyan Bill requires the NBA to liaise with the appropriate regulatory agency “to ensure that measures are in place to manage and control risks identified during the risk assessment process”. In contrast, the GMO Amendment Bill provides that in considering an application the Council shall have regard to “proposed risk management measures”. The approach contained in the Kenyan Bill is

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<sup>276</sup> Section 22(3)

advantageous for two reasons. The risks to be managed are those the NBA identified itself. Second, the appropriate regulatory agency is in one way or the other accountable to the NBA. In the case of South Africa, the GMO Amendment Bill only requires that the proposed risk management measures are considered when considering an application. The powers entrusted to the registrar under the provisions of section 9(d)<sup>277</sup> of the Act may be exercised to ensure that “all users apply the appropriate measures to protect the environment and human and animal health during the exercise of any activity” with GMOs. Yet this is premised on the condition that “the registrar satisfies himself or herself” that all such measures are applied.

Compared with the provisions of the protocol on risk assessment (discussed in chapter two) it would appear that the Kenyan Bill sufficiently adopts the criteria provided in Annex III of the Protocol. The provisions of the fifth schedule of the Bill are in material aspects, similar to the provisions of Annex III of the Protocol. However whereas section six of Annex III provides for the carrying out risk assessment on case by case basis, the Bill is silent regarding the same.

Provisions on risk management in both countries are lacking in material aspects. Neither the Kenyan Bill nor GMO Amendment Bill has provisions requiring that a GMO undergoes observation commensurate to its life-circle before it is put into its intended use. Although the Protocol’s use of the word “endeavour to ensure”<sup>278</sup> suggests that this obligation is not mandatory, it is nevertheless reasonable that such a provision be included in the resultant legislation if an adequate (or a more protective) level of protection is to be achieved as envisaged in section 4(a) of the Bill as read with Article 2(4) of the Protocol.

From the foregoing it would justifiable to assert that, the GMO Amendment Bill is far from complying with the Protocol insofar as risk management is concerned. Whether new or revised regulations are to contain rules on risk management, such rules will not be a

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<sup>277</sup> As set out in section 6 of the GMO Amendment Bill

<sup>278</sup> Article 16(4) Protocol

substitute for substantive provisions of law. In any event, any such regulations will be subject, to the discretionary powers of the Council and the Minister.

Absence of adequate provisions on risk management in the GMO Amendment Bill may be cured by an array of the provisions of section 28 NEMA, on duty of care.<sup>279</sup> The duty of care imposes an obligation on every person who causes, has caused or may cause significant pollution or degradation of the environment, to take reasonable measures to prevent such pollution from occurring, continuing or recurring. Though NEMA may, cure some of the deficiencies on risk assessment and risk management inherent in the GMO Amendment Bill, the provisions in NEMA cannot be a substitute for biosafety legislation.

### **3.3.7 Socio-Economic Considerations**

Although the scope of socio-economic considerations to be taken into account under Article 26 of the Protocol is narrow, its provisions are clear and specific though weak by reason of use of the words “may take into account”. The importance of socio-economic considerations in the decision making process cannot be underscored. Failure or insufficient consideration of socio-economic factors in decision making, offends the principle of intergenerational equity. Maggio asserts that intergenerational equity constitutes a bridge for recognized mutual interests between environmental protection, socio-economic development and human rights law. Hence, further observes, striking a balance between current consumption and foregoing use of resources for future generations, has been a consideration of all societies.<sup>280</sup> Kenya and South Africa have taken different approaches as seen below.

#### **3.3.7.1 Kenya**

The Kenyan Bill makes consideration of socio-economic factors mandatory.<sup>281</sup> This, it is argued, is the main driving force on socio-economic considerations in the Bill. The Bill

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<sup>279</sup> Section 2(1) as read with section 2(vii) NEMA

<sup>280</sup> Maggio G, ‘Inter / Intra-generational Equity:Current Applications under International law For promoting the Sustainable development of Natural Resources, 4 Buff. Envntal L.J. 161 1996 – 1997 at 163 – 166.

<sup>281</sup> Section 24(1) Kenyan Bill

requires that in reaching a final decision, the NBA “shall take into account” several factors one of which is the socio-economic considerations arising from the impact of GMOs on the environment.<sup>282</sup> No further details are given. It has been argued that for the biosafety regulatory system of Kenya to be fair predictable and transparent, the details surrounding the inclusion of socio-economic considerations should be spelt out in more detail than is currently available in the Kenyan Bill.<sup>283</sup> However, failure to provide details cannot be dismissed as having an entirely negative effect. It may be understood to imply that the Bill gives the NBA wider discretion in determining which socio-economic considerations are relevant and applicable in a particular ecological or other setting. Secondly, the details can be provided for in the regulations and policy once in place.

Whereas the Protocol is concerned with the impacts arising from LMOs the Kenyan Bill not only complies with the Protocol in that respect, but it goes beyond the criteria set by the Protocol. It requires that the socio-economic considerations are those that arise from GMOs. This means that the Protocol is concerned with impacts of living organisms only while the Kenyan Bill applies to impacts of both living and non-living organisms on the environment. However the Bill is lacking insofar as it does not put emphasis on the value of biological diversity to the indigenous and local communities. The Bill may have deliberately avoided reference to “indigenous and local communities” probably for historical and political reasons. Apparently, determining who is and who is not indigenous is a sensitive political question to answer in Kenya today, especially when looked at from indigenous land rights in the context of colonialism. In any event the present wording of section 24(1) (e) is all-encompassing and as the word “environment” has many definitions,<sup>284</sup> it does not exclude the interests of the indigenous and local communities envisaged by Article 26(1) of the Protocol.

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<sup>282</sup> Section 24(1) (e) Kenyan Bill

<sup>283</sup> Jaffe G, *supra*(Comparative Analysis) pp. 32

<sup>284</sup> Bell S and McGillivray (*supra* pp. 7) assert that environment is a phrase with no singular definition and its normal meaning relates to surroundings.

### 3.3.7.2 South Africa

The current GMO Act is silent on socio-economic considerations in decision making. Section 5(g) of the Act provides that after consideration of the “risk assessment” and where required, “the environmental impact assessment”, the council may authorize the registrar to issue a permit for the purpose for which the application was made or for the release of a GMO into the environment. By stating what is to be considered in making a final decision, the Act out rightly ignores socio-economic considerations.

The GMO Amendment Bill 2005 introduces socio-economic considerations into the decision making process but in a weak and inconsistent manner. Section 5(1) (a) states thus:

The council shall-where an applicant applies...for a permit...determine whether that applicant must, in addition to his or her application, submit an assessment of the impact on the environment and socio-economic considerations of such activities<sup>285</sup>.

It is clear from this provision that socio-economic considerations are to be considered only when the council has determined that an assessment of socio-economic considerations is necessary. Moreover section 5(2)(a)<sup>286</sup> provides that when making a final decision the council “may” consider public input, environmental impact assessment *or* the potential socio-economic impact of such activities.

A careful construction of the wording of section 5(1) (a) and section 5(2) (a) <sup>287</sup> clearly suggests that in making a final decision, the council may consider either EIA or the potential socio-economic impact of such activities but not both. In any event, in some instances socio-economic considerations may not be taken into account. This is possible for two reasons. Where in the first instance the council in exercise of its powers under section 5(1) (a) determined that the applicant need not submit an assessment of socio-economic considerations. Having made that decision, the council cannot purport to take into account a non-existent assessment of socio-economic considerations in making its

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<sup>285</sup> Section 5(a) as set out in section 4 of the Bill.

<sup>286</sup> As set out in section 4 of the Bill

<sup>287</sup> As set out in section 4 of the Bill

final decision. Having determined that the applicant need not submit an assessment of the socio-economic considerations in the first instance, any attempt to require the applicant to submit an assessment of the socio-economic considerations at the time of final decision making is not only contradictory but it amounts to an abuse of the procedure and hence, objectionable.

Second, when making the final decision, the council may, apart from public input, consider EIA or socio-economic considerations, not both. Moreover, the elements of consistency and predictability are eroded by the existence of double standards. If socio-economic considerations are regarded as relevant they ought to should be considered from the beginning to the end. By failing to make a clear and unambiguous provision safeguarding the role of socio-economic considerations in decision making, it is argued that the Bill is not, in any material way, responsive to the findings in the landmark case of *BP Southern Africa (Pty) Ltd v MEC for Agriculture, Conservation and Land Affairs*.<sup>288</sup> In that case a dispute arose as to whether socio-economic considerations were relevant as a basis of refusing authorization to put up a filling station adjacent to other already existing stations. The court held that “the balancing of environmental interests with justifiable socio and economic development is to be conceptualized well beyond the present living generation”. The court observed further that section 24 of the constitution envisaged that the environment must be protected for the benefit of present and future generations.<sup>289</sup>

Although the Bill makes limited provisions relating to socio-economic considerations, the provision is a general one and does not specify the source and the areas likely to be affected most by the impact as envisaged by the Protocol. The Protocol is concerned with impacts arising from Modified Living Organisms (LMOs) and it puts emphasis on the value of biological diversity to the indigenous and local communities. The Bill neither makes reference to any these two aspects in its provisions on socio-economic considerations nor the environment. It merely states that before making a decision, the

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<sup>288</sup> 2004(5) SA 124(W)

<sup>289</sup> At 143D

socio-economic impact of the activity may be taken into account as an alternative to EIA and vice-versa.<sup>290</sup>

Failure of the Bill to make consideration of socio-economic considerations mandatory, may adversely affect the livelihood and interests of the poor population which, many times, does not afford sufficient food and shelter. In these circumstances, it is tenable to maintain that the Bill is inadequate. In addition, the Bill contradicts the draft Biosafety policy<sup>291</sup> published alongside the Bill. Section 3(30) of the draft policy states that “[t]he socio-economic and cultural factors,... must be taken into account” Apart from the likelihood of causing problems in implementation (due to inconsistency) if and when enacted, it leaves the question as to what and whose interests the resultant biosafety regime will serve, unanswered. Yet, considering that historically and even presently, the Act is serving the interests of the multinational companies and the biotechnology industry, it is acceptable to argue that the resultant legislation will, to a greater extent, still serve those same interests. Consequently to the extent that the Bill does not build a strong case for socio-economic considerations, it substantially retains the weak character of the parent act.

### **3.3.7.3 A Comparative Analysis**

From the foregoing, it is discernable that the two countries have attempted, though differently, to implement Article 26 of the Protocol. The Kenyan Bill adopts an approach which goes beyond the scope of the Protocol by addressing GMOs as opposed to LMOs. Like the Protocol the Kenyan Bill identifies GMOs as the source of the potential impacts. However it does not place emphasis on biological diversity in the manner the Protocol does. Instead, the Kenyan Bill refers to the environment generally. On the other hand, the Kenyan Bill contains mandatory provisions that require the NBA to take socio-economic considerations into account in decision making. That as it may be successful application of the provision cannot be ascertained unless and until it stands judicial or other test of the time.

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<sup>290</sup> Section 5 (2) (a)

<sup>291</sup> Department of Agriculture: Biosafety Policy GN No. 27913 of 26<sup>th</sup> August, 2005

The GMO Amendment Bill of South Africa provides for taking into account of socio-economic considerations though in a manner that leaves many loopholes which makes it possible for socio-economic considerations to be ignored or avoided altogether in the decision making process. By requiring the council to determine whether or not the applicant must submit an assessment of socio-economic considerations in addition to the application the provision renders consideration of socio-economic considerations discretionary. By making socio-economic consideration an alternative to EIA the Bill adopts ‘a plus and minus’ approach thereby lacking the much needed consistency and predictability in decision making.

An interesting trend is obtainable from the approaches taken by both countries. Whereas the GMO Amendment Bill of South Africa contains weak provisions relating to socio-economic considerations, the courts<sup>292</sup> have, prior to drafting of the Bill, strongly supported their consideration as an integral part of sustainable development. In that sense the Judiciary in South Africa has played a critical role in the development of environmental law and protection of the environment against the potential impacts of GMOs. In the case of Kenya the provisions on socio-economic considerations in the Kenyan Bill appear workable but unless tested, their effectiveness may not be ascertained fully. Since the courts in South Africa have already set higher standards than those set by the Bill, it serves no meaningful purpose for the Bill to maintain its current weak position. Secondly the attempt to comply with the Protocol in relation to socio-economic considerations has failed to the extent that the Protocol does not provide socio-economic considerations as an alternative to EIA. Adoption of the Kenyan approach is an acceptable starting point.

### **3.3.8 Monitoring**

Monitoring is the continuous assessment of information and comparing it to mandated parameters.<sup>293</sup> It has been defined as the repeated measurement of three separate but

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<sup>292</sup> See the Case of ‘BP’ note 96

<sup>293</sup> Kiss and Shelton, *International Environmental Law*, 3<sup>rd</sup> Ed. 2004, Transnational Publishers, New York

related factors: the quality of the environment and each of its compartments, activities or natural and anthropogenic inputs which may affect the quality of the environment and the effects of such activities.<sup>294</sup> Monitoring is used by states to “observe, measure, evaluate and analyze, by recognized scientific methods the risks or effects of pollution or environmental harm”.<sup>295</sup> Kiss and Shelton observe that monitoring provides constant feedback for decision making, from long-term protection to rapid guidance in emergency situations. They argue that to ensure progress the effectiveness of the monitoring must itself be monitored and assessed.<sup>296</sup> In the absence of provisions or adequate provisions on monitoring, it would be difficult to determine levels of performance and how to improve the regime due to lack of feedback. Whereas Kenya has some provisions on monitoring, South Africa has none as seen below.

### **3.3.8.1 Kenya**

Monitoring under the Bill is done by the regulatory agencies<sup>297</sup> and through inspection.<sup>298</sup> Section 32(1) provides thus: “...the authority may require regulatory agencies... to carry out...monitoring, inspecting and evaluating activities” involving GMOs. Section 32(2) requires regulatory agencies to monitor an applicant’s activities but only where it is appropriate to do so. When so doing, the regulatory agency has two obligations: to ensure that the applicant’s activities comply with the requirements of the Act and any conditions imposed in connection with an approval under the Act. Two, to inform the NBA with immediate effect any new scientific information the agency becomes aware of that may pose potential biosafety risks not known previously. The agency shall also inform the NBA of the measures to be put in place to ensure the ‘continued safe use’ of the GMO.<sup>299</sup>

On inspection, section 36 imposes an obligation on the inspector appointed under section 34 to monitor compliance with the Act and the regulations thereto, and submit inspection

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pp. 268

<sup>294</sup> 1992 OSPAR Convention, Annex IV Art. 1

<sup>295</sup> Birnie and Boyle *supra*, pp. 130

<sup>296</sup> Kiss and Shelton, *supra*, pp. 268

<sup>297</sup> Section 32(2) Kenyan Bill

<sup>298</sup> Section 36 Kenyan Act

<sup>299</sup> Section 32(3) Kenyan Bill

reports to the authority. Although the bill does not specify the intervals at which such reports shall be submitted, this may be specified in the regulations.

The Protocol imposes two obligations for a party: to monitor the implementation of its obligations under the Protocol and to report to the conference of the parties serving as the meeting of the parties to the Protocol (COP / MOP) on measures it has taken to implement the Protocol. By requiring regulatory agencies to monitor the applicant's activities and the inspector to monitor compliance with the Act and the regulations thereto, the Kenyan Bill is substantially consistent with the Protocol insofar as monitoring is concerned.

Although the provisions on monitoring contained in the Bill substantially conform to the requirements of the Protocol, it must be noted that the Protocol imposes minimum standards and not the ceiling. Insofar as the NBA has supervisory powers that enable the NBA to require regulatory agencies to monitor, inspect and evaluate activities involving GMOs it is only meaningful that as far as possible, determined parameters be provided (especially in the regulations) against which monitoring can be tested. The Bill does not enumerate some of the areas that monitoring must cover. On the other hand, the Bill does not specify the intervals within which monitoring, inspection and reporting are done. The immediate reporting provided for under section 32(3) of the Kenyan Bill relates to situations where the regulatory agencies become aware of significant new scientific information relating to approved activities that may pose potential biosafety risks that were not known previously. Apart from that provision, regular and continuous reporting is not provided for thereby depriving the NBA the necessary feedback needed for decision making. Although the NBA may have records of all biotechnology and biosafety activities<sup>300</sup> that record must be based on accurate and regular data collection.

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<sup>300</sup> Section 7(g) Kenyan Bill.

### **3.3.8.2 South Africa**

Neither the GMO Act nor the GMO Amendment Bill nor the regulations have any provisions on monitoring. The powers given to the inspectors pursuant to sections 15 and 16 of the Act are basically policing in nature with a view of detecting breaches of the Act. No provision is made for the collection of data or keeping biosafety records. The ensuing situation places South Africa in a deplorable position in relation to information gathering and information exchange.

### **3.3.8.3 A Comparative Analysis**

The biosafety Bill of Kenya has substantive provisions on monitoring and it imposes an obligation on regulatory agencies to monitor activities involving GMOs under their respective mandates.<sup>301</sup> Pursuant to the provisions of section 7(g) the NBA is obligated to “keep a record of biotechnology and biosafety activities in Kenya”. These provisions are sufficiently compliant with the provisions of Article 33 of the Protocol.

In the case of South Africa, no attempt has been made or at all to comply with the Protocol in the area of monitoring. Interestingly, under the GMO Amendment Bill, the registrar has powers to “communicate to the Biosafety Clearing House information specified in the regulations”. The current regulations are silent on monitoring yet a member state is required to report to the COP/MOP on “measures it has taken to implement the Protocol”.

### **3.3.9 Conclusion**

Implementation of the Protocol in the two countries is taking two different dimensions. Whereas Kenya has drafted the biosafety Bill 2005, South Africa is in the process of amending the current GMO Act “so as to give effect to international agreements” pertaining to GMOs. The effect of these two approaches is that the Kenyan Bill makes provisions governing GMO Activities as a whole while the approach taken by South Africa is specifically intended to fill gaps in the GMO Act that otherwise make the Act

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<sup>301</sup> Section 32(1-3) Kenyan Bill

inconsistent with international agreements pertaining to GMOs. These approaches are likely to give different results if and when the two Bills are enacted into law. Whereas the GMO Amendment Act will not adequately fill the gaps in question, the Kenyan Bill has made admirable attempts to comply with the Protocol compared to South Africa in the context of the themes under focus in this study.

The GMO Amendment Bill was drafted on an erroneous assumption that the current GMO Act is satisfactory save for the need to comply with the Protocol. The current GMO Act needs amendments not only for the purposes of complying with international agreements on biosafety but also because the legal regime established under the Act is glaringly inadequate and attempts to fill gaps cannot 'salvage' the Act. Attempts made to comply with the Protocol have also failed. The fact that the GMO Amendment Bill has no provisions relating to: objective, precautionary principle, public participation and monitoring as provided for by the Protocol or at all. Provisions (or lack of them) on risk assessment and risk management, is worrying. Currently, many of the inherent weaknesses of the GMO Act have been addressed mainly by NEMA to the extent that the GMO Act is like 'a fly on the shoulders of NEMA'. We now turn to the summary, conclusion and recommendations.

## CHAPTER FOUR

### SUMMARY CONCLUSION AND RECOMMENDATIONS

#### 4.1 Summary

The competing paradigms involving Scientists, industry, powerful nations and multinational companies worldwide, coupled with ethical, political, cultural issues arising from modern biotechnology and public demands for transparency, and other factors, have made biosafety legislation a complex and sensitive issue globally. The ensuing cold war between the proponents and opponents of genetically modified organisms (GMOs), has made it difficult, if not impossible, for the international community to accept and develop a holistic biosafety regime. Adoption of the Cartagena Protocol (the Protocol) in year 2000 was a result of a compromise reached between the two polarized camps in default of collapse of the negotiations prior to adoption of the Protocol. Efforts by Kenya and South Africa to comply with the provisions of the Protocol must grapple with the above imperatives and as a result, such efforts have not only (largely) failed but they are slow and have been and are being resisted. That being the case, developing holistic biosafety legislation that is relevant and workable in the two countries (and Africa as a whole) is at a minimum, an uphill task that is problematic and unforeseeable if not mired in controversy.

#### 4.2 Conclusion

The fact that legal regulation of modern biotechnology is a complex and an emotive issue has made legal regulation of modern biotechnology in South Africa and Kenya an intricate process. The various competing socio-economic, cultural, political and other interests have made it invariably difficult for the two countries to establish holistic biosafety regimes. Attempts to establish and maintain a balance between environmental protection, risks to humans and avoiding over-regulation of modern biotechnology have become political questions that are not easy to reconcile. This is so because there are powerful forces and nations which have vested commercial and political interests in GMOs. Referring to advances in biotechnology, Juma succinctly states thus:

These advances are taking place in an era of globalization and market liberalization that promotes greater competition among nations and regions around the world. The ability of any one country to compete effectively in this emerging global market is largely dependent on its technological capabilities. As a result one cannot easily separate debates on the commercialization of biotechnology products from the larger competition among nations and among multinational corporations in the global market. Within this context, current debates about biotechnology's impact on economic structures, human health and the environment co-exist within the broader framework of market liberalization and its implications for existing patterns of agricultural production in different parts of the world.<sup>302</sup>

This explains why modern biotechnology is part of a web of global concerns whose regulation cannot be divorced from the competing and quite often, irreconcilable interests that affect the content of biosafety legislation in many countries, Kenya and South Africa included. It is for this reason that attempts to develop biosafety legislation in the two countries must grapple with the forces which have a direct interest in the content and character of such legislation. Multinational companies such as Monsanto (supported by their governments and the host governments), are aggressively promoting GMOs in South Africa and Kenya and efforts to pass restrictive biosafety legislations are being resisted by such promoters. The close cooperation between scientists, industry and government in what is now termed as the "triple helix" which is responsible for the rapid adoption of transgenic crops, has resulted in loss of confidence<sup>303</sup> in the ability of governments to pass biosafety laws that are more protective of the environment and human health. South Africa and Kenya are not exceptions.

Caught up in this scenario, Kenya and South Africa have adopted different approaches to biosafety regulation. Kenya drafted the Biosafety Bill 2003 which never saw the light of the day. It has since been replaced by the Biosafety Bill 2005. South Africa has the GMO Act which became operational on 1<sup>st</sup> December 1999. The GMO Amendment Bill 2005 is primarily intended to make the GMO Act compliant with international agreements, the Protocol being one such a global treaty. This is to be achieved by filling the gaps in the GMO Act.

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<sup>302</sup> Juma C, *supra*, pp. 266.

<sup>303</sup> Juma C, *supra*, pp 268.

This study set out to compare implementation of the Protocol in Kenya and South Africa. The Kenyan biosafety regime was examined in the context of the biosafety Bill 2005 and the biosafety regime of South Africa in the context of the GMO Act and the GMO Amendment Bill 2005. The main goal of the study was to establish the extent to which current and proposed biosafety legislation in South Africa and proposed biosafety legislation in Kenya are consistent with or at variance with the Cartagena Protocol on Biosafety. In order to achieve the main goal three specific objectives were addressed: an overview of international and regional approaches to biosafety regulation was examined with a view of placing biosafety regulation in its appropriate context; a thematic comparison of some of the salient features of the Protocol was done. A litmus test was provided by way of an assessment to determine the extent to which the resultant legislation may be relevant and workable domestically. The study was guided by the conceptual framework contained in figure 1.

The findings of this thesis are threefold: First, the Protocol is a compromise treaty that lays minimum biosafety requirements limited to LMOs and hence its regime is narrow and its key provisions inadequate. Member states are not eager (whether willingly or not) to adopt more stringent provisions in their domestic legislation apart from failure to comply with the Protocol.

Second variance outweighs consistency in attempts by Kenya and South Africa to comply with the Protocol. However, it is evident that the Kenyan Bill is, to some extent, on the right road map towards a holistic approach (though it has a long way to go) than the GMO Act together with the GMO Amendment Bill 2005. In the areas where the two countries are at variance with the Protocol none of the relevant provisions in the two countries appear similar.

Third to the extent that the GMO Act (together with the GMO Amendment Bill 2005) does not provide for the precautionary principle, and is glaringly inadequate in its provisions on the themes under study, it miserably fails the litmus test of being relevant and workable domestically. The Kenyan biosafety Bill 2005 has made some strides in the

right direction but, even if enacted, effective implementation plays critical roles if the enacted legislation is to pass the litmus test. As Bell and McGillivray authoritatively observe, “whether and how, the law is enforced is just as important as what the law is”.<sup>304</sup>

The study noted an interesting trend that is emerging in attempts to comply with the Protocol. The regimes being established in both jurisdictions are elusive on aspects that were critical and contentious during the negotiations prior to adoption of the Protocol. These include issues of risk assessment, risk management, public participation and access to information. Whether by coincidence or not, these are some of the key issues at the centre of biosafety that the public is most concerned about. Moreover biosafety is all about avoiding, controlling and minimizing of risks associated with modern biotechnology.

In essence, although modern biotechnology is an invention of man, it gives rise to a complex web of socio-economic, cultural, ethical, political and other issues that man is unable to resolve.

## **4.2 Recommendations**

The following recommendations are relevant and useful in two important ways: Improving the quality and character of the resultant legislations; and, can be replicated in jurisdictions with similar predicament and weaknesses in their existing or intended biosafety regimes.

### **4.2.1 Kenya**

- (i) The objective contained in section 4(a) of the Bill needs to encompass two important elements: conservation of biological diversity, human health and pharmaceuticals for human use on one hand, and identification and labeling on the other hand.

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<sup>304</sup> Bell S and McGillivray D, *supra*, pp. 9

- (ii) The scope in terms of section 3(1) of the Kenyan Bill should specifically be stated in clear and unambiguous terms.
- (iii) Public participation in Kenya may be enhanced by holding at least one public ‘baraza’ (public meeting) at the intended scene. Formal announcements through the electronic media will also be useful. The anticipated regulations should provide for further mechanisms of enhancing public participation.
- (iv) On risk assessment Provision should be made for scrutiny or verification of the risk assessment report by an independent assessor in the event that the application is rejected before an appeal is preferred. This is appropriate in the interest of justice especially since the NBA is the one that carries out risk assessment and also makes the decision. Risk assessment should also include effects to human health. Specific provision should be made to ensure that each GMO undergoes an appropriate period of observation that is commensurate to its life-circle before it is put into its intended use.
- (v) On risk management, the NBA should have more control over the regulatory agencies that are obligated to manage and control risks. It is not enough to liaise with the regulatory agencies as liaising alone cannot avail the results envisaged by Article 16 of the Protocol.
- (vi) The Kenyan Bill should specify: the intervals within which monitoring must be done and the areas to be covered as opposed to making general provisions unless the anticipated regulations comprehensively do so.
- (vii) On risk assessment it is recommended that provisions be made for scrutiny or verification of the risk assessment report by an independent assessor in the event that the application is rejected before an appeal is preferred. This is appropriate in the interest of justice especially since the NBA is the one that carries out risk assessment and makes the decision. Risk assessment should also include the element of human health.

#### 4.2.2 South Africa

- (i) Stated objective(s) embracing the precautionary principle, transparency and predictability in the decision making process should be included in the GMO Amendment Bill as a matter of *urgency*.<sup>305</sup>
- (ii) The scope should encompass the aspects covered by the Protocol and also include pharmaceutical for human use.
- (iii) A strong Council with a defined legal status needs to be established and the excess powers of the registrar reduced as the Council is the statutory body that is accountable to the public.
- (iv) The AIA procedure should be spelt out clearly. Its provisions including the time frames should be adjusted and be included in the substantive provisions of the law rather than leaving such power to the discretion of the Council and the minister in the regulations.
- (v) The words “public input” need a definition. Elaborate provisions relating to public participation need to be provided for. The law should state clearly the role of the public in decision making and the responsibilities of the Council in relation to public participation. Publication of the notices should be extended to include formal announcements in the electronic media. Provision should also be made for one public meeting at the scene of the intended GMO activity.
- (vi) Risk assessment should be mandatory (with a few exceptions) in the decision making process. Substantive and clear provisions should be put in place in the GMO Amendment Bill to ensure that risk assessment is done in a transparent manner.
- (vii) Clear and unambiguous provisions are needed in the GMO Amendment Bill making consideration of socio-economic factors mandatory in view of the decision in *BP Southern Africa (Pty) Ltd v MEC for Agriculture, Conservation and Land Affairs*.<sup>306</sup>

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<sup>305</sup> Emphasis added.

<sup>306</sup> 2004(5) SA 124(W)

- (viii) Provisions as to monitoring are needed in the GMO Amendment Bill in compliance with the Protocol and also to enhance the quality of the resultant legislation.

#### **4.2.3 Kenya and South Africa**

Comprehensive biosafety policies and regulations should be put in place in both countries as part of the biosafety framework. The content of the policies and regulations will reveal the values being protected. To ensure biosafety we need to develop science policies that “appreciate the centrality of nature and connect science with society”.<sup>307</sup>

#### **4.2.4 Further Studies**

Legal regulation of modern biotechnology presents many challenges for scholars. The issues to be covered are as wide as they are varied. A few aspects may be pointed out. Similar comparisons need to be carried out between and among other jurisdictions in Africa; the themes discussed in this study can be investigated further as separate studies; the unresolved issues of the Protocol especially liability and redress, identification and labeling need to be addressed; and the issues relating to the Protocol and WTO are also critical.

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<sup>307</sup> Third World Network, (Biosafety Information Centre) “Key Regulatory Issues”, July 21, 2006, available at [www.biosafety-info.net/section.php?sid=11](http://www.biosafety-info.net/section.php?sid=11)

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