

**THE CARTAGENA PROTOCOL AND BIOLOGICAL DIVERSITY:  
BIOSAFE OR BIO-SORRY?**

**A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE  
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## CONTENTS

i) Dedication.....	5
ii) Acknowledgement.....	6
iii) Acronyms and abbreviations.....	7

### **CHAPTER I. RESERCH PROPOSAL.**

1.1 Background Information.....	8
1.2 Statement of the Problem.....	9
1.3 Justification of the Study.....	9
1.4 Objectives.....	10
1.5 Hypotheses.....	11
1.6 Research Questions.....	12
1.7 Literature Review.....	12
1.8 Methodology.....	15
1.9 Chapter Breakdown.....	16
1.9.1 Chapter Two: Global Biological Diversity.	
1.9.2 Chapter Three: Cartagena Protocol on Biosafety.	
1.9.3 Chapter Four: The Cartagena Protocol Versus Biodiversity: Does the Protocol Help or it Hinders Conservation of Biological Diversity?	
1.9.4 Chapter Five: Conclusion and Recommendations.	

### **CHAPTER 2. GLOBAL BIOLOGICAL DIVERSITY.**

2.1 Biological Diversity and the New Meaning of Security.....	17
2.2 The threat to Biological Diversity.....	20
2.3 Convention Biological Diversity versus Loss of Biodiversity.....	21
2.3.1 Negotiation and Entry into Force.	
2.3.2 Sovereignty versus Common Concern.	
2.3.3 Objectives of the Convention.	
2.4 Modern Biotechnology.....	23



2.5 Conclusion.....	26
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### **CHAPTER 3. THE CARTAGENA PROTOCOL ON BIOSAFETY.**

3.1 Introduction.....	27
3.2 Negotiation History for the Cartagena Protocol.....	27
3.3 Contentious issues During Negotiations of the Biosafety Protocol.....	29
3.3.1 The precautionary Principle	
3.3.2 The Scope of the Protocol	
3.3.3 Advanced Informed Agreement (A.I.A)	
3.3.4 Liability and Redress	
3.3.5 Labelling Requirements	
3.3.6 Information Sharing and Biosafety Clearing – House Mechanism.	
3.3.7 Socio-economic Considerations.	
3.3.8 The Relationship Between the Biosafety protocol and other International Agreements.	
3.4 An Overview of the Final Text of the Cartagena Protocol on Biosafety.....	34

### **CHAPTER FOUR: CARTAGENA PROTOCOL VERSUS BIODIVERSITY: DOES THE PROTOCOL HELP OR IT HINDERS CONSERVATION OF BIOLOGICAL DIVERSITY?**

4.0 Introduction.....	41
4.1 The Precautionary Approach .....	42
4.1.1 The Level of the Perceived Risk required to Bring into operation the Precautionary Action.	
4.1.2 Consideration of the Benefits of the LMOs in Taking Precautionary Action.	
4.1.3 What Action to be Taken when Precaution is Justified.	
4.1.4 What Level of Uncertainty is Required to Justify Precautionary Action.	
4.1.5 Suggested Alternative Embodiments of the Precautionary Principle in the Protocol.	
4.2 Advanced Informed Agreement (AIA) Procedure.....	52
4.2.1 Steps in advanced informed agreements	
4.3 Information Sharing and the Biosafety Clearing-House Mechanism (BCH) .....	59

**CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS.**

5.1 CONCLUSION ..... 64

    5.1.1 Introduction

    5.1.2 The Precautionary Principle.

    5.1.3 AIA Procedures and Accessing Information Required for Decision Making.

    5.1.4 Public Participation.

    5.1.5 Biosafety Capacity Building.

5.2 RECOMMENDATIONS ..... 68

    5.2.1 Introduction

    5.2.2 The Precautionary Principle

    5.2.3 AIA Procedure and Access to Information Required for Decision Making.

    5.2.4 Addressing Economic and Social-Cultural, Controversies Regarding LMOs.

    5.2.5 Biosafety Capacity Building.

    5.2.6 Creation and Use of Institutional Framework.

## DEDICATION

To my mother Teresa Moraa, my father George Mituga .My Sisters: Rose Osebe, Doreen kemunto and Mokogoti -Winnie Maria and my brothers: Erick Nyamweya, Vincent Taabu, Kevin Onduso and Newton Onkomba.My other mother, Kerubo.Brothers: Onkomba, Cocket and sisters: Mbera and Nyabonyi. Lastly my deceased grandmother, Sabina Gesare, who taught us the virtue of generosity and my uncle Omingo.

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It will be an exercise in futility to mention all those who assisted me come up with this work. Nonetheless it would be invidious to make special mention of my supervisor Dr Patricia Kameri-Mbote for her invaluable criticisms and guidance that has enabled me realise my dream.

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## ACRONYMES AND ABBREVIATIONS.

Art	Article.
AIA	Advance Informed Agreement .
BCH	Biosafety Clearing-House .
CBD	Convention on Biological Diversity .
Bt	<i>Bacillus thuringiensis</i> .
COP	Conference of Parties .
DNA	Deoxyribonucleic Acid .
EU	European Union .
Ex COP	Extra-ordinary Conference of Parties .
GMO	Genetically Modified Organisms .
GDP	Gross Domestic Product .
ICCP	Intergovernmental Committee for the Cartagena Protocol .
IGO	Intergovernmental Organisation .
IPR	Intellectual Property Rights.
IUCN	International Union for Conservation Nature and Natural Resources . (The World Conservation Union),
MOP	Meeting of Parties to the Protocol .
TRIPs	Trade Related Aspects of Intellectual Property .
UNEP	United Nations Environment Programme .
USA	United States of America .
WTO	World Trade Organisation .
WCED	The World Conference on Environment Development .



# THE CARTAGENA PROTOCOL AND BIOLOGICAL DIVERSITY: BIOSAFE OR BIOSORRY?

## CHAPTER ONE: RESERCH PROPOSAL.

### 1.1 Background Information.

The sustainable management of biological diversity is a major concern of the international community with the realisation that this diversity is being eroded at an alarming rate.<sup>1</sup> Biological diversity<sup>2</sup> is a global tremendous asset for both present and future generations hence intragenerational and intergenerational equity demands that it be conserved for the benefit of both generations. Biodiversity conservation is a matter of survival because of its importance “for maintaining the life sustaining systems of the biosphere.”<sup>3</sup> Biodiversity is of economic benefit because of its “critical importance for food, health and other needs growing world population.”<sup>4</sup>

In a bid to address the loss of biodiversity at the global level the Convention on Biological Diversity was adopted in 1992 and it came into force in 1993. The convention has a wide spectrum of provisions intended to promote biodiversity and limit the environmental impact of human development.

The Convention specifically contemplates regulation of living modified organisms (LMOs) by parties to the convention.<sup>5</sup> The Convention further provides for negotiation and adoption of an international Biosafety Protocol.<sup>6</sup> The Cartagena Protocol on Biosafety was concluded in 2000 and it came into force in 2003. This protocol was to address the concerns of biotechnology. The concerns to be addressed by the protocol are: safe transfer, handling and use of living modified organisms resulting from modern biotechnology because of their potential adverse effects on

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<sup>1</sup> Kameri-Mbote P (2002) *Property Rights and Biodiversity Management in Kenya*. Nairobi ACTS Press 1.

<sup>2</sup> In this dissertation “Biological diversity” and “Biodiversity” are used interchangeably.

<sup>3</sup> The Convention on Biological Diversity, 1992 at the preamble.

<sup>4</sup> *Ibid.*

<sup>5</sup> *Ibid* at art 8 (g).

<sup>6</sup> *Ibid* at art 19(3).

biological diversity taking also into account risks to human health.<sup>7</sup> The benefits of biotechnology were first understood but safeguards were required against its risks. Due to the uncertainty as to the risks involved while dealing with LMOs, the precautionary approach became the cornerstone of the protocol.<sup>8</sup>

### **1.2 Statement of the Problem.**

Biodiversity is closely intertwined with human needs; it is an essential resource for sustainable development, the conservation of which should be considered as an element of national security. It is the alarming rate at which the diversity is lost, which is causing great concern to the international community. *It is this problem which has given a basis for a legal and institutional framework at the national and international level to address the problem.*

One of the legal regimes that have been set up to address the issue of conservation and sustainable use of biological diversity is the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. It regulates the growth and development of modern biotechnology in particular the concerns of safe handling use and transfer of LMOs. In order to evaluate whether the Protocol advances or retards conservation of biological diversity, it is important to investigate the threats of biodiversity so as to understand the nature of the problems the protocol is supposed to address, then an analysis of the provisions of the protocol to evaluate their utility in conservation of biodiversity. This will be followed by an assessment of the congruence or lack thereof between the biodiversity problem and the Biosafety Protocol (against the background of the world's burgeoning population).

### **1.3 Justification of the Study.**

This study can be justified on the following grounds: Firstly, it is an attempt to address the alarming rate at which biodiversity is lost. This is important because biological diversity is an important resource for sustainable development. Habitat loss poses a real threat to biodiversity, and

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<sup>7</sup> Cartagena Protocol on Biosafety 23 Feb. 2000, preamble and art. 1

<sup>8</sup> *Ibid*, Preamble, arts. 1, 10, 11, 15 and annex iii



the main cause of habitat loss is the activities of the burgeoning population in their quest to increase agricultural production.

LMOs, which are products of biotechnology, have been seen as a way out of the food crises as it can be used *inter alia* in developing drought and pest resistant crops<sup>9</sup> and increasing per acre food production. On the other hand Biotechnology is "a new field and much about the interaction of LMOs with various ecosystems is not yet known."<sup>10</sup> Therefore there is need to regulate biotechnology so as to reap its benefits and at the same time guard against its risks to the human health and the environment. This is taken care of under the concept known as biosafety and the Cartagena Protocol on Biosafety addresses it. This study will therefore evaluate whether this protocol that regulates biotechnology is effective in stemming loss of biodiversity.

The second justification of this study is to emphasise the need to develop a biosafety infrastructure. This is important because it determines the level at which a country can harness biotechnology. This study is likely to show a need to strike a delicate balance between adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology (LMOs that may have adverse effect on the conservation and sustainable use of biological diversity), and harnessing of agricultural biotechnology as one of the important tools for biodiversity conservation.

#### **1.4 Objectives.**

The study has got a main objective, which is, to investigate whether the Cartagena Protocol on Biosafety (which has the precautionary principle as its cornerstone) enhances or it retards conservation of Biodiversity against the background of the world's growing population.

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<sup>9</sup> Sunday standard 19 Aug 2004 at p. 19.

<sup>10</sup> See generally [www.biodiversity.org/biosafety](http://www.biodiversity.org/biosafety) (visited on Aug 2004).

The second objective will be to assess the value of biodiversity and threats to biodiversity. The third objective is to examine the extent to which the Convention on Biological diversity addresses biodiversity in particular its provisions on biosafety. The fourth objective is to analyse the provisions of the protocol and how they seek to address biosafety and evaluate the extent to which the protocol stems the loss of biodiversity.

#### 1.4 Hypotheses.

The following are the hypotheses of this study. Firstly, habitat loss around the world poses the greatest challenge to biodiversity loss. Secondly, the burgeoning world population and the consequent demand for more food will accelerate habitat loss. Thirdly, if agricultural biotechnology is embraced it can increase food production therefore checking habitat loss and ultimately conserve biodiversity. Fourthly, biotechnology has got benefits but also risks to human health and the environment hence the relevancy of a regime to inform any efforts to harness biotechnology. Fifthly, there is need for developed countries to assist developing countries both financially and technologically in developing biosafety infrastructure in their endeavour to harness biotechnology.

An efficient biosafety infrastructure is to ensure the effectiveness of the protocol in enhancing conservation of biodiversity, because the diversity is a benefit to the entire globe. The greatest challenge on parties to the protocol is to put in place effective legal and administrative structure to implement the protocol. The precautionary principle states 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."<sup>11</sup> This principle is referred in the preamble and article 1 of the Protocol. Being the cornerstone of the protocol, the principle 'gives parties to the protocol latitude in designing the biotechnology and bio-safety laws and policies to be restrictive or permissive.'<sup>12</sup> Countries without financial or a scientific discipline to assess the risks of LMOs on their environments may put in place very strict precautionary measures for

<sup>11</sup> See Principle 15, UNCED, Final Dec. of the UN Conference on Environment and Development, Rio de Janeiro.

<sup>12</sup> See Kameri-Mbote P. *infra* note 24, quoting Robert L. Paarlberg in " The Politics of Precaution: Genetically Modified crops in Developing Countries, International Food Policy Research Institute" (2001) *The Johns Hopkins University Press, Washington.*

biosafety. The result will be that, biotechnology, which can increase production per acre, will not be used. The burgeoning population's option to satisfy food needs will be to clear more land in a bid to increase production. This will result to destruction of habitats, causing biodiversity loss.

## 1.6 Research Questions.

This study will be guided by the following research questions:

1. What is the value of biological diversity, and what are the threats to biological diversity?
2. What is the impact of the world's growing population on biological diversity?
3. To what extent do the provisions of the CBD address the conservation and sustainable use of biodiversity in particular its provisions on biosafety?
4. How do the provisions of the Biosafety Protocol with the precautionary principle as its cornerstone address biosafety?
5. Does the Cartagena Protocol enhance conservation of biological diversity or does it retards conservation of biological diversity?

## 1.7 Literature Review

The subject of conservation and sustainable use of biological diversity has attracted a number of studies; in particular there have been studies and commentaries on various aspects of biosafety. The judiciary has also had occasion of commenting on the precautionary principle as a central feature of the protocol. Robert L. Paarlberg;<sup>13</sup> Kameri-Mbote P;<sup>14</sup> Mugabe, J;<sup>15</sup> Jonathan H. Adler<sup>16</sup> have made contributions on the subject.

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<sup>13</sup> Robert Paarlberg as quoted by Kameri-Mbote *Supra* note 12 at p.6.

<sup>14</sup> Kameri-Mbote, P: Towards a Liability and Redress under Cartagena Protocol on Biosafety: A Review the Kenya National Legal System (2003).

<sup>15</sup> Mugabe, J: From Cartagena to Nairobi: Towards an African Agenda on the Biosafety Protocol: Background Paper for Panel Discussion at 5<sup>th</sup> Conference of The Parties to the CBD, 10 May 2000.

<sup>16</sup> Jonathan, H " More Sorry than Safe: Assessing the Precautionary principle and the Proposed International Biosafety Protocol." (2000) 33 *Tex Int L J.*173, 194-204.



Holly Saigo;<sup>17</sup> Florence Wambugu<sup>18</sup> and Deborah Katz<sup>19</sup> have also made notable contributions.

Florence Wambugu has recognised that it is developing countries which are in dire need of biotechnology to address food crises that face them. She stresses that "The African continent, more than any other, urgently needs agricultural biotechnology, including transgenic crops, to improve food production."<sup>20</sup> This position has been supported by the current president of Kenya who has stated that "we must embrace and apply modern technology in farming ... countries which have embraced agricultural biotechnology have ensured food security for their people "<sup>21</sup>but he puts a caveat that biotechnology is to be utilised "within the existing biosafety structure...."<sup>22</sup> Biosafety addresses the need to protect human health and the environment from the possible adverse effects of products of modern biotechnology. Therefore before introduction of LMOs to the environment a procedure that ensures protection is embraced.

Before introductions of LMOs to the environment, in particular when it comes to movement from one country to another there are two major principles, which inform the introduction. There is the advance informed agreement procedure (AIA) that enables countries to carry out risk assessment before introduction of LMOs to their environment. The AIA is coupled with the precautionary approaches, which allow countries to refuse importation of LMOs whose safety is uncertain due to insufficient scientific evidence. The preamble as well as article 1 of the Cartagena Protocol refers to the "precautionary approach" as contained in Rio Declaration in Environmental and Development. Article 1 states that "in accordance with the precautionary approach contained in principle 15 of the Rio Declaration on Environment and Development." Principle 15 states that " where there are threats of serious or irreversible damage, lack of full

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<sup>17</sup> Agricultural Biotechnology and the Negotiation of the Biosafety Protocol (2000) Vol. xii issue 3 *Georgetown Int Law Review* 779.

<sup>18</sup> Why Africa Needs Agricultural Biotechnology (1999) 400, *NATURE* 15.

<sup>19</sup> The Mismatch Between the Biosafety Protocol and the Precautionary Principle (2001) vol.xiii issue 4 *The Georgetown int Law Review*, 949.

<sup>20</sup> Sunday Standard, *supra*, note 9.

<sup>21</sup> *Ibid.*

<sup>22</sup> *Ibid.*

scientific certainty shall not be used as a reason of postponing cost effective measures to prevent environmental degradation."<sup>23</sup>

In addition the court explicitly recognises the right of parties to take decisions on whether to import LMOs in absence of adequate scientific knowledge. In the case of **Leach .v. Natural parks and wildlife Service and Shoal Haven City Council** the court had occasion to define the principle. Sten J in his dicta stated that:

In my opinion the precautionary principle is a statement of common sense.... It is directed towards the prevention of serious or irreversible harm to the environment in situations of scientific uncertainty. Its premise is that where uncertainty or ignorance exist concerning the nature or scope of environmental harm ... decision-makers should be cautious.<sup>24</sup>

The common denominator in the definitions of the precautionary approach is that it is applied where there is a threat of harm and scientific uncertainty. A number of notable writers have had occasion to comment about the precautionary principle. J. Morris has given the principle a sharp criticism on grounds of scientific ambiguity and as a pessimistic response to uncertainty in regulatory risk assessment knowledge. He goes on to say that there is no statement on the exact parameters of serious irreversible harm and of scientific certainty.<sup>25</sup>

Paul, E H and W.B John, have echoed the view of J. Morris in their comment about the precautionary approach as contained in Articles 10,11 of the protocol, they say that;

This language is complicated and ambiguous reflecting the sensitivity of the compromise struck. Depending on their interests parties may attempt to interpret the language as granting quite narrow or broad discretion on parties of import in making import decision.<sup>26</sup>

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<sup>23</sup> See principle 15, *supra* note 11.

<sup>24</sup> See Kameri-Mbote, P "Towards a Liability and Redress System Under the Cartagena Protocol on Biosafety: a Review of the Kenya national Legal System " quoting from the above case in 81 LGERA270.

<sup>25</sup> Kameri-Mbote P *infra* note 24 quoting, J Morris in: *Rethinking Risk and and the Precautionary*, (2002) *Nutterworth Heinemann London*.

<sup>26</sup> The Cartagena protocol on Biosafety: New Rules for International Trade in LMOs. (2000) 12 *Georgetown int. Environmental law Review*. 710-711.

Paul, E.H and W.B. John, appear to be supporting Robert L paarlberg's view that the principle gives state parties to the protocol latitude in designing their biotechnology and biosafety laws and policies whereby they can choose to be restrictive or permissive.

Where parties to the protocol are also parties to the World Trade Organisation (WTO), if a restrictive approach is taken and a country rejects an application for introduction of use of LMOs, the state may be taken to the WTO dispute settlement body for determination whether the precautionary principle has been applied as a trade barrier in disguise. From the foregoing it is clear that the views of those against the Protocol's effectiveness can be summed in the words of Henry I. M and C.Gregory, that:

Rather than creating a uniform predictable and scientifically sound framework for effectively managing legitimate risks, the biosafety protocol establishes an ill defined global regulatory process that permits overly risk -averse regulators to hide behind the precautionary principle in delaying or deferring approvals.<sup>27</sup>

In effect the protocol may inhibit the spread of LMOs especially to nations that need to increase agricultural productivity. The end result is habitat loss and consequently loss of the biodiversity.

The lacuna that is sought to be filled in this study is an emphasis of paradigm shift from giving a lot of attention to hypothetical risks caused by LMOs to focusing to the need to improve agricultural production and reduce agricultural stress on natural environment.

## **1.8 Methodology**

The study will rely on primary documents and secondary means of information retrieval. Articles and books from the University of Nairobi law library as well as the United Nations Environment Programme Library at Gigiri will be utilised. The newspapers will also be relied on especially on contemporary development on the subject. The Internet will also be utilised in this research.

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<sup>27</sup> Henry I.miller & Gregory Conco: The Protocol's illusionary Principle (2000) 18 *NATUREBIOTECHNOLOGY* 360.



## **1.9 Chapter Breakdown.**

### **1.9.1 Chapter Two: Global Biological Diversity**

Chapter one (I) will cover biodiversity as a basis for national and ecological security, values of biodiversity, threats to biodiversity and how the Convention on Biological Diversity addresses loss of biodiversity especially its provisions on biotechnology.

### **1.9.2 Chapter Three: Cartagena Protocol on Biosafety.**

This chapter will focus on the negotiations of the Biosafety Protocol, contentious issues during the negotiations. Particular attention will be given to the precautionary principle, the scope of the protocol, advance informed agreements procedure, information sharing and clearing-house Mechanism, liability and redress and relationship of the Protocol to other international agreements. The overview of the Cartagena Protocol and how it addresses biosafety will also be considered.

### **1.9.3 Chapter Four: The Cartagena Protocol Versus Biodiversity: Does the Protocol Help or it Hinders Conservation of Biological Diversity?**

In this chapter, the question of whether the Protocol is a promise or peril will be considered. Weaknesses of the Biosafety Protocol with regard to biodiversity conservation (if any) will be pointed out. Particular attention will be given to the, advance informed agreements procedure, information sharing and the biosafety clearing-house mechanism

### **1.9.4 Chapter Five: Conclusion and Recommendations.**

After the discussion of the problem highlighted above this chapter will cater for the conclusion and suggest appropriate recommendations on the best way to restructure the Cartagena protocol so that it can effectively regulate biotechnology without compromising its utilisation in conservation of biological diversity.



## CHAPTER TWO.

### GLOBAL BIOLOGICAL DIVERSITY

#### 2.1 Biological Diversity and The New Meaning of Security.

"Peace on earth depends on our ability to secure our living environment." Daily Nation ( Kenya) 9 October 2004, quoting from the speech of the Nobel Peace Price Committee when announcing Professor Wangari Maathai as the 2004 Nobel Peace Price winner.

Traditionally the threats to countries' stability and security have been perceived along the lines of lack of a strong army which can put up a resistance in case of any attack. Therefore traditional threats to security were military ones. This is the basis of allocation of huge sums of money in their annual budgets to strengthen their army and police force. Norman Myers has captured a new dimension of security. He states that "there is a new and different threat to our national security emerging -the destruction of our environment..."<sup>28</sup> Among the environmental threats is erosion of biological diversity, climate change, and depletion of ozone layer. It is now clear that national and international security depend on state of the world forests, climate, watersheds, rivers, oceans, soils, and, proper functioning of the atmosphere and erosion of biological diversity. Nations are therefore to zero in these factors in their security plans. Biological diversity can be used to explain this point.

Biological diversity<sup>29</sup> is a tremendous asset to humanity especially the biological resources<sup>30</sup> which if well harnessed can create economic and ecological security. Biodiversity regulate climate change and is an important source of raw material for agricultural, pharmaceutical and

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<sup>28</sup> See generally Norman, M (1993) Ultimate Security: The Environmental Basis of Political Stability. The Nobel Peace Price Committee on announcing Professor Wangari maathai as the 2004 Nobel Piece Price winner echoed this view. It stated that "peace on earth depends on our ability to secure our living environment." (Daily Nation of Kenya-9 October 2004.

<sup>29</sup> Biological diversity is the variability among living organisms from all sources including *inter alia*, terrestrial, marine and other aquatic ecosystems and other ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. See *supra* note 3, art.2.

<sup>30</sup> Biological recourses include genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. See *supra* note 3,art 2.

other industries.<sup>31</sup> The elements of the atmosphere, soil, water, plants and animals interact to bring about a self-sustaining system. The alteration of the interaction between these elements can affect the balance and proper functioning of the planet bringing about unprecedented adverse effect to the environment and human health. One writer has aptly observed;

The extensive deterioration of natural support systems and the declining economic conditions... pose threats to national and international security that now rival the traditional military ones. Ecological stresses and resource scarcities eventually translate into economic tresses with social and economic dimensions.<sup>32</sup>

The World Conference on Environment Development (WCED) recognised the security threat posed by environment degradation which include biological degradation; it was observed that, "the deepening and widening environmental crisis presents a threat to national security that may be greater than well – armed, ill-disposed neighbours and unfriendly alliances."<sup>33</sup> One of the globe's environmental threats which can lead to both ecological and economic insecurity is erosion of biological diversity. If the remaining World's biodiversity is allowed to disappear... humans own life will be at stake.<sup>34</sup>

Biological diversity, in particular the earth's biological resources of genes, species and ecosystems are essentially renewable resources – managed effectively, they can create the basis for sustainable development<sup>35</sup> Biodiversity is a source of major socio-economic and even ecological goods and services which are essential for the survival of man. It is because of this that biodiversity is viewed as a global asset which is for the benefit of the present and future generations. There are many values ascribed to biodiversity. *There is the economic value, which* can be either direct or indirect. The direct benefits are the provision of basic necessities of life

<sup>31</sup> Mugabe, J and Clark, N (1990) *Managing biodiversity: National Systems of Conservation and Innovation in Africa* ACTS Press, 5.

<sup>32</sup> Brown, L; *Redefining national security* (1986), *State of the World*, 204.

<sup>33</sup> World Commission on Environment and Development, *Our Common Future* (1987) 7.

<sup>34</sup> Mugabe, J and N. Clark, *supra* note 31.

<sup>35</sup> Sustainable development is development that meets the present needs without compromising the ability of future generations to meet their own needs. See World Commission on Environment and Development, *Our Common Future* (1987).

<sup>36</sup> Guruswamy L D *et al*, (1994) *International Environmental Law and World Order: a problem – oriented course book*, West Publishing co, at p. 822.



such as food, timber, and medicine. Nearly all medicine comes from plants and animals.<sup>36</sup> Another direct economic benefit of biodiversity is its contribution to the Gross domestic product (GDP) of countries.

Indirect economic values of biodiversity include most of the ecosystem services such as regulation of climate..." Climatic and ecological resources that influence agricultural activities are regulated by biological diversity."<sup>37</sup> Other indirect benefits include absorption of carbon dioxide by forest, provision of energy to non-photosynthesisers like man. Insects also play an important role in the process of pollination. Biodiversity has also the aesthetic value, which encompasses the beauty of species and habitat. This provides the opportunity for a host of activities such as bird-watching, game watching and scenery for film-making all of which have some economic benefit.<sup>38</sup> This serves to illustrate that the values of biodiversity are not mutually exclusive. They can exist concurrently.

Mugabe and Clark have succinctly captured the role of Biodiversity in cultural development where they say that:

Plants and animals play a major role in cultural evolution of many societies. In fact, the complexity and diversity of traditional socio-economic systems can also be measured by the range or diversity of both plants and animals genetic resources utilised by local communities in different parts of the world. For example the *Sukuma* of Tanzania used more than 300 plant species. They have accumulated a wide knowledge base and skill, in identifying, characterising and conserving plants. Moreover, they keep different kinds of crops and livestock. This ensures diversity not only in economic activities but also in genetic resources available in the socio-economic system.<sup>39</sup>

It is noteworthy that biological resources with direct benefit to man for example trees for timber are easy to value, but those which are of indirect contribution, for example absorption of carbon dioxide by trees/forests are difficult to evaluate in monetary terms. Suffice it to state the values

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<sup>37</sup> Mugabe and Clerk, *Supra* note 31 at p.7.

<sup>38</sup> See Generally, Ehrlich and Ehrlich, (1992).

<sup>39</sup> *Supra* note 31.

ascribed to biodiversity create a justification for development of mechanisms and institutional framework to conserve it for the benefit of present and future generation.

## 2.2 The threat to Biological Diversity.

Biological resources, which include genetic resources, organisms, population or other biotic components of ecosystems with actual or potential use or value to humanity,<sup>40</sup> are essentially renewable resources, which if managed effectively can create a basis for sustainable development. The current loss of biodiversity is higher than any time in human history hence raising concern and that is why legal and institutional frameworks have to be developed to address the challenge. One of the initiatives is the coming up with the Biosafety Protocol. In order to assess whether it enhances biodiversity protection it is better to understand the nature of the problems it is to address (causes of biodiversity degradation).

The causes of biodiversity degradation are many complex and interactive.<sup>41</sup> The greatest current threat to biodiversity is human destruction of habitats taking place worldwide.<sup>42</sup> While there may not be accurate statistics of biodiversity loss, there is a consensus that human activities contribute directly or indirectly to biodiversity loss. Biodiversity experts believe that continued loss of habitat could claim up to half of the species today,<sup>43</sup> in particular conversion of land to agricultural use is the single greatest agent of habitat conversion and associated displacement of species and increasing stress on biological diversity.<sup>44</sup> Low crop yields and increasing human population<sup>45</sup> create greater pressure on people to clear more land so as to increase food

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<sup>40</sup> Convention on Biological Diversity *Supra* note 3, art. 2.

<sup>41</sup> Mugabe and Clerk *Supra*, note 32 p.9.

<sup>42</sup> UNEP Global biodiversity (UNEP GEMS Environment Library No11) 24.

<sup>43</sup> See e.g. Ehrlich, P O and E O, Wilson "Biodiversity studies: Science and Policy" (1991) 253 UNEP GEMS Environment Library No11) 24.

<sup>43</sup> See e.g. Ehrlich, P O and E O, Wilson, "Biodiversity studies: Science and policy"(1991) 253 *SCIENCE* 758.

<sup>44</sup> Indur Goklany " Meeting global food needs: The Environment Trade – Offs Between increasing land Conversion and land Productivity" (1999) 6 *TECHNOLOGY* 107, 108.

<sup>45</sup> In the People Daily, 6 July 2004, it was recorded that the world population currently stands at 6 Billion. double what it was in 1960 with UN projecting an increase to 9 Billion within the next 50 years.



production to cater for increased population's food needs. If agricultural productivity per acre does not increase, it will mean the other option available is to put more land under cultivation and consequently losing more habitats. If there is no effort to enhance per acre productivity, global biodiversity degradation will be inevitable.

Another threat to biodiversity is modification of the habitat by introduction of exotic species. This is especially the case when invasive species are introduced to the habitat. This is considered to be the second leading threat to biodiversity loss.<sup>46</sup> While other threats to biodiversity cannot be ignored, it is important to underscore that habitat loss is the greatest threat to biodiversity. Therefore, conserving the species habitat is the key to preservation of biological diversity.

## **2.3 Convention Biological Diversity versus Loss of Biodiversity**

### **2.3.1 Negotiation and Entry into Force.**

Notwithstanding the fact that nations had long recognised the value of biodiversity, there was a dearth of international law regarding biodiversity preservation. On recognising the danger that may befall the international community from the alarming loss of biodiversity there was an awakening to come up with some sort of protection for biodiversity. It is with this in mind that the United States of America sponsored a resolution before the United Nations Environment programme (UNEP) governing council in 1987, requesting that an *ad hoc* group of experts evaluate the need of such a treaty.<sup>47</sup> The Intergovernmental Negotiating Committee produced the Convention on Biological Diversity and it was introduced to and signed by over 150 countries attending the earth summit in Rio de Janeiro in June of 1992. It remained open for signature until 4 June 1993 receiving 168 signatures. It entered into force on 29 December 1993 after the thirtieth ratification.

The Convention on Biological Diversity underscores the fundamental fact that environmental issues are to be handled in tandem with economic development. It expressly provides that

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<sup>46</sup> See World Resources Institute, World Resources. 1998 – 1999 at 197.

<sup>47</sup> See Rationalisation of International Conventions on Biological Diversity UN Environment Programme, 14<sup>th</sup> sess. Annex 1, at 58, UN Dec UNEP/GC 14/26 (1987)

conservation of biodiversity is matter of survival because of its importance " for maintaining the life-sustaining systems of the biosphere."<sup>48</sup> Biodiversity is of economic benefit because of its "critical importance for food, health, and other needs of the growing world population."<sup>49</sup> The unique attribute of the convention that raises various legal issues is that, though it deals with biological diversity, which is a common concern of mankind, the states are said to have sovereign rights over their own biological resources. The convention is therefore a compromise to balance the two seemingly contradicting concepts.

### **2.3.2 Sovereignty versus Common Concern.**

Prior to the Convention on Biological Diversity, biological resources<sup>50</sup> and genetic resources<sup>51</sup> were regulated under the principle of common heritage of humankind. Developed countries wanted this status quo maintained. On The other hand developing countries supported the position of nation control over resources within their sovereign jurisdiction.

The developing countries position was validated by the preamble, Article 1, Article 3 and 15 (1) of the CBD. The convention therefore succeeded in juxtaposing the traditional notions of sovereignty with contemporary ideas of the common concern of humankind. It succeeded in globalising environmental concerns. In that regard countries, which host biodiversity, are but stewards or trustees of the diversity for the benefit of mankind.

### **2.3.3 Objectives of the Convention.**

The convention on Biological Diversity has three main objectives, which are captured in Article 1. They include the conservation of biological diversity, sustainable use of its components and the

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<sup>48</sup>Convention on Biological Diversity, *Supra* note 3, at the preamble.

<sup>49</sup> *Ibid.*

<sup>50</sup> Biological resources include genetic resources, organisms or parts thereof, populations or any other biotic components of ecosystems with actual or potential use of value for humanity.

<sup>51</sup> Genetic resources mean genetic material of actual or potential value.

fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.<sup>52</sup>

In order for the above objectives to be realised the convention has got a comprehensive and holistic approach in ensuring promotion in conservation of biological diversity and at the same time limit the environmental impacts of human development<sup>53</sup> of potentially environmental harmful or diversity reducing activities, taking also into account risks to human health. Living modified organisms resulting from biotechnology were singled out for regulation. This regulation is to be addressed under the concept of biosafety, which refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology.

#### 2.4 Modern Biotechnology.

Biotechnology has been defined by convention of Biological Diversity as, "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use."<sup>54</sup> Through biotechnology there has been a development of a new technique, which allows the transfer of genetic material between species, and even manipulation of genes within a species so as to get desired traits. The products of these genetic transfers are known as living modified organisms.

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<sup>52</sup>Convention on Biological Diversity, *Supra* note 3, art. 1.

<sup>53</sup> Parties are called upon among other things to develop national strategies, plans or programmes of the conservation and sustainable use of biological diversity; to establish a system of protected areas such as parks or reserves or areas where special measures need to be taken to conserve biological diversity; and to regulate or manage biological resources important to biodiversity.

b) Promote the protection of ecosystems natural habitats.

c) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas.

d) Rehabilitate and restore degraded ecosystems.

e) Prevent the introduction of control or eradicate those alien species which threaten ecosystems, habitats or species *see supra* note 3 article 8. The CBD further requires parties to co-operate in research, technology transfer,

information exchange, technical and financial assistance all aimed at conservation of biological diversity and limiting the environmental impacts of human development so as to ensure sustainable development *see supra* note 3 articles 18, 16, 17, 20 and 21.

<sup>54</sup>Convention on Biological Diversity, *supra* note 3, Preamble.



Proponents support the science on the ground that it could be utilised to alleviate world hunger by producing food more efficiently and this will ultimately prevent conversion of habitats, which has adverse effect on biodiversity. However, critics argue that biotechnology may have adverse effects on the conservation and sustainable use of biological diversity.<sup>55</sup> They also argue that biotechnology can present significant ecological and human health problems without any gain in global food supply.

Biotechnology allows scientists to move specific genes within an organism or from one organism to another so as to get the desired traits. When applied to agricultural production, generally speaking the products of these processes can be described as "bioengineered" "genetically engineered" or "transgenic" or "living modified" organisms. Agronomic biotechnology has got advantages over the traditional plant breeding methods. Firstly, there is greater selectivity and precision in obtaining desired traits by selecting a gene of a desired trait and inserting it to DNA of the receiving plant effects this. There is also reduction in the amount of Agrochemical used. This is achieved by inserting genes that confer a genetic resistance to diseases and pests. This will reduce the application of more chemicals to check pests and diseases and ultimately reducing negative impact, the chemicals may have to the environment. It has been observed that new varieties of plants engineered for disease and pest resistance may require fewer applications of chemical pesticides than traditional varieties.<sup>56</sup> The third benefit of agricultural biotechnology is the creation of better consumer products for example products with high concentration of nutrients. There is also a claim that "plant viruses can be engineered to stimulate the human immune system when consumed, thus creating a food that acts in a manner similar to a vaccination."<sup>57</sup>

Even with the above benefits there are concerns about the safety of and risks posed by the new technology. The possible risks of agrochemical biotechnology include: Firstly, migration of

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<sup>55</sup> For example through genetic modification new species are introduced and existing ones are reduced thereby affecting biodiversity.

<sup>56</sup> See Thomas " International Regulation of Deliberate release Biotechnologies" (1991) 26 *Tex International Law Journal* 422,426-27.

<sup>57</sup> See Thomas, RD " Genetically Modified Nonsense" - [www.biotech-knowledge.com](http://www.biotech-knowledge.com):(visited on 7April 2000)

transgenes into non-targets organisms facilitating intercrossing<sup>58</sup> which may produce an unwanted variety. There may also be creation of "superweeds" and "superpests". Weeds and insects can evolve resistance to herbicides and pesticides, thus increasing the amount and kinds of chemicals that may be used. Therefore biotechnology has a risk of having insects and weeds evolving resistance to transgenic crops.

Oduor Ongwen has asserted that some genes like *Bt* can kill insects like bees, which are necessary for pollination.<sup>59</sup> Ongwen has also asserted their biotechnology has a risk of bringing biodiversity loss as it encourages monoculture of a single variety, which are vulnerable to attack by insects.<sup>60</sup> Biotechnology also has a risk to human health in the sense that the transplanted genes may produce proteins in plants, which may cause allergic reactions in people eating the food.<sup>61</sup> Finally biotechnology is a new field and much about the interaction of LMOs with various ecosystems is not yet known.

Suffice it to state that notwithstanding the above pros and cons of biotechnology its contribution to increased yields on agricultural production may prevent conversion of virgin habitats to agricultural lands; therefore conserving biodiversity. Though technology is limited by the risks that may accompany it, it is prudent not to throw it away as the "baby should not be thrown away with bath water." It is against the above background that biotechnology was singled out by the Convention on Biological Diversity for further regulation so as to reap its benefits and at the same time have safeguards against its potential adverse effects to the environment and human health.

Article 19 of the convention captures the dichotomy of benefits and risks of biotechnology under its heading "*handing biotechnology and distributing its benefits.*" (Emphasis added) This is a

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<sup>58</sup> Outcrossing occurs when domesticated plants hybrid with wild relatives, producing a new variety.

<sup>59</sup> East African Standard Newspaper; 23 June 2004, at p. 6.

<sup>60</sup> *Ibid.*

<sup>61</sup> *ibid.*



clear pointer that drafters understood its benefits but also wanted to guard against its possible risks. Under Article 8(g) of the CBD parties are to:

Establish or maintain means to regulate manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity taking also into account the risks to human health.<sup>62</sup>

In addition to article 8(g), Article 19 paragraph (3) of the Convention provides for registration and adoption of a protocol which will set out appropriate procedures including in particular, *advance informed agreement*, in the field of safe transfer, handing and use of living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. (*Emphasis added*). The two articles provide bases for the creation of the Biosafety Protocol

## **2.5 Conclusion.**

Taking into account the value of biodiversity and the threat to biodiversity, it is prudent to adopt the precautionary approach in conservation of biological diversity. This is especially where the threat is likely to cause a serious irreversible harm to biodiversity. Conservation of biodiversity will ensure that the elements of soil, water, animals and plants interact effectively to create a proper functioning planet. This will be a panacea to economic and ecological insecurity of the nations of the world.

The Convention on Biological Diversity that addresses biodiversity issues is the first global binding treaty to enter into force in the context of sustainable development. It focuses on conservation, development goals and environmental quality. The convention addresses harm to resources within individual nation's sovereign jurisdiction but it indicates that the resources are a common concern of humankind. Therefore there is need to develop partnership and co-operation in addressing biodiversity loss. One of the critical areas where concerted effort is required as a matter of necessity and urgency is in the field of biotechnology. The partnership is important because, the world is sailing in the same boat whereby if it sinks all of us will perish.

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<sup>62</sup> Cartagena Protocol, *supra* note 7, art. 8(g)

## CHAPTER THREE.

### THE CARTAGENA PROTOCOL ON BIOSAFETY.

#### 3.1 Introduction.

The world is a risky place. Almost everything we do, from driving, to eating.... to disposing of industrial wastes poses some personal or environmental risk.<sup>63</sup> One of the newest activities to raise concern because of its perceived risks is the planting of transgenic crops by making use of biotechnology. Though the movement of living organisms is largely covered by existing trade and pest control regulations<sup>64</sup> there was need for a legal regime to address the transboundary movement of LMOs, this was therefore addressed by the Protocol on Biosafety.

#### 3.2 Negotiation History for the Cartagena Protocol.

On the bases of Article 8(g) and 19(3) of the Convention on Biological Diversity, the conference of parties (COP) to the Convention on Biological Diversity at its first meeting (COP – 1) held in 1994 established an Open-Ended Ad Hoc Group of Experts to consider the need of a protocol.<sup>65</sup> On the basis of the group's report and recommendations, the COP-2 held in Jakarta Indonesia in 1995, parties agreed to negotiate a formal and binding protocol, which will comply with biosafety provisions of the convention. It was agreed that the international agreement should cover "the safe transfer handling and use of LMOs... Specifically focusing on transboundary movement of LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biodiversity ... " <sup>66</sup> The decision at Jakarta meeting also

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<sup>63</sup> Deborah, K "The mismatch between the Biosafety Protocol and the Precautionary Principle" (2001) vol. xii. Issue 4. *The Georgetown International Environmental law Review* 949

<sup>64</sup> See International Environmental Law Research Centre, *Report of a Workshop on Liability and Redress under Cartagena Protocol*. Workshop held on 22-26 Sep 2003 at Mombassa. See [www.ielrc.org](http://www.ielrc.org) (accessed on 1 Aug 2004)

<sup>65</sup> See Decision 1/9 in Report of the First meeting of the conference of the parties to the Convention on Biological Diversity at 66, UN. Doc. UNEP/CBD/COP/1/17 (1995)

<sup>66</sup> See Decision 1 1/5 in report of the second meeting of the Conference of the Parties to the Convention on Biological Diversity at 47 – 48 UN Doc. UNEP/CBD/COP/2/19 (1995) (Also called the Jakarta Mandate)



established the Open-Ended Ad-Hoc Group on Biosafety also called the Biosafety Working Group (BSWG) to work on the protocol and the deadline was set to be the end of 1998.

The COP relying on the report of Open-Ended Ad Hoc Group of Experts mandated the BSWG to develop a protocol falling within the scope of the CBD. BSWG was also to take into account the "precautionary principle" in addressing the risks of LMOs; and seek to minimise the unnecessary negative impacts on biotechnology. The COP stipulated that the BSWG rely upon the best available science for this work and proceed in a manner conducive to attracting the largest number of ratification possible.

The BSWG met a total of six times, between 1996 and 1995 when it held its sixth meeting (BSWG – 6). In accordance with decision 1v/3 of the COP, BSWG completed a controversial draft in Cartagena, Colombia and referred it to an extraordinary meeting of COP (Ex-COP) for possible adoption. The Ex-COP opened on 22 Feb 1999 in Cartagena Colombia however it had disagreements concerning the central features of the protocol and the parties were unable to reach consensus. The Ex-COP was suspended and it was to be reconvened not later than COP – 5, scheduled to occur in may 2000. The core contentious issues in the negotiation of the proposed protocol revolved around the scope of the protocol and its impact on trade in LMOs. It is noteworthy that during negotiations of the protocol three blocs supporting distinct positions emerged. Firstly there was the Miami Groups that included United States of America, Argentina, Australia, Canada, Chile and Paraguay. This group advocated for a narrow protocol that recognised intellectual property rights and limited regulations to products with a scientifically demonstrated ability to affect biodiversity.<sup>67</sup>

The "Like Minded Group" had a diametrically opposed view. They advocated for a strong, broad, binding protocol that followed the precautionary principle, that which included liability and compensation for any LMO- caused damages, that which excluded trade with non-parties and which took into consideration socio-economic impact as part of risk assessment procedure.<sup>68</sup>

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<sup>67</sup> See Christopher, S and Paul, F "A stalemate on Biosafety Pact" (24 March 1999) *National Law Journal*, C1.

<sup>68</sup> See Tewolde Berhan, GE " Outstanding issues of the Biosafety Negotiations" see <http://www.Capside.Org.sg/Souths/twn/title/tewolde-cn.htm>>(visited 8 June 1999)

The group included China, most members of the European union and most members of G – 77. The “Compromise Group” included Switzerland Norway, Korea and Japan and they advocated for a middle ground between the first and second groups. In some issues this group supported the like minded group” in a bid to force consensus and bring the Cartagena negotiations to an end.<sup>69</sup>

The Ex-COP was reconvened between 24 – 29 of January 2000 in Montreal where the protocol was adopted after a negotiation, which took six days. It was open for signature on May 15 2000 at the fifth meeting of the conference of parties to the CBD held in Nairobi. It came into force in September 11, 2003 ninety days after ratification by fifty – states as provided for in Article 37 of the protocol. Rwanda ratified the protocol on 22 July 2004 bringing the number to 104.<sup>70</sup>

### **3.3 Contentious issues During Negotiations of the Biosafety Protocol.**

As noted above, the negotiations were characterised by divisions. There were three major groups, that is, the “Miami Group” the “like minded Group” and the “Compromise Group”. As a result the negotiation had three blocs. Due to the interests sought to be protected that were in most cases diametrically opposed, a number of contentious issues emerged as illustrated below.

#### **3.3.1 The precautionary principle.**

The precautionary principles contained in the 1992 Rio Declaration on the Environment and Development<sup>71</sup> has been used in many other international environmental agreements that deal with uncertain risks. Although different versions of the principle are adopted the bottom line is that; preventative action should be taken even without full scientific certainty that an activity or substance poses a threat to the environment. During negotiations of the protocol the “like-minded countries” advocated for a strong binding protocol that followed the precautionary principle with

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<sup>69</sup> See Christopher, S and Paul, F. *supra* note 67.

<sup>70</sup> See [www.biod.org/biosafty](http://www.biod.org/biosafty)(visited on 10 Aug 2004).

<sup>71</sup> The Rio Declaration on Environment and Development of UNEP has a total of 27 principles underpinning sustainable development. The precautionary principle is principle number 15.

regard to transboundary movement of LMOs. The principle was to allow a country to reject imports of LMOs even if there is scientific uncertainty that the organisms will cause any harm.

The "Miami Group" which included United States of America advocated for a narrow protocol with limited regulation to products scientifically proven to affect biodiversity. They argued that the precautionary principle could be used to superficially or pretextually to delay trade in LMO."<sup>72</sup> Finally a compromise position was struck as illustrated by Article 1 of the protocol (which incorporates the precautionary approach of principle 15 of the Rio Declaration) and Article 10(6) and 11 (8), 15 and annex iii of the protocol. These articles require that; In the event of lack of scientific certainty... a party shall not be prevented from making a decision as appropriate, with regard to import of LMOs in question this language has been described as:

Complicated and ambiguous reflecting the sensitivity of the compromise struck. Depending upon their interest, parties may attempt to interpret the language as granting quite narrow or broad discretion to parties of import in making import decisions.<sup>73</sup>

Whatever interpretation can be given to the protocol the consensus is that it is an instrument in the hands of state parties, which can be utilised to restrict the import of LMOs.

### 3.3.2 The Scope of the Protocol.

In the course of negotiation there was a disagreement in the appropriate definition of a living modified organism. The definition was important in delineating the body of products to be regulated under the protocol. The "Miami Group" in particular United States of America contended that only genetically engineered organisms that are going to be released (for example for planting or testing) should fall within the regulatory definition.<sup>74</sup> The apprehension of the

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<sup>72</sup> Paul, E and John, B "The Cartagena Protocol and Biosafety: New rules for international Trade in Living Modified Organisms" (2000) vol. XII issue 3. *The Georgetown International Environmental Law Review* 710 – 11.

<sup>73</sup> See Christopher and Paul, *Supra* note 67, 216

<sup>74</sup> See Lisa Seachrist " Biosafety Protocol Fails to pass Muster in Colombia" (10 March 1999) *Bioworld Today* 46



U.S.A was that an all-inclusive definition would bring enzymatic cleaners and fabrics made from transgenic cotton within the purview of the protocol.<sup>75</sup>

Most countries, including the members of the European union, wanted initial inclusion of all LMOs and derivatives thereof within the purview of the protocol with the later addition of an annexe listing exceptions to the regulation.<sup>76</sup> This was cautious approach, which was to guard against automatic exemption and at the same time allows flexibility in a bid to accommodate developments in biotechnology. The compromise position struck at the end of negotiations is witnessed up to now whereby there are differences in definition and regulation of GM products in U.S.A and the European Union. In EU the GM product definition is process oriented whereby if the GM materials are used in the product process the end product requires regulation different from the conventional this products even if no more risks are posed than those of a conventional product.<sup>77</sup> In the USA the definition of a GM product is product centred whereby if a product is not fundamentally different from a conventional product there is no need for a separate regulatory treatment.

### 3.3.3 Advanced Informed Agreement (A.I.A).

This was another area of contention in particular the scope of AIA provisions that would require notification to an importing country before the shipment of LMOs. The United States of America argued that the proposed provisions of A.I.A were burdensome because they were to include all products of biotechnology. There was a requirement of a notice prior to exchange of *any* transgenic material. This requirement was watered down in the final protocol text as shall be seen below (*emphasis added*)<sup>78</sup>

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<sup>75</sup> See Lisa Seachrist *Supra* note 75.

<sup>76</sup> See Chee yokeling "U.S. Behind collapse of Cartagena Biosafety Talks " < [http:// www. Capside. Org .sg/ souths/ twn/ title/ cheey - cn. htm](http://www.Capside.Org.sg/souths/twn/title/cheey - cn. htm)>(visited Feb. 8, 2000).

<sup>77</sup> Oliver, C and David V France, The United States and the Biotechnology Dispute U.S – FR Analysis < [http://www. Brooking.edu/fp/cusf/analysis/biotech.htm](http://www.Brooking.edu/fp/cusf/analysis/biotech.htm). > Visited Jan 2001.

<sup>78</sup> See agricultural biotechnology: Hearings before the house of Comm on Agric. 106<sup>th</sup> Cong. 59-61 (1999)(statement by Roger Pine.Pres .of Corn Growers Association)

### **3.3.4 Liability and Redress**

This was another area of contention. During the protocol's negotiation. There were questions as to who will be liable and in what circumstances for any LMO -caused damages. The developing countries supported a strict liability of a party of the export for any damages caused by LMOS exported from its jurisdiction notwithstanding lack of fault on its part. They were for the inclusion of detailed provisions on liability and redress in the protocol. The developed countries supported the idea of liability and redress to be addressed under national law and within the context of private international law. This contentious issue was resolved by creating an enabling provision in the protocol (Article 27 of the protocol) that reflects a compromise position between the two groups. This is an enabling provision for setting in motion a process to consider the issue of liability and redress but all substantive discussions on liability and redress are left to the COP/MOP of the protocol.

### **3.3.5 Labelling Requirements.**

Throughout the negotiations U.S.A opposed a requirement placing special labelling requirements on living modified organisms even while such products were in transit<sup>79</sup>. The like-minded Group, which included the European Union, lobbied for a precise labelling of all LMOs shipped. A compromise was struck for a mild labelling requirement requiring the shipments bear a label stating that the shipment "may contain" LMOs In case the LMOs are intended to be used as food or feed or for processing.<sup>80</sup>

### **3.3.6 Information Sharing and Biosafety Clearing – House Mechanism.**

The information sharing mechanism was meant to facilitate the exchange of scientific technical legal information pertaining to living modified organisms. The apprehension of the USA and other developed countries was that, it could go against private intellectual property rights by

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<sup>79</sup> See BSWG – 6 Report annex II.

<sup>80</sup> See Biosafety Protocol , *supra* note 7 art. 18(2)(a).

forcing disclosure of proprietary knowledge and material some of which belonged to private companies. A delicate balance is to be struck between legitimate protection of intellectual property rights and education of other party member so as to facilitate sharing of information ultimately enhancing realisation of the objectives of the protocol.

### **3.3.7 Socio-economic Considerations.**

This point revolved around the idea of taking into account the social economic considerations of the importing country in allowing or objecting to the importation of LMOs. This is so as to prevent harm "arising from the import of LMOs on the conservation and sustainable use of biological diversity especially with regard to the value of biological diversity to indigenous and local communities."<sup>81</sup> Though developing countries saw this as a way of promoting conservation of biological diversity by indigenous communities some developed countries like US argued for its exclusion. This was on the basis that countries would, under the guise protecting their citizens, put in place exclusionary trade practices, thus misusing it.

### **3.3.8 The Relationship Between the Biosafety protocol and other International Agreements.**

Under this heading, the disagreement of various blocs in the negotiation was based on the fact that the protocol was an international agreement, involving issues of the environment. The question was which one will take priority in case of conflict with other multilateral Environmental agreements. For example, a number of agreements under world Trade Organisation (WTO) for example Agreement on the application of sanitary and phytosanitary measures (SPS Agreement), the Agreement on Technical Barriers to Trade and agreement of Trade Related Aspects of Intellectual property (TRIPs) contain provisions which have a bearing to the provisions of the protocol. The WTO sets up tough standards for environmental regulations seeking to restrict trade. A party may be a member of both WTO agreements and the protocol. In negotiating multilateral environmental agreements the practise has been to insert a 'savings clause' in the agreement to prevent parties from abrogating from their obligations under existing international law. The "Miami Group" supported this position. They wanted a saving

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Cartagena protocol ,*Supra* note 7, art. 26



clause included in the protocol. The European Union and other developing countries were opposed to its inclusion in the protocol on the ground that it could militate against decisions to deny LMO imports on environmental grounds. The compromise position settled for, which is contradictory, will be illustrated below.

The above negotiation history serves to illustrate why the protocol has some elements of compromise. This was necessary in order to balance the interests of various groups so as to have all of them on board.

### 3.4 An overview of the final text of the Cartagena Protocol on Biosafety.

The concept of biosafety refers to the need to protect human health and the environment from the possible adverse effects of products of modern biotechnology<sup>82</sup>. Article 1 captures the concerns of biotechnology, which the protocol deals with. These are the “safe transfer, handling and use of living modified organisms ... that may have adverse effects on the conservation and sustainable use of biological diversity taking into account risks to human health. The protocol specifically focuses on transboundary movements of LMOs.”<sup>83</sup>

A living modified organism has been defined as meaning any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.<sup>84</sup> A living organism is defined as a “biological entity capable of transferring or replicating genetic material including sterile organisms, viruses and viroids.”<sup>85</sup> Modern biotechnology has been defined by Article 3 to mean ‘the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or fusion of cells beyond taxonomic family, that overcome natural physiological reproductive or recombination barriers.”<sup>86</sup>

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<sup>82</sup> See International Environmental Law Research Centre, *Report of a Workshop on Liability and redress under Cartagena Protocol* held on 22-26 Sep 2003 at Mombassa available at < [www.ielrc.org](http://www.ielrc.org) > (accessed on 1 Aug 2004).

<sup>83</sup> See Report on Liability and redress, *ibid.*

<sup>84</sup> Cartagena Protocol on Biosafety, *supra* note 7, art 3.

<sup>85</sup> *Ibid.*

<sup>86</sup> *Ibid.*

Human pharmaceutical “addressed” by other “relevant international agreements or organisations” are excluded from the protocol.<sup>87</sup>

The protocol regulates transboundary movement, transit, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health.<sup>88</sup> The protocol addresses two categories of LMOs. Those intended for release to the environment and those intended for use in food, feed or processing. The intention of the dichotomy is to put in place a less onerous regime to the latter as compared to those intended for release to the environment.

The precautionary principle as the cornerstone of the protocol is captured by the preamble and Article 1 which states that the protocol's objective is to ensure protection in accordance with the precautionary approach contained in principle 15 of the Rio Declaration on Environment and Development. The definition section of the protocol does not contain the definition of precautionary approach but article 10 contains ample precautionary language. It states that:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the party of import, taking also into account risks to human health shall not prevent that party from taking a decision as appropriate, with regard to the import of the living modified organisms...<sup>89</sup>

This language is complicated and ambiguous but a reflection of the compromise struck during the contentious negotiation.<sup>90</sup> The parties give the language a wide or narrow interpretation when making import decisions depending on their interest. The ambiguous language explains why the

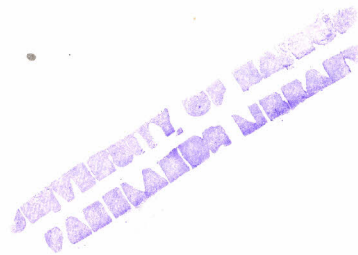
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<sup>87</sup> Cartagena Protocol, *Supra* note 7, art 5.

<sup>88</sup> *Ibid*, art 4.

<sup>89</sup> *Ibid* at art 10(6).

<sup>90</sup> See Paul, E and John, B. *supra* note 72.



precautionary principle manifests itself differently in the US and in the European, and particularly so in the context of GM foods.<sup>91</sup>

The procedure to regulate importation of LMOs is covered under the advanced informed agreement provisions in Article 7 of the protocol. The procedure is considered to be the heart of the protocol.<sup>92</sup> It calls upon parties to apply an "advance informed agreement" (AIA) to the first intentional transboundary movement of a LMO that is intended to be released into the environment of the importing party.<sup>93</sup> LMOs intended for direct use as food or feed or for processing are not subject to AIA procedures.<sup>94</sup> A meeting of the parties (MOP) may agree to exclude some LMOs from AIA procedure when they agree that the LMO is "not likely to have adverse effects on the conservation and sustainable use of biological diversity taking also into account risks to human health"<sup>95</sup> Article 7 makes the first shipment of any LMO intended to be planted as a crop or otherwise released to the environment conditional upon the approval of the importing country.

Article 8 covers notification under the AIA process. A party of export must provide a party of import with advance notice of intended shipment of LMOs. Once the importing nation is notified it is supposed to respond within 90 days acknowledging the receipt of the notification and provide an answer within 270 days on whether or not it approves of the import.<sup>96</sup>

The decision to permit, permit under some conditions or deny import of LMOs by the importing nation is to be informed by scientifically sound risk assessment as provided by Article 15 of the protocol. The AIA incorporate the precautionary principle whereby

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<sup>91</sup> Brian, P. "The Door opens slightly. Resent European Regulations on Genetically Modified Products and the Ongoing United States – European Union GM Product Dispute" (2004) vol XVII issue 2, *The Georgetown International Environment Law Review* 289.

<sup>92</sup> See article 19 (3) of the Convention on Biological Diversity *Supra* note 3.

<sup>93</sup> Cartagena Protocol on Biosafety, *Supra* note 7, art 7. It is possible for a party to require that both first and subsequent imports of LMOs be subjected to the AIA procedure. see kameri- Mbote, P. *Supra* note 24. p. 5.

<sup>94</sup> LMOs for direct use as food or feed or for processing are covered by a procedure under Article 11 of the Protocol.

<sup>95</sup> Cartagena Protocol and Biosafety, *supra* note 7, at art 7.



"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effect of a living organism...shall not prevent a party from taking a decision ...to the import of the LMO ...in order to minimise or avoid such potential adverse effects."<sup>97</sup>

The importing nation may also take into account consistent with their international obligations "socio-economic considerations arising from the impact of living modified organisms" in making its determination. Therefore the refusal of importation of LMOs can be based on both scientific and unscientific reasons. Arguably therefore the protocol grants the importing countries substantial discretion in the regulation of trade in LMOs not only for environmental reasons but also a consideration of social and economic values.

The aspect of handling, transport, packaging and identification of LMOs is covered by Article 18 of the protocol. This Article requires product documentation with respect to various LMOs. The LMOs intended for direct use as food, feed or processing are to be accompanied by a document stating that "they may contain" LMOs, they are not intended for introduction to the environment as well as contact point for further information. LMOs destined for contained use are to be accompanied by a document identifying them as LMOs, specifying any requirements for the safe handling: storage, transport and use and the contact point for further information. The LMOs intended for introduction to the environment of the party of import are to be accompanied by a document identifying them as LMOs, specifying their identity and relevant traits, any requirement for safe handling storage transport and use and the contact point for further information. Approval procedures in Article 10 require decisions to be made in accordance with Article 15.

Article 15 of the protocol tends to limit the precautionary language used in article 1. It requires decisions under article 10 to be made after risk assessments are carried out in a "scientifically sound manner."<sup>98</sup> Article 15 refers to Annexe III that instructs that when performing risk

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<sup>96</sup> Cartagena Protocol *Ibid* note 7,art 8-10.

<sup>97</sup> *Ibid*, art 10(6).

<sup>98</sup> *Ibid*, arts 10,15.

assessments lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indication of a particular level of risk, an absence of risk or an acceptable risk.

Article 16 of the protocol provides for risk management for risks associated with transboundary movement of LMOs. Parties are to maintain appropriate mechanisms; measures and strategies to manage and control risks identified in risk assessment provisions of the protocol. Each party is to take appropriate measures to prevent unintentional transboundary movements of LMOs. Parties are also to ensure that LMOs are observed for an appropriate period before use. Parties are also called upon to co-operate in identifying LMOs that may have adverse effects to the conservation and sustainable use of biological diversity.

Article 19 of the protocol provides for steps to be taken at the national level to facilitate implementation of the protocol. A party is required to designate one national focal point responsible on its behalf for liaison with the secretariat. Each party shall also designate one or more competent national authorities responsible for performing administrative functions required by this protocol. A party can designate a single entity to fulfil the functions of both focal point and competent national authority. In addition to this institutional arrangements of the protocol at the national level as provided in the protocol, the first meeting of COP – MOP called upon parties, as well as governments, organisations and other users interested in entering into partnership with the Biosafety Clearing- House to nominate an expert at the national focal point to carry out this role<sup>99</sup>

Article 20 addresses information sharing. It establishes the Biosafety Clearing-House to facilitate the exchange of scientific, technical, environmental and legal information and experience with living modified organisms, and to assist parties with protocol implementation. Educational efforts are particularly aimed at increasing biosafety knowledge of developing countries, countries with economies in transition and those that are centres of origin and centres of genetic diversity. The Biosafety Clearing -House is aimed at ensuring that countries with inadequate technology to assist them in areas like risk assessment. This is to ensure that implementation of advanced informed agreements achieve truly informed consent.

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<sup>99</sup> See Decision 35-1/3.

Article 22, and 28(3) of the protocol captures capacity building provisions. Parties are called upon to co-operate in development and strengthening of institutional and human resource capabilities in biosafety for purposes of implementing the protocol effectively. The access to and transfers of technology to developing countries in accordance with the convention is vital in the fulfilment of the protocol's objectives. These Articles capture the concept of common but differentiated obligations whereby the co-operation to capacity building is subject to different situations, capabilities and requirement of each party. Co-operation in capacity building includes scientific and technical training in the proper and safe management of biotechnology, in the use of risk assessment and risk management for biosafety and the enhancement of technological and institutional capabilities in biosafety.

Article 27 concerns the issue of liabilities for damage that may result from transboundary movement of LMOs. It is an enabling provision, which mandates the conference of parties serving as the protocol's meeting of the parties (MOP) at its first meeting, to adopt a process with respect to the appropriate elaboration of international rules and procedures in the fields of liability and redress.

Article 28 provides for financial mechanism and resources whereby the financial mechanism established in Article 21 of the convention shall ... be the financial mechanism of the protocol. The developed countries may also provide the developing country parties and parties with economies in transition with financial and technological resources for the implementation of the protocol through bilateral, regional and multilateral channels.<sup>100</sup>

Under Article 29 the Conference of Parties shall serve as meeting of the parties to the protocol and shall keep under regular review the implementation of this protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation.<sup>101</sup>

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<sup>100</sup> Cartagena Protocol. *Supra note, 7, art 28(6)*.

<sup>101</sup> *Ibid art 29(4)*.



Article 32 provides for the relationship between the convention on Biological Diversity and the protocol on Biosafety. The provisions of the Convention relating to this protocol shall apply to this protocol save where this protocol provides otherwise.<sup>102</sup>

In a nutshell, the negotiations of the protocol on Biosafety were characterised by blocs that fought for divergent interests. The "Miami Group" which included the U.S among others advocated for a narrow protocol recognising intellectual property rights and limited regulation to products scientifically proved to have an effect on biodiversity. There was also the "Like-Minded Group" which included the EU among other countries that advocated for a strong binding protocol build on the precautionary principle. There was also the "Compromise Group." in a bid to develop a consensus the spirit of give-and-take was encouraged and the final document as reflected from its negotiations to its final text is a reflection of the compromise struck among the groups so that all could be on board.<sup>103</sup>

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<sup>102</sup> Cartagena Protocol *supra* note 7, art 32.

<sup>103</sup> A glaring example of the Protocol's endeavour to take both groups on board which resulted to a contradiction is the preamble. It states *inter alia* that, the "Protocol should not be interpreted as implying a change in the rights and

## CHAPTER FOUR

### CARTAGENA PROTOCOL VERSUS BIODIVERSITY: DOES THE PROTOCOL HELP OR IT HINDERS CONSERVATION OF BIOLOGICAL DIVERSITY?

#### 4.0 Introduction

In chapter two it was indicated that the greatest threat to biodiversity is habitat loss. It was further indicated that the advancement of modern biotechnology could be harnessed, especially in production of living modified organisms that have the capacity to increase agricultural production. This will meet the demands of food of the growing world population hence preserving the habitats and containing the loss of biodiversity. However with the uncertainties of the risks of LMOs to the environment and human health, it is important to regulate biotechnology or its products to ensure that safety is not compromised. The Biosafety Protocol now addresses the regulation of biotechnology. It is noteworthy that LMOs can be effectively utilised if their use is not stifled by an overly burdensome and overprotective regime, provided that safety is not compromised at any one point. This is, ensuring free and wide usage of LMOs while at the same time checking against their risks.

The provision of article 19(3) of the BCD, which is one of the bases of Biosafety Protocol, envisages AIA as the central operative mechanism of the protocol. It is the two principles of the AIA and the precautionary approach, which are utilised by the countries in regulating importation of LMOs to their territories. The utilisation of the two principles is informed by risk assessment on the proposed LMOs.<sup>104</sup> To ensure that countries carry out effective risk assessment the Protocol provides for information sharing and the Biosafety Clearing-House mechanism<sup>105</sup>, and capacity building.<sup>106</sup> This is to ensure proper implementation of the Protocol.

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obligations of a party under any existing international agreements” while the same preamble states that “the above recital is not intended to subordinate this Protocol to other international agreements.”

<sup>104</sup> The Convention on Biological Diversity, *Supra* note 3, article 19(3), which states that “parties shall consider the need for and modalities of a protocol setting out appropriate procedures, in particular advance informed agreement...”

<sup>105</sup> Cartagena Protocol. *Supra* note 7, art. 20.

<sup>106</sup> *Ibid.*, art. 22.

This chapter takes a critical analysis of salient provisions on which biosafety is anchored with a view of determining whether the protocol institutes an effective regulatory mechanism which will promote conservation and sustainable use of biodiversity or it is a regime which can hinder conservation of biological diversity.

#### 4.1 The Precautionary Approach<sup>107</sup>

The precautionary approach is important because it does not encourage the practice waiting of certainty before taking action. If one were to wait to certainty before taking action, then this will open a leeway for only "reactive measures," which will be costly, as opposed to "preventive measures" resulting from precautionary approach, which are less costly. The Cartagena Protocol does not contain in its preamble and use of terms section<sup>108</sup> the definition of the phrase "the precautionary approach." It only references it in its article 1 as "the precautionary approach as contained in principle 15 of the Rio Declaration." However the protocol in its entirety contains ample precautionary language for example article 10, which provides that

Lack of scientific certainty due to insufficient scientific information regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the party of import, taking also into account risks to human health, shall not prevent a party from taking a decision, as appropriate, with regard to the import of the living modified organism...<sup>109</sup>

Though this article does not expressly use the term precautionary, suffice it to state that it advocates a precautionary approach. Though the protocol makes reference to principle 15 of Rio Declaration,<sup>110</sup> It places substantial restraint on its scope and implementation.<sup>111</sup> The scope of the Cartagena Protocol as contained in Article 1 is to the "safe transfer, handing, and use of living

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<sup>107</sup> There is a distinction in reference to a precautionary "Principle" or "Approach". A principle implies a general rule adopted as a guide for developing international environmental policy, whereas "approach" is defined as a way of considering or handling something, especially a problem." Ellen Hey, *The Precautionary Concept in Environmental Policy and Law: Institutionalising Caution* (1992) *Georgetown Environmental Law Review* 303,304.

<sup>108</sup> Cartagena protocol *Supra* note 7art. 3

<sup>109</sup> *Ibid* at art. 10.

<sup>110</sup> *Ibid*, art. 3.

<sup>111</sup> *Ibid* arts. 1,10,15 and Annex iii



modified organisms.” Article 15 and Annex III also put some limit the implementation of the precautionary approach. The main commitment of the Cartagena Protocol is Article 10, which provides for the decision-making procedure.<sup>112</sup> This Article requires decisions be made according to Article 15. Article 15 in turn requires decisions under Article 10 to be made after risk assessments are carried out in a “scientifically sound manner.” The scientifically sound manner requirement places a significant limit on the precautionary language. Article 15 in turn refers to Annex III, which gives objectives, use of risk assessment, the principles guiding the process, the methodology, steps and points to consider when carrying out risk assessment, however it states that:

Lack of scientific knowledge or scientific consensus should not be necessarily be interpreted as indicates a particular “level of risk” “an absence of risk” or “an acceptable risk”<sup>113</sup>

This statement amplifies further the precautionary approach as contained in the Protocol and in particular conditions under which it is to be applied.

The Cartagena Protocol incorporates the precautionary approach as one of its salient features. It gives the importing country the freedom to accept or reject imports where there is lack of scientific certainty as to their safety. However, *the freedom is not absolute* as it is to be exercised within the boundaries provided by the protocol. The right procedures and assessments must be followed before applying the precautionary approach in decision-making. Notwithstanding the guidelines provided by the protocol, it leaves fundamental questions on its application with regard to the transboundary movement of LMOs. This character of the protocol has prompted J Morris to criticise it “on grounds of scientific ambiguity, and perceived of as pessimistic response to uncertainty and gaps in regulatory risk assessment knowledge.”<sup>114</sup>

Against the above background it is noteworthy that the precautionary principle is one of the critical principles that is recognised throughout the concepts of conservation and sustainable use of biological diversity. It is applied in the biosafety arena as biosafety has conservation and

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<sup>112</sup> Cartagena Protocol, *supra* note 7, art. 1.

<sup>113</sup> *Ibid.* at Annex III note 4.

<sup>114</sup> Kameni-Mbote, P. Quoting J. Morris at *Supra* note 14, p 6.

sustainable use of biodiversity as one of its objectives. There is a unique manner in which the precautionary principle operate in the area of biosafety, in particular the manner in which it is affected by factors such as the extent of public concern about LMOs, and the belief that LMO technology is insufficiently understood and potentially unsafe. The precautionary approach has been adopted in a very direct way in the biosafety area, through its inclusion in the Cartagena Protocol on Biosafety. As stated there, the Precautionary concept embodies an apparent recognition that determining what is an acceptable level of risk is a matter for scientists, expressly stating that "lack of scientific Consensus should not necessarily be interpreted as indicating a particular level of risk, an Absence of risk or an acceptable risk."<sup>115</sup> Thus, where researchers have failed to investigate a potential risk because they assume it is low, this fact should not necessarily constitute evidence that the risk is zero or negligible.

The application of the precautionary approach in the realm of biosafety has been integrally connected with risk management and transparent decision-making, however that connection has been the basis of contention. In some cases, it has been argued that national reliance on stringent environmental impact assessment requirements stands as the implementing mechanism for the precautionary approach, so that no further reference to precaution is necessary. It can also be argued that even in these instances, the recognition of the importance of precaution is clear and important. In Parliamentary debate on this point in New Zealand, the then Minister for the Environment, the Hon. Simon Upton, in general a proponent of the assessment-is-precaution position stated:

The "Precautionary approach" ... is a question. It is a way of thinking. It is a way of approaching uncertainty. I really would be stunned if anybody could disagree with the words of this clause, which simply states that people "shall take into account the need for caution in managing adverse affects where there is scientific and technical uncertainty about those effects." I ask whether there is any business in New Zealand that would say: "Where there is technical uncertainty we shouldn't have any regard for caution." I think that would be a most unbelievably cavalier approach. I think it would run against the grain of good business practice in every respect. These are just plain common-sense words, and no baggage or

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<sup>115</sup> Cartagena Protocol, *supra* note 7, annex iii

superstructure is attached to them. We should apply due caution in the light of our knowledge, and that is what everybody does every day of their lives.<sup>116</sup>

Despite these words, the fact remains that the application of precaution is still a controversial question. The critical questions that constitute a clear manifestation of the gaps of the protocol's precautionary language are considered below.

#### **4.1.1 The level of the perceived risk required to bring into operation the precautionary action.**

Different agreements contain different embodiments of the precautionary principle, which differ in levels of risk required to trigger precautionary action. It has been argued that those agreements on activities with a high level of risk and little benefit, such as dumping, have lower thresholds of risk, which justify or trigger precautionary actions.<sup>117</sup> For example, the Bamako Convention sets the bar at activities that “may cause harm to humans or the environment.”<sup>118</sup> In contrast, agreements that deal with issues that involve risky and beneficial activities employ higher levels perceived risk in order to trigger precautionary action.<sup>119</sup> For example the CBD prescribes precautionary action when there is the “threat of significant reduction or loss of biological diversity.”<sup>120</sup>

The level of perceived risk required before precautionary action is taken in the case of the Biosafety Protocol is akin to that required in the disposal of waste, than to triggering levels of agreements of activities which present risks and benefits such as activities which generate greenhouse gases. The level in the protocol is expressed as “potential adverse effects.”<sup>121</sup> It can

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<sup>116</sup> New Zealand Royal Commission, 2000.

<sup>117</sup> Deborah Katz *Supra* note 19 p. 961.

<sup>118</sup> Bamako Convention on the Ban of the import to Africa and the Control of Transboundary Movement and Management of Hazardous waste within Africa, 30. January 1991.O.A.U/CONFER/COOR/ENV/MIN/AFRI/CONV. (I), Rev 1.30 ILM 773.

<sup>119</sup> Deborah Katz *Supra* note 19.

<sup>120</sup> Convention on Biological Diversity, *Supra* note 3 note 5 of the Preamble.

<sup>121</sup> Cartagena Protocol *Supra* note, 7, Article 10(6).



therefore be argued that the triggering levels of the precautionary action in relation to LMOs should be as provided in the latter case rather than in the former case as the Protocol apparently provides. This is because as LMOs have risks and at the same time benefits as discussed in chapter two.

#### **4.1.2 Consideration of the Benefits of The LMOs in Taking Precautionary Action.**

Some agreements contain a precautionary approach, which allow benefits of an activity and /or alternative risks of avoiding an activity before taking precautionary action. In guidelines provided by the European Commission, on what to do before using a precautionary measure, it was said:

A comparison must be made between the most likely positive or negative consequences of the envisaged action and those of inaction in terms of the overall cost to the community ...<sup>122</sup>

Agreements on dumping and related issues do not provide for consideration of benefits of the risky activity. Despite the fact that LMOs can play a role in conservation of biological diversity as indicated in chapter two, the precautionary approach does not recognize or acknowledge the benefits of LMOs in relation to the perceived risks even though guidelines for risk assessment are provided in annex III of the Protocol. The embodiment of precautionary approach provided in the Protocol resemble those provided in dumping agreements than those where there is a balancing act between risks and benefits to be accounted from an activity before taking precautionary action.<sup>123</sup> There is need for the Protocol to recognise a balance between risks and benefits of LMOs as a basis for allowing them to the environment or banning them.

#### **4.1.3 What Action to be Taken When Precaution is Justified.**

This also depends on the nature of the activity regulated by an agreement. The most limiting effects are found in agreements concerning dumping. Stringent measures will be taken if risks of

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<sup>122</sup> Communication from the Commission on the Precautionary Principle. Brussels, Feb, 2000 COM (2001) 1 final at 18: 6.3.4.

<sup>123</sup> Deborah Katz *supra* note 19: 964.

an activity are substantial when weighed against benefits and vice versa. The Convention on Biological Diversity is an example of agreements that provide for both risks and benefits. It calls for action to “avoids or minimize” effects of risky behaviour.<sup>124</sup> The British white paper encourages “precautionary action to limit use of potentially dangerous pollutants.”<sup>125</sup>

The European Commission Report discusses a range of possible reaction when precautionary measures are justified, it states:

In some cases, the right answer might be not to act.... a wide range of initiatives is available in the case of action, going from a legally binding measure to research project or a recommendation. *A total ban may not be a proportional response to a potential risk in all cases.* However, in some Cases it is the sole possible response to a given risk.<sup>126</sup> (Emphasis added)

Article 10(6) of the Cartagena Protocol on Biosafety provides for most stringent options. It allows a party to take “a decision, as appropriate, with regard to the import of the living modified organism in question” notwithstanding “lack of scientific certainty”...as to “the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity... taking also into account risks to human health. A party is therefore liberty to ban imports if there is a perceived risk.

Following the guidelines given by the European Community where it was stated, “... a total ban may not be a proportional response to a potential risk in all cases. However, in certain cases it is the sole possible response to a given risk,”<sup>127</sup> having analysed the potential benefits of LMOs in chapter two, it is our considered opinion that, a total ban on the basis of potential adverse effects will be too a stringent measure in a case of LMOs.

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<sup>124</sup> Deborah Katz *supra* note 19, 964.

<sup>125</sup> *Ibid.*

<sup>126</sup> Communication from the Commission on Precautionary Principle *Supra* note 122 at paragraph 5 and 6.

<sup>127</sup> *Ibid.*

#### 4.1.4 What Level of Uncertainty is Required to Justify Precautionary Action.

The Rio Declaration<sup>128</sup> and CBD<sup>129</sup> refer to lack of “full scientific certainty” while the Biosafety Protocol uses the term “certainty.” The difference between the two phrases “full certainty” and “certainty” would imply that the precautionary action is unjustified if there is some degree less than total knowledge about the effects of an activity. Be that as it may, certainty of safety is rarely achieved, as scientists cannot claim to know everything especially in LMOs, which is a new field where less is known on how it interacts with ecosystems and its likely side effects on human health. Since certainty is difficulty a goal to reach, the Protocol could have provided for *consensus* among the scientific community as to the degree of risk which can trigger precautionary action.

#### 4.1.5 Suggested Alternative Embodiments of the Precautionary Principle in The Protocol.

As discussed above, the precautionary principle takes various forms, depending on the subject matter of regulation. It has been observed that it manifests itself with various different elements in various international agreements covering subjects ranging from dumping to sustainable development. Generally, agreements on issues where there are large potential risks from an activity with negligible or no benefits at all attract stringent versions of the principle. They require lower thresholds of risk to justify precautionary action. On the other hand agreements with benefits as well as risks employ a modification of an “absolutist” form of the precautionary principle, which employ higher levels of triggering perceived risks.<sup>130</sup>

On analysis of the risks and benefit of the LMOs, they seem to fall within the same class of activities with multifaceted issues such as biodiversity and sustainable development as opposed to dumping of wastes. There is no doubt that the LMOs have benefits to the environment and human health but at the same time they have risks that can nonetheless be mitigated by various ways. A stringent precautionary principle is likely to restrict one of the most important tools for

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<sup>128</sup> 1992. Rio Declaration. *Supra.* note 11.

<sup>129</sup> Convention on Biological Diversity *Supra* note 3, Preamble.

<sup>130</sup> See Andre N. "What you Risk Reveals What You Value. " and Other Dilemmas Encountered In The legal Assault on Risk In (David F and Ellen H eds 1996) *The Precautionary principle and International Law: The Challenge of Implementation* 73.79.



biodiversity conservation- biotechnology. The most appropriate precautionary principle for Biosafety Protocol is one of restrained elements. The current Protocol however includes many stringent elements and therefore a need for a modified version. A modified version of the protocol should be as discussed below.

The current Protocol has "potential adverse effects" as a minimum threshold to trigger the precautionary action. It can be argued that, the essence of the precautionary principle is to adopt a preventative as opposed to a reactive measure. That if you wait for damage in order to take action the cost may be prohibitive or irreversible. A good example is the subject of ecosystems, whereby some ecosystems are non-renewable when destroyed. The Protocol's threshold for precautionary action is low; it is akin to activities that do not have benefits, for example dumping. This low threshold will restrict one of the most important tools for biodiversity conservation (LMOs that are products of biotechnology) by unduly restricting their movement. Therefore instead of "potential adverse effects" as a minimum threshold to trigger precautionary action, the "threat of serious or irreversible damage" should be the appropriate level to trigger precautionary action.

On the point on what action to be taken when precaution is justified the Protocol provides for the most limiting action/drastic action, that is banning the import altogether. This is akin to the action in Helsinki Convention<sup>131</sup> that provides for "action to avoid." The stringent measure is because of the substantial risks of the activity regulated by the Convention.

A total ban may not be a proportional response to a potential risk in all cases<sup>132</sup> and it is not appropriate for LMOs. In this point wisdom to guide on how to deal with LMOs can be got from the 1990 white Paper in Britain's Environmental Strategy, which provides a version of the precautionary principle that can be applied in LMOs. It states that :

"We must analyse the possible benefits and costs of action and inaction. Where there are significant risks of damage to the environment, the government will be prepared to take *precautionary action to limit* the use of potentially dangerous pollutants, even where scientific knowledge is not conclusive, if the balance of

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<sup>131</sup> See Economic Commission for Europe Convention on The Protection and use of Transboundary Watercourses and International Lakes, 6 Oct 1996, 31 ILM 1312.

<sup>132</sup> Communication from the Commission, *Supra* note 122.

the likely costs and benefits justifies it. This precautionary principle applies particularly where there are good grounds for judging that either that action taken promptly at comparatively low cost may avoid more costly damage later, or that irreversible effects may follow if action is delayed.<sup>133</sup> (Emphasis added)

In the Protocol it can be said that negotiation gave hypothetical risks posed by LMOs greater attention than the demonstrated need to improve agricultural production and reduce loss of biodiversity. Little attention was paid to the fact that the stress on natural environment can be reduced by per acre increase of production through biotechnology. It can be further argued that little attention was paid to rural devastation currently caused by expanding acreage under, low yielding, pest vulnerable (non- genetically engineered) crops.<sup>134</sup>

The precautionary principle should be modified to permit a country to take precautionary action to *limit the use* of LMOs (emphasis added) once imported instead of a more drastic measure of banning the import altogether. As highlighted above agreements concerning more unidimensional issues such as dumping do not provide for consideration of the benefits of the risky activity. The current Protocol provides for a version of the precautionary principle, which does not acknowledge the benefits of LMOs. This is notwithstanding article 19 of the CBD, which is one of the bases of the Protocol, acknowledging in its heading the benefits that can be accrued from biotechnology. The heading is "*handling biotechnology and distribution of its benefits.*"

The protocol should recognise benefits of LMOs and the precautionary principle in the Protocol should have a preliminary assessment provided for expressly or a provision for evaluation of risks and benefits of LMOs before a decision whether to take a precautionary action or not in allowing LMOs is considered. This will allow a more balanced view of LMOs as opposed to a precautionary principle where a decision may be based on perceived risks.<sup>135</sup> This will ensure that if a real proven environmental hazard can be ameliorated by an LMO, the probability of less severe consequences resulting from its use should not prevent using it. For example, if there is a possibility of a LMO affecting the health of persons (an hypothetical risk) and there is a certain

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<sup>133</sup> The Common Heritage: Britain Environmental Strategy, Sep1990, CM 1200(British White Paper).

<sup>134</sup> Robert Paarlberg, "Promise or Peril GM Crops in Developing Countries (2000) ENVIRONMENT, 26.

<sup>135</sup> See Cartagena Protocol, *supra* note 7, art 10.

threat of loss of biological diversity if LMOs are not utilised, LMOs can be used and the interest of people likely to be injured can be taken care of by strengthening the tort liability regime. A good example is US where strong *ex post* remedies are available hence a "US policy maker may not feel the need to be as precautionary as some states, because they are more confident of the ability of US tort law system to address any resulting harm after their occur."<sup>136</sup>

On the issue of scientific certainty, the precautionary principle in the protocol should not look to lack of scientific certainty but instead to a lack of consensus by those with credible and respected opinion on the topic. Certainty is high a standard in science as nothing can be proven completely safe and that a "guilty till proven innocent" attitude of precautionary principle will definitely impose a great barrier to progress in combating biodiversity loss. The above views have been echoed elsewhere. It has been stated, "Certainty of safety is rarely achieved as scientists can never assume to know everything. Instead there can be consensus within the scientific community, of the degree of risk."<sup>137</sup>

In conclusion the precautionary principle in the protocol should be adjusted to reflect the above analysed and suggested elements. If this is not done the Protocol's effect can be summed in the words of Henry I. M and C. Gregory, that:

Rather than creating a uniform predictable and scientifically sound framework for effectively managing legitimate risks, the biosafety protocol establishes an ill defined global regulatory process that permits overly risk-averse regulators to hide behind the precautionary principle in delaying or deferring approvals.<sup>138</sup>

In effect the protocol may inhibit the spread of LMOs especially to nations that need them to increase agricultural productivity. The end result is habitat loss and loss of the biodiversity.

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<sup>136</sup> See Brian P. The Door Opens Slightly *supra* note 91, 291.

<sup>137</sup> See for example Ronald B " The Latest Environmental Concept -The Precautionary Principle -Seeks to Stop Innovation Before it Happens.Very Bad Idea.(1999)*Reason* 3641.

<sup>138</sup> Henry I.miller & Gregory Conco: The Protocol's illusionary Principle (2000) 18 NATURE BIOTECHNOLOGY 360



## 1.2 Advanced Informed Agreement (AIA) Procedure.

This is the Central procedural mechanism set out in the Cartagena Protocol to regulate transboundary movement of LMOs. It enables countries importing LMOs to undertake risk assessment before accepting or rejecting LMOs into their jurisdiction. The AIA procedure is captured by Article 7 of the Protocol which is titled "Application of AIA Procedure." It is noteworthy to state from the outset that there are a number of articles in the protocol that are relevant in determining whether the AIA procedure as contained in article 8-10 and 12 of the Cartagena Protocol applies to a particular transboundary movement<sup>139</sup> of a LMO. The relevant articles are considered below.

Article 4 determines the scope of the Protocol, as a whole as opposed to the scope of the AIA procedure appears to exclude from the scope of the Protocol and by extension AIA procedure any movement of a LMO from the territory of one party into an area beyond national jurisdiction. For example movement of LMOs to high seas is not covered by the Protocol and yet biodiversity in these areas is a common resource of benefit to humanity.

Other articles of the Protocol that are relevant in determining whether or not the AIA procedure applies to particular transboundary movement of LMOs are for example Article 5 which exempts LMOs that are pharmaceuticals for humans from the scope of the Protocol. In order for the exemption to come into play, such LMOs must be addressed by relevant international agreements or organisations. Even though article 5 applies without prejudice to a party's right to decide to subject such LMOs to risk assessment, it can be said that articles 7-10 and 12 (AIA provisions) clearly do not automatically apply to such LMOs. Article 6 provides a more limited exception as it exempts LMOs "in transit" and LMOs "destined for contained use" from the application of the advance informed agreement (AIA).<sup>140</sup>

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<sup>39</sup> Transboundary movement is defined in article 3(k) of the Protocol as the movement of a LMOs from one party to another party, save for purposes of articles 17 and 24 where transboundary movement extends to movement between parties and non-parties.

<sup>40</sup> Cartagena Protocol, *supra* note 7, article 6.

Article 13(b) allows a party of import subject to certain conditions, to specify that import of certain LMOs to it will be exempted from AIA procedure.<sup>141</sup> Article 13(b) is subject to a proviso that adequate measures should be applied to ensure that there is safe transboundary movement of LMOs in accordance with the objectives of the Protocol. This proviso is intended to set the provisions of the Protocol as the minimum level of protection below which no party should fall. Therefore the Protocol sets the floor but no ceiling is set. It is to be observed that no supervisory mechanism for article 13 is provided under the Protocol and this may be a leeway to standards below those set out, in the Protocol. This has a potential danger of a country importing LMOs that are likely to be injurious to biological diversity and human health.

Article 14(3) also takes outside the scope of the Protocol's AIA provisions intentional transboundary movement of LMOs that take place pursuant to bilateral regulation or international agreements or arrangements as between the parties to those agreements and arrangements.<sup>142</sup> This article uses the phrase "shall not apply" which has the effect of ousting absolutely the AIA provisions of the protocol. It needs to be noted that such arrangements or agreements must not result to lower levels of protection than those provided in the protocol. The words "consistent with the objectives of the protocol" and "do not result in a lower level of protection" which set a standard for agreements and arrangements under article 14 are not defined and no specific mechanism is established to monitor and assess whether article 14 agreements or arrangements have met the requirements of the Protocol. This state of affairs may end up impeding the achievement of the objectives of the Protocol

Article 7 excludes from AIA procedure LMOs not destined for intentional introduction into the environment of the party of import.<sup>143</sup> It is notable that the Protocol does not expressly require an exporter or party of export to seek confirmation that the exported LMOs are or will be used only for the intended purpose once in the party of import. In such a scenario the importers may end up introducing to the environment LMOs initially imported for example for contained use. Some

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Cartagena Protocol *Supra* note 7 art. 13(1) (b).

*Ibid.* art. 14(3).

*Ibid.* art. 7(1).

parties in a bid to avoid AIA provisions can import LMOs for introduction to the environment under the guise of “not for intentional introduction into the environment”.

Article 7(4) also allows COP/MOP on a later date, to decide collectively to exclude additional LMOs from the application of the AIA procedure, on the basis of their being not likely to have adverse effects on conservation and sustainable use of biological diversity taking also into account risks to human health.<sup>144</sup> It is notable that the protocol gives no guidance as to what information or evidence might be required to support such a decision; this can therefore be a doorway for standards lower than those contemplated in the Protocol.

### 2.1 Steps in Advanced Informed Agreements.

The AIA procedure involves two parties who deal with transboundary movement of LMOs, that is, the exporter or party of export and importer or party of import. Each of them has obligations to discharge in order to effect the AIA procedure. Obligations of Exporters are contained in Article 8 which require the party of export to notify in writing the competent national authority of the party of import prior to the intentional transboundary movement of a living modified organism covered by Art 7(1) and the notification shall contain at minimum information specified in annex 1.<sup>145</sup> The party of import shall ensure accuracy of information provided by the exporter.<sup>146</sup> To ensure effectiveness of Article 8 it will need implementation in the domestic law of the parties to the Protocol.

The time frame indicated by article 9 on acknowledgement of notification is a good guide but there is no provision in the Protocol to enforce this time limitation, and an importing nation's failure to respond “does not imply...consent” to the shipment.<sup>147</sup> However, under article 34 it is provided that the “cooperative procedures and institutional mechanisms to promote compliance are to be agreed upon at a later date.”<sup>148</sup> This is a window of opportunity that can help in

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<sup>144</sup> Cartagena Protocol, *supra* note 7, article 7(4).

<sup>145</sup> *Ibid* article 8(1)

<sup>146</sup> *Ibid* article 8(2)

<sup>147</sup> *Ibid* article 9

<sup>148</sup> *Ibid* article 34



ensuring compliance. Alternatively implementation can be expedited by the state parties putting in place a domestic law to promote compliance of the article.

The decision to allow or reject the transboundary movement of LMOs into a state's jurisdiction or intentional introduction into its environment is made after risk assessments are carried out in a "scientifically sound manner."<sup>149</sup> Therefore AIA mechanism can only be meaningful if there is a deliberate effort to develop biotechnology infrastructure in countries that have little or no knowledge, experience or resources with which to address biosafety issues, for there can be no informed consent if there is no knowledge with which to assess the risks associated with biotechnology products.

The AIA procedure embraces the precautionary principle<sup>150</sup> therefore making it of central importance in decision-making when it comes to transboundary movement of LMOs. The importing party may also take into account "socio-economic considerations arising from the LMO" in making its determination. This implies that parties to the Protocol can effectively bar importation of LMOs irrespective of whether there is any scientific basis for refusal. The net effect of this state of affairs is increased restriction of LMOs, which have the potential of increasing food productivity.

It is important to point out that there is room to review a decision in view of change of circumstances or state of knowledge of a LMO. The request for review is to be responded to in 90 days. In order to verify and ascertain whether the new information or change of information is such as to warrant a change to the original decision, the 90-day time limit within which to respond is problematic for parties with limited human, technical and financial resources. Thus countries will find refuge in the precautionary principle when time is against them or when they lack the requisite technology.

Rather than act in accordance with the AIA procedure and notification requirements, parties may establish simplified procedures if they choose to, so long as the alternative measures ensure safe

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<sup>49</sup> Cartagena Protocol, *supra* note 7, arts. 10.15 and annex III.

<sup>50</sup> *Ibid* article 10(6).

transboundary movement of LMOs in accordance with the provisions of the protocol.<sup>151</sup> The net effect of this is that it “corrodes the AIA procedure as it alienates further opportunities to check accuracy of decisions.”<sup>152</sup> The condition of corrosion is bound to occur because the Protocol has no supervisory mechanism to ensure compliance of the article. However it should be noted that article 34 is an enabling provision for addressing compliance procedures and mechanisms.

The above analysis of the AIA procedure in the Protocol seems to focus basically on risks of LMOs. This is despite the fact that article 19 of the CBD, which is one of the bases of the Biosafety Protocol, acknowledges that biotechnology has got benefits and risks.<sup>153</sup> The protocol should focus on the risks as well as benefits of LMOs. It is germane to note that even if that were to be the case a number of countries especially developing and those with economies in transition lack the financial and human resource discipline to put in place the requisite scientific infrastructures to assess the risks and benefits of LMOs. For uniformity and a proper analysis of the risks and benefits of LMOs, there is need for an international body to carry out the role of analysing and balancing risks and benefits of LMOs for the benefit of developing and developed countries. The international body, which can be called, the Biosafety Authority can give guidance in form of regulations or international standards for use in trade in LMOs. This is of importance because biotechnology keeps on growing at a high rate prompting the introduction of new LMOs to the environment. With the international body in place, the LMOs can effectively be evaluated in order to determine on their viability and safety.

The idea of an international body to regulate biotechnology can be likened to the idea bred by then- judge Breyer Stephen. He recommended a separate administrative body that could guide risk assessments for general US environment and health policies. Breyer characterised the group he envisioned as “Mission oriented, seeking to bring a degree of uniformity and rationality to decision making in highly technical areas, with broad authority, somewhat independent and with significance prestige.”<sup>154</sup>

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<sup>151</sup> Cartagena Protocol, *supra* note 7, art. 13.

<sup>152</sup> See Kameri- Mbote P. *supra* note 24, p.8.

<sup>153</sup> Cartagena Protocol, *Supra* note 7, arts. 10,15 and Annex iii that concentrate on risks of LMOs.

<sup>154</sup> See Stephen B "Breaking the Vicious Cycle: Towards Effective Risk Regulation (1999).

the characteristics of the group could also serve as a model for an international regulatory body for LMOs. The body would be used to create standards and declare where to set the balance between risks and benefits instead of authorizing individual parties to assert their own interpretation of risks as in the protocol.<sup>155</sup> The result of different interpretation will result to a non-uniform implementation of the Protocol.

For the body to ensure uniformity in implementation of the Protocol, it will co-ordinate activities with competent national authorities and / or national focal points of member countries. These are bodies that will ensure implementation of the Protocol, and regulations of the proposed Biosafety authority at the national level. Members of the proposed body will have to come from state parties, as this will enhance uniformity in knowledge, interpretation and implementation of the protocol.

The summary of procedures to be followed by the body will be as follows: If an LMO is sought to be introduced to the environment, it will require analysis of its risks and benefits. Following this, a panel of experts drawn from competent national authorities of member states, academic institutions and even biotechnology companies are to meet to evaluate the LMO. The decision on whether the LMO is to be introduced to the environment shall be by consensus, as opposed to certainty<sup>156</sup>, which is not easy to reach in science. Consensus is to be preferred, as scientists can not claim to know everything in a particular field. Drawing members from party states to participate in evaluating an LMO will go a long way in facilitating transfer of technology and strengthening the human resource, which can competently handle LMO matters. The funding of activities of the body should be from member states and UNEP. The said body will therefore provide a forum for expert opinions, which can be expressed, considered and crystallised into workable uniform regulations.

It is important to analyse the place of the precautionary principle under the proposed arrangement of an international body. This is important because some countries, that do not want to fulfil their obligations under the Protocol, can hide behind it to achieve this. This can

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<sup>155</sup> Article 13 of the Cartagena Protocol on Biosafety for example provides for states setting up simplified standards.

<sup>156</sup> A level required under article 10 of the Protocol.



ly be the case under the current protocol where parties can prevent importation of LMOs on basis of even a perceived risk.<sup>157</sup>

best model of the precautionary principle under the proposed international body mechanism, which can make parties to fulfil their obligations by not hiding behind the precautionary principle, can be borrowed from the Agreement on Sanitary and Phytosanitary Measures (SPS).<sup>158</sup> The relevant part is in the context of uncertainty or lack of consensus regarding where to set a certain standard. The SPS Article 5(7) provides that "[I]n case relevant scientific evidence is insufficient, a member may provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information, including that from relevant international organisations, as well as sanitary and phytosanitary measures applied by other Members.

This provision and its relation to the precautionary principle was considered in *Hormones* cases decided by the Appellate Body of the WTO. Here the US and Canada accused EC of protectionist motives in refusing to import beef treated with natural and synthetic steroid hormones. EC defended itself that the science whether the hormones are safe is uncertain, and because the precautionary principle is law in EC they had to exclude beef from cattle treated with growth promoting hormones. It was held that article 5(7) reflects the precautionary principle, but that "the principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with members' obligations set in particular provisions of the Agreement."<sup>159</sup>

Therefore SPS treats scientific uncertainty differently than do agreements that expressly invoke the precautionary principle. While the precautionary principle is present in SPS it can not be used until risk assessment and standard setting by international bodies has failed to produce a safe measure due to insufficient scientific evidence. In SPS the standard setting body is Codex. It plays the appropriate role of determining where the balance of risks, benefits and uncertainties

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<sup>157</sup>This can easily be done under article 10

<sup>158</sup>See agreement on application of Sanitary and Phytosanitary Measures (SPS), Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, Annex 1A, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND.

<sup>159</sup>WTO, Measures concerning meat and meat products. Report of the appellate, WT/DS/48/AB/R January 10, 1998

ies. If a similar body is set under the Protocol, it can be used to set standard regulations, and balance risks and benefits of LMOs. Such a body will evaluate the risks and benefits of LMOs and provide appropriate guidelines for their use. It will provide a more cogent view of LMOs than does the Twin principles of AIA procedure and the precautionary principle. This can be possible if there is partiality and ability of the proposed body to base decision in detailed scientific studies of experts.

#### **4.3 Information Sharing and the Biosafety Clearing-House Mechanism (BCH)**

BCH is an information exchange mechanism to assist parties to implement the Protocol. The basis of the BCH is article 18(3) of the CBD, which creates the Clearing-House Mechanism. Therefore BCH is considered as part of the CHM but more specialized and tailored to fit the purposes of the Biosafety Protocol.

It is article 20 of the Protocol, which establishes the BCH as an information repository and a central vehicle for implementing the Protocol. It provides a worldwide web to facilitate exchange of information that is vital for implementation of the Protocol. Electronic and other systems for exchange of information will be utilised in a bid to expedite information exchange that is valuable in import decision making. The BCH will also provide access to other international biosafety exchange systems.<sup>160</sup>

The primary mechanisms for limiting the importation of LMOs are the AIA provisions. For AIA provisions to be of value, the BCH is required to be effective in providing reliable, authentic and valid information to be relied on by countries in making decisions concerning LMOs. This is because there can not be informed consent if there is no knowledge with which to assess the risks associated with biotechnology products.

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<sup>160</sup> Example of other biosafety exchange systems include *inter alia*: The International Centre for Genetic Engineering and Biotechnology at [www.icgeb.org/~bsafesrv/bsfdata1.html](http://www.icgeb.org/~bsafesrv/bsfdata1.html), and United Nations Industrial Development Organization (UNIDO)-, Biosafety information Network and Advisory Service (BINAS) [www.binas.unido.org](http://www.binas.unido.org).

As a worldwide web the BCH constitutes a network of focal points, international centres and institutions with knowledge or experience in LMOs. The focal points are institutions at the national level, which can be used in validating data registered on the BCH for their country. For the effective functioning of the BCH, resources and training is to be provided to developing countries and countries with economies in transition, as BCH requires participation of all countries. Article 20 captures the concept of partnership among nations and people in addressing the issues of environment and development. It reflects the concept of common but differentiated responsibilities. The protocol distinguishes between developed and developing countries and appears to make fulfilment of obligations of developing countries depended upon the fulfilment of technology transfer and financial resources obligations of the developed countries. This on the face of it appears to be a good arrangement which when analysed critically seems to yield little towards the implementation of the protocol.

During negotiations of the Protocol USA feared that information sharing provisions would bridge private intellectual property rights by forcing disclosure of proprietary knowledge and materials and was criticised at an earlier meeting<sup>161</sup> for insisting an addition of a companion article that allows for non-disclosure of confidential information.<sup>162</sup> Non-disclosure of confidential information was addressed by the protocol, in article 20(3) where parties are to make information available to BCH “without prejudice to the protection of confidential information.”<sup>163</sup> Therefore the BCH is to create a mechanism which draws a delicate balance between, educating those entities which have little knowledge of biosafety so that the implementation of AIA procedure, achieve a truly informed consent on one hand and legitimate protection of intellectual property rights on the other hand.

The BCH mechanism may be seen as giving a benefit by the right hand and taking away the means to enjoy it by the left hand, in the sense that, while the approach may be helpful in facilitating the sharing of information, it may create difficulties if the finer details regarding a LMO is not made available on the BCH web on the basis of confidentiality. For example in

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<sup>161</sup> See Biosafety Protocol. *Supra* note 7, art. 21.

<sup>162</sup> See Biosafety Protocol. *Supra* note 7, art 21.

<sup>163</sup> Cartagena Protocol. *supra* note 7, art 20(3).



article 10(3) it is provided that "a party of import should notify its decision on the first import of a LMO to the BCH..."<sup>164</sup> However, if detailed information about that LMO has to be kept confidential then on the basis of information available through the BCH it may not be possible for a subsequent exporter to determine with precision whether a LMO which has been authorised by a party is the same LMO that it intends to export to that party.

In order to ensure effectiveness in implementation of the Protocol there is need to ensure capacity building at the national level. This can be effected by co-operation amongst the parties in strengthening the human resource and institutional capacities in biosafety. For this to be done article 22(1) and (2) recognizes common but differentiated obligations whereby co-operation is required to ensure that "the needs of developing country parties... for financial resources and access to and transfer of technology and know-how in accordance to the relevant provisions of the Convention, shall be taken fully into account for capacity building in biosafety..."

It is noteworthy that information through BCH can be important if states have appropriate technology in order for them to carry out proper risk assessment of LMOs before introduction to the environment. The requisite technology for risk assessment of LMOs at the national level is therefore a must. It must be emphasised that technology transfer is not an end in itself; it is a means to an end. The technology transfer provisions in the CBD and in the Cartagena Protocol invariably envisage transfer of technology from those who have developed it (developed countries) to those who need it (developing countries). Developing states are placed in the position of recipients and they could either receive ready-made technology or could benefit from promotion of scientific or technological innovations of developed countries. Technology transfer in the Protocol is to be provided in the accordance with the Convention on Biological Diversity.<sup>165</sup> The Convention itself stipulates access and transfer of technology is to be on fair and most favourable terms including consensual, preferential terms and mutually agreed terms.<sup>166</sup> This when analysed in conjunction with other related provision, appear to favour the

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<sup>164</sup> *Ibid.* art 10(3).

<sup>165</sup> *Ibid.* art 20.

<sup>166</sup> Convention on Biological Diversity, *supra* note 3, art. 16.

idea of transfer of technology including that which is subject to intellectual property rights but to be provided in terms consistent with their protection.

The mode of transfer of technology, which can aid in the implementation of the protocol, is akin to that envisaged in the deliberations of the 1982 Convention on Law of the Sea.<sup>167</sup> From the procedures envisaged under the convention, it is clear that the transfer of technology was designed to take place in such a way not to amount to the purchase of cook-book whereby the purchaser-the enterprise or developing country- is left alone to follow the recipe written without practical assistance from the developer of the book. It is getting appropriate technology by participating in activities with those who have it

Under the Convention, exploitation of the seabed is to be done by the enterprise, an operational arm of the sea-bed authority, for the benefit of humankind. The relevant paragraphs of Annex III on the basic conditions on seabed mining require the transfer of seabed technology from multinational companies to both the enterprise and the developing countries. The transfer of seabed mining technology is most appropriate to take place in the context of a joint venture between those entities possessing it and those seeking it. The proposed text of the treaty proposed *inter alia*, measures directed towards the advancement of technology of the enterprise and the domestic technology of developing countries, particularly through the opening of opportunities to personnel from enterprise and from developing countries for training in marine science and technology and their full participation in activities of exploitation of common heritage of mankind.

For the Protocol to be implemented effectively, it should create a body to occupy the position of the Enterprise in seabed mining. It has been proposed above that the body be called the Biosafety Authority. The body should be financed by all party states according to their abilities. This is in line with the doctrine of common but differentiated obligations as envisaged under article 20 of the Protocol. The body can then acquire technology from private companies, state parties or other entities on “fair and reasonable terms and conditions” and the technology can be

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<sup>167</sup> United Nations Convention on Law of the Sea 1982.UN/Doc.A/ CONF.62/122. For details on transfer of technology to the enterprise and third world countries see LL.B IV. Class of 2004, University of Nairobi. Lecture notes/handouts of Law Science and technology by DR Adede (available with the author –omituga@yahoo.com).

used in analysing LMOs under the a umbrella of the proposed biosafety authority with all member states participating. Through this mechanism appropriate technology on LMOs will be available to state parties in a relatively easy way than that envisaged in the Protocol.

It must be emphasised that the process of acquiring technology to the suggested authority requires goodwill from the countries or entities that have it. It may be difficulty, especially technology subject to intellectual property rights. This is because the authority may lack a police machinery to demand technology transfer to itself, also states are sovereign entities which can not be compelled contrary to their interests. The way forward is now to enable the proposed authority financially to obtain technology from the market on fair and reasonable terms and conditions. In the spirit of common but differentiated obligations, financial contributions towards the suggested authority to enable it dispense its obligations should be based on the economic base of each member state.

Another approach for effective technology transfer is for developing countries to seek help in developing their own technological capabilities. State parties should promote international technical and scientific co-operation, whether between themselves or by developing training, technical assistance and scientific co-operation programmes in biotechnology. In the long run, the issue of technology will be resolved if state parties obtain their own technology. With the appropriate technology state will ensure maximum utilisation of LMOs while at the same time guarding against the possible risks to the environment and human health.



## CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS.

### 5.1 CONCLUSION.

#### 5.1.1 Introduction.

Notwithstanding the fact that genetic modification by use of biotechnology and biosafety are concepts that have not been well understood, two major issues come out clearly concerning LMOs: Firstly, there are those who believe in the potential of LMOs to significantly lead to loss of biodiversity. They assert that LMOs can have a negative impact on land not under cultivation and /or ecosystems and also adversely affect human health. Secondly there are those who view LMOs as having a potential to enhance global food security by increasing food production without the need to convert more land to cultivation. They argue that by the increase in food production without clearing more land this will ensure that biodiversity is conserved. The second group premise their argument on the fact that habitat loss is the greatest cause of loss of biodiversity. The Cartagena Protocol on Biosafety therefore intervenes to specifically address Transboundary movement of LMOs, so as to ensure that LMOs are not sent to a country without assessment as to their human safety and environmental impact.

After analysis of the provisions of the Protocol the conclusion is to be based on the question whether the Protocol as a global regime addresses issues related with biotechnology in a manner conducive to its sustainable use and development in biodiversity conservation. In other words, does the protocol retard conservation of biodiversity (Bio-sorry) or it enhances biodiversity conservation and protection of human health (Biosafety). Regard shall be had to salient features of the Protocol, which include *inter alia*: The precautionary principle, AIA procedure, biosafety capacity building and information sharing provisions.

#### 5.1.2 The Precautionary Principle.

Even though the Protocol references the precautionary principle in its preamble, the overall analysis of the Protocol shows that it permeates the Protocol in its entirety.<sup>168</sup> What needs to be

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<sup>168</sup> See : Cartagena Protocol, *supra* note 7 , arts. 10,12,15,16 and Annex III note 4

oted is that the precautionary principle has appeared in different international agreements and s embodiments in each case depend on the subject matter of regulation. Generally where the subject matter has risks without benefits a stringent version of the protocol is adopted, while where the subject matter has got benefits, which outweighs risks a less stringent version of the protocol is adopted.

The Cartagena Protocol has adopted a stringent version of the precautionary principle. The result of this approach will be the unnecessary restraint in trade of LMOs on the basis of unfounded fears or veiled attempts of protectionism. The Protocol establishes what can be called a safe haven with a strong precautionary principle wall behind which overly risk-averse regulators can hide in delaying, refusing or deferring approvals for import of LMOs. With the precautionary principles as stipulated in the Protocol, parties, under the guise of adopting precautionary measures to protect the environment and human health, could restrict one of the most important tools of biodiversity conservation – agricultural biotechnology.

For the use of the precautionary principle to be effective under the protocol there is need to apply the principle against the background of a comparison between the benefits and risks of LMOs. This will allow a balanced view of LMOs, as opposed to taking a precautionary action on the sole basis of the perceived risk of LMOs.<sup>169</sup> The question which ought to be asked before considering a precautionary action should be, “do the benefits of LMOs outweigh its risks or the cost of risk management?” If the answer is in the affirmative a party should be sparingly apply the principle and if it is negative a party should apply the precautionary principle.

### **5.1.3 AIA Procedures and Accessing Information Required for Decision Making.**

Information regarding LMOs is the oxygen of the AIA procedure, which is the central procedural mechanism, set out in the Protocol. It enables countries to undertake risks assessment of LMOs before shipment to their countries. Therefore the AIA procedure will be a dead letter without any

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<sup>169</sup> This is the position under the protocol's articles 10 (8) where “potential adverse effects” is good enough to justify a precautionary action.

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effects if a country lacks the capacity in terms of Scientific knowledge and infrastructure to carry out effective risks assessment.

The vital information for purposes of decision-making is not easily accessible, not even through the biosafety clearing - house mechanism (BCH mechanism). Inaccessibility is sometime caused by protection, ostensibly, by intellectual property rights (IPRs). This makes it difficult for a decision maker to have dependable, unbiased information that is indispensable to a decision maker in making an informed and responsible science – based decision. Even if the information was to be freely available countries especially developing and those with economies under transition lack institutional capacity and human resources to understand, assess it, and thus apply it to policy development and decision making on LMOs related proposals.

Therefore the AIA provisions go in tandem with information sharing provision of the Protocol (BCH mechanism). The two are not mutually exclusive as the effectiveness of AIA procedure depends on the extent of knowledge about LMOs. To facilitate effective information sharing, there is therefore need to strike a delicate balance between legitimate intellectual property rights protection and education of other members on issues of biosafety.

Decisions to import LMOs also require consideration of socio- economic considerations.<sup>170</sup> This makes the decision maker's task even more complex. He must determine whether there are social, cultural or economic risks and how to balance those risks against the potential gains of LMOs. The implementation of this provision has to be done carefully so as to allow legitimate protection of the social, cultural and economic interests of a country's citizens, while at the same time avoiding misusing this as a bar to importation of LMOs.

#### **5.1.4 Public Participation.**

Bruce M. Chassy on responding on questions on the barriers to biotechnology stated, "One real barrier is certainly customer resistance. If people are afraid of the technology, it is pretty hard to

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<sup>170</sup> Cartagena Protocol *supra* note 7 .art. 26.

deploy it.”<sup>171</sup> The fate of biotechnology therefore lies on the willingness of the public to accept or refuse products of biotechnology. The public needs to be educated on benefits and risks of LMOs and to be actively involved in decision making on LMOs. This transparency will ensure an effective way of embracing biotechnology and products.

#### **5.1.5 Biosafety Capacity Building.**

In order to ensure the implementation of the protocol at the national level, there is need to develop and strengthen relevant human resource and scientific infrastructure. This will ensure effective risk assessment and avoidance of hiding behind the precautionary principle because of incapacity to carry out risks assessment.

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<sup>171</sup> East African Standard Newspaper, 6-12 September 2004,P.21.

## 5.2 RECOMMENDATIONS

### 5.2.1 Introduction

LMOs exist and cannot be wished away or unmade. The way to go is to develop mechanisms to respond to the existence of the biotechnology that seems to be important and yet controversial. The starting point for any country wishing to use this technology, even before focusing on the basic requirement of the Protocol (risk assessment, the precautionary principle, AIA procedure, biosafety clearing-house) is to develop an overall policy on how risks and potential benefits of LMOs can be assessed and addressed. After the policy is put in place, the focus will then shift the requirements of the protocol as will be considered below.

### 5.2.2 The Precautionary Principle

Having concluded that the elements of the protocol as currently constituted consist of the stringent version that is not conducive for biotechnology development, there is therefore a recommendation for alternative embodiments of the precautionary principle with restrained elements. Before exercising the precautionary approach option regard should not be had on risks alone but the risks should be weighed against benefits of LMOs and other risks which may arise if LMOs are not used.

The following are therefore the proposed elements of the precautionary principle: “serious or irreversible damage” should be taken as a minimum threshold to trigger precautionary action. This is less restrictive compared to “potential adverse effect”<sup>172</sup> which is the minimum threshold required under current Protocol before taking precautionary action. The latter approach seems to be anchored on risks of LMOs while the proposed approach will accommodate benefits of LMOs before considering taking a precautionary action. With the current position in the Protocol a country can effectively bar the importation of LMOs irrespective of whether there is a scientific basis for refusal or not, this is likely to bar the optimum utilisation of this technology in biodiversity conservation.

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<sup>172</sup> Caragena Protocol. *Supra* note 7, art. 10.



With regard to the action to be taken once the minimum threshold is ascertained, the protocol gives a “blank- cheque” to party states to make a “decision as appropriate with regard to import of LMOs.”<sup>173</sup> This can justify even a drastic measure of banning an import altogether. Instead of this action it is proposed that a country take precautionary action to “limit the use” of the organism once imported. This action has been utilised in the British White Paper where the issue of benefits and risks of an activity was considered. It stated that:

“We must analyse... benefits and costs both of action and inaction. Where there are significant risks of damage to the environment, the Government will be prepared to take precautionary action *to limit the use* of potentially dangerous pollutants, even where scientific knowledge is not conclusive *if the balance of the likely cost and benefits justifies it*”<sup>174</sup> (emphases added)

The fact that an LMO is not safe should not bar a party from making use of it. For example if a real proven environmental hazard can be ameliorated by LMOs the possibility of less severe adverse effects of LMOs, should not prevent its use. It is therefore proposed that there should be expressly included in the precautionary principle of the Protocol, a provision for a preliminary evaluation of risks and benefits of LMOs before further decision of precautionary action is considered. The evaluation of the risks and benefits of LMOs can be assessed to inform any decision taken.

The precautionary principle as contained in the protocol looks unto “lack of scientific certainty”<sup>175</sup> as the appropriate level of risk required in order to take precautionary action. The defect of this position is that, proving that no adverse effects are available is not possible because scientists can never assume to know everything in a particular field, least of all biotechnology, a new field that is changing rapidly. What can be possible is *consensus* within the scientific community of the degree of risks. It is therefore recommended that the proper way to go is to adopt lack of consensus by those with credible and respected opinion in the field to be a precondition to taking a precautionary action.

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<sup>173</sup> Cartagena Protocol, *supra* note 7, art. 10.

<sup>174</sup> This Common Inheritance: Britain’s Environmental Strategy, Sep 1990, Cm 1200 (British White Paper)

<sup>175</sup> Cartagena Protocol, *Supra* note 7, art.10.

For proper analysis of risks and benefits of LMOs for the benefit of the developing, developed and countries with economies in transition, an international body is proposed for this exercise. It is to get funding from both developed and developing countries each according to its ability but the benefits of research are to be shared according to needs of the various countries.<sup>176</sup>

### **5.2.3 AIA Procedure and Access to Information Required for Decision Making.**

Information regarding LMOs is the oxygen of AIA procedure, but certain vital information is not easily accessible especially by developing countries ostensibly because of protection by intellectual property rights. This makes it difficult to access dependable and unbiased information, which is the decision maker's key to making responsible science-based decisions. Even when the information is freely available, there is inadequacy in the institutional capacity to understand and assess it, and thus apply it to policy development and decisions involving LMOs. A recommendation is therefore made for an international body<sup>177</sup> that will access the necessary information about LMOs and use it for the benefit of both developing and developed countries.

### **5.2.4 Addressing Economic and Social-Cultural Controversies Regarding LMOs.**

With the introduction of LMOs it is possible to have social, economic and cultural issues come into perspective. For example:

The *Sukuma* of Tanzania use more than 300 plant species. They have accumulated a wide knowledge base and skill in identifying, characterising and conserving plants. Moreover, they keep different kinds of crops and livestock. This ensures diversity not only in economic activities but also in genetic resources available in the socio-economic system.<sup>178</sup>

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<sup>176</sup> For a more detailed analysis of the nature, structure and functions of the proposed body see chapter four above, particularly under information sharing provisions under the biosafety clearing –house mechanism sub –topic.

<sup>177</sup> *Ibid.*

<sup>178</sup> Mugabe and Clark *Supra* note 31.

For a decision maker there is need to weigh the social cultural and economic concerns at stake and the benefits to be realized out of LMOs, then balance the two before considering introduction of LMOs to an area.

Since the fate of LMOs lies on the people in the areas of introduction, to avoid any controversies, one has to ensure informed public participation as a central ingredient to a decision making process. Transparency will give credibility to any decision arrived at. The public need to be informed of risks and benefits of LMOs or biotechnology products so as to make informed choices when dealing with LMOs. To improve transparency regulatory systems there is need to expand the quantity, quality and public accessibility of information on the regulation of LMOs as this will go along way in demystifying the technology. If this is not done there will be suspicion and people will be afraid of LMOs and “where people are afraid of technology, it is pretty hard to deploy it.”<sup>179</sup>

If there is involvement of all stakeholders in the decision making process (the public, non governmental organisations and all sectors of the civil society) it will help those who oppose the final decision to recognize its validity within the institutional systems. One stakeholder who needs to be singled out is the media. The negative publicity created by the media and its adverse effects on biotechnology is succinctly captured by Bruce M.Chassy who has asserted that:

The media basically is a conduit of what they hear; they try to tell the public everything that they hear about a particular topic of interest ...the opponents of biotechnology have persuaded the people not to use this technology...it does not judge whether the technology is good or bad and the story is true or false<sup>180</sup>

While it is important to take into account social economics and cultural considerations of people of a country in decision making, it is important to have a legitimate protection of a country's citizens interest but at the same time guard against using this as a vehicle to effect unwarranted restraints on biotechnology.

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<sup>179</sup> East Africa Standard, 6-12 Sep 2004 .p 21.

<sup>180</sup> *Ibid.*



### **5.2.5 Biosafety Capacity Building.**

The extent of application of biotechnology depends largely on the biotechnology infrastructure and human resources development at the national level. This is important especially in the field of risk assessment. The human resource will enable the assessment of information originating, for example, from the BCH and interpret it well to apply it in policy development and decision making on LMOs- related proposals. It is therefore important for governments to provide in their budgets some percentage of the budget for biotechnology development. The money a can be used *inter alia* to build laboratories and resource centres and equip them with the necessary equipment and facilities for biotechnology studies and research.

Development of human resources in the field can also be enhanced through training facilities available with those who have it. For example the government can send people for training with private companies with the largest pool of scientific expertise in biotechnology. An example of such a company is Monsanto of USA.

### **5.2.6 Creation and Use of Institutional Framework.**

Genetic modification and biosafety are concepts that have not been well understood. For example much about interactions of LMOs with various ecosystems is not yet known. There is therefore need to develop broader institutional control to address issues that have not arisen but may arise in future.

It is noteworthy that a law to regulate biotechnology is not mutually exclusive. It is to be considered together with legal regimes in other areas that may affect it either directly or indirectly. These are a number of policy avenues in which a choice made can have a significant impact on an opportunity and incentive for the development of biotechnology. These areas include *inter alia*: Natural biosafety law and policy; National trade law and policy; National intellectual property rights and policy; National food safety, health and consumer choices law and policy and Public research policy. Awareness on the manner in which the policy in each of

these areas addresses biotechnology issues is critical in ensuring that biotechnology development is not unduly stifled by other legal regimes.

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