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## **The Cartagena Protocol on Biosafety: A Comparative Analysis of the Domestic Implementation in South Africa and Uganda**

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Research Dissertation presented for the approval of the Senate in fulfillment of part of the requirements for a Masters of Laws in approved courses and a minor dissertation. The other part of the requirements for this qualification was the completion of a programme of courses.

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

**15<sup>th</sup> September 2007**

## DECLARATION

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

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Mutesasira P D

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## ABSTRACT

This study makes a comparative analysis of the current biosafety legislation in South Africa and the interim biosafety regulatory regime in Uganda. A set of common characteristics and components in biosafety regulatory systems with reference to related provisions of the Cartagena Protocol on Biosafety were used. The introduction of genetically modified organisms (GMOs) especially in agriculture has produced a new range of governance challenges in the fields of environmental safety and human health. The regulation of modern biotechnology in Africa is still in its infancy. Despite this, legislation is urgently required to regulate modern biotechnology. The study assessed how the Cartagena Protocol on Biosafety is implemented by South Africa and Uganda.

The study revealed that though the Cartagena Protocol has gone some way in regulating modern biotechnology, its implementation in countries such as South Africa and Uganda has not resulted in the harmonization of the domestic regulatory process. On the national level, the study noted that the biosafety legislation of South Africa and the interim biosafety regulatory regime of Uganda do not fully comply with the provisions of the Cartagena Protocol. This is mainly because each country has taken a different approach in implementing the protocol depending on its domestic priorities, imperatives and position in the global agricultural market. Finally, the study made recommendations on possible ways in which South Africa and Uganda can coordinate and harmonize their national biosafety regulatory systems. These will enable the two biosafety regulatory systems to become more compliant with the provisions of the protocol.

**Key Words:** Genetically Modified Organisms, Modern Biotechnology, Biosafety, Cartagena Protocol, Interim Biosafety Regulatory Regime, South Africa, Uganda.

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## LIST OF ABBREVIATIONS

AIA	Advance Informed Agreement
AU	African Union
BCH	Biosafety Clearing House
CA	Competent Authority
CBD	Convention on Biological Diversity
COP	Conference of Parties
DOA	Department of Agriculture
DNA	Deoxyribonucleic Acid
EIA	Environmental Impact Assessment
EU	European Union
FAO	Food and Agriculture Organization
GE	Genetically Engineered
GM	Genetically Modified
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
ILM	International Legal Materials
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
ISNAR	International Service for National Agriculture Research
IISD	International Institute for Sustainable Development
ISAAA	International Service for the Acquisition of Agri-biotech Applications
IOCU	International Organization of Consumer Unions
IPPC	International Plant Protection Convention
LMO	Living Modified Organism
LMO-FFPs	Living Modified Organisms Intended for direct use as Food or feed, or for Processing
MEA	Multilateral Environmental Agreement
NBC	National Biosafety Committee
NEMA	National Environmental Management Act 107 of 1998

NGO	Non-Governmental Organization
PAIA	Promotion of Access to Information Act 2 of 2000
PAJA	Promotion of Administrative Justice Act 3 of 2000
PIC	Prior Informed Consent
SAJELP	South African Journal of Environmental Law and Policy
SAGENE	South African Committee for Genetic Experimentation
SPS	Sanitary and Pyhtosanitary Standards Agreement
RECIEL	Review
TWINS	Third World International Networks
UN	United Nations
UNCST	Uganda National Council of Science and Technology
UNEP	United Nations Environment Programme
WHO	World Health Organization
WFP	World Food Programme
WTO	World Trade Organization

## **CHAPTER ONE:**

### **INTRODUCTION TO THE STUDY**

*“Biotechnology could contribute significantly to the achievement of the objectives of the Convention on Biological Diversity and the attainment of the Millennium Development Goals. However, it must be developed judiciously, and used with adequate and transparent safety measures”.*

*- Kofi Annan, Former United Nations Secretary-General.*

#### **A. Introduction**

Biological processes have been used for centuries to modify food in order to improve taste, palatability and safety, especially by using the technique of selective breeding. Biotechnology is not a recent phenomenon and can be traced to fermentation and cheese making process developed by the Egyptians over four thousand years ago.<sup>1</sup> The introduction of genetically modified organisms (GMOs) especially in agriculture has produced a new range of governance challenges in the fields of environmental safety and human health.<sup>2</sup> With the introduction of modern biotechnology, there have been a lot of mixed reactions and controversies.<sup>3</sup> This has eventually led to the emergence of two groups.<sup>4</sup> The first group consists of the proponents of GMOs led by the United States of America (USA). The proponents of GMOs are advocates of the permissive approach in the regulation of modern biotechnology and GMOs. The second group consists of the opponents of GMOs led by the European Union (EU). The opponents of GMOs are advocates of the precautionary approach in the regulation of modern biotechnology and GMOs. Global rules and regulations have

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<sup>1</sup>Bail C, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and development* (Earth Scan Publications, 2002). pp. 4.

<sup>2</sup> Aarti Gupta and Robert Falkner, ‘The Influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa’. pp. 23.

<sup>3</sup> Mackenzie R, Burhenne-Guilmin, & La Vina A, ‘*An explanatory guide to the Cartagena protocol on biosafety*’, 2003. IUCN Environmental Law Centre, IUCN, Gland, Switzerland and Cambridge, UK. pp. 5.

<sup>4</sup>The World Trade Organization (WTO), 2000. *Shorter Articles, Comments and Notes. International Trade in Living Modified Organisms: The New Regimes*. Available at [http://www.wto.org/english/tratop\\_e.htm](http://www.wto.org/english/tratop_e.htm). Accessed on 11 June 2007.

been established to govern modern biotechnology, the most recent being the Cartagena Protocol on Biosafety, which is now being implemented in a growing number of developing countries.

It is suggested that GMOs constitute both actual and potential risks to biological diversity and human health. The exact nature of these threats is still unknown because of the lack of in-depth research. Given the unpredictable nature of modern biotechnology, and its potential to have a negative impact on the environment, it is wise to proceed with caution.<sup>5</sup> By taking a precautionary approach in the context of the transboundary movement of GMOs, it is necessary to adopt a judicious blend between liberal trade and biosafety concerns.<sup>6</sup> The regulation of modern biotechnology in Africa is still in its infancy. Despite this, legislation is urgently required to regulate modern biotechnology. It is now apparent that genetically modified organisms (GMOs) are finding their way into the different regions of Africa, and so are the dangers that come with them.

South Africa was the first African country to enact legislation regulating modern biotechnology and GMOs. South Africa's biosafety legislation could be used as a reference for Uganda (that is in the process of adopting its proposed Biosafety Bill of 2005) and the rest of Africa in developing effective biosafety regulatory systems, as there are many lessons that may be learnt from it. However, over the past several years Uganda has made it a priority to establish a fully functional biosafety regulatory regime.

This study makes a comparative analysis of the current biosafety legislation in South Africa and the interim biosafety regulatory regime in Uganda. This will be done by comparing selected key features in both biosafety regulatory systems with

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<sup>5</sup> Barron N M, 'A Case Of Throwing Caution To The Wind: A Critical Analysis Of The EIA Provisions Contained In The GMO Act of South Africa'. 2003 SAJELP. pp. 94.

<sup>6</sup> Asif H Qureshi, 'The Cartagena Protocol on Biosafety and the WTO-Coexistence or Incoherence?'. pp. 835.

reference to related provisions of the Cartagena Protocol on Biosafety. The study is aimed at assessing how the Cartagena Protocol is implemented in South Africa and Uganda, and the compliance level of the biosafety regulatory systems of the two countries.

## **B. Definition of Terms**

Biotechnology is defined as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.<sup>7</sup> This includes the use of microbial, animal or plant cells or enzymes to synthesize, breakdown or transform materials. Biotechnology could be looked at from two perspectives; modern biotechnology and traditional biotechnology. This study shall focus on modern biotechnology. Genetically modified organisms (GMOs), also called Living modified organisms (LMOs), are living organisms that contain novel combinations of genetic material as a result of the application of biotechnology.<sup>8</sup>

Genetic modification (GM) is a process used to modify life forms by introducing molecular material deoxyribonucleic acid (DNA) from other life forms in order to alter their genetic make up and inheritable qualities permanently.<sup>9</sup> Genetic modification is different from traditional breeding of plant varieties. To date the current introduction of GMOs has been in agriculture so as to enhance traits useful in the production or marketing of foods.<sup>10</sup>

Biosafety is a collective term that refers to the safe development, transfer and application of biotechnology and its products. Biosafety may also refer to the

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<sup>7</sup> International Service for National Agriculture Research (ISNAR) Report No. 5, 1993. Available at <http://www.isnar.cgiar.org/reports/pdf>. Accessed on 5th June 2007.

<sup>8</sup> Smith E, 'Biotechnology', 4<sup>th</sup> Edition, 2000, pp. 3.

<sup>9</sup> Genetic modification involves three steps. The first step is identification and isolation of DNA segment or gene. The second step is the transfer of the isolated gene to another organism and the third step is the regeneration of a healthy organism after DNA transfer has been done into recipient cells.

<sup>10</sup> Countries that produce GMOs include; USA, South Africa, Argentina, Mexico, China and Canada. Genetically modified crops include: Maize, Soya bean, Cotton and Canola.

mechanisms put in place to regulate or control potential risks biotechnology poses to human health, the environment as well as their socio-economic impacts.<sup>11</sup>

### C. Historical Background and Origin of GMOs

The knowledge on which the techniques of genetic modification are based dates from the 1950s, when James Watson, Francis Crick, Maurice Wilkin and Rosalind Franklin discovered the structure of DNA, the now familiar double helix of nucleotides that bears the genetic information for the biosynthesis of proteins like enzymes, certain hormones (e.g. insulin) and whole parts of the body (e.g. nails, hair).<sup>12</sup> This new understanding opened up the possibility that the genetic coding of organisms could be altered to give them new characteristics that natural evolution or selective breeding could not produce.<sup>13</sup> In the 1970s, it became possible to isolate individual genes, refashion them and copy them in cells, huge commercial possibilities opened up. Ways of applying this new technology to medicine were developed quite rapidly. The technology could also be used in industry to produce new fine chemicals and pharmaceuticals using living organisms as “factories”.<sup>14</sup> Applying these methods successfully to plants took longer, the first genetically altered whole food, Flav’r Sav’r tomatoes came on the market in 1994 in the USA. Since then, the number and range of genetically modified products has steadily increased.<sup>15</sup>

The technique of genetic modification differs from selective breeding mainly because it removes genes directly from one organism and inserts them into the DNA of the cells of another. Genetic modification is faster and more exact than the generally random based approach applied in selective breeding.<sup>16</sup> Importantly, it

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<sup>11</sup> Republic of Uganda, National Biotechnology and Biosafety Policy, July 2003.pp.3.

<sup>12</sup> Mackenzie R, op cit n3 at 6.

<sup>13</sup> Royal Commission on Genetic Modification- New Zealand, *Report of the Royal Commission on Genetic Modification- New Zealand*, Auckland 2001.pp. 362.

<sup>14</sup> Mackenzie R, et. al, op cit n3 at 362.

<sup>15</sup> Royal Commission on Genetic Modification, op cit n13 at 362.

<sup>16</sup> Teel Julie, ‘Regulating Genetically Modified Products and Processes: An overview of Approaches’, *New York University Environmental Law Journal* 8 (2000). pp. 649.

also opens the possibility of transferring genes across natural borders between different organisms.<sup>17</sup> The commercial use of genetically modified organisms (GMOs) in agriculture is currently limited almost exclusively to different varieties from four crop species. These include: soybeans, maize (corn), oilseed rape (canola), and cotton.<sup>18</sup> In 2001, 99% of all GMO crop area world-wide was grown in four countries: 68% of the crop area planted with GMOs was in the USA, 22% in Argentina, 6% in Canada, and 3% in China. Worldwide, 46% of the total area that was sown with soybeans was sown with genetically modified (GM) soybean varieties, and for maize 7% of the total crop area was sown with GM maize varieties.<sup>19</sup>

Since 1994 the number of GMOs that may be marketed as human food has increased.<sup>20</sup> For example, up to 52 approved crop varieties (from 13 different species) in the USA; 43 (six different species) in Japan; 12 (five different species) in Australia and New Zealand; five (two different species) in the EU; and four (three different species) in South Africa.<sup>21</sup>

#### **D. Responses and Regulation of Modern Biotechnology**

Various biosafety responses and regulations have been established at international and national level to address biosafety concerns and Genetically Modified Organisms (GMOs). These include:

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<sup>17</sup> Katz Deborah, 'The Mismatch between the Biosafety Protocol and the Precautionary Principle', *Georgetown Environmental Law Review* 13 (2001), pp. 940 & 949.

<sup>18</sup> James Clive, 'Preview: Global Status of Commercialised Transgenic Crops': 2003, ISAAA Briefs No. 30 (2003). Available at <http://www.agbios.com/docroot/articles/04-014-001.pdf>. Accessed on 15th June 2007.

<sup>19</sup> Biotechnology Industrial Organisation, Agricultural Biotech Products on the Market, available at [www.bio.org/er/agri\\_products.asp](http://www.bio.org/er/agri_products.asp). Accessed on 15<sup>th</sup> June 2007.

<sup>20</sup> Hagen Paul E and Weiner John Barlow, 'The Cartagena Protocol on Biosafety: New rules for International Trade in Living Modified Organisms', *Georgetown International Environmental Law Review* 12 (2000), pp. 697, 698.

<sup>21</sup> South African National Department of Agriculture, 2007 (Genetically modified organisms that have been cleared for commercial release and/or for food and animal feed only). Available at <http://www.nda.agric.za/geneticresources/AnnexureB.htm>. Accessed on 15th June 2007.

## 1.0. International Responses and Regulation

There are four key international instruments that are relevant to the regulation of modern biotechnology, these include:

### 1.1. Convention on Biological Diversity (CBD)

The CBD was the first international legal instrument to indicate that biotechnology was a matter of concern for the international community and that consideration should be given to adopting regulations.<sup>22</sup> The CBD is the legal regime for the conservation and sustainable use of biodiversity. The CBD was adopted in 1992 at the UNCED in Rio de Janeiro and was opened for signature on 5 June 1992 and entered into force on the 29 December 1993.<sup>23</sup>

The aim of the CBD is to conserve biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources.<sup>24</sup> The CBD encourages the parties to develop national strategies, plans and programmes for the conservation and sustainable use of biological diversity.<sup>25</sup> The CBD further makes a provision urging the parties to consider need for a biosafety protocol.<sup>26</sup> Glazewski describes the CBD as a landmark in environment and development, as the CBD takes for the first time a holistic and integrated, rather than a species-based approach, to the conservation and sustainable utilization of natural resources.<sup>27</sup>

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<sup>22</sup> Sands P, '*Principles of International Environmental Law*', 2003 (Second Edition). pp.655.

<sup>23</sup> As at June 2007, there were 190 parties to the CBD. It is to be noted that the USA signed the Convention on June 5 1993, but has not yet ratified it because it lacks provisions that protect intellectual property rights as one of the primary grounds of not ratifying it. Available at <http://www.cbd.int/biosafety/shtml>. Accessed on 17th June 2007.

<sup>24</sup> Article 1 CBD.

<sup>25</sup> Article 6(a) CBD.

<sup>26</sup> Article 19 (3) of the CBD.

<sup>27</sup> Glazewski J, '*Environmental Law in South Africa*', 2005.pp. 259.

## **1.2. Cartagena Protocol on Biosafety**

The Cartagena Protocol on Biosafety (the protocol) was the key response to concerns about biosafety at the global level and was adopted in 2000 under the CBD.<sup>28</sup> The Protocol is primarily concerned with the transboundary movements of LMOs and has two key concepts: biosafety and precaution. The Protocol entered into force in July 2003 and has so far been signed by 37 African countries though many have not ratified it or developed laws to incorporate it into their legal framework.<sup>29</sup> Since African countries are faced with the challenge of dealing with the transboundary movement of LMOs, ratification and adoption of the protocol could be a useful option.

## **1.3. United Nations (UN) Guidelines for Consumer Protection**

On 16 April 1985 the United Nations General Assembly stipulated certain guidelines for consumer protection.<sup>30</sup> The guidelines are important as a basis to develop international standards to protect consumers especially those from the developing countries. Thus GMO-related legislation (especially the identification and labeling provisions) of the various jurisdictions should be measured against the outlined guidelines or principles of the UN guidelines for consumer protection.

## **1.4. The Codex Alimentarius Commission**

The Codex Alimentarius Commission is the joint World Health Organization (WHO)/Food Agricultural Organization (FAO) international body charged with the development of food standards. The World Trade Organization as being consistent with the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Standards (SPS) Agreement recognizes its standards. Since its inception in 1961, this body has drawn world attention to the field of food quality and safety. The Commission has encouraged food-related scientific and

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<sup>28</sup> Signed in Montreal on 29<sup>th</sup> January 2000.

<sup>29</sup> Convention on Biological Diversity website available at <http://www.cbd.int/biosafety/shtml>. Accessed on 17th June 2007.

<sup>30</sup> This was through the adoption of Resolution A/Res 39/248.

technological research as well as discussion. It has given top priority to the protection and interests of consumers in the formulation of food standards and related activities.

## **2.0. African Regional Responses and Regulation**

The African Biosafety Model Law was adopted by the African Union (AU) in July 2001,<sup>31</sup> and urged member states to use the African Biosafety Model Law to draft their own national legal instruments. This Model Law reflects a broad consensus on issues of biotechnology development and its regulatory framework utilizes the discretion given by the Cartagena Protocol for countries to adopt more stringent protective measures than the agreed minimum set out in the Protocol.

The Model Law further recognizes Africa as a centre and origin of diversity with regard to food and other crops and also makes a provision for consideration of socio-economic factors in assessing risks and opportunities.<sup>32</sup> The key Legal principles and approaches incorporated in the African Biosafety Model Law include precaution, state sovereignty on decisions regarding GMOs, and a liability and redress regime. The Model Law provides a holistic and comprehensive set of biosafety rules including those that are not dealt with by the Protocol.<sup>33</sup>

## **3.0. African Sub-Regional Responses and Regulation**

In Africa six regional economic communities, namely: the Economic Commission of West African States (ECOWAS), the East African Community (EAC), the Economic Community of Central African States (ECCAS), the Intergovernmental Authority on Development (IGAD), the South African Development Community (SADC), and the Arab Maghreb Union (AMU) have taken the lead in developing policy guidance on GMO research, production and marketing in their respective regions. The SADC

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<sup>31</sup> 74<sup>th</sup> Ordinary Session in Lusaka, Zambia.

<sup>32</sup> Jaffe G, 'Comparative Analysis of the National Biosafety Regulatory Systems in East Africa', EPT Discussion paper, January 2006. Pp.32. Available at [www.ifpri.org](http://www.ifpri.org) last accessed on 20<sup>th</sup> June 2007.

<sup>33</sup> Mayet M, Comments On The Ugandan National Biosafety Framework, September 2004. <http://www.biosafetyafrica.net/uganda.htm> . Accessed on 20th June 2007.

established an advisory committee on GMOs and the EAC also recommended reviewing and developing a common policy on GMOs.

#### **4.0. National Responses and Regulation**

There is need for harmonized and adequate national policies and laws to regulate biotechnology in Africa at the national levels. At least nine African countries including Uganda and South Africa have biosafety legislation, policy or guidelines to address the issue of biosafety and the regulation of GMOs. Biosafety legislation in South Africa consists of the Genetically Modified Organisms (GMO) Act,<sup>34</sup> the Genetically Modified Organisms (GMO) Regulations, and more recently the Genetically Modified Organisms (GMO) Amendment Act,<sup>35</sup> while the interim biosafety regulatory regime of Uganda consists of the Draft National Biotechnology and Biosafety Policy,<sup>36</sup> and the Draft Biosafety Regulations.<sup>37</sup> Developed country aid agencies and international organizations have taken keen interest in supporting the development of an enabling legal environment for transgenic research and biosafety. The AU biosafety capacity building project has also spearheaded the harmonization of biosafety legislation between member states based on the African Biosafety Model Law.

#### **E. Arguments for and Against Modern Biotechnology and GMOs**

With the introduction of GM technology there has been a lot of controversy and mixed reactions to this new technology and this eventually led to the emergence of two groups.<sup>38</sup> The first group consists of the proponents of GMOs and the second group consists of the opponents of GMOs. The views on the benefits offered by genetically modified organisms, and the extent to which those benefits might be

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<sup>34</sup> Republic of South Africa, Act 15 of 1997.

<sup>35</sup> Republic of South Africa, Act 23 of 2006.

<sup>36</sup> Republic of Uganda, July 2003.

<sup>37</sup> Republic of Uganda, October 2003.

<sup>38</sup> Controversies over GMOs began in Europe, where food safety was an important issue because of several unrelated incidents such as the “mad cow” disease that resulted in the EC ban on beef imports from Britain.

cancelled by the potential risks that GMOs pose to human health and the environment, are polarized.<sup>39</sup>

The advocates for GMOs, including the immensely powerful biotech industries, focus on the infinite potential applications for such revolutionary techniques. Emphasis is laid on the costs and energy savings that can be reaped by the agricultural sector in the form of reduced net input costs (including costs of pesticides and labour), increased profits,<sup>40</sup> and enhanced yields that will reduce agricultural clearing and thereby lessen habitat loss, and damage to the environment and biodiversity.<sup>41</sup> Amongst the more captivating innovations that GM technology has to offer is crops with more nutritional value, increased shelf life, and insecticide and herbicide resistant crops. More important than all these claims, however, has been the assertion that GM technology holds the key to famine and starvation by availing more food to feed the malnourished people and the promise that genetic modification could be used to overcome difficulties of poor arable land and drought. With regard to health benefits GM technology enables specialty in chemicals such as pharmaceuticals that provide better health care possibilities.

On the other hand the critics of GM technology argue that it poses significant economic risks, including the failure of the technology to deliver the promised benefits.<sup>42</sup> There are concerns that a GM crop could transfer modified genes to wild relatives<sup>43</sup> and potentially create a super weed, or could its self become a weed, potentially threatening biodiversity.<sup>44</sup> Critics of GMOs have also raised

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<sup>39</sup> Hughes D; Jewell T; Lowther T; *Environmental Law* 4<sup>th</sup> edition, 2002, pp. 352.

<sup>40</sup> These profits have to be shared by the farmers using the technology and the Manufacturers.

<sup>41</sup> Adler J H, 'Cartagena Protocol: Biosafety or Bio-sorry?', 12:3 *Georgetown International Environmental Law Review* (2000), pp. 761 at 772.

<sup>42</sup> Bail C, op cit n1 at 8.

<sup>43</sup> Research has documented that transfer of GM pollen by wind, rain, birds, insects, fungi, and bacteria can transport pollen over great distances no matter what the separation distance between GM crops and traditional crops.

<sup>44</sup> Lappe M & Bailey B, '*Against the Grain: The Genetic Transformation of Global Agriculture*' (1999). Available at <http://www4.fao.org/cgi-bin/faobib.exe>. See also Krimsky S & Wrubel S, '*Agricultural Biotechnology and the Environment; Science, policy and Social issues*'. 1996. Available at <http://www.springerlink.com/content/>. Accessed on 22<sup>nd</sup> June 2007.

health concerns that development of new foods, through transgenic transformations, may also have the potential to create new allergic risks and enhanced toxicity though such risks may be difficult to detect through current testing methods and manifest themselves only over time.<sup>45</sup> Of further concern is the extent to which GM technology has the capacity to enslave agricultural producers to biotech companies as was illustrated in the case of *Monsanto v Schmeiser*<sup>46</sup> through dependency on GM technology and intellectual property rights.<sup>47</sup> For example in India farmers pay an extra US\$50-65 per acre as a 'technical fee' over and above the price of seed.<sup>48</sup>

Lastly, there are ethical objections to GM technology. The main thrust of this argument is that GM technology is "unnatural", an unwarranted tampering with nature which ought to be avoided, 'for all the decline in formal religion, there remains a deep rooted belief that we tinker with nature at our peril'.<sup>49</sup> However, it is these latter objections that do not deal with the potential risks posed by GMOs, which add to the complexity of regulating genetically modified organisms.<sup>50</sup>

## **F. Statement of the Problem**

Genetically modified organisms are increasingly becoming a source of environmental risks. The environmental risks associated with modern biotechnology and GMOs have not yet been scientifically proven as there is still insufficient evidence as to what environmental risks they may pose. This has necessitated the adoption of some kind of international regulation of biotechnology such as the Cartagena Protocol. Though a precautionary approach has been adopted

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<sup>45</sup> In a surprising reversal of traditional political priorities, the force of concerns related to human health risks have been at the very least equaled by the pressure arising out of environmental concerns.

<sup>46</sup> [2004] SCC 34. In interpreting the word 'use' in Section 42, the majority of the judges used the plain meaning of the word, its purpose in Section 42, its context and the case law. By their interpretation, Mr. Schmeiser did use the patented invention in a way that deprived the inventor of the full benefit of the monopoly granted by the patent.

<sup>47</sup> Campbell T, 'Will Biotechnology feed the World's poor?', *Development Studies Centre, Kimmage Manor Dublin*, 1998. Available at <http://www.pmac.net/campbell.htm>. Accessed on 23rd June 2007.

<sup>48</sup> Farmers doing business with Monsanto's herbicide-resistant crop seeds must sign a contract stating that they will not buy herbicides or other chemicals from other companies.

<sup>49</sup> Hughes D, op cit n39 at 355.

<sup>50</sup> Ernestine M and Richard S, '*The GM Cold War: How Developing Countries can go from being Dominos to Being Players*'. *RECIEL* 13 (3) 2004.pp.247.

by many states, some states especially the developing countries including South Africa and Uganda do not have the capacity to regulate trade in GMOs due to a number of factors like poverty, corruption, undemocratic governance and, hunger. This has generated fears that developing countries are fast becoming dumping grounds and testing centers for GMOs and this may be harmful in the long run.

The trade in transgenic crops and GMOs is mostly carried out between developed and developing countries. This has created a need to protect developing countries from the risks posed by the GMOs since most of them are not in a position to bargain with the more powerful developed countries that export GMOs and the rich multi national corporations like Monsanto that produce GMOs. Though the Cartagena Protocol is aimed at addressing the needs and interests of the developing countries including South Africa and Uganda, these countries are still faced with many challenges that they are yet to overcome so as to effectively implement the Protocol.

Biosafety legislation in South Africa and the interim biosafety regulatory regime in Uganda is an illustration of the many hurdles that other developing countries especially African countries are facing in implementing the Protocol. Thus, this study therefore makes a comparison of the interim biosafety regulatory regime of Uganda and the existing biosafety legislation in South Africa. This is done by examining how the two countries have integrated their international obligations under the Protocol, in developing biosafety regulatory frameworks that are relevant to them and can easily be implemented.

### **G. Objective and Scope of the study**

Though there is still insufficient scientific evidence concerning the risks associated with biotechnology and GMOs many countries have adopted specific national laws to regulate modern biotechnology. As a consequence of the fact that the borders of countries do not restrict many of the problems associated with biotechnology many

states have adopted international solutions. These include the Cartagena Protocol specifically designed to deal with international challenges presented by GMOs and countries like South Africa and Uganda have had to implement the Protocol by integrating it in their domestic legislation on Biosafety.

The overall aim of the study is to make a comparative analysis of the biosafety legislation in South Africa and the interim biosafety regulatory regime of Uganda by comparing selected key features with the aim of determining their compliance with related provisions of the Protocol. The specific objectives of this study are: to give an overview of the international regulation of biotechnology with focus on the Cartagena Protocol. This will facilitate an assessment as to what extent the biosafety legislation in South Africa and the interim biosafety regulatory regime of Uganda have or will enable them to fulfill their international obligations with regard to biosafety. Lastly, the study aims at assessing whether both these biosafety regulatory systems have or will be of relevance in addressing the biosafety needs of Uganda and South Africa.

The biosafety legislation in South Africa and the interim biosafety regulatory regime of Uganda have been chosen for this study by comparing the different features in their biosafety legislation. South Africa was chosen for this study because it is considered as the “gateway” for GMOs in Africa and it has also enacted a Biosafety Act and perhaps Uganda could pick some tips as well as learn some lessons from South Africa before it finally adopts its Biosafety Bill of 2005.

However, the study does have some limitations. First, it examines the Draft National Biotechnology and Biosafety Policy and the Draft National Biosafety Regulations in Uganda. Both these biosafety regulatory policies are operating on an interim basis and are still in draft form. This is because the Biosafety Bill of 2005 has not yet been enacted into law. Since the Biosafety Policy is still in “draft” form, the analysis advanced in relation to legislation in both countries especially Uganda may

not be relevant if a biosafety Act is enacted. Secondly, it is imperative to note that environmental law is a very dynamic discipline and enactment of legislation is a political matter that is often influenced and delayed by politicians due to many factors. This may make some findings of this study inconsistent with the changed circumstances. Lastly, it cannot be claimed that this study is comprehensively exhaustive.

#### **H. Structure of the study/ Chapter synopsis**

So as to achieve its aims and objectives, this study consists of four chapters. Chapter one which is the introduction gives the historical background of biotechnology and GMOs, the historical development, arguments for and against GMOs, the problem statement, scope and objective of the study, structure of the study, and the research methodology. Chapter two gives an overview of the Cartagena Protocol by examining the provisions of the Protocol in more detail. Chapter three considers the domestic implementation of the Cartagena Protocol focusing on biosafety legislation in South Africa and the interim biosafety legislation in Uganda by carrying out a comparative analysis. Related provisions of the Protocol are used as the basis of this study. Lastly, chapter four presents the overall conclusion and also makes some recommendations.

#### **I. Research Methodology**

This is a largely a desktop based study which includes an analysis of the literature including the relevant primary and secondary sources of data. Newspaper articles and internet resources were used where appropriate. A comparative analysis of the biosafety legislation of South Africa on the one hand, and the interim biosafety regulatory regime of Uganda on the other hand was carried out. This was essential in satisfying the objectives of the study and understanding the intricacies that are generally associated with GMOs and modern biotechnology. Furthermore, it enabled an understanding of the specific challenges that are faced by the developing countries including Uganda and South Africa in this regard. The literature study

was essential in analyzing the domestic implementation of the Cartagena protocol that was discussed in the study. In addition, decided cases and documents published by international organizations and Non-Governmental Organizations (NGOs) were considered. Selected Key features of the Protocol are examined in detail in the next chapter.

## **CHAPTER TWO:**

### **THE CARTAGENA PROTOCOL ON BIOSAFETY: AN OVERVIEW**

The Cartagena protocol is one of the international agreements that have been concluded to regulate the transboundary movement of genetically modified organisms (GMOs). The Cartagena Protocol provides special rules and procedures for international regulation of GMOs. The Protocol has its base in concerns of developing countries, that because of capacity limitations, they will not be able to control effectively which GM products cross their borders or regulate adequately their use.<sup>51</sup> The Protocol is generally considered to have a more developing country-orientated position.<sup>52</sup> Selected key provisions of the Cartagena Protocol will be examined in the present chapter.

#### **A. Historical Background**

The issue of Biosafety emerged for the first time in the context of a global legally binding instrument during the negotiations of the Convention on Biological Diversity (CBD). GMOs constitute a potential risk to the biological diversity but the CBD does not specifically deal with the issue of GMOs. However, it is of direct relevance to the creation of protection regimes for all biological resources and biodiversity generally at the international level.<sup>53</sup> The CBD provides that each contracting party shall, as far as possible and appropriate, “establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms (LMOs),<sup>54</sup> resulting from technology which are likely to have adverse environmental impacts that could effect the conservation and the

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<sup>51</sup> Zarilli S, ‘International Trade in Genetically Modified Organisms and Multilateral Negotiations: A New Dilemma for Developing Countries’ (UN Conference on Trade and Development, 2000). pp.17. Available at <http://www.unctad.org/en/docs/poditctncdd1.en.pdf>. Accessed on 25th June 2007.

<sup>52</sup> Zarilli S, Ibid.

<sup>53</sup> In this context the CBD broadly delimits the rights of states and other relevant actors over biological resources.

<sup>54</sup> It is to be noted that, instead of GMO, the term LMO is used, this being the language of the Convention. However, because the definition LMO is largely consistent with that of GMO, the terms will be used interchangeably in this study.

sustainable use of biological diversity, taking also into account the risks to human health".<sup>55</sup> The basis for doing so was not specifically set out in the CBD but was left for future determination by a Protocol at a future date.<sup>56</sup> The CBD states that, "the Parties shall consider the need for and modalities of a Protocol setting out appropriate procedures, including, in particular, Advanced Informed Agreement (AIA), in the field of the safe transfer, handling and use of any LMO resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity".<sup>57</sup>

In 1994, at the first meeting of the Conference of the parties (COP), preparatory works were authorized in this regard based on these findings. The second COP set up the open-ended Ad Hoc Working Group on biosafety with a view to draft a protocol, which would especially focus on the transboundary movement of GMOs.<sup>58</sup> The Working Group was scheduled to forward the draft to the first Extra Ordinary Meeting of the COP to the CBD (ExCOP) immediately after its sixth meeting, held in 1999 in Cartagena. However, the negotiators failed to reach a compromise at this meeting in February 1999 in Cartagena,<sup>59</sup> Columbia from where incidentally the Protocol derives its nomenclature.<sup>60</sup> Thus, the meeting had to be suspended. After informal meetings the ExCOP was eventually resumed in January 2000 in Montreal where the Protocol was finally adopted on 29 January 2000.<sup>61</sup>

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<sup>55</sup> Article 8(g) CBD.

<sup>56</sup> Article 28 CBD.

<sup>57</sup> Article 19(3) CBD.

<sup>58</sup> COP Decision II/5, which established the so-called Jakarta Mandate. Discussed further in Kiss A & Shelton D, *International Environmental Law*, 2003 (Third Edition), pp. 267.

<sup>59</sup> A group of six countries (Canada, Australia, Argentina, Chile, and Uruguay) headed by the USA clashed with a coalition formed by the European Union and a bloc of over 100 'like minded' developing countries. The former wanted a zero-option approach, which would facilitate international trade in LMOs, while the latter wanted a comprehensive safety regime. See J. Glazewski, op cit n27 at 318.

<sup>60</sup> Aaron C & Stas Burgiel, 'The Cartagena Protocol on Biosafety: An analysis of results', An IISD Briefing Note. (2000). pp. 6.

<sup>61</sup> See Kiss A, op cit n58 at 630 for decision EM- I/3, UNEP/CBD/ExCOP/1/3, Annex.

The Protocol was opened for signature in May 2000, at the fifth COP to the CBD. The required number of fifty parties was attained in June 2003 and, in accordance with the provisions of Article 37 of the Protocol, the Protocol entered into force in September 2003. South Africa is a party but has not yet signed the protocol despite having participated actively in its negotiation. As of June 2007, the protocol had 143 parties and 101 parties had signed the protocol.

### **1.0. The Major Negotiating Groups at the Cartagena Meetings**

Five major groups had emerged by the final days of the Cartagena meetings. The first group consisted of the 'Miami Group'. The Miami group represented the major exporters of GMO crops and seeds, and the developed countries among them have some of the world's most advanced biotechnology industries.<sup>62</sup> This group's interest was to enable free trade of such genetically modified products without burdensome bureaucratic approval procedures, and without allowing room for "protectionist" trade barriers disguised as environmental protection.<sup>63</sup> The second group was the 'Like Minded' Group which was the largest negotiating group.<sup>64</sup> They supported the Protocol, in light of the unknown effects of LMOs on the environment and human health, and given the need to protect countries without adequate regulatory or institutional capacity to effectively handle LMO imports. The Like Minded Group supported a strong statement of the precautionary principle, and was the prime backer of tough and concrete text on liability and redress.

The third negotiating group was the European Union (EU), which negotiated as a bloc throughout the biosafety negotiations.<sup>65</sup> Regarding the scope, the EU had

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<sup>62</sup> The Miami group consisted of countries like Argentina, Australia, Canada, Chile, USA, and Uruguay. Their aim was to keep LMO-FFP outside the scope of the protocol's AIA procedure arguing that goods traded in these volumes were not amenable to the AIA, since such products were safe for consumption and not intended for introduction in the environment, their biodiversity impacts were minimal.

<sup>63</sup> Zarilli S, op cit n51 at 18.

<sup>64</sup> The Like Minded Group consisted mainly of developing countries and they called for a comprehensive scope, including LMO-FFPs, arguing that seeds and other LMO products intended for consumption might actually be planted in many developing countries.

<sup>65</sup> Given the public outrage over food safety scandals such as the mad cow disease and the dioxin-tainted chicken, the EU strove for a strong protocol including coverage of risks to human health.

pushed for inclusion of living modified organisms intended for direct use as food or feed, or for processing (LMO-FFPs), while acknowledging that they might merit special treatment under the AIA procedure. They also supported the precautionary principle and alternative considerations for contained use, transit and pharmaceuticals for humans.

The fourth group was the 'Compromise Group' that came up during the final days of the Cartagena negotiations. The Compromise group's specific intent was to bridge the major gaps between the other negotiating groups by developing compromise positions and alternative formulations.<sup>66</sup> The Group's inclusion of countries with high levels of biodiversity as well as those with advanced biotech industries provided additional cache for addressing the range of concerns of developed and developing countries.<sup>67</sup>

Lastly, the Central and Eastern Europe (CEE) also emerged as a separate negotiating bloc during the final days of the Cartagena and generally reflected a "middle-of -the-road" position.<sup>68</sup> With general support for including LMO-FFPs, the precautionary principle and preambular references to other international agreements, the CEE focused primarily on the practicality and applicability of various proposals.

## **2.0. The Major Issues of Debate at the Cartagena Negotiations**

During the Cartagena negotiations there were some major issues of debate. This section explains how these issues divided the five major negotiating groups, and what the results of the Protocol meant for each party. The first issue concerned the scope of the Protocol. The central question here was whether the Protocol should

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<sup>66</sup> The Compromise Group consisted of countries like Japan, Mexico, Norway, Singapore, South Korea, and Switzerland and, in Montreal, New Zealand. The Group did have joint positions supporting a comprehensive scope and the precautionary principle, although they acknowledged internal difference about the saving clause.

<sup>67</sup> Aaron C & Stas Burgiel, *op cit* n60 at 7.

<sup>68</sup> Aaron C & Stas Burgiel, *supra*. The CEE did not represent a divergent position in its own right, often falling in line either with the EU or the Like Minded Group.

cover a class of LMOs known as LMO-FFPs, LMOs that are intended for direct use as food or feed for processing.<sup>69</sup> It was finally agreed that LMOs-FFPs would fall under the Protocol's scope and negotiators then focused on whether they would fall under the scope of the Protocol's AIA provisions.

The second issue of debate concerned the precautionary principle.<sup>70</sup> Negotiations turned on the question of how to operationalise the precautionary principle. Some contented that any restrictions had to be based on sound science and rigorous risk assessment, as the precautionary principle could be used as an excuse to restrict trade in harmless goods in order to protect domestic producers. Others argued that the sound science argument was itself an excuse to limit the use of an established principle of international environmental law.

The third issue concerned the relationship of the Protocol to other International Agreements.<sup>71</sup> But the body of law foremost in the negotiators' minds however was the multilateral system of trade rules embodied in the World Trade Organization (WTO.) The concern was what would happen if the trade related provisions of the Protocol were challenged in the WTO/GATT or if a country was challenged for implementing the Protocol in a trade restrictive manner as was illustrated by the *Biotech Disputes Case*.<sup>72</sup> In previous negotiations the argument

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<sup>69</sup> Those that opposed the inclusion of such LMOs in the Protocol, argued that since such LMOs were not to be introduced in the environment, they posed no threat to biodiversity, and should therefore not be included in the Protocol. Those that supported the inclusion of such LMOs in the Protocol argued that it was not possible to ensure that this category of LMOs would not in fact be released into the environment, whatever the intention. They also argued that the Protocol should take into account the Human health risks (Health risks from biodiversity impacts and direct contact (allergies)) of LMOs-FFPs, rather than on food safety grounds.

<sup>70</sup> The precautionary principle is widely used in international environmental law and it is, as some contend, a principle of customary international law (See for example, P. Sands, op cit n8 at 212.)

<sup>71</sup> The other agreements in question include the Law of the Sea, international transit and transportation arrangements, and international health agreements that address human pharmaceuticals.

<sup>72</sup> (2006). In this case the complainants were USA, Canada & Argentina and they contested the EC's suspension of approvals as it was a breach of the SPS and other WTO Agreements. They argued that only the WTO Agreements were applicable. The EC argued that the CBD and the Protocol were directly relevant. The panel held that the CBD and the Protocol were not applicable and the complainants were not parties and the legal status of the precautionary principle in international law remains unsettled. The Panel further held that the EC acted inconsistently with its obligations under the SPS Agreement.

boiled down to whether to insert a 'saving clause' stating that nothing in the agreement shall alter the rights and obligations of the parties under existing international law.<sup>73</sup> The intent of the saving clause was to establish that in the case of conflict, the existing WTO rules would trump those of the Protocol.

The last issue of debate concerned liability and redress. The question here was whether, and in what form to create a liability and redress mechanism for any damage resulting from the transboundary movements of LMOs. Proponents argued that if such a mechanism was exercised, then by definition there would have been a need for it, if it were never exercised, no harm would result from its inclusion. This argument is strongly supported. The question of 'whether' was settled by the time of Montreal meeting, leaving just the questions of 'how' and 'when' open to the negotiators.<sup>74</sup>

## **B. Objective and Purpose of the protocol**

Reflecting the CBD mandate, the objective of the protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and the use of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity with specific focus on transboundary movements in accordance with the precautionary approach contained in principle 15 of the Rio Declaration on Environment and Development.<sup>75</sup> Generally, the purpose of the Protocol is to regulate transboundary movements of LMOs with the aim of eliminating or minimizing their adverse effects to the environment and human health.

## **C. Selected Key Provisions of the Protocol**

This section of the study discusses and examines selected key features of the Cartagena Protocol which include:

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<sup>73</sup> Aaron C & Stas Burgiel, op cit n60 at 3.

<sup>74</sup> Barron N M, op cit n5 at 123.

<sup>75</sup> Article 1 of the Protocol.

## 1.0. Scope and application

The scope of the Cartagena Protocol is established under Article 4, which specifies in what circumstances a party must apply the provisions of the protocol by specifying the activities,<sup>76</sup> and organisms to which the protocol applies. Article 4 of the Cartagena Protocol states that, the Cartagena Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms (LMOs) that may have adverse effects on the biological diversity, taking also into account the risks to human health. Some of the terms used in Article 4 are closely linked to Articles 5 and 6.<sup>77</sup>

As stated earlier in (2.0 of part A) the scope of the protocol was the subject of controversy during the negotiations as the developing countries pushed for the application of the protocol to all LMOs and the developed countries (led by the United States of America) in general pushed for a more limited scope of the protocol.<sup>78</sup> The structure and content of Articles 4, 5, and 6 of the protocol reflects the compromises finally agreed upon by the parties in Montreal, Canada, in January 2000.

## 2.0. Advanced Informed Agreement (AIA)

The key mechanism and the centerpiece of transparency framework of the Cartagena Protocol is the Advance Informed Agreement procedure (AIA). The AIA requires that before the first intentional transboundary movement of a specific LMO into its jurisdiction, the Party of import is notified of the proposed transboundary movement, receives information about the LMO and its proposed use, and is also given an opportunity to decide whether or not to allow the import of the LMO, and

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<sup>76</sup> The activities are transboundary movement (intentional and unintentional) that is defined in Article 3(k), transit (though the protocol does not contain a definition of transit) and, handling and use (though the protocol only contains a definition for contained use in Article 3(b)).

<sup>77</sup> Article 5 exempts, under certain conditions, the transboundary movement of one specific class of LMOs which are pharmaceuticals for humans from the applicability of the protocol and Article 6 provides a more limited exemption as it exempts LMOs in transit and LMOs destined for contained use from the application of the AIA procedure.

<sup>78</sup> Mackenzie R, op cit n3 at 53.

upon what conditions if any.<sup>79</sup> This is in fact a form of prior informed consent procedure (PIC) as used in the Basel and Rotterdam Conventions.<sup>80</sup>

### 2.1. Scope of application of the AIA procedure

The scope of application of the AIA procedure is laid out in Article 7(1) and 7(2).<sup>81</sup> Article 7(1) states that the AIA procedure shall apply prior to the first intentional transboundary movement of LMOs for “intentional introduction into the environment”. This phrase is however not defined in the protocol.<sup>82</sup> However, on the face of Article 7(1), it may be somewhat unclear whether AIA will be required each time a particular LMO is imported into a Party for the first time from a “new” Party of export, or whether it only applies the first time a particular LMO is imported into the Party of import from any Party – after which, assuming the first import is allowed, imports of the same LMO should be allowed under the same conditions from all Parties.<sup>83</sup> Instead Article 7(2) confusingly specifies that the term “intentional introduction” does not refer to LMOs intended for direct use as food or feed, or for processing.

Article 7(4) contains a different kind of exception regarding LMOs in transit, LMOs destined for contained use and LMOs identified in a “collective” decision of the COP as being not likely to have adverse effects.<sup>84</sup> The Protocol gives no guidance as to what information or evidence might be required to support such a

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<sup>79</sup> Mackenzie R, op cit n3 at 63.

<sup>80</sup> Gupta Aarti, ‘*Framing “Biosafety” in an international context: The Biosafety Protocol Negotiations*’, New York 1999, pp. 5. Some countries were however concerned that the use of the term ‘prior informed consent procedure’ could induce the perception that LMOs were as dangerous as hazardous wastes and chemicals and therefore, pushed for a replacement of this term by “advance informed agreement”.

<sup>81</sup> The obligations that are applicable to the LMOs covered by the scope of the AIA are mainly contained in Articles 8, 9, 10, 12, and 15 and Annex III of the Protocol.

<sup>82</sup> During the negotiation of the Protocol, there was some debate as to whether the AIA procedure should apply to *every* transboundary movement of an LMO into a Party or only to the *first* transboundary movement of a specific LMO into a Party of import.

<sup>83</sup> The use of the word “intentional” in Article 7(1) also raises certain interpretative issues: First, in the phrase “intentional transboundary movement of LMOs”, the word “intentional” might be interpreted as referring *either* to the transboundary movement *or* to the LMOs, or to *both*. Second, Article 7(1) and 7(2) refer to “intentional introduction into the environment”, but do not specify whose intention is relevant here.

<sup>84</sup> Alexander Behrens, (Unpublished Masters Thesis), ‘A legal analysis of MEAs dealing with hazardous products and hazardous waste’. University of Cape Town, ( 2004).pp 46

conclusion. Nonetheless, any such decision would need to be taken in the light of the precautionary approach. So in practical terms the AIA procedure will apply particularly to the growing of agricultural crops, the release of fish and of modified microorganisms.<sup>85</sup>

## 2.2. Notification

Article 8 addresses the first step in the AIA procedure, which is the notification of the proposed transboundary movement to the Party into which the LMO is to be imported. According to Article 8 (1), the exporting country or the exporter shall notify the importing country prior to the first intentional transboundary movement of an LMO that falls within the scope of the AIA procedure under Article 7(1).<sup>86</sup> The notification must take place before the first transboundary movement of the LMO into the Party of import is initiated. The notification shall contain, at a minimum, the information specified in Annex I.<sup>87</sup>

Article 8 places the primary obligation regarding notification on the Party of export. However Article 8 does not specify in what language the notification should be made whether it is the language of the Party of export, the Party of import, or some other language.<sup>88</sup> As with other provisions of the Protocol, in order to be effective, Article 8 will need to be implemented in the domestic law of Parties in relation to both exports and imports of LMOs. Article 8(2) obliges the Party of import to require the exporter to provide accurate information about the LMO under national law. The information referred to here is that required for the notification, as

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<sup>85</sup> Mackenzie R, op cit n3 at 65.

<sup>86</sup> The limitation of the procedure to the 'first' intentional transboundary movement is not explicitly stated in Article 8(1), but results from Article 7(1).

<sup>87</sup> Annex I covers a wide range of information, which may be loosely grouped into three categories: first, is information concerning the LMO itself aimed at providing the importing country with factual information; second, the regulatory status in the exporting party intended to inform the country of import about the cost benefit assessment of the state of origin; and lastly, the suggested methods for the safe handling and use.

<sup>88</sup> In practice, this issue is likely to be dealt with in national legislation of the Party of import on import procedures for LMOs.

indicated in Annex I.<sup>89</sup> Information provided under Article 8 may be subject to confidentiality requirements in accordance with Article 21.

### **2.3. Acknowledgement of receipt**

Article 9 requires the importing state to acknowledge receipt of the information to the notifier within 90 days of its receipt.<sup>90</sup> The acknowledgement shall include the date of receipt of the notification,<sup>91</sup> information whether to proceed according to the procedure specified in Article 10, or according to the domestic regulatory framework of the party of import that shall be consistent with the protocol.<sup>92</sup> The purpose of the acknowledgement of receipt of notification is to confirm receipt to the notifier and to confirm on a preliminary basis whether the notification is in order and that it contains the required information. Finally under Article 9(4), if the Party of import fails to acknowledge receipt of a notification within the 90-day deadline, its consent to the proposed transboundary movement is not automatically implied.

### **2.4. Decision procedure**

Article 10 of the Protocol sets out the procedure to be followed by the Party of import in reaching its decision. This decision is whether to allow the first transboundary movement of a LMO into its territory. Article 10(1) states that decisions taken by the importing party shall be in accordance with Article 15. The main requirements of Article 15(1) is that risk assessments in accordance with Annex III be carried out in a scientifically sound manner and must be aimed at evaluating the possible adverse effects of LMOs.<sup>93</sup> Article 10(2) provides that the importing state shall, together with the acknowledgement of receipt, notify to the exporting state as

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<sup>89</sup> The requirement applies whether or not, under the domestic law of the Party of export, it is the Party of export itself or the exporter who is required to notify the Party of import of the proposed transboundary movement of LMOs.

<sup>90</sup> Article 9 (1).

<sup>91</sup> Confirmation of the date of receipt of the notification is important in that it is this date which marks the beginning of the 270-day period within which the Party of import should reach its import decision under Article 10.

<sup>92</sup> Article 9(2)

<sup>93</sup> Risk assessment is addressed in more detail in Article 15 and Annex III to the Protocol.

to whether the transaction shall proceed only after the party of import has given a written consent or after no less than 90 days without a written consent.<sup>94</sup>

If the importing state opts for a written consent, Article 10(3) defines the time limit for an import decision and the possible content of that decision which is 270 days whether or not consent is granted, whether the period of 270 days shall be extended, or whether additional information is required. Except in a case where the consent is unconditional, the importing country shall also disclose the reasons on which its decision was based in accordance with Article 10(4). The reasons given for a decision are likely to be important in the event that the notifier wishes to challenge the decision or where the notifier subsequently requests the review of the decision. The negotiators of the Cartagena Protocol were faced with a question of which rules to apply, if the importing party fails to communicate its decision.

Article 10(5) states the failure to communicate, “shall not imply its consent” to the transboundary movement. However, Article 15 does not specifically state what rules will apply in this case. From the different wording of the provision, one can conclude that after a comparative analysis of Article 11(7),<sup>95</sup> Article 10(5) must be read as requiring explicit consent before any transboundary movement can commence. This provision is largely intended to protect countries which may, for whatever reason, have been unable to communicate a response within the 270-day period specified. However, it is not intended to make way for an open-ended undue delay.

Lastly, another important aspect that is not specifically catered for in the Protocol is the question whether exporting countries are bound to enforce consent

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<sup>94</sup> This means that it is up to every importing state to decide, on the merits of each single case, whether it wishes the application of the consent requirement. In practice, a Party of import may select to impose a general requirement in its national legislation for written consent prior to the first import of a specific LMO.

<sup>95</sup> Article 11(7) provides that a failure by a Party to communicate its decision “shall not imply its consent *or refusal* to the import”.

requirements, i.e. to allow the export only in cases where written consent has been notified by the importing country. The Protocol does not contain an explicit obligation on his regard. Nevertheless, as one of the main purposes of any procedure of prior informed consent is that exporting countries have to enforce importing countries' decisions.

## **2.5. Procedure for LMOs intended for direct use as FFPs**

LMO-FFPs are not subject to the AIA procedure that covers other LMOs, but are covered by a separate, less restrictive, procedure outlined in Article 11. These include:

### **2.5.1. Notification of National Regulations**

According to Article 11(1), a party that makes a final decision regarding domestic use of a LMO-FFP that may be subject to transboundary movement shall inform the parties through the 'Biosafety Clearing-House' (BCH) system with in 15 days of reaching that decision.<sup>96</sup> This notification shall contain the information as set out in Annex II,<sup>97</sup> and corresponds in large part to the information required in notifications made under Article 8 of the Protocol, although there are some significant differences.<sup>98</sup>

The purposes of the notification to the BCH under Article 11(1) are to put other Parties "on notice" that the LMO in question may be exported for food, feed or processing use and to provide relevant information on that LMO that another Party can use when deciding whether or not to allow the import of that LMO for food, feed or for processing in its territory.<sup>99</sup> It is therefore essential that all Parties have

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<sup>96</sup> The Biosafety Clearing House is the key mechanism of the Cartagena Protocol for centralized information exchange.

<sup>97</sup> Annex II contains information required concerning LMOs intended for direct use as food or feed, or for processing under Article 11.

<sup>98</sup> Thee information are similar to those required in Annex I for LMOs destined for deliberate release in to the environment, but are not so extensive.

<sup>99</sup> Mackenzie R, op cit n3 at 87.

access to this information.<sup>100</sup> Under Article 8(2) of the Protocol, Parties are required to ensure that under their domestic law there is a requirement for accuracy of information provided in relation to the LMO-FFP. Under Article 11 (3) any Party may request additional information from the authority identified in paragraph (b) of Annex II.

### **2.5.2. Domestic regulatory frameworks regarding import decisions**

Article 11(4) asserts the right of Parties to require prior approval of imports of LMO-FFPs by referring to national decisions on imports. Thus, although LMO-FFPs are outside the scope of application of the Protocol's AIA procedure, in their domestic regulatory framework Parties may still choose to require advance notification and approval of a proposed transboundary movement of a LMO-FFP. In addition, the domestic regulatory framework must be consistent with the objective of the Protocol. However Article 11 (4) does not contain an obligation, but merely asserts a parties' right to make a decision for import of LMO-FFPs under its domestic regulatory frame work that is consistent with the objectives of the protocol. Furthermore, beyond consistency with the objective of the Protocol, Article 11 does not specify any particular procedural requirements to be reflected in domestic regulatory frameworks applicable to imports of LMO-FFPs.<sup>101</sup>

Article 11(5) of the Protocol is intended to promote transparency and predictability, by requiring Parties to notify through the BCH relevant national frameworks that they will apply to imports of LMO-FFPs. It requires parties to make such decisions, laws and regulations available to the BCH. However the Protocol does not specify in which language or format the information on relevant national regulations is to be made available.

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<sup>100</sup> In practice, however, in some instances the domestic requirements of the importing Party may result in first imports of a LMO-FFP being subject to procedures similar to AIA. The importing country may well require prior notification of a first import of a LMO-FFP, as well as a risk assessment, and explicit approval.

<sup>101</sup> Of course, a Party may also be subject to other relevant international obligations, including those under the WTO Agreements.

Article 11(6) addresses the specific needs of developing countries or countries that have economies in transition including Uganda which do not yet have in place a domestic regulatory framework addressing imports of LMO-FFPs could nonetheless subject such imports to prior notification and approval procedures in a manner consistent with the Protocol's objective. Any such Party which does not have a domestic regulatory framework for LMO-FFP imports in place, but which wishes to subject such imports to prior assessment and approval, should indicate this to the Biosafety Clearing-House,<sup>102</sup> on which information has to be provided under Article 11 (1), and will be taken according to a risk assessment in accordance with Annex III and a decision made within predictable time frame not exceeding 270 days.<sup>103</sup>

If one compares the procedure for LMO-FFPs under Article 11 to that of LMOs destined for intentional introduction into the environment under the AIA procedure, two main differences can be observed. Firstly, while the Protocol itself mandates a specific procedure to be followed for LMOs of the latter category (the AIA procedure), it does not do the same for LMO-FFPs, but only offers developing countries the possibility to declare a specific procedure as applicable under the Protocol. So the importing party has to trigger off the procedure by a specific declaration and, thus, carries the relevant burden. Secondly, while the AIA procedure provides for the requirement of consent before a transaction can take place, under Article 11 (6), exports may also take place without explicit consent of the importing country.

In summary, it can easily be noticed that the procedural protection which is offered especially to developing countries by Article 11 is far lower than that

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<sup>102</sup> For practical purposes, a Party making such a declaration should also indicate the national authority to which notification of any proposed import should be made and this will be the competent national authority of the importing Party under Article 19 (or one of them).

<sup>103</sup> Annex III provides details on risk assessment required under Article 15 of the protocol.

presented by the AIA procedure.<sup>104</sup> Lastly, Article 11 (8) explicitly allows the parties to take a precautionary approach to decision-making on imports. In addition, the general rules concerning risk management and socio-economic considerations are also applicable.

### **3.0. Handling, transport, packaging and identification**

Article 18 addresses the handling, transport, packaging and identification of LMOs and has two main functions. First, is to ensure that LMOs are handled and moved safely to avoid adverse effects on biodiversity and human health. Second, is to provide information to those handling LMOs and to the Party of import. Article 18(1) imposes a general obligation on each Party to the Protocol to require safe handling, packaging and transport of LMOs subject to transboundary movement.<sup>105</sup> This provision is linked to more general obligations upon Parties to the Protocol and to the CBD to regulate, manage and control risks associated with LMOs.<sup>106</sup> A number of countries have in place rules and standards that are relevant to ensuring safe handling, packaging and transport of LMOs.

Article 18(2) requires Parties to take measures to ensure that LMOs subject to intentional transboundary movement are accompanied by documentation. This documentation should identify the LMOs and provide contact details of the individuals and institutions responsible for the movement of the LMOs. The documentation requirements in Article 18(2) are a means of identifying and tracking the transboundary movement of LMOs.<sup>107</sup> However, Article 18(2) does not specify the language of documentation accompanying LMOs and it also provides vague

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<sup>104</sup> Alexander Behrens, op cit n84 at 60.

<sup>105</sup> Article 18 (1) states that, in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

<sup>106</sup> Article 8(g) CBD; and Article 16 of the Protocol

<sup>107</sup> They are a key element in ensuring that Parties of import know when they are receiving a transboundary movement of LMOs, whether for import or in transit and in the event of accidental releases during transport, documentation can provide information that might assist efforts to reduce risk of damage.

identification requirements. Article 18(2) (a) addresses the documentation requirements for LMO-FFPs. Article 18(2)(b) sets out the basic requirements for documentation accompanying LMOs destined for contained use.

Lastly, Article 18 (3) states that the Conference of the Parties (COP) shall consider the need for, and modalities of developing standards with regard to identification, handling, transport and packaging. The Intergovernmental Committee on the Cartagena Protocol (ICCP) has initiated preparatory consideration of this issue. The vagueness of Article 18(1) and (2) illustrates that the parties could not arrive at greater compromise during negotiations. Instead, they postponed further measures to the COP.<sup>108</sup>

#### **4.0. Risk Assessment and Management**

The objective of risk assessment under the Protocol is, to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biodiversity, taking also into account risks to human health. Key elements of effective risk management include monitoring systems, research programmes, technical training and improved domestic coordination amongst government agencies and services. The actual process of deciding as such can be characterized as weighing of policy alternatives in light of considering the risk assessment and possibly other factors.<sup>109</sup>

#### **4.1. Risk Assessment**

Article 15 establishes the basic requirements for risk assessment under the Protocol, and refers to Annex III for further guidance. Article 15 and Annex III are, therefore, closely connected. The Protocol requires that decisions regarding the import of

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<sup>108</sup> Goldman Karen, 'Labeling of Genetically Modified Foods: Legal and Scientific issues', *Georgetown International Environmental Law Review* 12 (2000). pp. 717 & 721.

<sup>109</sup> Note however, that the Protocol does not contain a definition for risk assessment nor risk management. See for this definition, among many others, the "Codex General Standard for Contaminants and Toxins in Foods" of the Codex Alimentarius Commission, available at [www.who.int/fsf/Codexreview/GENERALSTANDARDCONTAMINANTSANDTOXINSInFOODS.pdf](http://www.who.int/fsf/Codexreview/GENERALSTANDARDCONTAMINANTSANDTOXINSInFOODS.pdf). Accessed on 29<sup>th</sup> June 2007.

LMOs for intentional introduction into the environment to be taken in accordance with a risk assessment.

Article 15(1) provides that risk assessments must be carried out in a scientifically sound manner and must be aimed at evaluating the possible adverse effects of LMOs.<sup>110</sup> There is no definition of the phrase “scientifically sound manner” in the Protocol. Indeed, there appears to be no internationally agreed definition of the phrase “scientifically sound”.<sup>111</sup> Furthermore, the Protocol does not explain the term “possible adverse effects”. The possible adverse effects of LMOs that are to be identified and evaluated are those that might affect the conservation and sustainable use of biological diversity, taking also into account risks to human health.<sup>112</sup>

Article 15(2) places an obligation on Parties of import to ensure that risk assessments are the basis for reaching decisions on proposed imports of LMOs that are subject to the Protocol’s AIA procedure. The Party of import may perform the risk assessment, or alternatively, the Party of import may require the exporter to carry out the risk assessment. In some countries, national authorities perform a risk assessment, on the basis of information provided by the applicant/ notifier.

Annex III specifies the modalities of risk assessment. Accordingly risks associated with LMOs should be considered in the context of the risks posed by non-modified recipients. Annex III, further, sets out the methodology for the risk assessment as well as the aspects that have to be taken into account. Thus, Annex III does not only point to the requirement of scientific soundness, but also provides a point of reference for the risk management technique.

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<sup>110</sup> This risk assessment must be in accordance with Annex III.

<sup>111</sup> Mackenzie R, *op cit* n3 at 108.

<sup>112</sup> Based on the wording of Article 15, and on the methodology for risk assessment set out in Annex III, it would appear that all such possible adverse effects are to be identified and these may include both short-term and cumulative, long-term effects, as well as direct, indirect and delayed effects.

In the context of risk assessment, one important and hotly debated question during the negotiations was what kind of adverse effects should be taken into account. Should the assessment be limited to adverse effects on the biological diversity or should those on human health also be considered. In South Africa and Uganda, risk assessment is done by way of Environmental Impact Assessment (EIA) but because of hindrances such as corruption and under funding, at times the objectives and the effectiveness of the EIA procedure is undermined. To make matters worse, the provision that the notifier bears the costs greatly compromises the whole process as chances are next to none that in such instances the assessment shall be neutral.

In a nut shell, the Protocol empowers governments to decide whether or not to accept imports of GMOs on the basis of risk assessments. While the country considering permitting the import of a GMO is responsible for ensuring that a risk assessment is carried out, it has the right to require the exporter to do the work or to bear the cost. This is particularly important for many developing countries including South Africa and Uganda.

#### **4.2. Risk Management**

No technology or human activity is completely risk-free. People accept new technologies because they believe the potential benefits outweigh the potential risks. The Protocol requires each country to manage and control any risks that may be identified by a risk assessment.<sup>113</sup> Article 16(1) deals with the management of risks posed by those organisms that fall within the Scope of the Protocol (i.e. all LMOs covered by Article 4) and refer to the provisions of Article 8(g) of the CBD. Article 16(1) places an obligation on Parties to set up appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol. However, the Protocol does not give any specific

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<sup>113</sup> Biosafety and the environment: An introduction to the Cartagena Protocol on Biosafety. Published by the Secretariat of the Convention on Biological Diversity, 2003. Available at [www.biodiv.org](http://www.biodiv.org). Accessed on 30<sup>th</sup> June 2007.

guidance on how suitable risk management strategies may be identified. In order to manage risk, risk management strategies need to be effective when applied in practice by those who will have the responsibility for implementing them.<sup>114</sup>

Article 16(2) refers to the measures to regulate, manage and control those risks that are identified through the risk assessment provisions of the Protocol, as described in Article 15(1) and 16(1). However, the Protocol does not comprehensively regulate the risk management process, but it deals with three related issues in this context. These include: scientific uncertainty, socio-economic considerations and necessity. The precautionary principle remains within the overall context of the decision-making according to scientific criteria. Most developing countries including South Africa and Uganda do not have efficient regulatory systems and agencies to carry out risk management and this frustrates the whole process.

Thus the Protocol therefore, requires each Party to notify and consult other affected or potentially affected governments when it becomes aware that GMOs under its jurisdiction may cross international borders due to illegal trade or release into the environment. This will enable the Parties to pursue emergency measures or other appropriate action. Governments must establish official contact points for emergencies as a way of improving international coordination.

### **5.0. Public awareness and participation**

It is clearly important that individual citizens understand and are involved in national decisions on GMOs. The Protocol therefore calls for cooperation on promoting public awareness of the safe transfer, handling and use of GMOs. Public awareness and participation is dealt with by Article 23 of the Protocol. Parties may on a discretionary or mandatory basis undertake to provide information on LMOs to

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<sup>114</sup> For example farmers or distributors of LMOs.

the public,<sup>115</sup> include public participation in LMO-related decision-making processes,<sup>116</sup> and provision of information to the public about access to the BCH.<sup>117</sup>

Article 23(1) does not explicitly require Parties to make specific information available to the public. The obligation is somewhat softer. Parties are required to “promote and facilitate” public awareness, education and awareness regarding LMOs, and are to “endeavour” to ensure public awareness and education on LMOs that may be imported. Article 23(2) of the Protocol lays down affirmative obligations on Parties to consult the public in the decision-making process regarding LMOs and make the results of such decisions available to the public. The obligation to consult the public applies generally to all decision-making processes regarding LMOs, including the making of decisions on imports of LMOs.

However, Article 23(2) does not provide specific guidance on the public consultation mechanisms to be adopted in decision-making processes and on how to make results of decisions on LMOs available to the public. This effectively leaves it up to the Parties to decide how this obligation should be implemented in their own national contexts. Under Article 23(3) each Party “shall endeavour” to inform its public about the means of public access to the BCH. Article 23(3) of the Protocol requires Parties to take steps to inform the public about the means of access to information contained in the Biosafety Clearing-House. However, the phrase “shall endeavour” in Article 23(3) appears not to create an obligation on the Parties to inform the public about the means of information of access.

Thus the Protocol therefore, calls for cooperation on promoting public awareness of the safe transfer, handling and use of GMOs. It specifically highlights the need for education, which will increasingly have to address GMOs as biotechnology becomes more and more a part of our lives. The Protocol also calls for

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<sup>115</sup> Article 23(1).

<sup>116</sup> Article 23(2).

<sup>117</sup> (Article 23(3)).

the public to be actively consulted on GMOs and biosafety. Individuals, communities and non-governmental organizations should remain fully engaged in this complex issue. This will enable people to contribute to the final decisions taken by governments, thus promoting transparency and informed decision-making. However, in many countries especially the developing countries the right of public participation and awareness is included in their biosafety legislation but it is hindered by many factors such as financial constraints, Language barriers and high illiteracy levels where by the local population does not even know that such a right exists and they are entitled to it.

### **6.0. Socio-economic Considerations**

Under Article 26 of the protocol, in making import decisions, parties can take into account socio-economic considerations arising from the import of LMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biological diversity to indigenous and local communities. Article 26 addresses the extent to which Parties are entitled to take socio-economic considerations into account in reaching decisions on imports of LMOs. Article 26 identifies the types of socio-economic considerations that Parties may take into account in reaching decisions on imports.<sup>118</sup> Article 26 of the Protocol requires that such considerations be taken into account consistent with a Party's other international obligations (for example, under international agreements other than the Protocol). Finally, it encourages Parties to cooperate on research and information exchange on the potential socio-economic impacts of LMOs.<sup>119</sup>

The range of socio-economic considerations contemplated in Article 26(1) of the Protocol covers only those “considerations arising from the impact 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”. This

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<sup>118</sup> Article 26(1).

<sup>119</sup> Article 26(2).

wording clearly indicates that not all socio-economic considerations may be taken into account, but rather only those that arise from the impact of LMOs on biological diversity.<sup>120</sup>

## 7.0. Supportive Measures

The preamble of the Cartagena Protocol acknowledges the need to take into account the limited capacities of some Parties especially the developing countries, “to cope with the nature and scale of known and potential risks associated with LMOs”.<sup>121</sup> The Protocol provides for measures aimed at mainly building the capacity of developing countries and economies in transition, in implementing the Protocol;<sup>122</sup> ensuring that import decisions are within the context of the AIA procedure;<sup>123</sup> the Information Sharing and Biosafety Clearing-House (BCH) mechanism;<sup>124</sup> and a system of financial resources to facilitate its implementation for developing countries.<sup>125</sup>

The supportive measures of the Protocol have to some extent generally addressed the needs of the developing countries including South Africa and Uganda. For example the Global Environmental Facility (GEF) which is the financial mechanism for the Protocol provides funds to ensure that at least a certain level of financial resources is available to developing countries. In addition, the ICCP in its second meeting endorsed the “Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol”, with a view to facilitate and support the development of capacity to effectively implement the Protocol.<sup>126</sup> But there are still some inadequacies that have to be addressed before developing countries can fully benefit from the supportive measures, in particular, it will be noted that many of the

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<sup>120</sup> Mackenzie R, op cit n3 at 163.

<sup>121</sup> Quresh A H, op cit n6 at 845.

<sup>122</sup> Article 22.

<sup>123</sup> Article 11 (9).

<sup>124</sup> Article 20.

<sup>125</sup> Article 28.

<sup>126</sup> Report of the ICCP, Second Meeting, Nairobi 1-5 October 2001, UNEP/CBD/ICCP/2/15. Available at <http://www.cbd.int/doc/meeting>. Accessed on 30<sup>th</sup> June 2007.

provisions that contain supportive measures contain no specific commitments and are couched in soft terms, and framed as mere obligations to co-operate.

### **8.0. Institutional Framework and Enforcement Aspects**

The Cartagena Protocol has various institutions and enforcement aspects that are meant to implement the Protocol and also ensure compliance as per Article 34 of the Protocol. First, the Protocol establishes the Conference of the Parties (COP) which it shares with the CBD and it serves as the Conference of the Parties to the Protocol (COP-MOP).<sup>127</sup> The COP has the powers to make decisions that are necessary to promote effective implementation of the Protocol and is also charged with undertaking further work on the issues that were left unresolved by the Protocol. Secondly, the Protocol establishes subsidiary bodies of the CBD in relation to the Protocol.<sup>128</sup> Under Article 30 of the Protocol, the subsidiary bodies may be asked to provide scientific, technical, or technological advice to the COP/MOP of the Protocol.

At present there is only one standing subsidiary body established by the CBD. This is the Subsidiary Body on Scientific, Technical and Technological Advice, established under Article 25 of the CBD. Thirdly, the Protocol provides for the Secretariat that is established by Article 24 of the CBD.<sup>129</sup> One of the main functions of the Secretariat is to administer the Protocol and to act as day-to-day contact point for the Protocol for Parties, international organizations and others. The Secretariat also prepares documentation for meetings of the governing and subsidiary bodies of the Protocol, and is also in charge of organizing and servicing the meetings. The Secretariat also plays an important role in the functioning of the Biosafety Clearing-House (BCH). Furthermore, the COP/MOP may assign additional specific functions and tasks to the Secretariat.

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<sup>127</sup> Article 29.

<sup>128</sup> Article 30.

<sup>129</sup> Article 31.

The Protocol also has various enforcement aspects that are meant to ensure compliance with the Protocol. Firstly, the Protocol relies on the national system for its enforcement by providing for national legislation to penalize transboundary movements in contravention of domestic measures implementing the Protocol.<sup>130</sup> Secondly, the Protocol sets up a monitoring mechanism where the Parties are to individually monitor the implementation of the Protocol, and report from time to time to the Conference of the Parties on “measures taken to implement the Protocol”.<sup>131</sup> Lastly, the Protocol requires that each Party shall designate one national focal point and one or more competent national authorities that shall be responsible for performing the administrative functions required by the Protocol.<sup>132</sup>

Enforcement provisions of the Protocol are necessary for the effectiveness of the Protocol since most of the provisions are couched in soft terms and the obligations are too general and not self-executing. This suggests that the Parties have to enact substantive domestic legislation and also put in place effective monitoring systems. There is also some kind of duplication of provisions by the Protocol as some are already provided for by the CBD.

## **9.0. The Unresolved issues**

The Cartagena negotiations were not able to address all the key unresolved issues that had not been conclusively agreed upon by the Parties by the end of the negotiations. These key unresolved issues included: Liability and redress; socio-economic considerations; property rights; reconciliation with the WTO rules; and the precautionary principle. As a result some key issues were not and still remain unresolved but were left at the discretion of individual states and others have been gradually addressed by the subsequent COP-MOPs.<sup>133</sup>

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<sup>130</sup> Article 25.

<sup>131</sup> Article 33.

<sup>132</sup> Article 19.

<sup>133</sup> The COP-MOP-III was held in Curitiba, Brazil in March 2006.

## **D. Conclusion**

The Cartagena Protocol can only ensure that the global use of biotechnology is safe if each and every country actively promotes biosafety at the national level. National policymakers and legislators have a vital role to play in establishing and strengthening laws and standards for reducing the potential risks of GMOs. Under the Protocol, it is governments that are ultimately responsible for preventing illegal shipments and accidental releases, managing any risks or emergencies and regulating national biotech industries. From an environmental point of view, one of the highlights of the Protocol is the precautionary principle. Because modern biotechnology is such a revolutionary science, and has spawned such a powerful industry, it has great potential to reshape the world around us. It is already changing agriculture and the food we eat.

Given the complexities and the high stakes, it is reassuring that the global community has already agreed on a regulatory safeguard at this early stage in the development of modern biotechnology. There can be no doubt that biosafety will remain at the top of the international environmental agenda for many years to come. A comparative analysis on implementation of the Protocol in South Africa and Uganda follows in the next chapter.

## CHAPTER THREE:

### A COMPARATIVE ANALYSIS OF THE DOMESTIC IMPLEMENTATION OF THE CARTAGENA PROTOCOL IN SOUTH AFRICA AND UGANDA

#### **A. Introduction**

National biosafety frameworks and regulatory regimes are a combination of policy, legal, administrative and technical instruments that have been developed to address safety for the environment and human health in the context of developing and applying modern biotechnology with focus on genetically modified organisms. South Africa and Uganda have varying biosafety regulatory frameworks but they contain a number of common components.

This chapter initially gives an overview of selected key features of the biosafety regulatory framework in South Africa and Uganda. This chapter later makes a comparative analysis of the biosafety legislation of South Africa on the one hand, and the interim biosafety regulatory regime of Uganda on the other hand with reference to related provisions of the Protocol. This comparison was be done by examining selected key main features of the Genetically Modified Organisms (GMO) Act,<sup>134</sup> Genetically Modified Organisms (GMO) Regulations,<sup>135</sup> and the more recently adopted Genetically Modified Organisms (GMO) Amendment Act,<sup>136</sup> in South Africa on one hand, and the Draft National Biotechnology and Biosafety Policy,<sup>137</sup> and the Draft Biosafety Regulations in Uganda,<sup>138</sup> on the other hand.

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<sup>134</sup> Republic of South Africa, Act 15 of 1997.

<sup>135</sup> R1420 in Government Gazette No. 20643 dated 26<sup>th</sup> November 1999, as amended by R828 of 21<sup>st</sup> June 2002, R576 of 2<sup>nd</sup> May 2003 and R469 of 23<sup>rd</sup> April 2004.

<sup>136</sup> Republic of South Africa, Act 23 of 2006. Came into force in April 2007.

<sup>137</sup> Republic of Uganda; Uganda National Council for Science and Technology, July 2003. (Document 38: Revised Draft Biosafety Regulations).

<sup>138</sup> Republic of Uganda, October 2003.

## 1.0. Background

### 1.1. South Africa

The regulatory process of genetically modified organisms (GMOs) in South Africa dates back as far as the late 1980's when there was no biosafety law in place. At that time the 1983 Agricultural Pests Act regulated the research and testing of transgenics and the South African Committee for Genetic Experimentation (SAGENE) served as the scientific advisory body on environmental releases of GMOs.<sup>139</sup> The first release of transgenics occurred in 1997.<sup>140</sup> The GMO Act was passed in 1997 but became operational in 1999 and the government also adopted the GMO regulations to address the other issues not mentioned in the GMO Act.<sup>141</sup> Recently the GMO Amendment Act was adopted in April 2007. The Department of Agriculture (DOA) administers the GMO Act and it establishes procedures and institutional structures that regulate GMOs in South Africa. Currently, South Africa is the only country on the African continent that grows transgenic crops commercially.<sup>142</sup>

### 1.2. Uganda

Over the years Uganda has taken significant steps to ensure safety in modern biotechnology applications. Currently Uganda's interim biosafety regulatory regime consists of the Draft National Biotechnology and Biosafety Policy,<sup>143</sup> and the Draft Biosafety Regulations.<sup>144</sup> Uganda signed the Cartagena Protocol on biosafety at the Conference of the Parties (COP) in Nairobi in May 2000 and ratified it in 2001. As a party to the Protocol, Uganda is obliged to properly and effectively implement the Protocol. The Uganda National Council for Science and Technology (UNCST) developed the interim Biosafety regulatory regime in Uganda and it defines the

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<sup>139</sup> Gupta A & Falkner R, op cit n2 at 32.

<sup>140</sup> The first crop to be granted approval by the National Department of Agriculture was Monsanto's GM maize (MON810) for commercial planting, and for animal and human consumption. Agbios GM Database available at [www.agbios.com/dbase.php](http://www.agbios.com/dbase.php). Accessed on 2nd July 2007.

<sup>141</sup> Government of South Africa, GMO Regulations Number 1420 of 26 November 1999.

<sup>142</sup> Mayet Mariam, 'A critical analysis of South Africa's labeling regulations for GM food, feed and products derived from GM-fed animals'. October 2004. Available at [www.biosafetyafrica.org](http://www.biosafetyafrica.org) last accessed on 2<sup>nd</sup> July 2007.

<sup>143</sup> Republic of Uganda, July 2003.

<sup>144</sup> Republic of Uganda, October 2003.

scope with in which institutions engaged in biotechnology may operate.<sup>145</sup> The interim biosafety framework in Uganda is coordinated by the UNCST. Currently Uganda has a Biosafety Bill that was published in 2005 but it has not yet been enacted into law. For purposes of this study the Biosafety Bill of 2005 of Uganda shall not be considered since it is not yet operational.

## **B. A Comparative Analysis of Selected Key Provisions**

This section of the study makes a comparative analysis of selected key features of the biosafety regulatory systems of South Africa and Uganda with reference to related provisions of the Cartagena Protocol. These include:

### **1.0. Objective**

The objective of a biosafety regulatory regime specifies the purpose and intention of parties.

#### **1.1. South Africa**

The GMO Act and the GMO Amendment Act do not have clearly stated objective but the preamble to the GMO Act subsumes the need for biosafety into the imperative to promote genetically modified organisms. In this regard, the preamble provides for ‘measures to promote the responsible development, production, use and application of genetically modified organisms’. It may therefore be presumed that the objective of the Act is therefore the promotion of the technology that it aims to regulate. It would perhaps have been more appropriate to state that the objective of the Act is to provide for a comprehensive regulation of genetically modified organisms in order to ensure that the environment, and human and animal health, is not harmed.<sup>146</sup>

The objective of the South Africa GMO Act stands in stark contrast with the approach taken in countries like the United Kingdom. The United Kingdom

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<sup>145</sup> Nyiira Z M, ‘Uganda biosafety framework, Uganda National Council for Science and Technology (UNCST), 2000, pp. 9.

<sup>146</sup> Barron N M, op cit n5 at 104.

Environmental Protection Act of 1990 declares that the essential purpose of control of GMOs is to prevent or minimize any damage to the environment that could arise as result of their escape or release from human control.<sup>147</sup>

## 1.2. Uganda

The Draft Biosafety Regulations do not have any provision specifically outlining their objective. But these Draft Regulations aim at providing a legal basis for the eventual implementation of a National biosafety system consistent with the provisions of the Convention of Biological Diversity (CBD) and the Cartagena Protocol on Biosafety by ensuring the protection of the environment, including humans, in the use of GMOs. The Draft National Biotechnology and Biosafety Policy states that “the objective of a biosafety regulatory system is to review and offer guidance and to monitor and evaluate biotechnology applications”.<sup>148</sup> This statement merely looks like a general definition targeted at no specific biosafety regulatory system and mainly lays emphasis on guiding, monitoring and evaluating applications.

## 1.3. Precautionary Principle

The precautionary principle represents an important tool for decision-making, which has arguably crystallized into customary international law.<sup>149</sup> The precautionary principle is also internationally accepted and it is also enshrined in the Rio Declaration on Development and the Environment and it postulates that, in cases when serious harm is threatened, positive action to protect the environment should not be delayed until irrefutable scientific proof of harm is available.<sup>150</sup> The precautionary approach is particularly important when dealing with the issues that are presented by GMOs. This is especially so, where the novelty of modern

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<sup>147</sup> Section 106(1) of the United Kingdom’s Environmental Protection Act of 1990.

<sup>148</sup> Uganda National Council for Science and Technology (UNCST), April 2003.

<sup>149</sup> It has been endorsed by virtually all recent environmental treaties, including regional treaties and global environmental treaties. It is enshrined in provisions of the CBD and is also incorporated in the National Environmental Management Act section (NEMA) 2(4)(a)(vii) of South Africa.

<sup>150</sup> Principle 15.

biotechnology and the incredible complexity of the living systems of our planet, make it impossible to predict the consequences of the release of GMOs into the environment with any degree of certainty.<sup>151</sup>

### **1.3.1. South Africa**

Unfortunately the GMO Act and the GMO Amendment Act of South Africa do not make any mention of the precautionary principle or approach yet the Protocol has precautionary approach as one of its central provisions.<sup>152</sup> The GMO Act has, rather effectively rendered the application of the precautionary principle ineffective by including the following provision that 'lack of scientific knowledge or consensus on the safe use of GMOs shall not be interpreted as indicating a particular level of risk, an acceptable risk or an absence of risk'.<sup>153</sup> Thus, the lack of scientific knowledge or consensus on the safe use of GMOs is not relevant, or should not be taken into account when dealing with GMOs. This is directly contrary to the spirit of the precautionary principle, which was intended to establish a bias in favour of the environment in situations of scientific uncertainty.<sup>154</sup>

The absence of provisions relating to the precautionary approach in the GMO Amendment Act, further illustrates that the government has failed to recognize its importance in protecting the environment given the uncertainty of risks that are associated with GMOs and biotechnology. As a consequence the GMO Act and the GMO Amendment Act in their present form are inconsistent with the Protocol.

The failure by the GMO Act of South Africa to implement the precautionary principle is a violation of Article 24 of the Constitution. Section 24 of the Constitution obliges the state to protect future generations and this may require the state to take precautions when the possible risks of science are uncertain.

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<sup>151</sup> Barron N M, op cit n5 at 109.

<sup>152</sup> Article 1 of the Protocol.

<sup>153</sup> Regulation 3(2).

<sup>154</sup> Barron N M, op cit n5 at 109.

### 1.3.2. Uganda

The preamble of the Draft National Biotechnology and Biosafety Policy provides for consistence with the 'precautionary principle' when dealing with the potential risks of genetic modifications in addressing the risks of GMOs. The preamble of the Draft National Biotechnology and Biosafety Policy takes cognizance of the precautionary principle though it does not specifically provide for a precautionary approach as stated in Article 1 of the Protocol. The precautionary principle rests on the need to recognize that harm to the environment can be irreversible and therefore "it is better to avoid any possible harm to the environment than to try and remedy it later".<sup>155</sup>

The adoption of the precautionary principle by the Draft National Biotechnology and Biosafety Policy in Uganda strongly suggests that Uganda has adopted a stricter view of protecting the environment from the dangers that are posed by GMOs exceeding the minimum criterion that is set out by the Protocol. In the Case of *Jane Lugolobi and 9 Others v Gerald Segirinya t/a Smart Curry Powder*,<sup>156</sup> the applicants sought an injunction against the applicant who was manufacturing curry powder in a residential area. The court stated that the precautionary principle has to be taken into account since it had not yet been determined what effects the dust and the noise from the machines that manufactured the curry powder had on human health and the environment.

### 1.4. Comparative Analysis

The objective of the protocol under Article 1 is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from the use of modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movement and all this is in accordance with the precautionary

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<sup>155</sup> Kidd Michael, *Environmental Law: A South African Guide*, Juta & Co. Ltd. 1997. pp.9.

<sup>156</sup> Misc. Application No. 371 of 2002, High Court at Kampala.

approach contained in principle 15 of the Rio Declaration on Environment and Development.

The Draft Biosafety Regulations of Uganda do not fully comply with the Protocol. This is because they do not have any clearly outlined objectives. Furthermore, instead of 'conservation and sustainable use of biological diversity, also taking into account risks to human health', the Regulations use 'protection of the environment including humans'. The draft biosafety regulations do not provide for specific application of the precautionary principle though the preamble of the Draft National Biotechnology and Biosafety Policy provides for consistency with the precautionary principle when dealing with the potential risks associated with genetic modifications. The draft regulations should be rectified to specifically provide for the precautionary approach so as to fully comply with the protocol. The Draft Biosafety Regulations also make no reference to 'specifically focusing on transboundary movement of LMOs'.

The GMO Act of South Africa totally ignores the precautionary principle and the GMO Amendment Act has not made any attempts to remedy the situation. The GMO Act and the GMO Amendment Act provide for risk assessments based on scientific evidence at the expense of the precautionary approach. It is suggested that the GMO Act and the GMO Amendment Act do not comply with Article 1 of the Protocol since scientific evidence cannot be conclusively relied upon as it is also prone to error and inaccuracy.

It is apparent that the Draft Biosafety Regulations of Uganda and the GMO Act and the GMO Amendment Act of South Africa do not comply with the Protocol because they do not have clearly outlined objectives that comply with the Protocol.

## 2.0. Scope

The scope provides parameters within which a biosafety regulatory system functions by identifying aspects that are covered and excluded by the biosafety regulatory system.

### 2.1. South Africa

The GMO Act states that the Act shall apply to:

1. The genetic modification of organisms;<sup>157</sup>
2. The development, production, release, use and application of genetically modified organisms;<sup>158</sup> and
3. To the use of gene therapy.<sup>159</sup>

Unlike the Cartagena Protocol as discussed in (1.0 of part C in Chapter 2), the GMO Act only makes reference to GMOs and not living modified organisms (LMOs). This creates the impression that the GMO Act has a very wide and general scope of application. The Protocol is concerned with the “transboundary movement, transit, handling and use” of GMOs that may have adverse effects on biological diversity, “taking also into account human health”. The GMO Act makes no mention of any of the above provisions of the Protocol. Though the GMO Amendment Act has been adopted, it has not done much to remedy the situation nor has it amended section 2 of the principal Act.

The GMO Act of South Africa is limited in Scope as it only applies to viable living GMOs and not products of GMOs. Furthermore, Section 1 of the GMO Act appears to absolve developers of GMOs from liability and shifts liability to users of GMOs. Such a provision amounts to overprotection of the biotechnology industry.

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<sup>157</sup> Section 2 (a).

<sup>158</sup> Section 2 (b).

<sup>159</sup> Section 2 (c).

## 2.2. Uganda

The goal of Uganda's interim biosafety regulatory regime is to comprehensively address all potential risks that are associated with GMOs. The Draft Biosafety regulations of Uganda apply to the generation, import, export, contained use, release or placing on the market or of any GMO or their living products.<sup>160</sup> Exempted from the Scope of the Draft Regulations are GMOs that are pharmaceuticals for humans, GMOs that have been determined by the competent authority as not having any adverse effects on human health and the environment, and the contained use, deliberate release and placing on the market of GMOs that have been authorized by the competent authority for placing on the market. Therefore, Uganda's interim biosafety regulatory regime has the ability to address the full range of potential environmental issues that might arise from any type of activity involving a GMO.

Uganda's interim biosafety regulatory regime only requires approval for each particular GMO at each stage of development and does not require a pre-market safety approval for each individual product derived from GMOs.<sup>161</sup> Instead, the food safety and environmental risks assessments for the particular GMO includes an analysis of the different products that might be produced from GMOs and whether those products may pose any environmental or food safety risks.<sup>162</sup> Although Uganda's biosafety regulatory regime addresses environmental issues, it has not yet set forth how it will assess any potential food safety risks that might arise from some GMOs.

In addition, the draft regulations do not distinguish GMOs based on the products that they produce or their intended purpose. Although there is a small likelihood that eating a particular genetically modified organism will have a harmful health effect. Biosafety regulatory systems should analyze all potential risks to

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<sup>160</sup> Regulation 2.

<sup>161</sup> The term "product" generally means foods and non-reproducing material such as edible oils, industrial materials, and pharmaceuticals.

<sup>162</sup> Jaffe G, op cit n32 at 44.

humans, including food safety issues.<sup>163</sup> The interim biosafety regulatory regime of Uganda states that potential risks to human health are to be addressed through a comprehensive biosafety regulatory system by stating that biosafety is defined to include risks posed to human health.<sup>164</sup> However, the scope of the interim biosafety regulatory regime of Uganda does not cover the other products derived from GMOs.

### **2.3. Comparative Analysis**

The Cartagena Protocol provides for circumstances in which a Party must apply the provisions of the Protocol. The Protocol under Article 4 provides that the provisions of the Protocol shall apply to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health. From the above explanation, one may get the impression that the Protocol only applies to living modified organisms (LMOs). The Draft Biosafety Regulations of Uganda apply to the generation, import, and export, contained use, release or placing on the market of any GMO or their living products.<sup>165</sup> On the other hand, the GMO Act applies to the genetic modification of organisms; the development, production, release, use and application of GMOs (including viruses and bacteriophages); and the use of gene therapy.

The above provisions suggest that the GMO Act only applies to GMOs and not LMOs and the Draft Biosafety Regulations of Uganda apply to GMOs and their living products. The GMO Act is also silent about the transboundary movement of LMOs and only refers to the production and release of GMOs. On the other hand, Draft Biosafety Regulations of Uganda apply to the import and export of GMOs and their living products, though there is no specific reference to the phrase 'transboundary movement'.

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<sup>163</sup> Jaffe G, *supra*.

<sup>164</sup> Republic of Uganda, Draft National Biotechnology and Biosafety Policy, 2004.

<sup>165</sup> Regulation 2.

The biosafety legislation of South Africa and the interim biosafety regulatory regime of Uganda do not have the wording specifically stating that their Scope 'shall apply to LMOs that may have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health'. Both biosafety regulatory systems are silent with regard to conservation and sustainable use of biological diversity and taking into account of risks to human health. However, the Draft Biosafety Regulations of Uganda state that GMOs that have been determined by the competent authority as not having any adverse effects on human health and the environment shall be exempted from the scope of the Cartagena Protocol.

It is suggested that, though the Draft Biosafety Regulations attempt to comply with the provisions of the Protocol, both the biosafety regulatory systems of Uganda and South Africa do not fully comply with the protocol. The Draft Biosafety Regulations of Uganda do not distinguish GMOs based on their products or their intended purpose and they also do not state how they will assess any potential food safety risks that might arise from some GMOs. The provisions in the GMO Act regarding the scope of its application are inadequate and unworkable to effectively serve the purposes and objectives of the Cartagena Protocol.

### **3.0. Institutional Framework and key Regulatory provisions**

Institutional frameworks and regulatory provisions are important in the supervision, enforcement and administration of biosafety regulatory system as this ensures compliance.

#### **3.1. South Africa**

The GMO Amendment Act establishes, as the key administrative and regulatory authority, a juristic person known as the Executive Council of GMOs('the Council'),<sup>166</sup> which consists of not more than ten members appointed by the Minister, eight of whom are required to be officers from eight national government

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<sup>166</sup> Section 3(a)(1).

departments having an interest in GMOs.<sup>167</sup> Under the GMO Amendment Act the objectives of the Council are:

...to advise the minister on all aspects concerning activities relating to genetically modified organisms, and ensure that such activities are performed in accordance with this Act.<sup>168</sup>

The GMO Act sets out the powers of the Council and it's the key decision-making body for the granting of permits, and takes trade and socio-economic issues into account when making decisions.<sup>169</sup> The council was welcomed and viewed as an independent body that would make decisions that were previously in the hands of the Department of Agriculture.<sup>170</sup> However, it is overoptimistic to view the council as an independent body, yet it consists of government officials that have historically had to deal with environmental decision-making, as they cannot be relied upon to robustly safeguard and promote community interests.<sup>171</sup> Essentially, civil society representation on the council is indispensable.

Secondly, the Act establishes an Advisory Committee ('the Committee') with which the Executive Council is obliged to consult with before granting approvals.<sup>172</sup> The Advisory Committee consists of ten members, eight of whom are required to have relevant scientific knowledge concerning GMOs.<sup>173</sup> Two of the members shall be from the public sector of which one person shall have knowledge of ecological matters and GMOs.<sup>174</sup> Glazewski defines the word "public sector" as superfluous and suggests that it should simply be read "public".<sup>175</sup> The Committee is essentially an advisory body that bases its decisions on scientific data. Section 11 of the GMO

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<sup>167</sup> Section 3(2)(a). The departments include: Agriculture; Science and Technology; Environmental affairs and Tourism; Health; Labour; Arts and Culture; Trade and Industry; and Water Affairs and Forestry.

<sup>168</sup> Section 4.

<sup>169</sup> Section 5.

<sup>170</sup> Glazewski J, op cit n27 at 283.

<sup>171</sup> AL Pole Gene-Pigs of the Multinational Biotechnology Industry (2002) Unpublished paper submitted in partial fulfillment of the academic requirements for the degree of master of Laws at the University of Natal, pp.10.

<sup>172</sup> Section 10.

<sup>173</sup> Section 10 (1)(a).

<sup>174</sup> Section 10(b) of the GMO Amendment Act

<sup>175</sup> Glazewski J, op cit n13 at 283.

Act sets out in detail the functions of the committee. Generally, these are to advise the minister, the council and appropriate bodies on matters concerning genetic modification and to carry out related functions.<sup>176</sup> The Committee replaced the SAGENE, which previously carried out this work. Mayet cautions that the requirement that the majority of the members emanate from the scientific community could hamper a full and thorough assessment of the implications of the introduction of GMOs into the environment.<sup>177</sup> This is because GMOs interact with the environment in a complex way, requiring a multi-disciplinary approach in order to assess the potential risks.<sup>178</sup>

Furthermore, the inclusion of the phrase 'public sector' is somewhat puzzling. Since the government is fully represented on the council it is questionable why an advisory committee should require further government representation. Of more concern, however, is the question of why civil society participation has been excluded.<sup>179</sup> Mayet believes that this is inconsistent with the tenets upon which South Africa's democracy is built, and with the principle of public participation in environmental governance advocated by Government policy.<sup>180</sup>

Thirdly, the Act establishes a Registrar that is appointed by the Minister in consultation with the Council and is charged with the administration of the GMO Act. The Registrar is empowered to exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him/her under the Act or by the Council and this includes the issue of permits and other related functions.<sup>181</sup> The Registrar may, at his/her own discretion, "fast track" any application for an activity involving GMOs for which a permit had previously been granted.<sup>182</sup>

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<sup>176</sup> Section 11(a) of the GMO Amendment Act.

<sup>177</sup> Mayet M, 'Critical Analysis of Pertinent Legislation Regulating GM in food and Agriculture in South Africa', unpublished paper produced for Biowatch South Africa. May 2001.pp.1.

<sup>178</sup> Mayet, supra at 17.

<sup>179</sup> Barron N M, op cit n69 at 104

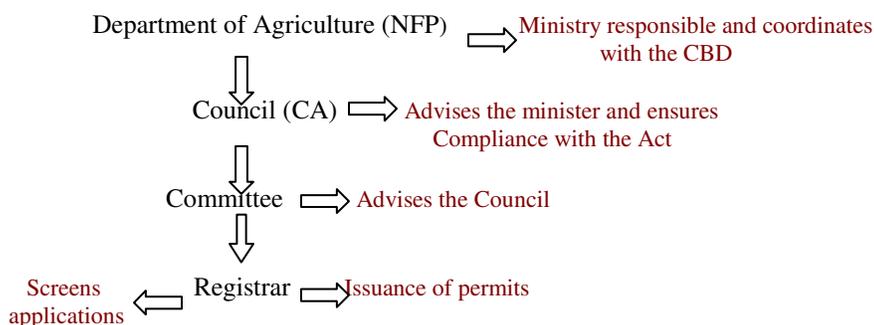
<sup>180</sup> Mayet M, op cit n166 at 17.

<sup>181</sup> Section 9 of the GMO Amendment Act.

<sup>182</sup> Barron N M, op cit n69 at 106.

It is suggested that the structure of the institutional frameworks in South Africa creates room for conflicts due to overlaps in such authorities' jurisdictions. An illustration of this is the inherent conflict between South Africa's section 78(1) of the Biodiversity Act and the GMO Act. The said section of the Biodiversity Act provides that no permit for release of GMO should be issued in circumstances where the Minister of Environmental Affairs and Tourism believes that it may pose a threat to the environment or any indigenous species unless a prior Environmental Impact Assessment (EIA) has been conducted. The Minister is expected, under section 78(2), to convey such belief to the authority that is charged with the responsibility of issuing permits under the GMO Act. The lacuna in this regard is that there is no provision in the GMO Act, which requires the Minister to be notified before applications for release are granted under the GMO Act. Interestingly, there are many issues that regulatory authorities have to contend with. These are: the complexity of biotechnology, fiscal restraints and globalisation. The institutional framework under the GMO Act of South Africa described above is summarized and set forth in illustration 1 below.

**Illustration 1: The institutional framework under the GMO Act of South Africa**



Source: Generated by the author

### 3.2. Uganda

In Uganda a number of institutions are involved in the various aspects of regulating modern biotechnology. The Draft Biosafety Regulations under regulation 3 provide for various institutional frameworks. The first institution is the National Focal Point

(NFP) which is the Ministry of Water, Lands and environment.<sup>183</sup> This is the Government ministry responsible for environment and liaises with the CBD Secretariat on behalf of Uganda.

Secondly, the draft regulations establish a Competent Authority (CA),<sup>184</sup> which is the Uganda National Council of Science and Technology (UNCST). The UNCST follows up, supervises and controls the implementation of the INTERIM biosafety regulatory regime of Uganda. The UNCST has all the powers to regulate modern biotechnology and the Government of Uganda may further specify duties stipulated in the relevant provisions of the draft regulations. However, the UNCST's capacity to coordinate biotechnology development has been constrained by inadequate financial and infrastructure provisions coupled with a lack of clear definition of roles of the various institutions.

Furthermore, a review of the UNCST Statute,<sup>185</sup> reveals that it does not contain typical regulatory power and functions. The UNCST Statute therefore, does not provide adequate legal authority and as a result the UNCST Statute does not support the Regulations. In addition nothing in the UNCST Statute identifies the UNCST as having a role in safeguarding the environment or human health from science and technology activities including GMOs. Therefore, while the UNCST is a government office that should be involved in setting up Uganda's biosafety policy, the statute authorizing its creation does not provide legal authority to regulate GMOs. So if the draft regulations are finalized on that authority, they may not withstand legal challenge. Thus, to provide adequate legal authority for the biosafety regulatory system, Uganda might consider either using other existing statutes or getting its parliament to pass biosafety legislation.<sup>186</sup>

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<sup>183</sup> Regulation 3(1).

<sup>184</sup> Regulation 3(2).

<sup>185</sup> Statute No. 1 of 1990.

<sup>186</sup> Jaffe G, stated that in late 2005, some Ugandans began the process of drafting biosafety-specific legislation to authority their biosafety regulatory system. Those preliminary drafts have not yet been made

Thirdly, the draft regulations establish the National Biosafety Committee (NBC).<sup>187</sup> The NBC is established by the Competent Authority (CA) which is the UNCST and it comprises of representatives from the government, non-governmental organizations, and the private sector that are relevant to the issues of biotechnology and biosafety to provide, as appropriate, policy recommendations and guidelines on biosafety. The NBC consists of a minimum of ten and a maximum of twenty members.<sup>188</sup> These are specialists in the fields covering a wide range of disciplines associated with biotechnology. The NBC meets regularly to review projects and deal with relevant policy issues that come up in biotechnology from time to time. The NBC provides technical advice on biosafety to government and maintains links with biotechnology institutions through institutional biosafety committees. The NBC currently derives its legal status from the UNCST Statute, but there are plans to strengthen the NBC legally through its own legislation.

Lastly, the draft regulations establish the Institutional Biosafety Committees (IBCs). The IBCs are established in all institutions conducting biotechnology research or involved in the import, export, contained use, release into the environment or placing on the market of GMOs or GMO products.<sup>189</sup> The IBCs ensure and control safety measures and approval requirements at the institutional level. The IBCs report on all activities within institutions on a case-to-case basis and the reporting period is agreed upon with the Competent Authority. Each IBC once formed consists of a biosafety officer and at least three other officers with relevant expertise. The institutional framework under the interim biosafety regulatory regime of Uganda described above is summarized and set forth in illustration 2 below.

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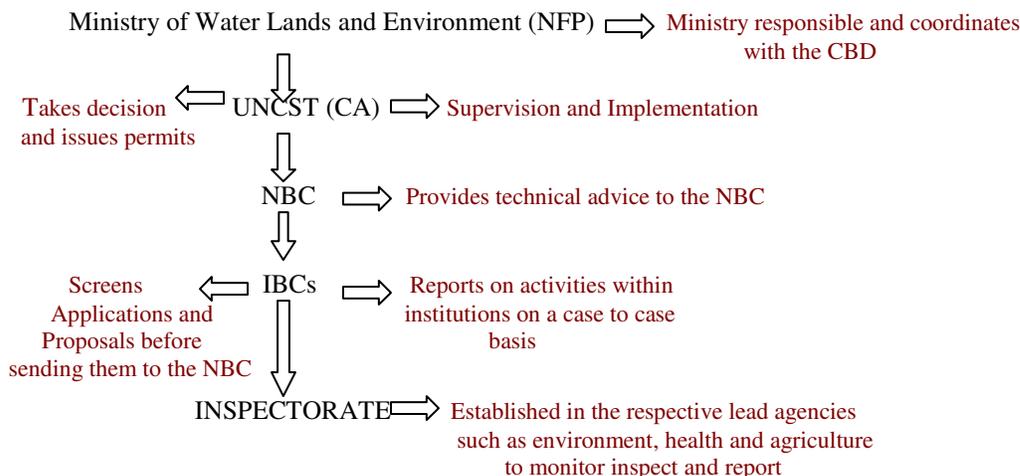
public nor have they been released as government draft documents. Thus, it is not included in this study's analysis.

<sup>187</sup> Regulation 3(3).

<sup>188</sup> Regulation 3(3)(i).

<sup>189</sup> Regulation 3(4).

## Illustration 2: The institutional framework under the interim biosafety regulatory regime of Uganda



Source: Generated by the author

### 3.3. Monitoring, Inspection and Reporting

Under Article 33 of the Cartagena Protocol as discussed in (8.0 of part C in chapter 2) calls upon each Party to monitor the implementation of its obligations under the Protocol. Article 33 further provides that, each party shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol. Article 33 imposes two obligations on Parties. The first obligation is to monitor their implementation of the Protocol and secondly, to report on measures that they have taken to implement the Protocol.

#### 3.3.1. South Africa

In South Africa neither the GMO Act nor the GMO Amendment Act nor the GMO Regulations contain any provisions relating to monitoring and inspection. There is provision for inspectors in the GMO Act and their duty is to police and patrol with the aim of preventing and detecting breaches of the GMO Act.<sup>190</sup> Like many developing countries, South Africa is also faced with the problem of manpower

<sup>190</sup> Sections 15 and 16.

shortage and inadequate funding to effectively monitor activities relating to GMOs. This in turn has affected the smooth running of operations like data collection and management.

### 3.3.2. Uganda

Under the interim biosafety regulatory regime of Uganda, monitoring consists of general surveillance and depending on the results of the risk assessment, case specific monitoring. An overview of the existing monitoring methods tailored for the Ugandan situation has not yet been put in place. The UNCST shall coordinate monitoring activities after the methods have been established.<sup>191</sup>

The draft regulations also make use of existing inspectorate bodies in Uganda for the monitoring and enforcement of the provisions of the law.<sup>192</sup> These inspectorates are established in the respective lead agencies for inspection reporting. These inspectorates include: the Uganda Revenue Authority Customs (URA) for commodity food imports and placing on the market of GMOs; The National Agricultural Research Organization (NARO) Committee for variety testing, field inspection and seed control; the Uganda National Bureau of Standards (UNBS) for commodity food imports; the Department of Forestry; the Uganda Wildlife Authority (UWA); and the Ministry of Health (MOH); the Phytosanitary Department of the Ministry of Agriculture, Animal Industry and Fisheries for plant imports, for contained use and environmental releases of GMOs. However, although the inspectorates have some experience in the conventional inspections in their traditional fields, they have limited experience and approaches for inspections of activities involving GMOs.

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<sup>191</sup> Mugoya C, Implementation of the National Biosafety Framework for Uganda, UNEP-GEF Project.2005. pp. 8.

<sup>192</sup> Regulation 3(5).

### 3.4. Comparative Analysis

Article 19 of the Protocol requires the Parties to designate National Focal Points (NFP) and Competent National Authorities (CA) to perform functions relating to the Protocol. Both the biosafety regulatory systems of South Africa and Uganda do comply with the Cartagena Protocol though at varying levels. The Draft Biosafety Regulations of Uganda establish the Ministry of Water, Lands and Environment and the UNCST as the national focal point and competent authority respectively. The GMO Act and the GMO Amendment Act of South Africa establish the Department of Agriculture and the Executive Council as the national focal point and competent authority respectively. The contrast here is that unlike in South Africa, in Uganda the Ministry of Water, Lands and Environment is the national focal point or the responsible and not the ministry Agriculture, Animal Industry and Fisheries.

Other institutions that are provided for by the Draft Biosafety Regulations of Uganda include the NBC and IBCs. The GMO Act also establishes the Advisory Committee and the office of the Registrar. The Draft Biosafety Regulations of Uganda are silent about the establishment of the office of the registrar or an officer of the same rank. The NBC under the Draft Biosafety Regulations of Uganda is the equivalent of the Advisory Committee under the GMO Act in South Africa. In their composition both the above institutions comprise of persons that have relevant knowledge of GMOs including those from the private sector. However the Draft Biosafety Regulations of Uganda go a step further by including the civil society and non-governmental organizations. South Africa should follow the same approach and include non-governmental organizations (NGOs) and the civil society on the Advisory Committee.

It is suggested that the institutional frameworks under the Draft Biosafety Regulations of Uganda are more decentralized than the institutions established under the GMO Act of South Africa. For example the Draft biosafety Regulations of Uganda establish the IBCs at all the institutions conducting biotechnology research

or involved in the export, import, contained use, release into the environment or placing on the market of GMOs or their products.<sup>193</sup> These IBCs report on activities within the institutions on a case-to-case basis in addition to clearing and reviewing prospective applications before they go to the NBC. The IBCs also conduct training. South Africa should also adopt a similar approach so as to efficiently manage and monitor GMOs throughout the country.

With regard to monitoring, the Protocol places two obligations on the Parties. First, is to monitor the implementation of the Protocol and secondly, to report to the COP/MOP to the Protocol on measures that it has taken to implement the Protocol. The Draft Biosafety Regulations of Uganda have provisions for monitoring that consist of general surveillance. The monitoring activities in Uganda are coordinated by the UNCST.

The Draft Biosafety Regulations impose a duty of monitoring on the applicant as part of the conditions during the application procedure. On the other hand, neither the GMO Act nor the GMO Amendment Act nor the GMO Regulations of South Africa contain any specific provisions relating to monitoring. There is a provision for inspectors in the GMO Act but their duties are limited to patrolling and policing with the aim of detecting and preventing breaches of the GMO Act.<sup>194</sup> Unlike the GMO Act of South Africa, the Draft Biosafety Regulations of Uganda make use of the existing inspectorate bodies for monitoring and enforcement of the law. This kind of coordination makes the work of the inspectors easier as they cannot do all the monitoring work on their own. This is usually because problems such as under staffing and under funding from the central government. The monitoring provisions of the biosafety regulatory framework in South Africa do not comply with the Protocol and this makes one to wonder whether the information

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<sup>193</sup> Regulation 3(4).

<sup>194</sup> Section 15 and 16.

that South Africa submits to the COP/MOP with regard to monitoring and enforcement of the Protocol is accurate and reliable.

#### **4.0. The Advance Informed Agreement (AIA)**

The Cartagena Protocol (see 2.0 of part C in chapter 2) under Article 11(1) provides that, a party that makes a final decision regarding domestic use of an LMO that may be subject to transboundary movement shall inform the parties through the Biosafety Clearing-House (BCH) system. This shall be within 15 days of reaching that decision. Article 11(1) functions as a means of information sharing with respect to domestic regulations in the field of LMOs. The domestic regulatory framework must be consistent with the objective of the Protocol.

#### **4.1. South Africa**

As provided for in the Protocol, the Advanced Informed Agreement (AIA) is meant to ensure that a party especially that of import is made aware before LMOs/GMOs are imported so that it can make a decision to import or not to import. Under the GMO Act and the GMO regulations, there are provisions for AIA. The GMO Amendment Act does not contain a specific section dealing with the AIA procedure but section 4 of the GMO Amendment Act substitutes section 5 of the GMO Act in its entirety. Provisions relating to the approval of applications are coupled with the powers and duties of the Council. The procedure to be followed by an applicant is provided for by the GMO Amendment Act under section 5 (1) (a) and (b) and is discussed in detail in (4.3) of this chapter.

The GMO Amendment Act also makes provision for factors to be taken into account while considering an application. These factors to be taken into consideration include: scientifically based risk assessment,<sup>195</sup> and proposed risk management measures,<sup>196</sup> public input,<sup>197</sup> EIA<sup>198</sup> and socio-economic factors<sup>199</sup>. The

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<sup>195</sup> Section 5(1)(c)(i).

<sup>196</sup> Section 5(1)(c)(ii).

<sup>197</sup> Section 5(2)(a)(i).

GMO Regulations also require certain activities to be under taken only after a permit has been granted and issued by the Registrar.<sup>200</sup> These activities include import and exportation, contained use, trail release, gene release and marketing of GMOs. However, this is one of the provisions that give the Registrar a lot of unchallenged powers that at times seem to exceed those given to him by the Council.

#### 4.2. Uganda

The interim biosafety regulatory regime of Uganda also has a component of the Advanced Informed Agreement procedure though it does not have a specific title on AIA. The Draft Biosafety Regulations define the advance informed agreement as “consent obtained from competent authority based upon full disclosure of all relevant information before ant activity is under taken”.<sup>201</sup> Regulation 13 titled “Export and Import of GMO or its Living Product” provides that any person who intends to export a GMO or its living product shall provide the competent authority a written AIA of the competent authority of Uganda.<sup>202</sup>

The AIA is a key mechanism and the centerpiece of transparency of any biosafety regulatory framework. The draft regulations require that before the first intentional introduction of a GMO or its living product into Uganda’s jurisdiction, the competent authority is notified so that it receives information about the GMO and its proposed use and is also given an opportunity to decide whether or not to allow the import of the GMO, and upon what conditions if any.

The Draft Biosafety Regulations further provide that the presentation of the AIA by an exporter shall in no way absolve the exporter from complying with any other laws governing foreign trade.<sup>203</sup> These other laws governing foreign trade

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<sup>198</sup> Section 5(2)( a)(ii).

<sup>199</sup> Section 5(2)( a)(iii).

<sup>200</sup> Regulation 5(1).

<sup>201</sup> Regulation 1 (a).

<sup>202</sup> Regulation 13 (1).

<sup>203</sup> Regulation 13 (2).

include the WTO Rules. Lastly, the Draft Biosafety Regulations provide that there shall be no authorizations for re-export of a GMO or its living products that are banned by the laws of Uganda.<sup>204</sup> This provision is good in a way that ensures that the rest of the world is protected from harm that could be caused from that genetically modified organism or its living products. Because once it is banned, it will not be re-exported to another country where it may be introduced into the environment.

However, apart from the heading of regulation 13, the provisions of the draft regulations do not mention any thing about the “import” of GMOs into Uganda. The provisions only mention the “export” of GMOs from Uganda. The Draft Biosafety Regulations define export as “the intentional transboundary movement from Uganda to another country”<sup>205</sup> and import is defined as “the intentional transboundary movement into Uganda”.<sup>206</sup>

### **4.3. Procedure**

This section of the study describes and examines the application and decision making procedures under the biosafety legislation of South Africa and the interim biosafety regime of Uganda.

#### **4.3.1. South Africa**

In terms of the GMO Act, the minister is empowered to make regulations regarding the application and for the issue of permits.<sup>207</sup> The GMO Act further states that, ‘no applicant may import to or export from the Republic of South Africa, or develop, or produce, use, release or distribute any genetically modified organism in the Republic of South Africa except in terms of a permit to under take such activity’.<sup>208</sup> Activities that require a permit have been listed in the relevant regulations to

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<sup>204</sup> Regulation 13 (3).

<sup>205</sup> Regulation 1 (d).

<sup>206</sup> Regulation 1 (g).

<sup>207</sup> Section 20(1)(a).

<sup>208</sup> Regulation 2(1).

include: the importation and exportation of GMOs, trial release of GMOs, and the general release and marketing of GMOs.

Regulation 2(1) is however, subject to the provisions of regulation 2(2) which states that 'a permit shall not be required for organisms that are used under conditions of contained use in academic and research facilities, and for those organisms that are specified in table 3'.<sup>209</sup> This mechanism is meant to serve as an exclusion list to fast track commercial releases of genetically modified seed, food and animal feed, and to expedite trade in GMOs. Strangely however, the table includes virtually all GMOs used in South Africa today.<sup>210</sup> Neither the GMO Act nor the GMO Amendment Act or the GMO Regulations of South Africa set out a specific decision-making mechanism regarding this category of GMOs. It is therefore possible for a decision to be made without public knowledge and participation and, perhaps more importantly, without conducting an EIA, before approval of the GMO.<sup>211</sup> The mechanism created here, as a possible exclusion of a permit requirement, has a potential to render the GMO Act meaningless.<sup>212</sup>

As noted above, a permit is not required for GMOs under contained use conditions in academic and research facilities. Rather, the facilities where the GMOs are being developed, produced, used or applied require registration.<sup>213</sup> However, the requirements for the registration of facilities do not go far enough in ensuring that abuses and circumvention of the stated purpose of research do not take place. The current method of approval by the National Department of Agriculture, namely, the issuing of one import permit for several GM varieties to be imported on one shipment, will not make not possible for South Africa to comply with the provisions

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<sup>209</sup> Table 3 to the regulations lists GMOs that have been cleared for commercial release and /or for food and animal feed only. These include cotton [Line 513], three strains of maize [Mon 180, T25 and T14], and Soya beans [Line 40-3-2].

<sup>210</sup> Glazewski J, op cit n27 at 320.

<sup>211</sup> Barron N M, op cit n5 at 106.

<sup>212</sup> Barron N M, supra.

<sup>213</sup> Mayet M, op cit n177 at 22.



shall be used for including detailed instructions for use and detailed labeling and packaging in accordance with the regulations.<sup>215</sup>

The main mechanism for the regulation of 'contained use' under the draft regulations is a registration system for premises. A permit is required for certain contained use activities and for the regulation of the 'deliberate release'. A permit is also required for the 'import or placing on the market' of GMOs under the draft regulations. Regulation 6 of the Draft Biosafety Regulations provides that the UNCST in accordance with the Biosafety Guidelines may decide that an application may proceed, proceed with such conditions as it may specify, or not proceed,<sup>216</sup> and such decisions shall be notified to the applicant within 270 days from the receipt of the application.<sup>217</sup> The Competent Authority (UNCST) may request for further information as it may deem necessary to make decision.<sup>218</sup> In an event where there is reason to suspect threats of damage, lack of scientific evidence shall not be used as a basis for not taking precautionary measures.<sup>219</sup>

Furthermore, the draft regulations provide that, for the approval for generation, import, export, contained use, release into the environment, or placing on the market of a GMO shall require the applicant to carry out monitoring and evaluation of risks.<sup>220</sup> And lastly, no approval of a GMO shall be considered and duly determined by the competent authority unless it will contribute to sustainable development, not have adverse socio-economic impacts, and accord with ethical values and concerns of communities and does not undermine traditional knowledge and technologies.<sup>221</sup>

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<sup>215</sup> Regulation 4(3).

<sup>216</sup> Regulation 6(1).

<sup>217</sup> Regulation 6(2).

<sup>218</sup> Regulation 6(3).

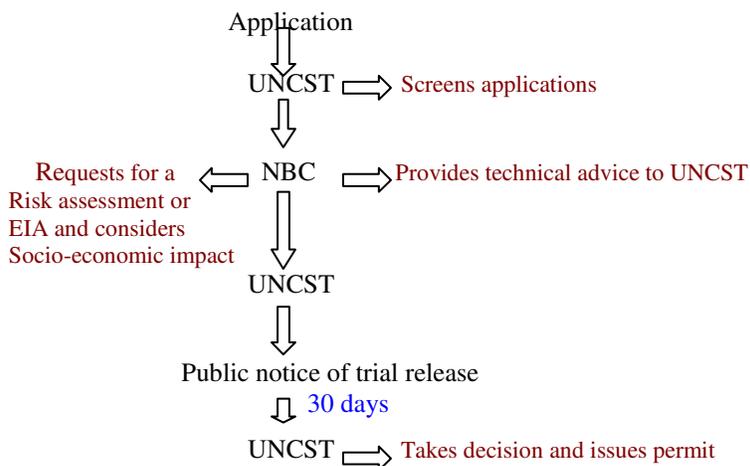
<sup>219</sup> Regulation 6(6).

<sup>220</sup> Regulation 6(5).

<sup>221</sup> Regulation 6(7).

A key component of a biosafety regulatory system is a clearly articulated safety standard, which is used to judge applications for approval by the competent authority. The interim biosafety regulatory regime of Uganda does not provide such a standard. In Uganda, neither the Biosafety policy nor the Regulations set forth a clear safety standard for approving GMOs. Though the draft regulations require that approval is required before undertaking any activity involving GMOs, they do not provide any criteria to determine whether to grant the approval or not. The approval procedure under the interim biosafety regulatory regime of Uganda described above is summarized and set forth in illustration 4 below.

**Illustration 4: The approval procedure under the interim biosafety regulatory regime of Uganda**



Source: Generated by the author

#### 4.4. Comparative Analysis

Both the biosafety regulatory systems of Uganda and South Africa do not have specific provisions titled Advance Informed Agreement (AIA). However, both biosafety regulatory systems do provide for the AIA procedure within their mechanisms in different ways. This is through the different procedures that are undertaken and the different factors that are put into consideration before an application is approved. The Protocol limits its self to the 'first intentional transboundary movement'. The Draft Biosafety Regulations of Uganda to a greater

extent comply with the Protocol as illustrated by regulation 13. Draft regulation 13 of Uganda provides that ‘any person that intends to export a GMO or its living product shall provide to the competent authority a written AIA’. However, this provision has shortcomings because it only provides for the ‘export’ and not the ‘import’ of a GMO as the AIA procedure is mainly concerned with the importation of GMOs. Since the regulations are still in draft form this provision needs to be corrected. On the other hand the GMO Amendment Act makes no mention of the first intentional transboundary movements of GMOs.

Whereas the Protocol under Article 6 provides that the AIA procedure shall not apply to GMOs in transit (see 2.1 of part C in chapter 2), both the Draft Biosafety Regulations of Uganda and the GMO Act and the GMO Amendment Act of South Africa are silent with regard to GMOs in transit. The Draft Biosafety Regulations of Uganda have a novel provision that states that there shall be no authorization for the re-exportation of a GMO or its living product that are banned by the laws of Uganda.<sup>222</sup> The GMO Act and the GMO Amendment Act of South Africa do not have such a provision but it is worth adopting because it ensures that the banned GMOs are not re-exported and released in another country.

Both the biosafety regulatory systems of Uganda and South Africa rely on registration and the permit system as the main mechanism for approval. In Uganda approval is granted by the UNCST and in South Africa the Council grants approval.<sup>223</sup> Whereas the UNCST in Uganda may decide that, an application may ‘proceed, proceed with conditions as it may specify, or not to proceed’,<sup>224</sup> the GMO Amendment Act only empowers the Council to ‘decide whether to approve’ an application. A thorough analysis of this provision under the GMO Amendment Act suggests that the Council has no specific powers to reject an application. Like most

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<sup>222</sup> Regulation 13(3).

<sup>223</sup> Regulation 4.

<sup>224</sup> Regulation 6.

developing countries, South Africa and Uganda face a problem of political interference especially by the ministers concerned during decision taking process.

With regard to time frames between the time of the receipt of the application and the final decision, the Protocol provides for a minimum of ninety days and a maximum of 270 days. The Draft Biosafety Regulations of Uganda comply with the Protocol because they also provide for a total of 270 days.<sup>225</sup> On the other hand the GMO Amendment Act does not have substantive provisions with regard to time frames between the notification date and the decision date, the provisions on time frames is left to the GMO Regulations that provide for different time frames for approval of different activities regarding GMOs. The approval procedures of applications under the GMO Amendment Act do not comply with the Protocol and its unfortunate that the new GMO Amendment Act failed to address this issue.

Both the biosafety regulatory frameworks of Uganda and South Africa consider other factors like socio-economic considerations. But the Draft Biosafety Regulations of Uganda under regulation 6(7) are more elaborate by further providing that 'no approval of a GMO shall be considered and duly determined by the competent authority unless it will contribute to sustainable development and not have adverse socio-economic impacts, and accord with ethical values and concerns of communities and does not under mine traditional knowledge and technologies'.

It is apparent that the biosafety regulatory framework of Uganda to a greater extent complies with the AIA procedure that is provided for by the Protocol though it also has its shortfalls. The AIA approach that is taken by South Africa still falls short of complying with the Protocol it creates a lot of uncertainty due to its vagueness.

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<sup>225</sup> Regulation 6 (2).

## 5.0. Risk Assessment and Management

The Protocol provides that, before any GMO is released (as discussed in 4.1 of part C of chapter 2), an evaluation of the impacts and risks posed to human health and the environment by the release should be carried out. This is meant to identify if there are any hazards posed by the GMO to human health or the environment, the magnitude of the harm, and what the risks are if the hazards are released.<sup>226</sup> Once the risks have been estimated, the assessment should identify whether or not any management procedures are required to control the risk and prevent or minimize damage to the environment or whether or not monitoring is required to determine that any risk control measure is effective.<sup>227</sup>

Risk management under the Protocol as discussed in (4.2 of part C in chapter 2) refers to means by which a user applies certain control measures to an operation in order to keep the risks to an acceptable level. Having identified and assessed the risk the next step is to consider how the risk can be minimized and best managed. The type of risk management to be applied depends on the novel organisms on the particular application. Risk management measures that are used to keep risks at a minimum include containment and assignment of biosafety levels.<sup>228</sup>

## 5.1. Risk Assessment

### 5.1.1. South Africa

Risk assessments are not mandatory in terms of the GMO Act and the GMO Amendment Act. This is because both the GMO Act and the GMO Amendment Act do not contain substantive provisions governing risk assessment. Rather, under section 5 (a) of the GMO Act the Council has extra ordinary wide discretionary powers to determine when an environmental impact assessment is required.

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<sup>226</sup> Delmer, D. 2005. *Agriculture in the developing world: Connecting innovations in plant research to downstream applications*. Proceedings of the National Academy of Sciences, 103 (44), pp.15740.

<sup>227</sup> The Uganda National Council for Science and Technology (UNCST), 'Guidelines on Biosafety in Biotechnology for Uganda, March 2002. pp.11.

<sup>228</sup> Kinderlerer, J. 2002. *Regulation of Biotechnology: Needs and burdens for developing countries*. Sheffield Institute of Biotechnological Law & Ethics, University of Sheffield, Sheffield U.K. Available at [www.cisdl.org/pdf/Biosafety\\_Scoping\\_Study.pdf](http://www.cisdl.org/pdf/Biosafety_Scoping_Study.pdf). Accessed on 18th July 2007.

Regulation 3(1) of the GMO Regulations, however, prohibits any person from undertaking 'any activity involving genetic modification unless a suitable and adequate assessment of the risks created thereby to the environment and human health has been made'. At first glance it appears as though this provision obliges the Council to consider the risk or environmental impact assessment before making a decision regarding the granting of a permit.<sup>229</sup> However, such an obligation exists only where the activity involves "genetic modification" and not where the activity involves for example, the release of GMOs into the environment.<sup>230</sup> Consequently, the Council retains its discretionary powers to determine when a risk assessment and an Environmental Impact Assessment (EIA) are required for all activities excluding the actual genetic modification of an organism.

It is submitted that in exercising its discretion, the Council is obliged to consider the National Environment Management Act (NEMA) principles enumerated in section 2 of NEMA. These NEMA principles apply throughout the South Africa to the actions of all organs of state that may significantly affect the environment.<sup>231</sup> A precise interpretation of the words 'may significantly affect the environment' is problematic. It is argued that the best if not the only, way to determine whether an action may "significantly" affect the environment is to conduct an EIA.<sup>232</sup> In the case of *Minister of Public Works and Others v Kyalami Ridge Environmental Association and Others*,<sup>233</sup> the Constitutional Court considered the meaning of the phrase 'may significantly affect the environment'. The court noted that in the circumstances the Kyalami residents had failed to show as a probability that the establishment of the Camp at Leeukop 'would' have a significant effect on

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<sup>229</sup> Barron N M, op cit n5 at 111.

<sup>230</sup> Section 1 of the GMO Act does not specifically define 'genetic modification'. Rather, it states that the term is to have a corresponding meaning to 'genetically modified organism', which is defined in section 1 as, 'an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both'.

<sup>231</sup> Section 2(1). It is to be noted that NEMA requires EIAs to be conducted in respect of activities that may *significantly* affect the environment. NEMA thus adopts a less onerous approach that encompasses a broader range of activities.

<sup>232</sup> Barron N M, op cit n5 at 111.

<sup>233</sup> 2001 (3) SA 1151 (CC).

the environment. This interpretation is incorrect, as the Kyalami residents ought only to have had to prove that the activity in question 'may' have had a significant effect on the environment.<sup>234</sup> In the case of *Hichange Investments (Pty) Ltd v Cape Produce Company (Pty) Ltd t/a Pelts Products & 4 Others*,<sup>235</sup> the question of what is to be considered as significant arose. The Court noted that, in light of the Constitutional right a person has to an environment conducive to health and well being, the threshold level of significance will not be particularly high.<sup>236</sup> This view is supported because the question of what is to be regarded as significant must be seen in the light of the constitutional right to an environment conducive to health and well being, as well as the relevant principles in NEMA.<sup>237</sup>

Neither the GMO Act nor the Regulations set out the principles or the parameters of the risk assessments, a factor that affects the Council when exercising its powers of requiring a risk assessment. It is also important to note that the regulations impose very short time limits for the regulators to respond to applications that require EIAs.<sup>238</sup> This means that regulators may have insufficient time to consider any risk assessments that may have been done. The short time frame is weighted in favour of expediting trade in GMOs rather than ensuring that adequate time is spent on assessing potential impacts on the environment.<sup>239</sup> Furthermore, the GMO Act allows the Council to make decisions based on risk assessments carried out by the applicant.<sup>240</sup> This means that, strictly speaking, the Council is unable to base its decision on an independent risk assessment. The Council is, however, obliged to consult the Committee. The Committee must in

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<sup>234</sup> Barron N M, op cit n5 at 112.

<sup>235</sup> Unreported judgment delivered on 20 October in the High Court of South Africa (Eastern Cape Division), Case No. 1050/01.

<sup>236</sup> *Hichange* at 33.

<sup>237</sup> Barron N M, op cit n5 at 112.

<sup>238</sup> That is, for the importation/exportation of a GMO or the contained use of a GMO, a determination must be made within 30 days. For the trail release and general release and marketing of GMOs, a determination must be made within 90 and 180 days.

<sup>239</sup> Barron N M, op cit n5 at 115.

<sup>240</sup> Section 5(a) of the Act read together with section 5(g) of the Act.

turn, invite written comments from 'knowledgeable persons' on any aspect of GMOs with in its brief.<sup>241</sup>

The GMO Act and the GMO Amendment Act both lay emphasis on scientific based risk assessments and the involvement of scientists.<sup>242</sup> The concerns with the scientific based approach in risk assessments is that it diverts attention away from the EIAs, socio-economic considerations as well as the involvement of experts in these fields.

### 5.1.2. Uganda

The interim biosafety regulatory regime of Uganda establishes mechanisms for risk assessments and management in addition to fundamental steps in risk assessment. In Uganda risk assessment is referred to as Environmental Impact Assessment (EIA). In Uganda, EIAs are governed by the Environmental Impact Assessment (EIA) Regulations.<sup>243</sup> The Draft Biosafety Regulations provide for risk assessments under regulation 8. Regulation 8 provides that a risk assessment of a GMO shall be carried out by an applicant or the competent authority as appropriate, on a case-by-case basis and shall be done in accordance with the national biosafety guidelines.<sup>244</sup> Regulation 8 further provides that the competent authority shall evaluate or cause the evaluation of the risk assessment report and consider the result of such an evaluation in making its decision on any application regarding GMOs.<sup>245</sup> These provisions illustrate that the Ugandan biosafety regulatory system assesses the risks that are posed by GMOs and the results are considered before the competent authority takes a decision regarding an application for a GMO.

The Regulations further provide that the competent authority may require the applicant to bear all the costs for evaluating the risk assessment report or

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<sup>241</sup> Section 11(d).

<sup>242</sup> Section 5(1)(c)(i) of the GMO Amendment Act.

<sup>243</sup> No. 13 of 1998.

<sup>244</sup> Regulation 8(1).

<sup>245</sup> Regulation 8(2).

carrying out the risk assessment, as the case may be.<sup>246</sup> Risk Assessments and EIAs are an important aspect of environmental Management in Uganda as illustrated by the case of *Advocates Coalition for Development and Environment (ACODE) v Attorney General*.<sup>247</sup> In this case the applicants an NGO contended among other things that the respondent had allocated a public forest reserve to the second respondent an investor for sugar cane planting without carrying out an EIA yet there was a change of land use involved in the process. The respondent argued that no EIA was required as long as measures to protect the environment had been taken. The Court held that if a permit was granted to the second respondent it would be null and void by the fact that no project brief and EIA was carried out as required by the law.

However, in some instances there is no provision for independent review of EIAs and risk assessments under the draft regulations. At times the applicant is required to pay the costs for carrying out the risk assessment and the evaluation of the risk assessment. This may however, compromise the whole process as chances are that the application of the applicant that has funded the whole process will not be rejected.

## **5.2. Risk Management**

### **5.2.1. South Africa**

With regard to risk management, neither the GMO Act nor the GMO Amendment Act specifically provides for risk management. It is only the GMO Regulations that make some reference to accidents arising from GMOs. The regulations require that in case of such accidents, the Registrar should be notified immediately both verbally and in writing. However, there are no other risk management measures like monitoring and periodic observation under the GMO Act.<sup>248</sup>

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<sup>246</sup> Regulation 8(4).

<sup>247</sup> Misc. Cause No. 0100 of 2004, High Court at Kampala.

<sup>248</sup> Section 7 of the Regulations under the GMO Act.

### 5.2.2. Uganda

The Draft Biosafety Regulations provide for risk management under Regulation 9. Regulation 9 provides that the competent authority shall impose such measures upon approval, as may be necessary, to avoid adverse effects on the environment, biological diversity and health, including the socio-economic considerations, arising from a GMO or its product.<sup>249</sup> Other risk management measures that are provided for by Regulation 9 include:

- a) Periodic observation of the GMO before its put to its intended use;<sup>250</sup>
- b) Order for the cessation of any activity that is under taken in violation of the provisions of the Regulations;<sup>251</sup>
- c) Order for the cessation of any activity that involves GMOs that are proven to cause risks to the environment, biological diversity or health;<sup>252</sup>
- d) Require person responsible for any activity to undertake such measures as may be necessary to prevent or limit harm to the environment, biological diversity or health, or to restore the environment to its previous state as far as feasible;<sup>253</sup>
- e) Take measures as necessary in the case of eminent danger to the environment, biological diversity or health caused by a GMO at the cost of the person responsible for causing such danger;<sup>254</sup> and
- f) Require the applicant to submit reports periodically in respect of the monitoring and evaluation of the risks carried out after the approval of the GMO.<sup>255</sup>

The provisions (regulation 9) as stated above relating to risk management in the interim biosafety regulatory regime of Uganda illustrates that many principles of

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<sup>249</sup> Regulation 9(1).

<sup>250</sup> Regulation 9(2)(a).

<sup>251</sup> Regulation 9(2)(b).

<sup>252</sup> Regulation 9(2)(c).

<sup>253</sup> Regulation 9(2)(d).

<sup>254</sup> Regulation 9(2)(g).

<sup>255</sup> Regulation 9(2)(h).

environmental management are considered. These include the polluter pays principle, the preventive principle, and the precautionary principle. Regulation 9 further provides for monitoring and evaluation reports that are submitted periodically by the applicant even though the GMO has already been approved by the competent authority.

### **5.3. Comparative Analysis**

Both the biosafety regulatory systems of South Africa and Uganda contain provisions on risk assessment and management. Article 15 the Cartagena Protocol (see 4.0 of part C in chapter 2) provides that risk assessments shall be carried out in a scientifically sound manner. The Protocol does not provide clear guidance where uncertainty arises in relation to risk assessment. The Draft Biosafety Regulations of Uganda comply with the Protocol because they have established mechanisms for risk assessment under Regulation 8. The applicant or the competent authority carries out the risk assessment under the Draft Biosafety Regulations of Uganda but the GMO Act of South Africa makes no mention of who should conduct the risk assessment. The Draft Biosafety Regulations of Uganda also provide for mandatory evaluation of the risk assessment report before it makes its decision, but under the GMO Act of South Africa, the applicant is required to submit an assessment on the impact on the environment if the Council determines that it is it is needed.<sup>256</sup>

The draft biosafety regulations in Uganda provide that the competent authority may require the applicant to bear the costs of carrying out the risk assessment or the evaluation of the risk assessment. This puts the competent authority in a compromising position because it will be difficult for them to be impartial and unbiased in reaching their decision if all their bills have been footed by the applicant. It is suggested that because of financial constraints, at most, the applicant should only bear the costs of the risk assessment but not the costs of the evaluation of the risk assessment. Both the biosafety regulatory systems of South

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<sup>256</sup> Section 5(1).

Africa and Uganda do not set out the principles or parameters of the risk assessments. This factor affects Council and the UNCST respectively when exercising their powers of requiring a risk assessment since time factor is an important aspect in carrying out risks assessments. In most cases a shorter time frame is preferred and this affects the quality of the risk assessments.

With regard to risk management, regulation 9 of the Draft Biosafety Regulations of Uganda requires the competent authority to impose such measures upon approval, as may be necessary, to avoid adverse effects on the environment, biological diversity and health, including socio-economic considerations arising from the GMO or its product.<sup>257</sup> The Draft Biosafety Regulations of Uganda also provide for a range of other risk management measures that include: periodic observation, ordering for cessation of the activity in case it violates provisions of the regulations, require a person that causes damage to take measures as may be necessary to limit the harm or restore the environment to its previous state at their cost, and requiring the applicant to submit periodic reports in respect of monitoring and the evaluation of risks carried out after approval of the project. In contrast, the GMO Act and the GMO Amendment Act of South Africa do not have any additional risk management measures like periodic observation and submission of periodic reports by the applicant even after the approval of the GMO. This leaves the risk management provisions of the GMO Act and the GMO Amendment Act of South Africa inadequate and wanting.

It is suggested that the biosafety regulatory system of Uganda to a greater extent complies with the Cartagena Protocol as far as risk assessment and management are concerned. But the biosafety legislation of South Africa still falls short of complying with the Protocol and its unfortunate that even the GMO Amendment Act has not done much to address this situation.

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<sup>257</sup> Regulation 9(1).

## 6.0. Public Awareness and Participation

Public participation in a biosafety regulatory system usually involves two separate components. First, is the public being given opportunity to provide comments and opinions on the laws, regulations, and policies before they are adopted. Secondly, the opportunity to provide comments before an application for GMOs is approved by the competent authority. Public participation is different from public awareness, where the government educates and informs the public about biosafety, biotechnology, and the regulatory process.

### 6.1. South Africa

The GMO Act and the GMO Amendment Act have no substantive provisions relating to public participation but the GMO Regulations,<sup>258</sup> provide for it though not in a clearly defined manner. In the context of the GMO Act, notification refers to the information the applicant is under legal obligation to supply to the competent authority together with the risk assessment report. The notification process is inextricably linked to public participation in so far as the public should be kept informed of the status of approvals, be furnished with the information supplied under the notification process and be given an opportunity to supply comments.<sup>259</sup> The Committee and the Council take these comments into account during the decision-making process. The consultation process is an essential component of environmental governance and justice.<sup>260</sup>

The GMO Act deals with public participation and notification only in the context of permit applications.<sup>261</sup> Notification must occur prior to an application for a permit. Notification is to be in the form of a standard notice published in the print

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<sup>258</sup> Section 6 GMO Regulations 1999 and the Regulations under NEMA.

<sup>259</sup> Barron N M, op cit n5 at 116.

<sup>260</sup> Jaffe G, op cit n32 at 23.

<sup>261</sup> See Regulation 6, which deals with public notification of proposed trial release and general release of GMOs.

media informing the public of the intended release.<sup>262</sup> The notice must contain, inter alia, a request that interested parties submit comments or objections in conjunction with the intended release to the Registrar with in no more than thirty days from the date of the notice.

The provisions in the GMO Act relating to public participation and notification are inadequate because of the following reasons:

First, the provisions only apply in the context of permit applications. So, for example, because a permit is not required for GMOs under contained use conditions in academic and research facilities, decisions regarding this category of GMOs can be made without public participation and in the absence of public knowledge. This category of GMOs effectively by-passes the decision making procedure set out in the Act yet the vast majority of international biosafety laws require step by step approvals of GMOs.<sup>263</sup> That is, releases of GMOs are approved first for the activity under contained use conditions, then for open field trials and then there is authorization for commercial releases. Authorizations are required at each stage of the process, and every stage of the activity is monitored for risks. Secondly, this implies that the notifications need not to be given to the public at large, but merely to those in the area in which the proposed release will occur. This is not satisfactory as the risks arising from the areas where the release takes place is of national importance.

Thirdly, the information that the applicant is required to furnish is inadequate for the purpose of equipping the public to participate in any meaningful way.<sup>264</sup> The GMO Act only provides for a right to access only to information regarding the 'evaluation of foreseeable impacts, in particular any pathogenic or

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<sup>262</sup> The publication must be made in at least three news papers circulating in the area the proposed release is to take place.

<sup>263</sup> Mayet M, op cit n177 at 21.

<sup>264</sup> Barron N M, op cit n5 at 117.

ecologically disruptive ones'.<sup>265</sup> Thus, the Public may be precluded from gaining access to information on the 'potential or likely' impact and risks posed by the GMO in question to the environment. This right is further tampered with, as the Council is empowered to determine, in consultation with the applicant, which information will be kept confidential.<sup>266</sup> In fact, the Council is obliged to consult the applicant in order to decide which information should be kept confidential. In addition to this, with the general power to determine what information is to be kept confidential, the Council is further empowered to treat information necessary to protect the intellectual property rights of the applicant confidential.<sup>267</sup>

Fundamentally, the risk assessment report itself should be made available to the members of the public for critical analysis. The argument that there is need for secrecy to surround risk analysis as a way of protecting propriety information in a competitive market has worn thin.<sup>268</sup> Commercial interests should no longer be allowed to trump the rights of the individual or the well being of the environment.<sup>269</sup> Fourthly, there is no provision for public participation in either the Executive Council or the Advisory Committee. Lastly, the Regulations impose a very short time limit for interested and affected parties to respond.<sup>270</sup> As a result the public is prevented from commenting meaningfully on any permit applications. There is need for more time in order to ensure that the imperative to expedite trade in GMOs does not preclude constructive public participation and the assessment of potential impacts on the environment.<sup>271</sup>

The provisions relating to public participation in the GMO Act do not comply with the NEMA principles contained in section 2 of National Environmental Management Act (NEMA). Section 2 requires that participation of all interested and

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<sup>265</sup> Section 18(2)(c).

<sup>266</sup> Section 18(2).

<sup>267</sup> Section 18(3).

<sup>268</sup> Barron N M, op cit n5 at 117.

<sup>269</sup> Barron N M, op cit supra at 118.

<sup>270</sup> That is, 30 days.

<sup>271</sup> Barron N M, op cit n5 at 118.

affected parties in the environmental governance must be promoted. Section 2 of the GMO Act further provides that all people must have an opportunity to develop the understanding, skills and capacity necessary for achieving equitable and effective participation. Participation by vulnerable and disadvantaged persons must also be ensured.<sup>272</sup> But the reality is that in most cases the affected parties are not identified, instead, the releases are shrouded in secrecy.<sup>273</sup> The lack of publicly available information on what is happening in relation to GMOs makes it extremely difficult to monitor whether or not the existing legislation is being complied with. That is, with out access to information, the public is not able to determine whether or not private parties or the Department of Agriculture are infringing the rights of the public under the Constitution,<sup>274</sup> the GMO Act and its regulations, NEMA, or international Conventions to which South Africa is party.

The situation is exacerbated by the confidentiality provisions in the GMO Act,<sup>275</sup> and the recalcitrant attitude of the National Department of Agriculture in relation to requests for information.<sup>276</sup> This has in fact led to court challenges on the grounds of the public's right to access to information held by the state under the provisions of section 32 of the constitution and the Promotion of Access to information Act (PAIA).<sup>277</sup> This was illustrated by the case of *The Trustees for the time being of the Biowatch Trust v the Registrar of Genetic Resources and Others*<sup>278</sup> where the applicant Non-governmental organization (NGO) invoked the right to information and the GMO Act to require the respondents to furnish reports on the commercial release of certain GMO crops in the South Africa agricultural sector.

An appeals procedure is provided for in the GMO Act, but this is only useful to members of the public if they know when an applicant has been notified of the

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<sup>272</sup> Section 2(4)(f).

<sup>273</sup> Barron N M, op cit n5 at 118.

<sup>274</sup> In particular section 24.

<sup>275</sup> Section 18 (1).

<sup>276</sup> Barron N M, op cit at n5 119.

<sup>277</sup> Republic of South Africa, Act 2 of 2000.

<sup>278</sup> Unreported case No. 23005/2002.

approval. The onus is on the public to find out when an applicant was notified of a decision, in order to lodge an appeal timeously, namely, within 30 days from the date the applicant was notified.

## 6.2. Uganda

The interim biosafety regulatory regime of Uganda provides for public awareness and participation. The Draft biosafety Regulations under regulation 5 provide for public awareness and participation. Regulation 5 states that the public shall be availed with information by the competent authority with in 30 days upon receipt of such information and this shall not prejudice the right to confidential business information.<sup>279</sup>

Furthermore, the public may make comments at the time of notification, where the competent authority arranges for a public consultation. The draft regulations further provide that a date of public participation and consultation is announced in the national media at least 30 days before the decision is made,<sup>280</sup> the competent authority in reviewing its decision shall take into account the views and concerns of the public expressed.<sup>281</sup> Lastly, the UNCST shall make public information regarding GMO approvals that have been granted or denied and risk assessment reports with respect to GMOs.<sup>282</sup> Apart from the Draft Biosafety Regulations, public participation Uganda especially regarding the EIA process is regulated by the Environmental Impact Assessment (EIA) Public Hearing Guidelines of 1999.<sup>283</sup>

With the above provisions, a Ugandan decision maker may feel more compelled to consider public comments before a GMO release can be approved. Public awareness and participation is an important aspect of environmental procedural rights in Uganda. This was illustrated by the case of *Advocates Coalition*

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<sup>279</sup> Regulation 5(1).

<sup>280</sup> Regulation 5(3).

<sup>281</sup> Regulation 5(4).

<sup>282</sup> Regulation 5(5).

<sup>283</sup> Issued pursuant to the National Environmental Statute No. 4 of 1995 and EIA Regulations S.I. No. 13 Of 1998.

*for Development and Environment (ACODE) v Attorney General*<sup>284</sup> where the court held that, if a change of land use permit was granted it would be null and void as the alienation of a forest reserve could only be done with due consultation and participation of the local community as provided for by the law.

### **6.2.1. Transparency**

Transparency is a very important aspect of any biosafety regulatory system as it creates public confidence in decisions taken.<sup>285</sup> The interim biosafety regulatory regime of Uganda has provisions that ensure that the systems are transparent. The Draft biosafety Regulations under regulation 5 (5) specifically state that the competent authority will make available to the public the risk assessment of the GMOs. The Draft Biosafety Regulations of Uganda under regulation 5 (1) and 5 (3) also balance the rights of the public to information with the rights of the developer or applicant to protect confidential business information. These provisions not only protect confidential information but they also ensure that the public receives at least a minimal amount of information about the GMO that cannot be claimed to be confidential.<sup>286</sup> These provisions are consistent with the Cartagena Protocol on Biosafety, which promotes transparency but allows for the protection of confidential information in Article 21.

### **6.3. Comparative Analysis**

The Draft Biosafety Regulations of Uganda comply with the provisions of Article 23 of the Cartagena Protocol on Biosafety. Under Article 23 of the Protocol the parties are required to ‘promote and facilitate’ public awareness and education on LMOs that may be imported. The Cartagena Protocol further calls on the parties to consult

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<sup>284</sup> Regulation 5(5).

<sup>285</sup> Pew Initiative on Food and Biotechnology. 2004. *Issues in the regulation of genetically engineered plants and animals*. Washington, D.C.: Pew Initiative on Food and Biotechnology. Available at <http://www.pewtrusts.org/ideas/index.cfm?page=8&issue=12&name=Grantee%20Reports-43k->. Accessed on 20<sup>th</sup> July 2007.

<sup>286</sup> McLean, M., R. Frederick, P. Traynor, et al. 2002. A conceptual framework for implementing biosafety: Linking policy, capacity, and regulation. The Netherlands: ISNAR. Available at <http://www.ifpri.org/isnararchive/publications/pdf/cr65.pdf> -. Accessed on 22nd July 2007.

the public in the decision making process and make the results of such decisions available to the public.<sup>287</sup> The Draft Biosafety Regulations of Uganda under regulation 5 provide for public awareness and Participation where the public is notified by the competent authority, the public makes comments, advertisement in the media, comments of the public are taken into account by the UNCST before decision is reached and confidentiality of business information is also taken into account.

The Draft Biosafety Regulations of Uganda also a step further by making provision for public awareness. It is a fact that there is limited public awareness and a lot of misinformation with the respect to the techniques, basic applications, opportunities, utility and safety of modern biotechnology and GMOs. The knowledge of modern biotechnology and its full implication for development are still confined to a few individuals and certain categories of Ugandan society. As a means of stimulating public participation, public awareness is a very important component that should not be over looked.

In Uganda public awareness campaigns have taken the form of sensitization workshops, development of a web site by the UNCST, translation of the biosafety regulatory policy in four main languages, dissemination of best practices in biotechnology and biosafety to target institutions, dissemination of information in the electronic media e.g. FM radio and TV programmes and development of a curriculum in biotechnology and biosafety for schools and colleges.<sup>288</sup> All the above measures are meant to ensure that the Ugandan public is fully aware of the events takes place in the field of biosafety and biotechnology so that they can effectively participate in the decision making process fully aware of their role. However, like in many developing countries, the public awareness campaigns in Uganda also do not

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<sup>287</sup> Article 23(2).

<sup>288</sup> Mugoya C, op cit n191 at 9-10.

have the desired impact on the target groups and these campaigns at times only appear on paper do not actually take place.

The South African GMO Act and the GMO Amendment Act of South Africa fall short of complying with the provisions of Article 23 of the Protocol. The GMO Act and the GMO Amendment Act do not have provisions specifically relating to public awareness and participation, currently public participation is provided for by the GMO Regulations.<sup>289</sup> The provisions of public participation in the Regulations are also framed in a limited context. Under the GMO Regulations, public participation and notification is only in the context of permit applications. Unlike the Draft Biosafety Regulations of Uganda, the 'Council' under the GMO Amendment Act is under a duty to consider all the comments and objections from the public when considering an application for the release of GMOs,<sup>290</sup> however, there is no duty to publish the decisions taken.

The biosafety legislation of South Africa makes no mention of public awareness as it only provides for 'public participation and notification'. With such provisions under the GMO Act, the public shall not be in a position to comment or respond to something that they have not been sensitized about. It is suggested that the biosafety legislation of South Africa should also make provisions for Public awareness.

Furthermore, the provisions on public awareness and participation under the GMO Act and the GMO Amendment Act do not only fall short of complying with the Cartagena Protocol, but they also do not comply with section 32 of the Constitution that provides for the right to information and the Provisions of the Promotion to Access of Information Act (PAIA).<sup>291</sup> The GMO Act and the GMO Amendment Act do not also comply with Section 33 of the Constitution that

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<sup>289</sup> Article 6 GMO Regulations 1999 and the Regulations under NEMA.

<sup>290</sup> Section 5(2)(a)(1).

<sup>291</sup> Republic of South Africa, Act 2 of 2000.

provides for procedurally fair administrative action and also Sections 3 and 4 of the Promotion of Administrative Justice Act (PAJA),<sup>292</sup> which sets out the requirements for procedural fairness. This is because the public is not given ‘adequate’ notice as required by PAJA.<sup>293</sup> Accordingly, the defects described above cannot be addressed by requesting for information under PAIA because the request for information under PAIA takes 30 days to process and the period for commenting on a GMO application also takes 30 days, calculated from the date of the published notice. So by the time a member of the public obtains the risk assessment report or any other document under PAIA, the period for commenting would have expired.

## **7.0. Socio-Economic Considerations**

Consideration of socio-economic impacts and issues during the decision making process is an important aspect of sustainable development and intergenerational equity. Taking into account of socio-economic considerations ensures that proposed projects are in harmony with the social well being of the people concerned and the surrounding environment.

### **7.1. South Africa**

While making decisions it is essential for the decision makers to take into account socio-economic considerations. The Cartagena Protocol has provisions on socio-economic considerations under Article 26 (see 6.0 of part C in chapter 2), though its wording “may take into account” does not create obligations to the parties to take them into account.<sup>294</sup>

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<sup>292</sup> Republic of South Africa, Act 3 of 2000.

<sup>293</sup> Section 3(2)(b)(i). Adequate notice, in the context of PAJA should contain the information included in a risk assessment and if possible the EIA report submitted by the applicant. In most cases the Public is only given a summary of the risk assessment.

<sup>294</sup> Kalibwani, F., Mugwagwa, J., Cohen, J., (2004). *Governing biotechnology in Africa: Toward consensus on key issues in biosafety*. NEPAD, FANRPAN, IFPRI, Johannesburg, South Africa, Harare, Zimbabwe, and Washington, D.C. Prepared for “African Policy Dialogues on Biotechnology-Southern Africa,” held on September 20-21, 2004 in Harare, Zimbabwe. Available at <http://www.ifpri.org/pubs/books/oc46/oc46.pdf>. Accessed on 22<sup>nd</sup> July 2007.

The GMO Act does not have specific provisions for socio-economic considerations in decision-making. The GMO Act under section 5 (g) provides that after consideration of the risk assessment and where required, the environmental impact assessment, the council may authorize the registrar to issue a permit for the purpose for which the application was made or for the release of a GMO into the environment. Section 5(g) of the GMO Act creates doubt as to whether the socio-economic considerations are as a matter of fact taken into account by the Council while making the final decision. The GMO Amendment Act introduces socio-economic considerations into the decision making process. However, the GMO Amendment Act provides for the taking into account of the socio-economic considerations in a vague manner.<sup>295</sup>

The above provisions of the GMO Act clearly illustrate that that socio-economic considerations are only taken into account by the Council only after it has determined that such a consideration is necessary. It is suggested that the Council should be obliged to take socio-economic considerations into account rather than doing it on a discretionary basis. To make matters worse, section 5(2)(a) provides that, when making a final decision the Council “may” consider public input, EIA or the potential socio-economic impact of such activities. Controversy surrounding the aspect of taking into consideration the socio-economic impacts in decision-making under the GMO Act is illustrated by the case of *BP South Africa (Pty) Ltd v MEC for Agriculture, Conservation and Land Affairs*.<sup>296</sup> The Court held that the balancing of environmental interests with justifiable socio and economic development is to be conceptualized well beyond the present living generation. The Court further observed that that section 24 of the constitution provides that the environment must be protected for the benefit of the present and the future generations.<sup>297</sup> This case clearly illustrates that socio-economic considerations contain an aspect of sustainable development and the principle of inter generational equity.

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<sup>295</sup> Section 5(2)(a)(iii).

<sup>296</sup> 2004(5) SA 124 (W).

<sup>297</sup> At 143 D.

In its provisions relating to socio-economic considerations the Protocol is concerned with the effects arising from LMOs while emphasizing the importance of biological diversity to the indigenous and local communities in such areas. The provisions of the GMO Amendment Act relating to socio-economic considerations appear general and vague as they do not specify the areas that will be affected and by what. The GMO Amendment Act simply states that before making a decision, the socio-economic impact of the activity may be taken into account as an alternative to the EIA and vice-versa.<sup>298</sup>

Socio-economic considerations in decision-making are meant to serve the interests of the population especially the local population that will be affected by that decision. The GMO Amendment Act has however, failed to make provision for mandatory consideration of socio-economic impacts. This puts the GMO Amendment Act in conflict with the provisions of the Protocol. Thus, the GMO Amendment Act has not been able to address the problem that was created by the parent GMO Act.

## **7.2. Uganda**

The interim biosafety regulatory regime of Uganda recognizes the need to address socio-economic considerations that may arise from GMOs. The Uganda Draft Biosafety Regulations provide that no approval shall be given unless the GMO will “not have adverse socio-economic impacts”.<sup>299</sup> However, the Regulations do not elaborate on what socio-economic considerations will be considered, how they will be analyzed, and how they will be factored into the decision making process. For a biosafety regulatory system to be fair, predictable and transparent, the details surrounding the inclusion of socio-economic considerations in the decision making process should be spelled out in more detail than is currently available in the Draft

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<sup>298</sup> Section 5(2)(a).

<sup>299</sup> Regulation 6 (7)(b).

Biosafety Regulations.<sup>300</sup> Without sufficient details, the system could be perceived as unfair to the applicants and the public who may not know how specific applications will be judged in this area.

Without additional details on the interaction between socio-economic considerations and the decision-making process, it is unclear whether the biosafety regulatory regime of Uganda might not comply with the Protocol.<sup>301</sup> Article 26 of the Protocol provides for taking into account socio-economic considerations of LMOs, but places conditions on that analysis.<sup>302</sup>

First, it limits the socio-economic considerations to those effects that arise from “the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to the indigenous and local communities”.<sup>303</sup> Thus, the plain language of Article 26 does not allow all socio-economic considerations of LMOs to be considered, but only those that directly arise from the impacts on biological diversity.<sup>304</sup> Some stake holders believe, however, that the socio-economic impacts of LMOs are much broader and could include concerns such as “impacts on farmers’ incomes and welfare, cultural practices, community wellbeing, traditional crops and varieties, domestic science and technology, rural employment, indigenous peoples, food security, ethics and religion, consumer benefits, and ideas about agriculture, technology and society.”<sup>305</sup> While those broader socio-economic considerations may be valid societal concerns relevant to GMOs, they may not be properly part of a biosafety regulatory system consistent with the Protocol.<sup>306</sup>

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<sup>300</sup> Jaffe G, op cit n32 at 32.

<sup>301</sup> Jaffe G, Ibid.

<sup>302</sup> Jaffe G, Ibid.

<sup>303</sup> Secretariat of the CBD, 2000. Available at <http://www.biodiv.org/>. Accessed on 24<sup>th</sup> July 2007.

<sup>304</sup> Mackenzie R, et al. 2003.

<sup>305</sup> La Vina A., and L. Fransen, ‘*Integrating socio-economic considerations into biosafety decisions: The challenge for Asia*’. Washington, D.C.: World Resources Institute. 2004. Available at [http://pdf.wri.org/lavina\\_fransen\\_socioeconomics.pdf](http://pdf.wri.org/lavina_fransen_socioeconomics.pdf). Accessed on 25th July 2007.

<sup>306</sup> Jaffe G, op cit n32 at 33.

Secondly, the Protocol states that the inclusion of socio-economic considerations must be done in a manner that is consistent with other international obligations.<sup>307</sup> In general, the WTO rules emphasize procedures for decision-making that primarily rely on scientific risk assessments and greatly limit the ability to make decisions based on non-safety concerns. For example, Sanitary and Phytosanitary Standards (SPS) Agreement does not set forth a risk assessment procedure that includes both scientific and socio-economic considerations.<sup>308</sup> Therefore, to try and comply with the plain language of Article 26 of the Protocol, countries such as Uganda which have included socio economic considerations in their biosafety regulatory regimes might tailor what they will consider to only what is allowed by Article 26 (e.g. socio-economic concerns directly linked to impacts on biodiversity). This may greatly narrow the scope of the socio-economic issues that the biosafety regulatory regime of Uganda can address. Broader socio-economic considerations, however, might be addressed through other means, such as voluntary processes implemented by research institutions and companies or other laws and regulations.<sup>309</sup>

It is suggested that any assessment of socio-economic considerations should ideally be conducted only when a GMO is ready to be commercially released. There is an assumption that when a GMO is used in a contained laboratory or in a confined field trial, that GMO will not persist in the environment and will therefore have minimal effects on the population and the environment. This therefore creates an impression that there will be no significant socio-economic considerations to analyze. If a country is concerned about conducting GMO research as a whole, those issues should be addressed in a policy context.<sup>310</sup> If socio-economic considerations

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<sup>307</sup> Kalibwani F, et al 2004.

<sup>308</sup> The World Trade Organization, 'Agreement on the application of sanitary and phytosanitary measures', 1995. Available at [http://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm). Accessed on 24<sup>th</sup> July 2007.

<sup>309</sup> Fransen L, A La Vina, F Dayrit, F, 'Integrating socio-economic considerations into biosafety decisions', Washington, D.C.: World Resources Institute. 2005. Available at [http://www.trade-environment.org/page/ictsd/projects/biotech\\_guide\\_b1ref.htm](http://www.trade-environment.org/page/ictsd/projects/biotech_guide_b1ref.htm). Accessed on 25th July 2007.

<sup>310</sup> Jaffe G, op cit n32 at 34.

are to be analyzed for individual GMO applications, the proper time is when that organism is seeking approval for commercial use.<sup>311</sup>

Taking into account of socio-economic considerations is now an important aspect of environmental management in Uganda. This is illustrated by the case of *Advocates Coalition for Development and Environment (ACODE) v Attorney General*<sup>312</sup> where the court held that, if a change of land use permit was granted to the second respondent, it would be null and void as the alienation of a forest reserve could only be done after conducting an EIA, taking into account of the socio-economic impacts of the proposed project and after due consultation and participation of the local community as provided for by the law.

### 7.3. Comparative Analysis

Both the biosafety legislation of South Africa and the interim biosafety regulatory regime of Uganda do not have specific provisions providing for taking into account socio-economic considerations, but they have differently attempted to comply with Article 26 of the Protocol in their approval procedures. The Draft Biosafety Regulations of Uganda provide that no approval for a GMO shall be given unless, where it has been established that the GMO will not have adverse socio-economic impacts.<sup>313</sup> However, the draft biosafety regulations of Uganda do not state what socio-economic considerations will be considered.

The range of socio-economic considerations contemplated in Article 26(1) of the protocol covers only those “considerations arising from the impact 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”. This wording of the Protocol clearly indicates that not all socio-economic considerations may be taken into account, but rather only those that arise from the impact of LMOs

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<sup>311</sup> Jaffe G, op cit n32 at 34.

<sup>312</sup> Jaffe G, Supra.

<sup>313</sup> Regulation 6(7)(b).

on biological diversity. There is need for the Draft Biosafety Regulations of Uganda to specify what socio-economic considerations will be taken into consideration otherwise the applicants may perceive the whole system as unfair.

The GMO Act and the GMO Amendment Act of South Africa also provide for taking into account of the socio-economic considerations although this is done in a vague manner. Firstly, the taking into account of socio-economic issues is left at the consideration of the Council. This means that these socio-economic considerations may easily be ignored by the council in the decision making process. Secondly, the GMO Amendment Act does not impose an obligation on the Council to take into account socio-economic considerations during the decision making process. And lastly, by making the socio-economic considerations as an alternative to the EIA, there is creation of doubt as to whether the socio-economic considerations are ever taken onto account while making the final decision.

It is apparent that, if both the biosafety regulatory systems of South Africa and Uganda are to fully comply with the Protocol, they should go an extra mile by incorporating provisions that specifically provide for taking into account the socio-economic considerations just as the Protocol does under Article 26. Though, I must say that the provisions for taking into account the socio-economic considerations under the Draft Biosafety Regulations in Uganda are more elaborate than the provisions of the GMO Amendment Act of South Africa.

## **8.0. Identification and Labeling**

*“Consumers can enquire from the seller of the food whether it is genetically modified or not and determine if they wish to consume it.”*

*- Thoko Didiza, Minister of Agriculture and Land Affairs<sup>314</sup>*

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<sup>314</sup> GM food concentrated in three provinces Business Day. December 2003.

Identification and labeling of genetically modified organisms especially foods, serves as an important function of providing the public and consumers with information regarding GMOs. However, its value also lies in its biosafety function regarding the traceability of a GMO, risk management and monitoring of the impacts of the GMO.

### **8.1. South Africa**

The Cartagena Protocol under Article 18 contains a number of labeling requirements in respect of GMOs. For example, Article 18(2)(a) requires each party to provide for documentation accompanying GMOs for direct use as food, feed or processing to be clearly identified as “may contain” GMOs. The GMO Act and the GMO Amendment Act are both silent and do not contain provisions for the mandatory labeling regimes. The absence of mandatory labeling provisions undermines consumer choice, prevents users from protecting themselves from liability and impedes the monitoring of human health.<sup>315</sup>

Currently, the only legal requirements regulating the labeling of food or food ingredients containing GMOs are provided by the Regulations made under the South African Foodstuffs, Cosmetics and Disinfectants Act.<sup>316</sup> These regulations regarding the labeling and identification of GMOs also do not have provisions requiring the mandatory labeling of GMOs and products derived from GMOs. Labeling is only required where the consumption or the nutritional value of the foodstuffs differs significantly from the characteristic composition of the foodstuff in its non-modified form.<sup>317</sup> A “significant difference” is defined in the regulations to exist only where the characteristics are different in terms of a scientific assessment of an appropriate analysis of data.<sup>318</sup> In other word, the regulations do not impose

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<sup>315</sup> Mayet M, op cit n142 at 3.

<sup>316</sup> Republic of South Africa, Act 54 of 1972 and published in Government Gazette 25908 of 16 January 2004.

<sup>317</sup> In terms of Regulation 2 of the Regulations made under the South African Foodstuffs, Cosmetics and Disinfectants Act.

<sup>318</sup> In terms of regulation 1 of the Regulations.

mandatory labeling for GMOs yet the libeling of GM foodstuffs is one of the most important ways of upholding the right of consumers to choose what they wish to consume. It is also a way of tracing GMOs through the food chain, and boosts the demand for the segregation of GM and non-GM ingredients in the food chain.<sup>319</sup>

The rationale for the South African government's decision not to require the mandatory labeling of GMOs include: it would result in the increase of food prices, it is not practical, systems that identify and label GMOs are subject to error and abuse, segregation of GMOs and non-GMOs is expensive and lastly that GMOs are safe and therefore, the need for labeling as a warning is unnecessary.<sup>320</sup> It is therefore, surprising that increased costs have been preferred as an excuse to avoid guaranteeing consumer choice.

## 8.2. Uganda

The Draft Biosafety Regulations have provisions for identification and labeling of GMOs under Regulation 11. The Draft Biosafety Regulations provide that any GMO or its living product shall specify the relevant traits and characteristics given in sufficient detail for purposes of traceability.<sup>321</sup> Regulation 11 further provides that, any product of a GMO shall be clearly labeled and packaged using the words in accordance with Annex II, part C, and shall comply with such further requirements, if any, imposed by the competent authority, or to indicate that is, or has been derived from, a GMO, and, where applicable, whether, it may cause reactions, allergies or other risks.<sup>322</sup>

As discussed above, the interim biosafety regulatory regime of Uganda gives consumers an opportunity to decide on what they want, i.e. whether to consume GMO products or not to do so. This is because it provides for the manufactures to

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<sup>319</sup> Mayet M, op cit n142 at 4.

<sup>320</sup> Department of Health Publication, 'Explaining GMO Food Labeling'. Available at <http://www.doh.gov.za/departments/foodcontrol/docs/explain.html>. Accessed on 30th July 2007.

<sup>321</sup> Regulation 11(1).

<sup>322</sup> Regulation 11(2).

clearly label their products for easy identification. In case a particular GMO or its products causes a negative impact on the environment or to human health it can easily be traced back to the producer or the manufacturer.

### 8.3. Comparative Analysis

Both the biosafety regulatory frameworks of South Africa and Uganda contain provisions on identification and labeling of GMOs. But the Draft biosafety Regulations of Uganda to a greater extent comply with the provisions of Article 18 of the Cartagena Protocol that require each party to provide for documentation accompanying GMOs for direct use as food, feed or processing to be clearly identified as “may contain” GMOs.<sup>323</sup> This is because regulation 11 of the Draft Biosafety Regulations expressly provides for mandatory labeling and identification of GMOs. The draft regulations go a step further by requesting the producers to indicate whether these GMOs may cause reactions, allergies and other risks. This gives the Ugandan consumer a freedom of choice.

On the other hand the GMO Act and the GMO Amendment Act of South Africa do not fully comply with Article 18 of the Protocol, mainly because they do not have specific provisions that expressly provide for mandatory labeling of food and food ingredients that contain GMOs. Identification and labeling of GMOs is only regulated by the regulations made under the South African Foodstuffs, Cosmetics and Disinfectants Act,<sup>324</sup> but these regulations do not also expressly provide for mandatory labeling of GMOs. As the case is, the South African consumer’s freedom of choice is undermined and prevents them from taking measures to protect themselves as some people are unwilling to knowingly consume food or food ingredients that contain GMOs, but because of the lack of mandatory labeling, they might have done so on so many occasions.

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<sup>323</sup> Section 18(2)(a.).

<sup>324</sup> Republic of South Africa, Act 54 of 1972.

It is suggested that the interim biosafety regulatory regime of Uganda addresses the issue of identification and labeling of GMOs better than the biosafety legislation of South Africa. The GMO Act and the GMO Amendment of South Africa should expressly provide for mandatory labeling of GMOs.

### **C. Conclusion**

Implementation of the Protocol in South Africa and Uganda is at different levels of development. The interim biosafety regulatory regime of Uganda is still a temporary mode of regulating biosafety as Uganda has not yet enacted the Biosafety Bill of 2005 into law. On the other hand, South Africa has a fully fledged biosafety framework. It is suggested that the interim biosafety regulatory regime of Uganda to a greater extent complies with the provisions of the Protocol while the biosafety legislation of South Africa still falls short of complying with the provisions of the Protocol. The biosafety legislation of South Africa has been criticized for its inadequate provisions regarding: identification and labeling, the precautionary principle, public participation and awareness, risk assessment and management and socio-economic considerations. The direction that the biotechnology policy in South Africa takes holds significance that goes beyond the country's borders as policy developments in South Africa are often seen as, whether legitimately or not, as the litmus test for how things will develop on the African continent as a whole including Uganda.

It is unfortunate that the GMO Act of South Africa does not fully comply with the Protocol. Matters have been worsened by the fact that even the GMO Amendment Act that was hoped to salvage the situation has not done much to remedy the defects of the parent GMO Act. This may however, be a blessing in disguise for countries like Uganda that have not adopted a substantive GMO legislation to learn a lesson or two from the GMO legislation of South Africa so that it does make the same mistakes. Some of the major issues that have been identified by the comparative analysis of the biosafety regulatory frameworks of South Africa

and Uganda are summarized and set forth in table 1 below. Conclusion and recommendations follow in the closing chapter.

**Table 1- Comparison of key selected provisions of the biosafety regulatory frameworks of Uganda and South Africa**

	<b>UGANDA</b>	<b>SOUTH AFRICA</b>
<b>Scope</b>	Covers all GE organisms and addresses environmental and health issues but does not address food safety issues.	Makes no reference to taking into account human health and is also not concerned with the transboundary movement, transit, handling and use of GMOs that may have adverse effects on biological diversity.
<b>Precautionary Principle</b>	Takes into account the precautionary principle.	Makes no specific provision for taking into account the precautionary principle.
<b>Transparency</b>	More Transparent as it provides for giving the public information on applications and other processes.	Less transparent as the public is given little information and also has limited access to information regarding applications.
<b>Advanced Informed Agreement Procedure (AIA)</b>	Has a component of the AIA procedure as consent obtained from the CA based on full disclosure before any activity is undertaken.	Takes into account the AIA procedure though it does not have a specific provision titled AIA.
<b>Risk Assessment and Management</b>	Provides for risk Assessments before applications are considered and also provides for Risk Management measures even after the approval of the application.	The Council may at its discretion request for a Risk Assessment or EIA to be carried out.
<b>Public Awareness and Participation</b>	Good involvement of the public in the decision making process, public is given information regarding applications and there is also public awareness campaigns.	Inadequate public participation in the decision making process, limited public access to information regarding applications and no public awareness.
<b>Socio-economic Considerations</b>	Taken into account but no details are given.	Taking into account of socio-economic considerations is at the discretion of the Council.
<b>Identification and labeling</b>	Provides for mandatory labeling and segregation requirements.	No mandatory labeling and segregation requirements.

Source: Generated by author

## **CHAPTER FOUR:**

### **CONCLUSION AND RECOMMENDATIONS**

The present chapter gives an overall conclusion of the study. Thereafter, it gives recommendations that will be useful in improving the biosafety regulatory frameworks of Uganda and South Africa hence making them more compliant with the provisions of the Protocol. Finally this chapter outlines the future perspectives in the field of biosafety, modern biotechnology and GMOs.

#### **A. Conclusion**

The study has presented how South Africa and Uganda have each implemented the Protocol through their biosafety regulatory frameworks. The two countries have recognized the benefits and potential risks posed by modern biotechnology, and have to differing extents, implemented legislation and regulations that have attempted to strike a balance ensuring the development of biotechnology and safeguarding the interests of the consumers and the environment. A comparative analysis of the national biosafety policy evolution in South Africa and Uganda suggests that the market and trade dynamics and/or a general overreaching concern with technological leadership and international competitiveness are driving policy choices in the two countries.

The Cartagena Protocol has, nonetheless, influenced policy debates and regulatory and institutional developments in these two countries. While South Africa has adopted substantive GMO legislation, Uganda has been working the past few years to establish a national biosafety regulatory system so that GMOs may safely be introduced in the agricultural sector. At the time of writing the interim biosafety regulatory regime of Uganda comprised of the Draft National Biosafety and Biotechnology Policy, and the Draft Biosafety Regulations. However, Uganda is in the process of adopting the Biosafety Bill of 2005, though it is not yet known how long this will take.

It is evident from this study that, though the Cartagena Protocol is being implemented in the two countries, this process has not resulted in the harmonization of the domestic regulatory process as the study has clearly shown that of the two countries reviewed, South Africa falls short when it comes to the precautionary principle, public awareness and participation, effective risk assessments and labeling and traceability of GMOs. Uganda on the other hand still has an opportunity to rectify the flaws in its biosafety regulatory framework since its still in draft form.

The prospects for South Africa and Uganda to choose their own paths in biosafety policy will to a larger extent be shaped by their domestic priorities and imperatives. This is also keeping with the original intent of the Cartagena Protocol, which is to empower the GMO importing countries to make informed judgments about the impact of transgenic crops on their domestic ecological, health and agricultural systems. It is suggested that the biosafety legislation of South Africa has tended to follow the permissive regulatory approach that has also been taken by countries such as the United States of America (USA). This is reflected in the recently passed GMO Amendment Act. This permissive approach to GMO regulation in South Africa may also be politically feasible in part because there is currently little widespread public knowledge or concern about transgenics. On the other hand, the biosafety regulatory regime of Uganda has followed a precautionary approach which has also been taken by bodies such as the European Union (EU).

The absence of a shared global approach to GMO regulation, combined with disunity among leading agricultural trading partners in the developed countries, has the potential to open the policy space for autonomous decision-making in the developing countries. This is partly because such conflicts will enable countries that desire to engage in trade with such countries to simultaneously combine openness and precaution towards transgenics in their domestic policies.

In interpreting global biosafety rules such as the Cartagena Protocol, leading developing countries on the African continent such as South Africa are choosing different combinations of promotional precautionary elements, reflecting their position in global agricultural trade and the domestic balance of interests. Where trade, market access and competitiveness are not driving the directions of biosafety policy, in many smaller developing countries such as Uganda, the implementation of the Protocol might be different, and in all likelihood more pronounced, insofar as visibility to biosafety concerns is concerned.

Notwithstanding the Protocol, the controversies around the global and domestic regulation of biotechnology especially between the proponents and the opponents of GMOs are unlikely to diminish in the near future, and instead look to escalate especially as the WTO weighs into the global debate. Critics of stringent and tough biosafety regulatory frameworks argue that these rigid biosafety frameworks may interfere with free trade, while others argue that free trade should not be interpreted to mean uncushioned hazards to the environment and human health. Nonetheless, this study supports the view that the globalization of modern biotechnology currently co-exists with regulatory diversity in the national biosafety policies of developing countries. This is because such globalization and associated global regulation itself remains heterogeneous.

## **B. Recommendations**

Through a detailed comparative analysis of the current and interim biosafety regulatory systems in South Africa and Uganda respectively, the study has identified a number of issues, that if addressed could improve those systems. Some of the major recommendations from the study are as follows:

1. The Draft Biosafety Regulations of Uganda require specific provisions clearly outlining their objective. This should be in line with the objective of the Protocol. The of the objective of the Draft Biosafety Regulations of Uganda

should aim at contributing to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from the use of modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movement and all this is in accordance with the precautionary approach.

The GMO Act and the GMO Amendment Act of South Africa require objective(s) that are consistent with the precautionary principle as provided for in the Protocol and Principle 15 of the Rio Declaration on Environment and Development.

2. The Draft Biosafety Regulations of Uganda should make specific reference to Living modified organisms (LMOs) just as the Protocol does. This will enable the draft regulations to have a wider scope of application. The scope of the Draft Biosafety Regulations of Uganda should also take into account the conservation and sustainable use of biological diversity and also take into account of risks to human health.

The Scope of the GMO Act and the GMO Amendment Act of South Africa should include the aspects covered by the Scope of the Protocol. Thus the GMO Act and the GMO Amendment Act of South Africa should apply to the transboundary movement, transit, handling and use of all LMOs, instead of only focusing on only GMOs and not their living products.

3. It is recommended that under the Draft Biosafety Regulations of Uganda as the National Focal Point (NFP), the Ministry of Water, Lands and Environment could work hand in hand with the Ministry of Agriculture, Fisheries and Animal Husbandry. This is because when transgenic crops are

introduced into the environment, their primary use is mainly for commercial agriculture. As the national competent authority, the Uganda National Council of Science and Technology (UNCST) should also be given a more clear definition of roles in relation to other institutions. Furthermore, the UNCST statute should be amended to give the UNCST typical regulatory power and functions so that it is give adequate legal authority to regulate GMOs. The UNCST should also consider establishing the office of a substantive administrative officer (the equivalent of the Registrar under the GMO Act of South Africa) that will be in charge of administering the interim biosafety regulatory regime and also issue permits.

Under the GMO Act of South Africa, the 'Council' and the 'Committee' should be more independent and constituted in a more all encompassing manner. This includes representing all the interested parties such as the civil organizations and non-governmental organizations (NGOs). There is also need to include other professionals like economists, anthropologists, environmentalists and sociologists so that the composition of the decision-making bodies is not scientifically skewed. There is also need to check the excess powers that are exercised by the Registrar especially with regard to issuance of permits and enabling the public to gain access to information in his custody. South Africa should also consider establishing institutions that are the equivalent of the IBCs in Uganda. Such institutions will effectively monitor biotechnology and GMOs from the sources where they are generated up to the application stage.

The GMO Act of South Africa should also make provision for cooperate governance and making use of existing inspectorate bodies for the monitoring and enforcement of the provisions of the Act. These inspectorates include the respective lead agencies for inspection reporting like customs and the bureau of standards.

4. Both the biosafety regulatory systems of South Africa and Uganda should adopt Advance Informed Agreement (AIA) procedures that are clearly outlined and comply with the Protocol. The Draft Biosafety Regulations of Uganda should be rectified to provide for the AIA procedure to apply not only to the 'export' but also most importantly to the 'import' of GMOs and their living products. The AIA procedure under the GMO Act of South Africa should make specific reference to the 'first intentional transboundary movement' and GMOs in transit just like the Protocol does.

The time frames provided for under the biosafety legislation of South Africa regarding the AIA procedure should be expressly included in the provisions of the GMO legislation rather than leave such powers at the discretion of the Council. The GMO Act and the GMO Amendment Act should follow the same approach taken by the Draft Biosafety Regulations of Uganda prohibiting the re-exportation of banned GMOs and their living products to any another country. This will also protect other countries from the hazards that may result from the banned GMOs.

5. The GMO Act and the GMO Amendment Act of South Africa should adopt more elaborate and meaningful provisions on public awareness and participation. The GMO Act should clearly impose an obligation on the Council to take into account public participation before decisions are taken. The GMO Act and the GMO Amendment Act could also follow the approach that has been taken by the Draft Biosafety Regulations of Uganda by also providing for public awareness. Placing of notices in the print media may not be enough to be considered as notice to the public since most of the population may not have access to newspapers but an alternative is resorting to the electronic media since it has wide coverage. More time should be allocated for the public to make comment. All EIA reports should be included in information given to the public, the content should be prescribed

and the public should not only be allowed to participate before a release but also during other activities that involve GMOs.

6. Both the biosafety regulatory systems of South Africa and Uganda should set out the principles and parameters of the risk assessments. This will ensure that reasonable time is accorded to risk assessments, as in most cases a shorter time frame is preferred and this affects the quality of the risk assessments. Risk assessments should be made mandatory as part of the decision making process under the GMO Amendment Act. This will increase transparency in the decision-making process.

The GMO Act and the GMO Amendment Act of South Africa should adopt additional risk management measures. Such measures include: periodic observation and submission of periodic reports by the applicant even after the approval of the GMO.

7. Both the biosafety regulatory systems of South Africa and Uganda should adopt clear approach of taking into consideration socio-economic factors most especially in the decision making process. The Draft Biosafety Regulations of Uganda should specify what socio-economic considerations would be taken into account.

The GMO Act and the GMO Amendment Act of South Africa should not leave the consideration of socio-economic issues at the discretion of the Council, as the Council could easily ignore the socio-economic issues in the decision making process.

8. The GMO Act of South Africa should expressly provide for mandatory labeling and segregation of food and food ingredients that contain GMOs so as to comply with Article 18 of the Cartagena Protocol. Instead of being

regulated by the regulations made under the South African Foodstuffs, Cosmetics and Disinfectants Act,<sup>325</sup> the GMO legislation of South Africa should specifically adopt provisions on identification and labeling of GMOs. This will enable consumers to make informed choices.

9. The GMO Act and the GMO Amendment Act of South Africa should adopt more adequate oversight and compliance tools. The GMO Act and the GMO Amendment Act should not rely predominantly on self-regulation. There should be provisions for independent review of Environmental Impact Assessments (EIAs) and Risk Assessments, should improve on monitoring compliance and reporting and there should also be a provision for suspension and withdrawal of permits.
10. The GMO Act and the GMO Amendment Act of South Africa should be more consistent through integration with other broader policy and regulatory framework. Such policy and framework includes: the CBD at the international level and the PAJA, PAIA, NEMA and the Biodiversity Act at the national and domestic level.
11. Uganda should enact legislation that will fully operationalise the Biosafety Regulations and the National Biotechnology and Biosafety Policy. This is because at present the interim biosafety regulatory regime of Uganda is currently operating under the UNCST Statute. This may expose the biosafety regulatory framework and all institutions established there under to legal challenges in the courts of law since it does not have legislation establishing it. Alternatively, Uganda could 'fast track' the enactment of the Biosafety Bill of 2005.

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<sup>325</sup> Republic of South Africa, Act 54 of 1972.

12. Both Uganda and South Africa towards should work towards strengthening and consolidating the already existing regional approaches in regulating modern biotechnology. The approach taken must also be in compliance with the African Model Law and the Cartagena Protocol on Biosafety. For the case of South Africa this can be done through SADC and for Uganda this can be done through the EAC. This will enable the two countries to form collective approaches in regulating biotechnology and GMOs, since no single country can regulate GMOs with out cooperating or getting assistance from other countries. This will also enable countries such as Uganda that do not yet have substantive GMO legislation to enact uniform and more practical biosafety regulatory frameworks.

To achieve the recommendations outlined above, it is important that stakeholders from all spheres of influence in South Africa and Uganda build alliances to establish effective legislation by lobbying and establishing consumer advocacy programmes at national, regional and international levels.

### **C. Future Perspectives**

The field of modern biotechnology and GMOs is a wide and complex one that involves many challenging aspects. Modern biotechnology is still a new facet in Africa and it leaves a lot of unresolved and unanswered questions. This calls for more similar comparative studies in other jurisdictions. The present study has revealed that in the field of modern biotechnology as in most other cases of potential risks and threats to the environment, international biosafety obligations (like the Cartagena Protocol on Biosafety) which impose restriction on the domestic management and implementation have been globally acceptable. This is because the use of modern biotechnology in one country is perceived to have a possible effect to global commons or the territory of other states.

Initially, during the Cartagena negotiations there was a wide spread assumption by the negotiators that the adverse effects of LMOs could only affect other states through trade. As a result, only trade regulations seemed politically agreeable as they do not affect the sovereignty of states with regard to the domestic management of GMOs, but rather seek to enable importing developing countries such as Uganda and South Africa to effectively exercise their existing sovereignty.

From an environmental point of view, and taking also into account approaches existing in the field of human rights law, this tendency as such may be criticized. However, even if one accepts it as a fact, one may criticize the limitation of the Cartagena Protocol on trade, as there are many other aspects of "international dimensions", which all reach beyond trade such as biotechnology. And one may doubt whether the effects of growing GMOs especially as food may, in the long run, be locally limitable in the developing countries. The Cartagena Protocol therefore, constitutes an important recognition of the responsibility of the developed countries in terms of trade with developing countries. It however, seems that the international regulation of biotechnology and GMOs will, in the long run, be insufficient to cope with the various kinds of transboundary environmental and health problems which biotechnology and GMOs pose.

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Zarilli S, 'International Trade in Genetically Modified Organisms and Multilateral Negotiations: A New Dilemma for Developing Countries' (UN Conference on Trade and Development, 2000). Available at <http://www.unctad.org/en/docs/poditctncdd1.en.pdf>. Accessed on 28 June 2007.

Zarrilli S, *'International Trade in GMOs and GM Products: National and multilateral legal frameworks'*, United Nations Conference on Trade and Development, United Nations, New York. 2005.

## 5. Case Law

Advocates Coalition for Development and Environment (ACODE) v Attorney General, Misc. Cause No. 0100 of 2004, High Court of Uganda at Kampala.

Biotech Disputes Case, (2006).

BP South Africa (Pty) Ltd v MEC for Agriculture, Conservation and Land Affairs, 2004(5) SA 124 (W).

Hichange Investments (Pty) Ltd v Cape Produce Company (Pty) Ltd t/a Pelts Products & 4 Others, Unreported judgment delivered on 20 October in the High Court of South Africa (Eastern Cape Division), Case No. 1050/01.

Jane Lugolobi and 9 Others v Gerald Segirinya t/a Smart Curry Powder, Misc. Application No. 371 of 2002, High Court of Uganda at Kampala.

Minister of Public Works and Others v Kyalami Ridge Environmental Association and Others, 2001 (3) SA 1151 (CC).

Monsanto v Schmeiser, [2004] SCC 34.

The Trustees for the time being of the Biowatch Trust v the Registrar of Genetic Resources and Others, Unreported case No. 23005/2002.

## 6. Relevant Websites

African Centre for Biosafety- <http://www.biosafetyafrica.org>.

Agbios Genetic Modification Database- <http://www.agbios.com/dbase.php>.

Biotechnology Industrial Organisation- <http://www.bio.org>

Biowatch South Africa- <http://www.biowatch.org.za>

Center for Food and Safety- <http://www.centerforfoodsafety.org>

Codex Alimentarius Commission- [www.who.int/fsf/Codexreview](http://www.who.int/fsf/Codexreview)

Earth Negotiations Bulletin- <http://www.iisd.ca/voltoc.html>

Food and Agricultural Organization (FAO) - <http://www.fao.org>

International Food Policy Research Institute (IFPRI) - <http://www.ifpri.org>

International Life Science Institute- <http://www.ilsa.org>

International Service for the Acquisition of Agri-biotech Applications (ISAAA) - <http://www.isaaa.org>

International Union for the Conservation for Nature- <http://www.iucn.org/themes/law/pdffdocuments/Biosafety.pdf>

National Environmental Authority (NEMA), Uganda- <http://www.nemaug.org/>

Republic of South Africa, National Department of Agriculture- <http://www.nda.agric.za>

Secretariat of the CBD- <http://www.biodiv.org>

The World Trade Organization (WTO) - [http://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm)

Third World Network (TWN) Website- <http://www.twinside.org.sg/bio.htm>

United Nations Environmental Programme (UNEP) - <http://www.unep.org>

World Health Organization- <http://www.who.org>

## APPENDICES

### Appendix 1

UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

P.O. BOX 6884

KAMPALA

### APPLICATION TO INTRODUCE OR RELEASE GENETICALLY MODIFIED ORGANISMS (GMOs) INTO UGANDA

#### PREAMBLE

The applicant is required to answer as many questions as possible to facilitate evaluation of the application.

Applicants are informed that assessments of the application will bear some financial cost, which will be met by the applicant. Applicants are required to provide further information as may be requested by National Biosafety Committee (NBC).

NAME OF APPLICANT .....

ADDRESS .....

TELEPHONE NO. .... FAX ..... E-MAIL .....

SIGNATURE .....

NAMES OF ALL INSTITUTIONS INVOLVED IN THIS WORK, THEIR ROLES,  
PHYSICAL ADDRESSES AND THE CONTACT OF THE PRINCIPAL INVESTIGATOR.  
(Provide information on a sheet(s) of paper

SOURCE OF FUNDS FOR THE ENTIRE WORK .....

**(SUBMIT THIS PAGE WITH THE APPLICATION WRITE UP)**

## Appendix 2

### CHECKLIST FOR ACCORDING APPROVAL TO A LABORATORY/FACILITY TO CARRY OUT BIOTECHNOLOGICAL WORK

It is suggested that various processes and procedures can be assessed qualitatively and quantitatively by means of a check list, for according approval to a laboratory for carrying out biotechnology work. The check lists suggested are as follows:

1. Locality:

-Urban

-Rural

-Peri-urban

-Residential/Industrial

-Mainland

-Island

2. Proximity to susceptible stock (e.g. Proximity between a wild potato population and a transgenic potato variety trial).

3. Restricted public access -Fenced

-Guards

-Locks

4. Staff identification -Staff movement restrictions.

5. Safety against -Flood

-Subsidence

-Landslide

-Earthquake

-Other

6. Is there room for development -Specify with diagram

7. Building -Generally suitable

-Old

-New

-Conventional/Prefabricated/Others.

-Windows -Double

-Sealed

- Shatterproof
- Doors -Sealed
- Self closing
- Airlocks
- Vision panel
- Marked hazard signs
- Walls - Suitable surfaces
- Floors - Easy to clean
- Non slippery
- Ceiling - Sealed entry of services
- Lighting - As required
- Drainage - Free drainage
- Forced drainage

#### 8. Laboratory fittings:

- Benches -Surfaces
- Impervious
- Continuous
- Safety equipments-Microbiological safety cabinets
  - Class 1
  - Class 2
  - Class 3
- Protected centrifuges
- Protected sonicators
- Protected homogenisers
- Taps -Hand
- Wrist
- Elbow
- Foot
- Electronic
- Space -Adequate
- Overcrowded

## 9. Ventilation: Infective agent handling area

- Air pressure -Negative to atmosphere
- Negative pressure
- Monitoring -Manometer
- Frequency observation
- Recording
- Electronic
- Temperature control
- Humidity control
- Air locks -Double air lock
- Simple (with door flaps)
- Separately ventilated
- Exhaust air -H.E.P.A. filters
- Single
- Double
- Quality of Filter
- Monitoring
- Testing methods
- Filter Container -Ladder Frame
- Canisters
- Input air -Filtered
- Quality
- Temperature.
- Input/Extract -Interlocked
- Standby Power Generating System -Specify capacity etc.

## 10. Range of work - Research

- Vaccine production
- Large animal work
- Small animal work
- Diagnostic
- Other

11. Effluent treatment -Heat
  - Chemical
  - Irradiation
  - Other
12. Storage of infectious material
  - Location
  - Minus 20 C
  - Minus 70C
  - Minus 60C
13. Pass-out facilities -Autoclave
  - Fumigation cabinets
  - Monitoring
  - Photocopying
  - Facsimile machine (Fax machine)
14. Structure-Disease Security Department
15. Disease Security Regulations
16. Other Security
17. Fire precautions
18. Staff training
19. Staff Selection
20. Visitor regulations
21. Procedures and provisions for emergencies

NB. The check list has been prepared keeping in view of the standard requirement of BL1 to BL3 laboratories.

**Appendix 3**  
**REPUBLIC OF SOUTH AFRICA**  
**DEPARTMENT OF AGRICULTURE**  
 GMO Act, 1997 (Act No. 15 of 1997)

DIRECTORATE GENETIC RESOURCES  
 Private Bag X973, Pretoria, 0001  
 Harvest House Room 261, 30 Hamilton Street, Arcadia, Pretoria, 0002  
 Tel: 12 n319 6253, Fax: 12 319 6329, E-mail: MichelleV@nda.agric.za

**APPLICATION FOR AUTHORISATION TO IMPORT LMO'S INTO SOUTH  
 AFRICA THAT ARE DESTINED FOR CONTAINED USE**

This document must be accompanied by (a) a cover letter, (b) completed application for the intended use of the LMO in SA (i.e. contained use or fast track application form) and (c) the correct fee in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997).

Activities with GMOs for research and academic purposes, conducted at containment levels 1 and 2 (determined through a risk assessment conducted by the officer in charge) within a laboratory or growth room in an academic or research facility, are exempted from the requirement of a contained use permit in terms of Regulation 2(2). A contained use permit is required once the research is scaled up from basic research to product development, or when conducting the activities in a greenhouse or when the containment level is 3 and above.

1. Name, address and contact details of the importer (contact point for further information)
2. Contact details of the Competent National Authority in the Part of Export.
3. Name, address and contact details of the exporter.
4. Common name, scientific name, commercial name or unique identifier code (OECD) of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organisms (LMO's)?
5. The intended date/dates of the transboundary movement, if known?
6. Port of entry within South Africa (name and city)?
7. A description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMO.
8. The regulatory status of the LMO within the Party of Export.
9. The intended use of the LMO in SA and what was it used for in the Party of Export?
10. The quantity or volume of the LMO to be imported into South Africa?
11. A complete list of the varieties/hybrids of the LMO.
12. Methods and plans for safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures.
13. Methods and plans used in South Africa for monitoring of the LMO.
14. Emergency procedures that will be applied in South Africa in the event of an accident with the LMO.
15. An evaluation of the foreseeable impacts, in particular any pathogenic and

ecologically disruptive impacts of the LMO's.  
 16. A completed affidavit to declare that the information provided is factually correct.

**Directions for the potential importer:**

(This page must be excluded from the documents submitted to the Registrar's office)

- Please complete all sections of the form CLEARLY.
- A template of the affidavit is obtainable from the Registrar's office.
- Please provide an application with confidential information and an additional application containing no confidential information. The latter application will be made available for public scrutiny.
- Every potential importer must submit a notification to the competent national authority within SA.

This notification shall contain of -

- A letter indicating the intent of the potential importer
- Completed import application form
- Completed application for intended use of the GMO in SA
- The correct fee in terms of the Genetically Modified Organisms Act, 1997
- Contact details of the competent national authority in SA is the following:
  - Dr JB Jaftha
  - Registrar: Genetically Modified Organisms
  - Senior Manager: Genetic Resources
  - Private Bag X973
  - Pretoria
  - 0001
  - Tel: 27 12 319 6214
  - Fax: 27 12 319 6329
  - E-mail: SMGRM@nda.agric.za
- Please take note that the Registrar's office may request additional information to the notification.
- The Registrar's office will acknowledge receipt of the notification in writing.
- The acknowledgement shall state -
  - the date of receipt of the notification;
  - whether the notification contains the required information; and
  - whether a permit is issued or not
- A permit for importation will only be issued once the Registrar has received the necessary clearance by the Executive Council.
- LMO's exempted from requirement of an import permit under the GMO Act are not necessarily exempted from requirement of an import permit in terms of the Biosafety Protocol.
- A Party is a Party in terms of the Cartagena Protocol on Biosafety.
- These procedures are also applicable for imports from non-Parties to the Cartagena Protocol on Biosafety.
- The potential importer is responsible for adhering to the requirements of and obtaining the consent from the Party of Export for the proposed transboundary movement.

- Please take note that although a notification as required by Article 8 of the CPB is not required for LMO's intended for contained use, SA requires such a notification as described earlier, and any other applicable procedures, within its domestic regulatory framework.

### **AFFIDAVIT/VERKLARING/STATEMENT**

(moet ingevul word in teenwoordigheid van 'n Kommissaris van Ede / to be completed in the presence of a Commissioner of Oaths)

Ek/I.....  
 ID-Nommer/Number..... Ouderdom/Age .....  
 Woonadres/ Residing address .....  
 Werkadres/working address .....  
 Tel .....(w) .....(h) .....(cell)  
 Verklaar onder eed in Afrikaans / bevestig in Afrikaans -  
 Declare under oath in English / confirm in English -  
 .....  
 .....  
 .....

Ek is vertrouwd met die inhoud van bostaande verklaring en begryp dit. Ek het geen beswaar/het beswaar teen die aflê van die voorgeskrewe eed. Ek beskou die voorgeskrewe eed/bevestiging as bindend vir my gewete.  
 I am familiar with, and understand the contents of this declaration. I have no objection/have objection to taking the prescribed oath. I consider the prescribed oath as binding to my conscience.

Plek/Place: ..... Datum/Date: .....

Tyd/Time: .....

Handtekening/Signature: .....

Ek sertifiseer dat bostaande verklaring deur my afgeneem is en dat die verklaarder erken dat hy/sy vertrouwd is met die inhoud van hierdie verklaring and dit begryp. Hierdie verklaring is voor my beëdig en verklaarder se handtekening/merk/duimafdruk is in my teenwoordigheid daarop aangebring.

I certify that the above statement was taken from me and that the deponent has acknowledge that he/she knows and understands the contents of the statement. The statement was sworn to/affirmed before me and deponent's signature/mark/thumb print was placed thereon in my presence.

Te/At: .....op/on .....om/at .....

.....

Kommissaris van Ede/Commissioner of Oaths

(inligting i.v.m. fisiese en posadres moet verskaf word, bv. Stempel van die polisiestatie details to be provided on physical and postal address e.g. stamp of police station)

.....

Magsnommer /Rang/Naam - drukskrif

Force number/Rank/Name - print

## Appendix 4

**REPUBLIC OF SOUTH AFRICA**  
**DEPARTMENT OF AGRICULTURE**  
GMO Act, 1997 (Act No. 15 of 1997)

DIRECTORATE GENETIC RESOURCES  
Private Bag X973, Pretoria, 0001  
Harvest House Room 261, 30 Hamilton Street, Arcadia, Pretoria, 0002  
Tel: 12 n319 6253, Fax: 12 319 6329, E-mail: MichelleV@nda.agric.za

**APPLICATION FOR AUTHORISATION TO IMPORT GMO'S THAT HAVE  
GENERAL RELEASE AND/OR COMMODITY CLEARANCE STATUS IN SOUTH  
AFRICA**

**Directions to the applicant:**

- This application form should only be utilized to apply for (i) importation of a particular GMO event that already has general release status in South Africa, or (b) a commodity import of several GMO events previously approved in terms of commodity clearance.
- When an application is made for a commodity import, the application must be accompanied by a declaration from the Competent National Authority within the Party of Export, stating the GMO events commercially available within the Party of Export.
- Please complete all sections of this questionnaire. Please provide reasons if a particular section of this form is not completed ("not applicable" will not be accepted - one must provide reasons why a particular question is not applicable).
- Please provide one copy of the application with confidential information for use by the regulatory bodies appointed in terms of the Genetically Modified Organisms Act, 1997 (Act no. 15 of 1997). This copy must be clearly marked: CONFIDENTIAL
- Please provide one hard and an electronic copy of the application containing no confidential information. This copy must be clearly marked: NON-CONFIDENTIAL, and may be made available for public scrutiny.
- A Party is a Party in terms of the Cartagena Protocol on Biosafety.
- An application for an import permit must reach the office of the registrar well in advance and it is strongly advised that the importer must be in a possession of a valid import permit under the GMO Act before the consignment leaves the country of export.

**APPLICATION FOR AUTHORISATION TO IMPORT GMO'S THAT HAVE GENERAL RELEASE AND/OR COMMODITY CLEARANCE STATUS IN SOUTH AFRICA**

1. Name, address and contact details of the importer (contact point for further information).
2. Contact details of the Competent National Authority in the Party of Export.
3. Name, address and contact details of the exporter.
4. Common name (e.g. maize) of the genetically modified organism(s) that may be present in the consignment?
5. Scientific name (e.g. *Zea mays*) of the genetically modified organism(s) that may be present in the consignment?
6. Commercial name/event (e.g. MON810) of the genetically modified organism(s) that may be present in the consignment?
7. Unique identifier(s) of the genetically modified organism(s) that you have listed above?
8. A complete list of the varieties/hybrids of the GMO event(s) contained in the consignment.  
(For commodity imports: It is the responsibility of the applicant to obtain a written indication from the responsible authority in the Party of Export of the GMO events that may be contained in the consignment. If this certificate is not available at the date of making your application due to delays in the Party of Export, please attach the latest confirmation, i.e. confirmation received within the shortest time period from this application, of the events contained in a consignment originating from the same Party of Export.)
9. The intended date/dates of the transboundary movement, if known?
10. Port of entry within South Africa (name and city)?  
(Please take note that a permit is issued per consignment and per port of entry. We do not issue permits that are applicable for multiple consignments being discharged at different ports of entry.)
11. The regulatory status of the GMO within the Party of Export.
12. Authorised use of the GMO in the Party of Export?
13. Please provide details pertaining to the intended (contained) use of the GMO in SA?  
(If the GMO event(s) contained in the consignment to be imported do not have general release clearance and/or commodity clearance at the time that this application is made, your application will not be approved.)
14. The quantity or volume of the GMO to be imported into South Africa?
15. A completed affidavit to declare that the information provided is factually correct.  
The following questions must be completed in the case of a commodity import:
16. Methods and plans used for safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures.
17. Methods and plans used in South Africa for monitoring of the GMO.
18. Emergency procedures that will be applied in South Africa in the event of an accident with the GMO.

**AFFIDAVIT/VERKLARING/STATEMENT**

(moet ingevul word in teenwoordigheid van 'n Kommissaris van Ede / to be completed in the presence of a Commissioner of Oaths)

Ek/I.....  
 ID-Nommer/Number..... Ouderdom/Age .....  
 Woonadres/ Residing address .....  
 Werkadres/working address .....  
 Tel .....(w) .....(h) .....(cell)  
 Verklaar onder eed in afrikaans / bevestig in afrikaans -  
 Declare under oath in English / confirm in English -  
 .....  
 .....  
 .....

Ek is vertrouwd met die inhoud van bostaande verklaring en begryp dit. Ek het geen beswaar/het beswaar teen die aflê van die voorgeskrewe eed. Ek beskou die voorgeskrewe eed/bevestiging as bindend vir my gewete.  
 I am familiar with, and understand the contents of this declaration. I have no objection/have objection to taking the prescribed oath. I consider the prescribed oath as binding to my conscience.

Plek/Place: ..... Datum/Date: .....

Tyd/Time: .....

Handtekening/Signature: .....

Ek sertifiseer dat bostaande verklaring deur my afgeneem is en dat die verklaarder erken dat hy/sy vertrouwd is met die inhoud van hierdie verklaring and dit begryp. Hierdie verklaring is voor my beëdig en verklaarder se handtekening/merk/duimafdruk is in my teenwoordigheid daarop aangebring.

I certify that the above statement was taken from me and that the deponent has acknowledge that he/she knows and understands the contents of the statement. The statement was sworn to/affirmed before me and deponents' signature/mark/thumb print was placed thereon in my presence.

Te/At: .....op/on .....om/at .....

.....  
 Kommissaris van Ede/Commissioner of Oaths

(inligting i.v.m. fisiese en posadres moet verskaf word, bv. Stempel van die polisiestatie details to be provided on physical and postal address e.g. stamp of police station)

.....  
 Magsnommer /Rang/Naam - drukskrif

Force number/Rank/Name - print