Governing Biotechnology in Africa: Toward Consensus on Key Issues in Biosafety

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[1] This paper has not been peer-reviewed. It is a "living paper" in the sense that it will be revised and updated during the course of the African Policy Dialogues on Biotechnology initiative, based partly on discussions at the sessions, partly on peer reviews, and partly on the evolution of biosafety policy in Africa. Readers are free to cite the paper, but they should do so recognizing that its contents are likely to change in the near future.

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Executive Summary

The last decade has been a defining moment for policy makers in Africa, especially for those charged with policy for the agricultural sector. Despite the highest level of agricultural technological advancement in the world over the decade gone by 75 percent of the population in Africa still wallows in abject poverty, threatened by hunger and food insecurity. Most of the food insecure are smallholder farmers who wake up every morning to till the soil.

The advent of genetic engineering in agriculture has clearly changed the content and nature of the debate on how to respond to food insecurity. So, too, has the debate on how to achieve longer-term agricultural growth and food security through self-sustaining processes of growth. To many stakeholders in Africa, along with genetically modified food will come genetically modified agricultural technologies. Two extreme positions appear to polarize this debate: extreme pro-genetic engineering and extreme anti-genetic engineering positions.

The extreme pro-biotechnology groups catalogue potential benefits of the technology and often dismiss any concerns about potential risks. They tend to portray biotechnology as the panacea to combat food insecurity in Africa. On the other extreme are the anti-biotechnology activists who see no evident benefits and associate the technology with nothing but danger and risks. They would like the development, commercialization and application of the technology stopped. The two extreme views have tended to confuse many African policy-makers and sections of the public because of the lack of reliable information and guidance available to these groups. There is increasing uncertainty and confusion in many of the African governments' responses to a wide range of social, ethical, environmental, trade and economic issues associated with the development and application of modern biotechnology.

The absence of African consensus and strategic approaches to address these emerging biotechnology issues has allowed different interest groups to exploit uncertainty in policy-making, regardless of what may be the objective situation for Africa. Both pro and anti-biotech advocacy groups can affect African decision making adversely, as they portray agricultural opportunities in extremes, making it appear like it is an "either–or" situation.

It is this in recognition of this polarization in biotechnology decision-making processes in Africa, and even among scientists, that NEPAD and the International Food Policy Research Institute (IFPRI) have established a regional platform, "The African Policy Dialogues on Biotechnology" through which African countries can engage in dialogue and develop a consensus on the controversies, risks, challenges and myths surrounding the growth and development of biotechnology in Africa.

This paper attempts to highlight the key issues in biosafety that require African consensus, and in so doing, provide a framework that will guide the dialogue for building a consensus on how to govern biotechnology in Africa. The aim of this paper is not to provide a detailed description or overview of all biosafety issues. Nor is the aim to go through all the biosafety issues covered by the Cartagena Protocol on Biosafety. Rather, the aim is to point out those dimensions of biosafety that are divisive and thus call for an African consensus, drawing implications for capacity building efforts by African countries. This paper thus is not exclusive or exhaustive, but rather a living paper that is designed to be elastic and accommodative of new and additional ideas and issues that will be raised by the different stakeholder groups in the ensuing dialogue. The paper is expected to change and grow as the dialogue process grows to new and higher levels of debate.

As a framework document, the paper will try to respond to key questions in Biosafety likely to be critical in informing the debate. The paper will serve as a living document that will inform decision makers as to the options and considerations they must take into account as they develop national biosafety frameworks. It will draw on information and data from many sources, to illustrate Africa's current stage of development in research and regulation.

The paper will guide the debate by responding to the following questions and concerns:

Section1: Why do we need to move towards African Consensus on Governing Biotechnology? Why the African Policy Dialogues?

Section 2: What is the current status of Biotechnology in Africa? What is the level of spread? What techniques and what products are out there and in which countries?

Section 3: What were the key issues in the Biosafety debate of the CBD and what was the compromise reached? What was the position of the Africa group in the negotiation of the Cartagena Protocol?

Section 4 What really is the scientific cause of risk posed by genetic engineering? What are the main divisive issues in Biosafety, in Africa, at this point in time?

Section 5: What, then, are the most critical capacity building requirements essential for establishing sufficient National Biosafety Capacity for implementing the protocol effectively?

Section 6: What is the current status of Biosafety Frameworks in Africa? What is a National Biosafety framework, in the first place? And what stages are critical in establishing such a framework? And how many countries have such a framework in Africa? And at what stage(s) are they?

Section 7: What are some of the other on going Biosafety initiatives in Africa?

Section 8: What can we conclude from our analysis?

The authors of this paper firmly believe that the responses given to these key questions in the eight sections of the paper – will clearly define the need for consensus and kick-start the dialogue process. We do note, however, that the issues presented in this paper cut across a broad spectrum. An attempt to categorise them would place them into, at least, 5 major categories: Policy, Social Economic, Environmental, Technological, and cross-cutting. In seeking to priotise the dialogue process – it would seem logical to address the cross-cutting issues with some urgency. Four thematic issues, seem to be cross-cutting in nature, and need urgent African Consensus as a basis for developing Africa's Biosafety systems:

- The Precautionary Principle
- The Social – Economic Considerations
- Liability and Redress or Compensation
- Public Awareness and Capacity Building

African consensus around these issues will ensure that the risks posed by biotechnology do not overwhelm the African population, but that at the same time – the potential benefits are not lost in haste or lack of caution.

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1 Overview: Why Consensus?

There is a paradox at the heart of African agriculture. Despite the myriad attempts by experts to prescribe strategies for rolling back hunger and poverty, and despite the highest level of agricultural technological advancement in the world today, 75 percent of the continent's population still wallows in abject poverty, constantly threatened by hunger. Most of the food-insecure in Africa are the millions of smallholder farmers that wake up every morning to till the African soil - the only resource available to them. They work the soil with rudimentary and traditional tools and use very limited external inputs due to their limited resource base.

This paradox raises many questions: How can African agriculture become viable, responding to market forces, while ensuring food security and environmental sustainability? How can African agriculture become a true engine of economic growth for the African continent? How can African agriculture be a source of vitality and livelihood for African communities? What has led to the failure of experts' prescriptions to jump-start African agriculture? What is the niche in African agriculture that can trigger a real "agricultural revolution?"

The crisis in Argentina in 2001 illustrated, again, a frustrating and unjust reality: there is no direct relationship between the amount of food a country produces and the number of hungry people who live there. In 2001, Argentina harvested enough wheat to meet the needs of both China and India. Yet Argentina's people were hungry. Argentina's status as the world's second largest producer of GM crops – largely for export – could do nothing to solve its very real hunger problems at home. Access to sufficient and good quality food continues to be elusive in Africa, and the reasons are well known to be more often of social, economic and political nature rather than a matter of not sufficient food being produced at the global level.

However, following two years (2002-2003) of erratic rainfall, a number of countries in Africa suffered serious production shortfalls. Inadequate, poorly timed, or inappropriate policy responses to low domestic food supplies combined with and low human, infrastructural and organisational capacity in domestic markets left millions of people at risk of starvation in the region. Thirteen years ago, in 1991, similar interactions among poor weather, policy failures and market failures left millions of Africans similarly exposed.

But the food emergency situation of 2002- 2003 was different from the 1991-1992 in one crucial respect - thousands of tons of food available to cover shortages contained unspecified amounts of genetically modified (GM) grain – specifically Bt Maize – and were thus considered suspect or even poisonous by some countries, like Zambia, unsure of the implications of GM food on human health as well as the environment. Efforts to accommodate this uncertainty pit erstwhile partners in national and regional food relief against one another in an increasingly heated political environment.

The presence of GM food in the region did not only raise political temperatures, it also rendered inordinately more difficult a range of other basic tasks and operations in food relief—such as moving grain through ports and across borders. Perceived risks associated

with GM food created an entirely new set of transaction costs. How, for instance, in mid-2002 was Malawi to move maize donated by USA, and thus containing Bt-Maize, through Tanzania in the absence of complementary Biosafety Protocols in Tanzania and Malawi, and in the absence of associated testing machinery? Ad hoc measures had to be hammered out, under extreme pressure, on such seemingly mundane issues as: how to load grain into rail cars and trucks with minimal "escape;" how to cover the loaded cars and trucks; how long to allow the loaded cars and trucks sit in given positions. The opportunity cost associated with such logistical hurdles, coupled with the region's general reticence towards potential life-saving but GM food, elicited intense scrutiny and opprobrium from food donors and relief agencies.

Countries, especially in the Southern Africa region, immediately begun to respond to the GMO debate. At a meeting of the SADC Council of Ministers for Food, Agriculture and Natural Resources (FANR) - held on July 5, 2002 in Mozambique – the lack of a harmonised regional position on GMOs was noted to be creating serious problems in the movement of food and non-food items. Consequently the council advised member states to engage in bi-lateral consultations and to explore mechanisms to facilitate movement of humanitarian food that may contain GMOs. The FANR Ministers approved the establishment of an Advisory Committee to develop guidelines to safeguard Member States against potential risks of GMOs in the areas of Trade, Food Safety, Contamination of Genetic Resources, Ethics, and Consumer Concerns (SADC, 2003).

Clearly, the content and nature of the debate on how to respond to food crises have been fundamentally and possibly irreversibly altered. So, too, have been those in the debate of how to achieve longer-term Agricultural Growth (AG) and Food Security (FS) through self-sustaining processes of growth fuelled by technological advance in agriculture. To many stakeholders, along with GM food will come GM agricultural technologies. Enduring uncertainties and controversies over the relevance, efficacy, sustainability and safety of those technologies appear to render such a progression unpalatable.

A key recognition, however, is that the uncertainties and controversies surrounding the role of Biotechnology in agricultural development and food security are not confined to Africa. They are global in scope. In most cases these uncertainties and controversies appear to have two dimensions - one dimension applies to relatively well-informed stakeholders – the other to relatively un-informed stakeholders. Because the relatively un-informed, either by design or by default, often rely on the relatively well-informed for guidance – there is urgent need for the well-informed stakeholders in Africa to engage in positive dialogue that will generate consensus among them over the existing uncertainties and controversies – and in so doing provide informed guidance to the many uniformed stakeholders.

Will African countries include strategies for biotechnology[2] and biosafety[3] when planning agricultural research agendas? African decisions in this regard are not only important to each country, but have increasing interest to international, regional, and national development organizations. These decisions can be politically controversial, as was seen in controversies arising from consumption of food for famine assistance.

[2] Biotechnology has been defined as, any technique that uses living organisms or substances from these organisms to make or modify a product to improve plants or animals or to develop microorganisms for specific uses.

[3] Biosafety: the goal of ensuring that the development and use of transgenic plants and other organisms does not negatively affect plant, animal or human health, genetic resources or the environment.

The absence of African consensus and strategic approaches to address emerging biotechnology issues allows different interest groups to exploit uncertainty in policy-making, regardless of what may be the objective situation for Africa. Both pro and anti-biotech advocacy groups can affect African decision making adversely, as they portray agricultural opportunities in extremes, making it appear like it an "either–or" situation - that countries must chose between GM seeds or technologies over those of traditional breeding, organic farming, or farmer-based selection.

Recognizing this polarization in biotechnology decision-making processes in Africa, and even among scientists, NEPAD and the International Food Policy Research Institute (IFPRI), in collaboration with FARNPAN, have established a regional platform, "The African Policy Dialogues on Biotechnology" through which African countries can engage in dialogue and develop a consensus on the controversies, risks, challenges and myths surrounding the growth and development of biotechnology in Africa.

Crop and livestock innovations through biotechnology come from commercial and public sector research, and each may benefit smallholder or commercial farmers. If such distribution is possible, and markets assured, then biotechnology becomes one tool to help overcome poverty. Presently, only a few commercial GM crops are approved for use in Africa, and these are all in South Africa, with the exception of insect resistant cotton in Burkina Faso.

New GM crops and livestock products are being developed from African research and collaborating partners. However, these products all need regulatory review and approval. Building regulatory capacity is underway across countries and sub-regions, in part related to the emphasis provided by the Cartagena Protocol for Biosafety and the UNEP-GEF framework project. Such regulatory capacity ensures both human and environmental safety while balancing opportunities and perceived risks from biotechnology.

A key cluster of issues that underpin the controversy on biotechnology relates to risk, risk perception, risk assessment, and risk management. Issues under the cluster—with the banner of biosafety—are many, controversial and complex. Different African countries have different interests, as well as, understanding and interpretation of these issues and they may, therefore, not have consensus on the nature of policies, laws and institutions to address them. This is so despite the fact that many of the countries have signed, and an increasing number is ratifying, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The Protocol sets out international rules and mechanisms for ensuring safety in the handling, transport, use and release of living (genetically) modified organisms.

In an effort to provide a framework that will guide the African dialogue to build a consensus on governing biotechnology, this paper will provide an overview of genetic modification R&D activities in Africa, including specific cases of release and commercialization of GM products, conditions for approval, and main actors in the GM cases. The paper will also discuss the key policy, legal and other issues that underpin biosafety, and particularly those at the core of negotiations for and implementation of the Cartagena Protocol on Biosafety. The paper will then attempt to provide an assessment of the overall direction in which biosafety policy is moving in Africa – by discussing the current status of 7 national biosafety frameworks and reviewing key international and regional policy development programmes and processes being addressed by different organisations.

The paper will also elaborate efforts made by African negotiators to articulate common concerns and issues on which they were seeking reform and adjustment in the implementation of the Cartagena Protocol of Biosafety. The paper will then discuss the main issues for African countries to adopt common approaches for governing biotechnology, as well ideal regional and subregional processes through which consensus achieved.

This paper will serve as a living document that will provide information to inform decision makers as to the options and considerations they must take into account as they develop national biosafety frameworks. It will draw on information and data from many sources, to illustrate Africa's current stage of development in research and regulation. The living nature of this paper will allow for additional information – especially on countries not included, to be added at a later stage – as more data become available. The paper will be available to guide the development of subsequent discussion, consensus, and content for subsequent African policy dialogues.

2 The Context: The Current Status of Biotechnology in Africa

The role of modern biotechnology in the economic transformation and sustainable development of Africa is the subject of increasing debate and controversy. The debate can be traced to the late 1980s but has acquired new dimensions as a result of a variety of factors including rapid scientific and technological advances, increasing commercialization of genetically modified foods, increasing food insecurity in Africa, and growth in the activities and influence of environmental activists. Recent famines and hunger in parts of Sub-Saharan Africa and the decision by some African governments to reject genetically modified food provided to their countries as aid have moved the debate from the confines of scientific and environmental groups to the centre of public policy and politics in the region.

There are two extreme positions that polarize the debate: extreme pro-biotechnology and extreme anti-biotechnology. The extreme pro-biotechnology groups catalogue potential benefits of the technology and often dismiss any concerns about potential risks. They tend to portray biotechnology as the panacea to combat food insecurity in Africa. On the other extreme are the anti-biotechnology activists who see no evident benefits and associate the technology with nothing but danger and risks. They would like the development, commercialization and application of the technology stopped. The two extreme views have tended to confuse many African policy-makers and sections of the public because of the lack of reliable information and guidance available to these groups. There is increasing uncertainty and confusion in many of the African governments' responses to a wide range of social, ethical, environmental, trade and economic issues associated with the development and application of modern biotechnology. This confusion is likely to deny African countries opportunities to derive benefits while at the same time minimizing risks from the technology. African countries need to be in a position to make informed choices and establish policies and strategies to diligently respond to developments associated with biotechnology. They should not continue to react to agendas set by interest groups in other regions of the world.

The Convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". The Food and Agricultural Organisation (FAO) acknowledges that, "interpreted in a narrow sense, biotechnology refers to a range of molecular technologies such as gene manipulation and gene transfer, DNA typing and cloning of plants and animals". Biosafety, on the other hand, is "a collective term used in reference to

policy-frameworks and actions for assessment and management of the safe application of modern biotechnology."

The broader definition of biotechnology shows that biotechnology is an old science, with many established uses in agriculture, medicine, forestry, environment management, industry, mining, among others. It is widely accepted that the development of biotechnology can be divided into three broad categories, generally referred to as generations of biotechnology.

The first generation refers to that phase of biotechnology that was based on empirical practice, with minimum scientific or technological inputs. This phase stretches all the way from 12 000 BC to the early 1900s. Developments in fermentation technology, especially during the period between the two World Wars, are what is generally referred to as the second generation/phase of biotechnology. Major products from this generation were antibiotics such as penicillin, and other products such as vitamins and enzymes. Another critical development that falls in this phase, beginning in the 1930s, is the development and use of hybrid crop varieties in the US Corn Belt, which resulted in dramatic yield increases.

The third generation or phase of biotechnology, also referred to as the new or modern biotechnology, is the present one. It encompasses such techniques as genetic engineering, cloning, genomics and a large range of other techniques all largely based on manipulation of the basis of life – hereditary/genetic material, which in the majority of living organisms is in the form of DNA (deoxyribonucleic acid).

African countries have been, and are employing various forms of biotechnological techniques in their agricultural, environmental management, forestry, medicine and industry since time immemorial. It is, however, without doubt that Africa is the region where biotechnologies are least developed. There are many different reasons for such a situation, but several schools of thought are convinced that the reasons for this are associated with the perennial economic problems affecting the continent (Sasson, 1993).

From studies conducted by the Biotechnology Trust of Zimbabwe in 2001 and 2002, and studies by other organisations such as the Rockefeller Foundation and ISNAR, the main area in which biotechnology techniques are being applied in African countries is agriculture, with the major thrust being crop improvement. Techniques such as tissue culture are being applied in almost all the countries, mainly because of the less intensive nature of this technique, in terms of human and infrastructural resources.

Modern biotechnological techniques, which include genetic engineering, are being employed in only very few of the countries, namely South Africa, Zimbabwe, Egypt, Kenya, Uganda and Malawi, and to a little extent Zambia and Mauritius. Out of all these countries, only South Africa has reached the commercialisation stage in so far as products of genetic engineering are concerned, with GM crops, namely insect-resistant cotton and maize as well as herbicide-tolerant soybean already being grown by both the commercial and small-scale farmers. The rest of the countries have either only recently approved contained trials of crops such as cotton and maize (e.g. Kenya, Uganda, Burkina Faso, Zimbabwe and Malawi), or do not as yet have any regulatory or scientific capacity to conduct such trials. Table 1 below outlines the status of development and use of biotechnology techniques in Southern Africa)

TECHNIQUES / CATEGORY	**AREAS OF APPLICATION**						
	Zimbabwe	***Zambia***	***Malawi***	***Lesotho***	***Mozambique***	***Swaziland***	***Namibia***
Tissue culture	Micropropagation and disease elimination - for Sweetpotato, Mushroom, Irish Potato, Horticultural Crops	Micropropagation and disease elimination - for Cassava, Sweetpotato, Irish potato, Mushroom planting material	Disease elimination and micropropagation for cassava, sweetpotato, Irish potato and horticultural crops	Irish potato production – micropropagation	Cassava and Irish potato production – micropropagation and disease elimination	Irish potato production - micropropagation	Cassava and Irish potato production – micropropagation and disease elimination
Genetic modification	Still at research level, mainly for crop improvement; cowpea, tobacco, maize, sorghum. Confined trials of Bt-maize and cotton conducted	Limited and still at research level; cassava improvement (virus resistance). Confined trials of Bt-cotton conducted on 1999/2000	Research level; cassava improvement (virus resistance). Bt-cotton trials conducted	None	None	None	None
Fermentation technology	Food processing, feed & vaccine production	Food and feed production	Food and feed production	None	None	None	Food processing (small-grain crops)
Marker-assisted selection	Research level; improvement of maize for drought and small-stock improvement.	None	None	None	None	None	None
Artificial insemination and Embryo Transfer	Cattle and small-stock breeding	Cattle breeding	Cattle breeding	None	None	Cattle breeding	Cattle breeding
Molecular diagnostics and molecular markers	Plant and animal disease-diagnostics, and diversity studies	Plant and animal disease diagnostics and diversity studies	Research level; animal disease-diagnostics and diversity studies	None; still using serological techniques	Still using serological techniques	Also still using serological techniques	Still using serological techniques
Biological Nitrogen Fixation	Soil fertility improvement; both legumes and inoculants	Using both legumes and inoculants	Using legumes only	Using legumes only	Limited use, even of the legumes	Using legumes only	Using legumes only
Manpower Training	Has specific biotech training programmes at both under- and post-graduate levels (UZ, NUST, Africa University)	Training done in the natural, veterinary and agricultural sciences. No explicit courses in biotech: UNZA	Training done in the natural and agricultural sciences (BCA). Most of the training is theoretical. Also, there are no explicit biotech courses	Undergraduate and post-graduate training in natural and agricultural science (NUL)	Limited training in the natural sciences, and agriculture (EMU)	Training at undergraduate level in natural sciences (UNISWA)	Same as Zambia and Malawi; but currently pursuing setting up an MSc Programme in Biotechnology at UNAM

Source: Biotechnology Trust of Zimbabwe (2002), FANRPAN (2004)

Techniques/Category	South Africa	Botswana	Mauritius	Tanzania	Angola	Seychelles	DRC
Tissue Culture	Has active programmes employing TC techniques for root and tuber crops, ornamental and horticultural crops and in animal vaccine production	Limited activities for root and tuber crops	Limited activity in sugar cane research	Techniques employed relatively extensively for root and tuber as well as horticultural crops	Not much is known	Not much is known	Not much is known
Molecular diagnostics and molecular markers	Plant and animal disease diagnosis	Limited use in plant and animal disease diagnosis	Still using serological techniques for diagnosis	Used in plant and animal disease diagnosis	Little known	Little known	Little known
Biological Nitrogen Fixation	Soil fertility improvement, through legumes and inoculants	Mainly through integration of legumes in cropping systems	Use of legumes	Mainly legumes, limited use of inoculants	Little known	Little known	Little known
Manpower training	Specific degree-level training programmes available at most major universities. Access to state-of-the art resources	Training offered in other natural science modules at UB	No explicit biotechnology training offered.	Training done in agricultural and other life science courses. A BSc degree in Biotech was recently introduced at Sokoine University. Country also benefiting from BIO-EARN programme	Little is known	Little is known	Little is known
Genetic modification	Most major universities, research institutions (both govt and pvt) have major projects employing GE techniques. Both crops and animals are covered in the research activities. Insect-resistant cotton and maize & herbicide tolerant cotton and soybean are already being grown commercially	Limited research work at the University of Botswana. No field trials approved	GM-sugar cane nearing field trials. Awaiting adoption of a biosafety framework	Limited research work; eg virus resistance in banana. No commercial releases, but trials on GM tobacco were conducted in	Little known	Little known	Little known
Fermentation Technology	Used widely in food and beverages as well as pharmaceutical industries	Used in brewing industry	Widely used in brewing industry	Used in brewing industry & vaccine production	Not much is known	Not much is known	Not much is known
Marker assisted selection	Maize and small grains breeding as well as livestock research and development	None	None	Genetic characterization of coconut, cashew, sweet potato, cassava and coffee	Little known	Little known	Little known
Artificial Insemination and embryo transfer	Livestock research, breeding and conservation	Livestock breeding	Limited use	Livestock breeding and conservation	Little known	Little known	Little known

Source: Biotechnology Trust of Zimbabwe (2002), FANRPAN (2004)

3 Biosafety: The Convention on Biodiversity and the Cartagena Protocol

The Biosafety debate in the negotiations of the Convention on Biodiversity (CBD), and the compromise reached in Article 8(g).

The whole issue of genetic engineering was new to developing countries in 1989-92, when the CBD was negotiated. Even at the factual level, very few Southern scientists knew much about it. It was IUCN and WWF that were instrumental in informing delegates at the beginning of the negotiations about the ideas now in the CBD[1] (IUCN, 1993, p. 2-3). In the United States, however, entrepreneurs were already creating biotechnology companies, but the biotechnology industry made no attempt to participate in the CBD negotiations.

In the negotiations for the CBD, a split occurred between the developing countries, which all wanted an international biosafety law, and the United States of America, which wanted biosafety laws to remain national.

Article 8(g) states this requirement as follows:
Each Contracting Party shall, as far as possible and as appropriate:
(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

Article 19 addresses the Handling of Biotechnology and Distribution of its Benefits, including:
3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

In 1993, UNEP established a scientific panel, Panel IV, to answer the question as to whether or not a biosafety protocol was needed. The members, except the one from the USA, agreed that a Protocol was needed, and the report was submitted to UNEP in April 1993. The United States gave a dissenting minority report stating that a protocol was unnecessary. With the change in leadership at UNEP in 1993, the Panel IV report was put aside. But many parties kept calling for a protocol and an open-ended *ad hoc* working group was convened in Madrid, Spain, in 1995, just prior to the 2nd CBD Conference of the Parties (COP) held in Jakarta, Indonesia. The *ad hoc* working group concluded that a protocol was indeed needed. It recommended that negotiations be started. This recommendation was accepted and the COP passed a decision stating that the negotiations be started. Even though the USA had not ratified the CBD, and only Parties could negotiate, the decision specifically allowed the USA to negotiate as if it were a Party. The negotiations started in 1995.

The African Group, realizing from past experience that Africa's economic and political weakness made it vulnerable to adventurism, took the negotiations seriously right from the start. The representatives for the discussions and negotiations were delegated by their

governments through the CBD focal point. In the first negotiation session in Aarhus, Denmark, in 1995, the Africa group elected the head of the Ethiopian delegation to chair it and to draft an African position. This was done and a meeting of the African Group in Addis Ababa in October 1996 carefully reviewed and approved the African position as a draft Protocol. The head of the Ethiopian delegation submitted the draft to the CBD Secretariat in the name of the African Region at the 3rd CBD COP held in Buenos Aries, Argentina, in November 1996.

Because of its clear and consistent intent, particularly the importance of the precautionary principle, socio-economic issues, and liability and compensation, the African position attracted the other developing countries, and together they formed what was eventually termed the 'Like-Minded Group'. The Like-Minded Group included the Africa Group, the Asia group, and the GRULAC group, but without Argentina, Chile and Uruguay, which joined the opposite position from that of the developing countries. Together with the USA, Canada and Australia, they came to be known as the Miami Group. These are the largest grain exporting countries in the world, who are also the largest producers of genetically engineered crops.

The Cartagena Protocol was expected to be finalized at a seventh and final negotiations session in Cartagena, Columbia, in February 1999, and then endorsed by an Ex-COP (Extra-ordinary COP) of the CBD. The most contentious outstanding issue was on provisions for the movement of genetically engineered commodities for food, feed or processing (FFP). The provisions would require the advance informed agreement (AIA) or prior informed consent (PIC) of the importing Party before such items could be shipped to that country. The Miami group held that this would interfere with trade. They, thus, wanted the Cartagena Protocol to be subjected the rules of the World Trade Organisation (WTO). But this was rejected by the developing countries. Later the same year, in December at the WTO Ministerial in Seattle, there was an attempt to bring trade in genetically engineered organisms and their products under the WTO, but this was again strongly rejected by all the developing country blocks.

In Vienna, September 1999, there was an informal consultation of all the parties to the Cartagena Protocol where many of the contentious issues and alternative texts from the February meeting were resolved[2]. All the negotiating groups were present: It was, therefore, made possible to complete the negotiations and for the Protocol to be adopted by the CBD at the continuation of the Ex-COP in Montreal, January 2000.

The Protocol came into force on 11 September 2003, and the first Meeting of the Parties (MOP) was held in Kuala Lumpur, Malaysia, in February 2004.

4 A Review of the Basis of the Risks in Biotechnology

The majority of the fields of biotechnology (for example, fermentation and tissue culture) pose virtually no risk be it to human health or to the environment. The main debate about risks arises from recombinant DNA technology, cell fusion and gene silencing. These can all be grouped together as genetic engineering. In agriculture, the proponents present these as having the potential to increase food production and usher in an era of food security. In medicine, there are promises to issue in a new era of medical treatment based on mending genetic faults, and tailoring treatments to the needs of the individual. Therefore, both the technology and the claims need to be examined very carefully.

4.1 The causes of the risks posed by genetic engineering

4.1.1 Cell Fusion

Cell fusion involves the mixing of two cell nuclei from different species into one nucleus. The genes from the 2 species then mix to form one genome. In nature, this takes place at the level of sex cells to form hybrids usually between two closely related species, for example between the Hamadryas and Anubis Baboons in the Awash Park. Animal hybrids are usually sterile. However, there are many examples known from plants where the hybrids may reproduce successfully and 'swarm' out, often out-competing one or both parents and replacing them.

The typical toughness or vigour of the hybrid is well known, and people have been exploiting this characteristic for longer in a few animals than in plants, viz. the mule. Commercial production of hybrid seed of crop plants started in the 1920s and 30s, at the same time agrochemicals were being developed, and their development has largely gone hand-in-hand since. Although the characteristics of the first generation hybrid are usually predictable, those of subsequent generations are less so. Hence farmers choosing to plant hybrid seed have to go back to the breeders of the hybrid each growing season.

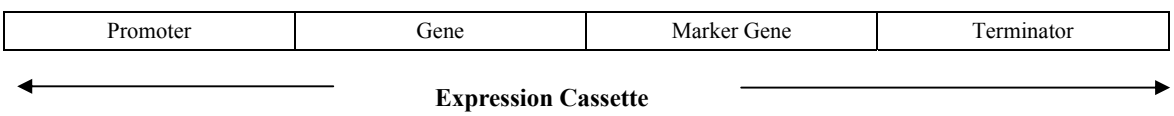
Before the development of recombinant DNA methods, cell fusion was sometimes used to bring together two different species on the chance that some useful traits would develop if the fused cell could be made to develop into a whole organism and become fertile. One example is Triticale, the fusion of two closely related species, wheat (*Triticum aestivum*) and Rye (*Secale cereale*). This crop combines the productive potential of wheat with the capacity to tolerate acid soils of rye. It took many years before Triticale could be given to farmers because of the problem of getting the plants to be fertile, i.e. to set seed.

4.1.2 Recombinant DNA technology

Recombinant DNA technology involves taking a gene or genes from one species and introducing it into the genetic makeup of another with the aid of a vector. The process is briefly described below:

In genetic engineering, the gene to be transferred is isolated. If transferred on its own, it fails to be expressed, i.e. it becomes a silent gene. Therefore, a part of a gene known to force expression, called a *promoter*, is attached to it. But the *promoter* could cause the expression of other silent genes as well. It may even enhance the expression of functional genes. Therefore, a part of a gene known to stop expression, *the terminator*, is also attached to it. This combination is called an *expression cassette*. Nevertheless, genes are known to have impact on the functions of other expressed genes even when not physically attached to them.[3] Therefore, it is possible that either or both the promoter and the terminator may affect or be affected by the actions of other expressed or non-expressed genes and thus modify the genetically engineered organism in ways that cannot be predicted.[4] A *marker gene*, usually one that makes the GE organism resistant to an antibiotic, is also attached in order to separate cells that have incorporated the recombinant DNA from those without it.

The expression cassette can be represented as follows:



Two or more expression cassettes may be linked end to end. The linked up expression cassettes constitute a *construct*. The construct is then sometimes directly pushed into the cells that are being engineered. Usually, however, it is introduced through a *vector*. A vector is a bacterium or virus that normally invades the cells of a species and causes a disease, but for genetic engineering they are disabled by having part of their genetic structure removed so that they do not cause a disease, but are still capable of breaking into a cell. The vector may also be a plasmid. The construct is then introduced into the disabled vector, and the vector thus smuggles the construct into the cells of the receiving species.

The construct may also be attached to a naturally occurring small gene called a *transposon,* which then acts as the vector to smuggle in the construct. *Transposons* are also called 'jumping genes' because they can move from species to species. The gene(s) attached to *transposons* may, therefore, easily contaminate unintended species. Whether introduced physically or through a vector, the genes in the construct become part of the cell and determine traits.

Antibiotic resistance trait is used as a marker to select the cells that have had the construct introduced into them. When the mixture of cells is treated with the antibiotic, those cells that are without the antibiotic resistance gene die, and it is the genetically engineered cells that survive.

The thus genetically engineered cells are then cultured and they develop into whole micro-organisms, plants or animals. We call these living things resulting from genetic engineering *transgenic* organisms, and the transferred gene is called a *transgene*. Until recently, all the components of the construct remained part of the new transgenic organism. Now there are reports that attempts are being made to remove both the vector and the marker genes, particularly if they confer antibiotic resistance.

It has in the past few years become possible to bind messenger RNA to the DNA sequence it corresponds to. This prevents the genes in the DNA from being expressed, i.e. they are silenced. This type of genetic engineering is not considered recombinant gene technology, but it is genetic engineering.

By way of a summary, it can be pointed out that the risks posed by genetic engineering arise from the following causes:

a) *The new combination of genes does not occur in nature, and therefore, the net result of genetic engineering cannot be fully predicted beforehand. The few attempts at human gene therapy have already shown the large number of non-predictable problems that can arise.*
b) *During digestion in the human gut, bacteria ingest portions of DNA from the broken-down cells in the food. Bacteria in soil and water also ingest portions of DNA from decaying plants and animals. If the food, or the decaying plants or animals, contain recombinant DNA, this can be taken up and transferred among bacteria, and from bacteria back into higher forms of life.*[5, 6] *This is one of the mechanisms by which antibiotic resistance has been transferred to pathogenic bacteria, making it more and more difficult to use antibiotics as medicine.*
c) *The mixing of genes inside genetically engineered cells is far from being precise. The construct can attach itself to any gene in the receiving organism. The genes may also rearrange and multiply, and not necessarily stay in the same condition as they were when*

they were put into the gene construct. The expression of traits thus becomes unpredictable and unstable.

d) *Inside the transgenic organism, the vector may come into contact with and recombine spontaneously with a gene sequence that reactivates it. This would turn the vector into a disease agent, possibly new and more dangerous.*
e) *The effects of the promoter and terminator are not predictable, and there may be many unexpected consequences.*
f) *The transgenes become part of the plant or animal, including the sex cells. Animal breeding is usually controlled by people, but not always. Plants use many agents other than people to transfer pollen, and none of these are under direct human control. It is thus possible for transgenes to move through plant populations and bring unwanted impacts to the growers of crops as well as other components of the natural biodiversity. The appearance of 'super weeds' resistant to most herbicides is one result of such uncontrolled transfer of transgenes.*[7]
g) *The new transgenic organism may start producing biochemicals that are toxic, or cause allergenic, carcinogenic, or terratogenic effects in humans and/or animals.*

4.2 Main issues in Biosafety in Africa

The aim of this section is not to provide a detailed description, or even an overview, of biosafety issues. A lot of technical literature on genetic engineering and biosafety is now available. The aim is not even to go through all the biosafety issues covered by the Cartagena Protocol on Biosafety - "An Explanatory Guide to the Cartagena Protocol on Biosafety", has been published by the IUCN, WRI and FIELD. The aim here, is to point out those dimensions of biosafety that are divisive and thus call for an African consensus and those that have implications for capacity building efforts by African countries.

4.2.1 Living Modified Organisms or genetically engineered (modified) organisms

Both the CBD and the Protocol use only the term "Living Modified Organisms" (LMOs). But most people and documents, including national laws of industrialized countries**,** use the terms "Genetically Engineered Organisms (GEOs)" or "Genetically Modified" Organisms (GMOs). How do these relate?

"Living Modified Organisms" was introduced into CBD terminology by the grain exporting countries with the aim of accepting the regulating of living organisms only so that their products could enter into trade without questions being asked. GEO and GMO refer to both dead and living organisms, i.e. both the organism and its products. For food, a transgenic crop identified as containing GEOs/GMOs can be either in the form of seed, which is alive, or flour, which is dead.

The importance of the difference between LMO and GEO/GMO became clear when the negotiations for the Biosafety Protocol started. It became possible for the biotechnology industry to lobby and argue that the CBD, which made its decision to regulate LMOs, has *de facto* excluded products of LMOs from regulation.

In all other respects LMO means the same thing as GEO or GMO. This is because the combination of the Protocol Article 3(g), which defines LMO as resulting from "modern biotechnology", and Article 3(i), which defines modern biotechnology as the applications of

in vitro nucleic acid techniques including recombinant DNA technology and direct injection or cell fusion, show that, while alive, LMOs and GEOs/GMOs are the same. It is important to note, also, that the methylation of RNA to prevent gene expression, i.e. silencing, in a given organism would, under this definition, produce an LMO accepted by the Protocol as at par with one produced using a recombinant DNA technique.

After an LMO dies, strictly speaking it is no longer a concern of the Protocol. However, it is important to note that the Protocol does indeed accept that risks may be posed by products of LMOs (Paragraph 5 of Annex III and Article 20.3(c)):

> *... including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.*

4.2.2 The Precautionary Principle and the Substantial Equivalence Principle

The Cartegena Protocol on Biosafety bases its regulation of genetically modified organisms on the Precautionary Principle. The USA, which is not a Party to the Cartagena Protocol, has based its regulatory system for genetically modified organisms on the Substantial Equivalence Principle. The Precautionary Principle assumes that a genetically engineered organism is best treated as unsafe, unless proved otherwise. The Substantial Equivalence Principle assumes that a genetically engineered organism is the same as its non-modified counterpart, unless proved otherwise.

The Precautionary Principle, as used by the Protocol, is best expressed in Article 10.6, also repeated in Article 11.8, which states:

> *Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.*

This statement refers to the trans-boundary movement of LMOs. But it applies equally in the development, handling and use of LMOs and their products domestically since, according to Article 2.2, Parties are obliged to "ensure that the development, handling, use, transfer and release of any" LMO causes no risk.

The Precautionary Principle can be viewed as the inclination of most people to use caution when making decisions about situations with unknown variables. For the Parties to the Protocol, when the existing facts do not show with certainty that the LMO and its products are safe, a Party can prevent the importation and use of an LMO until reliable information becomes available.

Exporting corporations, or even exporting countries and their agencies, are likely to pressurize a developing country's Competent National Authority for Biosafety into accepting that there is indeed no risk. This pressure can be difficult to resist especially where there is insufficient trained human resource at the developing country's Competent National Authority to make

informed decision taking possible. It is, therefore, difficult for most African countries to effectively apply the Precautionary Principle.

Modern biotechnology started in public institutions, but it soon went almost entirely into the private sector, and there is now very little research in modern biotechnology by the public sector in developed countries. Where African public institutions are conducting modern biotechnology research, the funding has often come from the private sector of the developed world (see Section 7 of this paper).

The private sector is investing heavily in biotechnology because it sees a potential for profit and this is where Africa may have some reasonable worry. Should a claim of safety for an LMO by its own developer be taken without any questions being asked? All the more reason, therefore, that Governments should develop a rigorous system of evaluating and regulating risks of LMOs completely independent of the private sector.

What has happened in the United States of America does not help reduce the African dilemma. Apparently, one of the laws of the USA states that, if a new product is to be taken as food by humans, the maximum safe limit must first be established. What is to be taken by humans must then not exceed 10% of the safe maximum limit.

This ruling would have to be applied to a transgenic crop if it was to be considered new, i.e. if an LMO food crop was considered safe at the 100% level, this law meant that it must be mixed with non-LMO food, and not exceed 10% of the mix. The modern biotechnology companies found this onerous. Therefore, the USA regulatory system developed a doctrine of 'substantial equivalence', which states that, since the introduced genes (transgenes) are one or a few in comparison to the tens of thousands of genes in the species before it was changed to an LMO, their presence is insignificant. The LMO has, therefore, to be taken as safe after it has passed through the standard tests normally applied to all naturally occurring foods unless anomalies appear during use. If they do, they should be dealt with on a case-by-case basis.

It is, therefore, extremely interesting that in the USA the LMO is classified as 'novel' and can be patented, on the one hand, but on the other, it is not "novel" when it comes to risks to the conservation and sustainable use of biological diversity and to human health. Wouldn't the logical step have been to pass new laws appropriate for LMOs?

There is now a lot of effort by modern biotechnology companies and like-minded non-governmental organisations, to involve the private sector in the creation and implementation within countries of biosafety systems, including providing the expertise to write the legal documents. What Africa needs to ask is whether this is appropriate for African countries or whether they should resist it? Perhaps, for Africa, if a modern biotechnology company wants to help a country develop its own biosafety system, it would be best if the funds were made available without "strings" attached.

However, it is important that industry itself be allowed to be involved in putting in place the biosafety system, or in any decision taking involving modern biotechnology or LMOs - but the voice of the modern biotechnology industry should be heard by an independent body formulating a biosafety system for its country – in order to avoid conflict of interest.

4.3 Biosafety Issues that are more complex in developing countries than in industrialized countries

It is not only poverty, but also environmental and socio-economic reasons that make ensuring biosafety in African countries much more difficult than for industrialized countries. Developing countries are at a great disadvantage when it comes to ensuring the safety of biodiversity and human health when an LMO is released into the environment or used to treat a human disease. Because of this disadvantage, the Protocol, in Article 2.4, allows countries to set standards higher than, though not inconsistent with, those set by the Objective and General Provisions of the Protocol.

In practice, it will be difficult for developing countries to set higher standards because of pressure both from countries with a strong biotechnology lobby, and from local NGOs that have been set up with funding originating directly or indirectly from the biotechnology companies in order to open up a local market for LMOs in the developing countries. The push to promote Bt cotton in West African States is one example. If the developing countries give in to such pressure before they have their own capacity to assess and cope with the risks, they could be faced with serious risks that will affect not only the environment and health of present generations, but also coming generations into the unknown future.

4.3.1 Poverty

Africa has the highest number of least developed countries of any continent. These countries have very limited financial resources and few if any trained personnel. Therefore, the funds they can allocate for biosafety are bound to be very small, and the biosafety measures taken by them are likely to remain inadequate. Even more worrying is the fact that, should a risk materialize, combating it requires financial and technical capacity that the countries do not have. For these reasons, a risk that is acceptable in an industrialized country is likely to be unacceptable in a developing, especially LDCs. The Protocol recognizes this fact through a statement in its preamble paragraph 8, which states that: .“Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms”.

One would think that, given this situation, socio-economic conditions would constitute a very important component in decision taking as to whether to import an LMO or not. But the provision on socio-economic considerations, Article 26, is very weak.

Another complication from the state of poverty is to get senior members of government to appreciate the challenges posed by modern biotechnology, and the need to take them seriously. They are much more likely to listen to the promises than to take time to understand the risks. This can result in decisions being made hastily before the country has got its own biosafety framework in place and working.

4.3.2 More complex environment

Most African countries are found in tropical and subtropical areas where temperatures stay above freezing all year round, so that plants that are annual in Europe can keep on growing all year round and become perennials in Africa. Seasonality is mostly in terms of wet and dry periods, and, despite the Congo Basin, Africa is the driest of all the continents. Differences in climate combined with rivers, geology and altitude, have created many distinct environments

which often cover large areas and have little or no relation to the geopolitical boundaries on the ground. Plants and animals, and many peoples also, cross boundaries with impunity. A biological or agricultural problem in one country is likely to be shared with its neighbours.

It is also known that biodiversity is richest between the tropics. The tropical rain forest areas have the largest biodiversity on earth. Even semi-arid areas in the tropics and subtropics usually have larger and more complex biodiversity than the moist temperate forests of northern latitudes. Much of the biodiversity within a broad environment, such as the Somalia-Masai area of East Africa (for a dry example) is endemic – around 50% of the 2500 plant species recorded for this area are endemics. For the Guinea-Congo Basin, more than 8000 species of plants are known, of which over 80% are endemic, and similar high rates of endemism are found in small island developing states.[8] Africa has several of these.

The risks LMOs pose is one of passing their transgenes (and possibly other genes from the construct) to wild species. From this, it is obvious to see that the larger the biodiversity is, the more complex and uncertain becomes the evaluation of risks posed by LMOs to biodiversity.

To make matters worse, owing to the low technical capacity of developing countries, specific knowledge on their biodiversity is often very poor, and almost non-existent for micro-organisms. This paucity in information makes the evaluation of risks posed by LMOs to biodiversity even more important, but it is also time consuming and difficult.

It is often heard that specific LMOs have shown themselves to be safe in an industrialized country and the developing country should not be concerned. It is a misleading statement, but its use to pressurize developing countries into accepting LMOs without adequate risk assessment is growing.

The industrialized countries are mostly in temperate areas, i.e. outside the tropics. Their environment is largely determined by temperature, and the whole area becomes cold or warm depending on the season; the two do not mix. A micro-organism under contained use functions optimally at high temperatures. If it escapes into the open environment it may survive during the hot season, but it is less likely to survive the winter cold. In tropical countries, at least river valleys are always hot and wet. An LMO that has escaped from containment may survive indefinitely. Other aspects of risk assessment also become complicated because of the complex environment.

The determination of risk is, therefore, inherently more complex and critical in a developing than in an industrialized country. But the handicaps are greater in the developing country owing to poverty. Shortage of financial resources, scarcity of appropriately trained human resources and absence of technological know-how are usual in developing countries but create no problem in industrialized ones because these constraints do not exist.

4.3.3 Centre of origin and genetic diversity of crops

Africa has two important centres of crop origins and diversity, and a third ‘non-centre’. These are the Eritrean-Ethiopian highlands extending into Uganda in the East, the West Africa Regional Centre, particularly associated with the River Niger and the forests of Guinea through to Cameroon, and the Sahelian ‘non-centre’ along the southern border of the Sahara Desert from Sudan in the east to Senegal in the west. Despite its floristic richness, the highly diverse flora of Southern Africa is not associated with the domestication of a significant

number of crops, or perhaps our knowledge of the indigenous agriculture of this part of the continent is still poorly documented.

Centres of origin of domesticated plant species usually also contain wild relatives which can contain genes important for the continued development of the crop. These areas need to be especially protected from the mistaken release of an LMO crop, because once it is released, its genes could cross over and get into a large amount of the gene pool, as has been found for maize in several areas of Mexico. Once a gene has been released, there is no known way of re-capturing it. The impact of transgenes on wild relatives of crops is not known, but it is possible that they could interfere with the ecological balance of the various species and varieties with their environment, and even cause some species to become extinct, as has happened sometimes from naturally occurring hybrid swarms.

The responsibility of conserving these large gene pools for the good of humanity is already a serious burden on these developing countries, and special care has to be taken to ensure that unintended releases of LMOs do not occur. This fact is recognized in the Protocol, preamble paragraph 7, and in the information requirements set out in Annexes I & II, as well as risk assessment in Annex III. All Parties are expected to assist countries that are centres of origin and centres of genetic diversity through the Biosafety Clearing-House.

4.3.4 Greater diversity in environment-related health problems

There are more agents that cause or transmit diseases in humans in the tropics and subtropics than in the temperate countries, and new diseases are still emerging, viz. the ebola virus in Central Africa. This is no doubt partly owing to the larger biodiversity of the tropical and subtropical areas, and the closer contact between people and the surrounding biodiversity. It is possible to survive without building a house, and often houses are shared with both domestic animals and some wildlife. It is also probably because of the much longer history of the existence of humans in the African tropics than elsewhere in the world. There has consequently been a long period of co-evolution between disease causing agents and their human hosts with some diseases, notably malaria, being very difficult to find a control for in modern medicine. Malaria and the Anopheles mosquito are a serious target for genetic engineering research, but none of the institutions in Africa already carrying out biotechnology research, including tissue culture, are involved in the research on malaria.[9]

This makes evaluating the risks to human health posed by LMOs (Article 1 & 15.1) in a developing country much more complex than evaluating it in an industrialized country. Of course, the lower financial, technical and scientific capacity in the developing country makes the task onerous.

4.4 Scope of the Cartagena Protocol

The Scope of the Protocol (Article 4) states:

> *This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.*

Hence the Protocol as a whole deals with all living modified organisms, but the Advance Informed Agreement (AIA) procedure is mandatory only for LMOs intended for introduction

into the environment, i.e. for intentional release. The AIA procedure is discussed more fully below in section 4.5.

The expression, “taking also into account risks to human health” is vague. It came into the Protocol because most countries wanted human health to be included, while the countries with big pharmaceutical corporations wanted LMOs for human health excluded. The compromise reached was this clumsy expression, but Article 15 and Annex III on Risk Assessment make it clear that possible impacts to human health are to be included in the risk assessment by the importing country.

From Article 5 it would appear that the Protocol would not apply to the transboundary movement of LMOs, which are pharmaceuticals for human use. Instead these would be handled by other international agreements or organizations. In practice, the only all inclusive arrangement that deals with pharmaceuticals for humans is the WHO’s “Certification Scheme on Pharmaceutical Products Moving in International Commerce”. The industrialized (OECD) countries also have “the Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products”. Both the Certification Scheme and the Convention were in place long before genetic engineering came into being. They both focus only on the impact to human health, and not on any environmental impact. Therefore, the prevention of risks from LMOs that are pharmaceuticals to the conservation and sustainable use of biological diversity is not covered by any international agreement, arrangement or organization other than the Cartagena Protocol on Biosafety.

For possible impacts on the environment, therefore, all LMOs that are pharmaceuticals for humans come under the Protocol until such a time as WHO or any other international organization develops a system for dealing with their environmental impacts as well. It would seem logical then to subject LMOs that are pharmaceuticals to the advance informed agreement (AIA) procedure. There would be complaints by industrialized countries that this would slow down the importation of urgently required vaccines. This problem can be solved through national inter-institutional arrangements, and the question of which institution will be responsible for the risk assessment in a developing country can be settled through domestic legislation. Depending on the outcome, the Ministry of Health can arrange for the import of the pharmaceutical LMO after it receives a risk assessment and a suggestion for a decision from the responsible environmental agency.

It may not be immediately obvious how an LMO that is used only for treating humans can pose a risk to the environment. To begin with, some accidental spilling of the LMO suspension during handling and administration of the drug to the human individual is inevitable. Therefore, the pharmaceutical LMO is as good as deliberately released into the open environment, unless treatment is also given in a condition of contained use. Secondly, if taken orally, the pharmaceutical LMO, which will most likely be a micro-organism, can go through the digestive system of the patient and thence through sewage and, especially in developing countries directly, find its way into water bodies. It is also known that if the LMO breaks down, the transgenic DNA may be ingested by bacteria of the gut and then passed on to other bacteria when they conjugate.

Annex III Paragraph 5 expects products that are of LMO origin, i.e. “containing detectable novel combinations of genetic material” obtained through genetic engineering, may pose a risk and are to be subject to risk assessment. If an LMO drug is injected into the body, one

cannot be certain that the transgenes will not be excreted from the intercellular spaces through urine or other ways.

It must be noted that the Scope includes all LMOs. Therefore, pharmaceutical LMOs are not excluded from considerations by the COP/MOP. For example, they can, and should, be included in the liability and redress regime to be negotiated following Article 27 of the Protocol.

Article 6 exempts LMOs in transit and destined for contained use from the AIA procedure. It must be noted however that it also empowers a Party to prohibit any specified LMO that it considers poses an unacceptable risk from transiting through its territory. It does this by placing the information on such prohibitions in the Biosafety Clearing-House.

There is an obvious need for consensus in Africa on the need to regulate all LMOs, be they intended for release, for food, as pharmaceuticals, or for experimental and industrial application. So as not to hamper trade, only those LMOs likely to be seriously harmful should be banned from transiting.[10]

4.5 The Advance Informed Agreement (AIA) Procedure

The aim of the AIA procedure is to protect an importing Party from taking a decision without being fully informed on the intended use and risks from an LMO intended for release into the environment. The Party of export is made responsible for the accuracy of the information about the LMO (Article 8.2).

The AIA requires time-bound reactions from both the importer and the exporter. The sequence and time frame can also be identified in the following nine steps:

1. *The Party of export notifies or ensures that its own exporter notifies the Competent National Authority of the country of import (Article 8.1). The time frame starts with the arrival of the notification at the Competent National Authority of the importing Party.*
2. *Within 90 days of receipt of notification, the Competent National Authority acknowledges receipt of notification to the notifier (Article 9.1). Note that the Protocol leaves "notifier" undefined. But it can be seen from Article 8.1, that the notifier is the National Competent Authority of the exporting country or, where there is a legal requirement in the exporting country that the exporter takes the responsibility, the exporter is the notifier. The time frame is 90 days.*
3. *The Competent National Authority of the importing country notifies its decision to both the notifier and the Biosafety Clearing-House within 270 days of the date of receipt of notification (Article 10.3). If more time is needed, the 270 days is extended by a set time determined by the Competent National Authority of the country of import (Article 10.3.d). Let us call this time x. Therefore, the time frame becomes 270 + x days.*
4. *The Competent National Authority of the country of import may also require additional information (Article 10.3(c), Paragraph 8(f) of Annex III). The time it takes for the information to be received will be outside the time frame of 270 days. Let us call this y. Therefore, the time frame becomes 270 + x + y days.*
5. *Within this time frame, the country of import must give its decision (Article 10.3)*
6. *A failure by the country of import to communicate its decision within the 270 + x + y days shall not imply permission for the import to go ahead (Article 10.5).*
7. *The Party of import may, at any time, review and change its decision in light of new scientific information. In case it changes its decision, it has to inform the notifier and the Biosafety Clearing-House within 30 days explaining why the change was made (Article 12.1).*

8. *A Party of export or a notifier may, in light of changes in circumstances or owing to additional relevant scientific information, request a Party of import to review its decision (Article 12.2).*
9. *The Party of import shall respond in writing to such a request within 90 days of receiving the request. It shall also provide the reasons for its decisions (Article 12.3).*

LMOs intended for direct use as food, feed or for processing are subject to a simplified form of the AIA procedure. This is set out in Article 11 and Annex II of the Protocol. The simplified procedure does not require the following information: the intended date or dates of transboundary movement, the quantity or volume of the LMO to be transferred, the regulatory status of the LMO in the Party of export, and previous notification about the LMO made to other Parties. This is because the basic information about the LMO for food, feed or processing is made available through the Biosafety Clearing-House, which is accessible to any Party who requires it.

There is no time frame for this simplified AIA procedure. Instead, the country approving an LMO for use as food, feed or processing places the information about the LMO according to Annex II in the Biosafety Clearing-House. A potential Party of import can ask for more information, as in the full AIA procedure.

It is also possible for the Party of import to use its own national biosafety regulatory framework to allow or refuse the import of an LMO for use as food, feed or processing, and to use a risk assessment to support its decision. The European Union has done this consistently in order not to import GMOs from the United States. The decision has to be posted in the Biosafety Clearing-House, and exporters are expected to respect the decision.

Both the full AIA procedure and the simplified process for an LMO for use as food, feed or for processing provide the essential steps and thoroughness required for informed decision-making by a Party of import. Many developing countries may lack all the skills needed to make informed decisions, so Article 11.9 was included so that a Party can also indicate its needs in capacity building for taking decisions, and that Parties (particularly industrialized countries that export LMOs) should cooperate to meet these capacity building needs.

Consensus in Africa is needed on the requirement for decision makers in each country to be fully and accurately informed about any genetically modified organism before authorizing its production, use or transit through the territory of any African state.

4.6 Risk Assessment and Risk Management

All decisions on the development, handling, use, import or export of LMOs are to be based on the assessment of the risk that the LMO is likely to pose to biological diversity and to human health. Any decision taken without risk assessment could result negative impacts on the environment and/or human health. As we have seen in Section 4.3, the environment and human resource capacity of developing countries makes it unlikely that there is sufficient and appropriate scientific information available for a reliable risk assessment. The need for more caution in developing countries is, therefore, clear. That is why the precautionary principle is very important.

Article 15 states that risk assessment under the Protocol shall be based on the information received in the notification (Annex I), “and other relevant scientific evidence”. Any decision

on LMOs destined for release to the open environment has to be based on risk assessment (Article 15.2). It also allows risk assessment in all other decisions (e.g. Article 5 & 6).

Developing countries could also often find the needed risk assessment too expensive to be borne by the governments. It is because of this known problem that Article 15.3 states that "the cost of risk assessment shall be borne by the notifier (exporter) if the Party of import so requires."

Article 16.1 makes the risk assessment the basis for a country to "establish and maintain appropriate mechanisms, measures and strategies" to deal with the LMO in question if any of the risks materialize. However, it looks unrealistic to establish a whole risk management system for each LMO. Especially in the context of capacity building, some system is required for clustering risks likely to be posed by LMOs in general and, based on that aggregation, developing institutional and technical capacities with the appropriately trained human resources. Each African country could, in theory, create such a system, but preferably, regional expertise could be developed. Global norms can also be developed by the Secretariat of the Protocol or by sufficiently disinterested international organizations, such as the United Nations or the CGIAR.

Article 16.4 requires that risk management includes the continued observation of an LMO after its release (deliberate or accidental) into the environment for a time long enough to note if its population dynamics will have any negative impact on the population dynamics of any other species. This long period of observation is needed because such dynamics may require many generations to show up. Again cooperation among African countries, particularly those that share common biodiversity and environments would help make better use of the scarce expertise.

Article 16.5 requires Parties to cooperate in identifying risky LMOs and in "taking appropriate measures". The Secretariat of the Protocol can use this article to develop a recommendation to help developing countries build their respective system of risk management.

4.7 Public Awareness

Article 23 of the Protocol requires Parties to educate their public and raise its awareness on LMOs. This task cannot be left to the mass media because the journalists themselves usually have a low level of awareness, and very little grasp of technical information on modern biotechnology. African countries should, therefore, create opportunities for media people, particularly journalists to be both well-informed and also updated regularly because of the fast pace of developments in genetic engineering. Independent public education programmes should also be developed with as much in way of resources and competent people as the conditions in each country or region allow. Obviously, the resources are going to be inadequate, and the trained people to organize and deliver public education on modern biotechnology scarce. This deficit in capacity has to be rectified through a biosafety capacity building programme for the media, and for educators.

Article 23.2 requires Parties to consult the public in decision taking on LMOs. Most developing countries fail to consult their public in any decision-making. It will, therefore, require new political commitments in many developing countries to foster public participation. The COP/MOP has to apply sufficient pressure on Parties to be participatory in

decision-making consistent with their commitment in Art. 23.2. It is critical that the public gets involved. This is both because it is the public's right to know about decisions that can adversely affect their environment and health, and also because much useful local information that can help in decision taking can come from citizens, particularly local communities. Equally importantly, should the need arise for action to manage risks that have materialized, a public that has been informed and involved will be much more effective at taking such action than totally uninformed citizens.

4.8 Trade and Environment

Is there 'pressure' from industrialized countries and corporations on developing countries to expedite laws for biosafety requirements because of trade interests? Unfortunately the answer question is 'yes', as pointed out earlier in Section 4.2.2, although in almost all cases this pressure is invisible and thus difficult to acknowledge.

The most important trade partner for African countries is the European Union. In June 2003, the European Commission issued its '*EC policy on donations of GM- foods and seeds*', which clearly states the need for all countries to implement the provisions of the Cartagena Protocol.[11] Although the Policy document speaks specifically to the issue of GMOs in donations of food aid, it also clearly states the challenges to developing countries in dealing with such materials in trade agreements, viz:

> *The EC believes in the right of any Government to apply the principles of the Cartagena Protocol on Biosafety which creates an enabling environment for the environmentally sound application of biotechnology. Donors, including those who are not Parties to the Protocol, have to comply with the provisions of the Protocol when the beneficiary countries so require.*

The policy document also states the following:

The introduction of GMOs in developing countries raises specific issues:

1. *Legislation and its enforcement: many developing countries do not have a regulatory framework governing GMOs nor the resources to enforce such a legislation. Even those who have ratified the Cartagena Protocol are still in the process of developing their legislative frameworks.*
2. *Human health and environment: most developing countries do not have the capacity to perform a solid scientific risk assessment. The Cartagena Protocol is setting up a roster of experts that developing countries will be able to resort to in order to choose experts for risk assessment if needed. The EU recognises the right to any countries to choose their level of health and environmental protection and to rely on their own scientific assessment.*
3. *Intellectual Property Rights: since GMOs are patented, the spread of GM traits in local varieties can affect the rights of local farmers and local breeders to use and propagate their varieties.*
4. *Trade issues: asynchronous approvals of GMOs between countries affect trade not only between developed countries and developing countries but also between developing countries.*

Trade laws of the WTO have a strong enforcement mechanism: the trade embargo. Environmental agreements have no enforcement mechanism other than censure in Conferences of Parties (COPs). Such censure can be ignored. Therefore, there is a general fear among those concerned about the environment that, if a conflict of interest between trade and environment arises, environmental agreements will simply be ignored.

Trade rules favour industrialized countries. The WTO has 3 major trade agreements: one on trade in goods, one on trade in services and one on "trade-related aspects of intellectual property rights". The agreement in trade in goods does not force any country to open its borders to all goods. It only requires a country that has decided to import some goods, not to discriminate among exporting countries. But the country can discriminate among goods and can prohibit the import of any specified goods. The other two agreements require that a country keeps its borders open to any service giver or any intellectual property holder. Developing countries could compete with industrialized countries only in goods, not in services or intellectual property rights. As a consequence developing countries can export to industrialized countries only as wanted by the industrialized countries themselves. They cannot reciprocate by closing their markets to goods from industrialized countries because their markets have mostly been forced open by loan conditionalities and structural adjustment programmes. The most important sub-sector of trade in goods, that for agricultural products, is heavily subsidized by industrialized countries to the point where the inherently cheaper produce of developing countries has become uncompetitive.

The Agreement on Trade-related Aspects of Intellectual Property rights (TRIPs) is the most problematic trade law for developing counties in the context of modern biotechnology and LMOs.

Article 27.3(b) of TRIPs makes the patenting of micro-organisms and microbiological processes compulsory, and the patenting of other life forms optional. Many industrialized countries are allowing the patenting of LMOs and their subcellular components based on this article. This has two implications for endogenous development of modern biotechnology in a developing country. The cellular parts essential for modern biotechnology are already patented. This means that any endogenous modern biotechnology development will become bureaucratic and costly, having to negotiate the use of these patented parts from numerous patent holders. It also means that LMOs, even when developed in country, are controlled by these patent owners of subcellular parts. These patent owners are mostly in Northern America, Japan and Europe. The likely scenario is thus that, on the whole, LMOs in developing countries will be imported ones even when they are said to be domestically produced.

A country that is not a member of the WTO does not have to recognize patents on life. But if it is a member of the WTO, it is obliged to implement TRIPs. It must also be noted that, once a country allows the patenting of living things, it cannot change the patent law to weaken patenting; only to strengthen it.

Article 34 of TRIPs puts the burden of proof of innocence on the person accused of the infringement of a process patent. This means that when a LMO crop cross pollinates with the crop of a small holder farmer who has no idea of the LMO, his crop becomes contaminated by genes from the LMO. Most absurdly, the very smallholder farmer who has his crop altered is assumed to be a process patent infringer. There is no way through which he can prove that he is not an infringer.

The African Group at the WTO presented its proposal for the revision of TRIPs to the TRIPs Council that met on 4-5 June 2003. In its proposal, it restated its known opposition to the patenting of life.

The proposal to prohibit the patenting of "plants, animals, micro-organisms - essentially biological processes for the production of plants or animals, and non-biological and microbiological process for the production of plants or animals" - if adopted, would remove the need for the legal protection of Community Rights in so far as genetic resources, biological knowledge and technologies are concerned since one universal trait of community life has been that genetic resources, knowledge and technologies are given free to any one who wishes to use them.

Their emphasis that Article 27.3(b), which makes what they consider as the immoral patenting of life compulsory, is a contravention of Article 27.2, which allows countries not to patent if found "necessary to protect *order public* or morality..." This indicates that any country that so wished it could prohibit the patenting of life. It is in this context that their proposal to add a third paragraph to Article 29 of TRIPs, which requires that a patent applicant discloses "the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin", can become consistent with the prohibition of patenting life. They are thus taking a credible position in asking that each country be allowed to decide for itself as to whether it wants to patent life or not and, at the same time, to protect the interests of indigenous and local communities globally from those who choose to patent life and will thus not reciprocate in giving access.

The attempt at the protection of the interests of indigenous and local communities is presented as a draft "Decision on Traditional Knowledge"[12], which includes the rights to genetic resources, knowledge and technologies embodied in the Convention on Biological Diversity, the International Treaty on Plant Genetic Resources for Food and Agriculture, and the African Model Law for the Protection of the Rights of Local Communities, Farmers, Breeders and for the Regulation of Access to Biological Resources.

TRIPs must serve not only the industrialized countries - but the whole world - otherwise it will remain an instrument that breeds disaffection in the developing countries.

In March 2004, following the decision of the CBD COP7 to ask the World Intellectual Property Organization (WIPO) to undertake further work on patent disclosure requirements relating to genetic resources and traditional knowledge (TK), the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) agreed on the development of the building blocks for the protection of TK and expressions of folklore. The African group of countries submitted a text on objectives, principles and elements of an international instrument, or instruments. This proposal received widespread support in the Committee as a framework for its work.[13]

4.9 Socio-Economic Considerations

Article 26 of the Protocol is on socio-economic considerations when making decisions on import of LMOs. Although it gives special regard to impacts on the value of biological

diversity to indigenous and local communities, it allows these considerations only so long as they are 'consistent with their international obligations', mostly meaning the WTO trade agreements. As the poorest of the continents, Africa needs socio-economic issues to be considered seriously in any risk assessment. This is, however, going to remain contingent upon what Africa can achieve in the WTO, especially in the revision of TRIPS.

4.10 Identification and Labelling

Labelling was a highly divisive issue in the negotiations of the Protocol. The countries, which saw themselves as leading LMO producers, did not want to label. After a lot of intense discussion, it was accepted that 'labelling' would be replaced by 'identification'. However, it is obvious from Article 18.2(a), which accepts 'may contain' LMOs to be stated in the accompanying documentation, that labelling is a component part of identification.

COP-MOP 1 established and agreed the terms of reference for the work of an Ad Hoc Open-ended Group to negotiate lasting rules on the handling, transport, packaging and labelling of GMOs and products thereof. It also decided that, in the mean time, existing documentation that accompanies goods, e.g. invoices, should be used to give information on GMOs used as food, feed or for processing. The information must include: contact points for further information on the GMO, including the exporter, as well as the importer, the common and scientific names, and where available, the commercial name, the transformation event code and any unique identification, of the GMO.

The decision requested Parties to send to the Secretariat of the CBD any experience they may have and their views on the handling, transport, packaging and identification of GMOs by 30 June 2004. The decision also requested 'developed country parties and other donor Governments to make financial contributions necessary to facilitate the participation of experts from developing countries and countries with economies in transition' in the negotiations. Two meetings of the Ad Hoc Open-ended Group are scheduled to take place in 2005.

4.11 Liability and Redress

It would seem logical that if an LMO causes damage, the owner or developer of the LMO should become liable to pay compensation for any damage caused.

During the negotiations of the Protocol, the industrialized countries refused to even discuss the issue of liability and redress. But the African Group had submitted provisions on liability and redress to be part of the Protocol. The other developing countries supported the African Group. Therefore, in 1998 in Montreal, all developing countries had to refuse to negotiate on any issue if the industrialized countries were not willing to look at liability and redress. The industrialized countries thus had to start negotiating on liability and redress as well. The ensuing negotiations were, nonetheless, not very fruitful. But, as a compromise, a decision was taken to agree that a liability and redress regime would be negotiated once the Protocol came into force.

Therefore COP-MOP 1 agreed to create an Ad Hoc Open-ended Working Group to negotiate liability and redress and developed the terms of reference for its work (UNEP/CBD/BS/COP-MOP/1/15; BS-I/8). It also agreed on a schedule of negotiations. A technical Group of Experts

will have a 3-day meeting to prepare the documents for the Ad Hoc Open-end Group, and the Working Group will meet to negotiate twice in 2005, once in 2006 and twice in 2007, for five days each time. It is, therefore, expected to complete its negotiations in 2007.

A liability and redress regime is required more to put a constraint to irresponsible enthusiasm in genetic engineering than to actually correct mistakes: some mistakes in genetic engineering may well become so devastating that full redress will never be possible. Africa needs to position itself strategically on this – to ensure a safer world.

4.12 Compliance

The need to promote compliance with the provisions of the Protocol is recognized in Article 34 with the instruction that the first COP/MOP shall 'consider and approve cooperative procedures and institutional mechanisms to promote compliance.'

COP-MOP 1 agreed to "Procedures and Mechanisms on Compliance" (UNEP/CBD/BS/COP-MOP/1/15; BS-I/7) and established a Compliance Committee to ensure its implementation.

The Procedures and Mechanisms are aimed at helping those Parties that fail to comply owing to shortage or lack of capacity. Capacity building is, therefore, seen as essential for the Protocol. The Compliance Committee is expected to examine cases of non-compliance, provide advice or assistance, but also "take measures, as appropriate, or make recommendations to the Conference of the Parties serving as the meeting of the Parties" to ensure compliance. If a Party repeatedly fails to comply in spite of advice and assistance offered, its non-compliance will be published in the Biosafety Clearing-House or other measures may be decide by the COP-MOP.

Fifteen persons were elected to serve, in their personal capacities, in the Compliance Committee including three from Africa.

5 Capacity Building

Many of the provisions of the Protocol require specific capacities for their effective national implementation. National bio-safety capacity building should, therefore, include the following:

1. Training of human resources and provision of the necessary scientific equipment and supplies for biotechnological tests and related investigations to identify Living Modified Organisms (LMOs) and their products in order to enable a meaningful implementation of the provisions of the Protocol, especially in determining regulatory steps to be taken.
2. Develop competences to determine, implement, monitor and regulate conditions of containment appropriate for specific LMOs and the specific environments in the country.
3. Information management to establish, as necessary, and link up with the Biosafety Clearing-House of the Protocol and Clearing-House Mechanism the Convention, keep updating and make available to users databases on LMOs and, as appropriate, also products of LMOs. It should be noted here that though products of LMOs are not subject to the AIA procedure, Paragraph 5 of Annex III on Risk Assessment requires the inclusion of the products of LMOs in the risk assessment of the LMOs. Therefore, every provision in the Protocol that refers to risk assessment also refers to products of LMOs. Specifically, information management is needed for:

- *contained use of LMOs,*
- *LMOs and products thereof for pharmaceutical use,*
- *the transit of LMOs,*
- *genetically modified organisms that are unlikely to cause risk,*
- *information given through the notification of LMOs,*
- *information on LMOs used as food, feed or for processing,*
- *risk assessments of LMOs and products thereof,*
- *decisions made concerning importations of LMOs,*
- *the life cycles (or generation times) of LMOs and their related species into which the novel combinations of genetic materials may be transferred,*
- *LMOs that may pose risks to the environment or to human health and the specific risk management measures to be taken to respond to those risks,*
- *LMOs notified or otherwise reported as unintentionally released, especially those likely to reach the territories of another Party,*
- *information on the implementation of the Protocol,*
- *information on existing laws, regulations and guidelines, and illegal trans-boundary movements of LMOs that have taken place.*

4. The technical capacity to evaluate the socio-economic impacts of LMOs.
5. The legal and technical capacity to effectively criminalize the unauthorised transboundary movement of LMOs.
6. The institutional, technical, scientific, legal and administrative capacity to develop, establish and operate the following systems:
   - *Risk Assessment appropriate for the evaluation of all types of LMOs and their products with respect to human health and with respect to biological diversity;*
   - *Risk Management of all types of LMOs and their products under all environmental conditions in the territories of the Party;*
   - *Monitoring, evaluating and dealing with emergencies relating to unintended or illegal trans-boundary movement of LMOs and their products;*
   - *Monitoring the spread and impacts of LMOs in all the types of environment in the territories of the Party over time periods commensurate with the life cycle of each LMO;*
   - *Monitoring globally scientific and technological developments and other facts that may have implications on biosafety;*
   - *Handling, transport, packaging and identification of LMOs into, out of, and within the territories of the Party;*
   - *Handling Confidential Information without prejudicing biosafety;*
   - *Public participation in decision making regarding LMOs;*
   - *Regularly monitoring the implementation of the Protocol and reporting to the COP/MOP;*
   - *Compliance with the requirements of the Protocol.*
7. Develop and implement on a continuing basis a programme of need identification, the determination of the strategy of implementation and the actual carrying out of the strategy through formal education (both locally and abroad as appropriate for the Party concerned) for producing the requisite trained human resource capacity in carrying out the following activities:
   - *Test and identify all types of LMO for implementing, monitoring and regulating their safe development, handling, transport, use, export and import.*
   - *Study of the life cycles of the species of LMO as well as the biodiversity (genetic, species and ecosystem diversity) that may be affected by the LMOs in the territories of*

the Party and their implication for ecological stability and the management of risks to biodiversity and to human health.
- *Design and create databases and manage them so as to satisfy the users of the various types of biosafety information.*
- *Formulate, review and revise environmental law (required for the whole Protocol).*
- *Analyse the socio-economic implications of the impacts of LMOs on the society and economy of the Party.*
- *Organize on the job training programmes to appropriately orient customs employees, the police force, judges and inspectors to familiarize them with the Party's biosafety laws so that they may implement them appropriately.*

8. Develop negotiating capacity so as to protect the interests of the African country Parties during the outstanding negotiations and continue indefinitely in the regular COPs / MOPs, and in other fora under the Protocol.
9. Ensure capacity for compliance with the provisions of the Protocol, and the decisions of the COPs/MOPs.
10. To strengthen the Bio-safety Clearing House.
11. The COP/MOP to review the Protocol every 5 years to evaluate its effectiveness.

6 The Development of National Biosafety Systems

6.1 National Biosafety Frameworks

Tied in closely with the issue of research is the development and implementation of regulations to monitor the research and products thereof. According to the UNEP, a national biosafety framework is a system of legal, technical and administrative mechanisms put in place to address safety in the field of modern biotechnology. Although biosafety frameworks vary from country to country, their main elements are:

- *A regulatory system set in place to address safety in the field of modern biotechnology;*
- *An administrative system to handle requests for permits for certain activities, such as releases of GMOs/LMOs (living modified organisms);*
- *A decision making system that includes risk assessment and management for the release of LMOs; and*
- *Mechanisms for public participation and information.*

Development and employment of national biosafety systems is stipulated under both the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety, which, the majority of countries in Africa are party to. Article 8(g) of the CBD calls on parties to,

"Establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs, resulting from biotechnology, which are likely to have adverse environmental impacts, that could affect the conservation and sustainable use of biological diversity, taking into account risks to human health".

While Article 2.1 of the Protocol requires each party to "take necessary and appropriate legal, administration and other measures to implement its obligations under the Protocol" and Article 2.2 of the Protocol states that "Parties shall ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risk to human health".

The purpose of biosafety systems can thus be described as three-fold:

1. *Providing Choice - National biosafety frameworks allow a country to make an informed choice on whether it wants to import or use LMOs or not and to make this decision in a rational, participatory way.*
2. *Ensuring Safety - Development of a national biosafety framework will enable a country to set in place tools to assess, evaluate and manage any potential adverse effects associated with the transboundary movement, transit, handling and use of LMOs on the conservation and sustainable use of biological diversity, taking into account risks to human health, as well as socioeconomic considerations.*
3. *Meeting a Country's International Obligations - A national biosafety framework will enable a country to meet the requirements of the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety.*

6.2 Stages being followed

An analysis of the process followed or being followed by African countries in the development of biosafety systems revealed the following stages

6.2.1 Justification and Commissioning

A justification of why a country needs a national biosafety framework has to be presented by interested parties, a lead institute identified and the project commissioned. The justification is usually based on the purpose of the biosafety system as indicated earlier

6.2.2 Survey and Inventory

Includes the current status of biotechnology programmes, activities and capacity in a country, a review and assessment of existing legislation that may impact upon the use of modern biotechnology (e.g phytosanitary, pesticide, food health, import, export), a review of existing national biosafety frameworks in the region, a survey of existing national, bilateral and multinational cooperative programmes in capacity building, research and development (R&D) and application of biotechnology, a survey of existing mechanisms for the harmonisation of risk assessment and risk management, and a survey of the extent and impact of release of LMOs and commercial products.

6.2.3 Stakeholder Feedback Workshop

It is critical that stakeholders be appraised of the status of the technology and regulatory issues, and a way forward be agreed on before a team is set up to draft legislation for the country.

6.2.4 Drafting of the Framework

In most countries this is being my a multistakeholder team with representatives from key sectors such as agriculture, health and environment; both government and non-government players being represented

6.2.5 Stakeholder Workshop

There is need for discussion of the draft framework document once it has been prepared, and in some countries this discussion is done through workshops, while other mechanisms are also being used.

6.2.6 Incorporation of Stakeholder Inputs

Incorporation of Stakeholder Inputs Stakeholder inputs need to be incorporated into the document, and if resources allow, a final round of discussion can be entered into, before the draft is submitted to government for further development and enactment.

6.2.7 Draft Ready for Submission to Parliament

The relevant arm of government, who in most cases will have been part of the consultation process, is tasked to take up this activity.

6.3 Status of Biosafety Systems in Africa

As far as the development and implementation of biosafety frameworks is concerned, only four countries in the region, namely South Africa, Zimbabwe, Egypt and Malawi have legal mechanisms for biosafety. The rest are still at varying stages in the development of their biosafety systems (Figure 1). With respect to international obligations, and as mentioned earlier, the majority of African countries are signatories to and/or have ratified the Cartagena Biosafety Protocol, an addendum to the Convention on Biological Diversity, which governs safe transboundary movement of living modified organisms, among other provisions for ensuring safety in biotechnology. Table 2, below gives more details on the status:

Figure 1. Current status of regulatory development in Africa, focusing on actions related to the Cartagena Protocol.

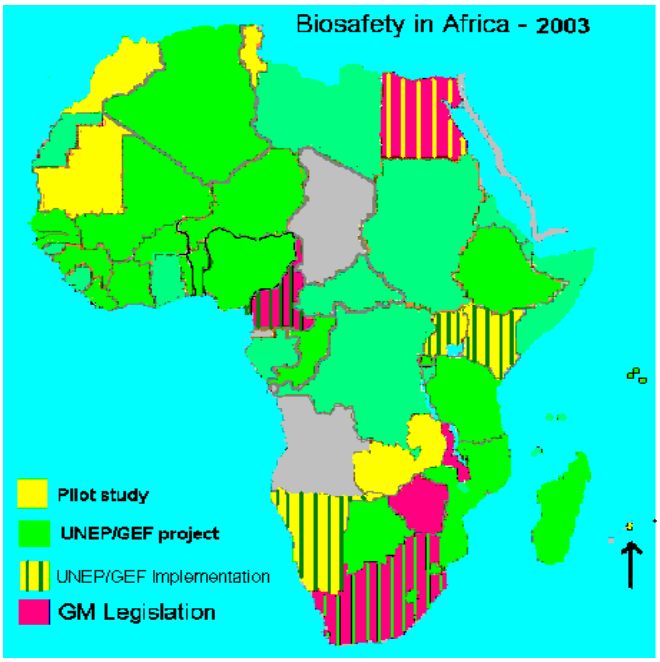


Figure courtesy of Muffy Koch, Golden Genomics

Biosafety Issue	*South Africa*	*Botswana*	*Mauritius*	*Angola*	*Tanzania*	*Seychelles*
Status of development and implementation of biosafety system	*Has had a legally-binding GMO Act since 1997; also has the institutional framework to administer the Act. The country has a number of both public and private laboratories adequately equipped to do GE work. Has over 110 plant biotech groups, over 160 plant biotech projects and over 150 trials.* ***Has a Biotechnology Policy. Has ratified the Cartagena Biosafety Protocol, participates in the UNEP-GEF Project***	***There is no biosafety legislation and policy in this country. There is a Cabinet Memo on GMOs, which stipulates obligations for declaration of GMO imports.*** *Process to develop a national biosafety framework was initiated in 2002 with UNEP/GEF funding. The National Coordinating Strategy Agency is the national focal point for Biosafety. S****igned and ratified the Cartagena Protocol. Participates in the UNEP-GEF Project***	*The country has a GMO Bill since 2001, which stipulates setting up of a National Biosafety Committee (NBC).* ***No biotechnology policy as yet. Has signed the Cartagena Protocol, and is in the UNEP-GEF project***	***There is no biosafety legislation or policy at the moment. There is a Ministerial Decree on importation of GMOs, and this is envisaged to lead to a Biosafety System.*** *Has signed and ratified the Cartagena Protocol, participates in the UNEP-GEF project*	*A National Biotech Advisory Committee was set up in Jan 2002. Policy preparation started in Mar 2002. 2nd draft of policy submitted in June 2003. 1st draft Biosafety Regulations (March 2003)* ***Has signed the Cartagena Protocol and participates in the UNEP-GEF project***	*Discussion of biotechnology and biosafety issues has only just started in this country to whose economy agriculture only contributes marginally. The main worry is that the country is a net food importer.* ***Has signed the Cartagena Protocol***
Use of Biosafety system in regulation of work on and/or use of genetic engineering	*The country already has a number of genetic engineering research work and products already on the ground, including commercial cultivation of GM horticultural crops and cotton and maize by small holder farmers*	*As indicated, there are no mechanisms in place to regulate GE and its products. The dependency of the country on agricultural produce from South Africa is a cause for concern.*	*Officially, there are no GE products that have entered the country. The NBC is tasked with monitoring registration and movement of GE products in the country. A locally developed GM (HT) sugar cane variety is awaiting release.*	*It is reported that GE grain imported by Namibia in 2001 was milled in Angola. Namibia's draft legislation guarded against contamination of the environment. Angola had and still has no regulations.*	*Tanzania has been a port of entry for GM maize provided as food aid to some countries in the region. Consignments were handled under the existing phytosanitary regulations.*	*Importations of foodstuffs have been handled under the existing food and food standards regulations*
Urgent Requirements	*Review of legislation, public awareness and participation*	*Legal framework, capacity-building, public awareness and participation.*	*Enactment of regulations, capacity-building, public awareness*	*Regulations, capacity-building, public awareness*	*Regulations, resource-mobilisation, public awareness*	*Awareness raising, regulations, capacity-building*

Table 2

Biosafety Issue	*Zimbabwe*	*Zambia*	*Malawi*	*Lesotho*	*Mozambique*	*Swaziland*	*Namibia*
Status of development and implementation of regulations and/or policies	*Has a legally binding biosafety system, which includes: a Biosafety Board and its Secretariat & the Biosafety Regulations and Guidelines.* ***Biotech covered under an S&T Policy****. Has some laboratories, which have capacity to detect GMOs.* ***Has signed the Catagena Protocol, participates in the UNEP-GEF Project***	*Has draft legislation and a National Biosafety Committee. Limited capacity for risk assessment.* ***Has a Biotechnology and Biosafety Policy. Regulations to be in place by end of 2004. Has signed the Cartagena Protocol, participated in UNEP-GEF Phase 1***	*Malawi has legally binding legislation on biosafety. A National Biosafety Committee was appointed though the country has limited capacity for risk assessment.* ***In process of developing a National Biotechnology Policy. Has signed the Protocol, participated in UNEP-GEF Phase 1***	*Multisectoral Task Force to draft biosafety and biotech policy was set up in 2001 within the Environmental Protection Unit.* ***Developing a National Biotechnology and Biosafety Policy. Policy was expected by end of march 2004. Has signed the Protocol, participates in UNEP-GEF***	*Set up a National Biosafety Working Group within the Ministry of Environment to come up with interim legislation on biosafety.* ***Legislation and policy still being developed. Has signed and ratified the Protocol; participates in UNEP-GEF***	*Multisectoral National Coordinating Committtee set up within the Environmental Protection Agency.* ***Working on acceding to the Protocol, participates in UNEP-GEF***	*Has a National Biosafety Committee (Namibian Biotechnology Alliance – NABA) and draft legislation.* ***Has a Biotechnology Policy. Has signed the Protocol, participated in UNEP-GEF phase 1.***
Use of Biosafety System in regulation of work on and/or use of genetic engineering	*Two field trials were approved in 2001 (for Bt-cotton and Bt-maize). No commercialisation approved as yet. Assessed applications for importation of GM-maize; importation granted with conditions*	*Interim Committee recommended rejection of GM-food aid (July 2002). Case of unapproved trial on GM-maize was reported in 1999 (personal communication with Monsanto- 2001)*	*Interim committee was consulted in the debate on whether Malawi should import GM-food aid or not. Malawi accepted GM-maize, with no conditions set.*	*There have not been any official reports on requests to conduct trials or import GM products. Absence of a biosafety system complicates the situation. However, some food products, especially from SA, are suspected to be GM.*	*Mozambique has already officially received GM-maize, under the condition that it has to be milled before distribution to consumers. A framework is still needed to ensure effective monitoring of GM –products*	*Same as Lesotho. Bt Cotton and maize are currently being grown by farmers in SA bordering with Swaziland and thus the fear for possible contamination*	*Accepted milled GM-maize in 2000. Rejected GM-maize in 2002, and instead received food-aid in the form of wheat as per recommendation by the National Biosafety Committee*
Urgent requirements	*Review of current legislation; to align with CPB, capacity-building, public participation in decision-making processes*	*Enactment of legislation, capacity-building, public awareness*	*Raising awareness on new legislation amongst stakeholders, capacity-building*	*Garnering support from policy makers, development of regulatory framework, capacity-building, public awareness*	*Development of regulatory framework, capacity-building, public awareness*	*Obtaining stakeholder, especially policy-makers' support, regulation development*	*Finalisation of regulation development process, capacity-building, public awareness*

Table 2

6.4 Challenges being faced in development of Biosafety systems

With respect to development of Biosafety systems, there are a number of challenges being faced, and one of the major ones is the non-availability or inadequacy of human resources, be they legal, technical or administrative. A possible solution is to tap the experience in the region by setting up a regional roster of experts.

It is usually a challenge to get the necessary political support. Biosafety might not be a priority area for politicians and it will not become one if there is poor justification for it or poor elevation of the lead institution. This situation is exacerbated by fights over institutionalization, roles and responsibilities. The issues might be seen to fall primarily under agriculture, health, environment or science and technology.

Gaining public participation and support is a challenge. It calls for effective mobilization and communication and finding a means to overcome the scramble for ownership. This situation starkly contrasts in developed countries where there are higher levels of awareness, greater availability of human capital and financial resources, and higher literacy levels and access to information.

Lack of financial support is often a constraint, with initiatives being characterized by few dollars chasing too many priorities. Limited support further constrains effective public participation. A partial solution is to institute a trade-off between cost and level of participation.

The final constraint is bureaucracy or red tape. In some countries, the solution has been to officially 'fast track' the process of developing a national biosafety framework.

7 Some On-going Biosafety Initiatives in Africa

There are currently several on-going international, regional and national level programmes and processes in Sub-Sahara Africa supported by a wide range of multilateral and bilateral donors to promote the development and implementation of biosafety systems. Activities under these programs and processes range from models supporting biosafety policy and framework development (e.g. The Africa model law and the UNEP-GEF projects) to awareness-raising workshops, development of communications materials (e.g., AfricaBio, ABSF), to hands-on technical training (e.g., SARB, BIO-EARN). Most of the support programs are heavily dependent on donor funding, have a relatively short time-frame and no strong institutional home, which raises concerns about their overall impact. It also appears that few capacity efforts are designed around clearly defined concepts for biosafety capacity building, or on a systematic needs assessment as a basis for interventions.

By far the leading player in biosafety capacity building in Africa comprises the UNEP-GEF supported projects on the development and implementation of national biosafety frameworks. Although the UNEP-GEF supported projects are quite comprehensive in scope, they are very much driven by the compliance requirements for countries that have ratified the Cartagena Protocol on Biosafety, and therefore leave ample room for well targeted support activities. Many of these work on the basis of multi-country programs and networks, which is considered as an efficient way to:

- Sharing regional experiences, knowledge and data;

- Promoting dialogue between policy makers, researchers and civil society by initiating the process on a regional basis;
- Catalyzing capacity development at national institutions;
- Pooling of capacity and resources at the (sub-) regional level, complementing expertise among countries (Bhagavan and Virgin, 2002).

7.1 The African Model law

The development of the African Model law on the *Protection of the Rights of local communities, Farmers, Breeders and Regulation of Access to Biological Resources* was a result of a number of initiatives from the Scientific, Technical and Research Commission of the OAU, now African Union, the Ethiopian Environmental Protection Authority and the Institute of Sustainable Development (ISD) – also based in Ethiopia.

The model law was sponsored by the government of Ethiopia and tabled for discussion at the 68th Ordinary Session of the Council of Ministers of the OAU held in Ouagadougou, Burkina Faso in June 1998. The law was adopted and the Council of Ministers recommended that Governments of member states should:

1. Give due attention as a matter of priority to the need for regulating access to biological resources, community knowledge and technologies, and their implications for Intellectual Property rights as entrenched in the international trade regime of the TRIPs agreement
2. Adopt the model legislation and initiate a process at National level of domesticating and enacting it into law
3. Initiate a process of negotiation among African Countries to formulate and adopt an African position on the Convention on Biological Diversity with emphasis on conditions for access to biological resources and protection of community rights
4. Develop an African position to safeguard the sovereign rights of member states and the vital interests of African local communities and forge alliances with other developing countries on the revision of TRIPs

The core principles behind the African Model law are:

1) **Food security and Sovereignty** – especially in recognition of the fact that Africa's role in the rapidly expanding genetic engineering industry has been mainly that of supplying raw materials for research and commerce and **The Right and Responsibility to keep seed free** because seed security is the foundation of food security..
2) **State Sovereignty and Inalienable Rights and responsibilities** - that no indigenous population, whether of individuals or community, nor the government can sell or transfer ownership of resources which are the property of the people and which generation ahs an obligation to safeguard
3) **Community Rights and Responsibilities** – that Indigenous people and their communities, and other local communities have a vital role in environmental management and development because of their knowledge and traditional practices. The Model law provides an opportunity to recognise and sustain Africa's rich cultural heritage and biological resources by recognising the system of pre-existing rights

4) **The Value of Indigenous knowledge –** 80% of the South's medical needs are met by community healers using local medicine systems. The African model law sets out to avoid being rigid and inflexible
5) **Full Participation in Decision Making –** The Model law explicitly recognises the need to ensure the full and equitable participation of the affected communities when deciding on the distribution of benefits arising from access to, and the use of, their biological resources, knowledge and technologies
6) **Access to Biological and Genetic Diversity –** Any access to any Biological resources and knowledge or technologies of local communities in any part of the country shall be subject to an application of the necessary Prior Informed Consent (PIC) and a written permit
7) **Prior Informed Consent –** as the giving, by the information collector, of complete and accurate information, and based on that information, the prior acceptance of that information collector by the government and the concerned local community to collect biological resources, or indigenous knowledge, or technologies
8) **Fair and equitable sharing of Benefits –** that the sharing of whatever accrues from the utilisation of biological resources, community knowledge, technologies, innovations or practices is a right for all local communities consistent with the CBD. **A community gene fund is proposed**
9) **Plant Breeders' Rights –** The model recognises both individual and institutional efforts and investments in developing new varieties of plants – and provides for both recognition and rewards. The plant breeder gets exclusive rights to produce and sell the new varieties produced
10) **No Patents on life Forms –** that the privatisation of life forms through any intellectual property rights regime violates the basic right to life and goes counter to the African sense of respect for life
11) **Towards Gender Equality –** that indigenous women have the right to control and use of biological diversity in their territories and that this should be included in decision making processes at all levels, in accordance with the cultural principles of the people in question. It provides for the appropriate recognition of women as the custodians of Biological diversity

These are the basic principles that are enshrined in this model legislation. African governments are called upon to domesticate these principles into their biosafety frameworks and IPR legislation.

7.2 The SADC Advisory Committee on Biotechnology and Biosafety (SACBB)

At a meeting of the SADC Council of Ministers for Food, Agriculture and Natural Resources (FANR) - held on July 5, 2002 in Mozambique – the lack of a harmonised regional position on GMOs was noted to be creating serious problems in the movement of food and non-food items. Consequently the council advised member states to engage in bi-lateral consultations and to explore mechanisms to facilitate movement of humanitarian food that may contain GMOs. The FANR Ministers approved the establishment of an Advisory Committee to develop guidelines to safeguard Member States against potential risks of GMOs in the areas of Trade, Food Safety, Contamination of Genetic Resources, Ethics, and Consumer Concerns (SADC, 2003). The committee provides advice to countries of the sub-region on issues associated with biotechnology and propose ways of harmonizing their policies and

regulations. The work of this committee will enable SADC countries to develop and adopt a proactive strategy to respond to issues raised by biotechnology.

7.3 UNEP/GEF

The UNEP-GEF global project on the development of National Biosafety Frameworks began in June 2001. This is a three-year project and can assist up to 100 countries in developing national biosafety frameworks so that they can comply with the Cartagena Protocol on Biosafety. The project will also promote regional and sub-regional cooperation on biosafety. The project is able to:

- Assist up to 100 eligible countries to prepare their National Biosafety Frameworks. Using a country-driven process, the global project will help each participating country to set up a framework for management of living modified organisms (LMOs) at the national level, allowing them to meet the requirements of the Cartagena Protocol.
- Promote regional and sub-regional collaboration and exchange of experience on issues of relevance to the National Biosafety Frameworks. This will help to make efficient use of financial and human resources, establish regional and sub-regional networks, and promote harmonization of risk assessment procedures and regulatory instruments.
- Provide advice and support to countries throughout the development of their National Biosafety Frameworks.

These projects, arising though the Global Environment Facility, work primarily through national focal points in the Ministries of Environment. As initial development of guidelines, research and review of agricultural biotechnology originated within Ministries of Agriculture, it is essential that full collaboration be exercised as GEF projects get underway. Dialogue on how best construct national frameworks, legislation and regulatory bodies should reflect policies consistent with environmental and human safety and with the promise, experience, and benefits of new technologies.

7.4 USAID Program for Biosafety Systems (PBS)

In May 2003, the US Agency for International Development decided to award the sum of USD 14.8 million to ISNAR to implement the five-year Program for Biosafety Systems (PBS). As stated in USAID's Request for Applications, the goal of PBS is to "more effectively address biosafety within a sustainable development strategy, anchored by agriculture-led economic growth, trade and environment objectives." PBS work is based on the framework for biosafety implementation that the IBS (ISNAR Biotechnology Service) team developed over the last years through its work in Egypt, Argentina, Kenya and other countries.

The goal of PBS is to "more effectively address biosafety within a sustainable development strategy, anchored by agriculture-led economic growth, trade and environment objectives." Responding to this goal, activities are grouped into four components: policy development/new models; risk assessment and BBI; facilitating regulatory approval; and skills/strategies for communication, public outreach and capacity building. The systems approach to biosafety will evolve through Country and Regional Advisory Groups, targeting policy development through National Biosafety Committees and national/regional policy-making bodies.

7.5 ASARECA

ASARECA (Association for Strengthening Agricultural Research in Eastern and Central Africa) is a non-profit, non-political sub-Regional Organization for the National Agricultural Research Systems (NARS) in ten Eastern and Central African countries. A Committee of Directors (CD) that oversees its activities and provides policy guidance governs ASARECA and maintains a Secretariat that services the CD, the regional Networks, programmes and projects.

The CD established a Working Group to review, analyze and develop a potential program for biotechnology and biosafety addressing the needs of the sub-region. The working group is composed of ten members (one from each ASARECA member country), and is supported by a Coordinator and the ASARECA secretariat. The working group was asked to conduct a broader dialogue among stakeholders; identify the major thrusts and objectives of the program and develop a fundable project proposal.

In consultation with stakeholders, the working group developed a funding proposal for a biotechnology and biosafety program for the ECA countries. The program will support the existing ASARECA crop and livestock networks, but will encourage strong linkages and partnerships with other international, regional, sub-regional and national biotechnology/biosafety initiatives. The proposed program will address the development objectives of the ECA countries by initiating a series of biotechnology R & D projects that clearly address the priorities of the region and an integrated regional approach to biosafety.

7.6 The Forum for Agricultural Research in Africa (FARA)

FARA initiated planning as per its potential role in the area of biotechnology and biosafety. It is looking to add value to work underway through the sub-regional bodies, including ASARECA, CORAF, and entities in southern Africa. At the same time, NEPAD, through its Science and Technology Platform, is tasked with harnessing biotechnology to improve agricultural productivity.

During its recent meeting (May 2003), FARA convened a pre-meeting on biotechnology. Findings of that meeting were passed to the full FARA plenary for agreement. At the same time, a post-FARA meeting was held to build consensus on what FARA may do in biosafety, however that report is not available yet. The pre-meeting recommendations were:

- Add value to national and sub-regional efforts:
- Advocacy role for research and capacity building
- Catalytic role as facilitating partnerships
- Knowledge hub for capacity building.

More detail for each of these suggestions will be under development. However, it is clear that FARA will adopt this agenda and move forward in both biotechnology and biosafety. Advancements or programs adopted by FARA have the potential to contribute a synthesis and “lessons learned” from sub-regional and national experiences. As such, FARA is an important partner for the World Bank.

7.7 African Agricultural Technology Foundation (AATF)

AATF is an African-led, public–private sector partnership set up to respond to the technology needs of resource-poor African farmers, nearly all of whom are smallholders. Such

technologies may be nonpatented, owned by the public sector, or proprietary from private sector institutions. Patented technologies will be obtained free of royalty fees from willing private-sector technology owners for subleasing to research institutions for adaptation to local conditions as need be. The entire technology development and transfer chain from the initial product development to marketing will be addressed. The Rockefeller Foundation and USAID provided the start-up funds for the AATF. There is a Design Advisory Committee (DAC) comprising heads of African NARS, the Rockefeller Foundation, and other donors like USAID, private biotechnology companies in the OECD, African Seed Companies, DANIDA, and DfID. The implementing Director is Dr Eugene Terry, former Director-General of WARDA. Plans are now underway for initial project selection, with working group meetings forthcoming, to discuss advantages and choices between the initial group of proposed projects. As these are adopted, they will present opportunities for additional support. Projects will explore a range of technologies (broad definition of biotechnology) and deliver these to farmers, all of which will need of future financial support.

7.8 Agricultural Biotechnology Support Project II (USAID; Cornell lead institution)

ABSPII is taking a regional approach to developing and delivering bio-engineered crops in Africa. Initial sub-regions are East Africa, with a focus on Kenya and Uganda, and West Africa, with a focus on Nigeria and Mali. ABSPII will conduct activities organized into Product Commercialization Packages. These will include technology development, licensing and regulatory approvals (in collaboration with PBS), marketing and delivery, and outreach and public awareness. A Package will be developed for each product identified during inclusive priority setting processes involving local stakeholders from the public and private sectors.

A close working relationship is being developed with ASARECA including involvement in helping to refine priorities in organization's Biotechnology Initiative. Identification of bio-engineered products to be addressed by ABSPII will be made using information gathered in this exercise. A regional coordinator will soon be appointed to maintain these close links and to help implement the product commercialization packages. In West Africa, a regional coordinator has been identified who will work closely with CORAF in the identification of potential products and in the implementation of development and commercialization activities.

7.9 NEPAD and Plans for Establishing African Centers of Excellence in Biosciences

Canada has recently announced its support in establishing African centers of excellence in "biosciences for agriculture". The new center will serve as a focal point for African scientists to develop the capacity to conduct, drive and fund advanced biosciences research programmes in priority development areas. This concept was also discussed in FARA’s biotechnology side event, introducing the NEPAD initiative in this regard. The principle of using centers to build scientific capacity in Africa was endorsed at a NEPAD workshop held in Pretoria, South Africa in February 2003.

The NEPAD suggestion is based on the recognition that individual country efforts will not provide the necessary capacity for cutting edge biosciences research, and that, in any case, most of the equipment and other infrastructure developments for biotech research are expensive and can greatly benefit from economies of scale, NEPAD has proposed the establishment of sub-regional hubs or centers of excellence in biosciences. A network of laboratories and facilities will work with particular centers, each to be strengthened/upgraded

as appropriate. The proposal would start with a pilot center for the East and Central African sub-region and then gradually build similar hubs for southern Africa, West Africa and North Africa.

7.10 ISAAA African Progam

ISAAA plans to extend its current successful portfolio of projects in Kenya to neighboring countries with similar crop production constraints, particularly Uganda and Tanzania. An estimated 40 million people live below the poverty line in these three countries. In the *banana project,* the demand in Kenya alone is for 30 million tissue culture plants. Bananas are a major food staple and a source of income for over 20 million farmers in Kenya, Uganda, and Tanzania. ISAAA will facilitate the large-scale adoption of this new technology for banana production by collaborating with organizations that have experience and capacity in extension, micro-credit, and marketing. ISAAA has already established micro-credit schemes with NGOs and has also initiated pilot scale activities that will be extended by partner organizations and funded independently by international development agencies.

The following improved traits will be explored in staple food crops for Africa:

- *Banana* plants that can be enhanced through the incorporation of transgenes that confer resistance to important diseases such as Black Sigatoka and Fusarium wilt and/or through the incorporation of output traits that confer improved nutritional qualities and remedies for micro-nutrient and vitamin deficiencies.

- *Sweet potatoes* that are more resistant to sweet potato feathery mottle virus (SPFMV) can be enhanced with transgenes for better resistance to other pests and diseases and/or improved quality. These may include traits such as *Bt* genes for weevil resistance; starch with improved structure, productivity, and digestibility; beta carotene enrichment to correct Vitamin A deficiency; and enhanced iron as a remedy for anemia.

Investing in human capital and institution building is a prerequisite for building national capacity in crop biotechnology, and ISAAA will strengthen its activities in capacity building.

The ISAAA AfriCenter will continue its activities in international forums to help ensure that Africans are engaged, informed, and able to decide on all issues related to biotechnology in Africa. Many international agreements, including those related to the World Trade Organization and the International Biosafety Protocol of the Convention on Biodiversity, will influence activities related to crop biotechnology in Africa. ISAAA will continue to provide advice and background information upon request, with the understanding that the governments of the sovereign states of Africa will be directly involved in the negotiations and decision-making.

8 Summary and Conclusions

Clearly, the content and nature of the debate on how to respond to food insecurity in Africa have been fundamentally and possibly irreversibly altered. So, too, have been those in the debate of how to achieve longer-term Agricultural Growth (AG) through self-sustaining processes of growth fuelled by technological advance in agriculture. The way forward for Africa, thus, lies in overcoming the forces of polarisation and building towards an African

Consensus, as well as, strategies that will help Africa exploit the benefits and opportunities in the field of Biotechnology – while minimising risks through a robust biosafety regime.

This living paper is, thus, a unique opportunity for African experts to flag all key issues in Biosafetydabate that require consensus as way forward for Africa. The living nature of the paper means that it is elastic and is open to more and more additional information from more and more stakeholders. This paper provides information to inform decision makers as to the options and considerations they must take into account as they develop national biosafety frameworks. It draws on information and data from many sources, to illustrate Africa's current stage of development in research and regulation as well as the critical way forward. The paper will guide the development of subsequent discussion, consensus, and content for subsequent African policy dialogues.

Guided by the provisions of the CBD and the Cartagena protocol, it is evident that Africa must brace itself to develop capacity, strategies and approaches to address the following issues:

- *A Clear distinction between Living Modified Organisms (LMOs) and/or Genetically Engineered Organisms (GEOs) / Genetically Modified Organisms (GMOs) – especially in policy documents – because they refer to different components*
- *The Precautionary Principle, versus the Substantial Equivalence Principle - the inclination to exercise maximum caution when making decisions about situations with unknown variables.*
- *Analysing and understanding the Scope of the Cartagena Protocol – as mainly being concerned about trans-boundary movement of LMOs and not necessarily their products*
- *Analysing and understanding the Advance Informed Agreement (AIA) procedure(or Prior Informed Consent – PIC) – as mandatory only for LMOs intended for realise into the environment*
- *Understanding the Risk posed to biological diversity and human health, as well as, the necessary risk management – as the basis for the development, handling, use, import and export of LMOs*
- *Public awareness – education and public awareness about LMOs must not be left to Mass media*
- *Trade and Environment - Is there 'pressure' from industrialized countries and corporations on developing countries to expedite laws for biosafety requirements because of trade interests? Is the Agreement on Trade-related Aspects of Intellectual Property rights (TRIPs) is the most problematic trade law for developing counties in the context of modern biotechnology and LMOs. Is the direction of the debate shifting from environment to trade?*
- *Social-economic considerations – when making decisions on importation of LMOs. This is one of the most critical issues – but is, however, going to remain contingent upon what Africa can achieve in the WTO, especially in the revision of TRIPS.*
- *Identification and Labelling – lasting rules on the handling, transport, packaing and labelling of LMOs and products thereof.*
- *Liability and redress - It would seem logical that if an LMO causes damage, the owner or developer of the LMO should become liable to pay compensation for any damage caused.*
- *Compliance – the need for advice and help to promote compliance with the provisions of the Cartagena protocol*

African consensus around these issues will ensure that the risks posed by Biotechnology do not overwhelm the African population – but that at the same time – the potential benefits are not lost in haste or lack of caution.

An attempt to categorise the contentious issues would place them into, at least, 5 major categories: Policy, Social Economic, Environmental, Technological, as well as, those that are cross-cutting. In seeking to prioritise the consensus building process – it would thus seem logical to address the cross-cutting issues with some urgency. Four thematic issues, that are cross-cutting in nature, need consensus urgently as Africa develops its Biosafety systems:

1. The Precautionary Principle
2. The Social – Economic Considerations
3. Liability and Redress or Compensation
4. Public Awareness

The African Policy dialogues on Biotechnology initiative is indeed “an idea whose time has time has come”.

Endnotes

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