MODERN BIOTECHNOLOGY POLICY AND LEGISLATION IN MALAWI

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1. INTRODUCTION

Malawi is faced with an expanding population and declining resource base from which food security can be achieved. The country has one of the highest population densities in Africa.

It also has a very high fertility rate, albeit the high mortality rate brought about by the aids pandemic. At the same time however a large part of the food production system is traditional and subsistence and barely copes with the increasing demand for food and other essential products necessary for human survival. The need therefore for new technologies to increase capacity in food production cannot be over-emphasised.

Biotechnology which uses living organisms or their substances to make or modify a product for a specific use has become very popular in the developed world and is receiving increasing attention in the developing world for the improvement of crop and animal production as well as in the pharmaceutical industry. On the other hand, the safety and health of these biotechnologies has not been conclusively demonstrated and there are increasing concerns not only with regard to possible adverse effects to human, animal and plant health but also the ethical dimension of these life-changing processes involved. Hence in Zambia the government has banned genetically modified (GMO) maize citing health risks even in the face of acute food shortages which could easily be reduced if GMO maize had been accepted. It follows therefore that it is essential that the promotion of the adoption and utilization of biotechnology must go hand in hand with a robust policy and legal framework, including accurate information dissemination, to protect the public from known and potential risks of modern biotechnology and sensitise them on the benefits of modern biotechnology.

In addition, there are increasing concerns regarding the sourcing of research materials and the sharing of benefits of such research between the developing countries which are in most cases the major sources of biotechnology research materials and the developed countries which have the equipment and technical expertise necessary for harnessing the use of the living organisms or their substances. There are question regarding intellectual property rights which these developed country research and industrial firms acquire from research materials acquired in the developing countries. Most developing country experts consider such biopiracy as an international crime. It harms the poor in the developing countries[1] who are compelled to buy products from their own biodiversity at unaffordable prices merely because the developed country firm has provided the research skills and the financial resources necessary to transform biodiversity products into marketable products. Hence while developing countries such as Malawi stand to benefit a lot from acquisition of biotechnology, the access to and use of the sources of such biotechnology must be properly regulated to prevent biopiracy.

This paper provides a critical appraisal of the policy and legal framework for the promotion and management of science and technology in general and modern biotechnology in Malawi in particular. The paper considers the policy and law pertaining to access to, control and use including safe management of modern biotechnology in Malawi. While the main focus is on modern biotechnology, the paper will also review the critical issue of public participation in biotechnology policy and management issues, especially as it affects the promotion and safe management of modern biotechnology. The paper is intended to provide a framework within which civil society can take a critical role in biotechnology issues using enabling policy

[1] See generally Report of the Commission on Intellectual Property Rights, UK Department for International Development, September, 2002: www.iprcommission.org; Zerner, C (ed) (2000) People, Plants and justice, Columbia, University Press, New York.

and legal framework to facilitate their effective participation. It also explores possible alternatives for developing and or strengthening appropriate institutional frameworks for promoting public participation in science and technology in general and access to and control and safe use and management of modern biotechnology products.

2. THE BENEFITS AND RISKS OF BIOTECHNOLOGY

Biotechnology has been in use in Malawi for a long time. A large component of this biotechnology is however traditional in nature and has to do with processes such as fermentation, animal breeding, plant breeding and tissue culture. The farming sector has consequently been the most important user of this technology in form of hybrid crop and animal varieties, and tissue culture technologies for propagation of banana, sugarcane and cassava crop planting materials. In addition the brewery industry has also benefited from this technology using the fermentation process while the medical industry has utilized this technology for human disease diagnostics and lately in the development of alternative malaria control mechanisms. These technologies can be further improved through use of more advanced techniques of modern biotechnology which can be used to enhance both quality and quantity of the product lines[2].

Modern biotechnology has a number of advantages. It can reduce breeding processes and hence increase yields thereby enhancing food security. Further, the combination of genetic material, which is not possible under natural conditions, provides opportunity for producing disease and pest resistant varieties. There are however many real and potential risks associated with the use of biotechnology.

Firstly, the techniques by-pass conventional breeding and use vectors to multiply genes and carry them into cells that would ordinarily exclude such genes. Unfortunately many of these vectors are derived from disease carrying viruses that have the capacity to invade cells and cause genetic change. The vectors are selected for their ability to overcome species barriers and therefore have the potential to invade and to infect a wide range of species. It follows therefore that such artificially induced genetic change may have adverse impacts on plant and animal life and pose health risks to human beings. As it happens developing countries such as Malawi have little or no capacity to assess the risks posed by products of genetically modified organisms[3].

Secondly, modern biotechnology products have the potential to marginalize traditional methods of food and agriculture production. There is a real threat that small-scale farmers may be lured to abandon their traditional farming and plant and animal breeding techniques that are best suited to their environments, capacity and knowledge. Not only does this prospect threaten biodiversity, it also exposes the farmers to perpetual dependency on western science and technology and its markets many of whose products are patented and have high monopoly prices. In addition, the attraction of increased crop and animal yields

[2] Maliro, MFA, et. Al. (2001) Status Of Biotechnology in Malawi: A Report on Consultations with stakeholders in Biotechnology and Biosafety in Malawi (University of Malawi: Bunda College of Agriculture, Lilongwe).

[3] See Salifu, P (2001) Public Awareness and Attitudes Towards Biotechnology Products in Malawi: A Case Study of Zomba District (Msc Thesis, Faculty of Science, University of Malawi) pp. 7-9.

and disease resistant varieties produced by modern biotechnology, may disturb traditional markets, employment and import substitution which often cushion small scale and subsistence farmers[4].

3. SCIENCE AND TECHNOLOGY POLICY

Malawi has for long time recognised the significance of developing science and technology to create the momentum for development. The National Research Council was established in 1974 to carry out this mandate. The country did not however have any policy to direct national efforts and focus attention on the most critical areas for the development of science and technology until 1991 when the first Science and Technology Policy was adopted by the Malawi Government. That policy was however not fully or effectively implemented for a number of reasons including:

- *The country's pluralistic approach in the management of science and technology;*
- *Lack of integration of the policy in overall development plans of government;*
- *Lack of human, financial and material resources; and*
- *Lack of necessary supporting legislation.*

The mandate of the NRCM was "to co-ordinate and promote the development of research" in Malawi. This mandate met two major obstacles which have adversely affected the performance of the institution. NRCM has been consistently under-funded and has therefore been unable to co-ordinate and develop research effectively. In addition, the NRCM has been moved five times between various ministries and departments since it was created in 1974. It started as a secretariat in the Office of the President and Cabinet, then merged with the Environmental Unit in the then Ministry of Forestry and Natural Resources, later became part of a full Ministry of Research and Environmental Affairs and is now part of the Office of the President and Cabinet[5]. The inability to find a permanent place in the governmental structure may suggest the lack of focus and sustained political commitment to development of science and technology. It is noteworthy as well that over the years the portfolio for science and technology has been given to the Ministry of Education.

It has been recognized therefore that the absence of an institution with the requisite mandate and resources to direct, develop and co-ordinate the country's science and technology system has adversely affected outputs in this field. Malawi lags behind many of its neighbours in the region in terms of technological advancement including science skills of its manpower[6]. The new policy therefore calls for the country "to move fast to intensify the development and application of science and technology without which real economic progress will not be realized"[7].

3.1 The guiding principles

The new policy has outlined a number of principles through which the country will "discipline her development by utilizing her human resources". The following are the principles:

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[5] See National Research Council of Malawi, (2002) Science and Technology Policy for Malawi (National Research Council, Lilongwe) pp. 1-2

[6] *Ibid*, p. 3.

[7] Ibid, p.3

- ✓ Assurance of political commitment to science and technology. This seeks to create awareness of the role of science and technology in development thereby enhance commitment to and provision of adequate resources for science and technology.

- ✓ Integration of science and technology into national development planning: There is need to pay specific attention to the development of a minimum national capability in science and technology as part of the planning process.

- ✓ Maximization of productivity through the application of science and technology. The capacity of the nation to create wealth is highly dependent on the role of science and technology.

- ✓ Application of science and technology to promote international competitiveness: Malawi needs to develop technology to produce goods with high technological inputs which have high value added and are therefore sold at high prices.

- ✓ Creation of a conducive policy environment for the advancement of science and technology. Malawi needs well-defined policies and plans for national science and technology development which can enhance the capacity of national institutions to undertake scientific and technological research and development.

- ✓ Investment in and development and retention of science and technology human resources: science and technology human resources are critical to the development of this sector and hence need to be developed and retained by providing the appropriate incentives and facilities.

- ✓ Application of science and technology to promote sustainable socio-economic development: use of environmentally friendly technologies is essential to achieve sustainable socio-economic development.

- ✓ Promotion of science and technology culture among civil society: increasing awareness of science and technology is critical to developing a culture that accepts and supports science and technology.

These principles provide opportunities for the country to promote science and technology by focusing on the most important areas that require attention. It is clear from the foregoing however that the promotion of science and technology is a multisector effort. The major challenge is to get the policy makers in the various sectors that address these issues to work together towards advancement of science and technology. An important proposal in the new policy is the revision of the institutional framework to guide and co-ordinate science and technology development in the country[8].

3.2 Institutional framework

The Science and Technology Policy proposes the establishment of a National Commission for Science and Technology (the Commission) as a key strategy for enhancing both the development and application of science and technology in Malawi. According to the Policy, the Commission will be established by an Act of Parliament and derive its authority from the Office of the President and Cabinet. This will ensure that the Commission has the necessary authority to direct and co-ordinate science and technology activities at the highest level. A science and Technology Bill Number 17 was

[8] Ibid, p.49.

published by the National Assembly in October 2002 sitting but was deferred to a later date due to shortage of parliamentary time.

Part III of the Science and Technology Bill, 2002 has provided for the establishment of the Commission which shall consist of 10 members who shall be appointed by the Minister from industry, academic, research and development institutions and from civil society. An additional 5 *ex-official* members will be Secretaries for Agriculture and Irrigation; Education, Science and Technology; Health and Population; Natural Resources and Environmental Affairs; and the National Economic Council.

The bill states that the Commission shall be appointed by the Minister. Unfortunately, the bill does not state, as the Policy suggests, the Minister responsible for the administration of the Act or indeed the appointment of the Commission. In accordance with the definition in the General Interpretation Act, 1966 the Minister charged with the matter in question will be the relevant Minister under the new Act. Without regard to the Science and Technology Policy, such Minister could easily be the Minister responsible for Education, Science and Technology or the President when he has assigned to himself the responsibility for the portfolio in question. According to the Policy, the Office of the President and Cabinet is the department responsible for administration of the Science and Technology bill and, in particular, matters relating to the appointment of the Commission. It is not clear however why the draftsman did not specifically stipulate in the Science and Technology bill the exact Minister responsible for the bill in general and the Commission in particular as has been the case in other recent pieces of legislation such as the Environment Management Act, 1996 or the Biosafety Act, 2002.

This ambiguity may affect the implementation of the bill when it is passed by Parliament. Indeed the bill fails to cater for the specific policy direction provided for in the Science and Technology Policy with regard to the need to locate the Commission under the authority of the Office of the President and Cabinet so that it *"reaches the highest levels and all sectors of economic and social development of the Government"*. Another departure from the Policy in the bill relates to the appointment of the chairperson of the Commission. According to the Policy the President shall appoint a high level personality to be chairperson of the Commission. This would have clothed the chairperson with the requisite authority to not only direct the advancement of science and technology in Malawi but also co-ordinate relevant sectoral agencies to ensure they act in tandem with the Policy and the Act. The bill however states that the Minister shall appoint the chairperson. Of course if the Minister happens to be the Office of the President and Cabinet then the high profile nature of the appointment and therefore the authority to be exercised may be assured.

The only provision that seems to be specifically aimed at raising the profile of the Act and the Commission is section 3 which stipulates that:

> *"Every public officer and any authority in Malawi exercising or performing powers, duties or functions in connection with or concerning the commitment of the Government in advancing science and technology in Malawi……shall in the exercise of his powers or the performance of his duties or functions, consider and treat the Policy and Statement as ranking paramount in the business of the Government and shall further consider it to be his paramount duty to act with all due diligence and dispatch…."*

It follows therefore that the bill elevates the Science and Technology Policy and the Statement of National Priorities in Science and Technology as a priority for the Government. The bill also enjoins public officers and authorities to place it high on their agenda. The Policy directions shall have the force of law by reason of the Science and Technology Bill when it is passed into law and thereby ensuring that they will be implemented and enforced as such. It is our argument nevertheless that this

general statutory principle should have been followed by specific mandates and high profile institutional frameworks as anticipated in the Policy itself.

It is worthwhile however to consider whether the establishment of the Commission under the Office of the President and Cabinet as suggested by the Policy would have necessarily provided the requisite authority on its own. The NRCM, for example, has for a long time been under the Office of the President and Cabinet, but that has not, *ipso facto*, given it the edge to carry out its functions and mandates effectively. It still suffers from under-funding and the perpetual problem of sectoral agencies working independently from one another.

The proposed institutional framework can work given the existence of commitment of both the political establishment and the sectoral departments whose functions, mandates and duties promote science and technology in Malawi. Hence while we concur with the Policy that there is need to locate the Commission in an institution with the requisite authority to command respect and give the necessary directions, there is no substitute for political commitment and buy-in by all stakeholders in the advancement of science and technology in Malawi.

3.3 Powers and functions of the Commission

Part IV of the bill provides in great detail the powers and functions of the Commission. These include creating awareness of science and technology matters; promoting the formulation and revision of policies, laws and strategies for science and technology; fundraising and promoting development of science and technology human resources; and creating incentives to attract and retain science and technology human resources. The executive management of the Commission will be carried out by a Secretariat which shall be headed by a Director General to be appointed by the Minister. In particular the Secretariat shall:

- ✓ provide technical and back up services to the Commission,
- ✓ prepare and present to the Commission science and technology programmes for approval
- ✓ maintain liaison with national and international agencies that provide technical and financial support for science and technology development; and
- ✓ co-ordinate all science and technology issues in the country.

It follows from the foregoing that that the Commission has very extensive mandates and functions to carry out to advance science and technology development in the country. What is not clear from both the Policy and the bill is whether the NRCM will be dissolved immediately after the establishment of the Commission. There is unlikely to be any need for the NRCM to continue to operate once we have a functional National Commission for Science and Technology.

Conflicts over biotechnology mandates

Part VIII of the bill, which deals with licences and permits, gives the responsibility for issuing licences and permits relating to science and technology (section 39) in general and biotechnology in particular (sections 36 and 37) to the Commission. Yet according to the Biosafety Act, 2002 the responsibility for biotechnology matters in general and the issuance of permits and licences in particular vests in the Minister responsible for environmental affairs[9]. It is noteworthy that the draftsman literary copied the provisions of the Biosafety Act, 2002 relating to issuance of permits and licences and incorporated them into the Science and Technology Bill (2002). The only

[9] See infra, page 20

modification is the substitution of the Minister in the Biosafety Act, 2002 with the Commission in the Science and Technology Bill. For example, the provisions relating to exemptions from licences, the matters to be taken into account when making a decision as to whether or not grant a licence as well as suspension, revocation and variation of licences (sections 38-45) in the Science and Technology Bill, 2002 are almost word for word with those in the Biosafety Act, 2002. The same is true with regard to matters relating to appeals in Part IX and the structure of the fines imposed under Part X. It is clear therefore that the draftsman was fully aware of the mandates and functions that he had given to the Minister responsible for environmental affairs under the Biosafety Act, 2002 when he later drafted the Science and Technology Bill, 2002.

Two points may be made in connection with this institutional conflict. The first is that from a purely technical perspective, according to normal rules of legislative interpretation, Parliament will be deemed to have recognized and used its powers to change its mind in the Science and Technology Act when enacted. Hence the Science and Technology Bill, 2002, will be deemed to have amended the Biosafety Act, 2002. The second is that from a substantive point of view, it would appear the Commission would have been well placed to deal with and co-ordinate matters of biotechnology since this is merely a part of technology which is the overall responsibility of the Commission under the Policy and bill. It is therefore essential that Parliament must re-consider the Biosafety Act, 2002 in the light of the Science and Technology Bill, 2002.

3.4 *Proposed Amendments to the Science and Technology Bill, 2002.*

Since the first draft of this paper was circulated in November 2002 the draftsman has proposed some changes to the Science and Technology Bill while it is in Committee Stage of Parliament. In terms of a notice dated 9th May, 2002 the following substantive changes have been proposed:

(a) Clause 37 is amended and is to read "Notwithstanding the provisions of the Biosafety Act (No. 13 of 2002) and any other Act, no person shall engage in any matter related to biotechnology without the prior consent of the Commission".

The effect of this proposed amendment would be to vest powers over matters of biotechnology in the Commission, hence the Biosafety Act in so far as it seeks to regulate biotechnology will be amended accordingly. In addition, the margial note to clause 37 which read "biotechnology licence" will read "biotechnology consent". Apparently there is a difference between the two.

(b) Clause 38 which was word for word with section 18 of the Biosafety Act, 2002 will be deleted. The aim of the proposed amendment is to vest the Environmental Affairs Department with the powers of licencing biotechnology use. Nevertheless the consent of the Commission under the Science and Technology Bill will be retained.

The effect of this proposed amendment is to establish a two tier 'licencing system over biotechnology in Malawi. It is not clear as to why such a bureaucracy is needed. There is definitely need to streamline responsibilities here. Further in spite of these proposed amendments, there is likelihood of continued conflicting mandates between the Commission and the Environmental Affairs Department. Clause 39 (the new clause 38), for example gives licencing responsibility over Science and Technology to the Commission. The boundary between biotechnology and science and technology will be a contested terraine since none of the legislation attempts to define these terms

(c) Clause 42 which was word for word with section 22 of the Biosafety Act will be deleted. The reason for the amendment is that it dwells very much on biotechnology. The reasoning seems to be that biotechnology is dealt with under the Biosafety Act. Hence the Commission apparently

will only deal with technology other than biotechnology. On the other hand, the Science and Technology Bill still gives the Comission powers to issue consents in any matter related to biotechnology. The difference, if any, between issuing consents and permits is a mystery.

It is clear therefore from the foregoing that conflicting mandates will continue between the Commission and the Environmental Affairs Department over biotechnology.

These comments raise a more fundamental issue. Do we need a separate policy and legislation for biotechnology and biosafety? This question affects both the substantive and institutional framework for biotechnology management and therefore the overall implementation of the policy and legislation. The Science and Technology Policy addresses biotechnology and biosafety issues and lays the framework for the implementation in terms of strategy. The points of aaction and strategies stipulated thereunder cover exactly the issues the Biosafety Act has covered. Indeed the current freamework of policies and legislation suggests that biosafety is a subset of biotechnology which is itself a subset of tehnology. Ideally one policy and legislaive instrument would be more appropriate. This would eliminate the current duplications which are giving the drafts a headache.

3.5 *The Science and Technology Fund*

Part VI establishes a Science and Technology Fund whose objectives are for the advancement of science and technology in Malawi. The fund shall consist of funds appropriated to it by Parliament, levies imposed by the Commission under section 32, advances made by the Minister responsible for finance under section 26, voluntary contributions or donations made in favour of the Fund and funds paid in respect of services rendered by the Commission.. The specific uses to which the Fund may be put are stipulated in section 28. These include financing, by way of loans or grants, research or studies in matters relating to the development of science and technology; making awards to persons qualified under the Act; and providing support for science and technology development and its application.

As in the Biosafety Act, 2002, this is a Government fund and no other stakeholders will be involved in its management. It is vested in the Minister who must administer it in accordance with Finance and Audit Act. The comments made in respect of the Biosafety Fund equally apply here. It is not clear, for example, why the Act did not vest the Fund in the Commission with so that it can be administered by the Commission which is a multi-sectoral body which may command confidence with potential benefactors of the Fund.

4. REGULATION OF GENETIC RESOURCES

Section 4 of the Environment Management Act, (EMA) 1996 provides for the ownership and protection of natural and genetic resources. It states that

The natural and genetic resources of Malawi shall constitute an integral part of the natural wealth of the people of Malawi and

a) shall be protected, conserved and managed for the benefit of the people of Malawi; and

b) save for domestic purposes, shall not be exploited or utilized without prior written authority of the Government.

This provision makes it clear that no single individual, organization, even Government owns the natural or genetic resources of Malawi. They are the property of the people of Malawi. This is in accordance with the Constitution of the republic of Malawi, for example, which vests all lands and territories of Malawi in the Republic, in the people of Malawi (section 207). The Government has supervisory and custodian functions in the same manner as a trustee has, to ensure that such trust property is utilized and managed for the benefit of the people of Malawi, who are its beneficiaries. In addition, and specifically targeting the potential for biopiracy of genetic resources, the provision makes it clear that the exploitation or utilization of the country's natural or genetic resources must not be taken outside Malawi for whatever purpose without prior consent or authority of the Government.

According to section 8 of the EMA 1996, the Minister responsible for environmental affairs is the responsible authority for promoting the protection of the environment and sustainable utilization and management of natural resources. He is also responsible for the administration of the Act. Hence the protection, conservation, management including sustainable utilisation of natural and genetic resources under section 4 is the responsibility of the Minister of Natural Resources and Environmental affairs. Section 2 of EMA 1996 defines natural resources as the natural resources of Malawi wherever located while genetic resources are defined as genetic material of actual or potential value. Hence biotechnology which uses living organisms or substances from those organisms (genetic materials) to make or modify a product is a technique that uses natural or genetic resources. It follows therefore that the use of biotechnology is regulated by the EMA 1996 and administered by the Environmental Affairs Department. This is the basis upon which the Biosafety Act, 2002 was drafted. Indeed the EAD could have drafted regulations under section 4 as read with section 77 of EMA 1996 without promulgating a new statute and thereby spending more time. EAD could however have delegated this particular function to the Commission under the Science and Technology Bill, 2002 since EAD's major function is that of sectoral co-ordination and not the actual management of natural resources. Indeed in terms of section 6 of EMA 1996, the Act does not in any way divest any lead agency of the powers, functions, duties or responsibilities conferred on it by any written law. Such an approach could have avoided the current conflict between EAD and the proposed Commission.

4.1 Procedures and Guidlines for Research

In fact in actual practice the NRCM has taken the lead in formulating policies and guidelines for the prospecting, research and development issues pertaining to the use of the country's genetic resources. The NRCM was empowered under a Presidential decree of 1974 to co-ordinate all research activities in Malawi and to ensure that all research projects contribute to national development. The NRCM has an inter-sectoral committee on Genetic Resources and Biotechnology which is mandated to grant approvals for the collection and exportation of genetic resources for research purposes. Unfortunately this Committee has no legal mandate from any existing legislation and its activities may easily be challenged at the moment. The approvals are required where foreign scientists come into Malawi to collect genetic resources or when local scientists collect genetic materials and export them to foreign research institutions. Through this approval mechanism it was hoped the country could monitor and control loss of genetic resources and realize benefits of the research results. The system did not work well as many foreign and local scientists continued to collect and export genetic materials without proper approvals. In response, the NRCM

produced *Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi, 2000* which regulates the collection of Malawi's genetic resources by foreign researchers and scientists to ensure that these resources remain valuable assets for socio-economic development[10].

The procedures and guidelines provide for the roles and responsibilities of Affiliating Institutions, being those institutions the researcher will work with; certifying institutions being government institutions designated to control certain sectors of genetic resources; and the NRCM. The latter grants research approvals while the certifying institutions issues certificates of collection to the researcher and provides counterpart staff to accompany the researcher while the affiliating institution provides the space and 'home' for the foreign scientist. Any export of genetic material will require a licence from the Minister responsible for Natural resources and Environmental Affairs. A non- refundable fee which defers depending on the use of the research must accompany all applications. Hence academic and research institutions attract a lesser fee than commercial or private institutions. The procedures and guidelines outline detailed responsibilities to ensure that foreign research is monitored and benefits the country. Some of the responsibilities of the various institutions are:

- ✓ to encourage productive research collection and collaboration with foreign recipients for collected materials in Malawi;
- ✓ to ensure that foreign researchers on field trips are always accompanied by appropriate staff paid for by the foreign researcher;
- ✓ to verify that duplicate specimens are deposited with an appropriate designated local research institution;
- ✓ to ensure that endangered species, including special studies such as those involving sharing of certain traditional knowledge, are not collected or carried out without a valid waiver from NRCM;
- ✓ to ensure that all research on genetic resources has the necessary approvals, certificates and or, where necessary, export licences;
- ✓ to ensure that the researcher compiles a complete list of all collected genetic resource materials and a copy submitted to NRCM within three months;
- ✓ to ensure that the researcher carries out his investigations in accordance with agreed methods and set guidelines;
- ✓ where the research involves use of traditional knowledge, to ensure that prior informed consent has been obtained from the communities concerned.

[10] See National Research Council of Malawi (2000), Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (National Research Council of Malawi, Lilongwe) pp. 1-3.

These guidelines and procedures are exhaustive and may seem cumbersome and bureaucratic. However, considering that it is very easy for foreign researchers to 'cut corners' where only one institution is involved and thereby frustrate the policy, it is essential that an elaborate framework such as this be implemented and complied with.

In addition to the guidelines above the NRCM is promoting the use of agreements to regulate the relationships between the collectors, NRCM and their foreign researchers . These instruments include:

- ✓ research agreements which define research collaborations between local research organizations and their foreign partners and rights and obligations between the parties in case of private sector collections; and

- ✓ material transfer agreements which define facilitation access to genetic resources for non-commercial use such as taxonomy/ethno botany or for routine purposes such as teaching.

The NRCM is in the process of drafting specimen agreements for this purpose. The specimens that have been drafted include:

- ✓ Material transfer agreement for academic collectors for research use only

- ✓ Material transfer agreement for non-profit making collectors

- ✓ Research agreement for profit making collectors

- ✓ Community resource rights clause for use with collection on customary land

- ✓ Material transfer agreement for personal use with no possibility of third party transfer

- ✓ Agricultural germplasm agreement for use with non profit collectors

- ✓ Immigration proforma contract

These drafts are intended to provide guidance for different researchers and their foreign partners. The Genetic Resource and Biotechnology Committee will be the authority to approve research agreements. The approved agreements endorsed by the Committee while those rejected will be returned for revision. Hence an agreement will only be valid after being signed by the parties and endorsed by the Committee. According to the procedures and guidelines, the Committee may withdraw certificates without notice or giving reasons to the researcher. This provision can easily be challenged since it offends principles of natural justice which apply under all situations under the Malawi Constitution.

Finally, the procedures and guidelines require the researcher to acknowledge Malawian input into the research on publications resulting from the research. Copies of the publications, including raw data in the case of academic non-proprietary research; or data or a subset of data, in case of proprietary research, must be sent to the affiliating institutions in a timely

manner. These provisions ensure that the results of the research are stored in Malawi and therefore available for future reference.

These procedures and guidelines will have to be revisited in the light of the Science and Technology Policy, 2002 and the Science and Technology Bill, 2002. They may be enacted as regulations so that they have some force of law and can therefore be enforced in terms of the existing legislation.

4.2 Material samples and technology change

The procedures, guidelines and draft agreements reflect growing attempts by developing countries to 'tame a slippery beast'[11]. It is widely acknowledged that what is lucrative is not the ownership of a sample rather the information that is extracted from the sample and it is the control of access to that information that is critical. Such transformation of sample material is beyond the ability of centers of origin such as Malawi to track. Hence any agreement to govern the exchange of such materials must deal not only with the multiplicity of transactions through which the sample may go but also '[12]a resources that is inherently fluid, immutable and dynamic'. The agreements that are being drafted continue to treat the resource as a sample and not information. Hence they cater for compensation in form of fees or royalties per sample. Such fees will generally be low since it is rarely certain that the sample will yield something very valuable. Even when it does, the claimants assume the collector will go back to the source for more in situ collections. However technology is making it easier to replicate the materials in the laboratory. And there is no guarantee that the source will be the only source. Further, there is little likelihood that sources of origin of materials can effectively control the successive use of the materials. Once the material has been handed over to a collector, there is little prospect that its use may be controlled. Material Transfer Agreements may be used to make these agencies to declare the sources of materials and to pay compensation to the suppliers. The situation may however be further complicated if a collecting agency goes into bankruptcy or is subsequently found to be bogus. Very few developing country institutions have the capacity to search for details and verify and therefore be able to monitor. Finally, technology is making it possible to store samples for a long time. By the time it is used the suppliers and the agreements will be very dim history indeed[13]. These are very real challenges to the procedures guidelines and the agreements being drafted.

4.3 Intellectual Property, indigenous knowledge and biotechnology

As observed in the foregoing paragraph, access to and control of information, especially privileged information which provides a competitive advantage for a firm discovering a new product, is the most important form of wealth and has created a wholly new economy. This has brought two separate but related problems for poor developing countries such as

[11] Parry, B (200) "The Fate of the Collections: Social Justice and the Annexation of Plant Genetic Resources" in Zerner, C (2000) (ed) People, Plants and Justice: The Politics of Nature Conservation (Columbia University Press, New York) p. 374 at387.
[12] Ibid, p393.
[13] Ibid pp. 386.

Malawi. Not only is access to such technology not equitably distributed, but also the intellectual property rights regime which enables the holders to exclude others from use of such technology makes it very difficult for developing countries to catch up. This in fact is the context within which the World Trade Organisation's agreement on Trade Related aspects of Intellectual property Rights (TRIPS) was adopted. The agreement allows for the 'commodification and monopolization of the embodied alterations made to the genetic and biochemical information'[14]. Such information is being patented by corporations and private research institutions mainly in the developed world as new products in their own right. "(P)ower and profit derive from the ability to actively restrict the circulation of information through the use of the patent"[15]. It is essential therefore for a country such as Malawi to deal with the question of intellectual property rights as an issue of development control and not merely as a private commercial matter. The availability and access to life saving medicines and sources of livelihoods may be adversely affected by the application of intellectual property rights[16].

The Science and Technology Policy recognizes the importance of intellectual property rights, especially patents, as a source of technological information essential for the beginning of any project for new product development. The Policy seeks to promote the use of patents for upgrading technology especially in the industrial sector of the economy. It stipulates a number of strategies for achieving this objective. These include setting up sound and user friendly patent information, assist in reviewing intellectual property legislation to make it in line with international practice and enhance interaction between Malawian inventors and those from other countries.

While noting the potential conflicts between cultural beliefs and scientific challenges, the Policy recognizes the significance of indigenous knowledge systems especially in relation to traditional medicine. The policy therefore calls for the identification, development and protection of indigenous knowledge systems. In particular the policy recognizes the inherent weakness of the classical "western" intellectual property rights regime to protect indigenous Knowledge systems whose ownership structure is largely communitarian in character and therefore cannot be protected by the individualistic western intellectual property regimes. The Policy stipulates a number of strategies for achieving the identification, development and protection of indigenous knowledge systems. These include commissioning studies to identify, isolate and document IKS, promote training in IKS, establish incentives to promote generation and utilization of IKS and develop legislation which protects rights of origin of IKS.

It is noteworthy that although the Policy identifies the potential conflict between IKS and the classical intellectual property regimes and therefore calls for the protection of IKS through appropriate legislation, it does not seek to harmonise the apparent conflict, which has been widely recognised, between the WTO TRIPS Agreement and the protection of biotechnology resources in the developing world. In fact the Policy calls for the amendment of the existing Patents Act and related legislation in order to comply with the TRIPS

[14] Ibid, p. 386.
[15] Ibid.
[16] See UK Commission on Intellectual Property Rights (2002) Integrating and Intellectual Property Rights and Development (Commission on Intellectual Property Rights, London).

agreement. It would be important for the Policy to specifically recognize the conflict that the TRIPS agreement has brought about especially with respect to biotechnology prospecting and the patenting thereof and then deal with specific policy objectives which the Malawi Government needs to follow with respect to the Agreement. In particular, the Policy should have paid specific attention to the response offered by African countries in the OAU Model Legislation for the Protection of Community, Farmers and Plant Breeders Rights, to utilize a window provided by the WTO TRIPS article 27 (3) (b) to develop sui generis for their own peculiar circumstances.

Further, the Policy does not address the institutional capacity building for IKS in Malawi. Organizations such as the Herbalists Association of Malawi and the farmers organizations which are directly involved in issues of IKS and the manner in which the intellectual property regime affects their work ought to be facilitated. These need to be sensitized and provided with the necessary framework and support to enable them contribute effectively to the implementation of the Policy.

5. BIOTECHNOLOGY AND BIOSAFETY

The Policy recognizes the important contributions that modern biotechnology is making to production systems in agriculture and health delivery. It further notes that apart from the establishment of the Molecular Biology and Ecology Research Unit established at the University which is an important entry point for the country to adopt third generation forms of biotechnology, the country's capacity in biotechnology has been limited to first and second generation forms of biotechnology such as fermentation and tissue culture.

The Policy further recognizes the significant steps taken by the Malawi Government in developing a legal framework governing biosafety issues in Malawi. Parliament passed the Biosafety Act at its last sitting in October this year. The Act is awaiting signature by the President and should become operational fairy soon. The Policy however outlines various strategies to promote the development of biotechnology in Malawi. These include establish and or strengthen centers of excellence in specific areas of biotechnology, increase awareness in biotechnology, enhance human resources capacity and establish a national programme of action, capacity to monitor and evaluate programmes of international co-operation in biotechnology. It is clear therefore that the Science and Technology Policy was drafted and adopted more or less at the same time that the Biosafety Act was enacted. Yet the conflicting mandates discussed earlier were not considered.

5.1 The Biosafety Act 2002

Following the country's signing of the Biosafety Protocol in 2000, a Biosafety Bill was drafted by the EAD after wide consultations with various stakeholders. Parliament enacted the bill at its last sitting in October 2002. This part reviews the major provisions of this legislation with specific attention to issues of stakeholder involvement in its implementation and enforcement.

Part II deals with the institutional framework and administration of the legislation including the specific functions and duties of the responsible agency. The Minister responsible for Environmental Affairs is given overall responsibility over the administration of the Act "and

such other officers subordinate to him as may be appointed under this part". This provision is repeated under section 5. The Minister is vested with several functions under the Act. These include formulating and reviewing guidelines on biosafety, liaising with institutions involved in biosafety, promoting awareness in biosafety and approving safety aspects of import, export, manufacture, processing and selling of genetically modified organisms.

The Ministry of Natural Resources and Environmental Affairs, especially the Environmental Affairs Department is the agency responsible for co-ordination of environment and natural resources issues in Malawi under the Environment Management Act 1996. Issues of biotechnology and biosafety in Malawi are a responsibility of different government or quasi government agencies. These include the departments of forestry, agriculture, health, trade and industry, the NRCM and statutory bodies such as the Malawi Bureau of Standards, the University of Malawi and the National Herbarium and Botanical Gardens. Within these departments and parastatal organizations, there are specialized research institutions which deal specifically with biotechnology products.

Hence, the Forestry Research Institute of Malawi (FRIM) as the research arm of the Department of Forestry is involved in forestry plant breeding and propagation; Chitedze and Bvumbwe Research stations and the Central Veterinary Laboratory of the Ministry of Agriculture are involved in agricultural plant and animal breeding as well as animal disease diagnostics; within the University of Malawi, Bunda College of Agriculture, Chancellor College and College of Medicine are involved in research in plant and animal breeding, molecular markers and diagnostics respectively.

There is therefore the need for an institution that can co-ordinate the development of biotechnology in terms of policy direction, funding framework and issues involving international co-operation. The EAD as the agency responsible for co-ordination of environmental issues was given that role. There is need however to harmonise the provisions of the Biosafety Act, 2002 and the Science and Technology Bill, 2002 to streamline functional responsibilities of various agencies.

5.2 The Biosafety Fund

Part III establishes a Biosafety Fund whose objects shall be the safe management of biotechnology activities. In particular, section 12 stipulates the uses to which the fund may be employed. These include:

- Research and training to promote the safe management of biotechnological activities.

- Acquisition of land, equipment, materials and other assets for the construction of buildings in order to promote the objects of the fund;

- The cost of any scheme which the Minister considers to be in the interest of the safe management of biotechnological activities;

It has been established that the country's human resources and infrastructure facilities in biotechnology management are very inadequate (Maliro M et. al, 2001). The Fund would

therefore cater for a major gap in the country's efforts to promote and safely manage biotechnology.

The sources of the Fund are stipulated in section 7 (2). These include

- Monies appropriated by Parliament for the purpose;
- Fees, levies and penalties payable under the Act; and
- Voluntary contributions and donations received for the purposes of the Fund.

The sources are, on the face of it, adequate to constitute a viable fund for the management of biotechnological activities in the country. It is noteworthy, however, that a number of pieces of legislation pertaining to environment and natural resources management in the last few years have established funds to cater for the promotion of statutory objects under their enabling legislation but none of these funds are in place. These include the Environmental Fund under the Environment Management Act, the Fisheries Fund under the Fisheries Conservation and Management Act, 1997 and the Forestry Fund under the Forestry Act 1997. It is not certain therefore that Government will find the necessary resources to establish the Biosafety Fund. Moreover, considering the obscure nature and hence the kind of priority that may be placed on it by Government, it is unlikely that we can see a Biosafety Fund soon.

This is a situation which requires lobbying by civil society including institutions that are involved in biotechnological activities to ensure the Fund is constituted and utilised for the purposes for which it has been established. Hence voluntary contributions and donations can be made to the Fund through civil society fund raising as well as those of the institutions involved in biotechnological activities, whether governmental or quasi government. These organisations can be involved in joint fund raising activities through project proposals. Such joint activities can attract funding from diverse sources and increase the country's chances of advancing in biotechnological activities.

There is however one major obstacle which can significantly reduce civil society enthusiasms for such fund raising. The Fund is purely governmental (section 9) and does not allow any space for civil society participation in its set up or management. This is a major short fall in the legislation and will adversely affect fund raising activities. Most donors and contributors are demanding transparency and accountability in funds management. Due to government record in previous funds management, some donors or potential contributors would not be very comfortable with a wholly government managed fund.

The presence of civil society in the management of the fund would have encouraged donors to contribute to the Fund. Moreover in view of the fact that government activities in research including and especially new research such as biotechnology are unlikely to be increased due to funding constraints, it would have been more meaningful to seek to facilitate civil society, private and quasi governmental research activities through the Fund. A trust fund encompassing the participation of major stakeholders would have been more

participatory and facilitate more players in the promotion and safe management of biotechnology research.

5.3 Licences and Permits

GMO licences

Part IV of the Act requires that a person shall not engage in the following activities without obtaining and except in accordance with licence granted under this Act, namely:

- genetic modification of organisms (GMOs);
- importation, development, production, testing, release and use and application of GMOs; and
- use of gene therapy in animals or human beings

The Minister responsible for environmental affairs is the licencing authority responsible for the granting, renewal, variation, suspension and revocation of licences. In certain special cases the Minister may grant a permit to an applicant to engage in activities stipulated above without a licence. Permits may be issued for scientific research and experimental purposes, and emergency supply of food for human beings. Such a permit may exempt the holder from any of the provisions of the Act.

Other Licences

The Act further requires business retailers to take out a product licence if they want to be engaged in trading in GMOs or their products. Section 19 provides that no person may engage in the business of selling, exporting, supplying or procuring for sale, export or supply or manufacture of GMOs or their products without a licence issued under the Act. There are also requirements for licences for persons engaged in the business of manufacturing of GMOs or their products, wholesale dealing in GMOs or their products and retail pharmacy business. The Minister may however specify in the *Gazette* circumstances in which importation of GMOs or their products may be exempted from the provisions of section 19.

The Act stipulates in some detail the matters the Minister shall consider before issuing a licence under the Act. These relate, *inter alia*, to the safety, efficacy or quality of GMOs or their products as well as the premises, procedures and equipment to be used (section 22). In addition the Minister shall consider whether the person is a fit and proper person to deal in GMOs or their products under the particular licence applied for (section 23).

Upon being satisfied of these matters the Minister shall then issue the licence subject to such general or special conditions as he shall deem fit. The general or special conditions that the Minister may impose on the licence may provide for adequate safeguards to ensure that the GMOs or their products will be properly managed. They provide for space for the compromise where it may appear to the Minister that giving a blanket licence will threaten the environment such as plant and animal life including human beings.

The Act however does not provide for the participation of either governmental or quasi-governmental institutions in considering whether or not a licence should be granted. There is no provision for members of the general public or civil society to lodge objections to applications for GMO or other licences under the Act. Although the list of matters to be considered by the Minister before issuing a licence are exhaustive and may assist in GMO environmental impact assessment, there is clearly need to ensure that other stakeholders who may be affected by the licence provide in the decision making process and voice their concerns accordingly.

Hence the only available remedy is an appeal under the Act. However, since the question of an appeal is *post facto*, any relief granted may come too late after damage has already occurred. That is why an EIA style licence and permit application process would be much more preferable and effective as not only can it reduce potential harmful effects of GMOs and their products but it can also provide the necessary mitigation measures and prepare the affected communities for the foreseeable impacts of the GMOs.

5.4 GMO Labeling and Advertisement

According to section 26 all containers or packages used in the course of business of selling or supplying GMOs or their products must be properly labeled in accordance with regulations made under section 41. Subsection 2 prohibits false descriptions or marks of containers or packages of GMOs or their products and descriptions or marks of GMOs or their products which are likely to mislead as to their nature, quality, efficacy or quality. This also applies to any leaflets supplied with together with GMOs or their products (section27). Any violation of these provisions is an offence and attracts a penalty as provided for under section 40 of the Act.

The Act further provides power for the Minister to make regulations which may prohibit advertisements that are likely to lead to the use of GMOs or their products or of a type that may be stipulated in the regulations. The regulations may also prohibit use of words or phrases likely to mislead the public as to the nature or effects of the organisms or products (section 28).

6. ENFORCEMENT AND APPEALS

Part IV provides for powers of inspectors who shall be appointed by the Minister. The Act does not state as to where the inspectors will be appointed from. This leaves room for the inspectors to be appointed from any department as long as they are competent in biotechnology or biosafety and as long as there is no conflict of interest. It follows therefore that the Minister would not have to make fresh appointments where there is capacity in sectoral departments. The inspectors are given extensive powers to enter, search and seize any article or sample from premises where they suspect there is contravention of the Act. The inspectors may also require the production of such documents or books relating to the organisms or their products as they may. Non-compliance with an inspector's demands in terms of the Act or the making of any false declarations to the inspectors is an offence. The Act protects commercial information and it is an offence to disclose information obtained pursuant to the Act to an unauthorized person.

Part VIII deals with appeals against decisions made or acts carried out under the Act. Thus an appeal may be lodged within thirty days against any decision relating to the granting of licences under the Act or any decision applicable to the appellant made under the Act. The Minister shall appoint an Appeals Committee to hear such an appeal. It is interesting to note that an Appeals Committee may be appointed by the Minister to hear an appeal against a decision made by the Minister himself. Two things are likely to happen to the detriment of the appellant: either the Minister will not appoint the Committee if he feels he will be embarrassed or, if he does, he will appoint a Committee that may be biased. Of course the decision of the Minister may be challenged in the High Court. Secondly, a decision of the Appeals Committee may be subject to judicial review according to section 37 (3). It is however essential that the Act should constitute an appeals body that is credible and does not depend on the goodwill of the Minister for its availability.

Further, the Act suggests that only persons who are directly affected by a decision can institute an appeal. Section 35 states that the appellant must be aggrieved by the decision or that the decision must be directly applicable to him. Thus persons who merely feel a general duty to enforce the law or to correct a wrong have no standing. Non-governmental organizations and other members of civil society may not institute an appeal on behalf of disadvantaged communities because any such appeal would not directly affect them. This restriction will adversely affect the implementation or the enforcement of the Act.

The Powers of the Appeals Committee are established under under section 37 (1). It can confirm, vary or set aside any decision before it; it can refer the matter back to the Minister for his re-consideration; it can compel persons to testify before it and can call, admit or exclude such evidence as it may deem fit for its own use.

Finally the Act provides for penalties for violation of the Act. There is a fine of K1000000.00 or an amount equal to the financial gain obtained by the person found guilty, whichever will be greater. These are very high penalties and may provide the necessary deterrence. They are definitely proper considering that the perpetrators are likely to be profit making bodies or at least adequately funded organizations. In addition, the court may order that the offending GMOs or their products be forfeited or destroyed and any costs incurred thereby be recoverable from the convict as a civil debt.

7. CONCLUSIONS AND RECOMMENDATIONS

Malawi has taken significant steps to improve the advancement of science and technology. A Science and Technology Policy was approved in August 2002, while a Science and Technology Bill was published for consideration by the National assembly in October 2002. A Biosafety Act was enacted in October, 2002. All these instruments deal in one form or another with the subject of biotechnology. The policy and legislation provide a framework for the enabling principles and strategies including the institutional framework for facilitating the co-ordination, promotion, development and safe use and management of biotechnology and its products. This review has noted that there are conflicting mandates among implementing agencies which need to be resolved.

The Biosafety Act has provided a detailed regulatory framework for GMOs and their products. Admittedly, the country may lack adequate resources to provide the necessary

skills and manpower for the effective management of GMOs. However, the Act has the necessary mechanisms for ensuring that the promotion and development of GMOs and their products is done in a safe and responsible manner. What may be critical is the dissemination of information about GMOs and their products so that the public can utilize the policy and legislative framework effectively. This is a task which should jointly be undertaken by Government and non-state actors.

There are some gaps and uncertain provisions in the policy and legislation which this analysis has outlined. They are summarized below with the recommendations for possible improvements. These are:

7.1 Institutional Arrangements

- ✓ It is important for the legislation to clarify the functional responsibilities of the Commission and the EAD. A reading of the Biosafety Act and the Science and Technology Bill suggests that both agencies can grant GMO and other biotechnology related licences. We recommend that this function be given to either of the institutions but not both.

- ✓ The establishment of the Commission may contribute to the advancement of science and technology in Malawi if its authority and mandate are sufficiently elevated as to command respect from all relevant sectors. However the Science and Technology Bill is at variance with the Science and Technology Policy in this respect. The Commission under the bill is appointed by the Minister as opposed to the President as recommended in the Policy. We recommend that the Commission be appointed by the President and be answerable to him or her. Of course this alone will hardly substitute for a sustained political commitment.

- ✓ The Biosafety Act completely ignores the involvement and participation of non-state actors in the safe use and management of biotechnology. The Minister is given powers to promote biosafety issues with no regard to involvement of civil society. The Science and Technology Bill on the other hand incorporates non-state actors through membership of the Commission. We recommend that the Act should require the responsible Minister to consult other relevant agencies including non-state actors in the exercise of the powers under the Act.

7.2 Funding

- ✓ Both the Biosafety Act and the Science and Technology Bill provide for the establishment of funds to promote the objects of the statutes. The first observation that has been made is that so many statutes have established funds that are not operational. There is no evidence that these new statutory funds will actually be operational. On the contrary, with cost cutting measures being announced by the Ministry of Finance on a regular basis, there is very little chance that the funds will actually be funded. The second point is that the establishment of the funds as purely government funds reduces their chance of being funded when traditional government donor agencies withhold aid on the grounds of

mismanagement. We recommend that the funds be established as trust funds to be managed by a board of trustees that includes both state and non-state actors. Such funds may attract some donors who are demanding transparency and accountability and see little or none in government institutions.

- ✓ Alternatively the government may wish to consider establishing one fund to cater for the environment and natural resources sectors. Even then the involvement of civil society will still need to be seriously considered to increase the chances of the fund being funded.

7.3 Regulation and management of genetic resources

- ✓ The collection and use of genetic resources from the developing world is raising increasing concerns. The NRCM has put in place measures and strategies to ensure that such collection is sustainable and also provides benefit to Malawi as a source of origin. Procedures and guidelines have been developed and draft specimen agreements between local researchers and their foreign counterparts are being prepared to facilitate effective management. These procedures however proceed on the basis that the collection is a physical sample for which fees and loyalties for its use must be paid. It ignores the increasingly important informational resource that is extracted from the sample which is very difficult to track down. Such a resource may be stored for a long time and used when the source can hardly be identified and when the agreement is unlikely to be enforceable. The solution would be to charge an adequate fee at the time of collection, unfortunately one can never tell the true value then.

- ✓ The Science and Technology Policy recommends that Malawi amend the Patents Act so that it complies with the WTO TRIPS agreement. This agreement is however a subject of major concern from developing country experts who believe it will only benefit western multinational firms. These companies will patent genetic material collected at a pittance from the developing countries and sell the products thereof at unaffordable prices back to the developing world. We recommend that Malawi should develop sui generis policy and legislation taking advantage of article 27 (3)(b) of TRIPS. In particular Malawi should develop such policy and legislation along the lines of the OAU Model legislation for the Protection of community, farmers and breeders rights that was endorsed by SADC Ministers.

7.3.1 Policy Framework

We recommend that biotechnology and biosafety be regulated under one policy and legislative framework. One institution not involved in the use of biotechnology be designated to co-ordinate the safe use and management of biotechnology.