PROCEDURES AND GUIDELINES FOR ACCESS AND COLLECTION OF GENETIC RESOURCES IN MALAWI

A. PREAMBLE

Malawi is endowed with rich biological diversity and genetic resources with great potential to provide diverse chemicals, enzymes and genes. These resources, if used properly and in a sustainable manner, can contribute to the socio-economic development of the country. The uses for these resources can vary from plant extracts for herbal products, naturally occurring enzymes in industrial manufacturing to organic molecules used to design new pharmaceutical drugs. They can also be used as a source of diverse genes in the breeding of crop and animal varieties with high performance.

Malawi is party to several international treaties, conventions and agreements that have implications on genetic resource utilisation and exploitation. These include the Convention on Biological Diversity (CBD) to which Malawi acceded in 1992. The CBD places great emphasis on national and community sovereignty over genetic resources and biodiversity and moves away from the notion that these resources and knowledge are the common heritage of mankind. The World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPs) calls for parties to adopt a wide range of intellectual property rights regimes, including patents, plant breeders rights, and trade secrets. Agricultural genetic resources agreements are treated within the International Union for the Protection of New Variety (UPOV Convention), which defines rights to new varieties which may be created by plant breeders to which Malawi is not yet a party. In addition, the non-binding International Undertaking on Genetic Resources explicitly recognizes the concept of rights to traditional land races, which may be created or preserved by rural and indigenous communities throughout the developing world.

These treaties bind the government of Malawi under International Law to enact the necessary regulations for their implementation. Hence since 1992, the Government of Malawi (GOM) and key stakeholders on the environment have been devising new approaches and formulating the requisite policies and legislation to guide Malawi forward in its environmental management endeayours. The National Environmental Action Plan (NEAP), adopted in 1994, documented the depletion of the country's natural resources and provided a guideline for action-oriented programming. The NEAP included loss of biodiversity among the nine major environmental problems in Malawi. The National Environmental Policy (NEP), approved by cabinet in 1996, places emphasis on the management of the environment and genetic resources by the community. The NEP is enshrined in the Environmental Management Act, approved by Parliament in 1996. The Act, among other things, imposes restrictions on the collection and export of genetic resources without the prior informed consent of the responsible Minister. The Act ensures that the country's genetic resources are protected and sustainably utilised for future generations. It is, therefore, important that this protection adequately covers all avenues that can be used by unscrupulous prospectors to collect and export Malawi's valuable genetic resources. It is also important that proper documentation be kept on genuine research efforts that involve the collection and export of such genetic resources.

The National Research Council of Malawi (NRCM) is empowered under the 1974 Presidential Decree to coordinate all research activities conducted in this country and to ensure that any research project proposed for execution is geared to national development needs and goals. The NRCM's Genetic Resources and Biotechnology Committee (GRBC) is, therefore, mandated

to grant approvals for the collection and exportation of genetic resources for research purposes. Such approvals are granted only on advice from designated national institutions. Through this mechanism the GRBC

is expected to monitor and document genetic materials that are collected or researched upon by foreign scientists including those dispatched by local researchers to foreign institutions. However, this system is not being fully implemented and as a result, foreign researchers and institutions have continued to collect Malawi's genetic resources without proper approvals and permits. In addition, local researchers have continued to export and exchange genetic resources without proper approvals and records. This has led to situations where genetic resources are being lost without proper records and without Malawi realizing benefits from the results of such research and the commercialization of the research results. It has, therefore, become necessary to develop guidelines that sets up the procedures for the seeking of approvals for research and collection of genetic resources. The guidelines are intended for use by:

- 1. Foreign scientists and research institutions that plan to conduct research involving the collection of genetic resources;
- 2. Local scientists and research institutions that plan to collect and export genetic resources for analysis or as part of an exchange programme with a foreign institution, scientists;
- 3. Local scientists and research institutions that are funded by an external source on research projects involving the collection of Malawi's genetic resources.
- 4. Malawi Government officials at ports of entry

The guidelines are not intended to restrict innovative research in genetic resources but serve to ensure that Government is committed to promote research in the proper management and sustainable utilization of biodiversity for research so that the country is benefiting from the utilization of its resources.

B. OBJECTIVES OF THE GUIDELINES

The Council expects that research that involves the collection of Malawi's genetic resources by foreign researchers and scientists follow set guidelines to ensure that genetic resources remain valuable assets for socio-economic development. In essence, the guidelines shall serve to achieve the following objectives:

- 1. Ensure that research of Malawi's genetic materials does not lead to loss of biological diversity.
- 2. Ensure that exchange of genetic resources germplasm and commercialisation of research results are done in such a way that Malawi benefits economically from whatever is exported.
- 3. Encourage the establishment of gene banks and genetic data banks (in-situ and ex-situ) and formation of strong linkages with the banks including the SADC gene bank.
- 4. Ensure that research projects that involve exchange of genetic resources and germplasm are effected in a manner that encourages collaboration with foreign researchers.
- 5. Ensure that expatriate researchers/collectors work closely with competent local researchers to safeguard Malawi's interest.
- 6. Ensure that research projects on genetic resources are only those that are geared towards Malawi's socio-economic development and that their execution does not lead to fragmentation and duplication of research efforts.
- 7. Encourage research projects on proper management, conservation and sustainable utilisation of genetic resources

C. CATEGORIES OF RESEARCHERS

For purposes of these guidelines researchers shall be categorized as follows:

1. Foreign researchers or institutions

These are researchers or institutions wishing to conduct research that involves the collection and/or export of genetic resources from Malawi. These are sub-divided into the following:

i. Academics and Research Institutions:

These are students/scholars, academic and research institutions outside Malawi seeking to conduct research that involves the collection and/or export of genetic resources for academic research use.

ii. Non-Profit institutions:

These are institutions outside Malawi seeking to conduct research that involves the collection and/or export of genetic resources for natural products research and development. These include registered charity organisations, NGOs and trusts.

iii. Commercial Public or Private Institutions:

These are commercial companies outside Malawi seeking to conduct research involving the collection and/or export of genetic resources for natural products research and development and eventually to market the products on the international markets.

2. Local researchers or institutions

These are researchers ordinarily resident in Malawi and institutions wishing to export genetic resources to researchers and institutions outside Malawi for analysis or on exchange basis.

i. Academics and Research Institutions:

These are students/scholars, academic and research institutions within Malawi seeking to export genetic resources to foreign institutions for academic and research use.

ii. Non-Profit institutions:

These are institutions within Malawi, requesting permission to export genetic resources for natural products research and development. These include registered charity organisations, NGOs and trusts.

iii. Commercial public or Private Institutions:

These are companies within Malawi seeking to export genetic resources for natural products research and development and eventually to market the products to international markets.

D. PROCEDURES AND REQUIREMENTS FOR APPLICATION

The procedure of approval of research that involves collection of genetic resources shall involve several institutions including Affiliating institutions, Certifying institutions and the National Research Council of Malawi (NRCM). Affiliating institutions are those that the researcher will work with in conducting research work. These institutions will need to have requisite resources (equipment, facilities and staffing) to undertake the proposed work. Certifying Institutions are those government institutions designated to control certain sectors of genetic resources. A list of those is provided in appendix 1. These institutions will review research proposals prior to submission to NRCM. Following approval by NRCM, Certifying Institutions will be required to issue a certificate of collection to the Scientists in addition to providing the counterpart staff to accompany foreign researchers on collection mission. The NRCM's GRBC will be responsible for approval of research programmes involving collection of genetic resources. In addition, foreign and local researchers wishing to export any genetic resource will need to seek export license from the minister of Natural Resources and

Environmental Affairs as stipulated by the Environmental Management Act. All applications for research on genetic resources shall meet the following requirements:

- 1. The local researcher shall be from or affiliated to a recognized research or academic institution while foreign researchers shall be those that are affiliated to a recognised foreign and local research or academic institution.
- 2. Each application shall be submitted to the Council, through the affiliating institution, at least 2 months before the commencement of the research and shall include a curriculum vitae of the lead researcher.
- 3. A non-refundable fee submitted to the National Research Council of Malawi as follows shall accompany each application as follows:
 - i. Foreign researchers and institutions wishing to conduct research involving the collection and/or exportation of genetic resources in Malawi.

Academics and research institutions -US\$ 150 Non-profit institution -US\$ 300 Commercial public or private institution-US\$ 600

ii. Local institutions wishing to conduct research involving the collection and/or exportation of genetic resources outside Malawi.

Academics and research institution -US\$ 50 Non-profit institution -US\$ 150 Commercial public or private institution -US\$ 200

The fees are subject to review from time to time.

- 4. Each application shall be submitted according to the format in Appendix 2. In addition it shall include an attachment of the research project details including title, names, researchers, objectives, description of problem area, hypothesis, materials and methods (methodology), workplan, expected output, CVs.
- 5. Each application by foreign researchers shall include evidence of affiliation to local and foreign academic or research institution. It will be up to the applicant to negotiate for the affiliations. The Council regards the affiliation as a contract between the foreign researcher and the affiliating institution. Approval shall not be granted unless affiliations are confirmed by the local affiliating institution.
- 6. The applicant shall specify the quantity of the genetic resources to be collected. The Chairman of the GRBC shall, however, reserve the ultimate right and authority to authorize the collection of the genetic resources applied for in the quantity he/she shall deem reasonably necessary depending on the nature and scale of the reasons for which the collection is being sought for.

E. RESPONSIBILITIES OF AFFILIATING AND CERTIFYING INSTITUTIONS

- 1. Encourage productive collection and research collaborations with foreign recipients on collected materials in Malawi.
- 2. Ensure that foreign researchers on field trips are always accompanied by local counterparts. The researchers must meet expenses of the counterpart such as transport, accommodation and daily allowances.

- 3. Verify that duplicate specimens of all collections are deposited with an appropriate designated Malawian research organisation/ institution.
- 4. Ensure that endangered species listed in the Appendix to the Convention on International Trade in Endangered Species and Malawian endangered species are not collected without a valid waiver obtained from National Research Council of Malawi (NRCM). The certifying organisations will from time to time inform GRBC on areas defined as special studies. No Collection of rare endangered germplasm is allowed without a valid waiver obtained from NRCM. In terms of genetic resources, special studies are defined as those studies involving:
 - i. sensitive areas such as sharing of certain traditional knowledge on use of genetic resources;
 - ii. endangered rare plant and animal species, human bodies/parts.
- 5. Ensures that all research on genetic resources has necessary approvals and certificates before commencement of the project and in case of export, that a valid export license is obtained from the responsible Minister.
- 6. Ensure that the researcher compiles a complete list of all collected genetic resource materials and a copy submitted to the National Research Council of Malawi within three months of completion of field work.
- 7. Ensure that the researcher carries out his/her investigations according to the agreed research methods and collect the genetic materials following the set guidelines; have the progress of his/her investigations monitored; affiliating institution to make available to NRCM 3 copies of any research findings obtained from the research work.
- 8. Ensure that prior informed consent (PIC) has been obtained from communities/authorities under whose jurisidiction falls the desired genetic resources prior to commencement of any research work that involves the collection of such resources.
- 9. Must ensure that these guidelines are adhered to for proper management and sustainable utilization of Malawi's genetic resources and traditional knowledge.

F. RESEARCH AND MATERIAL TRANSFER AGREEMENTS AND

CERTIFICATES

Research and Material Transfer Agreements shall be used to define research collaborations between local research organizations and foreign research partners and to define rights and obligations respectively between parties in the collection and use of the genetic resources. In supporting the cause and spirit of these national procedures and guidelines for access and collection of genetic resources as set out in here, collectors shall be obliged to sign any relevant material transfer agreement that shall be available in force from time to time. These agreements shall be provided by NRCM or any of the certifying institutions. In absence of these material transfer agreements, the general procedures and guidelines as set out in here shall wholly apply but subject to conditions, rules and regulations that Government of Malawi shall deem necessary to put in place at that time. Designated certifying organizations (provider) shall facilitate the administering of the material transfer agreements at an institutional level and shall forward them to the chairman of the Genetic Resources and Biotechnology Committee for final certification and endorsement.

- 1. The Genetic Resources and Biotechnology Committee shall be the sole authority to approve Research and Material Transfer Agreements on genetic resources. Secretariat shall review requests for certificates, Research and Material Transfer Agreements signed by recipient and provider.
- 2. The GRBC shall co-opt relevant stakeholders such as legal experts, certifying organisations, NGOs, local communities, or the private sector, as appropriate to review Research and Material Transfer Agreements.

- Approved Research and Material Transfer Agreements shall be endorsed by the GRBC.
 Rejected ones shall be returned to the provider organisation with a detailed description of revisions required for approval.
- 4. Material Transfer Agreements administered by or on behalf of the GRBC as specified above shall be valid upon signing by both the provider and recipient.

G. WITHDRAWAL OF CERTIFICATES

- 1. The GRBC reserves the right to withdraw any certificates without notice or giving reasons to the researcher/collector or institution.
- 2. Violators of Malawi's genetic resources regulations shall be punishable by fine or imprisonment or both and may be subject to further prosecution as prescribed by the Environmental Management Act.

H. PUBLICATIONS AND DATA

- 1. External researchers are required to acknowledge Malawian collaboration and participation on publications written out accordingly.
- 2. Four copies of all publications arising from the collections in Malawi shall be sent to the affiliating institution in a timely manner
- 3. In the case of academic, non-proprietary research or otherwise, all raw data generated by the recipient shall be deposited in a timely manner with the affiliating institution as provided.
- 4. In the case of proprietary research, data or a redacted subset of data generated by the recipient shall be deposited in a timely manner with the affiliating institution according to the terms of the negotiated Research Agreement.

Click here for Appendices

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APPENDIX 1: LIST OF CERTIFYING INSTITUTIONS

(Subject to revision from time to time)

Categories Of Genetic Resources

A. Agricultural Resources

1. Department of Agricultural Research and Technical Services (DARTS)

Contact Address:

The Director, DARTS, P.O. Box 30779, Capital City, Lilongwe 3, Malawi.

Tel: 01784 299

2. Department of Animal Health and Industry

Contact Address:

The Director, P.O. box 2096, Lilongwe 3, Malawi.

Tel: 01744 455

B. Natural Resources

3. Forestry Research Institute of Malawi (FRIM),

Contact Address:

The Deputy Director of Forestry (Research), FRIM, P.O. Box 270, Zomba

Tel: (265-5) 01522866 or 01522548

Fax: (265-5) 01522782

4. Department of Fisheries,

Contact Address:

The Director of Fisheries, P.O. Box 593, Lilongwe, Malawi.

Tel: (265) 01721766 Fax: (265) 01721117

5. Department of National Parks and Wildlife

Contact Address:

The Director for National Parks and Wildlife, P.O. Box 30131, Capital City, Lilongwe 3.

Tel: (265) 01784 059, 01782982

Fax: 01784 059, 01782982, 01740 367

C. Other Institutions

6 Ministry of Health and Population

Contact Address:

The Secretary for Health

P.O. Box 30377, Capital City, Lilongwe 3, Malawi.

Tel: 01783 044 Fax: 01783 109-33

APPENDIX 2: MALAWI GENETIC RESOURCES COLLECTION APPLICATION FORM

SECTION A

(To be filled by the Applicant)

1. N	ame of Appl	licant (Recipi	ent)					
2. Pı	rofession							
3. A	ddress							_
Tel:	Tel:		_ Fax:					
E-ma	ail							
4 Ty	pe of mater	rials being sou	ught for					
	Species name		Туре		Quantity	Part(s) of Material to be collected e.g. roots, leaves	Collection Site (s)	
	Common	Scientific	Family	Order				

- 5. Purpose of collections (Tick where applicable)
 - Research
 - Propagation
 - Teaching

• Other(s) (Specify)
6. Proposed collection dates
7. If the research is not going to be done in Malawi explain why?
8. Names and Addresses of collaborating scientists/institution(s)
SECTION B
(To be filled by the Certifying Institution)
9. Type of materials being sought for (Append copy of request)
BotanicalZoological
• Others
10. State the importance and relevance of the proposed work to Malawi
11 Has similar work been done in Malawi
12 State any other related project that can benefit from the results of the research work
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13 Conse	rvation Stat	us of Req	uested N	Naterials (T	ick where app	olicable)				
Species name		Туре		Quantity	Part(s) of Material to be collected e.g. roots, leaves	Collection Site (s)				
Common	Scientific	Family	Order		100,00					
14 Recon	nmendation	s of Head	of Instit	ution.						
15 Name	and signatu	re of the	Head of	Institution	•					
(<i>Official</i>					Biotechnology	y Committee (GRBC)) collect				
(a) Appro	oved					-11t				
(b) Rejec	ted	-								
(c) If rej	ected give r	- easons								
(d) Appro	oval/Rejecti	- ion numbe	er							
18. Signature of the GRBC Chairmanstamp)										
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