

PART I – PRELIMINARY

Regulation

1. Citation.
2. Interpretation.
3. Application.

PART II – CONSERVATION OF BIOLOGICAL DIVERSITY

4. Environmental Impact Assessment Licence.
5. Conservation of threatened species.
6. Inventory of biological diversity.
7. Monitoring of status.
8. Protection of environmentally significant areas.

PART III – ACCESS TO GENETIC RESOURCES

9. Access permit.
10. Notification of application.
11. Determination of application.
12. Form of access permit.
13. Communication of decision.
14. Validity and renewal of access permit.
15. Terms, conditions of an access permit, etc.
16. Suspension, cancellation, etc., of access permit.
17. Register of access permits.
18. Material Transfer Agreement.

PART IV – BENEFIT SHARING

19. Application of this Part.
20. Benefits sharing.

PART V – MISCELLANEOUS

21. Confidentiality.
22. Transition.
23. Offences.
24. Penalties.

SCHEDULE

FIRST SCHEDULE – FORM OF APPLICATION OF AN ACCESS PERMIT

SECOND SCHEDULE – FEES

THIRD SCHEDULE – FORM OF ACCESS PERMIT

**ENVIRONMENTAL MANAGEMENT AND CO-ORDINATION
(CONSERVATION OF BIOLOGICAL DIVERSITY AND
RESOURCES, ACCESS TO GENETIC RESOURCES
AND BENEFIT SHARING) REGULATIONS, 2006**

[L.N. 160/2006.]

PART I – PRELIMINARY

1. Citation

These Regulations may be cited as the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006.

2. Interpretation

In these Regulations, unless the context otherwise requires—

“**access**” means obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bio-prospecting, conservation, industrial application or commercial use;

“**access permit**” means a permit that allows a person to access genetic resources issued under regulation 4;

“**benefit sharing**” means the sharing of benefits that accrue from the utilization of genetic resources;

“**endangered species**” means any species which is in danger of extinction throughout all or a significant portion of its range (due to man-made or natural changes in the environment);

“**genetic material**” means any genetic material of plant, animal, microbial or other origin containing functional units of heredity;

“**habitat**” means the place or type of site where an organism or population naturally occurs and includes areas colonized by introduced organisms;

“**holotype**” means the single specimen chosen for designation of a new species;

“**intangible components**” means any information held by persons that is associated with or regarding genetic resources within the jurisdiction of Kenya;

“**inventory**” means a detailed list, report or record of resources, or the process of making such a list, report or record;

“**Material Transfer Agreement**” means an agreement negotiated between the holder of an access permit and a relevant lead agency or community on access to genetic resources and benefit sharing;

“**natural environment system**” means relatively intact ecosystems of unique value, such as perennial and seasonal wetlands, highly diverse aquatic ecosystems, or ecosystems promoting a high concentration of rare and unusual species;

“**Prior Informed Consent**” means an international operation procedure for exchanging, receiving and handling notification and information by a competent authority; and

“**threatened species**” means any species of plant or animal which is likely to become an endangered species within the foreseeable future throughout all or significant portion of its range.

3. Application

These Regulations shall not apply to—

- (a) the exchange of genetic resources, their derivative products, or the intangible components associated with them, carried out by members of any local Kenyan community amongst themselves and for their own consumption;
- (b) access to genetic resources derived from plant breeders in accordance with the Seeds and Plant Varieties Act (Cap. 326);
- (c) human genetic resources; and
- (d) approved research activities intended for educational purposes within recognized Kenyan academic and research institutions, which are governed by relevant intellectual property laws.

PART II – CONSERVATION OF BIOLOGICAL DIVERSITY

4. Environmental Impact Assessment Licence

- (1) A person shall not engage in any activity that may—
 - (a) have an adverse impact on any ecosystem;
 - (b) lead to the introduction of any exotic species;
 - (c) lead to unsustainable use of natural resources,

without an Environmental Impact Assessment Licence issued by the Authority under the Act.

(2) In this Regulation, “**exotic species**” means any species of plant or animal or microorganism (life form) whose natural range does not, or did not in the past, exist in a specific part of, or the whole of Kenya and which out-competes all other life forms.

5. Conservation of threatened species

(1) The Authority shall, in consultation with the relevant lead agencies, impose bans, restrictions or similar measures on the access and use of any threatened species in order to ensure its regeneration and maximum sustainable yield.

(2) Without prejudice to the generality of the foregoing, the Authority shall, in consultation with the relevant lead agencies—

- (a) issue licenses for the establishment and maintenance of facilities for the recovery and rehabilitation of threatened species;
- (b) determine full recovery and rehabilitation measures of threatened species to ensure its restoration into its natural habitat.

6. Inventory of biological diversity

(1) Within twenty-four months from commencement of these Regulations, the Authority shall, in consultation with the relevant lead agencies, identify and prepare an inventory of biological diversity of Kenya.

(2) The inventory shall include threatened, endangered, or rare species.

(3) The inventory shall be maintained and updated every year thereafter by the Authority.

(4) The inventory shall be a public record of the Authority and shall be accessible, in a prescribed manner, to any person on application to the Authority, and upon payment of such fees as may be prescribed by the Authority.

7. Monitoring of status

The Authority shall, in consultation with the relevant lead agencies, monitor the status and the components of biological diversity in Kenya and take necessary measures to prevent and control their depletion.

8. Protection of environmentally significant areas

This Part shall apply to any area of land, sea, lake or river which the Minister has, by notice in the *Gazette*, declared to be a protected natural environment system for purposes of promoting and preserving biological diversity in accordance with section 54 of the Act.

PART III – ACCESS TO GENETIC RESOURCES

9. Access permit

(1) Any person who intends to access genetic resources in Kenya shall apply to the Authority for an access permit in the form set out in the First Schedule, and such application shall be accompanied by the fees prescribed in the Second Schedule to these Regulations.

(2) The application shall be accompanied by evidence of Prior Informed Consent from interested persons and relevant lead agencies, and a research clearance certificate from the National Council for Science and Technology.

10. Notification of application

The Authority shall, upon receipt of the application, give notice thereof by publication in the *Gazette* and at least one newspaper with nationwide circulation, or in such other manner as the Authority may consider appropriate, specifying—

- (a) the name and other particulars of the applicant;
- (b) the activity to be undertaken for which the access permit is required; and
- (c) the time within which representations or objections in respect of the proposed access permit may be made to the Authority.

11. Determination of application

(1) The Authority shall, on receipt of representations or objections to the proposed access permit from the public, review the application and if satisfied that the activity to be carried out shall facilitate the sustainable management and utilization of genetic resources for the benefit of the people of Kenya, issue an access permit to the applicant.

(2) Where the Authority has reasonable grounds for refusing to issue an access permit, it shall inform the applicant of the reasons of such refusal in writing.

(3) A person aggrieved by refusal of the Authority to grant a licence may appeal to the Tribunal in accordance with section 129 of the Act.

12. Form of access permit

The Form set out in the Third Schedule is prescribed as the form of access permit.

13. Communication of decision

The Authority shall, within sixty days of receipt of an application for an access permit, determine the application and communicate its decision in writing to the applicant.

14. Validity and renewal of access permit

(1) An access permit shall be valid for a period of one year from the date of issue and shall not be transferable.

(2) Upon expiry, an access permit may be renewed for a further period of one year upon payment of the fee prescribed in the Second Schedule and upon such terms and conditions as the Authority may deem necessary to impose.

15. Terms, conditions of an access permit, etc.

(1) An access permit shall contain such terms and conditions as the Authority may deem necessary to impose.

(2) In addition to such terms and conditions as may be contained in an access permit, the following conditions shall be implied in every access permit—

- (a) duplicates and holoypes of all genetic resources collected shall be deposited with the relevant lead agency;
- (b) records of all intangible components of plant genetic material collected shall be deposited with the Authority;
- (c) reasonable access to all genetic resources collected shall be guaranteed to all Kenyan citizens whether such genetic resources and intangible components are held locally or abroad;
- (d) all agreements entered into with respect to access of genetic resources shall be strictly for the purposes for which they were entered into;
- (e) the furnishing of quarterly reports to the Authority on the status of research, including all discoveries from research involving genetic resources and/or intangible components thereof;
- (f) the holder of an access permit shall inform the Authority of all discoveries made during the exercise of the right of access granted under the access permit;
- (g) the holder of an access permit shall provide the following reports—
 - (i) a semi-annual status report on the environmental impacts of any ongoing collection of genetic resources or intangible components thereof;
 - (ii) a final status report on the environmental impacts of collection of genetic resources or intangible components thereof, in the event that the collection is of a duration of three months or less;
- (h) the holder of an access permit shall abide by the laws of the country.

(3) The Authority may, on its own volition or on the application by an access permit holder, vary the conditions of an access permit.

16. Suspension, cancellation, etc., of access permit

(1) The Authority may suspend, cancel or revoke any access permit issued under these Regulations where the holder thereof is in contravention of any of the conditions imposed on the access permit or those implied under these Regulations, or of the agreements concluded pursuant to its grant.

(2) The Authority shall, before suspending, cancelling or revoking an access permit, give a written notice of its intention to suspend, cancel or revoke the permit to the holder thereof, and shall accordingly invite the holder to make representations within thirty days from the date of such notice.

(3) Where the Authority suspends, cancels or revokes a permit, it shall publish the order suspending, cancelling or revoking the permit in the *Gazette* and in at least one newspaper with nationwide circulation.

(4) The provisions of regulation 11(3) shall apply *mutatis mutandis* to the suspension, cancellation or revocation of an access permit.

17. Register of access permits

The Authority shall keep, manage and update as appropriate a register of all access permits which it has granted, and the register shall be a public record of the Authority and shall be accessible, in a prescribed manner, to any person on application to the Authority, and upon payment of the fees prescribed in the Second Schedule.

18. Material Transfer Agreement

Notwithstanding any provisions contained in these Regulations, no person shall transfer any genetic resources outside Kenya unless such person has executed a Material Transfer Agreement.

PART IV – BENEFIT SHARING

19. Application of this Part

This Part shall apply subject to the laws in force relating to intellectual property rights.

20. Benefit sharing

(1) Without prejudice to the generality of the foregoing, the holder of an access permit shall facilitate an active involvement of Kenyan citizens and institutions in the execution of the activities under the permit.

(2) The facilitation by the holder of an access permit shall include enjoyment of both monetary and non-monetary benefits arising from the right of access granted and the use of genetic resources.

(3) Monetary benefits include—

- (a) access fees or fee per sample collected or acquired;
- (b) up-front payments;
- (c) milestone payments;
- (d) payment of royalties;
- (e) licence fees in case genetic resources are to be utilised for commercial purposes;
- (f) fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- (g) salaries and preferential terms where mutually agreed;
- (h) research funding;
- (i) joint ventures;
- (j) joint ownership of relevant intellectual property rights.

(4) Non-monetary benefits include—

- (a) sharing of research and development results;
- (b) collaboration, co-operation and contribution in scientific research and development programmes, particularly biotechnological research activities;
- (c) participation in product development;
- (d) admittance to *ex situ* facilities of genetic resources and to databases by participating institutions;
- (e) transfer to Kenya of genetic resources of knowledge and technology under fair and most favourable terms, including concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;

- (f) strengthening capacities for technology transfer to Kenya;
- (g) institutional capacity building;
- (h) human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- (i) training related to genetic resources with the full participation of Kenya and where possible, in Kenya;
- (j) access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- (k) institutional and professional relationships that can arise from access and benefit sharing agreements and subsequent collaborative activities;
- (l) joint ownership of relevant intellectual property rights.

PART V – MISCELLANEOUS

21. Confidentiality

(1) On the request of an applicant of an access permit, the Authority may hold some information relating to access to genetic resources the subject of the application as confidential.

(2) Where an access permit is granted, information held as confidential under paragraph (1), with respect to the relevant applicant, shall not be accessible to a person inspecting the register of access permits in accordance with regulation 17.

22. Transition

A person carrying out any activities involving access to genetic resources immediately before the coming into force of these Regulations shall, within six months from the coming into force thereof, take all necessary measures to ensure full compliance with these Regulations.

23. Offences

A contravention or failure to comply with any of the matters provided in these Regulations shall constitute an offence.

24. Penalties

Any person convicted of an offence under these Regulations shall be liable to imprisonment for a term not exceeding eighteen months, or to a fine not exceeding three hundred and fifty thousand shillings, or both.

FIRST SCHEDULE

[Regulation 9.]

FORM OF APPLICATION FOR AN ACCESS PERMIT

Applicants applying as individuals should fill Part I.

Applicants applying as corporates (organisations) should fill Part II.

All applicants must fill Part III.

All applicants must submit ten (10) hard copies and one (1) soft copy of this application to the Authority.

FIRST SCHEDULE—*continued*

PART I – FOR APPLICANTS WHO ARE INDIVIDUALS

- (a) Name of applicant
- (b) Identification Card No./Passport No.
- (c) Postal Address
- (d) PIN No.
- (e) Permanent Residential Address
-
- (f) Qualifications (Curriculum Vitae to be attached)

PART II – FOR APPLICANTS WHO ARE CORPORATE (ORGANIZATIONS)

- (a) Name of Organization
- (b) Permanent Address
- (c) Registered Address
- (d) Registration No. (Attach copy of certificate of registration)
- (e) Qualification of individuals in the project (Curriculum Vitae to be attached)
-
- (f) Details (if any) of—
 - (i) holding and subsidiary institutions; or
 - (ii) individuals connected to the project
- (g) Name of the contact person in regard to this application and the position held in the organization

PART III – FOR ALL APPLICANTS

1.0 Financial Details

Sources:

- (i) The total budget of the project
- (ii) Details of any corporate or individual sponsors of the project
-
-

2.0 Technical Particulars

- (a) What are the details of your previous collection/research (if any) conducted in any of the East African countries (Kenya, Uganda and/or Tanzania)?
- (b) With regard to genetic resources for which access is sought, the following must be provided:
 - (i) scientific names of taxa;
 - (ii) specific sites in which access will be undertaken;
 - (iii) possible location;
 - (iv) parts of the genetic resource to be collected (tissues, cells, seeds, leaves, microbes, etc.);
 - (v) derivatives and/or products;
 - (vi) quantities to be collected;
 - (vii) any known uses of the genetic resources;
 - (viii) in case of genetic resources held *ex situ*, details of the relevant depository institution(s).
- (c) With regard to the planned collecting mission, the following must be provided:
 - (i) identification of the provider(s) of the genetic resources for which access is sought;
 - (ii) collection methods to be used;
 - (iii) if there are Kenyan nationals or institutions to be used, their particulars;

FIRST SCHEDULE—continued

- (iv) expected date of commencement and completion of the activity;
- (v) information regarding immigration status in Kenya of foreign individuals that will visit Kenya.
- (d) Proposed use of genetic resources:
 - (i) form of use to which the genetic resources will be put;
 - (ii) expected research results;
 - (iii) geographical location in which each element of the research programme will take place.
- (e) Details of any royalties, payments and/or other compensation that the applicant offers for access to genetic resources.
- (f) Will the applicant require assistance to identify and access the genetic resources described in this application? If yes, give details of the assistance that will be required.
- (g) A copy of the Prior Informed Consent document signed by the relevant lead agencies, local community or private owner of the genetic resources.
- (h) A copy of research clearance document from the National Council of Science and Technology.
- (i) Any other information in the possession of the applicant which might be useful for the National Environment Management Authority to make an informed decision in granting an access permit.

3.0 Renewal Details

Is this an application for renewal of an access permit?

YES NO

Access Permit No. Granted on (Date)

All applicants are forewarned that it is an offence to give false information to the National Environment Management Authority punishable under the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006.

I undertake to provide progress and full reports as required under the Regulations.

I declare that to the best of my knowledge the information given in respect of this application is true.

For individual applicants:

Name of Applicant

Signature

Date

For Companies/Institutions—

(Affix company seal)

In the presence of—

Name of Director

Signature

Name of Director/Company Secretary

Signature

Date

SECOND SCHEDULE
[Regulations 9, 14(2), 17.]

FEES

	<i>KSh.</i>
(a) To apply for an access permit—	
(i) Individual applicants	20,000.00
(ii) Corporate applicants	50,000.00
(b) To renew an access permit—	
(i) Individual applicants	10,000.00
(ii) Corporate applicants	25,000.00
(c) To peruse the register of access permits—	
(i) Residents	1,000.00
(ii) Non-residents	5,000.00

THIRD SCHEDULE
[Regulation 12.]

FORM OF ACCESS PERMIT

This permit is hereby granted to Mr./s.
.....
.....

..... (*insert name, contact address and description of applicant*) in accordance with regulation 11 of the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006 for the collection of the following genetic resources:

..... (*insert description of the genetic resource, its derivative product(s) or intangible component(s) as stated in the Materials Transfer Agreement*) located at

..... (*insert geographical description of the location of the genetic resources*).

This permit is issued subject to the Regulations and all agreements concluded pursuant to its grant, and may be suspended, cancelled or revoked should the holder breach any of those agreements and the conditions of issue and those contained in the Regulations.

M/S. (*insert name of applicant*) being the holder of this permit, including his agents and assignees, undertake to abide by the conditions of this permit and to promptly report to the National Environment Management Authority any matter that may prejudice the interests of Kenya and other parties concluded pursuant to the grant of this permit.

Signed: Date:

*Director General,
National Environment Management Authority*