

Higher Council for Environment and Natural Resources

Regulations Governing Procedures for Accessing Genetic Resources and Associated Traditional Knowledge for the Year 2025

Pursuant to the powers vested in it under Article (27) of the Environmental Protection Act of 2001, and based on the text of Article 26 of the same Act, and the provisions of the Interpretation of Laws and Texts Act of 1974, and the provisions of the Act ratifying the Nagoya Protocol on Access to Genetic Resources and Sharing of Benefits Arising from their utilization of 2014, I issue the following regulation.

Chapter One (Preliminary Provisions) **Name of the Regulation and Commencement of its Implementation**

1) This regulation shall be called: “Regulation for Organizing Procedures for Accessing Genetic Resources and Related Traditional Knowledge for the Year 2025,” and shall come into effect from the date of its signing.

Scope of Application of the Regulation

2 (1) This Regulation apply to:

- a. Genetic resources and the sharing of benefits arising from their utilization.
 - b. Traditional knowledge associated with genetic resources.
2. The provisions of international agreements and treaties relating to genetic resources and associated traditional knowledge ratified by the State shall be applied in a manner that fully achieves their objectives.

Interpretation

3. (1) In this Regulation, unless the context otherwise requires:

The Secretary-General; refers to the Secretary-General of the Higher Council for Environment and Natural Resources.

The Council refers to; the Higher Council for Environment and Natural Resources.

The Applicant refers to; the person who wishes to access genetic resources and/or associated traditional knowledge from Sudan for use.

The Competent Authority refers to; the authority responsible for the genetic resource and associated traditional knowledge, in accordance with its powers under laws, administrative orders, or policies.

The Protocol; is the Nagoya Protocol on Access to Genetic Resources and the Sharing of Benefits Arising from their Utilization, supplementary to the Convention on Biological Diversity.

The Convention; The Convention on Biological Diversity.

Genetic Resources refers to; any genetic material of actual or potential value that can be found on-site or off-site under the control of the State.

The Authorized Committee refers to; any committee established by the competent authority by a decision and delegated some of its functions, including licensing applications.

The Competent Technical Bodies refer to; the relevant government institutions concerned with genetic resources.

The License refers to; the written certificate issued by the competent authority confirming the issuance of the necessary license to obtain genetic resources, associated traditional knowledge, or both.

Access means; the access and transfer of samples of genetic resources, including associated traditional knowledge and information, whether through physical possession or by any other means. This includes collecting samples from within their natural locations or accessing them from outside their natural locations.

Benefits mean any monetary or non-monetary benefits arising from the use of genetic resources and their derivatives, or associated traditional knowledge, or both.

Benefit-sharing means the fair and equitable sharing of benefits arising from the use of genetic resources and their derivatives, or associated traditional knowledge, with the provider of these resources or associated traditional knowledge, or both.

Mutually agreed terms are an agreement between the provider of genetic resources or traditional knowledge, or both, and the user, approved by the competent national authority, specifying the terms of access to and use of these resources and how the benefits arising from such use will be shared.

Traditional knowledge related to genetic resources refers to; all knowledge related to genetic resources originating from indigenous or local communities and acquired through intellectual activity within a traditional context, passed down through knowledge, skill, innovation, practice, and learning.

Prior Informed Consent; This refers to written consent from the provider of genetic resources or the holder of associated traditional knowledge, given well in advance of any access to genetic resources or associated traditional knowledge, and based on full and objective disclosure of information.

Provider of Genetic Resources; This refers to any natural or legal person who provides genetic resources, whether on-site or off-site, in accordance with their authority or rights.

User; This refers to any natural or legal person who requests to use genetic resources, associated traditional knowledge, or both.

Checkpoint; This refers to the checkpoint established pursuant to the provisions of Article (18) of these Regulations.

(2)The words and phrases used in this Regulation shall have the meanings assigned to them in the Environmental Protection Act of 2001, the Environmental Councils Unification Act of 2020, or any law that replaces it, and in the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

Objectives of the Regulation

4. This regulation aims to:

- a) Provide measures for access to genetic resources and associated traditional knowledge.
- b) Ensure the fair and equitable sharing of benefits arising from their utilization.
- c) Contribute to the conservation of biodiversity and the sustainable use of its components, in accordance with Sudan's obligations under the Nagoya Protocol and the Convention on Biological Diversity.
- d) Combat biopiracy.
- e) Achieve a balance between the protection of the country's genetic resources and their utilization, along with associated traditional knowledge, in coordination with relevant stakeholders.
- h) To provide a transparent and predictable method for review and decision-making regarding access to genetic resources and associated traditional knowledge, and the fair and equitable sharing of benefits arising from their utilization.
- i) To promote public awareness and participation in activities related to access to genetic resources and associated traditional knowledge.
- j) To contribute to building institutional and human capacities in the fields of genetic resources and associated traditional knowledge.

Chapter Two

Responsibilities of the Competent Authority

6 (1) The Council shall be the competent authority and the advisory and executive body with respect to genetic resources and associated traditional knowledge for the purposes of implementing the Nagoya Protocol and the Convention on Biological Diversity.

(2) Without prejudice to the generality of the provisions of paragraph (1), the powers and responsibilities of the Competent Authority shall be as follows:

- a) Developing and implementing the policies, plans, and programs necessary to achieve the objectives of the Nagoya Protocol, in coordination with relevant entities.
- b) Granting permits for access to genetic resources or associated traditional knowledge, or both, after examining applications and making

a reasoned decision in accordance with the provisions of these Regulations.

c) Ensuring that the terms of prior informed consent and the conditions mutually agreed upon between the provider and user of genetic resources and associated traditional knowledge, or either of them, comply with the requirements of these Regulations, their implementing texts, and the provisions of the Nagoya Protocol.

d) Establishment of a register of genetic resources and conservation efforts.

e) Supporting and encouraging efforts to conserve genetic resources.

f) Developing, updating, and using voluntary codes of conduct, guidelines, best practices, and standards regarding access to and benefit-sharing;

(g) Coordinating among relevant stakeholders regarding genetic resources and associated traditional knowledge.

(h) Imposing fees as determined by regulation and with the approval of the Minister of Finance.

i) Monitoring access to genetic resources and associated traditional knowledge in coordination with the checkpoint(s) and relevant entities.

j) Developing measures to raise awareness of the importance of genetic resources and associated traditional knowledge and issues related to access and benefit-sharing.

k) Having the authority to intervene in negotiations to reconcile the provider of genetic resources or associated traditional knowledge with the user thereof, in coordination with the competent authorities.

l. Contribute to the monitoring and documentation of traditional knowledge related to genetic resources.

m) Establish a committee by resolution and delegate to it certain tasks, including reviewing licensing applications and ensuring that the resource user obtains prior informed consent from the genetic resource provider or holder of associated traditional knowledge, under mutually agreed terms in accordance with the Nagoya Protocol.

(n) Encourage users and providers of genetic resources to incorporate mutually agreed terms regarding the implementation of these terms into their reporting requirements.

Obligations of the User of Genetic Resources

7 .Users of genetic resources or associated traditional knowledge must:

a. Submit to the Council the information, knowledge, and results obtained.

b. Provide the information, data, documents, and records requested by checkpoints.

Chapter Three

Permit for Access

8.(1) No person may access to genetic resources or associated traditional knowledge subject to the sovereignty of the State for the purpose of personal use without authorization from the Council based on the recommendation of the authorized committee.

(2) Ensure that the applicant has obtained prior informed consent to their request from the provider of the genetic resource or the holder of the associated traditional knowledge, under mutually agreed terms and conditions, in accordance with the requirements of the Nagoya Protocol.

Application Requirements

9. Applications for access to genetic resources shall be submitted to the Council using the prescribed form, subject to the following conditions:

- a) A detailed description of the genetic resource which intended to be accessed or the associated traditional knowledge.
- b) The intended use of the genetic resource and associated traditional knowledge.
- c) The Council's oversight of the genetic resource, subject to obtaining the prior informed consent of the holder of the traditional knowledge associated with the genetic resource.
- (d) Any other conditions deemed appropriate by the Council.

Prohibition of transfer of Permit

10. A permit granted under this regulation for access to genetic resources or associated traditional knowledge, or both, may not be assigned or transferred to any third party unless expressly permitted in writing in the permit granted to the authorized user and in accordance with the mutually agreed terms.

Cancellation of Permit

11 (1) The Council may cancel any permit granted to any person for access to genetic resources if the permit is violated in accordance with Article 10, if the purpose of the permit has changed, or if the permit was granted based on false or inaccurate information provided in the application.

(2) The Council must notify the person whose permit is being reviewed of the reasons for the decision and their right to appeal.

Exceptional Measures

12 (1) Exceptional measures shall apply to requests for genetic resources in emergency situations arising from natural disasters and epidemic diseases that pose a certain or imminent threat to human or animal health or biodiversity in an unavoidable manner.

Chapter Four Benefit Sharing Types of Benefits

13. Benefits arising from the use of genetic resources consist of monetary benefits, non-monetary benefits, or an agreement encompassing both, with the involvement of relevant local communities in decision-making processes, in consultation with competent state and local authorities.

Requirement for Mutually Agreed Terms

14 (1) The Council may not make any decision approving the granting of a license for genetic resources, their derivatives, or any associated traditional knowledge unless the application is accompanied by proof of the conclusion of a contract, on mutually agreed terms, between the provider and the user of the genetic resource or associated traditional knowledge.

(2) The contract referred to in paragraph (1) must include the following terms:

(a) Fair and equitable sharing of the benefits arising from the use.

- (b) The rights and obligations of the contracting parties, the provider and the user of the genetic resource or associated traditional knowledge.
- (c) Use by a third party, where applicable;
- (d) Change of purpose, if applicable;
- (e) Dispute resolution provisions;
- (f) Intellectual property rights;
- (g) Results obtained.

Share of Local Community in the Benefits from In-Situ Genetic Resource

15 In the case of collecting genetic resources from within In-Situ, the share of local communities in the benefits arising from their use must be determined to support them in conserving genetic resources, without prejudice to the state's and jurisdiction's ownership and sovereignty over the genetic resources.

Compliance with the Protocol and Mutually Agreed Terms

Internationally Recognized Certificate of Compliance

16 (1) A declaration issued in accordance with the provisions of these Regulations and published in the Access and Benefit-Sharing Clearing-House constitutes an internationally recognized certificate of compliance.

(2) The certificate of compliance form must include, at a minimum, the following information:

- (a) The unique certificate code.
- (b) The name of the licensor issuing the certificate.
- (c) The date of issue.
- (d) The person granted prior informed consent,
- (e) The purpose of use: commercial or non-commercial.
- (f) Confirmation of mutually agreed conditions.

The National Focal Point for the Nagoya Protocol and its Functions

17.1 The Secretary General of the Higher Council for Environment and Natural Resources shall be the National Focal Point for the Nagoya

Protocol and shall be responsible for carrying out the functions of the National Focal Point stipulated in the Nagoya Protocol.

(2) Without prejudice to the generality of the foregoing, the Focal Point shall be responsible for the following:

(a) Developing an effective communication strategy to raise awareness and exchange information.

(b) Coordinating and facilitating communication between relevant authorities and stakeholders.

(c) Publishing information in the Clearing House on Access and Benefit-Sharing of the Convention on Biological Diversity, including licenses issued by the Council.

(d) Cooperation and coordination with other countries to monitor compliance with the requirements of the Nagoya Protocol and these regulations concerning the use of genetic resources and associated traditional knowledge obtained from the country, and informing them of cases of non-compliance and receiving notifications thereof.

(e) Leading and coordinating efforts to prepare the required national reports in accordance with the provisions of the Nagoya Protocol, implementing Sudan's obligations, and expressing its views in the meetings and activities of the Nagoya Protocol implementation bodies.

(f) The General Secretariat of the Council shall perform the functions of the secretariat of the competent authority.

Checkpoints

18 (1) Upon the recommendation of the Delegated Committee, the Secretary-General shall, by resolution, appoint checkpoints to monitor the implementation of the provisions of these Regulations and the Nagoya Protocol.

Checkpoint Responsibilities

19 The checkpoint shall have the following responsibilities:

(a) To collect and receive information relevant to the authorization, prior informed consent of the provider of the genetic resource or associated traditional knowledge, the conclusion of mutually agreed terms, and the use of genetic resources, as applicable, at any stage of research, development, innovation, pre-marketing, or marketing, and to report this information to the Council.

(b) To monitor the release of any genetic resources or associated traditional knowledge for use obtained under these Regulations.

Users of genetic resources or associated traditional knowledge shall provide the information stipulated in the paragraph above to the checkpoint.

(c) To ensure that genetic resources subject to the provisions of these Regulations that are imported for use from States Parties to the Nagoya Protocol have been obtained in accordance with the requirements of the Protocol and that an internationally recognized certificate of compliance exists, as appropriate.

Cross-Border Cooperation

20 (1) In cases where a genetic resource is in its natural setting within the territory of the State and any State Party to the Protocol, cooperation and coordination shall be undertaken with the competent authorities in that State for the implementation of the Protocol.

(2) When sharing traditional knowledge related to genetic resources between one or more local communities in Sudan and one or more States Parties to the Protocol, cooperation shall be undertaken with the competent authorities in those States, with the participation of the local communities in decision-making and arrangements for utilizing this knowledge and sharing the benefits arising from its use.

Chapter Five Financial Provisions

Financial Resources

21 The financial resources of the competent authority consist of the following:

- a) Appropriations allocated to it by the State;
- b) Permit fees and any other fees approved by the Minister of Finance and National Economy upon the Minister's recommendation;
- c) Contributions, donations, grants, and loans approved by the Minister of Finance upon the recommendation of the Secretary-General;

d) Any other resources approved by the Minister of Finance upon the recommendation of the Secretary-General.

Maintaining Documents, Books, and Records

22 .The competent authority shall maintain accurate and complete accounts of all revenues and expenditures, and all related books and records, in accordance with sound financial and accounting principles applicable in the country.

Annual Budget and Auditing

23 (1) .The competent authority shall prepare an annual budget in accordance with applicable accounting principles.

(2) The National Audit Office, or its designee, shall audit the competent authority's accounts at the end of each fiscal year.

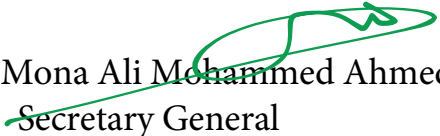
Appeals

24. 1. The Secretary General of the Higher Council for the Environment and Natural Resources, after consulting with the Minister of Justice, shall form a committee called the Appeals Committee, comprised of individuals with expertise and knowledge in the legal field, genetic resources, and traditional knowledge. This committee shall consult on appeals against decisions issued by the Council within two weeks of the decision's issuance.

2. Furthermore, any party aggrieved by a decision of the Appeals Committee, as stipulated in paragraph (1), may appeal to the competent court within one week of the decision's issuance.

Certificate

I certify that the Higher Council for the Environment and Natural Resources issued this regulation on the day 3 of the of Jumada al- Akhira of the year 1447, corresponding to 24 of Nov. of the year 2025



Dr. Mona Ali Mohammed Ahmed
Secretary General