

# **National Policy on Access to Biological Material and Fair and Equitable Benefit Sharing**

**Ministry of Environment & Wildlife Resources**

**1. Name: National Policy on Access to Biological Material and Fair and Equitable Benefit Sharing**

**2. Effective Date :**

**3. Introduction**

**I. Background**

The terrestrial and aquatic areas (i.e. freshwater and brackish) within Sri Lanka, and in the maritime waters under its jurisdiction, are internationally known to harbour a very rich terrestrial, wetland, coastal and marine biodiversity. Sri Lanka ranks first among Asian countries in terms of species richness per unit area for flowering plants, fishes, amphibians, reptiles and mammals, and possesses many endemic species not found elsewhere in the world. Notably, among indigenous species, over 28% of the island's flowering plants and 42% of the indigenous vertebrate species are endemic to the island, and endemism exceeds 80% in some groups of invertebrates (such as land snails and freshwater crabs), that are well investigated. Species diversity is also believed to be high among fungi, lower plants and some groups of micro-organisms. These attributes contribute to a unique and rich indigenous biological diversity. Likewise, the practice of agriculture for centuries in the country has led to crop selection and varietal improvement by farmers, resulting in a wide range of crops, including traditional varieties and land races. Many new crop varieties with favorable characteristics have also been developed more recently in the country. Sri Lanka has a number of traditional livestock breeds, and several cross-breeds have been produced using genes from local breeds to enhance livestock productivity. These factors have combined to give rise to a wide range of indigenous biological resources (bio-resources) that are used for commercial and non-commercial purposes. These resources often also have traditional knowledge associated with them. Sri Lanka's rich biological diversity, including genetic resources, is important for economic development in the country, and has potential to meet current and future needs to ensure food security, good health, nutrition, and wellbeing of her people, particularly in view of the adverse impacts of climate change.

As a Party to the Convention on Biological Diversity (CBD), Sri Lanka promotes conservation and sustainable use of its biological diversity as addressed by the first two objectives of the convention. Accordingly, there are many laws and policies that address the needs of *in-situ* and *ex-situ* conservation of the country's biological diversity. This Policy targets the third objective of the CBD which is addressed by Article 15. This Article is designed to provide incentives to Parties rich in genetic resources that are potential 'Providers' of such resources to conserve national biodiversity. This is by creating the required relationships with other Country Parties that use genetic resources, to promote fair and equitable sharing of benefits (i.e. by way of payment,

technology transfer, capacity building, research exchange, royalty payments, recognition, etc.) between users and providers.

Access and Benefit Sharing (ABS) was first addressed in Sri Lanka's Biodiversity Conservation Action Plan (BCAP) of 1999 in the context of genetic resources and genetic material. A situation analysis was done when preparing the Addendum to the BCAP of 1999. This was followed by a more comprehensive analysis by the Ministry dealing with Environment in 2006 through the National Capacity Needs Self-Assessment (NCSA) project which comprehensively identified measures, mechanisms, implementation structures, and capacity needs for an effective National Access (to genetic resources) and Benefit Sharing (ABS) regime. It also identified the need for a Policy to guide such a regime. The National Biodiversity Strategic Action Plan covering 2016-2022 also highlights the need to address 'Access to genetic resources'. Subsequently, the need was felt to cover the country's biological material rather than only genetic resources, and to recognize and uphold the rights of traditional knowledge holders who hold information about the use of such material.

The constitution of Sri Lanka maintains sovereign rights over its biological resources. The most relevant national laws and policies that relate to the National Policy on Access to Biological Material and Fair and Equitable Benefit Sharing (NPABM&FEBS) are provided in **Annex 1**.

## **II. Need**

Although Sri Lanka has adopted measures to conserve its biodiversity and to prevent bio-theft and bio-piracy, such misappropriation continues to occur. To preclude this, it is necessary to develop clear national policies, strategies, mechanisms and capacities to effectively deal with all potential users of Sri Lanka's biological material and associated traditional knowledge. Such 'users' would include actors within the country, countries that are Parties and non-Parties to the CBD, as well as natural and legal persons from such countries.

Further, Article 15 of the CBD considers only (a) *in-situ* genetic resources within Parties that are "a country of origin", and (b) genetic resources acquired by Parties in accordance with the Convention. Therefore, Sri Lanka's Access to Biological Material and Fair and Equitable Benefit Sharing (ABM&FEBS) regime needs to regulate access to the country's biological material that fall within and outside the scope of the CBD, by using the principles of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). Further, 'Access' to biological material should cover not only 'Access' to genetic resources for productive use, but may also include other materials, such as specimens that are sent out of the country for taxonomic identification, which may subsequently be used as genetic resources. Consequently, Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) under which 'Access' is provided are important factors for consideration in a National ABM&FEBS Regime.

It is also important that a National ABM&FEBS Regime recognizes sovereign rights of the state over its biological diversity, and hence biological material. This needs to be supported by a functional legislative framework that can safeguard Sri Lanka's interests to conserve and sustainably use its biological material, and control 'Access' to the country's biological resources and associated traditional knowledge, while enabling equitable sharing of benefits from the use of such material. While the legal framework in the country is adequate to enable 'Access' which adheres to PIC and MAT, illegal access occurs due to poor enforcement of existing laws and the absence of regulations to cover some biological resources. It is also essential that in-country capacity is built within relevant institutions and individuals to successfully operationalize a National ABM&FEBS regime for fair and equitable benefit sharing and relevant technology transfer. This includes the need to build capacity for biotechnology, uphold the rights of traditional knowledge holders, and negotiate issues relating to 'Access and benefit sharing' with external country parties and others.

### **Applicability & Scope**

- i. The National Policy on Access to Biological Material and Fair and Equitable Benefit Sharing (NPABM&FEBS) establishes an effective mechanism to enable 'Access' to biological material for their genetic or biochemical features or informational value. This will be in a sustainable manner, through regulation of: commercial use, research, other uses and export of any biological material, including any derivative components, products and constructs, as well as associated traditional knowledge, and the use in further research and development in and outside the country.
- ii. 'Access' to biological material as used in this Policy covers 'Access' to any animal, plant, micro-organism or other material sought for commercial use & other uses of its genetic or biochemical features or related informational value.

### **IV. Purpose & Context**

The NPABM&FEBS covers research and commercial use of Sri Lanka's biological material including genetic resources, their derivatives and associated traditional knowledge. It is designed to provide clear objectives, principles and procedural directions to enable setting up a National ABM&FEBS regime that offers fair and equitable benefits from use of the country's biological material and traditional knowledge associated with such use where relevant. It will support development of in-country capacity for modern biotechnology that uses biological resources, with due consideration for relevant Intellectual Property Rights (IPR) issues. The Policy renews the commitment of the Government of Sri Lanka to conserve biological diversity for the benefit of present and future generations, while assuring sustainable use of biological material for research, education, and commercial purposes in a transparent manner.

## **V. Rationale**

By acting as an umbrella policy, The NPABM&FEBS will bind all relevant Parties concerned with the conservation and sustainable use of Sri Lanka's biological diversity and those concerned with 'Access' and benefit sharing from the use of such biological material.

There is need to prevent any misuse or abuse of any biological material present in Sri Lanka while mainstreaming 'Access' to components of biological diversity and the sharing of fair and equitable benefits arising from such 'Access' into the national development process.

### **4. Policy Goal**

Ensuring the fair and equitable sharing of benefits arising from biological material, while securing ownership of such material and associated traditional knowledge among the people of Sri Lanka, with appropriate public participation, to support conservation and sustainable use of biological material in the country.

### **5. Policy Principles**

The 'National Policy on Access to Biological Material and Fair and Equitable Benefit Sharing' of Sri Lanka is based on the following principles:

- I.** Sri Lanka has sovereignty over its national biological resources and has authority to determine 'Access' to biological material and ensure its conservation and sustainable use, subject to national legislation.
- II.** Any person seeking 'Access' to biological material for their genetic or biochemical features or informational value should abide by the ABM&FEBS procedure set in place by the government of Sri Lanka and covered under this Policy.
- III.** The value and importance of traditional knowledge and practices relating to conservation and sustainable use of Sri Lanka's biological material, including the use of genetic resources, is recognized and upheld.
- IV.** The fair and equitable sharing of benefits generated from research and commercial use of Sri Lanka's biological material, and associated traditional knowledge, should provide economic and social incentives for their conservation and sustainable use, and contribute to the wellbeing of current and future generations.
- V.** Sri Lanka remains committed to fair and equitable sharing of benefits from providing 'Access' to biological material, and reserves the right to handle any misappropriation of the use of biological material by 'Users' through relevant national and international laws and agreements.

## **6. Policy Statements**

- I.** Sri Lanka shall respect the sovereignty and importance of genetic material of all living and extinct species and associated traditional knowledge that have been derived from her shores to ensure maximum benefits to the country.
- II.** Appropriate policy, legal measures, mechanisms and capacity will be developed and maintained to regulate 'Access' to biological material and fair and equitable benefit sharing to enable its sustainable use.
- III.** Any transfer of biological material to which 'Access' is provided shall be through a Material Transfer Agreement (MTA) with an authorized state agency, for which Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) would be prerequisites.
- IV.** Fair and equitable benefits from providing 'Access' to biological material will be ensured.
- V.** A mechanism will be developed for sharing benefits arising from monetary and non-monetary uses of biological material with all stakeholders, including use of market-based mechanisms.
- VI.** A multi-stakeholder, integrated approach/mechanism will be developed and implemented to share the benefits of biological resources with grassroots communities, and to encourage conservation of biological diversity and associated traditional knowledge.
- VII.** The rights and needs of traditional knowledge holders and users, including local communities that hold or use such knowledge, will be upheld during procedures for Access to Biological Material and Fair and Equitable Benefit Sharing.
- VIII.** Intellectual Property Rights issues and benefits to Sri Lanka will be adequately addressed, when entering into partnerships and collaborations for ABM&FEBS, by ensuring that IPR recognizes the rights of Sri Lanka, including commercial rights.

## **7. Policy Implementation Strategies:**

- I.** Devising an appropriate institutional mechanism to enable an effective National ABM&FEBS regime and to provide the necessary skills training and capacity building.
- II.** Development of the required legal framework, including development of Material Transfer Agreements (MTA), Prior Informed Consent (PIC), *Sui generis* systems, and benefit sharing mechanisms based on realistic guidelines, by the use of all relevant laws, strengthening existing laws, and developing appropriate regulations as needed to enable fair and equitable benefits from providing 'Access' to the country's biological material.
- III.** Development of a meta-database of genetic resources and related traditional knowledge holders in Sri Lanka.

- IV. Promotion of education and awareness and capacity building at systemic, institutional and individual levels to establish an effective National ABM&FEBS mechanism in Sri Lanka.
- V. Development of a regular and effective evaluation and monitoring system for all actions relating to 'Access' through a National ABM&FEBS regime.
- VI. Responsibility & Authority: Ministry dealing with environment

## 8. Monitoring & Evaluation

The Ministry dealing with environment will be responsible for the following:

- I. Acting as an apex coordinating body to enable implementation of the process required to operationalize ABM&FEBS through formulating and establishing an appropriate mechanism with a focal unit and other appropriate 'Access' determining agencies (e.g. Forest Department, Department of Wildlife Conservation, Department of Animal Production and Health, Department of Agriculture, Department of Fisheries and Aquatic Resources and Sri Lanka Customs Department) to ensure correct decision making, monitoring and evaluation.
- II. Monitoring of laws and policies impacting on a National ABM&FEBS regime.
- III. Monitoring the entire ABS process, including 'Access' requests for use of Biological Material, and referring them to the appropriate 'Access' granting authorities.
- IV. Evaluating all actions that deal with the export and exchange of Biological Material.
- V. Evaluating Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) in relation to 'Access to biological material'.
- VI. Evaluating Material Transfer Agreements (MTA) and providing suggestions for future improvements.
- VII. Monitoring the direct and indirect benefits derived from biological material by the country and holders of traditional knowledge and components of biodiversity.

## 9. Glossary

**Access:** Access to biological material means the utilization of such material from Sri Lanka sought for commercial use & other uses of its genetic or biochemical features or related informational value, irrespective of whether they are accessed *in-situ* or *ex-situ* for the purpose of conducting any research and/or development on the genetic and/or biochemical composition, including through the application of biotechnology, as well as conducting of any research and development on derivatives of biological or genetic resources from Sri Lanka.

**Biological diversity:** The variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the

ecological complexes of which they are part; this includes the diversity within species, between species and of ecosystems.

**Biological resources:** All components of biological diversity, including genetic resources, organisms or parts thereof, populations, or any other biotic components of ecosystems with actual or potential use or value for humanity.

**Biological material:** Components of biological diversity, including species, genetic resources, organisms or parts thereof, populations, or any other biotic components of ecosystems, or located in *ex-situ* conservation facilities and other *ex-situ* facilities, and all genetic material, including those that have been made by recombination and modification and all substances that are made by the direct expression of the said genetic material.

**Genetic resources:** Genetic material of actual or potential value (i.e. including any plant, animal, microbial or other origins containing functional units of heredity that are of functional or potential value).

**Genetic material:** Any material of plant, animal, microbial or other origin containing functional units of heredity.

**Conservation of biological resources:** The wise use, management and protection of biological resources for their inherent value and for the benefit of society, bearing in mind that future generations have as much right to those resources as our own.

**Country of origin of genetic resources:** Country which possesses genetic resources *in-situ*. This would include populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in Sri Lanka or are naturalized, cultivated over a hundred years or more.

**Derivatives:** Derivatives means naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity

***Ex-situ* conditions:** Conditions where biological diversity exists outside their natural habitats.

***In-situ* conditions:** Conditions where biological diversity exists within ecosystems and natural habitats, and in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

**Sustainable use:** Use of components of biological diversity in a way, and at a rate, that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

**Traditional knowledge:** The body of knowledge emerged and nurtured through the traditions and insights of the people living within a specified geographical area.

**Products and Constructs:** Any product that uses biological material in the Process of production.

## **Annex 1: List of Related Policies and Laws**

### **Policies**

1. National Wildlife Policy of 2000
2. National Forestry Policy of 1995
3. National Environmental Policy of 2003
4. National Agricultural Policy of 2007
5. National Fisheries & Aquatic Resources Policy of 2006
6. The National Policy and Strategy on Wetlands 2006
7. National Watershed Management Policy of 2004
8. The National Policy on Invasive Alien Species (IAS) of Sri Lanka, Strategies and Action Plan of 2016
9. The National Livestock Breeding Policy of 2010
10. National Biosafety Policy of 2005

### **Laws**

1. The Fauna and Flora Protection Ordinance Act No. 02 of 1937 and its subsequent amendments
2. The Forest Ordinance Act No. 16 of 1907 and its subsequent amendments
3. National Heritage & Wilderness Areas Act No. 03 of 1988
4. The National Environmental Act No. 47 of 1980 and its amendments
5. The Coast Conservation Act No. 57 of 1981 and its subsequent amendments
6. The Fisheries and Aquatic Resources Act No. 02 of 1996 and its subsequent amendments
7. The Plant Protection Act No. 35 of 1999
8. The Seed Act No. 22 of 2003
9. The Soil Conservation Act No. 25 of 1951 and its subsequent amendments
10. The Animals Act No. 29 of 1958 and its subsequent amendments
11. The Animal Diseases Act No. 59 of 1992
12. The National Aquatic Resources and Development Agency Act No. 54 of 1981
13. The Promotion of Export Agriculture Act No. 46 of 1992
14. The National Zoological Gardens Act No. 41 of 1982
15. The Botanic Gardens Ordinance No. 31 of 1928 and its subsequent amendments
16. Customs Ordinance for the general regulation of customs in Sri Lanka No 17 of 1869