

Access and Benefit Sharing of Biological Resources

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Introduction: - Since time immemorial the people have been using biological resources to meet their basic requirements of food, shelter and protection. The survival of the human being, especially the poor are closely dependent on biological resources; this includes food, primary health care, cattle rearing etc. Wild relatives of agriculture crop plants act as gene pool so also the wild animals for domesticated animals. Biological material is also needed to develop new products. Biodiversity plays a vital role in the hydrology, water is harnessed and filtered by natural ecosystem, and also biodiversity plays an important role in keeping the integrity of landscape intact. Human settlements generally took place in and around the richest ecosystems and the people have lived in harmony with nature since time immemorial. These populations are among the poorest in the world and depend entirely on natural resources. Wide range of sectors undertake research and develop commercial products from genetic resources derived from these ecosystems; they include the pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavor, botanicals, and food and beverage. All these sectors use genetic resources and demand access to these resources. It is important to recognize the role and contribution of these native peoples and communities in maintaining and conserving these resources, so that this bio resource capital is conserved till posterity and also share with them the benefit arising out of the utilization of these genetic resources.

Convention on Biological Diversity: - The convention on Biological Diversity (CBD) is a multilateral international treaty that provides national governments with sovereign rights over genetic resources and associated traditional knowledge. The convention was open for signature at **Earth Summit** in Rio de Janeiro on 5th June 1992 and entered into force on 29th December 1993. The aim of the CBD is to ensure that countries receive a fair share of the benefits from their biological resources and traditional knowledge in return for conserving and allowing access to these resources. Till to date 193 countries are signatory to CBD. The CBD has 42 articles.

Objectives of the Convention on Biological Diversity: -

1. Conservation of Biological Diversity
2. Sustainable utilization of biological diversity
3. Fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

CBD and Access and Benefit Sharing from Genetic Resources and Associated Knowledge: - The CBD seeks to establish a comprehensive international regime for the sustainable management of biological resources. It requires parties to facilitate access to genetic resources for environmentally sound uses and to take legislative, administrative, and policy measures to ensure the equitable sharing of benefits arising from such uses.

The fair and equitable sharing of the benefits derived from biodiversity is one of the central objectives of the Convention on Biological Diversity (CBD). The CBD acknowledges the significant environmental, economic and social value of biodiversity. It also seeks to ensure that the rights of countries and communities over their biological resources and related knowledge are respected, and that the benefits derived from their use are equitably shared. The CBD thus sets out commitments for maintaining the planet's ecological foundation in the context of sustainable development strategies.

Relevant Articles of Convention of Biological Diversity (CBD): -

Article 8: In-situ Conservation:

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices

Article 15: Access to Genetic Resources: - It has following provisions:

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the

financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16: Access to and Transfer of Technology: - It has following provisions:

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms, which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international

Article 19: Handling of Biotechnology and Distribution of its Benefits: It has following:

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research

activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization: These Guidelines are prepared to serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10 (c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing. These guidelines are **voluntary** in nature means they are intended to guide both users and providers of genetic resources on a voluntary basis; **easy to use** means to maximize their utility and to accommodate a range of applications, the Guidelines are simple; **practical to use** means the guidelines are practical and are aimed at reducing transaction costs; **acceptable** means intended to gain the support of users and providers; has element of **complementarity** means the guidelines and other international instruments are mutually supportive; **evolutionary in nature** means are intended to be reviewed and accordingly revised and improved as experience is gained in access and benefit-sharing; **flexible in nature** means are useful across a range of sectors, users and national circumstances and jurisdictions and are **transparent** means are intended to promote transparency in the negotiation and implementation of access and benefit-sharing arrangements.

Objectives of the Bonn Guidelines: following are the objectives:

(a) To contribute to the conservation and sustainable use of biological diversity;

(b) To provide Parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits;

(c) To provide guidance to Parties in the development of access and benefit sharing regimes;

(d) To inform the practices and approaches of stakeholders (users and providers) in access and benefit-sharing arrangements;

(e) To provide capacity building to guarantee the effective negotiation and implementation of access and benefit-sharing arrangements, especially to developing countries, in particular least developed countries and Small Island developing States among them;

(f) To promote awareness on implementation of relevant provisions of the Convention on Biological Diversity;

(g) To promote the adequate and effective transfer of appropriate technology to providing Parties, especially developing countries, in particular least developed countries and Small Island developing States among them, stakeholders and indigenous and local communities;

(h) To promote the provision of necessary financial resources to providing countries that are developing countries, in particular least developed countries and Small Island developing States among them, or countries with economies in transition with a view to contributing to the achievement of the objectives mentioned above;

(i) To strengthen the clearing-house mechanism as a mechanism for cooperation among Parties in access and benefit-sharing;

(j) To contribute to the development by Parties of mechanisms and access and benefit-sharing regimes that recognize the protection of traditional knowledge, innovations and practices of indigenous and local communities, in accordance with domestic laws and relevant international instruments;

(k) To contribute to poverty alleviation and be supportive to the realization of human food security, health and cultural integrity, especially in developing countries, in particular least developed countries and Small Island developing States among them;

(l) Taxonomic research, as specified in the Global Taxonomy Initiative, should not be prevented, and providers should facilitate acquisition of material for systematic use and users should make available all information associated with the specimens thus obtained.

In 2002, the Conference of the Parties (COP) to the CBD adopted the Bonn Guidelines. The Guidelines have two main aims:

1. To guide countries as providers in setting up their own national legislative, administrative or policy measures for access and benefit-sharing, such as recommending

the elements that should make up a prior informed consent (PIC) procedure.

2. To assist providers and users in the negotiation of mutually agreed terms (MAT), by providing examples of what elements should be included in these agreements.

Basic principles and elements of prior informed consent (PIC): The Guidelines stress the need for any potential user of genetic resources to seek the PIC of the resource provider. Basic principles of an effective PIC system should include:

- Legal certainty and clarity
- Access to genetic resources should be facilitated at a minimum cost
- Restrictions on access to genetic resources should be transparent, based on legal grounds, and not run counter to the objectives of the Convention

The basic elements of effective PIC may include:

- Clear establishment of Competent National Authorities (CNAs) who can grant PIC
- Procedures for obtaining PIC from the CNAs
- Clearly specified timing and deadlines
- Specifications of use
- Mechanism for consultation of relevant stakeholders

Basic principles and elements of mutually agreed terms (MAT): The Guidelines outline principles and basic requirements to be considered in the development of MAT, including:

- Legal certainty and clarity
- Facilitating the transaction through clear information and formal procedures
- Reasonable periods of time for negotiations
- Terms set out in a written agreement

The Guidelines provide an indicative list of MAT, which include:

- Type and quantity of genetic resources, and the geographical/ecological area of activity
- Any limitations on the possible use of material

- Whether the genetic resources can be transferred to third parties and under what conditions
- Recognition of the sovereign rights of the country of origin
- Capacity-building in various areas to be identified in the agreement

The Bonn Guidelines are relevant for governments for developing national ABS Mechanism and also for institutions and individuals looking to negotiate access and benefit-sharing agreements such as PIC and MAT.

Nagoya Protocol and Access and Benefit Sharing from Genetic Resources and Associated Knowledge:

From 2004 to 2010, Parties to the CBD negotiated the international regime in the Ad-hoc Open-ended Working Group on Access and Benefit-sharing (ABS WG) of the CBD. At the Tenth meeting of the Conference of the Parties to the Convention on Biological Diversity, held in Nagoya (Japan), in 2010, Parties adopted by consensus the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. The Nagoya Protocol on Access and Benefit-Sharing is a new international treaty adopted under the auspices of the Convention on Biological Diversity (CBD) in Nagoya, Japan on 29 October 2010. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity and implementing the three objectives of the CBD. The Nagoya Protocol when in force, will become the core element of the international regime on ABS. The protocol will enter into force when 50 countries ratify it. The protocol has 36 articles.

Objectives: The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

The Nagoya Protocol will create greater legal certainty and transparency for both providers and users of genetic resources by:

1. Establishing more predictable conditions for access to genetic resources
2. Helping to ensure benefit sharing when genetic resources leave the contracting Party providing the genetic resources

By helping to ensure benefit sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human wellbeing. The Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to access to genetic

resources, benefit sharing and compliance.

Access Obligations: Domestic-level access measures are to:

1. Create legal certainty, clarity and transparency
2. Provide fair and non-arbitrary rules and procedures
3. Establish clear rules and procedures for prior informed consent and mutually agreed terms
4. Provide for issuance of a permit or equivalent when access is granted
5. Create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use
6. Pay due regard to cases of present or imminent emergencies that threaten human, animal or plant health
7. Consider the importance of genetic resources for food and agriculture for food security

Benefit-sharing Obligations: Domestic-level benefit-sharing measures are to provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources, as well as subsequent applications and commercialization, with the contracting Party providing genetic resources. Utilization includes research and development on the genetic or biochemical composition of genetic resources. Sharing is subject to mutually agreed terms. Benefits may be monetary or non-monetary such as royalties and the sharing of research results.

Compliance Obligations: Specific obligations to support compliance with the domestic legislation or regulatory requirements of the contracting Party providing genetic resources, and contractual obligations reflected in mutually agreed terms, are a significant innovation of the Nagoya Protocol. Contracting Parties are to:

1. Take measures providing that genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established, as required by another contracting Party
2. Cooperate in cases of alleged violation of another contracting Party's requirements
3. Encourage contractual provisions on dispute resolution in mutually agreed terms
4. Ensure an opportunity is available to seek recourse under their legal systems when disputes arise from mutually agreed terms
5. Take measures regarding access to justice
6. Take measures to monitor the utilization of genetic resources including by designating effective checkpoints at any stage of the value-chain: research, development, innovation, pre-commercialization or commercialization

The Nagoya Protocol addresses traditional knowledge associated with genetic resources with provisions on access, benefit sharing and compliance. It also addresses genetic resources where indigenous and local communities have the established right to grant access to them. Contracting Parties are to take measures to ensure these communities'

prior informed consent, and fair and equitable benefit sharing, keeping in mind community laws and procedures as well as customary use and exchange.

Mechanism for effective implementation of Nagoya Protocol: The Nagoya Protocol's success will require effective implementation at the domestic level. A range of tools and mechanisms provided by the Nagoya Protocol will assist contracting Parties including:

1. Establishing national focal points (NFPs) and competent national authorities (CNAs) to serve as contact points or information, grant access or cooperate on issues of compliance
2. An Access and Benefit-sharing Clearing-House to share information, such as domestic regulatory ABS requirements or information on NFPs and CNAs
3. Capacity-building to support key aspects of implementation. Based on a country's self-assessment of national needs and priorities, this can include capacity to:
 - Develop domestic ABS legislation to implement the Nagoya Protocol
 - Negotiate MAT
 - Develop in-country research capability and institutions
4. Awareness-raising
5. Technology Transfer
6. Targeted financial support for capacity-building and development initiatives through the Nagoya Protocol's financial mechanism.

Biological Diversity Act, 2002 and Access and Benefit Sharing from Genetic Resources and Associated Knowledge: -

The Act provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. Chapter II of the Act, provide the regulation of Access to Biological Diversity prohibiting **certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority:**

3. (1) No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.

(2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub-section (1) are the following, namely:

(a) A person who is not a citizen of India;

(b) A citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961;

(c) A body corporate, association or organization-

- (i) not incorporated or registered in India; or
- (ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management.

Results of research not to be transferred to certain persons without approval of National Biodiversity Authority:

4. No person shall, without the previous approval of the National Biodiversity Authority, transfer the results of any research relating to any biological resources occurring in, or obtained from, India for monetary consideration or otherwise to any person who is not a citizen of India or citizen of India who is non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961 or a body corporate or organization which is not registered or incorporated in India or which has any non-Indian participation in its share capital or management.

Explanation: - For the purposes of this section, "transfer" does not include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government.

Sections 3 and 4 not to apply to certain collaborative research projects:

5.(1) The provisions of sections 3 and 4 shall not apply to collaborative research projects involving transfer or exchange of biological resources or information relating thereto between institutions, including Government sponsored institutions of India, and such institutions in other countries, if such collaborative research projects satisfy the conditions specified in sub-section (3).

(2) All collaborative research projects, other than those referred to in sub-section (1) which are based on agreements concluded before the commencement of this Act and in force shall, to the extent the provisions of agreement are inconsistent with the provisions of this Act or any guidelines issued under clause (a) of sub-section (3), be void.

(3) For the purposes of sub-section (1), collaborative research projects shall-

(a) conform to the policy guidelines issued by the Central Government in this behalf;

(b) be approved by the Central Government.

Application for intellectual property rights not to be made without approval of National Biodiversity Authority:

6.(1) No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National

Biodiversity Authority before making such application. Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned:

Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.

(2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

(3) The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.

(4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.

Prior intimation to State Biodiversity Board for obtaining biological resource for certain purposes:

7. No person, who is a citizen of India or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization except after giving prior intimation to the State

Biodiversity Board concerned: Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity, and *vaids*.

Chapter III: Approval by National Biodiversity Authority for undertaking certain activities:

19. (1) Any person referred to in sub-section (2) of section 3 who intends to obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization or transfer the results of any research relating to biological resources occurring in, or obtained from, India, shall make application in such form and payment of such fees as may be prescribed, to the National Biodiversity Authority.

(2) Any person who intends to apply for a patent or any other form of intellectual property protection whether in India or outside India referred to in sub-section (1) of section 6, may make an application in such form and in such manner as may be prescribed to the National Biodiversity Authority.

(3) On receipt of an application under sub-section (1) or sub-section (2), the National

Biodiversity Authority may, after making such enquiries as it may deem fit and if necessary after consulting an expert committee constituted for this purpose, by order, grant approval subject to any regulations made in this behalf and subject to such terms and conditions as it may deem fit, including the imposition of charges by way of royalty or for reasons to be recorded in writing, reject the application: Provided that no such order for rejection shall be made without giving an opportunity of being heard to the person affected.

(4) The National Biodiversity Authority shall give public notice of every approval granted by it under this section.

Transfer of biological resource or knowledge:

20. (1) No person who has been granted approval under section 19 shall transfer any biological resource or knowledge associated thereto which is the subject matter of the said approval except with the permission of the National Biodiversity Authority.

(2) Any person who intends to transfer any biological resource or knowledge associated thereto referred to in sub-section (1) shall make an application in such form and in such manner as may be prescribed to the National Biodiversity Authority.

(3) On receipt of an application under sub-section (2), the National Biodiversity Authority may, after making such enquiries as it may deem fit and if necessary after consulting an expert committee constituted for this purpose, by order, grant approval subject to such terms and conditions as it may deem fit, including the imposition of charges by way of royalty or for reasons to be recorded in writing, reject the application: Provided that no such order for rejection shall be made without giving an opportunity of being heard to the person affected.

(4) The National Biodiversity Authority shall give public notice of every approval granted by it under this section.

Determination of equitable benefit sharing by National Biodiversity Authority:

21. (1) The National Biodiversity Authority shall while granting approvals under section 19 or section 20 ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

(2) The National Biodiversity Authority shall, subject to any regulations made in this behalf, determine the benefit sharing which shall be given effect in all or any of the following manner, namely:

(a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;

(b) transfer of technology;

(c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;

(d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;

(e) setting up of venture capital fund for aiding the cause of benefit claimers;

(f) payment of monetary compensation and non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

(3) Where any amount of money is ordered by way of benefit sharing, the National Biodiversity Authority may direct the amount to be deposited in the National Biodiversity Fund: Provided that where biological resource or knowledge was a result of access from specific individual or group of individuals or organizations, the National Biodiversity Authority may direct that the amount shall be paid directly to such individual or group of individuals or organizations in accordance with the terms of any agreement and in such manner as it deems fit.

(4) For the purposes of this section, the National Biodiversity Authority shall, in consultation in consultation with the Central Government, by regulations, frame guidelines.

As per Biological Diversity Act, 2002, it is the responsibility of National Biodiversity Authority to deal with the persons and entities listed under section 3, 4, 5 and 6 if they wish to access the biological resources or associated knowledge but for the section 7 which specifically deals with a person who is a citizen of India, association or organization, which is registered in India, it is the responsibility of State Biodiversity Boards to deal with them if they wish to access the biological resources and associated knowledge for commercial purposes.

Chapter IV: Functions of State Biodiversity Board:

23. The functions of the State Biodiversity Board shall be to—

(a) advise the State Government, subject to any guidelines issued by the Central Government, on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of the benefits arising out of the utilization of biological resources;

(b) regulate by granting of approvals or otherwise requests for commercial utilization or bio-survey and bio-utilization of any biological resource by Indians;

(c) perform such other functions as may be necessary to carry out the provisions of this Act or as may be prescribed by the State Government.

Power of State Biodiversity Board to restrict certain activities:

24.(1) Any citizen of India or a body corporate, organization or association registered in India intending to undertake any activity referred to in section 7 shall give prior intimation in such form as may be prescribed by the State Government to the State Biodiversity Board.

(2) On receipt of intimation under sub-section (1), the State Biodiversity Board may, in consultation with the local bodies concerned and after making such enquires as it deems fit, by order, prohibit or restrict any such activity if it is of opinion that such activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or equitable sharing of benefits arising out of such activity: Provided that no such order shall be made without giving an opportunity of being heard to the person affected.

(3) Any information given in the form referred to in sub-section (1) for prior intimation shall be kept confidential and shall not be disclosed, either intentionally or unintentionally, to any person not concerned thereto.

Chapter XII: Appeal:

52. Any person, aggrieved by any determination of benefit sharing or order of the National Biodiversity Authority or a State Biodiversity Board under this Act, may file an appeal to the High Court within thirty days from the date of communication to him, of the determination or order of the National Biodiversity Authority or the State Biodiversity Board, as the case may be: Provided that the High Court may, if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal within the said period, allow it to be filed within a further period not exceeding sixty days.

Provided also that any appeal pending before the High Court, before the commencement of the National Green Tribunal Act, 2010, shall continue to be heard and disposed of by High Court as if the National Green Tribunal had not been established under section 3 of National Green Tribunal Act, 2010.

52A. Any person aggrieved by any determination of benefit sharing order of the National Biodiversity Authority or a State Biodiversity Board under this Act, on or after the commencement of the National Green Tribunal Act, 2010, may file an appeal to the National Green Tribunal established under section 3 of the National Green Tribunal Act, 2010, in accordance with the provisions of that Act.

Execution of determination or order:

53. Every determination of benefit sharing or order made by the National Biodiversity

Authority or a State Biodiversity Board under this Act or the order made by the High Court in any appeal against any determination or order of the National Biodiversity Authority or a State Biodiversity Board shall, on a certificate issued by any officer of the National Biodiversity Authority or a State Biodiversity Board or the Registrar of the High Court, as the case may be, be deemed to be a decree of the civil court and shall be executable in the same manner as a decree of that court.

In Consequence of Section 21 of the Biological Diversity Act, 2002, the Criteria for equitable benefit sharing are further clarified in **Biological Diversity Rules, 2004**. Section 14 defines the procedure for access to biological resources and associated knowledge; section 15 deals with the revocation of access or approval; section 16 deals with restriction on activities related to access to biological resources; section 17 deals with the procedure for seeking approval for transferring results of research; section 18 deals with the procedure for seeking prior approval before applying for intellectual property right; section 19 deals with the procedure for third party transfer under sub section (2) of section 20 and the criteria for equitable benefit sharing is provided in section 20 of the Rules. These criteria are:

- 1) The Authority shall be notified in the Official Gazette to formulate the guidelines and describe the benefit sharing formula.
- 2) The guidelines shall provide for monetary and other benefits such as royalty; joint ventures; technology transfer; product development; education and awareness raising activities; institutional capacity building and venture capital fund.
- 3) The formula for benefit sharing shall be determined on a case-by case basis.
- 4) The Authority while granting approval to any person for access or for transfer of results of research or applying for patent and IPR or for third party transfer of the accessed biological resource and associated knowledge may impose terms and conditions for ensuring equitable sharing of the benefits arising out of the use of accessed biological material and associated knowledge.
- 5) The quantum of benefits shall be mutually agreed upon between the persons applying for such approval and the Authority in consultation with the local bodies and benefit claimers and may be decided in due regard to the defined parameters of access, the extent of use, the sustainability aspect, impact and expected outcome levels, including measures ensuring conservation and sustainable use of biological diversity.
- 6) Depending upon each case, the Authority shall stipulate the time frame for assessing benefit sharing or short, medium, and long term benefits.
- 7) The Authority shall stipulate that benefits shall ensure conservation and sustainable use of biological diversity.
- 8) Where biological resources or knowledge is accessed from a specific individual or a group of individuals or organizations, the Authority may take steps to ensure that the agreed amount is paid directly to them through the district administration. Where such individuals or group of individuals or organizations cannot be identified, the monetary benefits shall be deposited in the National Biodiversity Fund.

- 9) Five percent of the assessed benefits shall be earmarked for the Authority or Board as the case may, towards administrative and service charges.
- 10) The Authority shall monitor the flow of benefits as determined under Sub-rule (4) in a manner determined by it.

Process of ABS applications in India:

In its efforts to achieve the objectives of the Convention of Biological Diversity (CBD), the Government of India enacted the Biological Diversity Act in 2002 and notified the Rules there under in 2004. The National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs) and the Biodiversity Management Committees (BMCs) oversee the implementation of the Act and Rules at national, state and local levels respectively. India is one of the few countries in the world that has gone beyond dealing with ABS as a technical issue involving inordinate amount of discussions amongst a various group of experts and policy makers. Section 3, 4, 6 and 7 of Biological Diversity Act 2002 and Rules 14-19 of the Biological Diversity Rules 2004 lay down a clear, predictable and transparent process for access to Indian biological resources and/or associated traditional knowledge. India is perhaps the first country in the world that has been able to tap into the magnitude of ABS having dealt with a large number of applications. ABS agreements under the Biological Diversity Act are divided into four categories:

Form 1: It deals with direct access to biological resources and/or associated traditional knowledge;

Form 2: It deals with the transfer of research result relating to biological resources from India;

Form 3: It deals with applications for intellectual property rights;

Form 4: It deals with transfer of biological resources and/or associated traditional knowledge to third parties by individuals/entities who have accessed these resources and knowledge through Form 1.

Who is required to make ABS applications?

1. All individuals other than Indian citizens require the approval of the National Biodiversity Authority when they access/use biological resources and associated knowledge occurring in India or obtained from the country for commercial or research purposes or for the purposes of bio-survey or bio-utilization.
2. Indians and Indian institutions do not require the approval of the National Biodiversity Authority when they engage in the above-mentioned activities and state biodiversity boards of the respective states will deal with them.
3. Any application for intellectual property rights based on Indian biological resources irrespective of whether such applications are filed by Indians or non-Indians requires the prior approval of the NBA.

What is excluded under the Biological Diversity Act?

1. Normally traded commodities (provided the material is used only as commodity).
2. Uses by cultivators and breeders e.g. farmers, livestock keeper and beekeepers and traditional healers e.g. vaid and hakims.
3. Collaborative research between Indian and foreign institutions that conform to the notified guidelines by the Ministry of Environment and Forest, Government of India has its approval.
4. Human Genetic material and Value Added Products.
5. Application for protection under Protection of Plant Varieties and Farmers Rights Act, 2001.

Access and Benefit Sharing Issues: -There are some key issues:

Trans boundary nature of genetic resources and associated knowledge: -The biological diversity or genetic diversity and associated knowledge doesn't recognise the political or physical boundaries and has trans boundary nature and can be available at several places. Therefore, there is a need of a multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in trans boundary situations whether at domestic level or at international level for which it is not possible to grant or obtain prior informed consent and also there is no proper and widely accepted mechanism for benefit sharing among various knowledge holders. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally." But it is easier said than done. This is also needed as per Nagoya Protocol.

The Access and Benefit-sharing Clearing-House: - There is a need to establish an Access and Benefit-sharing Clearing-House as part of the Clearing-House of the Convention. It shall serve as a means for sharing information related to access and benefit sharing. In particular it shall provide access to information made available by each Party relevant to the implementation of the Nagoya Protocol.

Awareness-raising: - Though several years has passed since Earth Summit when CBD was adopted by global community, yet the understanding about the convention, various protocols and Biological Diversity Act, 2002 is very low till to date. People at large don't understand the gravity of loosing the biological diversity and associated knowledge, the clarity of roles and responsibility is not there and also what kind of benefit it could bring to them. Therefore, it is needed to start awareness raising campaigns and people need to be made aware of their role and responsibilities and the threats that could be there if the biodiversity is depleted at the same rate. The Nagoya Protocol also provides that each Party shall take measures to raise the awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues.

Capacity building and development: - There is a lack of capacity to implement the CBD, various protocols and Biological Diversity Act, 2002. Capacity development and strengthening of human resources and institutional capacities to effectively implement them is urgently needed. In this context, it is imperative to facilitate the involvement of indigenous and local communities and relevant stakeholders. Nagoya Protocol provides that Parties shall cooperate in the capacity building and development.

Customs and Customary Law and Traditional Knowledge: - How the customary law and practices define, shape and sustain traditional knowledge within indigenous peoples and local communities, this needs to be understood. Where indigenous peoples and local communities wish to strengthen the role of customary law in the governance of their traditional knowledge, what resources or support would be helpful needs to be identified? What are the existing ways of recognizing or respecting customary law and practices, beyond indigenous peoples and local communities? The possibility of bringing these in the folds of national law needs priority. The awareness and capacity building is needed. How can customary law and practices and traditional knowledge be recognized specifically within IP system?

Documentation of resource and associated knowledge: Biological diversity plays a vital role in the preservation and maintenance of world's cultural, environmental, ecological and economic systems. Biodiversity is closely linked to livelihood of many people, agricultural production and sustainability, conservation and protection of unique flora, fauna and natural environment, human health and nutrition, traditional knowledge, skills and technologies, cultural and social integrity. Documentation is the systematic recording of all form of biological resources, their products, variability in them and associated knowledge, skill and technology and put them in the legal framework to give protection to the holders of resources and knowledge. Documentation of biodiversity and associated knowledge and the holders of the knowledge are legally done in India under Biological Diversity Act, 2002 in the form of the People's Biodiversity Registers (PBRs). This is a highly technical and time consuming activity and needs lots of scientific validations and this process has already begun in India. If Fair and equitable sharing of the benefits arising out of the utilization of genetic resources, which is the third pillar of CBD and is also in the preamble of the Biological Diversity Act, 2002 is to be done then the legal documentation of biodiversity and associated knowledge in the form is PBR's is must.

Lack of clarity on the engagement with outsiders: The people or communities holding the knowledge and resources needs to grant Prior Informed Consent (PIC) if they agree to grant PIC and the outsiders needs to obtain PIC prior to accessing any bio resources or associated knowledge from the holder of the knowledge or resources as ultimately this PIC will lead to Mutually Agreed Terms (MAT) between the provider and user, which will be acceptable to both the parties, but these outsiders enter into partnerships with providers of genetic resources in distinct ways, have specific sets of stakeholders, negotiate prior informed consent in diverse ways, and have different approaches through which they reach mutually agreed terms with regard to benefit-sharing and intellectual property. Agreements within and across sectors also vary considerably with regard to the

legal remedies they use for compliance and enforcement. So it becomes very complicated and difficult to regulate and monitor, therefore, there is a need of clarity on the issue of partnership between provider and users. There is a need of simple, easy to understand and legal formats for PIC and MAT.

Researches for commercial purposes verses for academic purposes: There is a thin line between the researches done purely for academic purposes and researches done for commercial purposes. It is very difficult to ascertain, when the research done for academic purpose gets converted into commercial activity. Section 5 of the Act exempts collaborative research from the requirements of securing prior approval of the NBA. The exemption covers collaborative research between Indian and foreign Institutions and aims to facilitate research and while removing any encumbrances to the same. For research to qualify as collaborative research under Section 5, the guidelines for collaborative research as approved by the Central Government will have to be followed. While much of the collaborative research initially has no real commercial intent but does have clear commercial aims. This blurs the line between collaborative research that is exempted under the Biological Diversity Act and commercial use that requires the prior approval of the National Biodiversity Authority (NBA) and benefit sharing. There is need for clear guidelines for accessing the resource and associated knowledge for commercial purpose and for academic purpose.

Non availability of robust marketing system hampering the Benefit Sharing: Though slowly the country is gearing to implement the CBD, various protocols and the Biological Diversity Act, 2002, yet the benefit to the community or the knowledge holders as envisaged in CBD and BD Act, 2002 are yet to reach them and one of the reason is the non availability of assured market system. There are several actors playing their role in the value chain till the bio resource or knowledge reaches the ultimate user, and this long value chain ultimately result into lesser amount of return. Therefore, there is need for doing value chain assessment and the user and provider needs to come to same page, with better understanding for successful access and benefit sharing of the bio resources and associated knowledge.

Administrative and Monitoring Issues: Bio resources or genetic resources and associated knowledge is dealt by several agencies and it is very difficult to keep track on the issue of access to bio resource, whether the provisions of the BD Act are being followed or not, whether PIC has been taken from the holders of the resource or knowledge, whether MAT has been signed both by provider and users. Sensitization and awareness raising is the only answer to this kind of problem, all agencies and departments dealing with the bio resources needs to understand their role and responsibilities as per law and start cooperating with NBA, SBBs and BMCs in the implementation of the BD Act, 2002 and the provisions of CBD. CBD and BD Act, 2002, establish a system for access and benefit sharing (ABS) in relation to genetic resources. It recognizes that access to these resources must be subject to the prior informed consent (PIC) of the provider and based on mutually agreed terms (MAT), including fair and equitable sharing of any resulting benefits. Also, it is requires that access to related traditional knowledge occur with the approval of the holders of such knowledge, who must also participate equitably in the resulting benefits.

ABS Terminology:

1. ABS regime – The Conference of the Parties to the Convention on Biological Diversity (CBD) decided in 2004 to create an international regime on access to genetic resources and sharing of the benefits arising out of their utilisation through an ABS regime. Negotiations on an international ABS regime started in 2005, but it is predicted that it will take up to ten years to complete the establishment of such a regime.

2. Access – To obtain biological resources or knowledge associated thereto within national jurisdiction for the purpose of research, or for commercial utilization, or for bio-survey and bio-utilization.

3. Agreement – An agreement is a mutual understanding between two or more legally competent persons with respect to their rights and duties regarding their past or future actions. Every promise and every set of promises forming considerations for each other are agreements.

4. Agriculture – The art and science of growing plants and raising animals for food, other human needs, or economic gain.

5. Agro-biodiversity – Biological diversity of agriculture related species and their wild relatives.

6. Benefit Claimer - "benefit claimers" means the conservers of biological resources, their byproducts, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application.

7. Benefit – Economic and academic advantages arising from research on the utilization of genetic resources.

8. Benefit Sharing – Equitable sharing of the benefits (both monetary and non-monetary), arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers. As per Biological Diversity Act, 2002, benefits can be shared by means of – grant of joint ownership of intellectual property right; transfer of technology; location of production, research and development unit in such areas, which will facilitate better living standards to the benefit claimers; association of Indian scientist, benefit claimers and local people with research and development in biological resources and bio-surveys and bio-utilizations; setting up of venture capital fund for aiding the cause of benefit claims; and monetary and non-monetary benefits.

9. Biological Diversity - means the variability among living organisms from all sources and the ecological complexes of which they are part, and includes diversity within

species or between species and of eco-systems.

10. Biodiversity Act - National statutory legal instruments developed to implement CBD obligations, including regulation of the access and benefit sharing mechanism from genetic resources and associated traditional knowledge.

11. Biological Resources - means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material.

12. Bio-survey and Bio-utilization - means survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and include characterization, inventorization and bioassay.

13. Biodiversity Management Committee (BMC) – As per Act of India, BMCs are committees constituted by local bodies in their jurisdiction. BMC are constituted for the purpose of promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms and chronicling of knowledge related to biological diversity. BMCs are statutory bodies at local level.

14. Bio-prospecting – The collection, research and use of biological and/genetic material for purpose of applying the knowledge derived there for scientific and/or commercial purposes. Bio- prospecting entails the search for economically valuable genetic and biochemical resources from nature.

15. Bio-piracy – The appropriation of biological resources without the prior informed consent of the owners of local people or government.

16. Bio-trade - The collection, production, transformation, and commercialization of goods and services derived from native biodiversity under the criteria of environmental, social, and economic sustainability.

17. Byproduct - A molecule or a combination or mixture of natural molecules including crude extracts of live or dead organisms of biological origin that comes from the metabolism of living beings. Any part taken from biological and genetic resources such as hides, antlers, feathers, fur, internal organs, roots, trunks, branches, leaves, stems, flowers and the like, including the compound indirectly produced in a biochemical processor cycle.

18. Clearing House Mechanism – An effective information service (established by CBD) to promote and facilitate scientific and technical cooperation, knowledge sharing and information exchange, and to establish a fully operational network of parties and partners.

19. Commercial Utilization - means end uses of biological resources for commercial

utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping.

20. Country of Origin – The country from where the genetic resources and/ or biological material originated. A country of origin can be a primary or a secondary center of origin for the material.

21. Country providing Genetic Resources – The country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

22. Cultivars - A variety of plant that has originated and persisted under cultivation or was specifically bred for the purpose of cultivation.

23. Cultural Diversity - Culture takes diverse forms across time and space. This diversity is embodied in the uniqueness and plurality of the identities of groups and societies making up humankind. As a source of exchange, innovation, and creativity, cultural diversity is as necessary for humankind as biodiversity is for nature. In this sense, it is the common heritage of humanity and should be recognised and affirmed for the benefit of present and future generations

24. Derivatives - A product including information developed, or part taken, or extracted from a biological or genetic resource, e.g., varieties, strains or breeds, blood, proteins, oils, resins, gums, genes, seeds, spores, bark, wood, leaf matter, or formulae; includes products incorporating material or formulae as above.

25. Domesticated or Cultivated Species – Species in which the evolutionary process has been influenced by human to meet their needs.

26. Folk Varieties – A cultivated variety of plant that was developed, grown and exchanged informally among farmers.

27. Fair and Equitable Sharing – means sharing of benefit as determined by the National Biodiversity Authority under section 21.

28. Genetic Material - The Convention on Biological Diversity defines genetic materials as materials of actual or potential value. They may be any material of plant, animal, microbial, or other origin, containing functional units of heredity. These may include a whole organism, parts of an organism, or biochemical extracts from tissue samples that contain deoxyribonucleic acid (DNA), or in some cases ribonucleic acid (RNA). In the context of an ABS regime, this is the key element and is the ultimate biological information that can be used to develop and derive a new product or transgenic biological

material.

29. Genetic Resources – All genetic materials of actual or potential value; the value need not be commercial or monetary, but may be scientific or academic in nature.

30. Genetically Modified Organisms (GMO) – A microorganism, plant, or animal whose genetic characteristics have been modified by inserting a modified gene or a gene from another variety or species; genetically modified organisms (GMOs) may be microorganisms designed for use as bio-pesticides, or seeds that have been altered genetically to give a plant better disease resistance or growth.

31. Indigenous People - Peoples in independent countries whose social, cultural, and economic conditions distinguish them from other sections of the national community, and whose status is regulated wholly or partially by their own customs or traditions, or by special laws or regulations.

32. Intellectual Property – Creation of the mind: inventions, literary and artistic work, and symbols, names, images, and designs used in commerce.

33. Local Bodies - means Panchayats and Municipalities, by whatever name called, within the meaning of clause (1) of article 243B and clause (1) of article 243Q of the Constitution and in the absence of any Panchayats or Municipalities, institutions of self-government constituted under any other provision of the Constitution or any Central Act or State Act.

34. Landrace – Primitive cultivars that was grown by ancient farmers and their successors.

35. Monetary Benefit – Benefit include access fee/fee per sample, collected or acquired, up-front payments, milestone payments, payments of royalties, license fee in case of commercialization, special fee, salaries and other mutually agreed, research funding, joint venture and joint ownership of relevant IPRs.

36. Mutually Agreed Term (MAT) – A set of terms and conditions agreed between the provider and user of the genetic resources for prospecting purposes.

37. Normally Traded Commodities (NTCs) - The notification issued by Ministry of Environment and Forests, Government of India under section 40 of Biological Diversity Act, 2002, of the bio resources exempted from the purview of the Act.

38. Patent – An intellectual property right granted to an inventor, giving him/her/them exclusive rights of use on such invention, for a stipulated period of time, provided the invention is made public by disclosure. Patents on their own do not grant anything but only provide legal means by which the inventor can prevent anybody else from using the invention. Patents are country specific.

39. People's Biodiversity Registers (PBRs) – It is a register that contains comprehensive information on availability and knowledge of local biological resources, their medicinal or any other use and any other traditional knowledge associated with them. The preparation of PBRs is mandated under Biological Diversity Act, 2002.

40. Prior Informed Consent (PIC) – A set of administrative procedures for deciding on whether to grant access to biological resources on defined terms.

41. Provider – A person who provide biological resources and associated knowledge.

42. Research - means study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use.

43. Regime - A set of rules, policies, and norms of behaviour that cover any legal issue and that facilitates substantive or procedural arrangements for deciding that issue.

44. Sovereign Right - Rights which appertain to independent sovereign states to legislate, manage, exploit, and control access to their natural resources; they include the right to determine the property regimes applicable to those resources, what rights of ownership can be entertained, and how ownership is established.

45. Sui generis – Literally one of its own kind.

46. Sustainable Use - means the use of components of biological diversity in such manner and at such rate that does not lead to the long-term decline of the biological diversity thereby maintaining its potential to meet the needs and aspirations of present and future generations.

47. Traditional Knowledge - Refers to the knowledge, innovations, and practices of indigenous and local communities around the world; developed from experience gained over the centuries and adapted to the local culture and environment, traditional knowledge is transmitted orally from generation to generation. It tends to be collectively owned and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds. Traditional knowledge is mainly of a practical nature, in the field of biological diversity.

48. Up-front Payments – It is anything of value, usually money, delivered at the time a contract is signed.

Value Added Product - Products, which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.

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