

Global governance and national mechanisms in India for regulating access to genetic resources and benefit sharing

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Abstract

Global governance is a concept that advocates sustainable development as the primary consideration for managing biological resources, and operates through international agreements/multilateral treaties/global conventions with their own provisions and obligations. The 1992 Convention on Biological Diversity was the first major step taken by humankind for promoting the conservation of bioresources, their sustainable use and sharing (in a fair and equitable manner) of the benefits arising from their commercial utilization. The 2010 Nagoya Protocol on Access and Benefit Sharing (ABS) provides regulatory framework for users' authorized access to genetic resources and providers' sharing of the benefits with the owners of those resources. National obligations on ABS under the global governance system are met by enacting national laws and rules for regulation of ABS and their implementation, in turn, involves various agencies, institutions and organisations working at different levels. This paper aims at creating awareness on the complex interplay of ABS governance at the international and national levels.

Key words: Plant genetic resources, access and benefit sharing, ABS mechanisms, ABS governance, global governance of ABS regimes, regulatory system for ABS in India

Introduction

Governance of Genetic Resources

Genetic resources, including the traditional knowledge associated with them, form an important subset of biological resources as they provide the essential building blocks for developing superior crop varieties, improved livestock breeds, pharmaceutical drugs and bio-based commercial products. Governance systems for access to them and for sharing the benefits (ABS)

arising from their commercial utilization may be seen from several aspects such as perspectives of the primary stakeholders, provisions of the national regulatory framework and the country's legally binding obligations under international treaties to which it is a Contracting Party [1]. Although the Convention on Biological Diversity (CBD), adopted in 1992, recognized sovereignty of nations over their natural resources, and also on setting terms of access to them subject to their national legislation, yet the bilateral, multilateral and international treaties as well as global conventions have a way of overriding the sovereign rights of nations in view of the contractual nature of these agreements [2].

Governance of genetic resources needs to be looked from three dimensions, namely, perspective of their developers and users, governance at the state and national levels, and national obligations under international treaties/agreements [3].

The first dimension of developers and primary users comprises local farming communities, public sector research institutions, seed companies and multinational corporations. They represent the main stakeholders and key beneficiaries. The second dimension involves policy makers, legislators, managers and administrators. The third dimension relates to national obligations under multilateral environment and trade agreements. Under the last category, three major international agreements, namely, CBD, ITPGRFA and WTO-TRIPS have impacted the access to genetic resources globally and also at the national level, more so in the developing countries. The first two treaties highlight the conservation of bio-resources, their sustainable use, regulated access and fair and equitable

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benefit sharing while the third focuses mainly on patenting/ protection laws that grant monopolistic/ exclusive rights to IPR holders/ breeders to the exclusion of the rights of farmers and other primary beneficiaries. These three are legally binding treaties and India is a contracting party to them. Considering that agrobiodiversity is a subset of the total biological diversity, and a very important one, it is imperative that all these international agreements need to be implemented in harmony with each other [4].

Global developments on access to genetic resources and benefit sharing

In order to understand the landscape of international governance of genetic resources, it is important to appreciate the on-going governance efforts and identify the problematic areas where more attention is required for moving forward. An overview of the global developments, bearing on access to genetic resources and benefit sharing, is presented below:

Linkages between international laws and the national legal and policy framework for harmonious and effective implementation

Policies describe the objectives and missions of a government and how it proposes to achieve those objectives using various tools. Laws, on the other hand, are the standard rules and regulations that are compulsory to be followed by all the people of that country and there are provisions in those laws for punishment for those who violate them. In other words, laws help a government in setting up legal and institutional framework to achieve the aims spelt out in its policy statements. National laws are enacted by the parliament and enforced by the national government within its national boundaries. International laws, in contrast, arise often from legally binding national obligations under international agreements, treaties, conferences and conventions. They expand the jurisdiction of national laws beyond their national boundaries.

Impact of the UN Conference on the Human Environment, 1972

UN Conference on the Human Environment, held in Stockholm in 1972, took some important decisions concerning environment and sustainable development and had a significant impact in India. The 42nd Amendment to the Indian Constitution was made in 1976 adopting Article 48A (Directive Principles) stating that the State shall endeavour to protect and improve the

environment and to safeguard the forests and wildlife of the country. The subject of wildlife and forests was transferred from the state list to the concurrent list of the constitution through this decree, providing enormous powers to the Central Government in this area. In addition, Article 51A (g) (Fundamental Duties) was also introduced to protect and improve the natural environment including forests, lakes, rivers, wildlife and to have compassion for living creatures. The Wildlife (Protection) Act, 1972 (as amended in 1991), the Water (Prevention and control of pollution) Act, 1974, the Air (Prevention and control of pollution) Act, 1981 and the Environment Protection Act, 1986 were enacted to fulfill the commitments made by India during the Stockholm Conference. A separate Department of Environment was created in 1980 and a separate Union Ministry of Environment & Forests was established in 1985.

The International Undertaking on Plant Genetic Resources, 1983

In 1983, the FAO established a Commission on Plant Genetic Resources (later renamed the Commission on Genetic Resources for Food & Agriculture), the first permanent intergovernmental forum devoted to conservation and development of genetic resources. The Commission's first major action was to adopt a non-binding resolution known as the International Undertaking (IU) on Plant Genetic Resources (PGR). It worked on the basic principle that PGR are common heritage of humankind and, hence, should be made available without restriction. Many commercial seed companies disliked the IU because it required that elite genetic stocks (including improved and current breeders' lines) should also be made available without restriction. Under this influence, the United States and many other developed countries declined to sign the IU. Efforts to conciliate the concerns of developed and developing countries resulted in two 1989 amendments to the Undertaking and resulted in the United States and Canada joining the Commission but they still did not sign the IU. In 1993, FAO adopted Resolution 7/93, calling for intergovernmental negotiations for revision of the IU to harmonise its contents with those of the CBD. Accordingly, provisions of the IU were suitably revised in harmony with those of the CBD and the revised version was adopted in 2001 as the legally-binding International Treaty on Plant Genetic Resources for Food & Agriculture.

The 1992 Convention on Biological Diversity (CBD): The Turning Point

In 1992, the United Nations hosted an Earth Summit in

Rio de Janeiro and it gave birth to the legally binding Convention on Biological Diversity (CBD). Objectives of the CBD include the conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The CBD marked the end of the 'common heritage' notion of genetic resources and it asserted that nations have sovereign rights over natural resources within their boundaries, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. Access, where granted, shall be on mutually agreed terms (MAT) and subject to prior informed consent (PIC) of the Contracting Party providing such resources. The United States is the only major country that has not ratified the CBD.

Implementing CBD gained momentum soon after its entry into force in December 1993 as several nations passed legislation to claim sovereign rights over their bioresources and to implement CBD's provisions. For example, the Philippines established a system for access to biological resources by an executive order issued in 1995 and the Andean Community, in its Decision No. 391 taken in 1996, adopted a Common Regime on Access to Genetic Resources. India enacted the Biological Diversity Act in 2002 and framed Rules under it in 2004.

The Nagoya Protocol to CBD on ABS, 2010: A New Beginning

The Nagoya Protocol to CBD on ABS is a new international treaty on ABS, adopted in October, 2010 to support implementation of the third objective of CBD, namely, the fair and equitable sharing of benefits arising from the utilization of genetic resources. It is based on the twin principles of prior informed consent (PIC) and mutually agreed terms (MAT) enshrined in the CBD. This Protocol on ABS entered into force on 9 October, 2014 prompting the Parties to CBD to prepare for its implementation by taking appropriate policy, legislative and administrative measures. India signed the Protocol on 11 May, 2011 and ratified it on 9 October, 2012. This Protocol requires that Provider Parties adopt measures that need to:

- Create legal certainty, clarity and transparency for access to genetic resources
- Provide fair and non-arbitrary rules and procedures

- Establish clear rules and procedures for prior informed consent and mutually agreed terms
- Provide for issuance of an internally accepted certificate when access is granted.

In India, the Union Ministry of Environment, Forests & Climate Change is the nodal ministry for implementing the Nagoya Protocol on ABS with its Additional Secretary Shri Hem Pande serving as the National Focal Point. The National Biodiversity Authority (NBA) has been designated as the National Competent Authority for this purpose and the format for the Internationally Recognized Certificate of Compliance has also been approved. Efforts are now on to designate the Check Points. Other key provisions to make the ABS regime functional include developing user country measures as well as the provider country measures.

Concerns on the relationship between ABS provisions under CBD and other international legal regimes bearing on genetic resources led to inclusion of Article 4 of the Nagoya Protocol stating that the Nagoya Protocol does not apply to Parties to the specialized instrument in respect of specific genetic resources covered by and for the purpose of that specialized instrument. The scope of other existing regimes will therefore be crucial to define which genetic resources are covered by the Nagoya Protocol. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), for example, has been in force since 2004. It is a global instrument designed to promote conservation of plant genetic resources for food and agriculture, and to help protect farmers' rights, and also to ensure fair and equitable sharing of benefits arising from the use of PGRFA. The Plant Treaty has established a Multilateral System (MLS) under which GR of crops, listed in Annex-1, are exchanged without individual regulation, subject to a standard material transfer agreement (SMT). One challenge concerning this instrument is that not all parties to the CBD are members of the Plant Treaty. Another concern is that ABS in the Plant Treaty differs from the ABS regime of the CBD.

Another alarming development is that the FAO Commission on GRFA is now discussing ABS mechanisms for six groups of genetic resources, namely, animals; aquatic; invertebrates; plants; forest; and microbial genetic resources [5]. Any agreement in the Commission on a need for specialised regimes for ABS holds potential to exclude commercially valuable groups of ABS governed by the CBD and the Nagoya

Protocol. Another international platform for regulating access and benefit sharing has reached agreement with the World Health Organisation in 2011 giving green light to two SMTAs concerning exchange and use of viral genetic resources with pandemic potential for humans. The question of access and benefit sharing from genetic resources in the area beyond national jurisdiction has also been on the agenda of the UN Convention on the Law of the Sea. This could include, for example, genetic resources taken from the seabed and/or the high seas. Discussion under the auspices of the Antarctic Treaty is also progressing on how to regulate genetic resource material from one of the world's most remote, yet biologically unique areas.

The Nagoya Protocol establishes clear rules for accessing, trading, sharing and monitoring the use of the world's genetic resources that can be used for pharmaceutical, agricultural and cosmetic purposes. By establishing this framework, it seeks to ensure that genetic resources are not used without prior consent of the countries that provide them, and that the communities, that possess the traditional knowledge associated with the use of these resources, also enjoy the benefits of sharing them with the rest of the world.

The Protocol seeks to increase transparency in transfer of genetic resources through its Access Benefit-Sharing Clearing House (ABS-SH), which is an online platform for exchanging relevant information [6]. Its goal is to enhance clarity on procedures for access to genetic resources as well as monitoring their use.

The International Treaty on Plant Genetic Resources for Food and Agriculture: A New Approach to promote Global Food Security

Recognizing the interdependence among countries regarding crop genetic resources, representatives of 116 member-nations of FAO approved in Rome on 3 November, 2001 a new International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) to promote global food security. The FAO revised the text of the IU on PGR to bring its provisions in harmony with those of the CBD and then adopted it as the legally binding International Treaty. Farmers' Rights were recognized under this Treaty but its realization was left to the national governments in their jurisdiction. The issue of collecting genetic resources from countries of their origin, prior to CBD, still hangs on but the designated accessions stored in CGIAR's International Gene Banks have been brought under the jurisdiction of FAO.

Of the nations participating in that FAO conference, only the United States and Japan abstained, citing concerns about a lack of clarity regarding the effect of the Treaty on intellectual property rights (IPR). The Plant Treaty, which entered into force on 29 June, 2004, provides a Multilateral System (MLS) of Access and Benefit-Sharing to facilitate exchange of PGRFA. The MLS applies to an initial annex of 35 food crops and 29 genera of forages. Because this list is a result of political compromises, some crops that might have been expected to be covered, such as soybean, groundnuts, and sugar cane are conspicuously missing. It is notable that the MLS covers only those PGRFA which are "in the public domain;" and those which are held in trust, in *ex situ* collections, by IARCs.

The Treaty forbids recipients of PGRFA through the MLS to claim any IPR that may limit the access to them or their genetic parts or components, in the form received from the MLS. There are, however, some hazy areas on this aspect that need to be addressed [7]. Unlike the CBD, which provides for bilateral negotiations to establish the terms of access and benefit sharing for each specific exchange of materials, all germplasm exchanges under the MLS will be subject to SMTA. Monetary benefits will be paid to the Global Crop Diversity Trust Fund to be used primarily to support farmers who conserve and sustainably use PGRFA. However, the financing of germplasm conservation activities has been addressed only in general terms, making this aspect of the treaty potentially difficult to implement.

Implementing the ITPGRFA in India

The Union Ministry of Agriculture & Cooperation is the nodal Union Ministry for implementing the ITPGRFA and the Joint Secretary (Seeds) is the National Focal Point, assisted by the DARE and NBPGR. A notification has been issued exempting the exchange of designated accessions of genetic resources of crops listed in Annex-1 of the ITPGRFA from the provisions of Sections 3 and 4 of the Biological Diversity Act for research, breeding and training purposes. Germplasm exchange will be done based on signing the SMTA as approved under this Treaty.

Trade Related Intellectual Property Rights (TRIPS)

The TRIPS Agreement under WTO, which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on IPRs. It requires Member countries to make patents available for any inventions, whether products or processes, in

all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability.

There are three permissible exceptions to the basic rule on patentability. One is for inventions contrary to *ordre public* or morality including inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The second exception is that Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. The third exception is that Members may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, any country excluding plant varieties from patent protection must provide for an effective *sui generis* system of protection. The term of protection available shall not end before the expiry of a period of 20 years counted from the filing date. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Compulsory licensing and the government use, without the authorization of the right holder, are allowed.

India amended its Patents Act, 1970 to permit patenting of products and also of micro-organisms, as required under the TRIPS Agreement, and also enacted the Protection of Plant Varieties and Farmers' Rights Act, 2001.

In a bid to harmonise provisions of the CBD and WTO-TRIPs, the Doha Ministerial Declaration had asked for 'Disclosure of Source and Origin' to be made mandatory in patent applications which were also required to have an International Certificate of Compliance to the CBD confirming PIC and MAT provisions. Doha Round of negotiations is, however, underway since 2001 though the progress made so far is much below the developing countries' expectations.

National Legislation in India for Implementing the International Treaties on ABS

Under the CBD, the Sovereign Authority to determine access to genetic resources rests with the national governments and it is subject to their national legislation. The Biological Diversity Act, 2002, was enacted in India to fulfill this requirement and also to provide further support to other complementary national laws in force, namely, the Wildlife (Protection) Act, 1972 (as amended in 1991), and the Protection of Plant Varieties & Farmers'

Rights (PPVFR) Act, 2001. It also provides suitable linkage to the provision for patenting of products and processes/ technologies, based on the use of bio-resources and associated indigenous traditional knowledge (ITK), under Section 10 (4) of the Patents (Amendment) Act, 2002. The stage is thus set for developing a national movement for implementing these combined provisions for access and benefit sharing to ensure food and livelihood security based on conservation, inclusive development and sustainable use of bio-resources [8].

Access and Benefit Sharing under India's Biological Diversity Act, 2002

This national legislation has the following objectives:

- to regulate access to biological resources of the country with the purpose of securing fair and equitable share in benefits arising out of the use of biological resources and associated traditional knowledge;
- to conserve and promote sustainable use of all components of biological diversity;
- to respect and protect traditional knowledge of local communities related to bioresources;
- to secure sharing of benefits with local people as developers and conservers of biological resources and holders of knowledge and information associated with their use;
- to promote conservation and development of areas of importance from the standpoint of biological diversity by declaring them as biological diversity heritage sites;
- to provide support to on-going programmes on protection and rehabilitation of rare, endangered and threatened species;
- to ensure increasing involvement of institutions and state governments in the broad scheme of implementing the Biological Diversity Act, through constitution of appropriate committees.

In addition to promoting conservation and sustainable use of all categories of bio-resources, this umbrella legislation regulates access to them while determining mode/quantum of fair and equitable benefit sharing, and signing agreements with the users based on mutually agreed terms.

In exercise of the powers conferred by Sub-

Section (1) and (4) of Section 8 of the Biological Diversity Act, 2002, the Central Government has established the National Biodiversity Authority (NBA), on 1st October, 2003. The main functions of this Authority are:

1. To lay down procedures and guidelines to govern the activities provided under Section 3, 4, and 6: Permission to foreigners/non-resident Indians/ foreign entities.
2. To regulate activities and advise the government of India on research/ commercial use of bio-resources, bio-survey and bio-utilization.
3. To grant approval under Section 3, 4 and 6 based on the following considerations:
 - Certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority (Section 3).
 - Results of research not to be transferred to certain persons without approval of National Biodiversity Authority (Section 4) (Transfer of Research Results).
 - Applications for seeking IPR rights not to be made without prior approval of the NBA (Section 6).
4. To grant approval to certain persons seeking transfer of already accessed biological resource/ associated traditional knowledge (Third Party Transfer) (Section 20).
5. To determine and impose terms of equitable benefit sharing, arising out of the use of accessed biological resources and associated traditional knowledge (Section 21).
6. To advise the State Governments in the selection of areas of biodiversity importance to be notified under Section 37(1) as heritage sites and measures for their management.
7. To take any measure, on behalf of the Central Government, necessary to oppose the grant of IPR in any country outside India on any bioresource obtained from India or knowledge associated with it which is derived from India.

In essence, this Act seeks to regulate access to India's biological resources, and associated TK, with a view to securing equitable sharing of benefits arising from their use. Recognising that the Indian citizens owe

allegiance to the Indian Constitution and can be called upon by the courts in person to ensure compliance to this Act's provisions, a differentiating way has been adopted under which the following categories of persons/ body corporate / associations/ organizations are required to obtain prior approval of the NBA for seeking access to India's bio-resources (and associated TK) for research and commercial use or engaging in bio-survey and bio-utilization activities [Section 3 and Section 19):

- A person who is not a citizen of India
- A citizen of India, who is non-resident
- A body corporate, association or organization – not incorporated or registered in India; or incorporated or registered in India but has any non-Indian participation in its share capital or management.

All the users are also required to seek prior approval of NBA for transferring research results abroad [Section 4), for applying for IPR (Section 6) and also for third party transfer of the granted approval (Section 20), by submitting applications in specified formats and after payment of prescribed fee for each of the above mentioned purposes

Access of Indian citizens to bio-resources for research is unrestricted and free. However, the Section 7 states that 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 use except after giving prior intimation to the concerned State Biodiversity Board.

Restrictions Imposed on Granting Access [Section 24 (2) read with Rule 15

Certain restrictions have been imposed under Rule 16 on NBA's, and also SBBs' approvals for activities related to access to bio-resources, requiring the Authority to take steps to restrict or prohibit requests for such access on considering the following reasons:

- The request for access is for any endangered taxa;
- The request for access is for any endemic and rare species;
- The request for access may result in adverse effect on the livelihoods of the local people;
- The request for access may result in adverse

environmental impact which may be difficult to control and mitigate;

- The request for access may cause genetic erosion or adversely affect ecosystem functioning;
- When the use of resources is for purposes contrary to national interest and other related international agreements entered into by India.

Penalties

Whoever contravenes or attempts to contravene or abets the contravention of the provisions of section 3 or section 4 or section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both [Section 55 (1)].

Whoever contravenes or attempts to contravene or abets the contravention of the provisions of section 7 or any other order made under sub-section (2) of section 24 shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both. Section 55 (2)]

If any person contravenes any direction given or order made by the Central Government, the NBA or the SBB for which no punishment has been separately provided under this Act, he shall be punished with a fine which may extend to one lakh rupees and in case of a second or subsequent offence, with fine which may extend to two lakh rupees and in case of continuous contravention with additional fine which any extend to two lakh rupees everyday during which the default continues. [Section 56]

The offences under this Act shall be cognizable and non-bailable. [Section 58]

The provisions of this Act shall be in addition to, and not in derogation of, the provisions in any other law, for the time being in force, relating to forests or wildlife. [Section 59]

Exemptions provided under the BD Act

The following exemptions have been provided under this Act to promote bona fide use of bioresources for research and non-commercial use:

- Indian citizens/entities accessing bio-resources for research/ bio-survey and bio-utilization for research in India are exempted from provisions

of this Act.

- Provisions of Section 3 (access to bio-resource) and Section 4 (transfer of research results) shall not apply to the approved collaborative research projects, conforming to the extant policy and guidelines issued by the Ministry of Environment and Forests such as the notification dated 8 November, 2006.
- Provision of Section 6 shall not apply to any person making an application for any right under the Protection of Plant Varieties and Farmers' Rights Act, 2001. Where any right is granted under this law, the concerned authority granting such right shall endorse a copy of such document (granting the right) to the NBA.
- Accessing biological resources for conventional breeding or traditional practice in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry, bee keeping, etc. in India is exempted from the provisions of this Act.. However, "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 interventions, covered u/s 2(f), are not exempted.
- Publication of research papers or dissemination of knowledge, in any workshop exempted from provisions of Section 4 of the Act if it is in conformity with the Guidelines issued by the Central Government for this purpose.
- 'Value added products', which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form as defined u/s 2(p).
- Provisions of Section 7 (prior intimation to SBB for commercial use) shall not apply to the local people and communities including village healers/ *vaid*s, farmers and other traditional growers and also to Indian users of these bio-resources for research (not when seeking intellectual property rights).
- Items such as normally traded commodities, as notified by the Central Government u/s. 40 would be exempt from purview of this Act.
- Exchange of designated accessions of genetic

resources of crops listed in Annex-1 of the ITPGRFA have been exempted but the recipients can not apply for any IPR without prior approval of the NBA.

Authorised Access to Biological Resources required prior to seeking IPR

Any person seeking any kind of IPR in or outside of India for any invention/ technology/product or process based on any biological resource (or associated information) obtained from India, is required to obtain prior permission of the NBA [Section 6]. In addition, the Patent (Amendment) Act, 2002, requires the patent applicant to disclose the source and geographical origin of the used biological material in the patent application, when used in an invention [Section 10 (4)].

The Act provides for its implementation through a 3-tier system comprising the National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs) and the Biodiversity Management Committees (BMCs) at the local communities level. Functions of this system at all the three levels have been well defined.

Notification on Guidelines on Access and Benefit Sharing

Regulation of Access to Biological Resources (and associated TK) and Benefit Sharing: Notified under Biological Diversity Act on 21 November, 2014

These Guidelines provide:

- legal certainty,
- clarity and transparency,
- simplified procedure to the Indian researchers / Govt. institutes to carry out basic research outside India.
- Options of benefit sharing for different users
- Graded benefit sharing system,
- Establishing supply chain from source to manufacturer.
- Upfront payment on high economic valued bioresources (Red sanders, Sandal etc.)
- Apportioning accrued benefits to the community/ BMC.

Facilitating non-commercial research by Indian researchers / Government Institutions

- Through this guideline, NBA introduced a special Form for the Indian research/scientists or Govt . Institutes to carry/send the biological resources

outside India for doing research. (like CSIR, ICAR, ZSI, BSI, Govt. Universities)

- Govt. institutes may send the biological resources outside to carry out studies to avert emergencies like epidemics etc.
- Determination of benefit sharing; Monetary and/ or non-monetary modes, as agreed upon by the applicant and the NBA/ SBB concerned in consultation with the BMC/ Benefit claimer, etc.

Determination of Benefit Sharing Component

- a) Benefit Sharing for Commercial Utilization of Bioresources:

Annual gross ex-factory sale of the product	Benefit sharing component
Up to Rs. 1,00,00,000	0.1%
Rs. 1,00,00,000-Rs. 3,00,00,000	0.2%
Above Rs. 3,00,00,000	0.5%

- b) Transfer of research results:

The benefit sharing obligation shall be 3.0 to 5.0% of the monetary consideration received.

- c) Intellectual Property Rights:

If applicant himself commercialize the process/product/innovation	0.2-1.0% of Annual Ex-factory gross sale (minus govt. taxes)
If applicant assigns/ licenses the process/product/ innovation to a third party for commercialization	3.0-5.0 % of the fee received in any form and 2.0-5.0 % of Royalty

Alternative option for procurement of bioresources from a supply chain

Where the trader sells the biological resource purchased by him to another trader or manufacturer, the buyer,

if he is a trader - pay 1.0 to 3.0% of the purchase price.

If he is a manufacturer – pay 3.0 to 5.0% of the purchase price.

If the buyer submits proof of benefit sharing by the immediate seller in the supply chain - The buyer's liability shall be only on that portion of the purchase price for which the benefit has not been shared in the supply chain.

In cases of biological resources having high economic value such as sandalwood, red sanders, etc. the benefit sharing may include an upfront payment of not less than 5.0%, on the proceeds of the auction or sale amount, as decided by the NBA or SBB, as the case may be.

If the sale is through auction, the successful bidder or the purchaser shall pay the amount to the designated fund, before accessing the biological resource.

Collection of Fee by BMC

Collection of fees, if levied by Biodiversity Management Committee (BMC) for accessing or collecting any biological resource for commercial purposes from areas falling within its territorial jurisdiction under sub-section (3) of section 41 of the Act, shall be in addition to the benefit sharing payable to the NBA/SBB under these regulations.

The Way Forward

There is a growing need for developing partnership with the private sector in conserving, sustainable use and managing bioresources in the country. Pharmacy industry and herbal food sector deserve greater attention in the context of conservation and sustainable use of raw bio-resources used by them. India has the potential of becoming a major global player in marketing of herbal formulations, medicines and products [9]. Next step should be to harmonise provisions for benefit sharing under CBD and WTO-TRIPS [10]. For implementing the two main principles of ABS mechanism under CBD, namely, "Prior informed consent" and "Mutually agreed terms", legal requirement of a CBD-compliance certificate needs to be adopted as an essential attachment with applications submitted to patent offices for seeking patents on products or processes based on bio-resources and associated TK. This may be in the form of an 'international certificate of compliance' issued by the national authority of the provider country.

The Nagoya Protocol to CBD on ABS holds much promise and its provisions need to be fully utilized towards greater resource mobilization in general, and better monitoring the commercial utilization of India's bioresources abroad in particular [11]. Capacity building is the key factor in this context and the recently established Centre for Biodiversity Policy and Law at Chennai, through Indo-Norway Technical Cooperation Programme may prove helpful for this purpose.

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