

# Interplay of National and International Laws on Access to Biological Resources and Benefit Sharing

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International laws, emerging often from legally binding global conventions and treaties, operate through national laws extending their jurisdiction beyond their national boundaries but may also sometime override them. When a country becomes contracting party to several such treaties, and their provisions seem to be in conflict, problems may arise in fulfilling national obligations. Provisions on intellectual property rights under the Convention on Biological Diversity (CBD) and the WTO-TRIPS Agreement over products and processes, based on biological resources, illustrate this point. Likewise, provisions on sharing of benefits arising from the use of genetic resources under CBD and the Nagoya Protocol on one side and the International Treaty on Plant Genetic Resources for Food & Agriculture and the FAO Commission on Genetic Resources for Food & Agriculture on the other, seem to differ in many ways. This paper discusses the complex interplay of governance of access to genetic resources and benefit sharing at the international and national levels.

**Key Words:** Biological resources; Genetic resources; Access and benefit sharing; ABS mechanisms; ABS governance; Global governance of ABS; Regulatory system for ABS in India

## I. ABS Governance at the National and International Levels

Global regulation of access to biological resources and sharing of benefits arising from their commercial utilization is one of the three most discussed topics today, the other two being the multilateral trade and climate change. Negotiations under various fora in this context require a clear understanding of the complex interplay of international laws and national legislation so as to maintain a harmonious and synergistic relationship among them.

An international law, or the law of nations, is primarily a system governing the relationship among nations who have become contracting parties to legally binding international treaties and are required to adapt their national legal framework to meet their national obligations under the provisions of those treaties. However, it happens sometimes that the national obligations under some international treaties on specific topics, like access to biological resources and benefit sharing, may appear to be in conflict as seen from the relevant provisions under the Convention on Biological Diversity (CBD) and WTO-Trade Related Intellectual Property Rights (TRIPS) or even those of CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA or the Plant Treaty).

To go a step further, perceptions on the relationship between international law and national law also differ regarding supremacy of one over the other. There are two contending concepts: monism and dualism (Park and Yanos, 2006; Muller, 2013). The idea of monism assumes that international law and national law are simply two components of a single legal system and regards 'law' as one entity. In other words, both are interrelated parts of one single legal structure and form a unity, though international law may have supremacy over the national law in cases of conflict. Monism in practice envisages that the legal institutions of a country, such as its judiciary, legislature and executive, should ensure that national rights and obligations in this context conform to international law.

Dualism, on the other hand, assumes that international law and national law of States are two separate and distinct legal systems. Being different legal orders, international law would not as such form part of the domestic law of a State. Where rules of international law apply within a State, they do so as a result of their adoption under the national law and not under the international law. Dualism refrains from any controversy as to supremacy of one legal system over the other recognizing that each one is considered supreme in one's own sphere and operates on a different level but recognizes that, ultimately, national (state) interests can override the international interests

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in some situations.

There are, however, some distinctions between national law and international law. Firstly, the subjects of national law are individuals, while the subjects of international law are Nation States. Secondly, juridical origins of the two legal systems are different, *i.e.*, the source of national law is the will of the representatives of public expressed through the State while the source of international law is the common will of contracting parties (Nation States). Thirdly, national law is a law of the sovereign (national government) over individuals (citizens) whereas international law is a law, not above, but among Sovereign States.

## II. Access to Biological Resources and Benefit Sharing (ABS)

Governance systems for access to genetic resources and sharing of benefits (ABS) arising from their commercial utilization may be seen from several positions 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 (Halewood *et al.*, 2014). Although the 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 (Oberthur and Rosendal, 2014).

Regulation of genetic resources has three distinct dimensions, namely, perspectives of their developers and users, governance at the state and national levels, and national obligations under international treaties/agreements (Rana, 2010).

The first dimension comprises local farming communities (developers, conservers and end-users of their genetic resources who are the primary stakeholders), public sector research institutions and genebanks (trustee custodians of germplasm collections and users for public good), and seed companies/corporations (users for commercial utilization meant for private benefits). They together represent the main stakeholders and key beneficiaries. The second dimension involves policy makers, legislators, managers and administrators regulating authorised access while promoting conservation with sustainable use. 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 biodiverse developing countries. The first two treaties highlight the conservation of bio-resources, their sustainable use, regulated access and fair and equitable benefit sharing while the third focuses mainly on patenting/crop variety protection laws that grant monopolistic/exclusive rights to IPR holders/breeders to the exclusion of the rights of farmers and other primary beneficiaries. All the three are legally binding treaties and India is a contracting party to them. Considering that agrobiodiversity constitutes 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, more particularly in countries like India whose national economy is primarily based on agriculture (Tvedt, 2014).

## III. Global Developments on ABS

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:

### 1. International Laws and the National Legal and Policy Framework

National policies describe the objectives and missions of a government indicating how it proposes to achieve those objectives by issuing relevant guidelines. 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 contravene 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 from customary laws, judiciary pronouncements, and more often, from legally binding national obligations under international agreements, treaties, conferences and conventions. In a way, they expand the jurisdiction of national laws beyond their

national boundaries but they also impact them.

## **2. *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. Impact of these decisions in the Indian context may be clearly seen in the 42<sup>nd</sup> Amendment to the Indian Constitution, enacted in 1976, adopting Article 48A (one among the Directive Principles which cannot be challenged in any court of law) 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 thus 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. In addition, a separate Department of Environment was created in 1980 and a separate Union Ministry of Environment & Forests (with Climate Change added subsequently) was established in 1985.

## **3. *The International Undertaking on Plant Genetic Resources, 1983: A New Initiative***

In 1983, the FAO established a Commission on Plant Genetic Resources (later renamed the Commission on Genetic Resources for Food and 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 in 1983 for setting up 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 to researchers 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 their influence, the United States and many other developed countries declined to sign the IU and adhere to it. Efforts to conciliate the concerns of developed and developing countries resulted in two 1989 amendments to the Undertaking paving the way for the United States and Canada signing the IU but they still declined to adhere to its binding obligations. In 1993, FAO adopted the Resolution 7/93, calling for intergovernmental negotiations for revision of the IU to harmonise its contents with those of the CBD, acknowledging thereby the sovereignty of States over their natural resources. Accordingly, provisions of the IU were suitably revised to bring them 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 and Agriculture.

## **4. *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) under UNEP besides several other treaties. The CBD has 193 Contracting Parties making it almost globally accepted treaty though the USA is the only major country that has not yet ratified it. Its objectives 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.

To recapitulate, the CBD marked the end of the 'common heritage' concept 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 it is subject to national legislation.

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.

### 5. *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. Sixty nations have already ratified this legally binding Protocol and many more are in the process of doing so. 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 internationally recognized certificate of compliance when access is granted.

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, industrial, cosmetic and other 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 share the benefits arising from its commercial utilization. The Protocol seeks to increase transparency in transfer of genetic resources through its Access Benefit-Sharing Clearing House (ABS-CH), which is an online platform for exchanging relevant information (Morgera *et al.*, 2014). Its goal is to enhance clarity on procedures in provider countries for access to genetic resources and also to monitor their commercial utilization in user countries.

### 6. *The International Treaty on Plant Genetic Resources for Food and Agriculture: New Approach to promote Global Food Security*

Recognizing the interdependence among countries regarding crop genetic resources, representatives of 135 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 had 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. India's legislation on Protection of Plant Varieties and Farmers' Rights, 2001 has led the way in this direction but there is need to evaluate its effectiveness. It is now widely recognized that a reliable way to realize Farmers' Rights is to enable them to save, exchange and sell the seeds of improved and IPR protected varieties grown by them, and also to assist them in improving their locally adapted crop varieties through participatory breeding while paying greater attention to the needs and circumstances of resource-poor farmers who are the real guardians of much of the agricultural biodiversity [FAO, 2010].

Of the nations participating in that FAO conference, that adopted the ITPGRFA, 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 presently 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 Standard Material Transfer Agreement (SMTA) provides a mechanism for overcoming potential difficulties of enforcement by empowering FAO, as the entity chosen by the Governing Body, to represent its

interests as a third party beneficiary under the SMTA, and to initiate action where necessary to resolve disputes.

The Treaty forbids recipients of PGRFA through the MLS to claim any IPR on them in the form received from the MLS as that may limit access to them or their genetic parts or components. There are, however, some hazy areas on this aspect that need to be addressed (Andersen *et al.*, 2010).

The ITPGRFA differs substantially from the CBD, as this treaty as a whole applies to one specific group of organisms, *i.e.*, plant genetic resources for food and agriculture (PGRFA). The MLS for ABS has become the legal instrument for the already ongoing exchange of accessions of PGR stored in the international collections, while adding a number of national collections to the MLS [See Box 1]. It still remains to be validated whether the

MLS has led to more exchange of, and better access to, PGRFA. Further, the issue of genetic resources collected from countries of their origin, prior to CBD, still hangs on though the designated accessions stored in CGIAR's International Genebanks have been brought under the jurisdiction of FAO.

The Multilateral System for ABS under the Treaty, as mentioned above, applies only to PGRFA under specific circumstances, *i.e.* when certain accessions of PGRFA are in the public domain, are accessed for specific uses, and under the condition that no IPRs hinder the further exchange and access of the material received from the MLS. These limitations in the scope of the MLS need to be better understood if we are to clarify the legal relationship between the two instruments.

### Box 1

#### Benefit-sharing under the Multilateral System of ITPGRFA

Facilitated access to genetic resources, that are in public domain and are included in the Multi-lateral System, is itself recognized as a major benefit for researchers and plant breeders. Other benefits arising from the use of PGRFA that are to be shared on a 'fair and equitable' basis include:

##### (1) Exchange of information

This includes catalogues and inventories, information on technologies and results of technical, scientific and socio-economic research on PGRFA including data on characterization and evaluation.

##### (2) Access to and transfer of technology

Contracting Parties agree to provide or facilitate access to technologies for the conservation, characterization, evaluation and use of PGRFA. The Treaty points out various means by which transfer of technology is to be carried out, including participation in crop-based or thematic networks and partnerships, commercial joint ventures, human resource development and through making research facilities available. Access to technology, including that protected by IPR, is to be provided and/or facilitated under fair and most-favourable terms, including on concessional and preferential terms where mutually agreed. Access to these technologies is provided while respecting applicable property rights and access laws.

##### (3) Capacity building

This Treaty assigns priority to programmes for scientific education and training in the conservation and use of PGRFA, to the development of facilities for conserving and using PGRFA and to the carrying out of joint scientific research.

##### (4) Sharing of monetary and other benefits arising from commercialization

Monetary benefits include payment into a special Benefit-Sharing Fund of the MLS of a share of the revenues arising from the sale of PGRFA products that incorporate material accessed from the MLS. Such payment is mandatory where the product is not available for further research and breeding, for example, as a result of certain types of patent protection. In the SMTA, adopted by the Governing Body at its First Session in 2006, the payment is set at 1.1% of the gross sales generated by the product less 30% (*i.e.* 0.77%).

When the CBD was finalized, negotiating parties recognized that some important issues were left without satisfactory solutions in international law as reflected in section 4 of Resolution 3 adopted by the Nairobi conference, where the text of the CBD was agreed, which reads: 'Further recognizes the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: (a) Access to *ex situ* collections not acquired in accordance with this Convention; and (b) The question of farmers' rights.' These issues were referred to the FAO in the context of suitably revising the contents of the International Understanding on PGRFA. The issue of genetic resources collected from countries of their origin, prior to CBD, still hangs on but the designated accessions stored in CGIAR's International Genebanks have been brought under the jurisdiction of FAO.

The MLS is highly relevant for ABS because it is the first sectoral approach to ABS, and could provide useful lessons for the implementation of ABS, including whether and if so, how, sectoral ABS can be dealt with to meet the objectives of the CBD (under NP Art. 4 and Art. 19). Sixth Session of the Governing Body of the ITPGRFA, scheduled to be held in Rome on 5-9 October 2015, is expected to provide further guidance on this aspect.

### **7. Trade Related Intellectual Property Rights (TRIPS) Agreement under WTO**

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. The WTO now has 153 member nations and 29 others with observer status.

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 the 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.

It is noteworthy that the agricultural plants sector is currently the only one where access is granted under two ABS systems operated by the CBD and the FAO. In addition, two other systems are available for securing IPRs over them, namely, patents and plant breeders' rights [See also Box 2].

#### **Box 2**

##### **Some Notable Points**

Animal genetic resources are not covered under the ITPGRFA and WTO-TRIPS whereas CBD and also its Protocol on ABS cover all genetic resources holistically. CGRFA under FAO is now engaged in developing an international treaty on animal genetic resources on the pattern of ITPGRFA.

Accessions of PGR, that are stored in the National Genebank, need to be carefully scrutinized to identify designated accessions for placing them under public domain and making them available for exchange under ITPGRFA. For the PGR, not covered under the ITPGRFA, there is need to continue regulating their access and ensure benefit sharing as provided under the Biological Diversity Act, 2002. There is also an urgent need to prepare inventory of high value traits of our genetic resources and to monitor their commercial utilization abroad.

#### **IV. Overlapping Provisions on ABS under CBD, ITPGRFA and TRIPS**

Unlike the CBD, which provides for bilateral negotiations to establish the terms of access and benefit sharing for each specific exchange of materials, all multilateral germplasm exchanges under the MLS would be subject to SMTA. Monetary benefits would 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.

Concerns on the relationship between ABS provisions under CBD and other international legal regimes bearing on genetic resources led to inclusion of Article 4 in 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 would 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 PGRFA, 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 genetic resources 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 CGRFA is now discussing ABS mechanisms for six more groups of genetic resources, namely, animals; aquatic; invertebrates; plants; forest; and microbial genetic resources (FAO, 2015). Any agreement in the Commission on 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 also reached agreement with the World Health Organisation in 2011 giving green signal

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 Seas and this may include, for example, genetic resources taken from the seabed and/or the high seas, taking them out of purview of CBD. In addition, 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. To sum up, dimensions of global governance of ABS (related to bioresources) are being expanded and there is need for increasing clarity and also convergence.

#### **V. Regulating Access and Benefit Sharing in India: Procedures**

Under CBD, the sovereign authority to determine access to genetic resources rests with the national governments and it is subject to national legislation. To fulfill national obligations under the CBD, India enacted the Biological Diversity Act in 2002 through a systematic consultation process and also framed the Biological Diversity Rules under it in 2004. 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 [See Box 3].

This Act also provides further support to other relevant 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.

The Act provides for its implementation through a 3-tier system comprising the National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs)

**Box 3****Salient Features of the Biological Diversity Act, 2002:**

- Regulates access to biological resources of the country with the purpose of securing equitable and fair sharing of benefits arising out of the use of biological resources; and associated traditional knowledge (TK) relating to biological resources;
- Promotes conservation and sustainable use of all components of biological diversity;
- Aims at respecting and protecting traditional knowledge of local communities related to biodiversity;
- Provides for sharing of benefits with local people as developers and conservers of biological resources and holders of knowledge and information associated with their use;
- Promotes conservation and development of areas of importance from the standpoint of biological diversity by declaring them as biological diversity heritage sites;
- Lends support to on-going programmes on protection and rehabilitation of rare, endangered and threatened species;
- Encourages increasing involvement of institutions and state governments in the broad scheme of implementing the Biological Diversity Act, through constitution of appropriate committees.
- Recognizes four broad categories of users who are required to apply in different kinds of specified forms along with payment of prescribed fees. These categories are based on stated objectives of the applicants and include accessing biological resources for research /biosurvey & bio-utilization /commercial utilization, transferring results of research on bioresources, seeking IPR over products /innovations based on use of bioresources. And third party transfer of already accessed bioresources.

and the Biodiversity Management Committees (BMCs) at the local communities level. Functions of this system at all the three levels have been clearly defined and all the Union States have constituted SBBs.

In exercise of the powers conferred by Sub-Section (1) (4) of Section 8 of the Biological Diversity Act, 2002, the Central Government established the National Biodiversity Authority on 1st October, 2003. For major functions of NBA, see Box 4.

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 (2) and Section 19):

- A person who is not a citizen of India  
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- 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.

For more information, see Box 5.

Access to bioresources for research by Indian citizens, and companies registered in India and not having any foreign share in their management, is unrestricted and free. However, 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 which grant the required approval based on relevant rules and procedures for this purpose (Sections 23 and 24) and imposes benefit sharing terms



**Box 4****Main Functions of the National Biodiversity**

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:
  - (i) Certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority (Section 3).
  - (ii) Results of research not to be transferred to certain persons without approval of National Biodiversity Authority (Section 4) (Transfer of Research Results).
  - (iii) 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 establish and operate the National Biodiversity Fund.
7. 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.
8. 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.

**Box 5****The Principle of Common but Differentiated Responsibilities**

1. The Biological Diversity Act differentiates between Indian citizens/Indian entities and foreign citizens/foreign entities (including Persons of Indian Origin) requiring the latter category to obtain prior approval of NBA for accessing India's bioresources for research/commercial utilization or for undertaking biosurvey and bio-utilization. Whereas the Indian citizens are required to approach the concerned State Biodiversity Board, the foreign citizens/foreign entities need to apply to NBA.
2. The Act also requires Indian citizens to take prior approval of NBA for transferring the results of research, conducted on bioresources, to foreign citizens/foreign entities.

**Box 6****Restrictions Imposed on Granting Access to Bioresources  
under Section 24 (2) read with Rule 16**

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.

based on the guidelines notified for this purpose in November, 2014.

See Boxes 6 and 7 for some restrictions imposed on granting access to bioresources and also some exemptions from the provisions of this Act.

However, all the users, Indian citizens as well as foreigners, are required to seek prior approval of NBA for transferring results of their research on bioresources to foreign persons/entities [Section 4], for applying for IPR on products/processes based on bioresources (Section 6) and also for third party transfer of the already accessed bioresources (Section 20), by submitting applications in specified formats along with payment of prescribed fee for each of the above mentioned purposes.

**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)].

**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 for 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, Sandalwood etc.)
- Apportioning accrued benefits to the local communities /BMCs.

**Facilitating non-commercial research abroad by Indian researchers /Government Institutions**

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

**Box 7****Exemptions Provided under the Biological Diversity 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 cannot apply for any IPR without prior approval of the NBA.

India for doing research (like CSIR, ICAR, ZSI, BSI, Government Universities) Government 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 the amount of Benefit Sharing:**

#### **a. Benefit Sharing for Commercial Utilization of Bioresources:**

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

#### **b. Transfer of results of research:**

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

#### **c. Intellectual Property Rights:**

Relevance	Terms of Benefit Sharing
When applicant himself commercialises the process/ product/ innovation	0.2 to 1.0 % of the annual ex-factory gross sale (minus government taxes).
When applicant assigns/ licenses the process/ product/ innovation to a third party for commercialisation	3.0 to 5.0 % of the fee received in any form and 2.0 to 5.0 % of the royalty received.

#### **d. Alternative option for procurement of bioresources through 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, he is to pay @ 1.0 to 3.0% of his purchase price.
- If he is a manufacturer, he is to pay 3.0 to 5.0% of his purchase price.
- If the buyer submits proof of benefit sharing paid by the immediate seller in the supply chain, then the buyer shall pay benefit sharing on that portion of the purchase price for which the benefit has not been paid along the supply chain.

In cases of biological resources having high economic

value, such as sandalwood and red sanders, 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.

Information on penalties for contravention of this Act or abetting such contraventions is provided in Box 8.

### **VI. Present Status of Implementing the Biological Diversity Act**

India's 5<sup>th</sup> National Report to CBD, submitted in 2014, provides an overview of the status of implementing the provisions of CBD along with the progress made in implementing the Biological Diversity Act and the Rules framed under it. Following the establishment of NBA in 2003, SBBs have also been constituted in all the 29 states and over 38,000 BMCs set up. Nearly 1900 Peoples' Biodiversity Registers (PBRs), documenting local bioresources and associated traditional knowledge, have also been developed and validated.

NBA has provided financial assistance of over rupees 100 million towards strengthening SBBs and BMCs and developing PBRs. NBA has also set up expert committees on 'access & benefit sharing', 'agro-biodiversity' and 'normally traded commodities'. Fifteen National Designated Repositories have been recognized for safekeeping of voucher specimen/reference samples and a core expert group has also been constituted to address concerns of these repositories and develop guidelines. Another core expert group has been constituted to develop a unified model agreement deed to replace the existing four kinds of agreement forms. Effort is also on to develop on-line processing of all applications.

Guidelines on collaborative research projects were notified in 2006 for claiming exemption from the Act's provisions under Section 5. Much awaited guidelines on ABS have also been notified in November 2014 to speed up implementation of ABS provisions under the Act. NBA has already approved 633 applications out of 985 applications received by it under different categories and entered into 171 benefit sharing agreements with the users of bioresources [See Box 9].

Guidelines, exempting designated accessions of crops listed in Annex-I of the ITPGRFA from Sections 3 & 4 of the Act, have also been notified for smooth implementation of this Treaty. The expert committee on

**Box 8****Penalties for Contravention of the Biological Diversity Act**

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 may 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]

**Box 9****Status of the processing and approval of applications as on 30 April, 2015**

Items	Form I	Form II	Form III	Form IV	Total
Number of applications received	186	40	681	78	985
Number of applications approved	85	16	494	38	633
Number of applications in process	66	13	159	24	262
Number of applications closed	44	14	34	17	109
Number of BS agreements signed	40	12	93	26	171
Total	421	95	1461	183	2160

Normally Traded Commodities has now prepared a list of over 420 species for exemption under Section 40 of the Act so long as these are traded as commodities. Over 14 States have developed and notified lists of threatened species under their jurisdiction. More than 160 million rupees have already been deposited in the National Biodiversity Fund for payment to benefit claimers and to promote conservation and sustainable use of bioresources. Some SBBs, notably those of Gujarat, West Bengal and Uttarakhand, have gone ahead and signed a large number of benefit sharing agreements with the user companies in their states, securing thereby the much needed funds required for their functioning aimed at conservation of bioresources and their sustainable use at the ground level, besides ensuring fair and equitable sharing of benefits

arising from their commercial utilization.

High level consultations have been held with the Council of Scientific & Industrial Research, Indian Council of Agricultural Research and the Indian Patent Office to address concerns and ensure smooth implementation of the Act. National consultations have also been held with major stakeholders, including pharmaceutical and seed sectors, to provide further clarifications on definition of some terms under Section 2 of the Act. Effort is now on to expand the list of Frequently Asked Questions displayed on NBA's website to provide the required guidance. An expert Committee is also working on developing a unified version of the four types of benefit sharing agreements, presently in vogue, with a common basic format attached with four

kinds of annexes meant for granting access for research and commercial utilization, transfer of the results of research on bioresources, IPR and third party transfer of bioresources. In another significant move forward, it has been agreed to notify 427 plant species as Normally Traded Commodities which will be exempted from provisions of the BD Act as long as they are traded as commodities.

## **VII. Implementing Provisions of CBD, ITPGRFA and TRIPS Agreement in India**

In India, the Union Ministry of Environment, Forests & Climate Change is the nodal ministry for implementing the CBD and also the Nagoya Protocol 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 (Rana, 2012). National Biodiversity Authority (NBA) has been designated as the National Competent Authority for this purpose. Format for the Internationally Recognized Certificate of Compliance has also been approved. Efforts are now on to designate the Check Points to monitor commercial utilization of India's bioresources or patenting of their derivatives/products in other countries. Other key provisions to make the ABS regime functional include developing user and provider country measures.

Union Ministry of Agriculture and Cooperation is the nodal 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 would be based on signing the SMTA as approved under this Treaty.

For implementing the WTO-TRIPS agreement, Union Ministry of Commerce is the nodal ministry in India. 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 but the progress made so far is much below the developing countries' expectations.

## **VIII. The Way Forward**

The CBD continues to provide the overall legal and policy framework for ABS with regards to genetic resources as reflected in the mid-term assessment of the progress made towards implementing the Global Strategic Plan for Biodiversity 2011-2020 (CBD, 2014). There is now an urgent need, however, to harmonise provisions for benefit sharing under CBD and WTO-TRIPS. For implementing the two main principles of ABS mechanism under CBD, namely, "prior informed consent" and "mutually agreed terms", legal requirement of a CBD-compliant and internationally recognized certificate, to be issued by the national authority of provider country, needs to be adopted as an essential attachment with the applications submitted to patent offices for seeking patents on products or processes based on bio-resources (and associated TK).

Notwithstanding the lack of clarity on some of its Articles, the Nagoya Protocol to CBD on ABS holds much promise and its provisions need to be fully utilized towards better monitoring of the commercial utilization of India's bioresources, and associated traditional knowledge, in other countries (Morgera *et al.*, 2014, Richerzhagen, 2014). However, the Nagoya Protocol's provisions are binding only on those countries who have become Contracting Parties to it and, hence, the real

advantages of this Protocol would depend upon how it is implemented at the national level. Recent notification of the Guidelines on ABS in India has galvanized this process but creating more awareness on this subject and further capacity building are required to make a real headway in this direction.

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