

# Policy Issues in PGR Management

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## Introduction

The global PGR management movement started taking shape in 1960s when the Consultative Group on International Agricultural Research (CGIAR) initiated a number of programmes for management of PGR including collecting missions, establishment of gene banks and related research activities. Consequently, the holdings in *ex situ* collections sizably increased. Presently over 7.0 million accessions are estimated to have been conserved in more than 1300 gene banks worldwide. This enormous rise in number of gene banks coupled with the understanding that the PGR were the “heritage of mankind”, had led to the belief of unrestricted access to PGR for sustainable utilization. The free availability of germplasm especially from *ex situ* collection of CGIAR centers has helped most countries including India to strengthen their crop improvement programmes. India has benefited tremendously by importing germplasm varieties and even new crop species from other countries, which have improved our agricultural productivity and lead to diversification of crop species

However, things have changed fast in the last decade of the 20<sup>th</sup> century, most obviously due to the trends of globalization and privatization. As a result, a paradigm policy shift was witnessed in the international policy environment from “Heritage of Mankind” to “Sovereign rights to Nation”. Also, during this period, with technological advances in the field of molecular biology and genetic engineering, appreciation of the monetary and non-monetary value of genetic resources has grown. This has led to increasing conflict over rights and responsibilities of these resources. The current international debate on legal regimes for plant genetic resources has its origins in the late 1970s and early 1980s when industrialized countries started granting patents on improved plant varieties and the developing countries became concerned over such extension of intellectual property rights to the varieties. This led to an extended debate and international co-operation in the recognition of plant-related intellectual property rights, resulting in a greater attention being paid to questions of ownership of genetic resources. At the same time concerns for sustainable use of biological diversity were also raised.

One of the major events which led to this shift in the way genetic resources were being used and exchanged was the Convention on Biological Diversity (CBD) which came into force in 1993, which was adopted during the Rio Earth Summit of the United Nations. It was the first legally binding institutional mechanism, providing for conservation and sustainable use of all biological diversity and intends to establish the process of the equitable sharing of benefits arising out of the use of biodiversity. The CBD reaffirms national sovereignty over genetic resources (Article 15.1) and stressed that the authority to determine access to genetic resources rests with the national governments and is subject to National legislation. Article 15.4 and Article 15.5 provide for a bilateral approach to access/exchange between countries on prior informed consent and mutually agreed terms.

The second development was lead by the Commission on PGR (CPGR), now Commission on Genetic Resources for Food and Agriculture (CGRFA), established to govern the non-binding International Undertaking on Plant Genetic Resources (IUPGR). The IUPGR was adopted by the FAO conference at Rome in November 1983 with the objective to ensure that “PGR of economic and or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant

breeding and scientific purposes. This undertaking is based on the universally accepted principle that PGR are a heritage of mankind and consequently should be available without restriction”.

In 1993, the FAO adopted the resolution 7/93 for the revision of IUPGR in harmony with the CBD to address the outstanding issues of access to PGR on mutually agreed terms including *ex situ* collections (held by CGIAR Centres) not addressed by the CBD and also the realization of farmers rights. The revised text of IUPGR was submitted to the 31<sup>st</sup> Session of FAO Conference that adopted it as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) on 3 November, 2001(FAO, 2001).

### **The Convention on Biological Diversity**

The CBD was conceived in the 1980s and was negotiated under the leadership of the United Nations Environment Programme (UNEP). It was adapted in June 1992 at Rio de Janeiro, at the Earth Summit, and is effective since December 1993.

The objectives of CBD are “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of utilization of genetic, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding”. The convention reaffirmed that states have sovereign rights over their biological resources and that the states are responsible for conserving these resources and using them in a sustainable manner. The countries that signed the CBD were required to integrate considerations of sustainable use of biological diversity into relevant sectoral or cross-sectoral plans programmes and policies.

### **Our National Legislation: The Biological Diversity Act of India, 2002**

Keeping in view the vast diversity and traditional knowledge based on use of this biological diversity, the Biological Diversity Act of India (BDA) was formulated after India became signatory to the CBD in 1993. It was developed through an intensive consultation process involving central government, state governments, institutions of local self-government, scientific and technical institutions, experts, non-governmental organisations, industry etc. This act was passed by the Parliament in December 2002, and has the following objectives based on the principles of CBD.

- i) to regulate access to biological resources of the country with the purpose of securing equitable share in benefits arising out of the use of biological resources, and associated knowledge relating to biological resources;
- ii) to conserve and sustainably use biological diversity;
- iii) to respect and protect knowledge of local communities related to biodiversity;
- iv) to secure sharing of benefits with local people as conserves of biological resources and holders of knowledge and information relating to the use of biological resources;
- v) conservation and development of areas important from the standpoint of biological diversity by declaring them as biological resources;
- vi) protection and rehabilitation of threatened species;
- vii) involvement of institutions of self-government in the broad scheme of the implementation of the Act through constitution of committees.

For the effective implementation of the BDA, the central government is obliged to undertake activities, national strategies, plans, and programmes for conservation and sustainable use of biological resources, with the following institutional mechanisms, namely the **National Biodiversity Authority (NBA)**, **State Biodiversity Boards (SBBs)** and **Biodiversity Management Committees (BMCs)**.

The NBA deals with matters relating to requests for access by foreign individuals, institutions or companies, and those relating to transfer of results of research to any foreigner. Imposition of terms and conditions has been provided to secure fair and equitable sharing of benefits arising out of utilization of biological resources. Approvals for seeking any form of Intellectual Property Rights (IPR) in or outside India for an invention based on research or information pertaining to a biological resource or associated knowledge obtained from India would also be dealt by NBA. It takes measures for identification and monitoring biodiversity rich areas and notifies threatened species. It may also declare some resources to be exempted from the provisions of this Act including resources normally traded as commodities. The NBA, also takes measures necessary to oppose the grant of intellectual property rights in any country outside India, on behalf of the Central Government on any biological resource obtained from India or knowledge associated with biological resource which is derived from India.

SBBs constituted for every state in India deal with matters relating to access by Indians for commercial purposes and restrict any activity, which violates the objectives of conservation, sustainable use and equitable sharing of benefits.

Institutions of self-government in their respective areas constitute a BMC for conservation, sustainable use, and documentation of biodiversity and chronicling of knowledge relating to biodiversity. The NBA and SSBs can consult BMC on matters related to use of biological resources and associated knowledge within their jurisdiction.

Traditional knowledge associated with Biological Resources is proposed to be protected. It is also proposed that the State Governments will notify National Heritage Sites, which are important from the standpoint of biodiversity, in consultation with institutions of local self-governments.

**Provisions for Regulation of Access to Biological Diversity** : Section 3 of the Act restricts certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority, and these include:

- (a) a person who is not a citizen of India;
- (b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961;
- (c) a body corporate, association or organization
  - (i) not incorporated or registered in India, or
  - (ii) Incorporated or registered in India under any law for the time being in force, which has any non-Indian participation in its share capital or management.

Section 4 provides conditions for transfer of results of research related to biodiversity. It states, that no person can transfer the results of any research relating to any biological resources occurring or obtained from India, for monetary consideration or otherwise, to any person who is not a citizen of India; or a body corporate or organization which is not registered or incorporated in India; or which has any non-Indian participation in its share capital or management, without the prior approval of the NBA.

However, 'transfer' does not include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government.

Exemption to provisions of section 3 and 4 has been provided in section 5. Sub section (1) of section 5 states that, "the provisions of section 3 and 4 shall not apply to collaborative research projects involving transfer or exchange of biological resources or information relating thereto between

institutions, including Government sponsored institutions of India, and such institutions in other countries, if such collaborative research projects satisfy the conditions specified in sub-section (3): (a) collaborative research projects should conform to the policy guidelines issued by the Central Government in this behalf and (b) be approved by the Central Government. All collaborative research projects other than those referred to in sub-section (1) which are based, on agreements concluded before the commencement of this Act and in force shall be void.

Section 6 deals with the application for intellectual property rights. The section states that “No person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India, without obtaining the previous approval of the NBA before making such application”. This permission, however, may be obtained after the acceptance of the patent but before sealing the patent by the patent authority concerned.

Section 7 is regarding prior intimation to State Biodiversity Board for obtaining biological resources for certain purposes, and it states “No person who is a citizen of India or a body corporate, association or organisation which is registered in India shall obtain any biological resource for commercial utilisation or bio-survey and bio-utilisation for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned”. The provisions of this section shall not apply to the local people and communities of the area, including *vaid*s and *hakims*, who have been practicing indigenous medicine.

New regulations have been put in place after India in 2014 after signed and ratified the Nagoya Protocol on Access and Benefit sharing, which came into force in 2010. These regulations further clarify on the set of uniform international principles of ABS agreements for sharing bioresources. It provides for monetary benefit sharing rates for different category of users. It also provides for simpler procedures for students and Institutions undertaking basic research or for emergencies, in other countries by applying in Form B with the undertaking by the researcher and the foreign supervisor that the material will be used only for the specified research and any leftover material would be destroyed on completion of the research. Such approvals shall be granted by NBA within 45 days.

## **Implication of the BDA**

### ***IPRs and benefit sharing mechanisms***

The CBD mandates its member countries to enact national laws that would facilitate prior informed consent and benefit sharing in a fair and equitable manner, prior to access and use of biological resources and traditional knowledge. Several countries have already enacted laws to put in place the access and benefit sharing (ABS) regime. Under section 6 of the BDA, there is a clear message that nobody can apply for IPR without taking prior permission from NBA. The NBA can impose benefit sharing fee or royalty or both or ask for sharing financial benefit arising out of commercialization of the material. Section 7 envisages that no person or organisation from India, can have access to biological resources for commercial purpose, without prior information of the SBB concerned, except local communities, *vaid*s and *hakims*.

### ***Related provisions in other legislations***

The mechanism of benefit sharing for PGR and the traditional knowledge (TK) has been well taken care of at the national level in the following acts:

- (i) In the provisions of section 26 (1) of Protection of Plant Varieties and Farmers' Rights (PPVFR) Act 2001, wherein the Authority shall publish and invite claims of benefit sharing for the applicant variety to be registered, in the manner as may be prescribed;
- (ii) In section 10.4 (D) of Patent (Amendment) Act 2002 (5), If the patent applicant mentions a biological material in the specification, the application shall be completed by depositing the material to the authorised depository institutions and by fulfilling conditions, such as, the disclosure of the source and geographical origin of the biological material in the specification, when used in invention. The biological material is to be deposited not later than the date of the patent application. The depository institution would make the biological material available to public after publication of the patent [Section 11(A)].

However, at the international level there is an urgent need to harmonize the provisions under CBD and Trade Related Aspects of Intellectual Property Rights (TRIPS), if the interest of the all parties namely the stakeholders of biological material/traditional knowledge, the consumer and the intellectuals are to be safeguarded. The Article 7 of TRIPS agreement clearly emphasizes that the “protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and dissemination of technology, to the mutual advantage of producers and users of the technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”. The key issues, which need to be considered for amendment of the TRIPS Agreement for harmonization with provision of CBD, are:

- (i) disclosure of the source and country of origin of the biological resources and of the traditional knowledge used in the invention;
- (ii) evidence of prior informed consent through approval of authorities under the relevant national regime; and
- (iii) evidence of fair and equitable sharing under the relevant national regime (8).

This aspect needs to be deliberated at the international institutions that the farmers/communities of developing countries possessing a wealth of biological resources are benefited as per CBD provisions.

### **International Treaty of Plant Genetic Resources for Food and Agriculture**

This treaty is legally binding international commitment to the improvement of the world's key food and feed crops. Its objectives, set out in Article 1, being the conservation and sustainable use of PGR for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with the convention on biological diversity, for sustainable agriculture and food security. It covers all PGR relevant to food and agriculture and it has entered into force on June 29, 2004.

#### ***The Multilateral System***

The key component of the Treaty is a multilateral system (MLS) of facilitated access and benefit sharing that directly supports the work of breeders and farmers everywhere. The MLS for facilitated access applies to a specified list of Plant Genetic Resources for Food and Agriculture (PGRFA), balanced by benefit-sharing in the areas of information exchange, technology transfer, capacity building and commercial benefit-sharing. At present, the multilateral system applies to a list of over 64 plant genera, including 35 crop and 29 forage plants, agreed on the basis of interdependence and food security. The conditions for access and benefit sharing will be set out in a “Standard ‘Material Transfer Agreement’” (SMTA), established by the governing body at its first meeting after the treaty enters into force.

Access under MLS is to be provided only for the purpose of utilization and conservation for research for breeding and training for food and agriculture subject to property rights and access laws. An

important point is equitable sharing of the benefits arising from the commercialization of a product that uses PGR from the MLS, except when the product is available without restriction for further research and breeding.

While ensuring access to PGR for plant breeders, the treaty prevents their monopolization, in particular, by the large players. It also provides for the International Agricultural Research Centres of the CGIAR to secure legal framework for the *ex situ* collections that they hold in trust, and on which their research programmes are based. A clear and predictable framework for access to PGR is also set out for the private sector that may promote investment in agricultural research.

### ***Obligations of the contracting countries in the Treaty***

The countries are required to provide for facilitated access to PGR as per the Article 12.. Access to such PGRFA needs to be accorded “expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved,” (Article 12 b) Also, the available passport data and subject to applicable law will have to be made available with the PGRFA provided.

The obligations defined above, therefore, entail appropriate national network to strengthen a single window system of exchange. Genetic resources of all the crop genera specified in the list of crops, need to be maintained at respective crop institutes/designated sites for expeditious supply. Also, the treaty appears be a good opportunity for making requests for PGRFA from member countries. Gaps in our existing collections can be identified and PGRFA thus identified can be obtained from member countries.

### **Import Regulations for PGR in India**

Access to PGR for research purpose from outside India is regulated by quarantine regulatory provisions under Plant Quarantine (PQ) order 2003 of the principal Destructive Insect and Pest Act of 1914. There are two mandatory requirements for material imported into India for research use. These are, it must be accompanied with an import permit issued by Director NBPGR and a Phytosanitary Certificate issued from country of origin. For bulk import for consumption as food or seeds, the import permit is issued by the Directorate of Plant Protection, Quarantine and Storage, Department of Agriculture and Cooperation, Govt. of India. For import of transgenic germplasm a statutory clearance from Review Committee on Genetic Manipulation (RCGM) of the Department of Biotechnology, Govt. of India is required to be obtained before applying from import permit.

### **International Legal Instrument Affecting Genetic Resources Management: Summary**

#### **I Convention on Biological Diversity (CBD)**

##### **Scope/ Applicability**

- Covers all biodiversity related issues.
- Provide general principles for access and benefit-sharing concerning materials collected after the coming of CBD and not covered by the International Treaty on PGRFA.

##### **Status/ Jurisdiction**

- Legally binding for countries that have ratified (196 as on February 2018).
- Ratifying countries must adopt appropriate legislation/ regulations and/ or bring existing ones into harmony with the Convention.

**A) CBD/ International Protocol on Biosafety (Cartagena Protocol)** (*Relevant Indian Legislation ;Guidelines for safety of Biotechnology by DBT, 2002 under the Environment Protection Act (EPA) 1986*)

**Scope/ Applicability**

- Provides international regulatory framework for trade and protection of environment from adverse effects of products of modern biotechnology.

**Status/ Jurisdiction**

Adopted in January 2000.

**B) International regime on access and benefit sharing (Nagoya Protocol on ABS)****Scope/ Applicability**

- Internationally recognized framework for fair and equitable sharing of benefits arising from utilization of genetic resources through designated check points and ensures compliance with mutually agreed terms.
- Binding for all parties

**Status/ Jurisdiction**

- Adopted during 10<sup>th</sup> CoP of CBD at Nagoya Japan in October, 2010. Open for signatures by contracting parties from 2<sup>rd</sup> Feb, 2011 to 1<sup>st</sup> Feb, 2012.
- International Legal Instruments

**II International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)****Scope/ Applicability**

- Covers all PGRFA (does not regulate non-food and non-agricultural uses) and addresses diverse topics, including conservation, use, international cooperation, technical assistance and farmer's rights.
- Establishes multilateral system (MLS) for selected crops (over 35 food crops/29 forages species).
- Sets rules for access and benefit-sharing for these materials, both *ex situ* and *in situ*, while respecting property rights.

**Status/ Jurisdiction**

- Adopted by FAO Conference in 2001.
- Entry into force after the 40<sup>th</sup> country ratified in November 2004.
- Currently 144 contracting parties .
- Legally binding for all countries that ratify and not applicable to those that do not.
- Countries that ratify will be required to bring national laws and regulations into conformity with the Treaty.
- CGIAR Centres have signed agreements with the Treaty's Governing Body in order to adhere to the Treaty formally, and put all the material available with them under the MLS.

**III WTO- TRIPS Agreement****Relevant Indian legislations**

- *Protection of Plant Varieties and Farmer Rights Act 2001,*
- *Patent (Amendments) Act 2005,*
- *Geographical Indications of Goods (Registration and protection)Act 1999*

**Scope/ Applicability**

- Members States must comply with minimum standards of protection of IP.
- Must ensure protection of microorganisms, non-biological and microbiological processes and plant varieties that meet protection criteria.

**Status/ Jurisdiction**

- Entered into force in January, 1995 after the Marrakesh Ministerial Meeting in April, 1994.
- Legally binding on all WTO Members.
- Has Possibility for trade sanctions for those found not in compliance.

**IV WTO-Agreement on Application of Sanitary and Phytosanitary Measures**

#### *Relevant Indian Legislation*

*(Plant Quarantine (Regulation of Import into India) Order 2003 and its amendments issued under the DIP Act, 1914)*

#### **Scope/ Applicability**

- Covers measures adopted by countries to protect human or animal life from food- borne risks; animal or plant- carried diseases; plant pests and diseases to ensure food safety and prevent the spread of pests among animals and plants.

#### **Status/ Jurisdiction**

- Adopted by 153 WTO members presently.
- International Legal Instruments

### **V International Plant Protection Convention**

*(Relevant Indian Legislation)*

- *Plant Quarantine (Regulation of Import into India) order 2003 and its amendments issued under the Destructive Insects and Pests (DIP) Act 1914*
- *Seed Bill (2010)*

#### **Scope/ Applicability**

- An instrument and forum for harmonizing phytosanitary measures used in regulating international exchange of plants and planting material

#### **Status/ Jurisdiction**

- Established in 1952 (last revised in 1997).

### **VI Union for Protection of Plant Varieties (UPOV)**

**(India is not a member of UPOV)**

#### **Scope/ Applicability**

- UPOV aims to maximize plant breeding efforts by providing a model for securing protection under UPOV for plant breeders' rights for plant varieties.

#### **Status/ Jurisdiction**

- Four versions; only 1991 is still open for joining.
- Legally binding on Parties

### **VII FAO Global Plan of Action**

#### **Scope/ Applicability**

- Covers all GRFA.
- Contains specific “activities” on *in situ* conservation and development, *ex situ* conservation, utilization and institutions and capacity building.

#### **Status/ Jurisdiction**

- Adopted in 1996 by the 4<sup>th</sup> International Technical Conference on PGRFA (150 countries).
- Legally non-binding.
- Serves as a framework, guide and catalyst for PGRFA, and thus has a bearing on and a relation to a legally binding agreement.

### **VIII FAO-CGIAR Agreements Placing collections under the auspices of FAO, 1994.**

#### **Scope/ Applicability**

- Agreements apply to the management, availability and transfer of specifically designated germplasm.

#### **Status/ Jurisdiction**

- 12 Centres (those having *ex situ* collections) had signed binding agreements with FAO.

## Conclusions

Request for plant germplasm access from outside India for research purposes, were processed at NBPGR before notification of the Biological Diversity Act. These are now regulated through the Biological Diversity Act 2002, as discussed above. The PGR exchange which is essential for ongoing research is now governed by different set of rules. For import of PGR into India an import permit is required from India from the designated Authorities. It is now important to define the ownership of the material (developer, breeder, addition of value, custodians etc.) when we give and take germplasm for research. The obligations associated with the exchange need to be respected, more so the in the context of IPRs and p

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