



# Intellectual Property Rights (IPR) issues related to access and use of genetic resources

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## Abstract

Genetic Resources (GR) refer to genetic material of actual or potential value. Use of GR refers to the process of researching their beneficial properties and using them to increase scientific knowledge and understanding, or to develop commercial products. There is continuous search for newer resources to meet the future demands that arise with the emergence of new diseases, abiotic stresses, climate change, and enhanced demand for food and nutritional security. GR are exchanged and searched continuously for specific traits to improve yields and nutritional value in crops and animal genetic resources. Every nation is concerned with acquisition of diverse and superior germplasm for conservation and utilization. The rapid advancements in the fields of molecular biology, biotechnology and bioinformatics, led to the emergence of new legal, political and technological regimes regulating access to GR. Three international negotiations impacted the access to GR, these are the Convention on Biological Diversity (CBD), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as part of the Agreement establishing the World Trade Organization (WTO) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The regulation regarding access to GR, increasing application of IPRs and the vast potential of biological wealth yet to be tapped through bio-prospecting and genetic engineering, has placed greater demands on nations to adjust to the changing scenario of GR management. Currently access to GR is under the provisions of CBD and access to GR is based on mutually agreed terms (MAT), subject to prior informed consent (PIC). In response to CBD, India enacted the Biological Diversity Act (BDA), 2002 and established the National Biodiversity Authority (NBA) in 2003. Access to PGR from India is therefore regulated by BDA, 2002. The Nagoya Protocol which entered into force from October 2014 defines the international regime within the framework of CBD to promote and safeguard the fair and equitable sharing of benefits arising from the utilization of genetic resources. The paper discusses these agreements in detail with reference to access and use of GR.

**Key words:** Access, CBD, GR, IPR, MTA, Regulation

## Introduction

Genetic material is any material of plant, animal, microbial or other origin containing functional units of heredity and Genetic Resources (GR) refer to genetic material of actual or potential value. The development of improved types used today and those that would be cultivated in future is based on utilization of GR. These have helped in broadening the genetic base of within species and among species and in also diversification through stability and sustainability. There is continuous search for these resources to meet future demands and need that arise with the emergence of new diseases, climate change and food demands (De Jonge 2009). Plant genetic resources are exchanged and searched continuously for specific traits to improve crops in terms of yield and nutritional value. Every nation is concerned with acquisition of diverse genetic resources, their conservation and utilization.

India is rich in plant genetic resources and was considered one of the eight 'centres of origin' of crop plants and two sub centres of crop plant origin as described by Vavilov (1926). It is described as one of the twelve mega centres of crop diversity (Zeven and de wet, 1982), and now considered to have two of the 34 hot spots of biodiversity (Myers et al., 2000). Endless diversity of useful genes and traits has been utilized for crop improvement from Indian plant genetic resources. About 166 cultivated species are reported to be native to this region along with 320 wild relatives distributed in different agro-ecological zones in India (Arora, 1991). Those have been collected, used and improved for centuries. Short statured, lodging

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resistant, input responsive, high yielding introductions of wheat and rice played a pivotal role in ushering in the era of Green Revolution; and those carrying cytoplasmic-nuclear male sterility and fertility restoration genes brought in the era of hybrid breeding in crops like sorghum, pearl millet and rice that enabled the exploitation of heterosis (Singh et al. 2003). For sustainable agriculture, food and nutritional security, the planners and policy makers at national and international level decided to strengthen the activities related to genetic resources management. Under the Indian Council of Agricultural Research (ICAR) a very strong Germplasm Management System operates in a collaborative and partnership mode with other organizations through five national bureaux namely, National Bureau of Plant Genetic Resources (ICAR-NBPGR), National Bureau of Animal Genetic Resources (NBAGR), National Bureau of Fish Genetic Resources (NBFGR), National Bureau of Agriculturally Important Microbes (NBAIM) and National Bureau for Agricultural Insect Resources (NBAIR). The system has contributed immensely towards safeguarding the indigenous genetic resources and regulating access for enhancing the agricultural production and productivity in the country.

The scenario for exchange of the GR till 1970's was such that farmers were considered as the breeders and conservers of genetic resources and breeders obtained seeds by buying, collecting or being provided seeds they had full rights to do anything with the GR with-out restriction. It was the era of unrestricted exchange, unrestricted utilization and unrestricted marketing and hence every country gained more than it contributed. It promised self-sufficiency in food, food security and improved economy. During 1970s, Breeding Rights (BR) were implemented in many developed economies and this encouraged an expansion of private sector breeding. Two developments led to expansion of patent rights one was rapid development of biotechnology research methods and the recognition of biotechnological methods as an important tool/enabled invention. This was a landmark expansion of patent rights to cover living plants and animals and stronger patent rights were incorporated into WTO-TRIPS.

Perception changed, with biodiversity being regarded as a treasure under national sovereignty and the paradigm shift from free flow of genetic resources to a restricted exchange was officially introduced when Convention on Biological Diversity (CBD) came into force. Many developing countries required to address

IPR issues for the first time. Access to germplasm is now politicized and legally controlled, subject to international agreements as well as national legislations.

#### **Access to genetic resources**

Being signatory to the Convention on Biological Diversity (CBD), Govt. of India enacted the Biological Diversity Act (BDA), 2002 and also notified the Biological Diversity Rules (BDR) 2004 and established National Biodiversity Authority (NBA) in 2003. At national level, access to biological resources from India is now regulated by BDA, 2002 and BDR, 2004.

#### **Access to genetic resources by non-Indians**

As per the Act, Non-Indian entity defined in the Act as per Section 3 (2) cannot access any biological resources or knowledge associated, for research, commercial utilization, bio-prospecting or bio-utilization, without proper approval of NBA. However, no such permission is needed for publication of the research in a journal or seminar, or in case of a collaborative research made by institutions approved by Central Government ([www.nbaindia.org](http://www.nbaindia.org)).

The person/entities required to take the approval of the NBA are : A person who is not a citizen of India; a citizen of India, who is a non resident as defined in Clause (30) of section 2 of the Income tax Act, 1961; a body corporate, association or organization- (i) not incorporated or registered in India; or a body corporate, association or organization 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.

#### **Access to genetic resources by Indian citizens**

Indian citizen are not required to obtain any prior approval for carrying out research activities, however for bio survey, bio utilization, commercial utilization, Indian citizens or body corporates need to take permission from the concerned State Biodiversity Board.

As regard to IPR, if a person need to apply for patent or other form of intellectual property protection based on the research arising out of biological resources obtained from India the permission of the NBA is required. The NBA while granting such permission may request for benefit sharing or royalty based on utilisation of such protection. Benefit sharing out of usage of biological resources can be done in

monetary or non-monetary forms.

### **Import provisions under the plant quarantine (Regulation of Import Into India) Order, 2003**

#### ***Import of genetic resources for research purposes***

The Plant Quarantine (Regulation of Import into India) Order 2003 (PQ Order 2003) governs the import of genetic resources for research purposes. Director, ICAR-National Bureau of Plant Genetic Resources (ICAR-NBPGR) has been authorized to issue import permit for import of germplasm transgenic or genetically modify for research purposes and receive imported materials from custom authorities for its quarantine inspection, clearance, and further distribution to the researchers in the country. As per the procedure for import of germplasm for research or experimental purposes, the Government of India has made it obligatory for all plant breeders and researchers intending to import seed/planting materials, to fulfill the two mandatory requirements, First is the procurement of an import permit before import of any material into India and Second is the phytosanitary certificate issued from the country of origin (These two documents must accompany every consignment of seed/planting material imported from abroad for research purposes). The provisions of PQ Order are applicable to import of transgenic seeds as well, and in addition clearance from Department of Biotechnology (DBT) is mandatory.

The recipient desirous of importing seed/planting material has to apply to the Director, ICAR-NBPGR on a prescribed application form (PQ Form 08). The IP is issued in form PQ 09 in triplicate.

For private Seed Companies, the Research and Development activities of the firm should be recognized by Department of Scientific and Industrial Research (DSIR) and the certificate to this effect is to be submitted along with the PQ08 form.

#### ***Import of genetic resources for commercial purposes***

Commercial and bulk import is permitted based on the recommendations of Export Import Committee (EXIM) Committee of Department of Agriculture, Cooperation and Farmers Welfare (DACFW), Ministry of Agriculture and Farmers Welfare (MoAFW). The application needs to be submitted to Department of Plant Protection, Quarantine and Storage (DPPQS), which is located at NH-IV, Faridabad.

### **Export provisions as per the Biological Diversity Act (BDA), 2002 and Biological Diversity Rules, (BDR), 2004**

The request for access to genetic resources occurring in India, only for research purposes is to be considered under the following categories:

#### ***Category 1: Export of germplasm not covered under any collaborative research project with research institutes/counter parts, public-private transfer, private entities (Indian Citizen/Non-Indian), as per Section 3 (2) of the BDA, 2002***

For export of germplasm not covered under any collaborative research project, prior approval from the NBA is required. The application form in the prescribed format along with the prescribed fee needs to be submitted to NBA. The application is now available online (<http://absefiling.nic.in/NBA/login/auth>).

#### ***Category 2: Export of germplasm under collaborative research projects/work plans, under Section 5 of the BDA, 2002***

As collaborative research project which conform to the policy guidelines are exempted under Section 5 of BDA, 2002 (Ministry of Environment, Forests and Climate Change (MoEFCC) Notification S.O.1911(E) dated 8<sup>th</sup> November, 2006), ICAR-NBPGR facilitates the approval from Department of Agricultural Research and Education (DARE). No research results shall be communicated or transferred to any third party in any manner without entering into an agreement with National Biodiversity Authority.

#### ***Category 3: Export of Annex 1 crops under ITPGRFA and FAO designated accessions of CG Centres located in India***

Facilitated access to plant genetic resources for food and agriculture under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), 2001 to all its member countries, for the crops mentioned in Annex 1 of ITPGRFA is solely for utilization and conservation for research, breeding and training. Department of Agriculture, Cooperation and Farmers Welfare (DACFW) Ministry of Agriculture and Farmers Welfare (MoAFW), Government of India, is the national focal point (NFP) for ITPGRFA in India. Guidelines are developed and as per these guidelines, ICAR-NBPGR being the nodal agency for the management and exchange of PGR for research purposes in India will coordinate the supply of PGRFA

of Annex 1 Crops for the purpose of the Treaty, in consultation with other relevant national research institutions/organizations. PGRFA collected before 1993 and held in 'trust' by IARCs shall also be made available in accordance with the provisions of SMTA pursuant to agreements between IARCs and FAO, in accordance with the relevant provisions of this Treaty. The SMTA shall be signed prior to transfer of PGRFA only as hard copies and the Director, ICAR-NBPGR, shall be the authorized signatory. For FAO designated material being exported by the IARCs, the SMTA shall be signed by the authorized signatory of the provider IARC. For export of PGRFA, the IP from the importing country shall be required. The transfer of material remains subject to normal phytosanitary inspection and clearance.

**Category 4: Indian researcher/government institution to carry/send germplasm for non-commercial research/ or research for emergency purposes other than collaborative research**

Any Indian researcher/government institution who intends to carry/send the biological resources outside India to undertake basic research other than collaborative research as referred to in section 5 of the Biological Diversity Act, 2002 need to apply to the NBA and the NBA, on being satisfied with the application accord its approval within a period of 45 days from the date of receipt of the application (Gazette notification GSR 827 dated 21.11.2014).

**Access procedures within India for use of plant genetic resources by Indian researcher/users within country**

All the requests for the supply of PGR stored/maintained by ICAR-NBPGR/NAGS should be sent to the Director, ICAR-NBPGR, New Delhi, in the requisition proforma for the supply of seed/planting material or Form GEX 01, along with MTA signed by recipient. GEX 01 and MTA are available at ICAR-NBPGR website ([www.ICAR-NBPGR.ernet.in](http://www.ICAR-NBPGR.ernet.in)). It is desired that national identity exotic collection (EC) and indigenous collection (IC) numbers allotted to accessions by ICAR-NBPGR must be maintained by all users and should not be changed (Anonymous 2016).

**Access to IP protected material/registered germplasm and technologies**

Access to any IP protected technology or GR is generally at the terms and conditions of the developer

unless it is declared by the developer to be in public domain. The user, therefore, must read the conditions to access very carefully and comply. They may need to sign an appropriate agreement or undertakings. Material Transfer Agreement (MTA) describes the conditions under which the transfer of material is made for specific use and addresses various issues such as ownership of the transferred material and its derivatives. The conditions of liability, confidentiality and third party transfer are defined in the MTA. Thus, they are contractual agreements used for transfer or acquisition of material and technologies.

Access to technologies developed by ICAR institutions is governed by ICAR Guidelines for Intellectual Property Management and Technology/Transfer/Commercialization (Anonymous 2006, 2018). While transferring the technologies it is advised to have non-exclusive transfers. In case of IPR enabled technologies, exclusive license may be issued and licence fee or royalty need to be negotiated on mutually agreed terms.

**Access to plant varieties registered under Plant Varieties & Farmers Right Act (PPV&FRA)**

The PPV&FR Act, 2001 was enacted to grant intellectual property rights to plant breeders, researchers and farmers who have developed any new or extant plant varieties. The Intellectual Property Right granted under PPV&FR Act, 2001 is a dual right – one is for the variety and the other is for the denomination assigned to it by the breeder. The rights granted under this Act are heritable and assignable and only registration of a plant variety confers the right. Essentially Derived Varieties (EDV) can also be registered under this Act and it may be new or extant. Farmers are entitled to save, use, sow, re-sow, exchange or sell their farm produce including seed of a registered variety in an unbranded manner. The rights granted under this Act are exclusive right to produce, sell, market, distribute, import and export the variety.

However, the Section 30 (Researchers Right) provides for researchers exemption, wherein a researcher can use a protected variety for research and breeding for development of a new variety. The permission of the breeder is required only in case if a protected variety is required as a parental line of a hybrid where repetitive use is essential for seed production of the hybrid. Also such permission is required if the researcher needs to use the variety for the purpose of developing an Essentially Derived



Variety (EDV) either through GM technology or other genetic manipulation [Section 23 (6)], when the characteristics of the original variety remain the same except the single introduced trait through genetic manipulation.

### Conclusion

Emergence of new IPR regime, in relation to GR calls out modalities for benefit sharing between the private and public sectors to ensure continuity of germplasm exchange and synergy between the two sectors. Well-defined procedures are in place with regard to access to GR. Although, biological resources/living things and essentially biological processes are not patentable, certain concerns are still debatable as who owns these resources? How to ensure that we do only what we are allowed when these resources and technologies are being exchanged with certain conditions? How do we ensure that others also do only what they are allowed as recipients of GR as per these agreements? The science of exchange therefore, needs to be based on ethical principles as well as mutual faith.

### References

- Anonymous. 2006. ICAR Guidelines for Intellectual Property Management and Technology Transfer/Commercialization. ICAR, New Delhi. 122p.
- Anonymous. 2018. ICAR Guidelines for Intellectual Property Management and Technology Transfer/Commercialization (Revised in 2018). ICAR, New Delhi. 115p.
- Anonymous. 2016. Guidelines for Management of Plant Genetic Resources in India. ICAR-NBPGR, Pusa Campus, New Delhi, 142+xxivp.
- Arora R. K. 1991. Plant diversity in Indian Gene Centre, Plant Genetic Resources. Conservation and Management (Eds. R. S. Paroda and R. K. Arora), IBPGR, Regional Office, New Delhi, India, pp. 25-54.
- De Jonge. 2009. Plants, Genes and Justice: An enquiry into fair and equitable benefit-sharing. Unpublished Ph. D. Dissertation, Wageningen: Wageningen University.
- Dhillon B. S. and Anuradha Agarwal. 2005. Plant Genetic Resources: Ownership, Access and Intellectual Property Rights *In*: Plant Genetic Resources: Oilseed and Cash Crops (Eds. B. S. Dhillon, R. K. Tyagi, S. Saxena and Anuradha Agarwal), Narosa Publication, pp. 1-20.
- Myers N., Mittermeier R. A., Mittermeier C. G., Fonseca G. A. B. and Kents J. 2000. Biodiversity hotspots for conservation priorities. *Nature*, **403**: 853-858.
- Singh R. V., Chand D., Tyagi V., Verma N., Singh S. P. and Dhillon B. S. 2003. Important crop germplasm introduced into India during 2001, *Indian J. Plant Genet. Resour.*, **16**(2): 87-90.
- Vavilov N. I. 1926. Studies on the origin of cultivated plants. *Bull. Appl. Bot.*, **26**: 1-248.
- Zeven A. C. and de wet J. M. J. 1982. Dictionary of cultivated plants and their regions of diversity, excluding most ornamentals, forest trees and lower plants. 2nd Rev. Ed., Wageningen : Pudoc, Centre for Agricultural Publishing and Documentation, , 263 p.

#### Suggested websites:

<http://agricoop.nic.in/guideleines/seeds>

<http://nbaindia.org/>

<http://nbaindia.org/content/25/19/1/act.html>

[http://nbaindia.org/uploaded/pdf/Gazette\\_Notification\\_of\\_ABS\\_Guidlines.pdf](http://nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidlines.pdf)

[www.nbpg.ernet.in](http://www.nbpg.ernet.in)

[www.plantauthority.in](http://www.plantauthority.in)

[www.plantquarantineindia.nic.in](http://www.plantquarantineindia.nic.in)