

Mechanisms for Operationalization of Access to Germplasm in India in the New Regime

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Introduction

The diversity in life forms is the basis of continuous evolution of life on earth. The dependence of human beings for food, fodder, shelter and other needs on various components of biodiversity, especially the plant genetic resources (PGR), is also undoubted. Sustainable use of PGR for food and agriculture is, therefore, of critical importance. Since most countries depend largely on PGR that have originated elsewhere, it is essential and extremely important to develop mechanisms for the access and sharing of these resources among and within the nations. It is, more so, after the realization of owners rights, breeders' rights (1970s) and Intellectual Property Rights (IPRs), and owing to the advances in biotechnology during 1990s.

Access to genetic resources under different regimes is governed by: (i) "Sovereign rights of Nations" under the legally binding Convention on Biological Diversity (CBD), 1992. The Convention provides for appropriate access to genetic resources and transfer of relevant technologies on mutually agreed terms and subject to prior informed consent and, (ii) "Facilitated access" to plant genetic resources for food and agriculture under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), 2001 which has a provision of "Multilateral System" of exchange under mutually agreed terms.

Of these, the CBD (1992) had obligated all parties (Convention Countries) to provide for conservation of biological diversity, sustainable use of its components and equitable sharing of the benefits arising out of the use of biological resources. This also includes provisions for regulation of access to biological resources reaffirming the sovereign rights of nations over their biological resources. The Biological Diversity Act (BDA) of India was formulated after India became signatory to the CBD, and it provides for all the objectives of CBD as mentioned above (Brahmi *et al.*, 2004a).

Established Institutional Mechanism under the BDA

For effective implementation of the Act it is envisaged to have 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 to secure fair and equitable sharing of benefits arising out of utilization of biological resources and 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 knowledge associated thereto obtained from India, are also dealt by NBA.

The SBBs are being constituted for every state in India to 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 would constitute a BMC for conservation, sustainable use, and documentation of biodiversity and chronicling of knowledge relating to biodiversity. BMC shall be consulted by the NBA and SBB on matters related to use of biological resources and associated knowledge within their jurisdiction.

Provisions for Regulation of Access to Biological Diversity

Chapter II of the BDA deals with regulation of access to biological diversity (Sections 3-7). Section 3 of the Act restricts non-Indians defined in the Act, not to undertake biodiversity related activities, without approval of National Biodiversity Authority.

Section 4 provides for conditions of transfer of results of research related to biodiversity with the approval of the NBA. Such transfer includes 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.

However, 'transfer' does not include publication of research papers or dissemination of knowledge in any

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seminar or workshop, if such publication is as per the guidelines issued by the Government of India.

Exemption to provisions of section 3 and 4 has been provided in Section 5. Sub section (1), for collaborative research projects involving transfer or exchange of biological resources or information relating thereto, including Government sponsored institutions of India, and such institutions in other countries. Such collaborative research projects should conform to the policy guidelines issued by the Central Government in this regard and be approved by the Government of India. The Ministry of Environment and Forests (MoEF) has issued such guidelines vide notification no. S.O. 1911(E) dated 8 November, 2006. These guidelines cover exchange of germplasm and information under collaborative research projects including bilateral and multilateral agreement, memorandum of understanding, work plans, under any international collaborative research projects.

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 of the patent by the patent authority concerned. NBA may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

Access to PGR with Reference to Protection of Plant Varieties and Farmers Rights (PPVFR) Acts, 2001

The researchers have been given exemptions under the PPVFR Act, to use a protected variety for research, including development of new varieties, except in case of commercialization of the newly developed variety or in case of repeated use of a variety as a parental line (Brahmi *et al.*, 2004 b).

Registration of New Varieties

The applications for registration of new variety under the PPVFR Act need to be accompanied with complete passport data of parental lines used for breeding, including geographical location in India from where the material was obtained. Secondly, proof of lawful acquisition of the material used for breeding is also required to be submitted.

Therefore, the breeders are required to maintain full passport data of material used and documentary evidence of its acquisition. This can be a Material Transfer Agreement (MTA) or written certified document showing consent of the owner of the material. These could be farming communities, public sector institutions or private organizations (Dhillon *et al.*, 2006).

Access to PGRFA under the Multilateral System of ITPGRFA

Access under this system is to be facilitated to all member countries, for the crops mentioned in Annex 1 of ITPGRFA and solely for utilization and conservation for research, breeding and training. This does not include chemical, pharmaceutical and/or other non-food/ feed or industrial uses (Dua *et al.*, 2004). The access is to be accorded free of charge or if charged, the fee should not exceed the minimal cost involved. The governing body of the Treaty has ratified a Standard Material Transfer Agreement (SMTA) for use among member countries. Salient provision of the SMTA is that the material received under the multilateral system of the treaty shall be freely available to others for use in research, breeding and training. The third and subsequent parties accessing the material shall be bound by the same conditions of the SMTA. The recipients can not claim any IPRs on the material in the form received and if any commercial utilization is done, the benefits would be returned to a trust fund of the Treaty. This sharing of benefits would be to the tune of 1.1% of the total share of profits.

The Consultative Group on International Agricultural Research (CGIAR) institutions have also agreed to be part of the multilateral system and access to germplasm of all their mandate crops would be under the condition of SMTA.

Existing Access Regulations in India

Access to PGR for research purpose from outside India has been regulated by quarantine regulatory provisions under Plant Quarantine Order, 2003 (Regulation of Import into India) of the Destructive Insects and Pests (DIP) Act of 1914, known as PQ Order, 2003. Material imported into India is to be accompanied with an import permit issued by the Director, National Bureau of Plant Genetic Resources (NBPGR) and Phytosanitary Certificate (PSC) issued from the country of origin. Under the PQ order, freedom of import commodities from pests of quarantine importance has been incorporated. "Additional/ Special Declarations on the basis of standardized Pest Risk

Analysis (PRA) particularly for seed/planting material have been taken care of. Four categories of agricultural imports have been included in the revised order. These are: (i) Prohibited plant species (Schedule IV), (ii) Restricted species where import permitted only by authorized institutions (Schedule V), (iii) Restricted species permitted only with additional declarations of freedom from quarantine/ regulated pests and subject to specified treatment certifications (Schedule VI), and (iv) Plant material imported for consumption/industrial processing permitted with normal phytosanitary certificate (Schedule VII).

For import of transgenic germplasm, a statutory clearance (Fig. 1) from Review Committee on Genetic Manipulation (RCGM) of the Department of Biotechnology, Govt. of India is required to be obtained before applying for import permit (Singh *et al.*, 2001).

The responsibility for import and export of plant genetic resources for research purposes, whether under

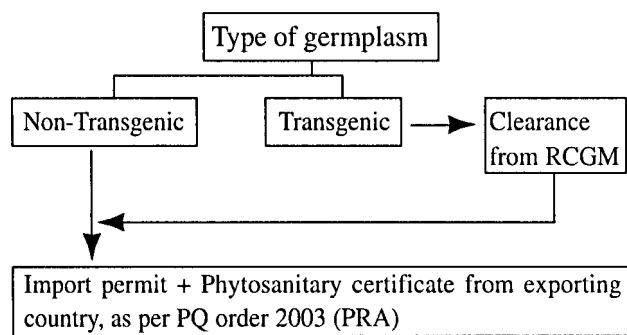


Fig. 1: Clearance procedure for import of germplasm

memoranda of understanding (MoUs) for collaborative research projects developed among countries for research purposes or by for individual public or private organizations, has been delegated by the Ministry of Agriculture to the Indian Council of Agricultural Research (ICAR)/ Department of Agricultural Research and Education (DARE). NBPGR is the nodal agency recognized for PGR exchange within the country as well as outside the country. After enactment of the Biological Diversity Act, and Protection of Plant Varieties and Farmers' Rights Act and ratification of International Treaty on Plant Genetic Resources for Food and Agriculture by India, NBPGR has to follow new rules for exchange of plant genetic resources for food and agriculture for which the following checklist needs to be kept in view:

1. Status of indentor or the requesting party is to be considered (Fig. 2). The public sector research organizations may address the request to the holder of germplasm or route the request through Director NBPGR. The germplasm will be sent as per the provisions under MTA. The MTAs lists the mutually agreed conditions for the transfer done between two parties, and has some essential clauses, viz. name(s) and addresses of both parties, name(s) identity and other passport details of the materials to be exchanged, purpose of transfer, cost involved, treatment of derivatives after further research IPR(s) generated, acknowledgements and arbitration conditions or dispute settlement etc. (Tiwari, 2006).
2. For Indian private seed companies with all Indian collaborators and full Indian funding, the material may be sent after confirming the R&D status of the company (Govt./State Govt. approved/notified) and under the conditions of Material Transfer Agreement (MTA).
3. For Indian private seed companies with foreign collaborators or foreign funding, the request shall be directed to NBA. The same will be applicable to multinational seed companies with centres in India.
4. Exchange of germplasm with CGIAR organization based in India or with Centres in India would be based on the bilateral MoUs signed between ICAR and these institutions from time to time and shall be restricted only to their mandate crops.
5. Export of germplasm under bilateral agreements and other MoUs/Work Plans between India and other countries shall be for the specific crops mentioned is submitted to DARE after recommendations from NBPGR and to NBA for final approval (Fig. 3).
6. For exchange of PGRFA under the multilateral system of the ITPGRFA, only those crops that are mentioned in Annex I to the Treaty shall be considered. Presently, Annex I covers 35 food crops and 29 forage genera based on world food security and interdependence of countries. This exchange shall be only among the contracting countries (countries signatory to the Treaty) and under the conditions of SMTA, as discussed above, approved by the Governing Body of the Treaty.

Conclusion

Access to germplasm and information under the new regime in India has to taken into account the established

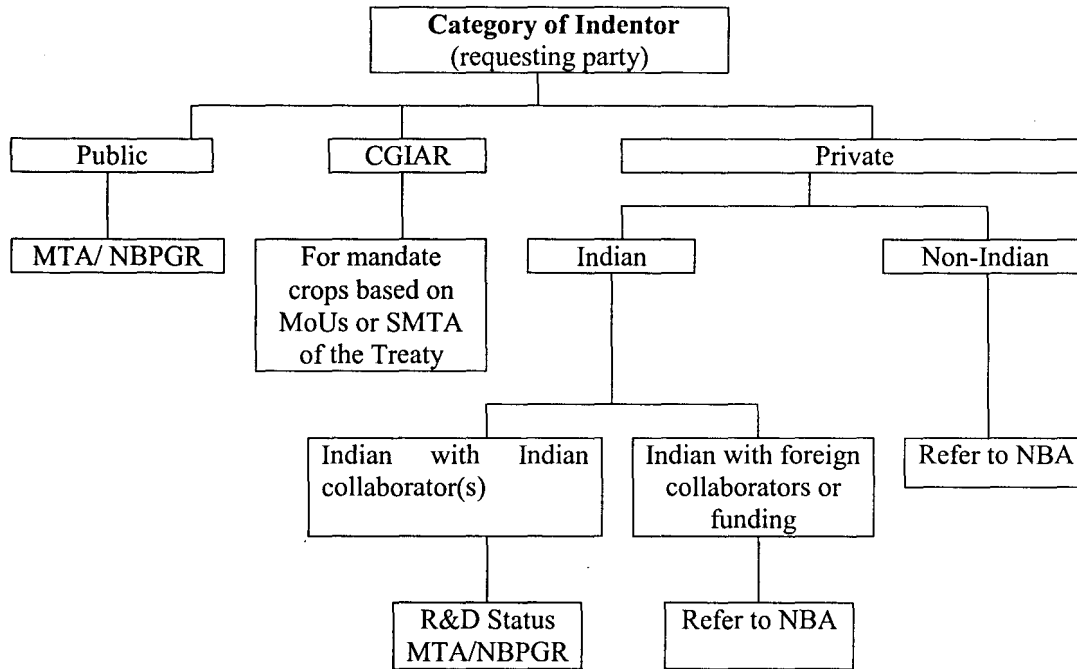


Fig. 2: Procedure for handling cases for request of germplasm

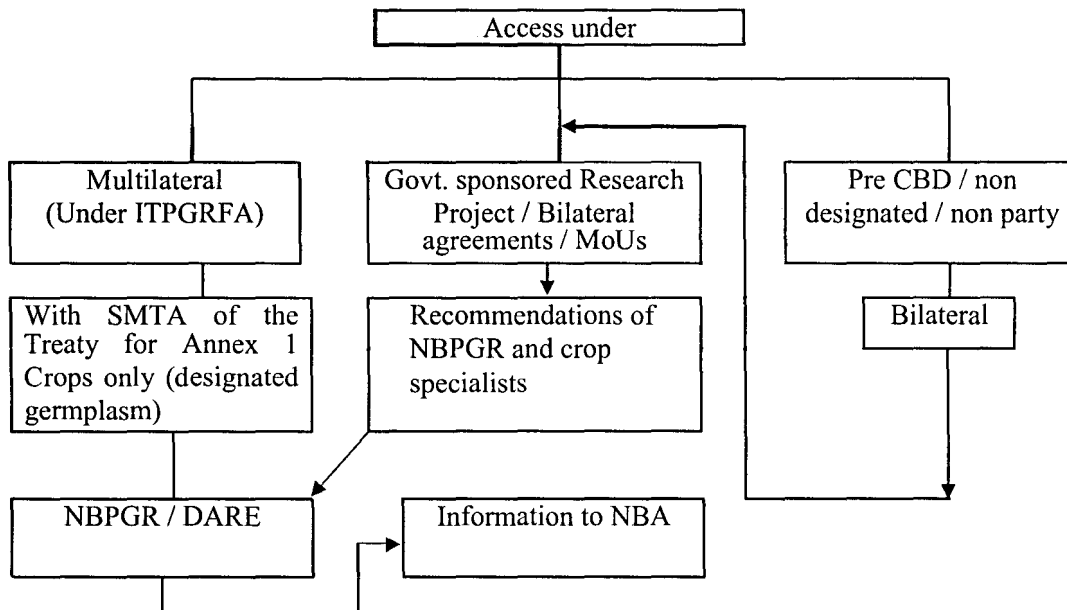


Fig. 3: Conditions for access under different conditions

institutional mechanism and various acts in force relating to agrobiodiversity. The requests of indentors are to be dealt with depending on the status of requesting party and the conditions for access under different categories. NBPGR/DARE, the nodal agency for the purpose, has to regulate the access based on projects approved by Govt. Department, State or Central Government, or MoU/

Workplan and other relevant agreements, key investigators/ institute involved, details of the biological resources/ associated knowledge to be exchanged (exported), special status of material if any as per any international agreement (e.g. FAO designated, INGER Nurseries, etc.), intended use for research only and quantity for exchange to be limited to experimental

purpose only. Conditions of MTA also need to be strictly followed and monitored.

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