



Implementation of the Multilateral System of the Plant Treaty in India: Exploring Linkages with Biological Diversity Act, 2002

Centre for Biodiversity Policy and Law
National Biodiversity Authority

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Foreword and Acknowledgements

This report titled “Implementation of the Multilateral System of the Plant Treaty in India: Exploring Linkages with Biological Diversity Act, 2002” is an outcome from the CEBPOL Theme – Interface with Multilateral Environmental Agreements and other Organizations (MEAs). The theme MEAs primarily aims to carry out assessment of interrelationship amongst key themes in order to promote implementation in a mutually supportive manner. One important activity under this theme is to develop strategy papers on inter-linkages between agreements and processes to enhance effectiveness and better implementation at national level. Dwelling upon these, the current report assesses the synergistic implementation in India, of the obligations under the FAO International Treaty on Plant Genetic Resources for Food and Agriculture within the framework of the Biological Diversity Act, 2002.

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Executive Summary

India is a Contracting Party to the Convention on Biological Diversity (CBD), 1992 and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), 2001. The implementation of the CBD was through the enactment of the Biological Diversity Act in 2002. The obligations enacted under the Treaty got partly implemented in India through the Protection of Plant Varieties and Farmers' Rights Act, 2001. Through this legislation, the obligations to create farmers' rights was fulfilled. But the major objective of the Treaty to facilitate germplasm exchange of plant genetic resources for food and agriculture through a multilateral system of access and benefits sharing (ABS) was pending till 2015. This part of the Treaty obligation was implemented by creating an exception within the Biological Diversity Act, allowing the PGRFA of the Treaty to be governed by the Guidelines enacted for the purpose. This paper seeks to explore the linkages between the Biological Diversity Act, 2002 enacted by the Ministry of Environment, Forest and Climate Change and the "Guidelines for the Implementation of International Treaty on Plant Genetic Resources for Food and Agriculture for Facilitated Access under the Multilateral System, 2015 (hereinafter MLS Guidelines)" issued by the Ministry of Agriculture. This report aims to examine the synergies at operational level of the Biological Diversity Act and the MLS Guidelines.

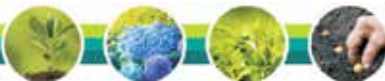
(Key Words: access and benefit sharing, plant genetic resources for food and agriculture, multilateral system of benefit sharing, facilitated access in India)

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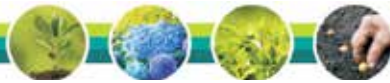
Acronyms

ABS	–	Access and benefit sharing
BMCs	–	Biodiversity Management Committees
CBD	–	Convention on Biological Diversity
CGIAR	–	Consultative Group for International Agricultural Research
DAC	–	Department of Agriculture, Cooperation and Farmers' Welfare
FAO	–	Food and Agriculture Organisation
GEFC	–	Germplasm Export Facilitation Committee
IARCs	–	International Agricultural Research Centres
IPRs	–	Intellectual Property Rights
ITPGRFA	–	International Treaty on Plant Genetic Resources for Food and Agriculture
MLS	–	Multilateral System for Access and Benefit Sharing
MoEF&CC	–	Ministry of Environment, Forests and Climate Change
NBA	–	National Biodiversity Authority
NBPGR	–	National Bureau of Plant Genetic Resources
NFP	–	National Focal Point
PGRFA	–	Plant Genetic Resources for Food and Agriculture
PPVFRA	–	Protection of Plant Varieties and Farmers' Rights Act, 2001
R&D	–	Research and development
SBB	–	State Biodiversity Board
SMTA	–	Standard Material Transfer Agreement



I. Introduction

The Biological Diversity Act enacted in the year 2002 provides for the legal and institutional mechanism for implementing Article 15 of the Convention on Biological Diversity (CBD) dealing with regulation of access to genetic resources based on prior informed consent and mutually agreed terms. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is another international instrument creating a multilateral system for access and benefit sharing in respect of plant genetic resources, distinctive from the bilateral framework of the CBD while recognising the sovereign rights of nations. The obligations under these overlapping regimes of CBD and ITPGRFA are achieved by the Government of India through the Biological Diversity Act and the Protection of Plant Varieties and Farmers' Rights Act (PPVFRA), 2001. The PPVFRA implements the obligations in respect of farmers' rights as emanating from the Treaty whereas implementation of the multilateral system of ABS is enabled by way of creating an exemption under section 40 of the Biological Diversity Act. The "Guidelines for the Implementation of International Treaty on Plant Genetic Resources for Food and Agriculture for Facilitated Access under the Multilateral System, 2015 (hereinafter MLS Guidelines)" issued by the Ministry of Agriculture lays down the institutional structure and procedural mechanism for operationalizing MLS. In India, harmony to a greater extent in respect of the above two international instruments is achieved by the coordinated actions of the Ministry of Agriculture and the Ministry of Environment, Forest and Climate Change (MoEF&CC) along with their various line departments. This report aims to examine the synergies at operational level of the Biological Diversity Act and the MLS Guidelines. Section I provides an overview of the ABS regulatory framework in India. Section II briefly describes the multilateral system of access and benefit sharing under the Treaty. Section III explains how the multilateral system is implemented in India. Section IV discusses the overlaps in the bilateral and multilateral framework and Section V provides the recommendations for better synergies



II. The Access and Benefit Sharing System in India under the Biological Diversity Act, 2002

The Biological Diversity Act established a three tier system to regulate access to biological resources in India and for the fair and equitable sharing arising out of their utilization¹. Based on this, three different layers of governance are constituted for regulating different activities over the biological resources and knowledge associated therewith in India.

A. National Biodiversity Authority

The National Biodiversity Authority (NBA) is established under section 18(3) of the Biological Diversity Act, 2002 with inter alia the mandate to regulate the following activities;

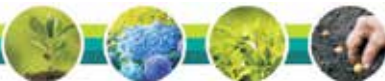
- a) Obtaining of biological resources and knowledge associated therewith for research², commercial utilization³ and bio-survey and bio-utilization⁴ (section 3)

Persons/entities who are required to obtain prior approval from NBA are:-

an individual;

- (i) a non-Indian or
- (ii) non-resident Indian (as defined under section 2(30) of the Income Tax Act 1961)

-
1. India regulates access to biological resources which is broader in scope than regulation of access to genetic resources as mentioned in Article 15 of CBD. Biological resources are defined in section 2(c) of the Biological Diversity Act as “plants, animals and microorganisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value but does not include human genetic material”.
 2. Section 2(m) of the Biological Diversity Act defines research as “study or systematic investigation of any biological resources or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use”.
 3. Section 2(f) of the Biological Diversity Act defines commercial utilization as “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 intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping”.
 4. Section 2(d) of the Biological Diversity Act defines bio-survey and bio-utilization as “survey or collection of species, subspecies, genes, components and extracts of biological resources for any purpose and includes, characterization, inventorization and bioassay.



OR

a body corporate, association or organisation;

(i) which is not incorporated or registered in India; or

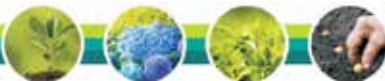
(ii) which is incorporated/ registered in India having any non-Indian participation in its share capital or management

b) Transfer of the result of any research relating to biological resources occurring in or obtained from India (section 4)

Any person or entity wishing to make a transfer of research result over the biological resources occurring in or obtained from India, shall obtain prior approval from NBA before making such transfer. This obligation is applicable only when the research result is transferred to a person/entity which is bound to obtain prior approval from NBA for carrying out the activities of research, commercial utilization and bio-survey and bio-utilization. Whether the transfer is in return for monetary consideration or otherwise shall not be decisive factor in this regard. However, the Act specifically excludes publication of research papers or dissemination of knowledge in any seminar or workshop from the meaning of transfer of research result so long as such publication is as per the guidelines issued by the Central Government. It is notable that no guidelines are issued by the Central Government in this regard as of now and hence NBA is not extending this regulatory power to information dissemination through research publications, seminars and workshops.

c) Obtaining of IPR over inventions based on research or information over biological resources obtained from India. (section 6)

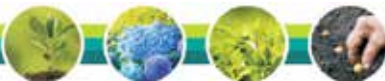
Any person/entity intending to obtain IPR over any invention based on research or information on a biological resource obtained from India is required to obtain prior approval from NBA before making such application for IPR. It is further specified that, in the case of patents, the permission from NBA may be obtained after the acceptance of the patent but before the sealing of the patent. After 2005 amendment of the Patents Act, 1970, the acceptance and sealing system is replaced by the simple procedure of grant of patents. Thus, while filing a patent application, a person need not wait for prior approval and this helps the patent applicant to maintain his priority under the patent system. However, approval needs to be obtained before the grant of the patent.



Further, the Act provides that any person applying for any right under any law relating to protection of plant varieties enacted by the Parliament are exempted from the obligation to take prior approval from NBA under section 6. In effect, applicants seeking patent protection in India and outside as well as plant variety protection in any country other than India are regulated by section 6 of the Biological Diversity Act.

d) Transfer of already obtained biological resources under section 3. (section 20)

Regulation of transfer of biological resources is another activity which falls within the regulatory powers of NBA. Section 19 of the Act provides for the procedure to be followed by NBA while granting approvals under section 3, 4 & 6. Section 20 of the Act provides that any person who has been granted an approval based on section 19 shall transfer the biological resources or knowledge associated thereto which is the subject matter of the said approval, only with the permission of NBA. Out of the three different types of approvals discussed above, biological resources form the subject matter of approval only in section 3, i.e., to obtain them for research, commercial utilization or bio-survey and bio-utilization. Other approvals are permission for obtaining IPR and for transfer of research result where the subject matter is not a biological resource or associated knowledge, rather a product or process or output based on the use of biological resources. Moreover, trying to regulate the transfer of all biological resources subject to approvals under sections 4 and 6 would complicate situations wherein NBA would also be trying to regulate the movement of biological resources from an Indian to another Indian or an Indian to an entity with 100% Indian share capital or management or between two entities with 100% Indian share capital or management. Also when a person/entity does not have the obligation to obtain biological resources for doing research, commercial utilization or bio-survey and bio-utilization, the reason that they have obtained an IPR or transferred the research result to a regulated person/entity does not seem compelling to regulate the further transfer of the biological resources related to the invention or protected variety or the research result to a similar entity. Hence, NBA currently regulates only the transfer of already accessed biological resource by a person/entity with approval under section 3, to **any person/entity** in India or outside.



- e) Non-commercial research or research for emergency purpose outside India (Regulation 13 of the Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014)

NBA provides prior approval for Indian researchers and government institutions intending to carry or send biological resources outside India to undertake basic research. Prior approval from NBA is also required for any government institution intending to send biological resources to carry out urgent studies to avert emergencies like epidemics etc.

- f) Deposition of microorganisms in foreign repositories for claim of novel species

Prior intimation to NBA must be made by Indian researchers and scientists who intend to deposit microorganisms for claim for novel species for publication in international journals as required under the International Bacteriological Code of Nomenclature. Though there is no specific provision in this regard in the Act, Rules or guidelines, Form C available in NBA website facilitates the process.

Equitable sharing of benefits arising from the utilization of biological resources and knowledge associated thereto

The approvals granted under section 3, 4, 6 and 20 of the Biological Diversity Act are subject to the terms and conditions imposed by NBA including imposition of charges by way of royalty. The terms and conditions of the approval are mandated to secure equitable sharing of the benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge associated thereto. The equitable benefit sharing is expected to be in accordance with the mutually agreed terms and conditions between the person applying for approval, local bodies concerned and the benefit claimers. The benefit sharing is determined by NBA and shall be given effect in all or any of the following forms,

- joint ownership with NBA or identifiable benefit claimers,
- transfer of technology,
- location of production and R&D units in areas facilitating better living standards to benefit claimers,



- association of Indian scientists benefit claimers and local people in R&D and bio-survey and bio-utilization,
- setting up of venture capital funds, and
- payment of monetary compensation and other non-monetary benefits to benefit claimers

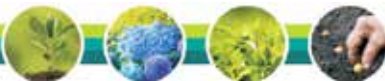
The amount of money ordered by way of benefit sharing may be deposited in the National Biodiversity Fund and where the benefit claimers are identifiable, the amount may be paid directly to such benefit claimers in accordance with agreements if any, or in such manner as prescribed by NBA.

B. State Biodiversity Boards

As per section 7 of the Biological Diversity Act, 2002, most the state governments in India have established State Biodiversity Boards to regulate obtaining of biological resources by Indian citizens, or body corporates, associations or organisations registered in India for (i) commercial utilization; or (ii) bio-survey and bio-utilization for commercial utilization. The State Biodiversity Boards may prohibit or restrict any such regulated activity if it is of the opinion that such activity is detrimental to the objectives of conservation and sustainable use of biodiversity or equitable sharing of benefits arising of such activity.

C. Biodiversity Management Committees (section 41)

Biodiversity Management Committees (BMCs) are constituted at the local level for the purpose of promoting conservation, sustainable use and documentation of biodiversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms and chronicling of knowledge relating to biological diversity. The Biodiversity Management Committees are to be consulted by NBA and State Biodiversity Boards while taking any decision relating to the use of biological resources and knowledge associated with such resources occurring within the territorial jurisdiction of the Biodiversity Management Committee. The Biological Diversity Act also empowers the BMCs to levy charges by way of collection fees from any person accessing or collecting biological resources for any commercial purposes from areas falling within its territorial jurisdiction.



III. The International Treaty on Plant Genetic Resources for Food and Agriculture, 2002

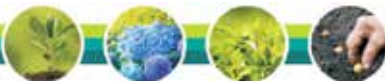
The Food and Agriculture Organisation (FAO) of the United Nations adopted the International Treaty on Plant Genetic Resources for Food and Agriculture in 2001 as a tool to address the issue of food security and loss of crop diversity in the era of climate change. The two basic underlying reasons for the formulation of this global treaty are

1. the special nature of plant genetic resources for food and agriculture characterised by human management of traits through selection and breeding and interdependence of countries over agricultural crops for food security; and
2. the need to ensure the availability of plant genetic resources for food and agriculture which constitute the raw materials for crop genetic improvement.

Multiple food crops with resistance to pests and diseases, and greater tolerance to acute climatic pressures like drought, flood, extreme temperature, salinity etc. with increase in global food production are inevitable for combating the challenges of food security. This warrants the availability of broader genetic base for the development of new varieties through research and breeding which in turn would rely on the continuing exchange of crop genetic material. With this end, the Treaty is formulated as a legally binding international agreement operating on the underlying principle of conservation and sustainable use of crop diversity which got translated into its prime objective. In order to achieve this goal, the Treaty has devised an innovative multilateral system of access and benefit sharing in respect of plant genetic resources for food and agriculture.

The Multilateral System (MLS) of Access and Benefit Sharing

The multilateral system of the Treaty is an access and benefit sharing mechanism pertaining to 64 of the most important crops of the world that account for 80% of all the human consumption. The Treaty declares these 64 crops (contained in Annex I of the Treaty), in effect, as a gene pool widely distributed across the globe and accessible to everyone for research, breeding and training in relation food and agriculture. In order to fall within the scope of the multilateral system, the genetic resources belonging to these 64 crops (Annex I resources) must be under

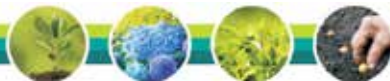


the management and control of the Contracting Parties of the Treaty and under the public domain. Annex I resources held by the ex-situ collections of the International Agricultural Research Centres (IARCs) of the Consultative Group of International Agricultural Research (CGIAR) also form part of the multilateral system. The Treaty also ushers the Contracting Parties to encourage natural and legal persons in their jurisdiction who hold the Annex I resources to include them in the MLS. The access and benefit sharing system under the MLS encompasses three different elements: (i) facilitated access by Member States; (ii) benefit sharing by the persons/entities who have obtained access to the Annex I resources; and (iii) benefit distribution to the international community of farmers. The obligations in relation to access and benefit sharing are regulated by the Standard Material Transfer Agreement (SMTA) adopted by the Treaty system, incorporating the various mandates contained in Article 10-13 of the Treaty.

i) Facilitated access by Member States (Article 12 of the Treaty r/w Article 5 & 6 of the SMTA)

Facilitation of access to Annex I crops of the Treaty to other Contracting Parties is the obligation of each member State of the Treaty. Such facilitated access must be made available to both legal and natural entities from other Contracting Parties. The facilitated access rests upon the pillars of obligations created by the SMTA for the providers and recipients of the material from the MLS. The SMTA creates the following obligations for the provider of the Annex I crops:-

- a. Access shall be expeditious, without the need to track individual accessions and free of/or with nominal charges;
- b. All available passport data and non-confidential descriptive information shall be made available with the transferred plant genetic resource;
- c. Access to an Annex I crop under development, including the material being developed by farmers, shall be at the discretion of the developer during the period of development
- d. Access to PGRFA protected by IPR and other property rights shall be consistent with relevant international agreements and national laws;
- e. Provider shall periodically inform the Governing Body of the Treaty about the material transfer agreements entered into which in turn will be made available to the FAO, which is the third party beneficiary under the Treaty.



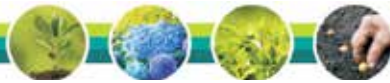
Based on the above conditions, the first transfer of the Annex I resource would be made by the providing country to the legal or natural person belonging to another Contracting Party. The above conditions would be applicable to all the subsequent providers of the accessed resource.

The recipient of the MLS material who is given facilitated access under the Treaty system is bound by the following conditions of the SMTA.

- a. The material accessed shall be used or conserved only for the purpose of research, breeding and training for food and agriculture and shall not include any chemical, pharmaceutical, and/or non-food/feed industrial uses;
- b. Recipient shall not claim any IPR or other rights limiting the scope of facilitated access to the material or its genetic parts or components, in the form received from the MLS;
- c. If the material accessed through the MLS is conserved by the recipient, such material, its passport data and other non-confidential descriptive information shall be made available to the MLS using SMTA;
- d. Transfer to subsequent recipient shall be based on the terms and conditions of the SMTA entered with the provider, through a new SMTA and the Governing Body of the Treaty shall be notified of such transfer;
- e. With respect to Annex I materials under development, transfer must be based on the terms of the SMTA, by entering into a new material transfer agreement, identifying the material received from the MLS specifying that the material under development is derived from that MLS material and notify the Governing Body of the Treaty about the transfer;
- f. A material transfer agreement for the plant genetic material under development may provide for additional conditions relating to further product development including payment of monetary consideration.

ii) Benefit Sharing Obligations on the recipient

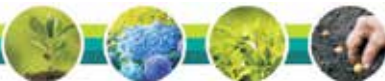
The recipient has a benefit sharing obligation towards the Treaty system wherein the benefits shared may be both monetary and/or non-monetary. The obligation to share monetary benefits is conditional to the cumulative occurring of three conditions: (a) the recipient commercialises a product that is a plant genetic resource for food and agriculture; (b) the product developed



by the recipient incorporates the material from the MLS; and (c) the product developed by the recipient is not available without restriction to others for further research and breeding. When the obligation to pay monetary benefits is triggered, the recipient is bound to pay one point one percent (1.1%) of the total sale of the product or products less thirty percent (30%) to the FAO Trust Fund established under the Treaty. If the product developed by the recipient is commercialized and available for further research and breeding without any restriction, the recipient is encouraged to make voluntary contributions to the Trust Fund. All the non-confidential information that result from research and development carried out on the MLS material shall be made available to the MLS by the recipient. The recipients are also highly encouraged to share non-monetary benefits in the form of exchange of information, access to and transfer of technology and capacity building. On the expiry of IPR over the product that incorporates material from MLS, the recipient is encouraged to place a sample of the product in the MLS for further research and breeding. On assignment of IPR over the products developed from the MLS, the benefit sharing obligations also would be transferred to such third party. As an alternative to the monetary benefit sharing obligation contemplated above, the recipient may opt for a crop based payment scheme at the rate of 0.5% of the sale of any products that are plant generic resources for food and agriculture belonging to the same crop.

iii) Benefit Distribution under the Treaty System

The Treaty provides that access for research and breeding is the greatest benefit of the system. In the MLS, distribution of benefits is not based on the reciprocity of access. The international community of farmers are the beneficiaries of the Trust Fund of the Treaty. The Funding Strategy of the Treaty establishes the operational procedures for distribution of benefits with different stages like opening a call for proposals, submission of pre-proposals, screening and response to pre-proposals, submission of proposals from approved pre-proposals, appraisal of project proposals, approval of project funding etc. The proposals are to be sent through the Member States of the Treaty. In order to be eligible for funding, the projects must meet the objectives of the IT, fall within the priority areas established from time to time by the Governing Body and benefit the Contracting Parties that are developing and least developed countries.

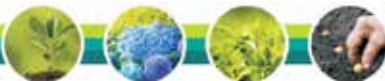


Special provisions in relation to IARCs of the CGIAR

As described earlier, the Annex I resources held in the ex-situ collections of the IARCs have been made subject to the MLS by virtue of Article 11.5 of the Treaty. However, the pre-CBD ex-situ collections of the IARCs was a point of concern at the time of adoption of the CBD as they were as collected in accordance with the FAO international Undertaking on Plant Genetic Resources for Food and Agriculture and its Global System for Conservation and Sustainable Use of Plant Genetic Resources. The CBD regulates access to genetic resources by the country of origin or country that has acquired the resources in accordance with the CBD. In furtherance to Resolution 3 of the Nairobi Final Act for Adoption of the Text of the CBD, the FAO started revising of the International Undertaking of the Plant Genetic Resources for Food and Agriculture (IUPGRFA) and tried to address the issue of ex-situ collections not covered by CBD. Article 15.1 of the Treaty reiterates this position.

Under Article 15 of the Treaty, the IARCs should enter into agreement with the Governing Body of the Treaty with respect to the ex-situ collections held by them under the following terms and conditions; (i) the PGRFA listed in Annex I of the Treaty shall be governed by the terms and conditions of the SMTA; (ii) With respect to the non-Annex I resources collected before the entry into force of the Treaty or materials assembled following SMTA will also be governed by the SMTA; and (iii) in the case of non-Annex-I resources received and conserved by the IARCs after the coming into force of the Treaty, access must be consistent with the mutually agreed terms entered into between the IARC concerned and the country of origin/ country that has acquired the resource in accordance with the Convention. In short, all the Annex-I resources and the pre-Treaty collections or the collections obtained following SMTA and currently held by IARCs would be regulated by the SMTA.

Article 15.2 of the Treaty depicts the agreement of its Contracting Parties to provide facilitated access to Annex I resources under the multilateral system to IARCs who have signed agreements with the Governing Body of the Treaty. Further, Article 15.4 of the treaty also encourages the Contracting Parties to provide such IARCs, on mutually agreed terms, PGRFA not listed in Annex I which are important to the programmes and activities of the IARCs.

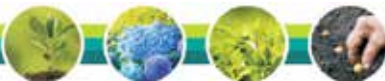


iii) Implementation of the Multilateral System of the Treaty in India

The multilateral system of the Treaty is implemented in India by way of creating an exemption under section 40 of the Biological Diversity Act, 2002. By virtue of its notification dated 17th December 2014 under section 40 of the Biological Diversity Act, 2002, the Ministry of Environment, Forests and Climate Change (MoEF&CC) declared that the Department of Agriculture and Cooperation may, from time to time, specify such crops from amongst the Annex I crops of the ITPGRFA, to be exempted from the application of section 3 and 4 of the said Act. In furtherance to this notification, the Department of Agriculture and Cooperation (hereinafter DAC) vide its office memorandum OM No.13-5/2013-SD-V dated 16th February 2015 declared that all the crops listed in Annex I are exempt from the application of sections 3 & 4 of the Biological Diversity Act for the purpose of utilization and conservation for research, breeding and training for food and agriculture. The DAC also declared that the exempted crops will be governed by the Guidelines for the Implementation of International Treaty on Plant Genetic Resources for Food and Agriculture for Facilitated Access under the Multilateral System issued by the Department vide office memorandum dated 30.07.2014.

Guidelines for the Implementation of International Treaty on Plant Genetic Resources for Food and Agriculture for Facilitated Access under the Multilateral System (MLS Guidelines)

The MLS Guidelines, as the name suggests, is specifically crafted to enable facilitated access to PGRFA in fulfilment of the obligations under the Treaty, in tune with the relevant national legislations regulating access to plant genetic resources for food and agriculture in India. The Guidelines are divided into five sections; Section I gives an introduction to the Guidelines. Section II is further divided into subsection A and B wherein Subsection A deals with General Guidelines for the national focal point and Subsection B for the Nodal Agency to process applications for the export of PGRFA. Section III talks about benefit sharing; Section IV details the maximum permissible quantity of seed/planting material for export and Section V gives the glossary of terms and acronyms.



Facilitated Access under the MLS Guidelines

The facilitated access in India is carried out through the coordinated activities of the National Focal Point and the Nodal Agency of the Treaty created in India. The competent authority established for the purpose of facilitated access under the Treaty system is the Department of Agriculture and Cooperation (DAC). DAC is also the National Focal Point of the Treaty in India. Under the MLS Guidelines, 2014, access requests are to be made only to the National Focal Point (NFP). On receipt of the request, the Germplasm Export Facilitation Committee (GEFC) will be constituted by the NFP for examining the request on a case to case basis and for submission of its recommendations to the NFP. The ex-officio members from different departments of DARE, ICAR, and NBPGR in addition to two representatives from the DAC, Ministry of Agriculture under the Chairmanship of Director, NBPGR constitute the GEFC. If approved by the NFP based on the recommendations of the committee, the National Bureau of Plant Genetic Resources (NBPGR), the Nodal Agency will coordinate the supply of the requested material. Export of germplasm will be facilitated only if an Import Permit is issued by the country to which the material is to be exported. Export under the MLS will be facilitated only to the Contracting Parties of the Treaty and any natural or legal person is entitled to apply for an import permit under the relevant national legislations. Pursuant to the approval and the formal requirement of import permit, the seed / planting material shall be exported to the requesting country under the provisions of the SMTA. The NBPGR will be the authorised signatory/ provider of the material and the SMTA has to be signed prior to the transfer only as hard copies.

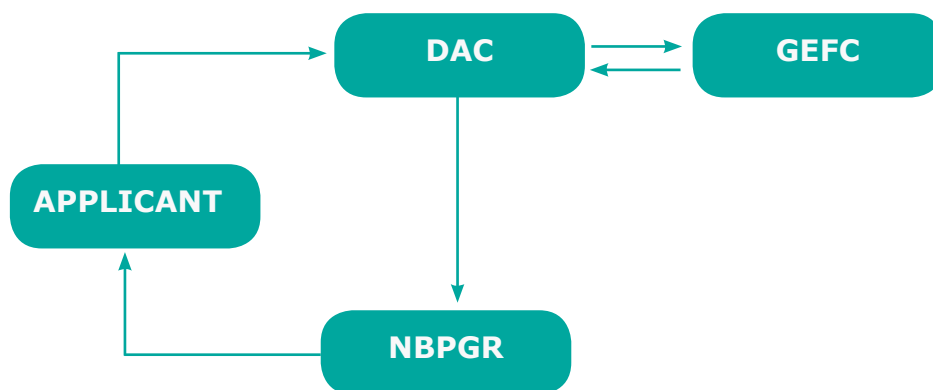
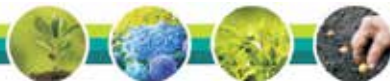


Diagram 1. Institutional Structure



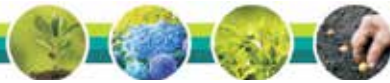
Scope and Coverage

Section II A Paragraph 3 of the Guidelines provides that the facilitated access under the Guidelines is confined to the accessions of PGRFA designated by Government of India belonging to Annex I crops only. Section II B Paragraph 1 of the Guidelines further reiterates that access shall be provided only for Annex I PGRFA notified by India under the MLS of the Treaty. In the introductory part of the Guidelines, it is specified that India has presently identified 26563 accessions belonging to 9 crops (barley, chickpea, finger millet, lentil, paddy, pearl millet, pigeon pea, sorghum and wheat) of the Annex I PGRFA for facilitated access and that further expansion of or inclusion in this list will be done as and when warranted. ***Thus, currently, the multilateral system established in India covers the specified accessions of 9 Annex I crops in the Guidelines with the possibility of further additions to the same when designated by DAC.***

The specific guidelines for the nodal agency for facilitated access as detailed in Section II-B in Paragraph (1) suggests that the nodal agency shall also provide access to germplasm of Indian origin already available with IARCs collected before 1993. In the introductory part of the Guidelines, it is made clear that PGRFA collected before 1993 and held in trust by IARCs can be accessed in accordance with the provisions of the SMTA. NBPGR is facilitating access to the Annex I and Non-Annexure 1 crops resources held by IARCs in India. There is no change with respect to the application procedure in such cases and the signing of the SMTA between the applicant and the IARC will continue ⁵.

The scope of facilitated access is limited only for the purpose of utilization and conservation for research, breeding and training for food and agriculture. The purpose of access shall not include chemical, pharmaceutical and/or other non-food/ feed/ industrial uses. Access requests for purposes other than research, breeding and training food and agriculture would be governed in accordance with other relevant national legislations on a bilateral basis, i.e. under different provisions of the Biological Diversity Act, 2002. Similarly, the facilitated access

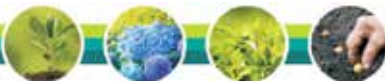
5. Information gathered through personal meetings.



under the MLS Guidelines is available only to the Contracting Parties of the Treaty and access requests from non-Members would be determined purely on a bilateral basis, based on the provisions of the Biological Diversity Act.

Benefit Sharing

The benefit sharing provisions of the Guidelines provide that benefit sharing would be as per the terms of the SMTA. The Guidelines also reiterate that access to PGRFA itself is the major benefit of the System. Benefit sharing will be in the form of exchange of information, access to and transfer of technology, capacity building and sharing of monetary benefits arising from commercial utilization. The recipients can opt for paying the fixed percentage out of the annual sale of the product or the crop based alternate payment scheme.



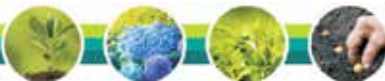
IV. Access and Benefit Sharing: Overlaps in the bilateral and multilateral frameworks

With the adoption of the MLS Guidelines in India by virtue of the notification of the MoEF&CC under section 40 of the Biological Diversity Act, the multilateral access and benefit sharing mechanism for plant genetic resources for food and agriculture exists in India as a special mechanism within the Act itself. A coherent, synergistic and mutually supportive operation of the two regimes is required to build confidence among the stakeholders of the two systems. The overlapping zones are analysed below to ascertain areas of concern in this regard.

i) Access for the purpose of research, breeding and training for food and agriculture

The facilitated access under the MLS is solely for the purpose of research, breeding and training for food and agriculture. Pharmaceutical, chemical and other non-food/ feed and/ or industrial uses are not covered by the MLS. So, if the designated Annex I resources in India are used for pharmaceutical, chemical etc. purposes, prior approval under Section 3 of the Biological Diversity Act would be required for carrying out such activities. Further, the term research is defined in the Act as “study or systematic investigation of any biological resource or technological application that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use”. The exemption facilitates one to do any kind of research for the purposes of the Treaty, including that within the meaning of section 3 of the Act. Breeding and training are not defined terms and training is not an activity covered by the Biological Diversity Act. Accessing the Annex I PGRFA for training, even without the exemption created under section 40 and the notification therein would not be covered by the Biological Diversity Act. The term breeding finds reference in the Biological Diversity Act in the definition of commercial utilization which is a regulated activity under sections 3 and 7. The definition of commercial utilization provided in section 2(f) exempts “conventional breeding” from its scope. When the notification by MoEF&CC exempts “breeding”, it would mean that the ***scope of the exemption is extended even to modern breeding with genetic manipulation also.***

The applicability of section 3 of the Biological Diversity Act is confined to specified persons/entities in section 3 (2) of the Act. The facilitated access described by the MLS Guidelines elaborates cases which requires export of the germplasm, and is silent as to how access

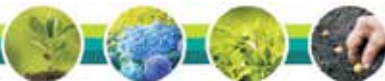


could be provided to persons/entities carrying out research, breeding or training in India. This leads to confusion on the availability of the exemption to ***individuals/entities falling within the scope of section 3 and wishing to carry out research, breeding or training on the designated accessions in India.***

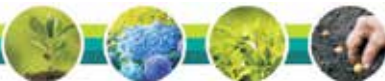
As mentioned earlier, the transfer of accessed biological resources also falls with the regulatory domain of NBA and an exempted category of biological resources from section 3 would exclude the applicability of section 20 of the Act over them. Considering the fact that the designated accessions of Annex I PGRFA is excluded from section 3, no permission needs to be taken under section 20 of the Act for subsequent transfers of the PGRFA accessed by signing SMTA with NBPGR. All subsequent transfers are to be done through signing a new SMTA by the subsequent providers and recipient. There is a need to bring a clearly defined position with respect to designated accessions of Annex I crops that will be utilized by individuals/entities falling under section 3(2) of the BD Act and intending to do research, breeding or training in India, well within the purposes specified by the Treaty which will in turn clarify the applicability of section 20 in such cases. It is expected that this would bring better synergies in implementing these two legal instruments and provide legal certainty to the stakeholders concerned.

ii) Transfer of research result: Section 4 of the Biological Diversity Act is applicable to “any person” transferring the result of research to the entities specified in section 3(2). The exemption created under the Act read with the MLS Guidelines makes transfer of research results relating to the designated accessions of Annex I crops free of regulatory restrictions. Thus, transfer of research results over designated accessions will not be covered under the BD Act or the MLS Guidelines.

The non-applicability of sections 3 and 4 of the Act are determined by a series of factors; (a) the recipient should produce an import permit from a Contracting Party of the Treaty other than India; (b) the access requested must be in relation to the designated accessions of India falling within Annex-I of the Treaty; (c) the purpose of access must be for utilization and conservation for research, breeding and training for food and agriculture. If all the factors identified above occur cumulatively, the MLS provisions would govern access. In all other circumstances, the access to designated accessions would be based on the provisions of the Biological Diversity Act.

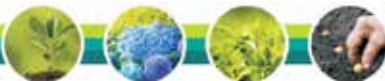


- iii) Prior approval for obtaining IPR: The regulatory jurisdiction of NBA under section 6 of the Act would prevail over designated accessions of Annex I PGRFA. Whoever proposing to obtain IPR over any invention based on research or information on a biological resource, including the designated accessions of Annex I PGRFA is required to take prior approval from NBA for the purpose. However, there is no provision in the SMTA that binds the first and subsequent recipient of the MLS materials about the legal mandate in India to take prior approval from NBA for obtaining IPR.
- iv) Collections held by private entities: The MLS Guidelines cover only the designated accessions maintained by the NBPGR. But these biological resources are widely available through other channels like private collections. Considering the fact that the availability of the specified exemption to section 3 and 4 to designated accessions would be available only when the materials are accessed through the DAC-NBPGR route, obtaining resources through any other channels will not be valid. Also considering the fact that the designation/inclusion of crops within the multilateral system is the exclusive domain of the DAC, owners of private collections are free to file applications before DAC for inclusion of their collections. Further, it is for the DAC to put in place procedures in relation to such inclusion of private collections within the MLS with defined criteria for designation. Considering that inclusion of genetic resources within the MLS deprives the country of origin from the direct benefits of access and utilization of the resources, DAC may, in its wisdom impose additional conditions such as reciprocity for facilitating access to private collections. To sum up, access other than the DAC-NBPGR route will not entitle a person to the access and benefit of exemption under sections 3 & 4 and would constitute an offence under section 55 of the Biological Diversity Act.
- v) Applicability of MLS Guidelines upon Indian citizens and Indian entities without any non-Indian participation: There is no specific provision in the Guidelines dealing with the use of the designated accessions by Indians and Indian entities falling within the purview of section 3 as well as section 7 of the Biological Diversity Act proposing to carry out research/breeding/training in India. Section 7 of the Biological Diversity Act provides that citizens of India and entities which are registered in India shall intimate the State Biodiversity Board concerned, before obtaining any biological resources for commercial utilization or bio-survey and bio-utilization for commercial utilization. Thus, the applicability of section 7



remains unchanged for the persons and entities covered under the said provision when there is commercial utilization of the designated crops belonging to Annex I. Permission for such commercial utilization of the resources is subject to the obligation to share the benefit with the concerned State Biodiversity Boards. However, such benefit sharing obligation may create an unrest among stakeholders especially in light of the fact that their counterparts carrying out research, breeding training and commercialization outside India do not have benefit sharing obligation. It is to be noted that SBBs determine the scope of access and benefit sharing obligations on their own for the biological resources obtained from within their territorial jurisdiction. If DAC can take proactive steps to include all persons/entities falling within the scope of sections 3(2) and 7 of the BD Act to be regulated by the MLS Guidelines, NBA may strive to achieve better synergies by directing the State Biodiversity Boards, in exercise of powers conferred under Rule 12 (xiv) of the Biological Diversity Rules, 2004 to exempt the Indians and Indian entities doing commercial utilization of designated Annex I resources from the ABS obligations under section 7.

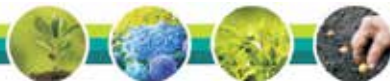
- vi) Benefit sharing obligations under the MLS vis-à-vis the Biological Diversity Act: The benefit sharing obligations under the multilateral system will be triggered on the cumulative happening of the triple requirements under the ITPGRFA, i.e. (i) commercialization of a product that is a PGRFA (ii) incorporating material received from the MLS and (iii) and such product is not available without restriction for further research, breeding and training. The benefit sharing obligations under section 3 and 4 of the Biological Diversity Act is not applicable to designated accessions under the MLS system in India. However, the designated accessions are not exempted from the benefit sharing obligations under section 6 of the Act. Section 6 (1) of the Act mandates approval from NBA for seeking IPR based on any research or information on a biological resource obtained from India and imposes the obligation to share benefits arising from the commercial utilization or transfer of the IPRs obtained. In effect, if any type of IPR has to be obtained based on any research or information on the MLS PGRFA obtained from India, the permission of NBA is mandatory. Subsection (4) of section 6 exempts the application of section 6 (1) when rights are granted in India under the Protection of Plant Varieties and Farmers Rights Act (PPVFRA), 2000. Permission of NBA is not required for obtaining any rights under the PPVFRA. But if one wants to obtain patent in any jurisdiction including India or



breeder's rights in any country other than India, permission of NBA is a pre-requisite for such applications. Both under the ITPGRFA and SMTA, the recipient of the MLS material is bound by the condition that he shall not obtain any IPR over the material in the form received the MLS or their genetic parts or components limiting the facilitated access to the material. IPRs being the prominent tool generating maximum benefits to its holder, it could not be expected that the Treaty system would ever intend to create total restriction on IPR generation from facilitated access. Generation of IPR over the MLS material may create an access restriction and there can be commercialization of IPR too, but if the end product is not a PGRFA, the recipient has no obligation to share the benefits to the Trust Fund of the Treaty. For example, isolation of a gene sequence having a particular genetic trait may qualify for patent protection in some jurisdiction, but will not qualify for benefit sharing obligation under the Treaty as well as the Guidelines. Similarly, the end product may be sold with genetic use restriction technologies or contractual clauses creating access restriction without benefit sharing obligation. So, creation of an invention other than a PGRFA and taking IPR and commercialising the same would not trigger the benefit sharing obligation. The applicability of section 6 in facilitated access stands as a check to ensure that the recipient is not claiming any IPR over the MLS material and if any such rights are claimed, the resulting benefits are shared with the National Biodiversity Authority. However, there is no provision in the SMTA or the Guidelines reminding the recipient of his benefit sharing obligations under section 6 of the Biological Diversity Act.

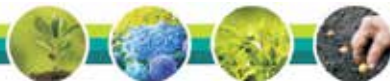
V. Recommendations for Better Synergies

- Exemption from applicability of section 3 and 4 of the BD Act for designated Annex I resources should not be confined to those who are doing research outside India. The MLS Guidelines must incorporate the procedure for access to designated accessions by persons/entities under section 3(2) proposing to do research, breeding or training in India for food agriculture.
- If the exemption of designated accessions could be made available to all the entities covered by section 3(2), NBA may direct the State Biodiversity Boards to exempt Indian



citizens and Indian entities (without foreign participation in share capital or management) from the ABS obligation under section 7 for commercial utilization or bio-survey and bio-utilization for commercial utilization of designated Annex I resources for the purposes of food and agriculture. Such exemption shall not cover benefit sharing obligations arising in respect of other purposes such as chemical, pharmaceutical and other non food/feed industrial uses.

- DAC may incorporate appropriate elaborations or additional conditions as appropriate and wherever possible, in the standard material transfer agreement, with respect to section 6 of the Biological Diversity Act that the recipient of the material seeking to obtain IPR over the designated material accessed from NBPGR to obtain prior approval from NBA.
- DAC may lay down appropriate criteria and procedure to include private collections in the MLS.
- Statement of caution may be uploaded in the websites of NBA and DAC that access to designated Annex I crops other than through the DAC-NBPGR route would be illegal, amounting to an offence under section 55 of the Biological Diversity Act.



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About CEBPOL

Government of India in collaboration with the Norwegian Government has established "Centre for Biodiversity Policy and Law (CEBPOL)" at the National Biodiversity Authority (NBA), an autonomous and statutory body of the Ministry of Environment Forest and Climate Change towards strengthening of expertise in Biodiversity Policy and Law in India. This programme is executed by the NBA in collaboration with Norwegian Environment Agency through the Royal Norwegian Embassy, New Delhi, India.

The Centre aims to provide advice and support to the Government of India and Norway on Biodiversity Policy and Law related issues including complex negotiations on Access and Benefit Sharing and Traditional knowledge as well as governance issues relating to biodiversity at the National and International level. The Centre proposes to help NBA in the effective implementation of International agreements on conservation, sustainable use and the associated access and benefit sharing components of it.

CEBPOL is set up as a specialized Centre of Excellence in Biodiversity Policy and Law to network, organize and consolidate expertise on issues of Biodiversity Policy and Law in India and Norway. The Centre, located at NBA, would function as an independent think tank on Biodiversity Policy and Law. In addition, CEBPOL aims to contribute to the effective implementation of the Biological Diversity Act 2002 and Rules 2004.

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