

**WORKSHOP
PROCEEDINGS**

*Brainstorming Session on Harmonisation of Seed
Movement, Regulations and Procedures*

September 22nd 2016

Chennai



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Key Words

- **CABI**- Centre for Agriculture and Bioscience International
- **ABLE AG**- Association of Biotechnology Led Enterprises- Agriculture Focus Group
- **NBA**- National Biodiversity Authority
- **ITPGRFA**- International Treaty on Plant Genetic Resources for Food and Agriculture
- **ABS**- Access and Benefit Sharing
- **NTC**- Notification on Normally Traded as Commodities
- **EU**-European Union
- **MLS**- Multilateral System
- **PGRFA**- Plant Genetic Resources for Food and Agriculture
- **PPV&FRA**- Protection of Plant Varieties &Farmers' Rights Authority
- **CBD**- Cannabidiol
- **ICAR**- Indian Council of Agricultural Research
- **SAUs**– State Agriculture Universities
- **CGIAR**-Consultative Group for International Agricultural Research
- **MoAFW**-Ministry of Agriculture & Farmers Welfare

Summary

Centre for Agriculture and Bioscience International (CABI) in collaboration with **Association of Biotechnology Led Enterprises- Agriculture Focus Group (ABLE AG)** and **CropLife Asia** organized a brainstorming session on the Harmonization of Seed Movement, Regulations and Procedures on September 22nd, 2016 in Chennai. The **National Biodiversity Authority (NBA)** kindly agreed to hold the workshop at their premises. The workshop was attended by top NBA officials- NBA Chairperson Dr B. Meenakumari, Mr T. RabiKumar and Dr K.P. Raghuram among others. Other participants included seed industry representatives, government officials from Ministry of Agriculture and several NGOs.

The workshop provided a brief background of the earlier workshops held in 2014 and 2015. The main objective of the workshop was to highlight key issues faced by the industry such as clarification of rights provided to breeders section 40 of the Biological Diversity Act “BDA” where biological resources are normally traded as commodities and notification on 7th April, 385 species, and access and use of microbes to develop innovative solutions for farmers; exemption from BDA and transfer of research under **International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)**.

Dr Meenakumari highlighted the role of public and private sector in seed production and movement. She emphasized on the key responsibilities of NBA and welcomed suggestions of industry. The workshop further deliberated on the issues of access and use of pests, microbes and weeds to develop innovative solutions, applicability of the PPV&FR Act, 2001 seed movement and BDA, clarity required on Section 40 with NTC exemption, challenges with the **Access and Benefit Sharing (ABS)** system among other topics. The panel discussion finally deliberated on the key area and way forward was suggested, which has been tabulated in the proceedings. Further discussions will be held on the suggested areas as follow up meetings either directly with the industry or workshops.

Proceedings of the Brainstorming Session on Harmonisation of Seed Movement, Regulations and Procedures

Opening Remarks

Dr KavyaDashora, Centre for Agriculture and Bioscience International (CABI) welcomed the **National Biodiversity Authority (NBA)** team and all the participants. A brief background of the earlier workshops held in 2014 and 2015 was given by her and she highlighted the key points discussed and the road travelled in two years. In the previous workshops, the need of information sharing and active participation of all stakeholders was identified as a crucial step to move ahead, a single window clearance has been suggested by Directorate of Plant Protection, Quarantine & Storage (DPPQS) for all matters. The main agenda for this session is to seek clarity on export exemptions, non-Indian entity under Companies Act and seek views on use and access of biological resources for alternative and innovative uses, she added.

Dr Ravi Khetarpal (CABI) welcomed the delegates and thanked NBA for their participation as well as their cooperation in organising the session at NBA. He emphasized the key expectation of building relation between NBA and the non-public sector for conservation of biological resources, seed/germplasm movement and other issues and particularly access and benefit sharing. He highlighted four key issues on which the opinions of NBA need to be sought- clarification of rights provided to breeders section 40 of the Biological Diversity Act “BDA” where biological resources are normally traded as commodities and notification 7th April, 385 species, and access and use of microbes to develop innovative solutions for farmers; exemption from BDA and transfer of research under **International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)**.

Technical Session 1: Access and Use of Biological Resources

Session Chair: Dr B. Meenakumari/ Dr Ravi Khetarpal

1. Introduction to Biological Diversity Act, 2002 and Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014

Dr B. Meenakumari, Chairperson, NBA, in her opening remarks, welcomed the suggestions of seed sector companies. The policy initiatives in the seed sector and the role of public and private sector in seed production and movement were highlighted. She stressed on importance of sustainable agriculture and briefed about the Convention on Biological Diversity, its mandate and salient features of the Biological Diversity Act and role of the NBA in regulating the biological resources. The objective of BDA is to provide for conservation, sustainable use of its components and sharing of benefits arising out of the use of biological resources and/or traditional knowledge and it regulates access to biological resources and associated knowledge used for research, or commercial utilization or bio-survey and bio-utilization; transfer of results of research applying for intellectual property rights in or outside India; and transfer of accessed material to third parties. She also highlighted the various provisions of the BDA viz. Section 59 focussing on conservation, Section 3 and 19 related to access to biological access for commercial utilisation, Notification on Normally Traded as Commodities (NTC) under Section 40 and the guidelines on access to biological resources and associated knowledge and benefits sharing regulations, 2014. The concept of Access and Benefit Sharing (ABS) which refers to the way in which germplasm resources are accessed, and benefits resulting from their use shared between users and providers were explained. Five different categories of ABS agreements were explained and she emphasized that out of 814 applications cleared by NBA, so far 259 agreements have been executed; and similarly the State Biodiversity Boards are also initiating ABS agreements with section 7 Persons on the applications submitted by them in their respective states. The main challenges involved are inadequate awareness among stakeholders, trust among stakeholders and receipt of incomplete applications.

Mr T. Rabikumar, Secretary, NBA discussed the operational issues related to the BDA and importance of benefit sharing. He explained that decisions are being taken by a Governing Body of NBA consisting of experts spanning across different organizations and, thus, NBA is not the sole decision making authority. He also added that the list of 385 species included in the NTC notification dated 7th April, 2016 is dynamic and open to addition/deletion of

species, if situation warrants. With regard to exemption of pests and microbes, he informed that pests and microbes per se fall under the definition of the biological resources as per section 2(c) of the BDA and there is no explicit exemption provided in the BDA. He also expressed that issues, if any, on this aspect, proposals may be submitted to the NBA within the scope of legal framework for consideration.

2. Crop protection and Food security – Views on access and use of pests, microbes and weeds to develop innovative solutions

Dr Shivendra Bajaj gave presentation on use of insects, pests, pathogens, microbes and weeds as testing tools to develop innovative solutions in agriculture. These organisms are used as testing candidate for new products/varieties by natural infestation or artificial infestation in a field or tests in a controlled environment and not integrated or embedded in such new products/varieties in any manner, either in parts or as a whole. They are also used as monitoring and diagnostic tools for pests and diseases. The use of these organisms as screening tools does not pose any threat to the biological diversity existing in the area nor does it involve developing them into commercial products. The purpose of use is to contribute to a study and suggest a way forward to research community.

He referred to EU ABS Regulation (Regulation (EU) No 511/2014) as guidance document on the scope and application of insects, pests, pathogens, microbes and weeds as testing tools. As per the EU ABS regulations, the genetic resources as testing/reference tools are not the research objects but only serve to confirm or verify the desired features of other products developed or under development. Certain upstream activities like maintenance and management of a collection for conservation purposes, including storage of resources or quality/phyto-pathology checks, and verification of material upon acceptance carried out in support of research should not as such be considered 'utilisation' in the meaning of the regulation. Also the mere description of a genetic resource in phenotype-based research such as morphological analysis normally would also not amount to utilisation.

With the reference to EU ABS guidelines Dr Bajaj raised important point at the forum requesting for its consideration. The access and use of insects, microbes, pathogens and weeds that are agricultural pests from different locations throughout India for use as testing tools in the development of new plant varieties and evaluation of crop protection molecules (for insecticides, fungicides and herbicides) should be exempted from the purview of BDA as the insects, pests, pathogens and weeds will not themselves be used as commercial products.

Dr. MalathiLakshmikumaran cited an example that aphids released on mustard plant are just a testing tool to test whether mustard variety is resistant or susceptible to aphids. In any case, the mustard variety will be commercialized and not the aphids.

Dr. Prasad also echoed that the access of pests and microbes etc. are just a tool and not adding anything to the plant. Infact, it increases the workload of NBA, he added.

3. Implementation of ITPGRFA – Facilitated access and sustainable use of Annex 1 crops under MLS and benefit sharing obligations under the Plant Treaty

Ms Thelma Soriano gave the presentation on International Treaty on Plant Genetic Resource for Food and Agriculture (ITPGRFA) focussing on its genesis and concept. She highlighted that the treaty is focused solely on Plant Genetic Resources for Food and Agriculture (PGRFA). Many of the cultivated crops could not have survived in the wild without human intervention. The treaty was drafted in recognition of the special nature of the PGRFA. PGRFA are different from medicinal plants found in the rain forests and the value in agricultural genetic resources lies in diversity within a crop rather than at the species level. The importance of PGRFA in attaining and maintaining food security was highlighted as they are the building blocks of plant breeding. The traits in plants are modified by the farmers for producing better plant varieties. The main provisions of the treaty involve sustainability, farmers's rights, access and benefit sharing, and its multilateral system. Countries are interdependent on each other for PGRFA as most countries depend for their food and agriculture on crops that originated elsewhere. The contracting parties to the PGRFA are required to promote an integrated approach and develop and maintain appropriate policy and legal measures. The various initiatives to encourage sustainable use include promotion of diverse farming systems, strengthening of research that enhances biological diversity, promotion of participatory plant-breeding efforts to develop locally adapted varieties, broadening the genetic base of crops, promoting the use of local and locally adapted crops, adjusting breeding strategies and seed regulations as necessary. The treaty has also provision on farmers' rights including the protection of traditional knowledge and the right to participate equitably in benefit-sharing and in national decision making about plant genetic resources.

She elaborated the multilateral system that applies to Plant Genetic Resource for Food and Agriculture (PGRFA) of crops listed in Annex 1 of the treaty. The list of crops is based on importance for food security and interdependence. The multilateral systems likewise apply to

the rules regarding facilitated access and rules regarding benefit sharing. The multilateral system of the treaty, PGRFA are pooled for research, training, and breeding of member Parties under a Standard Material Transfer Agreement as these genetic resources are pooled, there is no individual owner with whom individual contracts for access and benefit-sharing must be negotiated. Access is also a major benefit of the multilateral system. ITPGRFA facilitates access to the genetic materials of the 64 crops for research, breeding and training for food and agriculture, however, most fruits and many vegetables such as banana, tomato, and onion, have yet to be included in the list.

She mentioned that a country's existing access and benefit sharing legislation implemented to comply with the CBD might make it difficult for it to implement the multilateral system. However, many Parties implement the Treaty and its Multilateral System through administrative measures without the need for new legislation while in some cases new legislation might be required. She encouraged the non-member states to accept the treaty to achieve worldwide multilateral system of access and benefit sharing PGRFA.

Mr Satyakam Dundigalla raised important questions related to implementation on ITPGRFA related to facilitated access to Annex 1 crops under Multilateral System (MLS) and Sustainable use of Annex 1 crops. With a view to achieving the fullest possible coverage of the MLS, the contracting parties invite all other holders of the plant genetic resources for food and agriculture listed in Annex I to include plant genetic resources for food and agriculture in the MLS. However, there needs to be clarity on the mechanism for inclusion and the timeline contracting parties also agree to take appropriate measures to encourage natural and legal persons within their jurisdiction who hold plant genetic resources for food and agriculture listed in Annex I to include such plant genetic resources for food and agriculture in the MLS. However, appropriate measures are not stated. As per rules, within two years of the entry into force of the treaty, the governing body had to assess the progress in including the plant genetic resources for food and agriculture referred to in paragraph 11.3 in the MLS following which the decision on continuation of the access was to be taken. ITPGR has become effective from 2007 and the two year period has lapsed and there is lack of clarity on the revised timeline. He also raised questions on access norms to legal and natural persons who do not include their PGR in MLS.

Technical Session 2: Seed Movement Regulations and Harmonization

Session Chair: Dr MalathiLakshikumaran/ Dr N.K. Dadlani

1. Seed movement – Applicability of the PPV&FR Act, 2001 and Biological Diversity Act, 2002 and related notification /guidelines/regulations

Dr Sangeeta Mendiratta talked about Seed Movement & BDA Regulations. She raised few concerns from the new notification on NTC exemption. The new notification on NTC exemption under Sec 40 of BDA, 2002, appears to regulate seed trading as commodity for exemption in selected crops while under the Seed Control Order, 1983, seed is considered as essential commodity. The new Gazette notification on NTC proposes to take out a number of crop seeds from the exemption list which is in contrast to Notification 30th October, 2009 under Sec 40 of BDA, 2002. The new notification would also adversely affect the measures taken by central government to promote export of seeds and planting material under the Export and Import (EXIM) Policy. The other concerns are that once the listed biological resources are exempted from BDA, there should not be any action against failure of submitting copy of self-declaration form. The restrictions imposed by BDA on the free exchange of specimens adversely impacts taxonomic and biodiversity research in India. There is need to liberalize the regulation to promote uninhibited exchange of specimens for taxonomic research.

She raised points to seek clarity on registered breeder's and researcher's rights as Protection of Plant Varieties & Farmers' Rights Authority (PPV&FRA) and BDA pose contradictions. Under BDA, prior approvals are mandatory for accessing any biological resources for Research / Commercial utilization (Sec 3) which is a contradiction under researcher's rights.

Mr Surya Rao started his presentation with an introduction to CBD, Nagoya Protocol, ITPGFRA and the Biodiversity Act, 2002. He emphasized that the public and private seed industry are fully aligned to the core principles of the Act/Treaty which includes conservation, sustainable use and fair & equitable benefit sharing, He stated that creation of new gene pools does not destroy any Biological Resources and is important for sustainable use of agro biodiversity.

He stated a few points for alignment related to seeds. Section 6(3)(4) under BDA, 2002 has contradictions with researcher's and farmer's rights under PPVFRA. Section 40 with NTC exemption does not provide clarity on approvals for export of commercial (indigenous) products. For the Access of Annexure-I crop species for research, breeding and training for food and agriculture who will be the approving authority for material presently not covered under accessions list and the process of access for conventional breeding purpose.

Mr. Gunasekharan clarified that joint secretary Seeds is the nodal contact for the same and the list of accessions has to be uploaded by NBPGR.

Mr. Surya further stated few points for alignment related to seeds: Breeding activities conducted by seed companies such as trialling, line/hybrid development, trait introgression (except transgenic) are considered "conventional breeding¹", a conclusion supported by Prof. Swapan Kumar Datta, Deputy Director General (Crop Science), ICAR to NBA on vide letter no. F.No. CS/4/20/2013/Seed, dated 29th April and seed production is considered as "Traditional Practice" in agriculture. For the Access of Annexure-I crop species for research, breeding and training for food and agriculture who will be the approving authority for material presently not covered under accessions list and the process of access for conventional breeding purpose.

He mentioned that exotic planting materials are out of NBA scope and can be exportable as long as they are not crossed with any indigenous material. However, there needs to be clarity on purview of NBA on exotic as well as indigenous seeds or planting material. There were also questions related to access of material from ICAR / SAUs / CGIAR / Govt. institutes for breeding/trialling purpose under MTA, open Field for breeding/trailing purpose, Commercial products from Market (with receipt) for breeding, conducting trials under SAU's / MLTs/Hot spot areas access of biological resources for conventional breeding. Similar concerns on NBA/MoAFW purview for transfer of biological resources related to transfer of biological resources for conventional breeding, lyophilized leaf samples, commercial products purchased from market (with receipt) for Research/trialling breeding, non-transgenic / conventional hybrids / varieties for conducting trials (SAU's/MLT's) in other and if the export of Commercial (Indigenous) products requires any approvals.

¹ Section 2 (f)

Dr Shashank Mauri talked about the multidisciplinary research and shared his experiences on seed research particularly the Seed Bill. He talked about the applicability of PPVFRA and focussed how it gives livelihood opportunities and access rights.

2. Access and fair and equitable sharing of benefits under the ABS Guidelines – Discussion on best practices

Dr Ravi Khetarpal presented CABI's Access and Benefit Sharing policy and practice for compliant use of biological material. The focus of CABI's policy is due diligence regarding access and benefit sharing and put in place best practices to comply with national legislation. New Brazilian ABS regulation: Biodiversity Law (Law 13.123) was taken as an example of simplified systems of access. CABI intends to negotiate open access under a standard Mutually Agreed Terms (MAT). He envisioned negotiating a model testing agreement or MoU to collect and use genetic resources that reduces the administration on both sides in negotiating for each separate collecting trip and also respects the best practice requirements on reporting on materials collected and the use they are being put to on a regular basis.

Ms Sanjit Batra presented the contradictions in India's ABS system. The commercial utilization, as defined in section 2(f) the Act, explicitly excludes conventional breeding or traditional practices. The definition and scope of the term "occurring in India" used in Section 3(1) remains ambiguous. As per OM dated Feb 2015, all crops listed in the Annex I of ITPGRFA are to be exempted from S. 3 & 4 of the BD Act for the purpose of utilization and conservation for research, breeding and training for food and agriculture, commercially traded seeds should to be a part of NTC list, the access permissions should not be required when there is no commercial purpose involved. The best practices suggested by her includes the retrospective nature of the Act, guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 were notified on Nov. 21, 2014 and the notification states that they will be applicable from the date of notification in the official gazette so they cannot be made effective retrospectively. She proposed that the main determinant for benefit-sharing should thus be the use and the value addition of the resource, rather than the resource itself. She concluded that continued dialogue and information exchange between users and providers of genetic and biological resources is vital and the process for granting access should be transparent, minimally bureaucratic, and should promote communication and collaboration.

Dr.Malathi raised a valid question to the august group that access and benefit sharing guidelines came into effect from November, 2014, so how it can be applicable for the access done in the past.

In response, Mr. Rabikumar clarified that guidelines don't have any retrospective effect and have come into effect from the date of notification only

Panel Discussion

Session Chair: Dr B. Meenakumari / Dr Rajvir S Rathi

Participants in the Panel discussion:

- Mr T. Rabikumar, NBA
- Dr K P Raghuram, NBA
- Mr M. Gunasekaran, MoA&FW
- Dr Shashank Mauria, ICAR
- Dr R D Prasad, IIOR
- Dr N K Dadlani, APSA
- Dr Raju Kapoor, Dow Agro Sciences
- Dr MalathiLakshmikumaran, Laksmikumaran and Shridharan

Dr.RajvirRathi highlighted that the panel discussionwill have three broad areas of discussion includingITPGRFA& MLS system, Access and benefit sharing guidelines with focus on access of biological resources and the mechanism of implementation especially where access have been made in the past or commercial utilization has taken place & way forward. The industry is prepared to abide by benefit sharing guidelines of BDA, however, there are points that need to be clarified, he added. The industry concerns were addressed by the NBA officials.

The key points of discussion and the action plan are tabulated below:

Industry Concern	Response	Remarks	Way forward (Action plan)
NBA as Stakeholder			
Implementation and applicability of NBA guideline	Secretary NBA pointed out that germplasm is in possession of the companies and if being used for research today needs approval from NBA.	It was debated by the industry legal experts that the act can't be retrospective i.e. germplasm in acquisition of accompanies prior to notification of NBA guidelines in July 2004 cannot be governed by the BD Act.	Representation to be made at MoEFCC level
Exemption for use of microbes, insects and pests as testing tools for research	NBA informed that the said bio-resources will fall within the definition of the biological resources u/s 2(c). Hence, if these resources are accessed for the purposes envisaged in the BD Act, the person/entity will have to seek approval of the NBA as no exemption is provided in the Act.	The microbes useful for soil management should be exempted.	To be followed up both at NBA and MoAFW. NBA will not take suo moto action based on this meeting unless it is addressed through proper channel.
Conventional breeding	Definition of conventional breeding needs to be clarified through MoAFW, MoAFW had notified it previously. NBA informed that the definition of conventional breeding is to be interpreted by plain reading of the text within ambit of the BD Act.	As NBA being a regulatory Authority with a mandate to implement the BD Act, it may not agree to the views of the different Ministries if the views are not in line with BDA.	In view of the NBA's stand mentioned at previous column, this may not be required.
	Conventional breeding is exempted under "commercial utilization" but not under research and thus companies doing conventional breeding for research are not exempted.	There was a debate but there was no final reply from NBA.	To be clarified from MoAFW.
PPVFR to the breeders	It was a common opinion that export exemption of	Due to non-availability of PPVFR experts	To be followed up at PPVFR.

on import	protected varieties should be accepted by NBA	it would be taken up separately.	
Representation of industry in NBA meetings	It was informed that industry associations like CII and FICCI are represented in the NBA meetings.	The matter of more representation will be considered whenever occasion demands.	Updates from NBA needed.
Streamlining the application process	NBA informed that if the application is complete in all aspects, such applications are being processed and approval granted to the applicant by the NBA. Detailed guidelines for filling up of applications, documents that are required to be enclosed are hosted in the NBA's website. NBA has released beta version of e-filling of ABS application which will enable the applicants to apply at their convenience, correct mistakes, review the filled up form, check whether the form is correct and complete in all respects before submitting.	Nil	Nil
NBA and MoAFW as Stakeholders			
NTC notification	Seeds under Essential Commodity's Act should be part of the gazette notification under section 40, after detailed deliberations and views from NBA and MoAFW representatives, the subject concluded to be represented to JS seeds.	Mr. Gunasekaran informed that JS (Seeds) has already written in this regards to NBA.	Representation to be made to JS seeds, MoAFW.
	NTC notification exemption under Section 40: According to NBA the exemption is only to facilitate Trade but is not an exemption for research, bio-survey and bio-utilization or commercial utilization. Considering that as a large number of biological resources are being traded as commodities across the country in order to meet the daily needs of the people, it may not be appropriate to bring such items under the ABS regime and thus, such items are exempted from	Nil	

	<p>the provisions of the BD Act under section 40.</p> <p>However, if any of these items is intended to be used for any other purpose, the relevant provisions of the BD Act will apply as per the notification dated 7th April 2016.</p>		
MoAFW as Stakeholder			
ITPGRFA notification on exemption for access of Treaty crops	NBA informed that this is under MoAFW domain only and if MoAFW notifies more crops/accessions for inclusion they would be liable to accept the same. The process for inclusion of new accessions in MLS is by application to JS seeds (DAC) first.	MoAFW invites people to discuss the species included in the exemption list with JS seeds as nodal officer.	To be followed up at MoAFW
Status of germplasm under CG system	If the researcher is willing to provide accession number to NBPGR and share the material with other MLS, MoAFW can be bypassed.	The germplasm resting with CG centre should be brought under MLS because it is brought from different places.	To be followed up at MoAFW

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