Biodiversity Protection, Farmers and Breeders Right

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Lecture 11 : Biobanks – Governance issues

Welcome to the lecture 11 on Biobank and Governance Issues. In this lecture, we will take up the following concepts. Definition of a biobank and a biorepository, biological resource centers, the growth from individual to network centers, use and access terms, the relevance of access and benefit sharing and key issues in the governance. These are the keywords for the lecture. Before we understand the definitional aspects of biobanks, let us recall the conservation strategies which we discussed in the earlier week. Behind domesticated or cultivated species, when we look at this, we are looking at the context of where in-situ conservation is there at one end, naturally the habitat has the resource to take care of the conservation in nature.

And the other way of conservation which is ex-situ conservation, where we have collections in the form of botanical gardens, gene banks, seed banks and culture collections. Due to changes in habitat and environment, there is a mass destruction of several species and hence today ex-situ conservation has also taken center stage to provide collections for future purposes. Therefore, when we look at the collections that are available today, we look at conservation strategies which have grown over the period of time from individual germplasm centers to network germplasm centers. Today, these form a very important source of genetic material, biological material for use.

With this, let us understand what are bioresource centers. The bioresource centers basically are resource centers that are relevant for conservation activities to promote the research and development. Most centers today also provide data support in terms of data handling tools and databases related to the information on the collections. There are sources depending on the type of the germplasm which could have cultural organisms or the replicable parts. So, today the germplasm centers are not just only collection centers, they are also involved in extended activities of validation, conducting studies and also helping in the distribution of the collections.

Let us understand the definition of a biobank. In this case, we are looking at the definition of a biodiversity biobank. It is important to note that the guidance for the global genome biodiversity network was developed which spells out the different aspects of biological material collection, the steps of storage, processing and access. A biodiversity bank is a facility for collection, preservation, storage and supply of typically non-human biological samples and associated data which follows the standard operating

procedures and provides material for scientific use. A biorepository is a more of a general term in terms of looking at biological material.

As the extended activities are today there with respect to many biobanks, the relevance of biobank governance has become important to look at how the various activities can be regulated and the manner in which the collections can be utilized. As we understand there are several conservation challenges when we come to the context of plant genetic resources. At this point, I would like to mention that biobanks are of various the nature and scope is varied. As the course deals with the aspects of biodiversity protection and the context of plant genetic resources and farmer rights, we restrict the discussion to plant genetic resources. In terms of looking at developing biorepositories for plant material, the relevance of understanding the resource is important.

What is the regeneration ability for any particular type of germplasm? There are also risks involved and then there are also budgetary expenses which are necessary to look at in the context of plant genetic resources conservation. Increasing germplasm from several centers can also be a great limitation in terms of time span and in also in terms of the resource type. What you see in this illustration is the relevance of plant genetic resources for food and agriculture and how the multilateral system for access and benefit sharing operates. The three aspects of special features key role and the multilateral system is important to understand from the point of view of how the collections are derived, accessing of the germplasm, how to make the process more efficient in terms of reducing the time and exchange costs. The development of standards in relation to access and the use terms and ensuring that the multilateral system takes into consideration the need to increase and diversify food production.

This provides the emphasis on the fact that there is a key role when it comes to facilitated access of plant genetic resources for food and agriculture to ensure food security, to protect from pests and diseases and to build resilience to climate change. When we deal with the context of access to bio resources, we need to understand the relevance of the standard material transfer agreement, where we look at the context of how materials biomaterials can be utilized for research and development, where non-commercial purposes can be identified and where there are commercial purposes what are the rights and obligations of the recipient. So, article 6 of the clearly identifies the rights and obligations of the recipient, where generally the requirements in relation to use basically for conservation purposes of an have been identified and in such a case no claim to intellectual property would be there. Subsequent transfer of the genetic material will be subject to the standard material transfer agreement terms. Now, the recipient may choose to commercialize the product in which case there are fixed percentage of sales of commercial commercialized product, the mechanism is identified under the agreement.

In other cases where there are no restrictions to the use of a commercialized product, voluntary payment mechanism is possible. Wherever intellectual property rights are relevant, the need to transfer the benefit sharing obligations to third party have been clearly identified. So, understanding the terms of the material transfer agreement become relevant, internationally there are standard templates available. And today as we see the elaboration of the material transfer agreements to include many more aspects as we go forward, we will discuss that with some examples. For instance if you are looking at the millennium seed bank and understanding the access terms, for small seed samples of about 60 seeds or less, they are free of charge for non-commercial purposes.

And typically only an organization or an institute can actually make a request, the access to millennium seed bank is not available for any individual. There is a need to sign the material supply agreement after the approval for access is provided. There are also requirements for compliance that users must meet in terms of preventing the spread of invasive plant and plant pests and pathogens. Where applicable the need for a phytosaracteries standard has also been included. In countries which have not do not have a specific phytosaracteries requirement, there are options available for access even for such countries under the millennium seed bank access terms.

Another example is the CGIAR gene platform. As you can see in this illustration, the number of samples runs into several lakhs and the countries which are participating into this are also a big number. So, how does this gene platform function? As you can see in this illustration, the governance structure of the gene bank is given. There are several levels at which the process of the network, joining the network, the process of establishing standards, identifying what are called gene bank managers and how do they take forward the activities, these are clearly given in this particular illustration. So, there are several policies also which are identified time to time in order to take forward the activities.

So, here in the case of the CGIAR gene platform, the accessions are available on crops and trees under the international treaty for plant genetic resources for food and agriculture. Let us look at what are the participating banks. As you can see, this is an activity which is a network activity with contributions from all these several organizations dealing with different germplasm collections. In the year 2022, the CGIAR framework agreement was developed with a total of 12 organizations and any new center can join this framework after the compliance is met in relation to the framework and how these organizations interact in the entire CGIAR system is itself spelt out in the framework agreement. To that extent, it not only supports the material, but it also supports a lot of information.

So, the platform for big data in agriculture and responsible data management takes into consideration two different types of approaches. One is the open access for data where the researcher can utilize it for development and such data that is developed needs to be available on fair basis which means the data should be findable, accessible, interoperable and reusable. Not all data is available in the open form, certain data is in a restricted access mode wherever there are considerations of ethical aspects, confidentiality, privacy, wherever the data is covered by IP or proprietary rights, public interest and security concerns are also there which can also relevantly flag the data into a restricted access. Wherever there is ABS involved with respect to the access of biomaterial, then again there is restricted access subject to ABS is only when you can find the biomaterial access. So, as we see there are several organizations working in a network mode and the interaction brings in a complex set of processes which require not only the understanding of the nature and scope of the germplasm which is residing in the network mode, but how each individual organization interacts with the other in terms of providing the collection and another in terms of accessing the collection.

So, whenever we look at the context of the large germplasm centers as well as network centers, we identify certain key issues in the development of such biobanks. Material collection is an important area, understanding the operational needs is necessary, some type of germplasm needs complex processing and then there are diverse seed types when you look at a large gene bank. Material collection methods have also changed. In terms of access of information, the relevance of personal information identifies, de-identification of data has also taken relevance in terms of access of certain information. Authentication or validation of the information on the collection is also important.

In the process of accessing material, there are several considerations to look at. On one end, we are looking at to obtain collections, consent procedures, understanding of the processing steps. On the other end, we are looking at for access what are the access terms, obligations of the participants, community involvement and budgetary considerations have become important. From the point of view of the access to bio resources, the context of ABS is central when we look at the implementation of the Convention on Biological Diversity. Largely if you look at, it is into countries or centers providing resources which are providers and we look at centers or countries which are using resources which are users.

And in the understanding of the provider and user, it is important to look at the interaction from the point of view of provider measures and user measures. While not going into the detail, the relevance of article 15 of the CBD needs to be understood and the Nagoya protocol and access and benefit sharing provides a clear guidance in relation

to how the general framework of ABS can operate. There are different national focal points which are dealing with the aspect of looking at spelling out the terms in relation to access. The context of PIC and mutually agreed terms becomes relevant. There are different ways of looking at benefit sharing and all those they have become relevant not only from the country perspective, but also centers which are actually also storing and wherever there is a collection and exchange of seed and biomaterial.

So, in order to comply with ABS regulations and to function effectively, several aspects have been identified. The acquisition of biomaterial has to be done legally. In terms of collections, the management as well as maintenance of the data in relation to the biological material needs to be clearly outlined. So, that all the aspects of the material are available at the time of access. Any use of biological material should be consistent with respect to the terms and conditions which are laid out in the agreement.

In terms of supply of biomaterial, the terms as provided by the provider country need to be understood. Sharing benefits can be on the monetary or on the non-monetary basis. The context of intellectual property rights and for the value derived out of biological material in terms of the potential value, the benefit sharing should be understood from that context as well. Developing institutional policies is very relevant in terms of looking at effecting the entire ABS process which means a lot of capacity building and training is required. When we deal with large collections of biological resources, they are they ought to be issues that arise out of governance.

What you see in this illustration is some instances of where the need for increased research infrastructure has been realized. Training and the development of a legal framework, the engagement with the public, the need for having a governance mechanism in terms of advisory bodies specifically for biobanks, interaction with governmental agencies, the need to look at participant interest and protection of the interest in terms of informed consent principles, privacy, data protection all these have become relevant for biobank governance. In conclusion, what we derived from this lecture is the increasing relevance of seed banks for preserving crop biodiversity. How the integration of seed banks into a common platform has advantages? There are several platforms, this lecture discusses only two of those. Understanding the access for research and IP purposes is necessary.

MTAs vary in the nature and scope and a clear understanding of that is necessary to look at the access and obligations. Large biobank resources tend to have a clear governance mechanism for efficient management of the biobanks from the collection to the maintenance to the processing to the access of material. So, these are the few references for the lecture that you can utilize. Thank you.