

## **Biodiversity Protection, Farmers and Breeders Right**

**Prof. Padmavati Manchikanti, Prof. Narendran Thiruthy | IIT Kharagpur**

### **Lecture 26 : Regulatory Law - Comparative perspective**

Welcome to the lecture 26, which is the last lecture in week 5. We will deal with the aspects of regulatory laws, particularly the context of ABS from a little comparative perspective. The concepts that we will cover in this lecture are regulating biodiversity access in general, what are the ways, legal administrative policy measures, some representative examples of countries which have implemented, and the internationally recognized certificates of compliance. These are the keywords for the lecture. So, let me bring you back to the context of regulating biodiversity access. As you have heard in the earlier lectures, ABS regulation has assumed a lot of importance from the context of benefit sharing.

Therefore, post the Nagoya Protocol, countries which are implementing ABS measures or developing ABS measures have either laws that are under development, in many cases they have implemented, institutional arrangements are coming up, monitoring and compliance is one context. When we talk about ABS, now we also have the realm of not just the access to resources, but ABS emerging specifically in relation to traditional knowledge. And of course, the more recent context since 2014 where we are discussing the digital sequences and the ABS context. So, it is important to turn our attention back to article 1 of the CBD.

And you may note the third objective is what we see as the expansion through the entire meetings of the conference of parties. From the perspective of what you see in this illustration which is which we brought back into this lecture, the implementation of ABS as a very inclusive mechanism. Article 8, 15, 16, 19 of the CBD are very relevant, and this matched with the relevant articles of the Nagoya Protocol provide the framework with respect to how countries go about implementing the ABS measures. So, when we look at the Nagoya Protocol, it is important for us to look at some of the articles which lay down the context of it. Now, the utilization of genetic resources when it comes to the use of it for several applications, article 2 of the Nagoya Protocol mentions clearly the relevance with respect to conducting research and development to unravel the aspects of it including the applications of biotechnology.

Hence, biotechnology is also separately defined in the use of technological applications that are relevant to biological systems, living organisms, and derivatives. Derivatives itself has been specifically defined under the Nagoya Protocol. Now, when we look at the entire

negotiations under the Nagoya Protocol, they have been varied opinions when it comes to derivatives and the ABS context. So, the approach to fair and equitable benefit sharing brings into the context of how benefit sharing should be looked at. Article 5, the first clause brings in two important considerations.

One is the party that is providing resource may be a country of origin, another is that where the party has acquired genetic resources. So, these are the two contexts we look at. And then of course, we are looking at generally speaking the terminologies which are being used of user countries and provider countries. This is one way of classifying the countries into those which are accessing and those which are providing genetic resource. It may also be possible that the user country at some context is also a provider country.

So, this is one context of it. Then we are looking at how is it that the countries need to look at ABS regulation. From the point of view of that Article 5 2 is very informative in the sense that each party shall undertake legislative, administrative or policy measures as appropriate. Therefore, when we now look at country based implementation, we are looking at what we are looking at what are the measures in terms of the implementation of the laws, what are the administrative agencies and how is the policy mechanism being unraveled. And therefore, the other aspects of ABS regulation is not just about the access to the resource and the benefit sharing, but also compliance and that is where we look at the need for prior informed consent which is provided under Article 6.

And establishing clearly the rules and procedures and those need to be set out in writing is a requirement. Special attention has also been given to the context of intellectual property rights as what is highlighted here. So, therefore, countries have also come up with measures to either link up the context of access to genetic resources and IP or deal it with it in two legislations, but combining them through some administrative mechanism. ABS specifically related to TK is another context and therefore, this is in Article 7. In order to ensure traditional knowledge associated with genetic resources which are obtained from the indigenous or the local communities, the need for prior informed consent is one mechanism.

In other case, it may also be their approval and involvement. So, therefore, we have both these listings. It is not only that it is a one time access, access to genetic resources should be with respect to sustainable utilization and therefore, monitoring and utilization of genetic resources is what is another important consideration for countries to look at which means restrictions to access can be imposed at any point of time if the resource is in a depleted condition. Therefore, Article 17 brings in that context. There are different designated checkpoints.

Countries have either come up with the specialized agencies under different ministries or the patent offices or the IP offices have served to be the designated checkpoints and then we have the IRCC mechanism as part of the ABS clearinghouse. We will talk about it as we move on. So, therefore, let us look at some examples. These are only representative examples because there are several countries which are already implemented ABS. If you look at the context of India, we are looking at section 3, 4, 6, 7 in terms of regulating access.

So, regulating access can be for different purposes and this is where one is in relation to where those who are accessing resources from India from a foreign soil or foreign concerns they come under the purview of section 3. Those are for certain activities bio survey, bio utilization those. There are also scenarios where transfer of research results in relation to biodiversity can happen for which section 4 deals with it. This is not only the substantive part, there are also procedural requirements that need to be met. Now, section 5 provides the exemptions.

So, if there are collaborative projects between India and some other an Indian institution and some other institution abroad as part of the Indian understanding, then those are exempt and those are listed. So, those are where section 3 and 4 would not apply. Section 6 is specifically cast for intellectual property rights. We have dealt with this in one of our earlier weeks. Now, section 7 becomes important from the perspective that state biodiversity boards are the jurisdictions where we will be looking at access to resource.

So, intimation to the state biodiversity boards is one requirement under the law. So, when we look at the administrative mechanism, we are looking at NBA at the central level, state biodiversity boards, NBA's functions are enumerated under section 18 of the act. We have several state biodiversity boards who under the consultation of the NBA dole out different measures and then at the local level, we have the biodiversity management committees. This is an a very important mechanism because the act is bottom up. So, if the biodiversity management committees feels at the local level that access should not be provided, then state biodiversity board and at the central level there is a need for review.

So, when we look at the implementation, we are looking at what we are looking at ABS agreements coming under the purview of each of these different sections. And the procedural mechanism mandates several different forms and also details of the what is the resource to be accessed for what time it needs to be accessed and for what purpose the resource is being accessed. And a declaration also must be given by the applicant that none of this access will be in violation of the conservation objectives of the act. So, therefore, this is one important. Another thing we need to keep in mind is that there are restrictions on access if there are certain taxa.

From time to time, restrictions may be imposed considering the nature of the genetic resource, its condition. So, therefore, that is where we see the need for monitoring. So, ABS monitoring is not only prior to the ABS, pre-ABS, but also post-ABS and that is where the agreements also take that into consideration. There are several things obviously, excluded out from the biodiversity legislation in India. We talked about collaborative projects.

Of course, from the point of view of biodiversity, biological diversity itself, we know that human genetic material is not subject matter of the act. Plant variety protection has a separate legislation and so, those do not come into the purview of this. They are normal tradable commodities which all of us use and they are exempt. Then of course, we have those who are traditional cultivators, hakim, vaid, farmers, cultivators, growers, they regularly are using biodiversity for their subsistence. They do not need to take permission under the law.

So, when we look at Indian mechanism, we understand what are the laws, what is the administrative mechanism, how is the local governance mechanism working. Of course, in the earlier lectures you have gone through the people biodiversity registers which are very important in terms of looking at the evidentiary aspects of biological diversity including the associated TK and the information on people who are associated with those bio resources in terms of the information on the local communities. We take up Indonesia as one of the examples where we are looking at the implementation with respect to the decree for access of genetic resource of wild species and benefit sharing. Indonesia also takes into consideration the recognition of local wisdom on natural resource management. So, if there is a need for consultation that is provided by the regulation.

None of the access can be in contrary to the conservation objective. So, therefore, when we look at access we are also looking at reading another regulation in cohort. The guidelines for indigenous rules and protection of indigenous people become handy in terms of taking decisions in relation to the access. The Ministry of Agriculture, Ministry of Environment Forestry, Ministry of Marine Affairs and Health all have their duties in relation to the aspect of access to genetic resources. So, when you are looking at accessing permits, procedurally we see countries are different.

In the case of Indonesia 60 working days is what is the time period when it comes to commercial applications. The requirement of PIC is recognized, then the mutually agreed terms. If there is an application of the recommendation of Indonesia's Science Institute and their considerations then that regulation also will apply. So, you see that these things are different when it comes to and also the emphasis of where the ABS regulation is applicable

to, is it bioprospecting to what is the scope of it is also different. We come to Brazil as you are aware, one of the topmost countries where it comes to richness in biological diversity.

Post Nagoya protocol changes have been brought in. They have an electronic system of registration which is called the SisGen. Someone who is looking at accessing has to register into this system, and prior informed consent is a requirement even prior to the registration. There are several declarations that need to be met, and a more simplified procedure is on giving the details in relation to the use, the registration, followed by the verification of the receipts, and at the end of it you get a certificate of compliance. Now, South Africa again very rich in the biological resources has also implemented ABS.

Now, let us look at how this mechanism works in South Africa. Now, there is a Biodiversity Act, the National Environmental Management Biodiversity Act and the regulation which are read together when it comes to implementing ABS. In order to take forward the ABS, it is important to also include stakeholders, local stakeholders. And this is where it is interesting that the competent national authority which is the Department of Environmental Affairs has there are many indigenous communities which are affiliated to this particular agency. So, whenever there is an ABS request that comes up, because of the facilitation the governmental mechanism make sure that the local communities are able to participate.

So, you see two different communities the San community and the Kosak community, both of them are notified that there is an ABS request and they can also participate. So, therefore, this is another interesting mechanism involving the local governments part of it. And at the end of the patent office, wherever IP applications are being filed, patent applications are being filed, the monitoring happens from the point of view of looking at if the patent is based on indigenous the access to biological resources from an indigenous community. And in that case the permit is a requirement, proof of authority from the indigenous community is required for the application. And therefore, when we look at the intellectual property laws, we also see amendments not only in the patent legislation, but in several other legislations to take into consideration or including specific aspects of TK and recognizing its relevance with respect to access.

There is also a specific act the Protection Promotion Development and Management of Indigenous Knowledge Act 2019, which is all about taking into consideration or enhancing the protection of TK and the management of TK. So, if you look at the procedural context, there are different types of permits. We have biotrade permits, bioprospecting permits, integrated biotrade and bioprospecting permits. The time period for clearing ABS permits generally 120 working days in this case with possible extensions depending on if there is

information that is required further information, then yes there is extension possible. Now, there are different steps involved in the procedural aspects of the ABS permits when it comes to.

So, as you can see negotiations and agreements with providers, applications for biotrade, preliminary assessment and then technical and legal review, evaluation done. So, there is several steps which are specific to South Africa. From the point of view of a regional context, another example would be the European Union. ABS regulation and its implementation in the European Union, one can find it in terms of the post Nagoya implementation in the EU wide platform. Also there are separate rules identified with respect to the implementation of ABS regulation post 2015.

We see the requirement of due diligence being identified more clearly with respect to the EU. So, what is the information with respect to access, in which case users will need to comply with what we call the due diligence obligation. So, users will need to give specific information or detailed information of in the form of documentation of what is the genetic resource that is being looked at for access, the information about the genetic resource, and users will also need to look at providing a showing of how they are going to fulfill the benefit sharing obligations. So, this is where we see the requirement of also specific evidence in terms of the date, place, and source of biological material is also imperative. Then we come to the recognition of best practices.

This has been integrated in the EU regulation. What does that mean is that best practices have been recognized in the form of procedures that are developed, mechanisms that have been in are currently in place, and what are the tools that are being utilized to effectively implement ABS regulation. And so, therefore, this encourages association of users and other parties to utilize existing tools and also come up with best practices. And therefore, in some sense, it not only effectively increases the ABS regulation compliance, the there is also a reduction in the non-compliance or rather user risk is less.

This is where we see briefly the EU context. Let us also discuss the context of IRCCs which are internationally becoming more relevant. Now, the IRCC or the internationally recognized certificates of compliance are published by the ABS Clearinghouse. Each provider country submits this into the ABS Clearinghouse, and this forms a very important component of not only the details of the resource and the access, but also provides a harmonized mechanism of monitoring the utilization of genetic resources by users. There are several submissions that have already been made, and this also provides enhanced transparency when it comes to activities that are taken up in relation to the genetic resources that are the information that has been submitted. This is a requirement prior to the IRCC in terms of the PIC and MAT.

And so, therefore, this brings in the compliance with respect to the overall IRCC mechanism. So, users would be less burdened because the IRCC submissions follow a specific procedural mechanism. So, many submissions have been done already, many countries have submitted a lot of IRCCs, and as we see going forward this is one mechanism which is also beginning to develop as a very good ABS regulation. So, in this lecture we have dealt with briefly the context of ABS regulation taking some representative examples. As we see the context of different country based implementation, we look at the compliance of Nagoya protocol on one end, on the other end we are also looking at specific country based mechanism.

So, if you see many countries which are rich in indigenous knowledge, we see the joint application of those different regulations as well. So, as we go forward we also look at the context of ABS regulation with respect to other international treaties. For instance, we are looking at the international treaty for plant protection, UPOV we have, then there are several others similarly. So, when we see the ABS regulation from a wider context, we see that there is so much of scope for development with respect to ABS. So, we know that there are monetary and non-monetary basis of benefit sharing, we see increasingly the application of both.

There are also considerations when it comes to the general scientific historical aspects of biodiversity. For instance, what is the application of ABS regulation for museums, for general collectors who are collecting information, taxonomists, so and research groups which are working in these areas. So, this is another development that we see. So, in brief the conclusions for this lecture. Countries differ in their ABS implementation in terms of the measures, general measures which are implemented in relation to Nagoya protocol and then there are specific measures.

Some representative country examples have been taken to understand the substantive and procedural requirements. The legal administrative and policy mechanisms vary with respect to several aspects. IRCCs provide a great platform for larger engagement when it comes to ABS regulation. So, these are a few references with respect to ABS regulation and also the country based information which is also available at the CBD website [cbd.int](http://cbd.int). Thank you.