

Biodiversity Protection, Farmers and Breeders Right

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

Lecture 09: International Regime on ABS

Welcome to the course on Biodiversity Protection Farmers and Breeders Right. This lecture will be on International Regime on Access and Benefit Sharing. Access and Benefit Sharing refers to the access of biodiversity from the provider countries and its utilization for advanced scientific purposes. This will also include commercialization of biodiversity components. The concepts covered in this lecture are access and benefit sharing mechanism, prior informed consent, mutually agreed terms, monetary and non-monetary benefit sharing, user country measures, the ABS clearing house and the checkpoint communique. The keywords are ABS principles, genetic resource, users and providers, benefit sharing, prior informed consent and mutually agreed terms.

Access and benefit sharing is an internationally accepted legal obligation for all those who accesses and utilizes biodiversity or associated knowledge. So, it is applicable for both biological resource as well as associated knowledge. If a person accesses biodiversity or any components of biodiversity for the purpose of commercial utilization or scientific research, then he has to adhere to some legal obligations. So, these legal obligations are popularly called as access and benefit sharing obligations.

As a concept, access and benefit sharing facilitates access in a regulated manner. It ensures sustainable utilization. So, when access to biodiversity happens, it will be in a regulated manner so as to ensure sustainable utilization. And there will also be a mandate on benefit sharing as an obligation on the part of the user. So, every user will have to follow some legal regulations and the legal regulations on the one side will require sustainable utilization of resources and on the second side, it will require benefit sharing from the sharing of benefits from the commercial utilization of the resource.

So, this is an internationally recognized legal obligation under the Convention on Biological Diversity. Why access and benefit sharing is important? So, under the Convention on Biological Diversity, the providers have the authority to determine access to genetic resources and are entitled to receive a share of benefits arising from their utilization. So, the access and benefit sharing provisions under the Convention on Biological Diversity are designed to ensure that physical access to genetic resource is facilitated and at the same time, the benefits arising from their utilization are shared equitably with the provider countries. The access and benefit sharing is based on prior informed consent being granted by a provider to a user and the negotiations between

both the parties to develop mutually agreed terms and to ensure the fair and equitable sharing of benefits. So, these conditions are required under article 15 of the CBD which was adopted in 1992 and provides a global set of principles for access to genetic resource as well as their sharing of equitable benefits.

At the domestic level, benefit sharing measures are to provide for the fair and equitable sharing of benefits arising from the utilization of genetic resource with the contracting party providing such genetic resources. The utilization includes research and development on the genetic or biochemical composition of the genetic resource as well as subsequent applications and commercialization. The sharing will be subject to mutually agreed terms. The benefit sharing can be in monetary or even in non-monetary terms. So, who are all involved in the process of access and benefit sharing? So, the providers of genetic resource, the users of genetic resource, the national focal points, the competent national authorities and the indigenous and local communities are the actors who are involved in the access and benefit sharing process.

So, more than a legal obligation access and benefit sharing shall be seen as a process in which there are different actors. The providers of genetic resource are usually the sovereign states who are parties to the CBD. So, CBD has recognized that the countries have sovereign right over their genetic resources. So, that means, the countries are the providers of genetic resource. Under certain legal systems even the traditional communities or local communities or people who are conserving biodiversity are also seen as the providers of genetic resource.

The users of genetic resource can be sovereign states as well as companies who are interested in doing research or commercial utilization using genetic resources. National focal points represents the governments. So, they are part of the governments and represent the sovereign states who are parties to the CBD. The competent national authorities are usually statutory bodies or governmental authorities who are representing the interest of sovereign states in the access and benefit sharing process. The indigenous and local communities are recognized under the CBD as well as the Nagoya protocol for their role in conserving traditional biodiversity as well as protecting of traditional knowledge.

So, they also place an important role in the access and benefit sharing process. Who are the users and providers of bio resource as well as traditional knowledge? So, under the CBD the sovereign rights of the state governments the under the CBD the sovereign right of state parties are recognized. So, they are considered as the providers of genetic resource under the convention on biological diversity. So, usually in all cases the providers of genetic resource will be the governments or the sovereign states who are

parties to the CBD. But certain legal systems even recognize persons or conservers of biodiversity also has the providers of genetic resource.

The users represents the national governments or companies or individuals who are interested in doing research or commercial utilization using biodiversity. So, the entire process of access and benefit sharing is actually a negotiation or the entering into a mutually agreed terms between the providers and users of genetic resource. So, the users will be allowed to use genetic resource for the purpose of research and development while the providers will be entitled to receive a percentage of the benefits that the users will derive from the utilization of genetic resources. So, the providers of genetic resource are usually and the countries of origin which is recognized under the CBD. So, it is the country from which that genetic resource has originated or it can also include parties that have acquired genetic resources in accordance with the convention on biological diversity.

So, both the countries of origin as well as parties who has acquired the genetic resource in accordance with the convention are also considered as providers of genetic resource. So, there are several international legal instruments that give recognition to the concept of access and benefit sharing. But it emanated from the convention on biological diversity which was adopted in 1992. Subsequently the bond guidelines on access to genetic resource and the fair and equitable sharing of benefits arising from their utilization which was adopted in 2002 and the subsequent Nagoya protocol and access to genetic resource and the fair and equitable sharing of benefits arising from their utilization adopted in 2010 give effect to the principle of ABS. As I said the concept of ABS originated or was given first legal recognition under the convention on biological diversity.

The article 15 of CBD, the article 15 of CBD recognized that the authority to determine access to genetic resource rests with the national government and is subject to national legislation. So, it recognized that the countries have sovereign right over their biodiversity and thus the countries have authority to determine access to genetic resource. So, the access to genetic resource shall be subject to the domestic legislation of the provider country. So, the access to genetic resource shall be subject to mutually agreed terms and the prior informed consent of the contracting party providing such resource. So, the CBD required that access to genetic resource shall be subject to the prior informed consent of the contracting party providing such genetic resource.

So, if the genetic resource is originating from a particular country and if a company operating in another country want to use that genetic resource, then the prior informed consent of that country where this biodiversity is originating has to be taken before the

utilization take place. So, the article 15 give effect to the legislations of several countries which regulate the utilization of biodiversity. The obligation to take legislative administrative of policy measures with the aim of sharing in a fair and equitable manner the results of research and development and the benefits arising from commercial and other utilization of genetic resource is also recognized under article 15 of CBD. So, the benefit sharing can take place in two different manners under article 15. One is the sharing of results of research and development and it can also be the sharing of benefits arising from the commercial or other utilization of genetic resource.

So, this is emanating from the concept that technology transfer is extremely important for helping the developing countries or the underdeveloped countries. So, the Nagoya protocol on access to genetic resource and the fair and equitable sharing of benefits arising from their utilization under the Convention on Biological Diversity is a supplementary agreement to the convention and it provided a transparent legal framework for the effective implementation of one of the three objectives of CBD the fair and equitable sharing of benefits arising out of the utilization of genetic resource. So, the Nagoya protocol is actually a supplementary agreement to the Convention on Biological Diversity and it concentrated on the third objective of CBD that is fair and equitable sharing of benefits arising out of the utilization of genetic resources. The Nagoya protocol was adopted in the year 2010. Its objective is to ensure fair and equitable sharing of benefits arising from the utilization of genetic resource and thereby contribute towards the conservation and sustainable utilization of biodiversity.

The Nagoya protocol set out some core obligations for the contracting parties with regard to access to genetic resource, benefit sharing and compliance. So, the objective of Nagoya protocol was to provide for a clear and transparent regime for access and benefit sharing. So, it impose some obligations on the state parties to include certain things in their domestic legislations. So, the access and benefit sharing is actually subject to the domestic legislation of the provider country. So, unless the provider country's national legislation is clear and transparent, it will create issues for access and benefit sharing.

So, the Nagoya protocol required that the domestic level access measures shall be clear, certain and transparent. So, it required the state parties to create legal certainty, clarity and transparency in their domestic regimes. It also provided for fair and non arbitrary rules and procedures. So, the countries who are party to the Nagoya protocol have an obligation to have fair and non arbitrary rules and procedures with regard to access and benefit sharing in their domestic legislation. It established clear rules and procedures for prior informed consent and mutually agreed terms.

It provided for the issuance of a permit or equivalent when access is granted. So, the

access is subject to the domestic legislation of the provider country. So, there shall be some evidence in the form of a permit or its equivalent when the provider country grants permission for an access. It also created conditions to promote and encourage research and contributed to biodiversity conservation and sustainable use. It paid due regard to present or imminent emergencies that threaten human animal or plant health.

So, there could be cases. So, in the normal scenarios the prior informed consent and mutually agreed terms is mandatory for access to genetic resource happen, but in certain exceptional scenarios like present or imminent emergencies some urgent action would be required. So, the Nagoya protocol also provides for accessing such present or imminent emergencies as well. It also considered the important of genetic resource for the purpose of food and agriculture and for food security. The article 5 of Nagoya protocol provides for fair and equitable sharing of benefits. The benefits arising from the utilization of genetic resource as well as subsequent applications and commercialization shall be shared in fair and equitable way with the party providing such resources.

The benefit sharing under the Nagoya protocol can be in monetary as well as in non-monetary terms. The annex to the Nagoya protocol gives some indicative list of monetary as well as non-monetary benefit sharing. The monetary benefit sharing means that the benefit sharing will be in monetary terms. So, that means, it can include access fees like fee per sample collected, it can also include upfront payment, milestone payment, payment of royalties or license fee or special fees. So, it can be anything which is in monetary terms and it can also include joint ownership of relevant intellectual property rights.

The benefit sharing can also be in non-monetary terms. So, non-monetary benefit sharing includes sharing of research and development results, collaboration in scientific research and development programs, participation in product development, contribution in education and training, technology transfer under the fair and the most favorable terms, strengthening capacities for technology transfer, institutional capacity building, joint ownership of intellectual property rights, food and livelihood security benefits, social recognition, contributions to local economy etcetera. So, if the benefit sharing is in is not in monetary terms, it has to be in non-monetary terms. The Nagoya protocol recognizes that in certain scenarios the genetic resource or the traditional knowledge will be held by indigenous and local communities. So, CBD had recognized that the countries have sovereign right to their genetic resources, but some countries recognize that the indigenous and local communities also have a right to self-determination and also have territories which are governed under special laws.

But some countries like India does not agree to the concept of indigenous or its inclusion

in international conventions and have always resorted to the use of the term local communities which is more suitable for Indian scenario. The benefits arising from the utilization are to be shared in accordance with the domestic legislation regarding the established rights of these indigenous or local communities. So, if the resource is held by indigenous or local communities, then the benefits arising from the utilization of such resource has to be shared in accordance with the established rights of these indigenous and local communities. And when it is traditional knowledge which is accessed from indigenous or local communities, then it has to be accessed only with the prior informed consent or approval and involvement of this indigenous and local communities and only after the establishment of mutually agreed terms. So, in case of genetic resource, normally it is the prior informed consent of the state or the mutually agreed terms with the state that is required for facilitating access.

But if it is genetic resource or traditional knowledge which is held by indigenous or local communities and the national legislation of that country recognizes their established rights. So, in such cases the access shall be subject to the prior informed consent of such indigenous or local community and also with their involvement in the establishing of MAT. The Nagoya protocol requires that party shall take necessary legislative, administrative or policy measures to provide for legal certainty, clarity, transparency of domestic access and benefit sharing regulation. So, if the benefit sharing regulation is so complicated, then access and benefit sharing will not become a reality. So, the purpose of access and benefit sharing regulation should be to facilitate access and also to ensure that there will be sharing of equitable benefits.

So, in order to ensure this, the legal regulation shall be clear and transparent. It shall provide for fair and non arbitrary rules and procedures for accessing benefit sharing. It shall provide for information on how to apply for prior informed consent. It shall provide for clear and transparent written decision in a cost effective manner and within a reasonable term. So, it shall provide for clear and transparent written decision in a cost effective manner and within a reasonable time.

The Nagoya protocol also provides for permit or its equivalent as an evidence of prior informed consent and mutually agreed terms. So, when the resource is taken from the provider country, its utilization may be happening in another jurisdiction. So, there shall be some evidence as to the grant of prior informed consent and establishing of mutually agreed terms. So, Nagoya protocol requires the state parties to provide for a permit or its equivalent as an evidence of prior informed consent and mutually agreed terms. And it also requires the state parties to notify the ABS clearing house once a permit or its equivalent is granted.

So, ABS clearing house is another mechanism which is established under the Nagoya protocol. The Nagoya protocol also sets out criteria and processes for obtaining the prior informed consent. It also provides for establishing clear rules and procedures for requiring and establishing mutually agreed terms. The Nagoya protocol requires that the mutually agreed terms shall be set out in writing and it may include dispute settlement clause to address scenarios where a dispute may arise between the provider and user of genetic resource. It shall also have terms on benefit sharing including on intellectual property rights.

It shall also have terms on subsequent third party use. So, there could be scenarios where a user is accessing biodiversity with the permission of the provider, but subsequently he may transfer the genetic resource to a third party or there could be scenarios where a third party will accrue the rights to use that genetic resource. So, the mutually agreed terms shall also have some terms and conditions with regard to third party use of the resource. There will also be some terms to address scenarios where there is change of intent. So, for example, a user has accessed the genetic resource for the purpose of research, but subsequently there is a change of intent and the user now wants to do a commercial utilization.

So, the mutually agreed terms will have some clauses which addresses such scenarios. Article 15 of the Nagoya protocol provides for establishing of user country measures. So, the so, the requirement of having clear and transparent domestic legislation is on the provider countries, but user country measures is an obligation which is on the uses of biodiversity. So, the Nagoya protocol under article 15 requires the parties to take appropriate effective proportionate legislative administrative or policy measures to provide that genetic resource utilized within their jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established as required by the domestic access and benefit sharing legislation or the regulatory requirements of the other party. So, thus article 15 requires the parties to have a domestic legislation in the form of user country measures.

So, this will ensure that if a utilization of a genetic resource is happening in their jurisdiction, the law there is a legal obligation to ensure that its access is in accordance with the prior informed consent of the provider country and also that mutually agreed terms have been established. So, it requires that the domestic access and benefit sharing legislation or the regulatory requirements of the provider country has to be taken care while any utilization of genetic resource happens in a user country. The parties are also take measures to address situations of non-compliance with such measures. The parties shall cooperate in cases of alleged violation of domestic access and benefit sharing legislation or regulatory requirements. So, the user country measures has to have these

different

parts.

So, on the one part it has to provide for legal measures to ensure that if a utilization of a genetic resource happens within the jurisdiction of the user country, then the use of the utilization shall be subject to the ABS legislation of the provider country. And it also have it also shall have measures to address situations of non-compliance with these measures. And if there is non-compliance or alleged violation of domestic access and benefit sharing regulation, then the parties shall cooperate in such cases. Article 16 of the Nagoya protocol provides for the establishment of checkpoints. So, article 16 requires the parties to designate one or more checkpoints.

The checkpoints must be effective and should have functions relevant to the utilization of genetic resource or the collection of information at any stage of research, development, innovation, pre-commercialization or commercialization. So, the checkpoints will be governmental agencies who have some role in monitoring research and development, innovation or commercialization. So, the checkpoints shall be relevant to the function of utilization of genetic resources. So, the designated checkpoints would then collect, receive as appropriate relevant information related to prior informed consent to the source of genetic resource or the establishment of mutually agreed terms. The parties shall as appropriate depending on the particular characteristics of a designated checkpoint, require the users to provide information like internationally recognized certificate of compliance.

So, the checkpoints will be some governmental agencies who have some role in monitoring activities like research and development, innovation, commercialization, etc. So, when the utilization of genetic resource happens within the jurisdiction of the user country a checkpoint in that country will ask for information with regard to whether the prior informed consent has been taken from the provider before utilizing the resource or that whether the mutually agreed terms has been established in accordance with the domestic legislation of the provider country. And the Nagoya protocol already provided for the grant of permissions through permit. So, the checkpoints can ask for the evidence of prior informed consent or the establishment of mutually agreed terms. So, in such situations the users can submit the permit which is issued by the provider country and it can also be in the form of internationally recognized certificate of compliance.

The internationally recognized certificate of compliance or the IRCC is provided under article 17 of the Nagoya protocol. Article 17 provides that a permit or its equivalent issued by the provider state and made available to the access and benefit sharing clearinghouse shall constitute an internationally recognized certificate of compliance. So, once the provider country grants the permission to a user then the information will be

uploaded to the access and benefit sharing Clearing-House portal. So, once this information is updated then the internationally recognized Certificate of compliance can be automatically generated from the portal. So, this certificate will function as an evidence of acquiring the prior informed consent and establishment of mutually agreed terms.

So, when the checkpoint ask for the information the user can provide this internationally recognized certificate of compliance. So, the IRCC shall serve as an evidence that genetic resource which it covers have been accessed in accordance with the prior informed consent and that the mutually agreed terms have been established as required by the domestic legislation of the provider country. The IRCC shall contain some minimum information as provided in article 17. The minimum information can be the name of the issuing authority, the date of issuance, the name of the provider, the unique identifier of the certificate like some unique identification number or file number or some other details, the name of the person or entity to whom the prior informed consent has been granted, the subject matter or the genetic resource covered by the certificate. So, this can be in the form of the scientific name of the genetic resource or it can also be in the form of common name of the genetic resource or it can also be in the form of some digital sequence information.

Another information which is required is confirmation that mutually agreed terms has been established and confirmation that prior informed consent has been obtained. The IRCC can also have information like whether the permitted use is of commercial nature or non-commercial nature. Article 16 of the Nagoya protocol provided for establishment of checkpoints. So, this is an obligation of every state party to establish checkpoints within their jurisdiction in order to ensure that the utilization of genetic resource within their jurisdiction is subject to the national legislation of the provider country. So, the checkpoints established under article 16 shall have the function of collecting information from the users of the bio resource.

So, when a utilization of biodiversity happens within the national jurisdiction, the checkpoints in that state will collect the information. And article 17 of the Nagoya protocol provides for issuance of checkpoint communiques. So, when the checkpoint receives the information, such information will be provided to the provider country and also updated to the access and benefit sharing Clearing -House. So, this will be updated to the ABS clearing house portal. So, the checkpoints role will be to collect this information and then pass on this information to the provider country.

So, this information which is provided to the provider country is known as checkpoint communiques. So, the checkpoints usual role will be to collect this information and then

update this information in the clearing house portal and then the checkpoint communicate will be issued to the provider state. So, this checkpoint communicate will have details with regard to the genetic resource which is being utilized in their country and the name of the person or the company which is utilizing this biodiversity, it will also include the type of utilization. So, the checkpoint communicates will aid the provider countries to monitor the utilization of their genetic resources. Article 11 of the Nagoya protocol provides for transboundary cooperation.

So, there would be instances where the genetic resource which is found inside to in one territory may be available in the national jurisdiction of another country as well. So, in such scenarios the party shall cooperate with the involvement of indigenous and local communities concerned in view of implementing the protocol and there will also be scenarios for the same traditional knowledge is shared by one or more indigenous or local communities in several state parties. So, in such scenarios the state parties shall cooperate as appropriate with the involvement of indigenous and local communities for the purpose of implementing the Nagoya protocol. The ABS clearing house mechanism is established under article 14 of the Nagoya protocol. The ABS clearing house or ABS CH is a platform for exchanging information on access and benefit sharing.

It is administered by the secretariat of the conventional biological diversity. The ABS clearing house is a key tool for facilitating the implementation of Nagoya Protocol and for enhancing legal certainty, clarity and transparency on the procedures of access and for monitoring the utilization of genetic resource along with value chain. So, all information regarding the domestic legislation of a provider country has to be updated in the ABS Clearing-House portal. So, any person who wants to access a genetic resource in a country from a country can look into the ABS clearing house portal and can understand the legal procedures that he has to comply. Similarly, when a permit is granted to a user of biodiversity that information will also be updated into the ABS Clearing -House portal.

So, the information with regard to the issuance of permits or IRCC will also be available in the ABS Clearing-House portal. Similarly, the checkpoint communicates which are issued by the checkpoints in a country will also be available in the ABS clearing house portal. So, ABS Clearing-House portal is actually a comprehensive resource platform for understanding the legal regulations with regard to access and benefit sharing in all the state parties to the Nagoya protocol. Apart from Nagoya protocol another international instrument with regard to access and benefit sharing under the conventional biological diversity is the Bonn guideline which was adopted in 2002. The Bonn guidelines on access to genetic resource and fair and equitable sharing of benefits arising out of their utilization is actually a voluntary guideline which is available for the state parties and is

intended to help them in developing their national legislations.

These guidelines have two main aims. First is to guide the countries as providers in setting up their own national legislative administrative or policy measures for access and benefit sharing such as recommending the elements that should make up prior informed consent. Second to assist the providers and users in the negotiation of mutually agree terms by providing examples of what elements should be included in these agreements. The guidelines are recognized as useful first step of evolutionary process in the implementation of access and benefit sharing regime. Second step, the Bonn guidelines assist the parties governments and other stakeholders in developing their national legislations. It will also help the different stakeholders while negotiating contractual agreements for the purpose of access and benefit sharing.

It gives guidance on the roles and responsibilities of national focal point and competent national authorities. It also gives in detail the different steps in the access and benefit sharing process. So, Bonn guidelines is in the form of a comprehensive guideline which details about the roles and responsibilities of different actors in the access and benefit sharing process. So, it gives in detail the expected roles and responsibilities of the national focal point and the competent national authority in a provider country. It also gives in detail the benefit sharing process, but the bonn guidelines is of voluntary nature and the final acceptance in every jurisdiction will be subject to the national legislation of that country.

The fair and equitable sharing of benefits arising from the use of genetic resource is one of the main objectives of the Convention on Biological Diversity. The bond guidelines help the countries to develop national legislation and take forward the negotiation process for access and benefit sharing. The Nagoya Protocol provided legal certainty to the concept and contributed towards establishing a coherent international regime for access and benefit sharing. Thank you very much for listening to the lecture. I hope you enjoyed the course.