

Biodiversity Protection, Farmers and Breeders Right

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Lecture 34 : Compliance Procedures under International Framework

Welcome to the course on Biodiversity Protection, Farmers and Breeders Right. This lecture will be about the compliance procedures under the international framework. The concepts covered in this lecture are fair and equitable benefit sharing, access to genetic resources and traditional knowledge, global multilateral benefit sharing mechanism, transboundary cooperation, compliance with domestic legislation or regulatory requirements for access and benefit sharing, monitoring the utilization of genetic resources, compliance with mutually agreed terms. Keywords are fair and equitable benefit sharing, genetic resources, traditional knowledge, conservation and sustainable use, global multilateral benefit sharing mechanism, transboundary cooperation. The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the implementation of one of the three objectives of CBD that is the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The Nagoya Protocol on ABS was adopted in October 2010 in Nagoya, Japan and it entered into force in October 2014. The Nagoya Protocol together with the Convention on Biological Diversity constitutes the international legal framework related to biodiversity governance. The Nagoya Protocol provides for a transparent legal framework for the effective implementation of the key objective of CBD that is the fair and equitable sharing of benefits arising from the utilization of genetic resources. The Convention on Biological Diversity recognizes the sovereign rights of countries over their natural resources in areas within their jurisdiction.

So, CBD recognizes the sovereign rights of state, the parties to the convention therefore, have authority to determine access to genetic resources in areas within their jurisdiction. Parties also have the obligation to take appropriate measures with the aim of sharing the benefits derived from their use. The Nagoya Protocol enforces the concept of state sovereignty by giving the countries the ability to determine, control and monitor the use of biological material accessed from a signatory. So, CBD in effect recognizes the sovereign rights of countries whereas, the Nagoya Protocol provides for a clear and transparent legal framework and which helps the countries in enforcing the national sovereignty and it gives them the ability to determine, control and monitor the use of biological materials. In accordance with article 15, benefits arising from the utilization of

genetic resources as well as subsequent applications and commercialization shall be shared in fair and equitable way with the providing party that is the country of origin of that genetic resource or a party that has acquired the genetic resource in accordance with the convention and such sharing shall be upon mutually agreed terms.

And each party of the Nagoya Protocol has an obligation to take legislative, administrative and policy measures with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities shall be shared in accordance with the domestic legislation of that country. The domestic legislation may provide for established rights of these indigenous and local communities and the transfer of genetic resource as well as traditional knowledge shall be in accordance with the mutually agreed terms. To implement the ABS principles, each party thus have an obligation to take legislative, administrative and policy measures. The benefits that are shared in accordance with the Nagoya Protocol can be in monetary terms and it can also be in non-monetary terms. Each party thus shall take legislative, administrative and policy measures in order to ensure that the utilization of traditional knowledge and the benefits that are arising from such utilization are shared in a fair and equitable way with the indigenous and local communities holding such knowledge.

The sharing of benefits as well as the access shall be in accordance with the mutually agreed terms. So, each party which is party to the Nagoya Protocol has an obligation to take legislative, administrative and policy measures as appropriate for ensuring that the utilization of traditional knowledge shall happen in accordance with the mutually agreed terms that has been entered with the local communities as well as the indigenous communities and also the accesses of the traditional knowledge. In exercise of sovereign rights over natural resources and subject to domestic access and benefits sharing regulations, access to genetic resources for their utilization shall be in accordance with the prior informed consent of the party providing such resources. In accordance with domestic law, each party shall take measures as appropriate with the aim of ensuring that prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resource where they have an established right to grant access to such resources. So, article 6 requires that access to genetic resource shall be in accordance with the prior informed consent of the party providing such resources.

So, prior informed consent of the party providing the resource is mandatory in order to legally access the genetic material from a country. So, there shall be legislations and other regulatory requirements which imposes the condition of taking the prior informed consent before accessing the genetic material. And in accordance with the domestic law every country shall provide for prior informed consent or approval and involvement of local communities and indigenous communities is obtained before the genetic resource is

accessed especially in cases where they have an established right to grant access to such resources. Each party through the Nagoya protocol which requires prior informed consent shall take the necessary legislative administrative or policy measures as appropriate in order to provide that there is clear legal certainty clarity and transparency of their domestic access and benefit sharing legislation or the regulatory requirements. So, the each country which is party to the Nagoya protocol has an obligation to have legal certainty clarity and transparency with regard to their domestic access and benefit sharing regulations.

The countries who are party to Nagoya protocol also should provide for fair and non arbitrary rules and procedures on accessing genetic resources. The countries also has an obligation to provide information on how to apply for prior informed consent. The countries shall provide for a clear and transparent written decision by a competent national authority in a cost effective manner and within a reasonable period of time. The parties shall also provide for the issuance at the time of access a permit or its equivalent as an evidence of the decision of the grant of prior informed consent and of the establishment of mutually agreed terms. And this shall also be notified to the access and benefit sharing clearing house under the CBD secretariat.

And where applicable in accordance with the domestic legislation they shall also set out the criteria or processes for obtaining the prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources. The parties to Nagoya protocol shall also establish creel rules and procedures for requiring and establishing mutually agreed terms and such terms shall include a dispute settlement clause in order to address the scenarios where there is a dispute between the provider and the user. Terms on benefit sharing including in relation to intellectual property rights, term on subsequent third party use if any and terms on changes of intent were applicable. So, this means that countries which are party to Nagoya protocol has an obligation under article 6 to enact clear transparent and transparent domestic legislations or regulatory laws with legal certainty and clarity. And these domestic regulations should provide the procedures that are required to follow for securing the prior informed consent of the providers.

The regulatory framework at the national level shall also provide for a proper dispute settlement clause, terms on benefit sharing especially in relation to intellectual property rights, terms on subsequent third party use, terms on change of intent. So that is after accessing the resource sometimes the intent of the user may undergo some change. So even if the initial access was for doing research for a particular type of activity, subsequently the user may want to use the same genetic resource for another type of activity. So in such cases what are the procedures that are to be followed by the user has to be mentioned in the regulations. Access to traditional knowledge associated with genetic resources is dealt under article 7.

So, in accordance with domestic law each country which is party to the Nagoya protocol shall aim of sorry I have to start this slide again, this slide alone I am starting. The access to traditional knowledge associated with genetic resources is dealt under article 7 of the protocol. So in accordance with the domestic law each party shall take measures as appropriate with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior informed consent or approval and involvement of these indigenous local communities and mutually agreed terms have been established. So there is mainly two requirements under article 7 of the Nagoya protocol. So the protocol requires that if the access of traditional knowledge is from a country which requires prior informed consent of the indigenous and local communities, then the prior informed consent and approval or involvement of the indigenous and local communities have to be secured before accessing the traditional knowledge and the law shall also ensure that the mutually agreed terms have been established as required by the domestic ABS legislation.

So article 8 of the Nagoya protocol speaks of certain scenarios where special considerations is required. The protocol requires the member countries to create conditions to promote and encourage research that contributes to conservation and sustainable use of biodiversity especially in developing countries. So for this purpose simplified measures on access for non-commercial research purposes has to be created. So the normal regulatory requirements under the domestic legislation may be very stringent. So in such scenarios following the same procedure for non-commercial research especially those non-commercial research which has the potential to encourage or contribute towards conservation and sustainable use of biodiversity may not be desirable.

So in such situations simplified procedures has to be created. The country shall also pay due regard to cases of present or imminent emergencies that threaten or damage human animal or plant health. So there shall be separate rules and regulations which are available for dealing with situations where expeditious access permissions are required in order to address any present or imminent emergencies that threaten or damage human animal or plant health. So following the normal regulatory procedures may not be desirable in such scenarios. So in order to address such scenarios simplified procedures has to be provided by every country which is party to the Nagoya protocol.

The country shall also consider the importance of genetic resources for food and agriculture and their special role for food security. So there is a separate treaty system which is the ITPGRFA or international treaty related to prangenetic resources for food and agriculture which deals with the agricultural crops that are having importance in relation to food security. So while Nagoya protocol recognize the rights of countries over their genetic

resources special consideration has to be given to those resources which are necessary for the purpose of food security. That is why article 8 urges the member countries to adopt special considerations in case of such genetic resources. Article 9 speaks about the contribution to conservation and sustainable use.

The parties to the Nagoya protocol shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and sustainable use of its components. Article 10 and article 11 speaks of two different scenarios were obtaining the prior informed consent in accordance with the domestic legislation or establishment of mutually agreed terms for the access of genetic resource or traditional knowledge may not be possible. So there could be certain scenarios were it is impossible to grant or obtained prior informed consent of a genetic resource. So this could be scenarios were the place from where the genetic resource or traditional knowledge is going to be accessed is outside the national jurisdiction of a party to the CVD. So in such scenarios a global multilateral beneficiary mechanism is more desirable.

The benefits shared by users of genetic resources and traditional knowledge associated with genetic resource through this mechanism shall be used to support conservation of biological diversity and sustainable use of its components globally. So article 10 speaks of a scenario were obtaining the prior informed consent of a country may not be possible. So this could be scenarios were the places from where genetic resource or traditional knowledge is accessed is outside the national jurisdiction of any country. So one example could be high seas or similar other places where no country in the world has national jurisdiction. So such places are outside the scope of conventional biological diversity.

So in order to address access from such places article 10 speaks of adopting a global multilateral beneficiary mechanism. Similar to this there could be scenarios were the same genetic resource are found inside to within the territory of more than one party. So in such cases article 11 urges the states to cooperate as appropriate with the involvement of indigenous or local communities for implementing the protocol. Similarly where the same traditional knowledge associated with genetic resource is shared by one or more of indigenous or local communities in several parties those parties shall endeavor to cooperate with the involvement of indigenous and local communities for implementing the objectives of the protocol. So in scenarios were the genetic resource or the traditional knowledge is having a trans boundary in nature that is the same genetic resource or traditional knowledge is occurring in the jurisdiction of several different countries.

So in such scenarios the prior informed consent or compliance with the domestic legislation of one single country may not be appropriate. So in such scenarios the country shall cooperate and provide for trans boundary cooperation in order to implement the protocol

in a better manner. Compliance with domestic legislation or regulatory requirements on access and benefit sharing is provided in article 15 of the protocol. Each country shall take appropriate effective and proportionate legislative administrative and policy measure to provide that genetic resource utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established. Party shall take appropriate effective and proportionate measures to address situations of non complaints.

Party shall as far as possible cooperate in cases of alleged violation of domestic access and benefit sharing regulation or regulatory requirements under the protocol. So article 15 speaks of user country measures which every country which is party to the Nagay protocol shall adopt. So this means that each party of the Nagay protocol shall take appropriate effective and proportionate legislative administrative or policy measure in order to provide that genetic resources which are utilized within their jurisdiction. So this means the genetic resource would have originated from another country and now it is brought into a country where it is going to be utilized. So the genetic resource may be of foreign nature.

So in such scenarios the country where the utilization is happening shall have a domestic framework which requires that the utilization of the genetic resource shall be in accordance with the regulatory requirements of the provider country. So in order to address situations of non compliance the user country measures shall provide appropriate effective and proportionate remedies and the party shall as far as possible and as appropriate cooperate in cases of alleged violation of domestic ABS regulations or regulatory requirements. Complaints with domestic legislation or regulatory requirements on ABS for traditional knowledge is given in article 16. So similar to what happens in the case of genetic resources with regard to traditional knowledge also every country which is party to the Nagay protocol has an obligation to adopt user country measures. So the user country measures in every country will require that access to traditional knowledge and its utilization shall be subject to the domestic regulatory requirements of the provider country.

Provider country means the country from where the genetic resource is accessed and every party to the Nagay protocol shall also adopt appropriate effective and proportionate measures to address situations of non compliance. And in case of alleged violation of domestic access and beneficiary regulations the parties to Nagay protocol has an obligation under article 16 to appropriately cooperate. Monitoring the utilization of genetic resources is given in article 17 of the Nagay protocol. Each party to the Nagay protocol shall take measures as appropriate to monitor and to enhance transparency about the utilization of genetic resources. The designation of one or more checkpoints is required as part of the user country measures.

The designated checkpoints would collect or receive as appropriate relevant information related to the prior informed consent to the source of the genetic resource and to the establishment of mutually agreed terms. Each party shall as appropriate and depending on the particular characteristics of the designate checkpoint require users of genetic resource to provide information related to the access and utilization of the genetic resource. Such information including the internationally recognized certificate of compliance or other confidential information that is provided to relevant national authorities or the party providing prior informed consent and to access and beneficiary clearing house as appropriate. The checkpoints must be effective and should have functions relevant to the implementation of the protocol. The country shall also encourage users and providers of genetic resource to include provisions in mutually agreed terms that requires sharing of information on the implementation of such systems including through reporting requirements.

The party shall also encourage the use of cost effective communication tools and systems. So, in effect article 17 of the Nagay protocol requires every member country to institute checkpoints. So, the checkpoints will be regulatory bodies which have some relation to the activities which are associated with the utilization of genetic resource. So, every country through a national legislation will designate checkpoint whose role is to collect information regarding the utilization of genetic resource and the following of domestic ABS requirements like the prior informed consent and establishment of mutually agreed terms. Article 17 of the Nagay protocol deals with the requirement of submitting internationally recognized certificate or any other document to the checkpoints.

So, when a utilization of a genetic resource happens the checkpoint will ask information regarding compliance with the domestic ABS legislations. So, and in such situations the user will have to either submit the internationally recognized certificate of compliance which is an evidence of obtaining the genetic resource by following the requirements of prior informed consent and establishment of mutually agreed terms. So, in case the internationally recognized certificate of compliance shall contain the following minimum information if it is not confidential. So, the IRCC will have information regarding the issuing authority, the date of issuance, the details of the provider that is the person or the country which is providing the genetic resource, the unique identifier of the certificate which is a unique number, the person or entity to whom prior informed consent was granted. So, that is the person who is going to be the user of the genetic resource.

The subject matter or genetic resource covered under the certificate. So, is it a genetic resource or a traditional knowledge and the nature of such genetic resource or traditional knowledge also has to be clearly specified in the IRCC. The IRCC shall also contain confirmation that the mutually agreed terms have been established and similarly

confirmation regarding prior informed consent or establishing of PIC shall also be given in the IRCC. The IRCC shall also give information as to whether the utilization is commercial or non-commercial in nature. Compliance with mutually agreed terms is provided in article 18 of the Nagoya Protocol.

Each party shall encourage providers and users of genetic resource and traditional knowledge associated with genetic resource to include provisions in mutually agreed terms to cover provisions like dispute resolution which includes the jurisdictions to which they will subject any dispute resolution processes, the applicable law, the options of alternative dispute resolution. So, while entering into the mutually agreed terms, the parties also shall have to contemplate situations where there is a chance of a dispute arising between the users and providers. So, in order to address such disputes, the mutually agreed terms shall provide the jurisdiction to which the parties will subject in case of any dispute, the applicable law, the option regarding alternative dispute resolution. Each party shall ensure that opportunity to seek recourse is available under their legal system and which is also consistent with the applicable jurisdictional requirements. Each party to the Nagoya Protocol shall take effective measures regarding access to justice and the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

To conclude, the Convention on Biological Diversity and the Nagoya Protocol constitutes the international legal framework for the access to genetic resources and traditional knowledge and the fair and equitable sharing of benefits arising from their utilization. The protocol casts the obligation on the signatories to take appropriate legal measures to ensure compliance with the domestic ABS legislations of the provider country. The parties shall have to take legal administrative or policy measures in the form of user country measures and notify checkpoints to comply with this obligation under the Nagoya Protocol. The references with regard to this lecture can be seen here. Thank you very much for listening to the lecture. I hope you are all enjoying the course.