

Biodiversity Protection, Farmers and Breeders Right

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Lecture 36 : Compliance Procedures in EU

Welcome to the course on Biodiversity Protection Farmer's and Breeder's rights. This lecture will be about the compliance, procedures in the European Union. The concepts covered in this lecture are subject matters regulated, scope of regulation, uses of genetic resources, access and utilization under the European Union regulations, obligations of users, monitoring user complaints, competent authorities and the focal point. The keywords of this lecture are European Union, competent authorities, focal point, monitoring user complaints and user country measures. The European Union and many of its 27 member states are parties to the conventional biological diversity and the Nagoya Protocol. Regulation 511 bar 2014 implements the Nagoya Protocol within the European Union.

The objective of the regulation are to protect the rights of countries and of indigenous and local communities that allow their genetic resource and associated traditional knowledge to be used while also giving the researchers in Europe improved simple and reliable access to quality samples of genetic resources. So, in effect the 2014 regulations implements the Nagoya Protocol within the European Union. It provides for an improved simple and reliable access procedures. The regulation obliges the users to check the genetic resources and associated traditional knowledge have been accessed in accordance with the applicable legal requirements in the country of origin and that the benefits are fairly and equitably shared.

The users are thus obliged to declare that they have exercised the due diligence required by the regulation. The users found in breach of the regulation would be exposed to sanctions under the domestic law of the member states of the European Union. So, the regulation in effect requires the parties to follow the standard of due diligence while accessing genetic resource and associated traditional knowledge for the purpose of research or any other utilization. The regulation aims to help the researchers and the industry to comply with the rules. Formal best practices will play an important role and association of users may request formal recognition of best practices on access and benefit sharing building upon the existing access and benefit sharing codes of conduct for the academic sector and for different industries.

The EU register of trusted collections such as seed banks and botanical gardens would be established in accordance with the 2014 regulations identifying the collections committed

to supplying only fully documented samples of genetic resources. The users acquiring this research material from a trusted collection would be considered to have complied with most of the due diligence obligations. The European Union platform would also be set up to streamline access conditions within the member states. The regulation establishes rules governing the compliance with access and benefit sharing for genetic resources and traditional knowledge associated with genetic resources in accordance with the provisions of Nagoya protocol and the convention on biological diversity. So, more than developing a national legal framework for regulating the genetic resources within the national jurisdiction, the European Union 2014 regulations is in the form of user country measures.

So, this requires the member countries of the European Union to adopt regulations that requires that any user within the European Union who is accessing a material from outside would have to comply with the regulatory requirements of the provider country. The regulation establishes rules governing compliance with access and benefit sharing for genetic resource and traditional knowledge associated with genetic resource in accordance with the provisions of Nagoya protocol. The effective implementation of this regulation will contribute to conservation of biological diversity and sustainable use of its components in accordance with the convention on biological diversity. The main subject matters that are regulated under the 2014 regulations are the genetic resource and the traditional knowledge which is associated with the genetic resource. The regulation applies to genetic resources over which the states exercise sovereign rights and to traditional knowledge associated with genetic resource that are accessed after entry into force of the Nagoya protocol.

It also applies to benefits arising from the utilization of such genetic resources and traditional knowledge. The regulation does not apply to genetic resources for which access and benefit sharing is governed by specialized international instruments that are consistent with and do not run counter to the objectives of the CBD or the Nagoya protocol. So, the regulation in effect covers genetic resources which are within the sovereign jurisdiction of any member country to the CBD. It also covers traditional knowledge associated with genetic resource which are accessed from indigenous people or local communities. The regulation will not apply to scenarios where there is access and benefit sharing regulations which are governed by specialized international instruments.

An apt example would be the international treaty of plangenetic resources which provides for a multilateral benefit sharing requirements. The regulation is without prejudice to member states rules on access to genetic resource or which they exercise sovereign rights. So, in effect the 2014 regulation does not speak about the genetic resource which are within the sovereign jurisdiction of the member states of European Union, but it only covers the user country measures with regard to utilization of foreign genetic resources within the

European Union. The regulation applies to genetic resource and traditional knowledge which are accessed and benefit sharing regulation or regulatory requirements of the party to Nagoya protocol are applicable. So, it applies to genetic resource and traditional knowledge on which a domestic ABS legislation is applicable.

Nothing in the regulation obliges a member state to supply information the disclosure of which it considers contrary to the essential interest of security. The words genetic resources and genetic material are defined in the 2014 regulations. Genetic resources means genetic material of actual or potential value. Genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity. So, that means, genetic resource in effect covers everything which comes under the meaning of the word genetic material.

And genetic material is given a definition in order to cover everything under the sun which is having a form of life. Access is another word which is used in the operative provisions of the 2014 regulations. Access is what determines whether a person becomes user of genetic resource or not. Access means acquisition of genetic resource or traditional knowledge associated with genetic resource in a party to the Nagoya protocol. User is a person who has obligations under the 2014 regulations.

The user means a natural or legal person that utilizes genetic resources or traditional knowledge associated with genetic resource. Utilization of genetic resource is what triggers the obligations under the 2014 regulations. Utilization of genetic resource is also defined. It means to conduct research and development on the genetic and biochemical composition of genetic resources including through application of biotechnology. Illegally access genetic resources is what attracts sanction under the 2014 regulations.

Illegally access genetic resource means genetic resource and traditional knowledge associated with genetic resource which were not accessed in accordance with national access and beneficiary legislation or the regulatory requirements of the provider country. So, illegally accessed genetic resource constitutes an action which can attract sanction under the 2014 regulations. Collection means a set of collected samples of genetic resource and related information that is accumulated and stored whether held by public or private entities. So, collection in effect means culture collections that retain samples of genetic resource. It can be either public or private collections.

The obligations of the users is also specified in the 2014 regulations. The users are required to exercise due diligence to ascertain that genetic resource and traditional knowledge associated with genetic resource which they have utilized have been accessed in accordance with applicable access and beneficiary legislation or regulatory requirements

and the benefits are fairly and equitably shared in accordance with mutually agreed terms and the domestic regulatory requirements of the provider country. Genetic resources and traditional knowledge associated with genetic resource shall only be transferred and utilized in accordance with mutually agreed terms if they are required by the applicable legislation or the regulatory requirements under the domestic legal framework of the provider country. The obligations of the users is also provided in the 2014 regulations. The users shall seek, keep and transfer to subsequent users the internationally recognized certificate of compliance as well as information on the content of mutually agreed terms relevant for the subsequent users.

So, the regulation covers the users as well as the other users to whom the present users have transferred the genetic material. So, users have an obligation to seek, keep and transfer to subsequent users the IRCC or the internationally recognized certificate of compliance and also the information on the content of the mutually agreed terms. In scenarios where the IRCC or internationally recognized certificate of compliance is not available in such situations other relevant documents which mentions the date and place of access of genetic resource or the traditional knowledge, the description of genetic resource or traditional knowledge, the source from which genetic resource or traditional knowledge has been directly obtained as well as subsequent uses of genetic resource, then the presence or absence of rights and obligations related to access and benefits sharing, the access permits wherever applicable and the mutually agreed terms including benefit sharing arrangements were applicable. So, such documents which have all this information shall also be sought and kept by the users and in case of transferring the genetic material to a subsequent users these documents shall also be transferred to the subsequent users of the genetic resource. When the information in their possession is insufficient or if there are uncertainties about the legality of access and utilization, then the users shall obtain an access permit or its equivalent and establish mutually agreed terms or discontinue the utilization.

So, in case a person is possessing the genetic material and there is insufficiency of information or uncertainty with regard to the legality of access, then in such cases he shall obtain the access permit or its equivalent and try to establish the mutually agreed terms. But if obtaining the access permit or establishing the mutually agreed terms is not possible or difficult, then he shall immediately discontinue the utilization of the genetic resource. The users shall keep the information relevant to access and benefit sharing for 20 years after the period of utilization ends. So, that means, even after the period of utilization ends the users shall have an obligation to keep the documents for a period of 20 years. The users obtaining a genetic resource from the collections including in the register of collections within the union referred to in the 2014 regulations will be considered to have exercised due diligence with regard to the regulation.

The register of collections is also provided in the 2014 regulations. The commission shall establish and maintain a register of collections within the union. The commission shall ensure that the register is internet based and is easily accessible for the users. The register shall include references of collections of genetic resource and of parts of those collections identified as meeting the criteria under the 2014 regulations. A member state shall upon the request by the collection holder under its jurisdiction consider the inclusion of that collection in the register.

So, in case a culture collection request the member state to include their name in the culture collection in the list of collection collections or the register of collections, then the member state shall verify the collection and see whether they meets the criteria set out in the 2014 regulations. And in scenarios were they meets the criteria the member state shall notify the commission without any undue delay about the name and contact details of the collection or its holder and the type of culture collection. The commission shall then include the information received from the member state in the register of collections. In order for a collection or a part of collection to be included in the register the collection shall demonstrate its capacity to apply standardized procedure for exchanging the samples, supply of genetic resource and related information to the third parties, the keeping of records of all samples of genetic resource and related information to the third parties, establishing and using unique identifiers wherever possible for identifying the genetic samples, use of appropriate tracking and monitoring tools for exchanging samples of genetic resource and related information between the collections. The member states shall regularly verify that each collection or part of the collection under its jurisdiction which is included in the register of collections meets the criteria that are mentioned in the 2014 regulations.

But and in scenarios were there is an evidence on the basis of information that a collection or a part of collection does not meet the criteria which is mentioned in the 2014 regulations. So, in such cases the member state shall have a dialogue with the culture collection holder and without undue delay identify remedial actions or measures. A member state which determines that a collection or a part of collection no longer complies with the regulation has an obligation to immediately inform the commission about this non-compliance. Upon receipt of that information the commission can remove that name of the culture collection from the register of collections which is maintained under the 2014 regulations. Competent authorities and focal point is also provided in 2014 regulations.

Each member state shall designate one or more competent authorities to be responsible for the application of the regulation. Member state shall notify the commission of the name and addresses of the competent authorities as of the date of entry into force of this

regulation. Member state shall inform the commission without any undue delay of any changes in name and address of the competent authorities. So, every member state shall designate competent authorities and focal point for enforcement of 2014 regulations. Their names shall be notified to the commission for their information.

The commission shall make public including via internet the list of competent authorities of the member states. The commission shall keep the list up to date. The commission shall also designate a focal point on access and benefit sharing who will be responsible for listening with the secretariat of the convention with regard to matters covered by the 2014 regulations. The monitoring of user compliance is also provided in the 2014 EU regulations. The member states and the commission shall request all recipients of research funding involving the utilization of genetic resource and traditional knowledge to declare that they have exercised due diligence.

So, every recipient of research funding in the European Union whose research involves utilization of genetic resource or traditional knowledge has an obligation to declare that they have exercised due diligence. Similarly, at the stage of final product development of a product which is developed via utilization of genetic resource or traditional knowledge, the user shall have an obligation to declare that they have complied with the 2014 regulations. Along with the declaration, they shall also submit information relevant like the internationally certificate internationally recognized certificate of compliance or the IRCC and the information related to establishment of mutually agreed terms. The users shall also provide evidence to the competent authority upon request. So, competent authority is empowered to seek evidence regarding establishment of mutually agreed terms and securing of internationally recognized certificate of compliance.

So, in case the competent authority asks, the users have an obligation to provide these evidences. The competent authorities shall transmit the information received to the access and benefit sharing clearinghouse. So, once the competent authority in a EU member state receives information regarding utilization of a genetic resource or traditional knowledge, they have an obligation to transmit the information to the ABS clearinghouse. The competent authorities shall cooperate with the access and benefit sharing clearinghouse to ensure the exchange of information. The competent authorities shall take due account of the respect of confidentiality of commercial or industrial information, where such confidentiality is provided by the union or national law to protect a legitimate economic interest.

Checks in user compliance is also provided in the 2014 EU regulations. The competent authorities under the 2014 regulations shall carry out checks to verify whether the users are complying with the obligations under the 2014 regulations. Member states shall ensure

that checks carried out pursuant to the 2014 regulations are effective, proportionate, decisive and dictate cases of user non-compliance. The checks shall be conducted in accordance with a periodically reviewed plan developed using risk based approach. When the competent authority is in possession of relevant information including on the basis of substantiated concerns provided by third parties regarding a user's non-compliance with the 2014 regulations, in such scenarios special consideration shall be given to such concerns raised by provider country.

So, a search or check shall be conducted in cases where a third party raises before the competent authority substantiated concerns regarding any non-compliance with the EU regulation. If the request for such check is coming from a provider country, then special consideration shall be given to such concern. The checks referred to in 2014 regulation may include examination of the measures taken by the user to exercise due diligence in accordance with 2014 regulations. Regulation and records that demonstrate the exercise of due diligence can also be verified. The instances where the user was obliged to make declarations under the 2014 regulation can also be examined.

On the spot checks may also be carried out as appropriate. Users shall have an obligation to offer all assistance necessary to facilitate the performance of checks as required under the 2014 EU regulations. Member states shall lay down rules on penalties applicable to infringement of the requirements under the 2014 EU regulations. The penalties provided by the member countries shall be effective, proportionate and dispositive. To conclude the European Union and most of the member states are parties to the CBD.

The regulation 2014 implements the Nagoya protocol within the European Union. The regulation aims to contribute to conservation of biological diversity and sustainable use of its components in accordance with provisions of the Convention on Biological Diversity. As regards to the scope these provisions apply to genetic resources or which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after entry into force of the Nagoya protocol for the European Union. It also applies to benefits arising from utilization of genetic resources and traditional knowledge associated with genetic resources. The references for this lecture can be seen here.

Thank you very much for listening to the lecture. I hope you are enjoying the course.