

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

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### **Lecture 35 : Compliance Procedures in India**

Welcome to the course on Biodiversity Protection, Farmers and Breeders Right. This lecture will be about the compliance procedures in India under the biodiversity governance framework. The concepts covered in this lecture are the Biological Diversity Act 2002, the 2002 legislation was recently amended in 2023. So, the Biological Diversity Amendment Act 2023 will also be covered in this lecture. The compliance procedures under the new act, the regulatory approval for research, the regulatory approval for commercial utilization, regulatory approval for obtaining of intellectual property rights will also be dealt in this lecture. The keywords of this lecture are biodiversity, compliance, regulatory law, patents and benefit sharing.

The legal framework for biodiversity governance in India was introduced in the year 2002 through the Biological Diversity Act 2002. Under the act there was biological diversity rules which came into force in 2004 at the central level and there were state rules which were notified by each state. So, the biodiversity governance framework under the Biological Diversity Act provided for a decentralized approach wherein some of the powers were vested with the central government and some of the powers were vested with the state governments. So, in accordance with the allocation of powers both the central government and the state governments had rule making powers.

So, in utilization of this power central government made the rules in 2004 and subsequently every state government made their own rules. The Biological Diversity Act 2002 was amended recently through the Biological Diversity Amendment Act 2023. So, the compliance procedures that exist under the present rules is based on the Biological Diversity Act 2002, but these provisions are expected to undergo some changes after the 2023 amendment takes effect. So, it is expected that there is going to be some changes in the Biological Diversity Rules at the central level and also at the state level. This lecture is based on the changes introduced through the 2023 amendment in the Biological Diversity Act 2002.

The Biological Diversity Act 2002 of even after it is the amendment in 2023 provides for a biodiversity governance framework which is depicted in this picture. So, if any component of biodiversity which is defined as bio resource in the Biological Diversity Act

is utilized for the purpose of research, transferring of research results, commercial utilization, bio survey, bio utilization or for obtaining of intellectual property rights. Then regulatory approval has to be taken either from the national biodiversity authority or the state biodiversity board in accordance with the legal status of the proposed user. Before the 2023 amendment prior approval was required for each of these activities, but 2023 amendment has diluted these provisions to some extent and now replaced some of the provisions which required prior approval earlier with intimation or registration. But in effect most of these activities even now after the 2023 amendment also requires regulatory approval either from the national biodiversity authority or from the state biodiversity board.

So, once the national biodiversity authority or the state biodiversity board decides to grant the approval, the approval will be in the form of a written agreement which will be on a stamp paper. So, once the agreement is executed the agreement will have certain terms and conditions which defines the rights and obligations of the user and the provider of resource. It will also deal with the benefit sharing component that is the quantum of benefits that the user of biodiversity will have to share after the utilization happens. So, once the utilization happens the benefit will have to be shared to either the national biodiversity authority or the state biodiversity board as given in the written agreement. So, once the NBA or the SBB receives the benefit it will be credited to a fund which is known as national biodiversity fund.

So, once it is credited it can be used for channeling the benefits to benefit climbers. So, if a benefit climber is identifiable then the amount can be directly given to the benefit climber, but if a benefit climber is not identifiable then it can be used for conservation and promotion of the bio resource. And in some cases it can be used for socioeconomic development of the areas from where the resource is collected also. Now, the 2023 amendment has included one more provision which allows the national biodiversity authority to utilize the fund to for activities to meet the purposes of the act. Now, let us see what are the significant changes made by the 2023 amendment to the biological diversity act.

One of the significant change is the difference in classification under section 3 2. Section 3 2 is one of the important provisions in the biological diversity act which determines whether the user has to take the approval from the state biodiversity board or the national biodiversity authority for commercial utilization. It also determines whether the user has to take prior approval for the purpose of doing research. If the user is a person or a individual or a entity which is coming under the section 3 2, then they have to take approval even for doing research. But if it is an individual or an entity which is not coming under section 3 2, then they have to take approval only for commercial utilization that too from

the state biodiversity board.

They are free to do research without taking any approval. Now, after the 2023 amendment section 3 2 and its definitive criteria have been changed to foreign citizens, non resident Indians and companies which are registered in a foreign country and companies which are registered in India, but which are controlled by a foreigner. Before the amendment it covered only companies which are having foreign shareholding in participation or management which meant that even companies with a insignificant percentage of shareholding will also come under the section 3 2, whereby they are required to take prior approval even for the purpose of doing research. So, now companies even if they are having some foreign shareholding or foreign participation in management, if they are not controlled by a foreigner as meant by the companies act, they does not have to take approval for doing research, but they have to take the approval for doing commercial utilization from the state biodiversity board. But if it is a company which is in effect controlled by a foreigner as defined in the companies act, then they have to take approval for doing research and also for doing commercial utilization from the national biodiversity authority.

So, this significant change is going to enhance the regulatory jurisdiction of the state biodiversity boards. Before the amendment only Indian citizens and companies which are registered in India and does not having any foreign participation only had to go to the state biodiversity board. So, the jurisdiction of the state biodiversity boards were very limited before the 2023 amendments, but now the regulatory jurisdiction of the state biodiversity boards is going to be much wider after the 2023 amendment. Another significant change that happened in the 2023 amendment is the inclusion of the definition codified traditional knowledge. Codified traditional knowledge is defined to mean the knowledge derived from authority books specified in the first schedule to the drugs and cosmetic act.

So, codified traditional knowledge does not have the common meaning it has in the contemporary context, but it means only knowledge that is existing in the authoritative text books that are given in the first schedule of the drugs and cosmetic act. The purpose of this definition is that whatever constitutes codified traditional knowledge as defined in section 2 clause EA will be exempted for Indians. So, before the 2023 amendments Indians were free to do commercial utilization using Indian traditional knowledge without taking any approval. Approval of state biodiversity boards were required only for the purpose of accessing bio resources for doing commercial utilization. So, in effect for Indians there was no regulation on traditional knowledge under section 7, but of course they had to take approval if they are planning to obtain any intellectual property rights.

But now the newly amended section 7 under the 2023 amendment increases the regulatory

scope for the state biodiversity board by making it mandatory even for Indians to take the approval from state biodiversity board if they are accessing traditional knowledge for commercial utilization. The only exception is when they are accessing codified traditional knowledge as defined in section 2 clause EA. So, this means that the 2023 amendment increases the regulatory scope by making it mandatory even for Indians to take regulatory approval if they are planning to use traditional knowledge for commercial utilization. Another significant change is access to traditional knowledge for commercial utilization by Indians made a regulatory regulated subject matter under section 7 of the biological diversity act. Another notable change is defining of the word India in section 2 GB of the biological diversity act.

Before the 2023 amendment the biological diversity act had only very limited jurisdiction as it was not extending beyond the territorial waters. But now India is defined in the biological diversity act to mean to include territorial waters, sea bed, subsoil underlying such waters, continental shelf, exclusive economic zone, any other maritime zone as referred in territorial waters, continental shelf, exclusive economic zone and other maritime zones act 1976 and the air space above its territory. So, in effect the defining the word India will in effect extend the scope and jurisdiction of biological diversity act to the continental shelf, exclusive economic zone and to air space above the terrestrial limit of India. Another significant change is exemption of registered Ayush practitioners under section 7. Section 7 before the 2023 amendments required in giving of intimation by Indian citizens and Indian companies if they are planning to do commercial utilization using Indian bio resources.

Now registered IUS practitioners are explicitly exempted from the purview of section 7. So, this means that registered IUS practitioners does not require approval if they are planning to do commercial utilization using Indian bio resource. Similarly another notable exemption is with regard to section 6 which deals with regulation of intellectual property rights. Before the 2023 amendments any person who is desirous of taking intellectual property right for an invention which is based on research or information on a biological resource which is obtained from India had to take prior approval from the national biodiversity authority. So, now there is a significant change brought in under the 2023 amendments and now Indian citizens or Indian companies who are not coming under the scope of section 3 2 have to only do a registration before they apply for the patent.

So, once the patent is granted and when they go for commercialization they have to take the prior approval from the national biodiversity authority. But if it is a foreigner or a foreign company or a company which is coming under the scope of section 3 2 is planning to take intellectual property rights then they have to take prior approval from the national biodiversity authority. So, in effect section 6 which is amended under the 2023 amendment

simplifies the approval process for Indian citizens and Indian companies who are not coming under section 3 2. So, now Indians and Indian companies have to only register the details while they are taking any intellectual property right and after the grant of the patent when they go for commercial utilization they have to take prior approval from the national biodiversity authority. So, thus the most notable aspect with regard to the 2023 amendment is the classifications under section 3 2.

Now, section 3 2 has been given a definition under the 2023 amendment which covers a person who is not a citizen of India. So, before the 2023 amendment also the position was the same. So, a foreigner or a citizen of a country outside India is coming under the scope of section 3 2. Similarly a citizen of India who is non-resident is also covered under section 3 2 these provisions has not been amended in the 2023 amendment. Similarly a body corporate association or organization which is not incorporated or registered in India that means a company which is incorporated outside India or in a foreign country or a company which is registered in another country meaning a foreign company is coming under the scope of section 3 2.

So, a person who is not a citizen of India, a person who is a non-resident Indian, a foreign company that is an institution or a company or an entity which is incorporated or registered in a foreign country was coming under section 3 2 even before the 2023 amendment. Now a body corporate association or organization which is incorporated or registered in India under any law for the time being enforced which is controlled by a foreigner within the meaning of clause 27 of section 2 of the companies act 2013 is coming under the scope of section 3 2. So, this means that a company which is incorporated or registered in a foreign country automatically comes under section 3 2, but even if the company is incorporated or registered in India that is registered under the companies act 2013 or any law which is enforced in India, but if it is controlled by a foreigner within the meaning of companies act then they will also be treated as a section 3 2 entity. The regulatory approval for Indians and Indian institutions can be seen here. So, if the user is an Indian citizen who is not a non-resident Indian or a Indian institution or an entity or a company which is incorporated or registered in India or which is registered or incorporated in India which is not controlled by a foreigner then they have to follow the regulatory approval process given here.

So, in such cases they does not need any approval for doing research. So, they are free to do research without taking any approval. If they want to do commercial utilization they have to take the prior approval from the state biodiversity board. After doing research for which they does not have to take any approval they are planning to transfer the research results to a section 3(2) entity. So, that is after doing the research now they want to transfer the research results. So, in such case they have to take the prior approval from the national biodiversity authority. In case of planning to obtaining any intellectual property rights they

have to register with the national biodiversity authority. So, instead of prior approval only registration is required, but if they are planning to do commercialization of the intellectual property rights then for that they have to take the prior approval from the national biodiversity authority. So, for intellectual property rights only registration is required, but after the grant if they are planning for commercialization of the intellectual property rights for that purpose they have to take prior approval.

If the user is a foreign citizen that is citizen of a foreign country or a non-resident Indian or a body corporate or association or organization which is not incorporated or registered in India meaning a company which is foreign in nature that is incorporated or registered in a foreign country or if it is incorporated or registered in India under any law for the time being in force which is controlled by a foreigner. So, even if it is registered or incorporated in India, but it is still controlled by a foreigner then they have to follow the regulatory approval course which is mentioned here. So, that means, for research they have to take prior approval from the national biodiversity authority. So, this is the significant difference with regard to section 3(2) companies and non companies. So, if they are not coming under section 3.2 they does not require any approval for doing research, but if they are coming under section 3.2 then they have to take prior approval even for doing research. For commercial utilization if it is not a section 3.2 company they had to take approval only from the state biodiversity board, but if they are coming within the scope of section 3(2) then they have to take prior approval from the national biodiversity authority. Similarly, after obtaining the bio resource now they want to transfer the biological resource to a foreign entity then they have to take prior approval from the national biodiversity authority. Similarly, they want to obtain an intellectual property right now they have to take prior approval from the national biodiversity authority. The e-filing of ABS applications can now be done through the online portal. This was officially launched on 30th March 2017 by Sri Anil Mathaodhav the then honorable minister of state for environment forest and climate change.

The ABS e-filing portal is hosted in national biodiversity authorities website which serves as an online platform for submission of applications seeking approval of NBA for various activities. This institution of online application process has now transformed the ABS application process from a physical filing and now it is not at all required for the users to file applications in a physical format meaning that they can file the application from anywhere around the world. But it has to be noted that the online application portal was developed before the 2023 amendment. So, this has to the forms and other aspects of the online application portal has to undergo some change in order to make it compliant with the 2023 amendment. The e-filing of ABS application portal which is the ABS e-filing portal is having a very user friendly architecture.

The login page is facilitated with a know your application wizard. So, if a person does not know which form he has to use he can always use the application wizard and try to understand the form which is applicable for him. The portal is also having a video tutorial which helps the applicant to easily understand the implications of the portal. There is a user manual instruction and contact details of help desk is also given in the portal. The ABS e-filing portal provides the user with a business friendly application portal.

It helps the NBA in decision making and also helps in collecting complete information which facilitates monitoring. The new portal is in compliance with the making India policy and digital India initiative of the government of India. These are the different forms which the applicant has to use for taking the approval from the national biodiversity authority and the state biodiversity boards. These forms are given in the biological diversity rules 2004. However, after the 2023 amendment changes are expected in the forms and even in the fees.

Form 1 as of now is covering research, biosurvey and bioutilization and commercial utilization. So, form 1 is applicable for foreign citizens, foreign companies who are coming under section 3.2. They have to take the approval from the national biodiversity authority for research, biosurvey and bioutilization and commercial utilization. They have to apply in form 1 by paying the prescribed fees of rupees 10,000.

Form 2 is applicable in case of transfer of research results. So, for transfer of research results form number 2 has to be used and a fee of rupees 5000 has to be paid. Form 4 is applicable for third party transfer of already accessed bio resource or knowledge. So, if a person who has already accessed the resource want to transfer the bio resource or the knowledge to a third party, then they have to apply in form 4 and have to pay a fee of rupees 5000. Form B deals with sending or carrying of bio resources outside India for non-commercial research and emergency purpose.

There is no fee which is applicable for form B. So, form B can be filed without payment of any fee. However, it has to be noted that all these forms may undergo some change when the rules are modified to meet the requirements of 2023 amendments. The SBB forms or the forms for filing an application under section 7 will be given in the state rules. The form number 1 to 4 mentioned here are given in the biological diversity rules 2004 and form B is mentioned in the ABS guidelines which was notified in 2014. The processing of ABS applications happens through a procedure which is depicted here.

Once the application is received, a preliminary scrutiny will be done by the ABS help desk. So, ABS help desk will go through the application and see whether there is any material defect in the application. Now all the applications are received through online and the

processing also happens through online e office portal. So, once the preliminary scrutiny is over, then the legal and scientific review of the application will be done. So, legal and scientific analysis of the contents of the application will be done in order to see whether the request can be approved or not.

If required, the National Biodiversity Authority will consult with an expert committee especially in cases where there is no clarity with regard to the sustainability of the proposed project or if there is some confusion with regard to the availability of the species which is going to be used. So, in such cases the regulatory authorities can consult with expert committees. So, once the decision is taken to approve the application, a draft agreement is sent to the user for execution. But if a decision is taken to reject, then a rejection order will be issued to the applicant. Once the applicant whose application is approved receives the draft agreement, then he has to fill the draft agreement and send it back to the National Biodiversity Authority.

The draft agreement will have clauses regarding benefit sharing component, submission of yearly reports, do's and don'ts, the third party transfer, intellectual property right aspect, etc.

So, once the signed agreement is received in the office of the regulatory body, then they will approve the application. Once the application is approved, the information will also be uploaded into the ABS Clearing House portal of the CBD secretariat and an IRCC or internationally recognized certificate of compliance will be generated. This internationally recognized certificate and the mutually agreed terms which is established in the form of written agreement will constitute the evidence with regard to compliance with the Biological Diversity Act 2002 or the national legislation in India in compliance with the Convention on Biological Diversity and the Nagoya Protocol. To conclude, the compliance procedures are given in the Biological Diversity Act 2002, the rules which are the central rules notified in 2004 and the state rules which are notified by different states and the guidelines on access to biological resource and associated knowledge and benefit sharing regulations which was notified in 2014. The Biological Diversity Act of 2002 is now amended recently under the Biological Diversity Amendment Act 2023 with a view to simplify the compliance procedure and streamline the approval process.

So, this is going to significantly change the compliance procedures under the Biological Diversity Act, but this will require change in the rules at the central level, rules at the state level and also the guidelines on access to biological resources and associated knowledge and benefit sharing regulations which was initially issued in 2014. 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.