

Constitution of India and Environmental Governance: Administrative and Adjudicatory Process

Doctor M. K. Ramesh

Department of National Law School of India University

Indian Institute of Technology – Bengaluru

Lecture – 30

Indian Biodiversity Legal Framework

From the international discourse on biodiversity law we step into the Indian biodiversity legal regime. The genesis and evolution of the Indian Biodiversity Law is as fascinating, as engaging and as significant as the international one. It is also, in terms of impact, also having the similar kind of an impact as the international one has, a terrific coincidence.

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I. BIODIVERSITY ACT, 2002, RULES, 2004 AND REGULATIONS



I. OBJECTS & BACKGROUND :

- CONSERVATION; SUSTAINABLE USE; EQUITY IN ACCESS AND SHARING OF BENEFITS DERIVED FROM THE USE OF THE RESOURCE AND THE EMPLOYMENT OF KNOWLEDGES ASSOCIATED WITH THEM
- FULFILMENT OF INTL. OBLIGATIONS
- CODIFICATION AND CONSOLIDATION OF LAWS AND PRACTICES
- PREVENTION OF PIRACY; ENSURING SAFETY AND SECURITY
- ASSERTION AND PROTECTION OF SOVEREIGN RIGHTS AND INTERESTS

II. NATURE AND SCOPE :

- NOT AN EXCLUSIVE LAW ON BIODIVERSITY - IN ADDITION TO AND NOT IN DEROGATION OF FOREST AND WILDLIFE LAWS (S.59)
- IN TERMS OF EXTENT, SCOPE AND APPLICATION, THIS GOES BEYOND CBD- COVERS EVERY CONCEIVABLE "GENETIC MATERIAL" (-INCLUDING , "GENETIC MAPPING"), "WITH ACTUAL OR POTENTIAL USE OR VALUE"



Look at the objectives and the background. Conservation is the primary obligation to be performed and taken care of; sustainable use is another, equity in access and in sharing of benefits derived from the use of resource and the knowledges associated with them. These actually constituted the objectives of the international one same is here as well and having been a party to it, the objective is to fulfil that obligation through a legal description here.

And it is also an exercise in putting together as much as possible all the laws concerning biodiversity. Prevention of piracy, ensuring safety and security of bio safety is another primary concern and assertion of the sovereign right and interest from the state is something which is paramount in the entire scheme of things here. In terms of the scope and the nature

of this law, one must note that this is not a law which exhaustively deals with biodiversity.

In the sense that this is a law which by and large has an overarching and overwhelming presence, but this is not alone. In addition to this law we also have forest and wildlife laws which have been enforced in India since long and so this law is supposed to be complementary to and not opposed to or overriding anything that is contained in forest and wildlife laws.

So together the biodiversity law the forest and wildlife laws would constitute by and large the hub of the biodiversity law in India. Another significant feature that you should know in the Indian law is that this is the law which goes even beyond the international one, the conventional biological diversity both in its extent, scope and application because it covers every conceivable genetic material including genetic mapping which has an actual or potential value.

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- WHILE THE LATTER REFERS TO BIORESOURCES , IN A FAIRLY GENERAL SENSE BY THE USE OF THE EXPRESSION, "GENETIC RESOURCES"
- ALONG WITH FOREST AND WILDLIFE LAWS COVERS EVERYTHING RELATED TO LIFE (-OF COURSE, EXCLUDING HUMAN GENETIC MATERIAL, LIKE CBD)
- THE LAW DEALS WITH BOTH THE BIO-RESOURCE AND ASSOCIATED KNOWLEDGE, PRACTICE AND TRADITIONS
- RECOGNISES A NEW GROUP OF RIGHT HOLDERS -"BENEFIT CLAIMERS" – AND REWARDS THEM, FOR BEING CONSERVERS OF BIO-RESOURCES, CREATERS AND HOLDERS OF KNOWLEDGES AND TRADITIONS ASSOCIATED WITH ITS USE AND APPLICATION
- III. AUTHORITIES AND FUNCTIONS:
- A. CENTRAL GOVT : S.48: NBA BOUND BY THE DIRECTIONS ISSUED BY CG; S.60:-POWER TO GIVE DIRECTIONS TO STATE GOVT.;S.62:RULE-MAKING POWER; S.65:POWER TO MAKE REGULATIONS;



As far as CBD is concerned it refers only to bio resources in a fairly general sense of the term by use of the expression genetic resources. Along the forest and wildlife law it covers perhaps everything concerning life excluding human genetic material. The law deals with both the resource concerning life and also the associated knowledge and practices and traditions in relation to life and life forms.

The other stand out feature is that this is the law which recognizes another special group of right holders. The term used here is benefit claimers. A community of people who have been responsible for conserving, protecting bio resources created and holding of knowledges and traditions associated with its use and application. Benefit claimers, not only it recognizes them, it reminds them as well for the services that they have rendered overtime.

The authorities and their functions in terms of their administrative architecture, it is very simple. It is very similar to the pattern that you see in every other central laws that it has a three-tier governance system. At the apex level you have the central one, the Central Government, the National Biodiversity Authority, the nodal agency, at the state level where the state government and the state biodiversity law and at the primary law we have the Biodiversity Management committee.

The Central Government is the supreme authority which imposes all directions on the National Biodiversity Authority which is bound by these instructions and not only that the Central Government under this law has a power to give directions to the state government even. It has the rule making power and it has the power of making of regulations a problem all over India.

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S.36: TO DEVELOP NATIONAL STRATEGIES FOR CONSERVATION; S.37: POWER TO NOTIFY, AREAS OF BIODIVERSITY IMPORTANCE AS BIODIVERSITY HERITAGE SITES; S.38:POWER TO NOTIFY THREATENED SPECIES ;S.39:POWER TO DESIGNATE REPOSITORIES FOR DIFFERENT CATEGORIES OF BIORESOURCES; S.40:POWER TO EXEMPT CERTAIN BIORESOURCES THAT ARE NORMALLY TRADED AS COMMODITIES (NTAC)

B. NATIONAL BIODIVERSITY AUTHORITY (NBA): (a) ESTABLISHMENT 1. COMPOSITION- S.8 ; 2. TERM OF OFFICE- S.9; 3. CHAIRPERSON- S.10; 4. REMOVAL OF MEMBERS- S.11; 5. MEETINGS- S.12 ;6. COMMITTEES- S.13 – AGRO-BIODIVERSITY AND OTHER COMMITTEES 7.OFFICERS AND OTHER EMPLOYEES- s.14 ; 8. DELEGATION OF FUNCTIONS - S.16

(b) FUNCTIONS AND POWERS: 1.REGULATE AND GRANT APPROVALS (Ss. 3,4,6,18,19,20,21) (- DEALT IN DETAIL, LATER-); 2. ADVICE (C.G & S.G (S.18); 3. RIGHT TO OPPOSE GRANT OF IPR IN ANY COUNTRY (S.18)



The Central Government has the power to develop national strategies for conservation. It has the function of notification of areas of biodiversity importance as biodiversity heritage sites. It has the power of notifying threatened species, to designate repositories for different

categories of bio resources and it has the power to exempt certain bio resources to be out of the purview of this law by designating them as normally traded as commodities.

We will discuss it a little later. At the central level we have the National Biodiversity Authority and in terms of its establishment and composition it must be considered as a wonderful institution which brings within it both the experience and expertise in different areas concerning life and life forms. Every department in the government in some form or the other, which has something to do with life and life forms is represented here.

And so our fine experts who are drawn from different scales of human activity has something or the other to do with bio resources, knowledges associated with them in law and things like that they are also part of this National Biodiversity Authority. Their terms of offices are three years period and the chairperson is supposed to be someone who is well versed in this area of human knowledge and discipline and has sufficient experience in this regard.

And as for the removal of members are concerned, it follows the same pattern that one should not compromise ones position while holding this position as a member, should not become an interested party in any of the thing that has been dealt under this law, should not have conflict of interest situations, should not be an insolvent, should not be declared offender or anything like that and so not only you should be well versed with this area.

But should be of a clean character as to be entitled, to be considered, to be a member of this particular body. Most of the decisions of the biodiversity authority are carried down through the meetings held in the biodiversity authority and in terms of the quorum there is no such fixed quorum as such, but by and large it requires some members to be present and since there is no minimum quorum that has been fixed it can be under extreme circumstances in a special circumstance.

The chairman, the member secretary and a few other members can confer and then take a call. Most of their actions of the National Biodiversity Authority there is a unique feature of this law of this particular institution arrangement is it operates through various committee that it has established and each of these committee dealing with different sectors of activities something to do with endangered species, threatened species, a group that can be there for determining access and sharing of benefits like that different groups are constituted they are

called as committees and there is a special committee exclusively for agro-biodiversity and these are really the think tank of the National Biodiversity Authority and they deal with perhaps everything that the biodiversity authority would deal with and they come out with a recommendations and suggestions with the biodiversity authority.

And by and large the National Biodiversity Authority acts upon these recommendations and suggestions that are made by this committee. One of the most democratic institutions that you can ever think of and it also of course has its offices and other employees having a member secretary and they are quite a huge number of scientist and other researchers who work in this organization.

And many other functions in the National Biodiversity Authority can be delegated to any agency to perform on its behalf depending upon the kind of proficiency and expertise in that particular sphere, in that particular sector in which this particular law would operate. In terms of functions of the National Biodiversity Authority this is the real hub of activity it regulates and grant approvals.

We will deal with that in greater details a little later. It advises the Central Government and state government so it is a great trust in the entire area of biodiversity and it has another very special power as the representative of the sovereign country it can even oppose a grant of intellectual property rights with regard to any of these knowledges associated to bio resources in any country outside India.

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(c) FINANCE, ACCOUNTS AND AUDIT: Ch. VII Ss. 26,27,28,29,30.

(d) NBA BOUND BY THE DIRECTIONS OF CG(S.48)

(C) STATE GOVT. - S.37, 49, & 63

(D) STATE BIODIVERSITY BOARD (SBB):(a) ESTABLISHMENT AND COMPOSITION - S.22 ; (b) POWERS AND FUNCTIONS- Ss, 23, 24, 25 (- PRIOR INTIMATION ABOUT ACCESS AND SECURING APPROVALS, BY INDIANS-(S.7) ; REGULATION OF THE ACTIVITY- RULES- FORMS FOR APPROVALS

(c) FINANCE, ACCOUNTS AND AUDIT- Ch. VIII, Ss.31,32, 33,34 & 35.

(E) BIODIVERSITY MMT. COMMITTEE (BMC) :1. CONSTITUTION & FUNCTIONS – OUGHT TO BE CONSULTED BY NBA & SBB, WHILE TAKING ANY DECISION, OVER THE USE OF BIORESOURCES OR ASSOCIATED KNOWLEDGE, OCCURING WITH IN ITS AREA UNDER ITS PURVIEW – PREPARE AND MAINTAIN BIODIVERSITY REGISTERS- CAN LEVY ACCESS FEE FOR THE COLLECTION OF BIORESOURCE FOR COMMERCIAL PURPOSE (S.41); 2. LOCAL BIODIVERSITY FUND - Ss. 42, 43, 44, 45, 46, & 47.



There are provisions with regard to finance, accounts and audit that this as a concrete body has its own independent identity and it carries on its activity in its own name. It is independent on the members who compose it and it is subject to usual governmental requirement of transparency in matters of accounts and audit and things like that and the National Biodiversity Authority would all invariably follow the directions of the Central Government.

Although it advises the Central Government it is bound by the directions issued by the Central Government from time-to-time. Similarly, the same thing is replicated the state level, the state government and similar kind of functions at the state level it makes rules and regulations to be operable within that particular state of course coming within the parameter of central act and rules.

And the state biodiversity board has very similar function the national authority. It has the same kind of a composition very representative, full of proficient people, full of experience and drawn from different ministries and department and in terms of functions and powers very similar to that of National Biodiversity Authority. The only difference is the use of certain terminology.

But in terms of seeking permission for approval of accessing and making use of bio resources in India. The process is the same, but the expression used is different. In the case of National Biodiversity Authority, the expression used is that will make an application of a request for accessing and putting to use a bio resource of a knowledge associated with it, but here it is called as prior intimation and would access and securing approvals by the Indians.

But in terms of operations prior intimation has the same application as seeking prior approval before access and securing any kind of resource for different kind of uses by anyone. The difference between the state biodiversity board, the national authorities, the national authority deals with international issues and as far as the state biodiversity board is concerned it deals with the access by Indians.

We will deal with that a little later when we get into the regulation part. It also has a similar kind of an obligation to deal with its finances, accounts and audit as the national one. Most significant aspect of this law as we can notice is wonderful institution that has been created

under this law called a Biodiversity Management committee BMC for short. In terms of bringing this into existence the local body has the prime responsibilities of constituting this particular body.

But once it is constituted the Biodiversity Management committee manages things by itself. Although the membership is limited to the period of three years as per the rules here as far as the composition of the membership of this particular body there is no time limit that has been prescribed in the result that once constituted it is bound to be there to be for all times to come and by terms the members can select their own chairman who would be in office for a three year period and then later they somebody else might that position.

If there are any vacancies once again the local body would meet and then take a call in filling out those vacancies and this is one body which have to be consulted by the National Biodiversity Authority and the state biodiversity board by taking any decision over the use of bio resources or associated knowledge occurring within its area and its topic and this is the body which is supposed to be prepare and maintained biodiversity registers.

And it has one another significant function which even local bodies do not have and that is the power of levying what is called as access fee for collection of bio resources for commercial purposes. So, anybody accessing the bio resources they may need the permission from the state biodiversity board and the national authority as the case may be, but to access and take over the resources out of this local permits of this Biodiversity Management Committee, it has to pay in free which can be levied an appropriate for its own activities by the Biodiversity Management Committee

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- **IV. REGULATION OF ACCESS :**
- **A.ACCESS OF BIORESOURCE/KNOWLEDGE- FOR RESEARCH/COMMERCIAL UTILIZATION/BIO-SURVEY AND BIO-UTILISATION:**
- **1. INDIVIDUALS/OTHER LEGAL ENTITIES- WITH A FOREIGN ELEMENT:**
- **(a)APPLICATION TO NBA(S.3)- FORM I-FEE- DUE CONSULTATIONS- DISPOSAL WITH IN 6 MONTHS- APPROVAL IN THE FORM OF AN AGREEMENT (-RULE 14); REVOCATION (R.15); RESTRICTIONS- CIRCUMSTANCES (R.16);**
- **(b) TRANSFER OF RESULTS OF RESEARCH: WITH NBA APPROVAL(S.4)- APPLICATION TO NBA-IN FORM II- FEE-TO BE DECIDED UPON WITH IN 3 MONTHS(R.17); EXCEPTIONS (S.5) THIRD PARTY TRANSFERS - ONLY WITH NBA APPROVAL(S.20)-APPLICATION-FORM IV-FEE- 6MONTHS FOR DISPOSAL- PUBLIC NOTICE OF APPROVAL(R.19)**
- **-INTERNATIONAL COLLABORATIVE RESEARCH: EXEMPTION FROM**



It also has a local biodiversity fund the funding will come and most of the money that has been derived out of access and sharing of benefits 75 percent of that money either by the centre or at the state level will have to go to its Biodiversity Management committee. So when once it is constituted it becomes most richest audience at the local level that is the significant feature of this it will have financial autonomy and it will also have the presence in dealing with many other activities concerned in bio resources in sense of version is what has been in completed in the whole scheme of things as far as the Biodiversity Management committee is concerned.

Let us get into the details of the regulations. First one how does one access bio resources or the knowledge either for research or for commercial utilization or bio survey and bio utilization, any individual or a legal entity a corporate firm or anything like that which has a foreign element in its characteristic feature. It may be a foreign national, it may be an NRI or it may be a corporate firm which has certain foreign presence available.

Even one share by a foreigner in an Indian company would rank as an entity with a foreign element in it has to follow that procedure laid down here it has to apply to the National Biodiversity Authority. The individual or the corporate entity with a foreign element need have to apply to the National Biodiversity Authority for accessing and use of bio resources in a particular form by paying the fee that has been prescribed for that.

And after due consultations the application will be disposed within six months period by the National Biodiversity Authority and the industrial feature of this series the approvals of the

National Biodiversity Authority and even the state biodiversity board could not see like that will be in the form of an agreement. So, the approval in what terms? How? This will be negotiated and then there would be a clear contractual arrangement worked out.

And that becomes a binding obligation to be confined to by the one who is going to access the resources and from the authority when once it finds that the obligations that are prescribed in this terms of arrangement between the authority and the party is violated it can revoke or it can impose restrictions and it has to clearly spell out the circumstances under which these restrictions will operate.

Why it has been revoked with just proper reasons it has to decide on that. So nobody can access bio resources for either for a research or anything like that or even for a commercial purpose if that individual is a foreigner or an NRI or a corporate entity with a foreign element in it and the one who has been given the abolition let us assume for doing research, if the person who has derived some information on the basis of such research so carried out upon approval.

He has no right to transfer the results of the research the way he likes because in terms of the agreement he would have clearly stipulated that why for this research has been carried out and how it is going to be put into application. So, the permission that has been given to the person is exclusive and if there is going to be any transfer of the results of that research then once again one has to go back to the National Biodiversity Authority for approval.

Look you had given me this right I got these results I just would like to transfer it to a third party can I do that. NBA approval is required for which a particular form has to be filled in and this will be decided by the National Biodiversity Authority within a period of three months. There are exceptions to third-party transfers and these exceptions are clearly spent out in this law.

Wherein it has been found that in circumstances when these transfers are permitted under the rules under this particular law and that has been confirmed by the party there could be such a kind of transfer. Application should be in a particular form and approvals are otherwise will be given public notice. So, people would know who has the permission to do what kind of research and what is the resultant going to be obtained all that would come this into the

public domain and if there is a request from international collaborators as such by this particular kind of an entity.

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OBTAINING APPROVAL FROM NBA – BY OBSERVING THE GUIDELINES ISSUED IN 2006 (-S.5); IF THE RESULTS OF THE RESEARCH LEAD TO IPR, FURTHER REQUIREMENT OF ENTERING INTO AN AN AGREEMENT WITH NBA AND DEPOSITION OF VOUCHER SPECIMEN WITH DESIGNATED REPOSITORY (S.39); WHERE, IT WOULD INVOLVE EXCHANGE OR TRANSFER OF DEAD OR PRESERVED SPECIMEN ETC., FOR TAXONOMIC REASONS- ONLY WITH THE APPROVAL OF CONCERNED DEPT./MINISTRY; NO SHARING OF INFO. WITH /TRANSFER OF RESULTS TO THIRD PARTIES WITH OUT AN AGRMT. WITH NBA ; PUBLICATION OF RESULTS ONLY WITH PRIOR APPROVAL OF INDIAN COLLABORATOR AND AFTER ACKNOWLEDGING THE CONTRIBUTIONS OF KNOWLEDGE HOLDERS

- GENERATION OF NEW KNOWLEDGE DURING THE COURSE OF IMPLEMENTATION, TO BE REPORTED – TO NBA, FOR DOCUMENTATION PURPOSES



There can be an exemption for seeking and securing approval from National Biodiversity Authority. Certain guidelines that has been made in the year 2006 in this regard are observed by that party then you do not need that permission on the approval by the biodiversity authority, but if the results of the research later lead to a claim on an IPR, intellectual property right and you have to come back to the National Biodiversity Authority.

You have enter into an arrangement with the biodiversity authority, deposit the specimen with the designated repository and then after the permission is given can go for registration under the intellectual property rights authority. Supposing the collaborative research would involve exchange or transfer of dead or preserved specimen for taxonomic reasons then you do not have to come to the National Biodiversity Authority there are several ministries and department in the government which deal with that.

There are in agricultural research, in science and technology ministry, you have certain units that are being created for this particular purpose. get the approval from the designated department and that has been done there is no need for coming to the National Biodiversity Authority for any approval or anything like that. The information so secured and so obtained through this exchange cannot be shared or the results cannot be transferred to a third party without an agreement with National Biodiversity Authority.

This has been stressed time and again because many a times these violations occur because when permissions are sought permission are given for a particular purpose only and that is the right that you get out of this particular arrangement, but when once it has to be passed on to somebody it is not just easily transferable, transfer only through the approval process the same way in terms of entering into an agreement or thing like that with the National Biodiversity Authority.

And if the results are to be published then once again you have to require the prior approval of the Indian collaborator and after acknowledging the contributions of the knowledge holders and once that is done it has to be published internationally otherwise it will be a clear violation because one is that you need to have the approval of your Indian collaborator who has assisted you.

And second you need to have a very clear sense of gratitude towards the one who has actually contributed to the knowledge based in this regard and soon you have to acknowledge as well. Generation of new knowledge during the course of implementation has to be reported to the National Biodiversity Authority for the purposes of documentation because in the course of research you think that you follow particular trajectory of research and development and you expect certain results to be obtained and for which you have got the permissions.

But if something new unprecedented or are known to you emerges and that new knowledge also should be brought on board for documentation purposes till the National Biodiversity Authority.

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- DISCOVERY / DEVELOPMENT OF ANY NEW TAXON/BREED ETC. THROUGH PROJECT TO BE REPORTED TO NBA AND VOUCHER SPECIMEN OF THE SAME DEPOSITED WITH THE DESIGNATED REPOSITORY

- THROUGH THE GUIDELINES ISSUED IN 2015, NBA INTRODUCED A SPECIAL FORM (-FORM B) FOR THE INDIAN GOVT. RESEARCH INSTITUTES / SCIENTISTS, TO CARRY/SEND THE BIOLOGICAL RESOURCES, OUTSIDE INDIA FOR RESEARCH PURPOSES – GOVT. INSTITUTES MAY SEND THE BIOLOGICAL RESOURCES OUTSIDE INDIA TO CARRY OUT RESEARCH STUDIES TO AVERT EMERGENCIES LIKE, EPIDEMICS – FOR ALL THESE, THE NBA IS REQUIRED TO GIVE ITS APPROVAL OR OTHERWISE DECIDE, WITH IN 45 DAYS OF THE APPLICATION

- **2. INDIAN CITIZENS: - ACCESS AFTER INTIMATION (= APPLICATION), IN THE FORM PRESCRIBED FOR THE PURPOSE, TO SBB(-S.7)- EXCEPTIONS (PROVISO.S.7)- SBB'S POWER OF REGULATION OF ACTIVITIES(S.24(2))**



Supposing there is a discovery and development of a new taxon through project being so carried out then it has to be reported to the National Biodiversity Authority and the voucher specimen of the same should be designated to be deposited with the designated repository for that purpose. The reason why all these details are being given and as you can make out from the slide here is essentially to ensure that no resource, no research in relation to that, no knowledge associated with the bio resources are done clandestinely. Any information that is generated which are done clandestinely are to be taken out of this country and so abundant care and caution is shown in crafting of this law and the rules under this as to ensure that everything is above all, everything with permission, the sovereign rate of the state is not in any way affected and things like that and on the other government of India it is the National Biodiversity Authority which will perform all these functions.

Now what about the regulations for access for Indian citizens? This is far more simpler. In the case of Indian citizens this can be done only after making an application in a particular form prescribe for the purpose to the respective state biodiversity board. If you are accessing in the state of Karnataka then you have the state biodiversity board of Karnataka to which you have to give an application in order to go to the national authority.

So, for Indian it is easier approach the local the state level biodiversity board you do not have to go to the national authority. You know the difference the differences between something which is foreign and something Indian is that in the case of foreign exercise of control and authority is very highly limited and so much of care and caution taken that you have to go to the highest authority which should be decide on this.

But here in case of national belonging to India then our Indian citizens it is only after intimation of the application to the state biodiversity board there are exceptions provided from that. The exception is that a local community or the people who are followers of a particular tradition or a convention and who are actually practicing the same over a period of time like the one who has been practicing like a professional, or vaid or practicing the Indian system or medicine like Yunani or Ayurveda, they do not need any permission.

It is business as usual for them because these are the ones which were actually responsible for number one, valuing our bio resources, these are the ones who formed different kinds of uses of this bio resources and these are the ones who has put those knowledges and their proficiency for the public good and this has to be nurtured and protected and for that purpose they do not need any permission and the only thing that is required is the state need have to take care of it.

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- **SBB TO ADOPT AND APPLY ABS EVOLVED BY THE CENTRE- CAN ADVISE STATE GOVT. OVER THOSE ASPECTS NOT COVERED IN CENTRAL GUIDELINES(S.23(a)) , FOR CREATING RULES FOR THE FORMER TO IMPLEMENT**
- **3. IPR APPLICATION - ONLY AFTER APPROVAL BY NBA(S.6)- APPLICATION TO BE UNDER FORM-III(R.18) – PATENT ACT,1970, COMPLEMENTS THE BDA, BY PROVIDING FOR MANDATORY DISCLOSURE IN THE APPLICATION, BEFORE IT, THE SOURCE AND GEOGRAPHICAL ORIGIN OF BIOLOGICAL MATERIAL AND TK USED IN THE INVENTION- ALSO PROVIDES FOR PRE- AND POST-GRANT OPPOSITION OF APPLICATIONS AND REVOCATION OF PATENT ON THE GROUND OF NON- OR WRONGFUL DISCLOSURE – GUIDELINES ISSUED BY CG, FOR PROCESSING APPLICATIONS RELATING TO TK AND BIOLOGICAL MATERIALS , PROVIDE PATENT EXAMINERS TO CHECK AND RETURN THE APPLICATION IF NBA'S PRIOR APPROVAL HAS NOT BEEN OBTAINED.**

Whatever rules that are evolved by the centre in determining the share in accessing and sharing of benefits as far as the bio resources and putting their application into different kinds of uses, that will be determined in the centre and through a gazette notification that is made available and the same must be adopted and applied at the state level by the state biodiversity board.

But in those areas where the national body has not evolved the ABS the access and benefit

sharing mechanism then it can advise the state government over those aspects which are not covered in the central guidelines. The state biodiversity board can do that and whatever rules that are created for that purpose are to be implemented by the state biodiversity board. There is a very important provision with regard to application for intellectual of their life.

With regard to the application of any bio resource or the knowledge associated with that. Further there is only one condition that is laid down that before the patent authorities give the or registers that particular right in someone who is making an application for that purpose this has to be done only after national biodiversity board has been appraised on this by the applicants and has got the green signal from the National Biodiversity Authority.

And so, if you just look at the patent act in India it complements the Biodiversity Act by providing for mandatory disclosures application before source under geographical origin of biological material and the traditional knowledge used in the invention so this is one way of prevent biodiversity. It also provides for pre and post grant opposition and revocation of patent on the ground or non-observance, or of non-disclosure of, or wrongful disclosure of certain information which has misled the authority.

Guidelines are issued with the Central Government or processing applications relating to traditional knowledge and biological material that provide the patent examine to check and return the application if the prior approval of National Biodiversity Authority has gone to take. So, there is a very close linkage between national biodiversity law and the patent's law with two institutions work together to really ensure that the right holder is the real right having the right to hold that right.

And is not someone who has pushed things under the carpet, hoodwinked at the authorities and has taken something which should not been his and so disclosures or perfectly in order under both the laws.

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- 4. PUBLIC NOTICE OF GRANT OF APPROVALS(S.19)
- B. DETERMINATION OF EQUITY IN SHARING OF BENEFITS (S.21) -ARISING OUT OF THE USE OF ACCESSED-RESOURCE-BY-PRODUCT/INNOVATIONS & PRACTICES ASSOCIATED WITH THEIR USE AND APPLICATIONS AND KNOWLEDGE RELATING THERE TO - ON MUTUALLY AGREED TERMS AND CONDITIONS- BY NBA.
- - IN SUCH A DETERMINATION OF SHARING OF BENEFITS, NBA IS REQUIRED TO COVER THE FOLLOWING ASPECTS: - JOINT OWNERSHIP OF IPR; TRANSFER OF TECHNOLOGY; LOCATION OF PRODUCTION AND R&D UNITS FOR THE BENEFIT OF BENEFIT CLAIMERS, LOCAL PEOPLE AND ASSOCIATION OF INDIAN SCIENTISTS IN R&D; SETTING UP OF VENTURE CAPITAL FUNDS; PAYMENT OF MONETARY BENEFITS; DEPOSITION OF BENEFITS IN NATIONAL BIODIVERSITY FUND; IDENTIFIABLE BENEFIT CLAIMERS-DIRECT PAYMENT ON NBA'S DIRECTIONS



Public notice or grant of approvals are given and in determining the equity, sharing of benefits very elaborate provision has been made. The resource, by-product, innovation and practices associated with their use and application and knowledge relating thereto are taken note of and this is done on mutually agreed terms and conditions by the National Biodiversity Authority.

The wonderful thing about the Indian law is it just does not say about determination as equity as a simple rule. It further follows it up with certain parameters. How do you determine share in the benefits of the conserver, protector, carrier, transmitter of knowledge and tradition in relation to bio resources? For that, in determination of it, the National Biodiversity Authority is to cover a number of aspects.

Like joint ownership of intellectual property right may be that between the holders and the one who is going to put the application joint ownership or transfer of technology, location of production and R&D units for the benefit claimers. These are the people for whose benefit this particular provision has been made there is a local people, there is a associated of Indian scientist who have actually been responsible are conserving, protecting and creating a tradition in relation to biodiversity conservation and protection and management.

There is also provision for setting up a venture capital funds, payment of monetary benefits is also worked out, deposition of benefits in the national biodiversity fund has to be made and identifiable beneficiaries are going to get direct payment on the directions of National

Biodiversity Authority. So, the idea is essentially the local community, the traditional practitioner or the ones who are responsible for the knowledge that has been developed or the practice that has actually propagated this particular life resource is duly recognized and evolved under this law.

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- **UNIDENTIFIABLE BENEFIT CLAIMERS- TO CONSERVE AND PROMOTE BIOLOGICAL RESOURCES AND TO DEVELOP AREAS FROM WHERE THE BIOLOGICAL RESOURCES /KNOWLEDGE HAS BEEN ACCESSED AND TO FACILITATE THEIR SOCI-ECONOMIC DEVELOPMENT - DETAILED AND ELABORATED UPON, IN THE GUIDELINES ISSUED BY THE CENTRAL GOVT. IN THIS REGARD, IN 2014-EVOLVED IN CONFORMINTY WITH THE NAGOYA PROTOCOL , 2010**
- **SINCE THE RELEVANT RULES IN THIS REGARD, UNDER THE BIODIVERSITY ACT, 2002, WERE ALREADY IN EXISTENCE , WITH THE MAKING OF THE RULES IN 2004 , LONG BEFORE THE NAGOYA PROTOCOL, THE GUIDELINES BROUGHT INTO APPLICATION NOW , IS NO MORE THAN AN EXERCISE IN ALIGNING THE INTERNAL FACILITATION MECHANISM WITH THE INTERNATIONAL ARRANGEMENT , BESIDES AN ELABORATION , AMPLIFICATION AND STEP BY STEP IMPLEMENTATION OF THE RULES .**



Suppose you are not able to identify the benefit claims, maybe they are spread over certain areas and you are not able to identify how many and where they are then the requirement for the authorities is money so derived out of this particular sharing arrangement need have to be used for conservation and protection of biological resources and develop areas where these resources or knowledges have been from where they have accessed and to facilitate the entire overall socioeconomic development of this community to which it has go back.

Detailed and elaborated upon by the Central Government in a set of guidelines issued in this regard for the first time in 2014 and this governed in conformity with as we have discussed earlier the Nagoya Protocol on ABS. One must notice here that the Biodiversity Act was made in the year 2002 and the rules were made in 2004 and both the act and rules long before at the international level. In the Nagoya protocol of 2010, the ABS system was detailed.

But long before that these were already a part of Indian law. So this is a law which is so formal looking that how it would be determined, who shall be able to get the benefit, how much, in what manner and how do you duly recognized evolve and incentivize those very

people who have been earlier suffering from the denial of something that was there that was the bio piracy and the piracy is being avoided.

And that was done even before at the international level a particular argument in this regard was worked out that is actually such a forward-looking legal document that we have come up within India long before the international community thought of coming up with a formula for their problems.

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• **C. EXEMPTIONS:**

1. HUMAN GENETIC RESOURCES
2. LISTED BIOLOGICAL RESOURCES WHEN LISTED AS NTAC (S.40)
3. DESIGNATED CROP VARIETIES BY DEPT. OF AGRICULTURE AND COOPERATION
4. RESEARCH PUBLICATIONS, THAT OBSERVE THE GUIDELINES OF THE GOVT. AND CERTAIN COLLABORATIVE RESEARCH PROJECTS (ss., 4 &5)
5. USE OF BIOLOGICAL RESOURCES DERIVED FROM CONVENTIONAL BREEDING (S.7 &S.2.(f))
6. TRADITIONAL PRACTICES IN USE IN AGRICULTURE, HORTICULTURE, POULTRY, DAIRY FARMING, ANIMAL HUSBANDRY OR BEE KEEPING (s.7)
7. LOCAL PEOPLE AND COMMUNITIES, INCLUDING GROWERS, CULTIVERS, LOCAL VAIDS AND HAKIMS (s. 7)



Several exemptions are there either from the operations of this law or from seeking and securing approval for access and sharing of benefits like human genetic resources they kept out of the law are through notification Central Government says that those bio resources or that which is derived from the bio resources which are normally traded as communities these under section 40 of this particular Act.

And if they are listed like that these do not come under the purview of this law for the simple reason that these are the ones which are in common use and that which is in common use, vogue and application, they did not have to get any special treatment as has been provided under this law. Please note that this law is made the only protect those bio resources which are prone to or sensitive to or expose to the common abuse, misuse, deceit, clandestine activity and for such things as to deny what is legitimately our sovereign right or what is legitimately the right of the communities and things like that.

There are designated crops and varieties by the department of agriculture and cooperation and since this is interested in developing Indian agriculture and farmer being the backbone of that, these can kept under the purview of this law. Research publications that observes the guidelines of the government and certain collaborative research projects need not have to come under the purview of this.

Use of biological resources derived from conventional breeding so the idea is to protect those conventions, those predictions and practices. So, if resources are derived from such a kind of a method they do not come under the purview of this law. Traditional practices and use in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping. These are also kept under the purview of strict regimen of this particular law. Local people and communities including growers, cultivars, local Vaid and Hakims practice in the Ayurveda and things like that they all are out of the purview of this law. They give protection, but they do not get any obligation.

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- -HOWEVER, "END USES" OF BIOLOGICAL RESOURCES FOR "COMMERCIAL UTILIZATION" (-SUCH AS, DRUGS, INDUSTRIAL ENZYMES, FOOD FLAVOURS, FRAGRANCE, COSMETICS, EMULSIFIERS, OLERORESINS, COLOURS, EXTRACTS AND GENES USED FOR IMPROVING CROPS AND LIVESTOCK THROUGH GENETIC INTERVENTION:S.2(f)), ARE NOT EXEMPTED

8. ANY APPLICATION MADE UNDER PPVFA, 2001, FOR ANY RT, EXEMPT FROM THE PROVISIONS OF S.6 ONLY (- ISSUES CONCERNING THE RTS. COVERED UNDER THAT ACT)

9. INDIAN CITIZENS/ENTITIES- ACCESSING BIORESOURCES, FOR RESEARCH/ BIOSURVEY AND BIO-UTILIZATION FOR RESEARCH IN INDIA - EXEMPT FROM THE REQUIREMENTS OF ABS



But supposing those deals and practices and they end as users of biological resources for commercial utilization which is not in accordance with those traditions and practices which is not in accordance with those that has been nurtured over a period of time like manufacture of drugs, industrial enzymes and food flavours etcetera they are not exempted. They need have to go through this very detailed process of regulation of making an approach of either the central and national biological authority or at the state level state biodiversity board for the necessary approval in that regard.

Any application made under the Protection of Plant Varieties and Farmers Rights Act for any rights under that law. It is exempt from the provisions of this particular provision that is concerning, sharing our benefits, concerning intellectual property right for the simple reason there is an alternative that is already in existence parallelly to the intellectual property regime under this particular legislation and so it will operate under that law.

Indian citizens or entities accessing bio resources for purely for the purpose of research, bio survey and bio utilization for research in India exempt from the requirements of access and sharing of benefits. They may have to make a formal application for permissions. Other than that, they do not have any obligation for following the requirement of access and benefit sharing requirement.

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• **V. GRIEVANCE REDRESSAL, CONFLICT RESOLUTION AND PENAL SANCTIONS:**

- **ANTICIPATION AND AVOIDANCE OF CONFLICTS – STANDOUT FEATURE OF THE BIODIVERSITY LAW ; CONSULTATIONS – TERMS OF AGREEMENT THROUGH CONSENSUS ; TRANSPARENCY IN GOVERNANCE – PUBLIC NOTICES OF DECISIONS –CONSTANT ENGAGEMENT OF BMCs IN CONSULTATIONS**

- **A FAIRLY WELL-STRUCTURED GOVERNANCE STRUCTURE, AT EVERY LEVEL, THAT IS INCLUSIVE OF EVERY CONCEIVABLE INTEREST GROUP AND EVERY CONCEIVABLE DEPARTMENTS AND MINISTRIES HAVING SOME CONCERN OR THE OTHER OVER THE SUBJECT**

- **SETTLEMENT OF DISPUTES BETWEEN SBBs & WITH NBA, NBA & CENTRAL GOVERNMENT, AS THE CASE MAY BE (S.50)**

- **APPEALS – TO H.C. (52) TO NGT (52A)**

- **PENAL SANCTIONS: SECTIONS:- 55,56,57,58**



Now suppose there is a dispute, supposing there is a grievance in regard to the decision that are made as a contractual arrangement entered into, how do they get redressed? What is the mechanism here? This is a unique law it does not go by the usual kind of a conflict resolution mechanism that we have that you go to the trail court, you go to the district court, you go to the high court and then you go the supreme court none of that.

In fact, basically the idea is essentially to put an ethical board through arrangement and contractual arrangement through informal consent processes, through consultative processes so with result that you anticipate and avoid conflicts. See when there is a dialogue, sorting of

differences becomes far more easier than you being prescribed certain norms and non-observance which may lead to confusions.

Clarifications can be sought and accordingly you can adjust. Newer kind of activities is there, enough abundance scope has been provided under this law for the purpose of governance and that is indeed the standout feature of this law. It is a very fairly well structured governance system and it is very inclusive and every conceivable interest group and every conceivable department and ministries having some kind of a relationship or the other over the subject are being brought within the whole scheme of governance, consultation, consensus building, decision making including the one who want to access you needed to have contractual arrangement.

And normally when you have that kind of an arrangement the conflicts are kept to the minimum, but still if within the organization itself there are conflicts, supposing there is a conflict and jurisdiction between one state biodiversity board and another state biodiversity authority then the National Biodiversity Authority will be umpire. It will decide the dispute between the two. But supposing there is a dispute between the National Biodiversity Authority and the state biological board or if there is a conflict between National Biodiversity Authority and even the Central Government.

And if that were to be there then the only recourse is to appeal to the high court or after the amendment to the law in 2010 when the National Green Tribunal came into existence the appeal will lie with the National Green Tribunal which is the special adjudicated body to deal with environmental issue with that appeal will go and then this issue is on par with and in no way less than that of a high court.

Of course, appeal will always lie in the Supreme Court from that, but this is the scheme of grievance redressal and conflict resolution. In terms of penal sanctions, it is very important to every authority listed here the National Biodiversity Authority and the state biodiversity board when they issue orders of approval, their orders just like that of the courts of law without constituting judicial bodies they are ordinarily administrators.

Apart from implementing this law, apart from administering these aspects of the law, apart from entering into arrangements, the orders issues have the same forces at judgment of the

court of law and so violation of that would actually lead to severe penal sanctions and these are not compoundable offences. Violation means penal actions, very strict rule. And so, anybody who comes with the purview of this law should take care. Should ensure that one would always remain on the right side of the law and not violate it under any circumstance.