

Biodiversity Protection, Farmers and Breeders Right

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

Lecture 16 : ABS Regulation and Benefit Sharing in India

Welcome to the course on Biodiversity Protection, Farmers and Breeders Right. This lecture will be about ABS regulation in India and the Benefit Sharing Options. The concepts covered in this lecture are ABS regulations issued in 2014, then the different modes of benefit sharing, determination of benefit sharing, activities which are exempted from the Biodiversity Act, the different options for monetary and non-monetary benefit sharing. The keywords of this lecture can be seen here. Section 19 of the Biological Diversity Act provides the procedure that has to be followed while granting approvals by the National Biodiversity Authority. So, under section 19 any person who is desirous of seeking the approval of NBA shall make an application along with the prescribed fees.

So, once the application is received, NBA can make necessary enquiries required in this regard and also it can also consult with an expert committee which is constituted for this purpose. So, usually National Biodiversity Authority consult with an expert committee on access and benefit sharing for this purpose. So, during this process NBA will look into various matters like availability of the resource, the threat status and various other factors. So, on the basis of these considerations if the NBA decides to grant the approval then by order it can grant the approval.

So, for this purpose NBA also has to follow the access and benefit sharing regulations and the approval can also be subject to different terms and the conditions which the NBA may deem fit. If any activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or fair and equitable sharing of benefits then the approval need not be granted. So, in such a scenario for reasons to be recorded in writing NBA can reject the application, but no order of rejection shall be made without giving the person an opportunity of being heard. So, before rejecting every application the affected person shall be given an opportunity of being heard. NBA also has to give public notice of every approval granted by the authority.

Section 21 deals with determination of benefit sharing by the National Biodiversity Authority. So, while granting approvals NBA shall ensure that the terms and conditions subject to which approval is granted, secures equitable sharing of benefits arising out of use of access biological resource or the traditional knowledge. So, that means that while granting the approval NBA also has to fix a benefit sharing component. So, the benefit sharing component becomes part of the approval process. So, that means NBA can

determine the benefits which has to be shared and it also has to establish mutually agreed terms.

So, usually mutually agreed terms or MAT will be in the form of ABS agreement and it will indicate the ABS component. So, for determining benefits NBA shall have to frame a guidelines in consultation with the central government. So, section 21 of the Biological Diversity Act provides for formulation of a guidelines for the purpose of determining benefits. The guidelines has to be framed in consultation with the central government. So, while determining benefits NBA will have to follow these guidelines issued under section 21 of the act.

The manner of benefit sharing is also provided in the act. National Biodiversity Authority shall subject to any regulations made in this behalf determine the benefit sharing which shall give effect to any of the following manners. So, first option can be grant of joint intellectual property rights. So, in case an innovation is developed from the research on a biological resource and an approval is going to be granted, then in such case the authority can determine that the benefit sharing can be in the form of grant of joint ownership of intellectual property rights. So, that means NBA or the community will become part of the patent application.

So, they will become the joint owners of the patent. Second option given in the act is transfer of technology. So, when a technology is developed the transfer of such technology can also constitute benefit sharing. Third option is location of production research and development units in such areas which will facilitate better living standards to the benefit claimers. So, if the biological resource is accessed from a locality, then the location of the production unit in such place or the research and development unit is placed in that area.

So, that will help in facilitating better living standards to the benefit claimers. So, benefit sharing can also be in this manner. Then association of Indian scientists, benefit claimers and local people in the R and D process. So, the companies who are accessing the biological resource can also involve Indian scientists or benefit claimers or the local people in the R and D process. Benefit sharing can be in such manner as well.

Another option is setting up of venture capital fund for aiding the course of benefit claimers. So, a fund can be constituted for the purpose of helping the benefit claimers. Another option is payment of monetary compensation and other non-monetary benefits as determined by the National Biodiversity Authority. So, apart from all these options, the benefit sharing can be also in monetary terms. So, that means, an amount can be fixed by the National Biodiversity Authority and the applicant will be obligated to make payment of that amount.

So, this provision provides for the different ways in which benefit sharing can happen and obligates National Biodiversity Authority to determine benefit sharing based on this framework. So, while determining benefits, NBI will also have to follow the regulations made in this behalf. So, that means, access and benefit sharing regulations which has to be issued under the Biological Diversity Act becomes an important component in the biodiversity governance framework in India. Monetary benefits and non-monetary benefits are the different options given under the Biological Diversity Act. So, in case of monetary benefit sharing, NBI can direct that the amount can be directly deposited into the National Biodiversity Fund constituted under the Act.

So, while granting approval, NBI is fixing a monetary component. So, that means, under the mutually agreed terms or the ABS agreement, a benefit sharing is fixed on monetary terms. So, either the amount is mentioned or a percentage of the profit generated by the industry is mentioned in the ABS agreement, then that amount has to be directly deposited into the National Biodiversity Fund. But in case if the biological resource or knowledge was accessed from a specific individual or group of individuals or organizations. So, in such case NBI can direct then that amount shall be directly paid to the benefit claimers.

So, instead of crediting it to the National Biodiversity Fund, NBI can direct that as the resource is taken from a specific locality or a specific individual or group of individuals, then the benefit sharing amount can also be directly paid to them. So, this is also provided under the Biological Diversity Act. Similar to the National Biodiversity Authority, the state biodiversity boards also have different powers under the Act. So, any person based on the legal status may have to either take the approval or from the state biodiversity board. So, in such case if it is if they are coming under the regulatory framework of state biodiversity board, then they have to give a prior intimation to the state biodiversity board.

So, once such application is received, the state biodiversity board shall examine the application and after proper enquiry it can either approve the application or reject the application. But, if it is deciding to reject the application, then an opportunity of being heard shall be given before the rejection. And for determination of benefits, the state biodiversity boards also has to follow the regulations issued by the National Biodiversity Authority under the Biological Diversity Act. So, the ABS regulations issued by the National Biodiversity Authority in consultation with the central government is equally applicable for the NBA and the state biodiversity boards. So, the power to frame ABS regulations is given mainly in two different places in the Biological Diversity Act.

So, if you look at section 18, it provides that it is an important function of National Biodiversity Authority to make regulations to provide for access to biological resource and

associated traditional knowledge thereto and for determination of fair and equitable sharing of benefits. So, that means, the issuance of regulations for the purpose of benefit sharing is an important function of National Biodiversity Authority under section 18. Similarly, in section 21, National Biodiversity Authority shall in consultation with central government by regulations frame guidelines. So, that means, in two occasions, the Biological Diversity Act cast this obligation on the National Biodiversity Authority to frame a guidelines for the purpose of determining equitable sharing of benefits. So, in accordance with this obligation, the ABS regulations was notified in 2014 after consulting the central government.

The ABS regulations is known as the guidelines on access to biological resources and associated traditional knowledge and benefit sharing regulations 2014 and this was notified in November 2014. The ABS guidelines provides for the mode of benefit sharing in case of access of biological resource or the associated traditional knowledge for research, biosurvey and bioutilization or for commercial utilization. So, in case of research, biosurvey or bioutilization or for commercial utilization, the benefit sharing will be in accordance with the provisions of the ABS guidelines 2014. Similarly, it also provides the mode of benefit sharing in case of intellectual property rights or in case of transfer of research results. It also provides for the collection of fees by BMCs.

So, we have already seen in one of the lectures that biodiversity management committees are empowered to levy charges by way of collection fees. So, the guidelines issued in 2014 clarifies that this collection fees is in addition to any benefit sharing which is fixed by National Biodiversity Authority or the State Biodiversity Board. The 2014 guidelines clarifies the procedures that has to be followed for the determination of benefit sharing by the National Biodiversity Authority. It also details the procedures that has to be followed by the National Biodiversity Authority for processing applications. The guidelines also gives a list of activities exempted from the provisions of the Biological Diversity Act.

Regulation 3 in the guidelines provides for the mode of benefit sharing in case of commercial utilization. So, in case of commercial utilization there are two options given in the ABS regulations issued in 2014. So, the first option is to pay benefit sharing on the basis of purchase price. So, regulation 3 speaks of the payment of benefit sharing on the basis of purchase price. So, where an applicant trader or manufacturer purchases directly from the JFMC, Forest Dweller, Tribal Cultivator or Gramsaba, the benefit sharing obligations on the trader will be in the range of 1 to 3 percentage of the purchase price and the benefit sharing obligations on the manufacturer shall be in the range of 3 to 5 percentage.

So, this is two different scenarios. So, first scenario is a trader is purchasing the bio

resource directly from the JFMC or the Forest Dweller or the Tribal communities or the Gramsaba and then the trader is obligated to pay benefit sharing in the range of 1.0 to 3.0 percentage of the purchase price. So, the percentage is fixed on the basis of the purchase price, but instead of the trader if it is a manufacturer who is purchasing then the benefit sharing will be in the range of 3 to 5 percentage.

But if the trader or the manufacturer has entered into a prior benefit sharing negotiation with the persons who are selling the bio resource that is the JFMC, Forest Dweller, Tribal Cultivator or the Gramsaba for the purchase of biological resource then the benefit sharing shall not be less than 3 percentage if it is a trader and it shall not be less than 5 percentage in case it is a manufacturer. So, thus it is possible that instead of following the benefit sharing under the first option it is also possible that the trader or manufacturer can directly enter into a negotiation with the JFMC or the provider of biological resource and in such cases the benefit sharing shall not be less than 3 percentage if it is a trader and shall not be less than 5 percentage if it is a manufacturer. And in certain scenarios the biological resource which is going to be utilized may be having high economic value. So, in such cases the benefit sharing may include an upfront payment of not less than 5 percentage of the proceeds of the auction or the sale amount. So, there could be scenarios where it is a high value resource which is auctioned.

So, then the benefit sharing shall be in the form of an upfront payment which is not less than 5 percentage of the proceeds of the auction or the sale amount. So, Regulation 4 speaks about the mode of benefit sharing for commercial utilization as the second option. So, first option we already seen which is on the basis of purchase price. The second option is on the basis of annual gross ex factory sale of the product. So, these options are available to the applicant and the applicant can choose whether it should be based on the purchase price or on the basis of annual gross ex factory sale of the product.

But in case of species which are having high economic value which we have already seen Regulation 3, then the benefit sharing has to be in the form of an upfront payment which is given in the regulation. So, if the applicant decides to follow the second option which is given under Regulation 4, then the benefit sharing shall be ranging from 0.1 to 0.5 percentage of the annual gross ex factory sale of the product. And this will be worked out based on the gross and annual gross ex factory sale minus government taxes as given below.

So, if the annual gross ex factory sale of the product is up to 1 crore, then the benefit sharing component will be 0.1 percentage of that annual gross ex factory sale. But if the annual gross ex factory sale is between 1 crore to 3 crore, then the benefit sharing component will be 0.2 percentage. If the annual gross ex factory sale of the product is

above 3 crores, then the benefit sharing component will be 0.

5 percentage of the annual gross ex factory sale of the product. Regulation 5 clarifies the position with regard to collection of fees by the biodiversity management committees. So, section 41 of the Biological Diversity Act provides that biodiversity management committees can levy charges by way of collection fee. So, this charges levied by the BMC is in addition to any benefit sharing which is payable to national biodiversity authority or the state biodiversity board under these regulations.

This is clarified in Regulation 5. Regulation 7 deals with the mode of benefit sharing for the transfer of results of research. So, applicant shall in case of transfer of results of research is obligated to pay monetary or non-monetary benefit as agreed between the applicant and the national biodiversity authority. But if it is monetary benefit, then the applicant shall pay to NBA 3 to 5 percentage of the monetary consideration received by the applicant. So, in case of transfer of results result to a third party, so the third party will be in a foreigner. So, in such a scenario the applicant will be receiving some monetary consideration from the third party.

So, that means, 3 to 5 percentage of the monetary consideration received by the applicant has to be paid as the benefit sharing to the national biodiversity authority. This is provided in Regulation 7. The mode of benefit sharing in case of intellectual property rights is given in Regulation 9. So, obtaining of intellectual property rights on a research which is based on biological diversity or traditional knowledge obtained from India is also a regulated activity under the Biological Diversity Act. So, the mode of benefit sharing in case of intellectual property rights is given in Regulation 9.

So, if the applicant himself is commercializing the process product or innovation, then the benefit sharing shall be 0.1 to 1 percentage of the annual ex-factory gross sale of the product minus government taxes. So, that means, there could be scenarios where the applicant of the patent himself is commercializing the product. It can be either an individual or a company. So, the company has applied for a patent for which they have taken the approval and the company themselves is commercializing the product.

So, in such case benefit sharing will be ranging from 0.1, 0.2 to 1 percentage of the annual ex-factory gross sale of the product. But, there could be scenarios where the patent applicant assigns or licenses the product process or innovation to a third party for commercialization. So, in such scenarios the patent applicant would have taken the approval from National Biodiversity Authority and subsequently they have assigned or licensed the patent to a third party.

So, in such scenario the benefit sharing shall be 3 to 5 percentage of the fee received and 2 to 5 percentage of the royalty which the applicant is receiving. This is provided in regulation 9 of the 2014 regulation. Regulation 13 provides for conducting of non-commercial research or research for emergency purposes outside India by Indian researchers and government institutions. So, regulation 13 is a facilitative provision under the 2014 guidelines. So, under regulation 13 any Indian researcher or a government institution who intends to carry or send biological resource outside India and if it is for the purpose of undertaking basic research which is not a collaborative research.

So, collaborative research is dealt under section 5 of the Biological Diversity Act. So, in case of collaborative research also approval is required unless it is approved by the concerned department of the government of India or the state government. So, in case it is not a collaborative research and an Indian researcher or a government institution just want to send the sample for the purpose of undertaking a basic research which is not for commercial purpose. So, then they have to apply in form B. Similarly, if a government institution the second part is applicable only for a government institution that if a government institution wants to send the sample to carry out some urgent studies to avert emergencies like epidemics then they can also apply in form B to the National Biodiversity Authority.

So, on receipt of a form B, NBA shall grant the approval within 45 days and on receipt of the approval the applicant shall deposit voucher specimen in the designated national repositories and a copy of the proof of such deposit shall be endorsed to National Biodiversity Authority. So, this means that in case the applicant want to send a sample abroad for the purpose of either basic research or if it the applicant is a government institution they want to carry out some urgent studies to avert emergency or epidemics then they can follow this route and then there is no need to apply in form 1 under the biological diversity rules, but instead they can apply in form B and the approval will be granted within a period of 45 days. Regulation 14 deals with the determination of benefit sharing. So, benefit sharing may be done either in monetary terms or in non-monetary terms. The determination of benefit sharing shall be based on consideration such as commercial utilisation of the biological resource, stages of research and development, potential market for the outcome of the research, amount of investment already made for research and development, nature of technology applied, timelines and milestones for initiation of research and development, risk involved in commercialisation of the product.

So, while an application is received either by the National Biodiversity Authority or the State Biodiversity Board they will look into these factors. So, based on this a benefit sharing component will be fixed within the range prescribed in the guidelines. Special consideration may be given to cases where technologies or products are developed for

controlling epidemics, diseases and for mitigating environmental pollution affecting human, animal or plant health. So, in case of products which are developed for controlling epidemics or diseases or mitigating environmental pollution which is affecting human, animal or plant health then special consideration can be given under Regulation 14. So, that means the benefit sharing can be fixed at the lowest range in such scenarios.

So, this call has to be taken by the National Biodiversity Authority while determining the benefits. Regulation 14 deals with the sharing of benefits. So, in case the approval is granted by the National Biodiversity Authority and NBA has directed that the entire amount has to be credited to the National Biodiversity Fund. So, in such case 5 percentage of the accrued benefits shall go to the NBA out of which half of it will be retained by the National Biodiversity Authority and the other half will be passed on to the concerned SBB as administrative charges. So, that means 5 percentage of the benefit received will be retained by the NBA and the SBB as administrative charges.

The 95 percentage of the benefits will go to the concerned BMC and the benefit claimers. But if the biological resources or traditional knowledge is sourced from an individual or group of individual or organization and they are identifiable then the entire amount can be directly paid to them. But in case the benefit claims are not identified then the fund can be used for supporting conservation and sustainable use of biological resource and to promote livelihood of local people from where the biological resource has been accessed. In case the approval is granted by the State Biodiversity Board then an amount not exceeding 5 percentage can be retained by them as the administrative charge. The remaining share shall be passed on to the BMC concerned or the benefit claimer when identified.

But where an individual group or organization is identified then the amount can be directly paid to them and if they are not identified then such funds shall be used to support conservation, sustainable use of biological resource and to promote livelihood of the people from where the biological resource has been accessed. Regulation 17 deals with the activities which are exempted from the approval of National Biodiversity Authority and the State Biodiversity Board. So, the first exemption is Indian citizens or entities who are obtaining the biological resource associated knowledge for the purpose of research, biosurvey or bioutilization for research in India. So, in case Indians are accessing for research then they are exempted from the provisions of the Biological Diversity Act. They have to take the approval only when there is a commercial intent.

Similarly, collaborative research projects which are approved by the concerned ministry or the department of the state government or the central government and if they confirms with the policy guidelines issued by the central government then they also does not have to take the approval. Similarly, local people and communities including growers and

cultivars of biodesource, whites and hakims who are practicing indigenous medicine are also exempted from the provisions of the act. The third exemption is accessing biological resource for conventional breeding or traditional practices in any agriculture horticulture or poultry without a commercial intent. So, if a farmer is doing commercial conventional breeding then they are also exempted from the provisions of the act. Publication of research papers or dissemination of knowledge confirming with the guidelines issued by the central government is also an exempted activity.

Similarly, there are several biological resources which are exempted as normally traded commodities under section 40 of the Biological Diversity Act. The 2014 guidelines also gives an indicative list of benefit sharing options in both monetary terms as well as non-monetary terms. So, in case of monetary benefits it can be in the form of upfront payment which is paid in advance, it can be in the form of one time payment, it can be in the form of milestone payment, it can be share of royalties or benefits accrued, it can be share of license fees, it can be a contribution to national state or local biodiversity funds, it can be funding for research and development in India, it can be joint ventures with Indian institutions and companies, it can also be in the form of joint ownership of relevant intellectual property right. In case of non-monetary benefits the options are providing institutional capacity building, transfer of technology, strengthening of capacities for developing technologies, contribution, collaboration related to education and training, location of production research and development units, sharing of scientific information relevant for conservation and sustainable use of biodiversity, conducting of research towards priority needs in India including food, health and livelihood security, providing scholarships and financial aid, it can also be in the form of setting up of venture capital fund for aiding the course of benefit claimers. To conclude the determination of benefits has to be done by the national biodiversity authority and the state biodiversity board in accordance with the provisions of the biological diversity act.

The framing of ABS regulations is an important statutory function of national biodiversity authority. So, the 2014 guidelines issued in this regard provide clarity and transparency to the ABS process, it also brings certainty to the biodiversity governance framework and eases the process of both the providers and users of biodiversity. Thank you very much for listening to the lecture, I hope you are all enjoying the course.