

Details of Comments Received

S.No	Name / Institution
1	Dr. Pushpangadan, Amity Institute for Herbal and Biotech Products Development, Thiruvananthapuram, Kerala
2	Shri P. Vivekanandan, SEVA, Virattipathu, Madurai, Tamil Nadu
3	Smt Sheetal Chopra, Deputy Director, IPR Division FICCI, New Delhi
4	Shri S. Ashok Kumar, Member, AP Biodiversity Board, Hyderabad
5	Smt Topi Basar, Assistant Professor, Faculty of Law, University of Delhi
6	Association of Biotechnology Led Enterprises (ABLE), Bangalore
7	Dr. Neelima Jerath, Member Secretary, Punjab Biodiversity Board, Punjab State Council for Science and Technology, Chandigarh
8	Shri Bala Prasad, Additional Principal Chief Conservator of Forests, Forest Department, Sanjenthong, Imphal, Manipur
9	Shri S. Elumalai, Faculty of Law, The School of Excellence in Law, Chennai
10	Dr Padmanabhi, Dept of Botany, M.S.University of Baroda, Vadodara
11	Shri Mayur Parekh, Advocate, Intellectual Management Consultant, Vadodara
12	Prof. M. P. Yadav, Member Secretary , Gujarat Biodiversity Board
13	Dr. Uma Melkania, G.B. Pant Nagar, Uttaranchal
14	Shri Tulika Singh, Assistant Director, National Seed Association of India, New Delhi
15	Dr. Duggaraju Srinivasa Rao, Associate Professor of Zoology, Noble College, Machilipatnam.

B2 – Specific Comments received on the draft TK Rules (Rules for Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity, 2009).

S.No.	Draft TK Rules	Comments Received
1	In exercise of the powers conferred under sections 36(5) and 62 of the Biological Diversity Act, 2002 and on the recommendations of the National Biodiversity Authority, the Central Government, hereby, makes the following rules, namely	
2	<p>1. Short Title and Commencement</p> <p>(1) These rules may be called the Rules for Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity, 2009.</p> <p>(2) They shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.</p>	
3	<p>2. Definitions – In these rules, unless the context otherwise requires,</p> <p>(a) “Abuse” means use or application of the traditional knowledge or one or more of its components, by any person, including a member of the traditional community or a traditional practitioner, in a manner that is in contravention of their traditional beliefs and practices, or which is against public order and morality, or against the interests of the traditional communities or, any action in contravention to these Rules;</p>	<p><u>Shri S.Ashok Kumar:</u></p> <p><u>Rule 2(a):</u> after ‘any person’ add <u>“or a group of persons”</u></p> <p><u>Rule 2(a)</u> after ‘traditional practitioners’ add <u>“any Firm or Company or Association”</u></p>
	<p>(b) “Accessor” means a person who accesses traditional knowledge for commercial gain and /or for research, and includes members of traditional communities who access traditional knowledge of any other community for commercial gain and /or research;</p> <p>(c) “Act” means the Biological Diversity Act, 2002 (18 of 2003)</p> <p>(d) “Authority” means the National Biodiversity Authority established under subsection (1) of section 8 of the Act</p> <p>e) “Benefit” means gains that can be monetary, non-monetary, welfare-based and any other form that comes out of an agreement between the accessor and the traditional community and / or National Biodiversity Authority, as the case may be, upon access of traditional knowledge or a component thereof and shall include</p>	<p><u>Shri S.Ashok Kumar:</u></p> <p><u>Rule 2(b):</u> after ‘a person’ add <u>“or a group of persons, Firm or Company or Association”</u></p> <p><u>SEVA:</u></p> <p><u>Rule 2 (b)</u> “Accessor” means a person who accesses traditional knowledge for commercial gain and /or for research <u>or for dissemination purpose</u></p>

	<p>i. access fee determined by the National Biodiversity Authority or the State Biodiversity Board as the case may be, in consultation with the traditional community at the time of accessing the traditional knowledge; benefits as described under section 27(2) of the Act; and</p> <p>iii. Milestone payments where applicable.</p> <p>(f) "Biodiversity Management Committee" means a Biodiversity Management Committee established by a local body under sub-section (1) of section 41 of the Act;</p> <p>(g) "Chairperson" means the chairperson of the National Biodiversity Authority;</p> <p>(h) "Collective rights" mean the rights which the traditional community as a group has been enjoying over the particular traditional knowledge for generations;</p> <p>(i) "Commercial gain" means commercialization of a component or components of traditional knowledge or derivatives thereof, in a way that is not being practised by the community which owns the said knowledge;</p> <p>(j) "Fee" means any fee stipulated in the Schedule;</p> <p>(k) "Informed consent" means consent to be obtained from the traditional community or the National Biodiversity Authority, as the case may be, in case where the traditional knowledge is already under access and use before the notification of this Act;</p> <p>(l) "Intellectual Property Rights" mean intellectual property rights including, copyrights, designs, geographical indications, patents and trademarks;</p> <p>(m) "License of Use" means the permission granted to the applicant by the National Biodiversity Authority for accessing the traditional knowledge;</p> <p>(n) "Livelihood" means the financial and/or other traditional / customary means for subsistence;</p> <p>(o) "Milestone payments" means periodic payments made to the traditional knowledge fund by the accessor which shall not be less than 10% of the gross revenue realized from the commercialization of products using traditional knowledge or derivatives thereof;</p>	<p><u>FICCI:</u></p> <p><u>Rule 2(l)</u> defining "Intellectual Property Rights" does not include a plant variety registered under the Plant Protection Varieties and Farmers Rights Act 2001</p> <p><u>Shri. Mayur Parekh, Advocate:</u></p> <p><u>Rule 2(l)</u> :The provision relating to the definition of IPR Sec.2(l)) must be enlarged so as to include plant breeders rights (PBR's) and confidential information/ trade secrets. It is better to include the word 'the subject matter of Sec.1 to 7 of Part II of TRIPS Agreement of WTO'</p>
--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

	<p>(p) “Misappropriation of traditional knowledge” means any form of appropriation, monopolisation, including claims of private ownership and/or intellectual property rights, and such other acts which deprive the traditional community whose traditional knowledge it is, from using, conserving and protecting the said knowledge, and from equitable benefit sharing arising out of any commercial utilization of said traditional knowledge and /or derivatives thereof, and also unsustainable utilisation of the genetic resources relating to that traditional knowledge;</p> <p>(q) “Misuse of traditional knowledge” means access to and/or use of traditional knowledge by persons not belonging to the traditional community whose traditional knowledge it is, without License to Use or against the terms and conditions of License to Use;</p> <p>(r) “National Standing Committee” means a committee set up by the Authority to examine and advise the Authority on applications for access to traditional knowledge;</p> <p>(s) “Prior-informed Consent” means a written authorisation given by the traditional community to an applicant in the prescribed manner, in consultation with the Biodiversity Management Committee and facilitated by the State Biodiversity Board, for the conduct of a particular activity that entails access to and use of the said traditional knowledge, based on an access application submitted in the prescribed manner containing complete and accurate access information on the purposes, risk, implications and environmental impact of the said activity, including any use that might be made of the said knowledge, and, wherever applicable, on its commercial value;</p> <p>(t) “State Standing Committee” means a committee set up by the State Biodiversity Board to examine and advise the Board on applications for</p>	<p><u>Mr. S. Ashok Kumar:</u></p> <p><u>Rule 2(p)</u> after ‘claims of private ownership’ add <u>“or corporate ownership”</u></p> <p><u>FICCI:</u></p> <p><u>Rule 2(q)</u> The above Rule needs to specifically state non patentability or any similar IPR registration prohibition for traditional knowledge (this would make attempts to gain such IPR registration void <i>ab initio</i> unlike the long drawn out disputes to revoke patents relating to Neem and turmeric).</p>
--	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

	<p>access to traditional knowledge;</p> <p>(u) “Traditional community” means a community holding traditional knowledge including families, people belonging to Scheduled Tribes as per Article 342 of the Constitution of India, and other notified tribal groups including nomadic tribes, and shall be represented by their representative bodies;</p>	
	<p>(v)“Traditional Knowledge” means the collective knowledge of a traditional community including of a group of families, on a particular subject or a skill and passed down from generation to generation, either orally or in written form, relating to properties, uses and characteristics of plant and animal genetic resources; agricultural and healthcare practices, food preservation and processing techniques and devices developed from traditional materials; cultural expressions, products and practices such as weaving patterns, colors, dyes, pottery, painting, poetry, folklore, dance and music; and all other products or processes discovered through a community process including by a member of the community individually but for the common use of the community; and</p>	<p><u>FICCI:</u></p> <p><u>Rule2(v):</u> Further the definition of the term traditional knowledge under section 2 (v) needs to be enlarged into as broad a scope as possible so as to encompass all traditional knowledge even if such traditional knowledge may be restricted to a particular geographic location or traditional community. This stipulation needs to be specifically incorporated into the definition.</p> <p><u>Mr. S. Ashok Kumar:</u></p> <p><u>Rule 2(v)</u> after ‘dance and music’ add “<u>folk songs, ballads, old sayings, cultural beliefs, cultural or art events</u>”</p> <p><u>SEVA:</u></p> <p><u>Rule2(v)</u> “Traditional Knowledge” means the collective knowledge of a traditional community including of a group of families, on a particular subject or a skill and passed down from generation to generation, either orally or in written form, relating to properties, uses and characteristics of plant and animal genetic resources; agricultural and healthcare practices, food preservation and processing techniques and devices developed from traditional materials; cultural expressions, products and practices such as weaving patterns, colors, dyes, pottery, painting, poetry, folklore, dance and music, <u>food recipes, local language / dialect;</u></p> <p><u>Dr. Puspangadan:</u></p> <p><u>Rule 2(V)</u> “Traditional Knowledge” means the collective knowledge of a traditional community including of an <u>individual, family</u> or a group of families.</p>
	<p>(w)“Traditional Practitioner” means person(s) who are members of a traditional community and have been practising traditional knowledge</p>	

	including healing and/or rendering medical service based on traditional knowledge and customary practice.	
	<p>3. Measures to be taken by National Biodiversity Authority for protection and promotion of traditional knowledge.</p> <p>(1) The National Biodiversity Authority shall recognize existing traditional forms of representative organizations of the traditional community, including family / community based organisations;</p> <p><i>Provided</i> that, where there are no representative bodies representing the said traditional community, the National Biodiversity Authority shall, through State Biodiversity Boards and Biodiversity Management Committee enable traditional communities to set up representative bodies keeping in view their customary practices and traditional forms of organization;</p> <p><i>Provided</i> also that where there is more than one representative organization representing a traditional community, the National Biodiversity Authority shall refer the matter to the Biodiversity Management Committee through the State Biodiversity Board for identifying the representative organization(s).</p>	<p><u>Dr. P. Pushpangadan,</u></p> <p>Rule3(1): The National Biodiversity Authority shall recognize existing traditional forms of representative organizations of the traditional community, including <i>an individual, family</i> or a group of families / community based organisations;</p>
	<p>(2) A traditional community shall, for the implementation of these Rules, be represented by its traditional representative body and that body shall be the authorised body for all matters pertaining to the implementation of these rules with reference to that community.</p>	<p><u>Dr. Neelima Jerath</u></p> <p>Rule 3(2) It may be clarified whether the traditional representative body would be a registered or a non-registered body.</p>
	<p>(3) National Biodiversity Authority shall facilitate the traditional communities to exercise their collective rights to their own access and use, and to regulate access by others including fair and equitable benefit sharing for such access and relief on abuse and/or misuse and/or misappropriation and/or infringement of the traditional knowledge.</p>	<p><u>SEVA:</u></p> <p>Rule 3(3) :National Biodiversity Authority shall facilitate the traditional communities to exercise their collective rights to their own access and use <i>(continues access to natural resources which may be grazing of animals in the forest or sustainable harvesting of wild flora / species)</i>.</p>
	<p>(4) National Biodiversity Authority shall ensure that members of any traditional community shall be allowed to access or practice the traditional knowledge of another traditional community for the purpose of earning their livelihood and not for commercial gain.</p>	<p><u>Dr. Neelima Jerath</u></p> <p>Rule3(4) How would 'Livelihood' and 'commercial gain' be defined? What would be the bottom line? Would collection and sale of a particular biological resource by a local person, valued at, say Rs.1.00</p>

		lakh per annum be termed as 'livelihood' or a 'commercial gain'? or else, what criteria be followed to differentiate between the two.
	<p>(5) The National Biodiversity Authority shall take steps to prevent abuse and/or misuse and/or misappropriation of traditional knowledge; and where such abuse, misuse or misappropriation has taken place, the NBA shall institute proceedings in the appropriate forum.</p> <p>(6) The National Biodiversity Authority shall ensure that the traditional communities make sustainable use of the resources on which their traditional knowledge is based; and that the traditional community shall protect, conserve and practice the traditional knowledge for the continued good of the traditional community.</p> <p>(7) The National Biodiversity Authority shall set up a fund called the Traditional Knowledge Fund under Section 27 of the Act and there shall be credited thereto all charges, fees, royalties and all sums received by the National Biodiversity Authority in the administration of these Rules.</p> <p>(8) The said Fund shall be applied for the benefit of the traditional communities and in the protection, conservation and continued practice of traditional knowledge, by way of monetary and non-monetary as well as welfare based measures that shall include but not be restricted to incentives for continuing use and public service, direct income supports, registration and accreditation of such practices, etc.</p> <p>(9) The National Biodiversity Authority shall take initiatives to introduce traditional knowledge education including local traditional knowledge in the formal and non-formal systems of education and shall involve knowledgeable members of traditional community for the same.</p> <p>(10) The National Biodiversity Authority shall maintain a Traditional Knowledge Register to register Traditional Knowledge as described in these rules.</p>	<p><u>Dr. Neelima Jerath</u></p> <p><u>Rule 3(9)</u> Plan of implementation needs to be defined</p> <p><u>Rule 3(10)</u> Clarify what would be the difference between the proposed TKR and the existing TKDL at the national level except digitization of the latter?</p>
5	<p>4. Traditional Knowledge Registers:</p> <p>(1) There shall be kept at the National Biodiversity Authority, a Traditional Knowledge Register wherein shall be entered the name, location, description of the traditional knowledge, as is revealed by the traditional</p>	<p><u>SEVA:</u></p> <p><u>Rule 4(1)</u> There shall be kept at the National Biodiversity Authority, a Traditional Knowledge Register wherein shall be entered the name, location, description of the traditional knowledge, as is revealed by the traditional community, or in</p>

<p>community, or in the already documented system, along with the names of the practising traditional community(ies) in the prescribed format, as and when such information regarding the concerned TK is intimated to the National Biodiversity Authority by the traditional community or by the <i>suo motu</i> efforts of the Authority or any of the State Biodiversity Boards or the Biodiversity Management Committee upon an application for access;</p> <p><i>Provided</i> that the traditional community concerned has permitted the documentation and the form of documentation of the said traditional knowledge;</p> <p><i>Provided</i> also that such permission is not needed in case of traditional knowledge that is already in the public domain and/ or the traditional community concerned is not identifiable.</p> <p>(2) On registering the traditional knowledge, the National Biodiversity Authority shall mark such knowledge as either "PUBLIC" or "CONFIDENTIAL," depending on whether the components of traditional knowledge are of confidential nature and are so indicated by the traditional community that applies for registration, or if the National Biodiversity Authority deems so.</p> <p>(3) The name and address of the accessor, if any, accessing the said traditional knowledge, along with the nature of use of the accessed traditional knowledge and benefit sharing mechanism, and of amendments, extension and revocation of access shall also be entered in the said Register.</p> <p>(4) The Traditional Knowledge Register shall be maintained in electronic or paper form or in any other form that captures the essence of the traditional knowledge.</p> <p>(5) All existing and future databases pertaining to traditional knowledge relating to genetic resources under the control of the Central or State governments, including the Traditional Knowledge Digital Library and the People's Biodiversity Register(s) shall form part of the Traditional Knowledge Register.</p> <p>(6) Subject to the superintendence and direction of the Central Government the Register shall be kept under the control and</p>	<p>the already documented system, along with the names of the practising traditional community(ies) <u>or an individual</u> in the prescribed format,</p> <p><u>Dr. Neelima Jerath</u></p> <p>Rule 4(1) Does this refer to a written permission or would oral permission suffice? This need to be clearly brought out.</p> <p><u>Shri S. Ashok Kumar:</u></p> <p>Rule 4(4): The effect of confidentiality on the T.K. register in electronic or any other form may be looked into.</p> <p><u>Dr. P. Pushpangadan</u></p> <p>Rule 4(5): Central or State governments, including <u>the data gathered under the All India Coordinated Research Project on Ethno biology (AICRP).</u></p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

	<p>management of the Chairperson.</p> <p>(7) The contents of the Traditional Knowledge Register shall not be disclosed without authorisation of the Chairperson.</p> <p>(8) No application for access of any Traditional Knowledge shall be allowed if the said traditional knowledge is not registered in the Traditional Knowledge Register; <i>Provided</i> that where traditional knowledge has already been accessed without obtaining prior informed consent the accessor shall approach the appropriate forum under Rule 5.</p>	
6	<p>5. Regulation of access to traditional knowledge and informed consent.</p> <p>(1) Any person desirous of accessing traditional knowledge or any component thereof shall apply to the National Biodiversity Authority in the prescribed form with the prescribed fee.</p> <p>(2) On receiving the application for access, the National Biodiversity Authority shall examine the application for compliance of formalities and refer the same to the National Standing Committee; whereupon said committee shall examine the application to check for registration of the traditional knowledge in the Traditional Knowledge Register.</p>	
	<p>(3) Where the traditional knowledge is found to be registered in the Traditional Knowledge Register, then the National Standing Committee shall refer the said application to the appropriate State Biodiversity Board (s);</p> <p><i>Provided</i> that if the traditional knowledge is registered in the name of one more traditional communities from at least three different states, then the process for obtaining informed consent and negotiation shall be initiated by the National Biodiversity Authority, in consultations with all the State biodiversity Boards concerned.</p>	<p><u>Dr. P. Pushpangadan</u></p> <p><u>Rule 5(3):</u> <i>Provided</i> that if the traditional knowledge is registered in the name of <u>more than one traditional community.</u></p>
	<p>(4) Where there are no State Biodiversity Boards and / or Biodiversity Management Committee, the National Biodiversity Authority shall direct the State(s) concerned to set up the State Biodiversity Board(s) and / or Biodiversity Management Committee(s) within 6 months from the date of such direction;</p> <p><i>Provided</i> that where the state fails to comply within the stipulated time, the State may request an additional time of a period no greater than 6</p>	<p><u>SEVA:</u></p> <p><u>Rule5(4):</u>Where there is no State Biodiversity Board set up then <u>traditional knowledge can be registered directly with NBA through volunteers, grama sabha, NGOs or scientists.</u></p>

	<p>months to set up the State Biodiversity Committee and / or the Biodiversity Management Committee;</p> <p><i>Provided further</i> that where the State fails to comply altogether, the National Standing Committee shall facilitate the consultation between the traditional community (ies) and the applicant for issuance of the prior informed consent and negotiations for the access and benefit sharing agreement.</p>	
	<p>(5) On receiving the application, the State Biodiversity Boards shall refer the said application to the appropriate Biodiversity Management Committees and traditional communities.</p> <p>(6) On receiving the application the traditional communities shall inform the State Biodiversity Board of their willingness or unwillingness to participate in consultation on prior informed consent.</p> <p>(7) Where the traditional communities communicates their unwillingness to participate in consultation on prior informed consent to the State Biodiversity Board the said Board shall communicate the same to the National Biodiversity Authority through the NSC; whereupon the NBA shall communicate denial of access to the applicant.</p> <p>(8) Where the traditional communities communicates their willingness to participate in consultation on prior informed consent to the State Biodiversity Boards, the State Biodiversity Board concerned shall refer the application to the State Standing Committee.</p> <p>(9) The State Standing Committee shall in consultation with the said traditional community and the Biodiversity Management Committee, conduct a comprehensive assessment including assessment on sustainability of the resources, social and environmental implications and potential value of the traditional knowledge, and produce a report along with recommendations and a resource management plan; <i>Provided</i> that where the State Standing Committee requires any further information, it may require the applicant to provide further details regarding the proposed use of the traditional knowledge.</p> <p>(10) On receiving the comprehensive assessment report of the State Standing</p>	

<p>Committee, the State Biodiversity Board shall facilitate consultation(s) among the applicant, the traditional community(ies) and the Biodiversity Management Committee(s) at the location(s).</p> <p>(11) Where there is no agreement on granting access to the applicant, the same shall be communicated by State Biodiversity Board to the National Biodiversity Authority through the National Standing Committee, who shall then communicate the denial of the access to the applicant.</p> <p>(12) Where there is a consensus on the granting of access to TK(s), the SBB shall initiate the process for negotiating the terms and conditions of the access, use and benefit sharing of the TK(s), taking into account the recommendations of the State Standing Committee; <i>Provided</i> that if there are more than one State Biodiversity Board, the same shall be communicated to the National Biodiversity Authority through the National Standing Committee, and the process for negotiating shall be initiated by the National Biodiversity Authority.</p> <p>(13) On agreement between the applicant and the traditional community, the latter shall affix their signatures on the prior informed consent form, and thereafter both parties shall affix their signatures on the agreement for access and benefit sharing.</p> <p>(14) Copies of the prior informed consent, agreement on access and benefit sharing and the Report of the State Standing Committee shall be submitted to the National Standing Committee by the State Biodiversity Board.</p> <p>(15) On receiving the prior informed consent, the access and benefit sharing agreement and the report of the State Standing Committee, if any, the National Standing Committee shall refer the same to the National Biodiversity Authority with appropriate recommendations for issuance of the “licence of use” incorporating the prior informed consent and the terms and conditions of the access and benefit sharing agreement.</p> <p>(16) The Authority shall issue the “License of Use” after being satisfied that due processes under the law have been complied with, and the</p>	<p><u>Dr. Neelima Jerath</u></p> <p><u>Rule 5(11)</u> Is this step necessary? Can SBB not write directly to NBA?</p>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------

	issuance of said "License of Use" shall not be against the national interest.	
7	<p>6. Regulation of access to traditional knowledge in the public domain not owned by any specific traditional community or owned by traditional community (ies) in more than three states.</p> <p>(1) Where the traditional knowledge is already in the public domain and is not specifically owned by any particular traditional community or if the traditional community(ies) is/are spread in more than three states, then the willingness to issue a prior informed consent and negotiating an access and benefit sharing agreement shall be done by the National Standing committee in consultation with the respective State Biodiversity Boards, Biodiversity Management Committees and traditional communities, wherever possible and recommendations made to the National Biodiversity Authority.</p> <p>(2) The National Standing Committee shall, in consultation with the respective State Biodiversity Boards, Biodiversity Management Committees and traditional communities, wherever possible, conduct a comprehensive assessment including assessment on sustainability of the resources, social and environmental implications and potential value of the traditional knowledge, and produce a report along with recommendations, resource management plan along with an access and benefit sharing plan;</p> <p><i>Provided</i> that where the National Standing Committee requires any further information, it may require the applicant to provide further details regarding the proposed use of the traditional knowledge.</p> <p>(3) The National Biodiversity Authority shall exercise its discretionary powers with regard to the allowance of access to particular traditional knowledge on the basis of report(s) submitted by the National Standing Committee.</p> <p>(4) Where allowance of access to said traditional knowledge is granted by the National Biodiversity Authority, the prior informed consent along with access and benefit sharing agreement shall be signed between the National Biodiversity Authority and the applicant; whereupon the National Biodiversity Authority shall issue the license of use.</p>	<p><u>Dr. Neelima Jerath</u></p> <p>Funding source with respect to Rule 6(2) for assessment of sustainability on sustainability of the resource, social and environmental implications and potential value of the TK etc. also needs to be identified.</p>

	<p>(5) Where allowance of access to said traditional knowledge is refused by the National Biodiversity Authority, the same shall be communicated to the applicant within reasonable time.</p>	<p><u>Shri S. Ashok Kumar</u> <u>Rule 7(5):</u> The implications of the Right to Information Act 2005 on the <u>proviso</u> to Rule 7(5) maybe examined.</p>
<p>8</p>	<p>7. Regulation of access to non-registered traditional knowledge.</p> <p>(1) Where an application is received under rule 5(2), and the traditional knowledge is not registered, the National Standing Committee shall evaluate the traditional knowledge for its availability in public domain.</p> <p>(2) Where the said traditional knowledge is found to be in public domain, the National Standing Committee shall conduct an assessment of the said traditional knowledge including sustainability of the resources, social and environmental implications and the current and potential value of the traditional knowledge, and recommend the said traditional knowledge to the National Biodiversity Authority for registration in the Traditional Knowledge Register as PUBLIC traditional knowledge, along with the said assessment report;</p> <p><i>Provided</i> that if the said traditional knowledge is not in public domain, the National Standing Committee shall refer the application to all / relevant State Biodiversity Board(s).</p> <p>(3) On receiving the recommendation for registration of traditional knowledge in public domain and the assessment report under Rule 7(2), the National Biodiversity Authority shall register the said traditional knowledge in the Traditional Knowledge Register and commence negotiations as specified in Rule 6.</p> <p>(4) On receiving the referral from the National Standing Committee under Rule 7(2), the State Biodiversity Board(s) shall identify the appropriate traditional community(ies) practising the said traditional knowledge through the Biodiversity Management Committee(s) and communicate the same to the National Standing Committee for registration of the traditional knowledge as either “PUBLIC” or “CONFIDENTIAL”;</p> <p><i>Provided</i> that such information shall be registered only with the consent of the traditional community.</p> <p>(5) Where the traditional knowledge is</p>	

	<p>PUBLIC and is identified with one or more traditional community(ies) of more than three states, the National Standing Committee shall conduct an assessment as stated in rule 7(2) and refer the application to the National Biodiversity Authority along with the assessment report, whereupon the National Biodiversity Authority shall start proceedings as in rule 6(2);</p> <p><i>Provided</i> that where the traditional knowledge is CONFIDENTIAL, the National Standing Committee shall recommend to the National Biodiversity Authority to register the said traditional knowledge as CONFIDENTIAL in the Traditional Knowledge Register, and shall refer the application back to the concerned State Biodiversity Board for obtaining prior informed consent and access and benefit sharing agreement under Rule 6(4).</p> <p>(6) Any third party including a civil rights group may approach the chairperson with information of a traditional knowledge or a component thereof which may include information about its abuse and /or misuse and /or misappropriation, whereupon the Chairperson shall refer the matter to the National Standing Committee to investigate the accuracy of such information, evaluate the so identified traditional knowledge and register the same, after obtaining the required consent from the traditional community concerned if so identifiable, and after appropriate classification as “PUBLIC”, “CONFIDENTIAL” and/or recommend action in case of abuse and/or misuse and/or misappropriation.</p>	
9	<p>8. Licence to Use</p> <p>(1) The National biodiversity Authority may issue a non assignable and non-transferable licence to use to an applicant, in response to a written application only and after following the prescribed procedures, to access a specified traditional knowledge, subject to the conditions stipulated in the said licence for a period not less than 1 year and not greater than 3 years, the said licence may be renewed for a further period not exceeding 3 years.</p> <p>(2) The Licence to Use issued to an accessor shall be published in the Official Journal and along with the supporting documents, including the prior informed consent, various assessment reports and the agreement between the parties concerned shall be published on the website of the National Biodiversity Authority as soon as</p>	

	<p>possible.</p> <p>(3) Any person who has an interest in the traditional knowledge concerned may, within six months of the publication of the agreement on the website of the National Biodiversity Authority, make an application for opposition or revocation of the agreement and the licence to use, to the National Biodiversity Authority in the prescribed manner.</p> <p>(4) On receipt of such notice of opposition / revocation, the National Biodiversity Authority shall refer the matter to the National Standing Committee for re-examination of the Agreement and the grant of licence.</p> <p>(5) The National Standing Committee shall re-examine the agreement taking into consideration all information made available to it by both parties, in writing and orally, and after detailed hearing of both parties, submit a report with recommendations to the National Biodiversity Authority.</p> <p>(6) On receipt of the re-examination report of the National Standing Committee and after giving the accessor and the opponent an opportunity of being heard, the Chairperson shall pass an order to maintain or amend or revoke the agreement and or the licence to use.</p> <p>(7) The accessor has the responsibility to inform the National Biodiversity Authority of any change in address and/or in his legal status, if any, within two weeks of such an event.</p> <p>(8) In case of misuse of Traditional Knowledge, the Licence to Use shall be revoked by the Authority and the accessor shall be liable under Rule 18 herein.</p>	<p><u>FICCI:</u></p> <p><u>Rule 8(3)</u> Procedures for Opposition or revocation of any license for use of traditional knowledge need to be set out in further detail (with specific forms/formats) to avoid ambiguity.</p>
10	<p>9. Sharing of Benefits</p> <p>(1) Sharing of all benefits arising out of the access to the traditional knowledge and /or its consequential commercial use shall be as negotiated between the traditional community and the applicant and facilitated by the State Biodiversity Board through the Biodiversity Management Committee(s).</p> <p>(2) All benefit share shall directly be paid to the traditional community by the applicant and shall be reported annually to the State Biodiversity Board, concerned and the National</p>	

	<p>Biodiversity Authority by both the applicant and the traditional community; <i>Provided</i> such benefits that arise from an agreement between the National Biodiversity Authority and the applicant shall accrue to the Traditional Knowledge Fund. (3) Details of all the reported benefits shall be published in the website of the National Biodiversity Authority as soon as possible.</p>	<p><u>Shri S. Ashok Kumar:</u> <u>Rule 9(3):</u> In case the applicant offers to provide in the form of infrastructure services to the traditional community such as laying or effecting repairs to village school building, or providing educational equipment to such school, construction or repair to the village fairs and festivals, jataras of tribal community or helping or running an Orphanage or an Old age Home etc for the community senior citizens etc, necessary provision should be made in these rules.</p>
	<p>10. Access Fee (1) The National Biodiversity Authority shall, at the time of approving the license to use, impose an access fee based on the negotiations between the traditional community and the accessor. (2) The access fee shall be deposited by the accessor at the Traditional Knowledge Fund established under rule 11.</p>	
	<p>11. Constitution of Traditional Knowledge Fund 11(1) There shall be constituted a fund to be called the Traditional Knowledge Fund and there shall be credited thereto –</p> <ul style="list-style-type: none"> (a) any grants and loans made to the National Biodiversity Authority for specific needs of the implementation of the Rules; (b) all charges and access fees received by the National Biodiversity Authority; (c) all monetary benefits that accrue to the National Biodiversity Authority upon an agreement signed for access between National Biodiversity Authority and the applicant; and (d) all sums received by the National Biodiversity Authority from such other sources as may be decided upon by the Central Government. <p>11 (2) The Fund shall be used for the protection, conservation and development of traditional knowledge and the traditional communities which shall include –</p>	

	<p>(a) channeling benefits to the benefit claimers;</p> <p>(b) conservation and sustainability of traditional resources, welfare and livelihood support for traditional communities and traditional practitioners;</p> <p>(c) ecological and cultural restoration programmes specifically related to traditional knowledge practices and such regions / sectors such as traditional medicine, health and educational practices, farming and other traditional livelihoods; and</p> <p>(d) socio-economic, ecological and cultural development of areas referred to in sub-rule (b) in consultation with the State Biodiversity Board(s), Biodiversity Management Committee(s) and traditional community (ies) concerned;</p> <p>(e) recognition and accreditation of traditional practitioners;</p> <p>(f) promoting the use and practice of common public domain traditional knowledge such as home remedies, customary healing and agricultural practices etc especially in formal and non-formal educational systems and among traditional communities.</p>	<p><u>SEVA:</u> Rule11 (2) (e) recognition and accreditation of traditional practitioners <u>or conservers;</u></p>
		<p><u>SEVA:</u> <u>Rule11(2)</u> <u>Add 11 (2) (g):</u> <u>Strengthening in-situ conservation of species races or breeds maintained by the communities through the activities identified by the communities.</u></p>

12. National Strategies, Plans, etc., for Conservation, Development, etc., of Traditional Knowledge and Resources.

(1) The National Biodiversity Authority shall develop national strategies, plans, programmes for the conservation, development and sustainable use of traditional knowledge including (a) measures for identification and monitoring of areas rich in traditional knowledge, (b) incentives and support systems for traditional communities and traditional practitioners, and (c) incentives for training and public education to increase awareness with respect to traditional knowledge.

(2) Where the National Biodiversity Authority has reason to believe that any area or traditional community rich in traditional knowledge and resources is being threatened by overuse, abuse or neglect, it shall issue directives to the State Government concerned to take immediate ameliorative measures and also offer the State Government concerned technical and other assistance that is possible to be provided.

(3) The National Biodiversity Authority shall recommend, as far as practicable wherever it deems appropriate, the integration, conservation, promotion and sustainable use of traditional knowledge and resources into relevant sectoral or cross-sectoral plans, programmes and policies.

(4) The National Biodiversity Authority shall undertake measures wherever necessary,

(a) for assessment of socio-cultural, economic and environmental impact of that project which is likely to impact or have adverse effect on traditional knowledge, traditional practices and biological diversity, with a view to avoiding or minimizing such effects and provide for public participation in such assessment; and

(b) to prevent the risks associated with the use of any technology or process or introduction of alien species that is likely to impact the conservation and continuum of the use and practice of traditional knowledge and/or its related biotic and abiotic resources.

	<p>13. Traditional Knowledge Facing Extinction.</p> <p>(1)Without prejudice to the provisions of any other law for the time being in force, the National Biodiversity Authority, in consultation with the State Biodiversity Board concerned, may from time to time notify any traditional knowledge or resource which is on the verge of extinction or likely to become extinct in the near future on account of</p> <p>(a) depletion of resources to sustain the traditional knowledge,</p> <p>(b) unwillingness of the traditional community to practise the traditional knowledge due to lack of opportunities, and</p> <p>(c) usurpation of the traditional knowledge for commercial gains, and prohibit or regulate access thereto for any purpose and take appropriate steps to preserve and ensure continuum of the same</p>	
		<p><u>Shri P. Pushpangadan</u></p> <p><u>Rule13 (1):</u></p> <p>Add Rule 13(1)(d) & (e)</p> <p><u>(d) dwindling number of the knowledge holders in a community as in Andaman Nicobar Islands</u></p> <p><u>(e) mass exodus of the community from their traditional environs due to employment opportunities and developmental activities.</u></p>
	<p>(2)The National Biodiversity Authority shall facilitate development of plans in consultation with traditional communities to protect, regenerate and propagate the traditional knowledge facing extinction, along with detailed conservation measures for the biological resources. The National Biodiversity Authority will also earmark dedicated funds to ensure that the continued practice of the traditional knowledge facing extinction.</p>	<p><u>FICCI:</u></p> <p><u>Rules 13(2):</u> If any biological resource is modified in any manner whatsoever which may affect its inherent/replicating properties, the same must be mandatorily disclosed in full with the best method of such modification (in <i>pari materia</i> with the doctrine of best method in Patent law) both to the National/State Biodiversity authorities. Further if such biological resource is commercially exploited in any manner whatsoever (whether a value added product or a byproduct under the Act or not), the fact of such modification along with any methodology (e.g.. radiation) must be prominently mentioned on packaging /disclosed to an intending user /customer of such product derived from such modified biological resource.</p>
	<p>14. Traditional Knowledge Heritage Zones.</p> <p>(1) Without prejudice to any other law for the time being in force, the National Biodiversity</p>	

	<p>Authority, in consultation with the State Biodiversity Board concerned, and on application from a Biodiversity Management Committee, notify in the Official Gazette, areas of importance as traditional knowledge heritage zones under the Act.</p> <p>(2) The National Biodiversity Authority, in consultation with the State Biodiversity Board concerned, shall prescribe regulations and guidelines for the management and conservation of all the traditional knowledge heritage zones.</p>	
	<p>15. Standing Committees.--</p> <p>(1) The National Biodiversity Authority shall constitute a National Standing Committee with a Presiding Member and not more than six other members of whom, one shall be a member from a civil society who is knowledgeable and experienced in matters of traditional knowledge practices and conservation, and at least three shall be representatives of traditional communities of India, provided that women shall constitute at least 30% of the total members.</p> <p>(2) The State Biodiversity Board shall set up a State Standing Committee with a Presiding Member and not more than six other members of whom, one shall be a member from a civil society who is knowledgeable and experienced in matters of traditional knowledge practices and conservation of the State, and at least three shall be representatives of traditional communities of the State concerned, provided that women shall constitute at least 30% of the total members.</p> <p>(3) The meetings of the National Standing Committee and the State Standing Committees shall be convened by the respective Presiding Member.</p> <p>(4) The duties and functions of the National Standing Committee and the State Standing Committees shall be as specified in these rules and as assigned by the National Biodiversity Authority or the State Biodiversity Board, as the case may be.</p> <p>(5) All decisions of the National Standing Committee and the State Standing Committees shall be taken by a majority of the membership.</p> <p>(6) The expenditure of the National Standing Committee shall be debitable to the same budget head to which the expenditure of the</p>	<p><u>SEVA:</u></p> <p><u>Rule15 (1):</u> The National Biodiversity Authority shall constitute a National Standing Committee with a Presiding Member and not more than six other members of whom, one shall be a member from a civil society who is knowledgeable and experienced in matters of traditional knowledge practices and conservation, and at least three shall be representatives of traditional communities of India <u>involved in current practice of traditional knowledge or conservation of biological resources,</u></p> <p><u>Dr. Neelima Jerath</u></p> <p>Rule 15(2) - Can the function of State Standing Committee not be carried out effectively by the State Board itself?</p>

	<p>National Biodiversity Authority is debited and that of each State Standing Committee to the same budget head to which the expenditure of the State Biodiversity Board concerned is debitable.</p>	
	<p>16. Budget, Accounts and Audit.</p> <p>The National Biodiversity Authority shall prepare a separate budget, maintain proper accounts and other relevant records, including the accounts and other relevant records of the Traditional Knowledge Fund, and prepare an annual statement of account in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor-General of India</p>	
	<p>17. Documents open to public inspection.</p> <p>(1) The following documents, subject to such conditions as may be prescribed, shall be open to public inspection at the National Biodiversity Authority, namely:-</p> <p>(a) the register and any document upon which a public entry in the register is based; <i>provided</i>, the entries marked in the Register as "CONFIDENTIAL" shall not be made available to the public;</p> <p>(b) all documents pertaining to an application for access, the reports of the National Standing Committee, State Biodiversity Boards and State Standing Committees and the prior informed consents, agreements, and Licences to Use;</p> <p>(c) every notice of opposition to the registration of a traditional knowledge, application for rectification before the chairperson, counterstatement thereto, and any affidavit or document filed by the parties in any proceedings before the chairperson; and</p> <p>(d) such other documents as the Central Government may, by notification in the Official Gazette, specify.</p> <p>(2) Any person may, subject to such conditions as may be prescribed, on an application to the Chairperson and on payment of such fee as may be prescribed, obtain a certified copy of any entry in the register or any document referred to in sub-rule (1).</p>	

	<p>18. Offences and Penalties:-</p> <p>(1) Whoever contravenes or attempts to contravene or abets the contravention of any of the provisions of these Rules, shall be deemed to have committed an offence and shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both.</p> <p>(2) Notwithstanding anything contained in Rule 18(1) whoever misappropriates and/or misuses and/or abuses traditional knowledge shall be deemed to have committed an offence and shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both.</p>	<p><u>SEVA:</u></p> <p><u>Rule18(2):</u> “misappropriates and/or misuses and/or abuses” <i>can be deleted</i></p>
	<p>(3) Protection of action taken in good faith: No suit, prosecution or other legal proceedings shall lie against any Authority in respect of anything which is in good faith done or intended to be done under this Act or the rules or regulations made there under.</p>	
	<p>(4) Cognizance of offences: No Court shall take cognizance of any offence under this Act except on a complaint made by –</p> <p>(a) the Central Government or any authority or officer authorized in this behalf by that Government; or</p> <p>(b) Any benefit claimer who has given notice of not less than thirty days in the prescribed manner, of such offence and of his intention to make a complaint, to the Central Government or the authority or officer authorized as aforesaid.</p>	<p><u>Shri S. Ashok Kumar:</u></p> <p><u>Rule 18(4):</u> That the offence committed under this Act is cognizable and that it attracts five years punishment or with a fine of ten lakh rupees shows that it is a criminal offence. Hence there is need to have a legal cell to deal with such cases and to give suitable guidance as the success or failure of a criminal case depends mainly on primary and secondary evidence produced.</p>
	<p>19. Appeal.—</p> <p>Any person, aggrieved by any proceeding or order of the National Biodiversity Authority under these Rules, may file an appeal in the Supreme Court within thirty days from the date of communication to him, of the proceeding or order of the National Biodiversity Authority, as the case may be;</p> <p><i>Provided that the Supreme Court may, if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal within the</i></p>	

	said period, allow it to be filed within a further period not exceeding sixty days.	
	<p>20. Execution of Proceeding or Order.— Every proceeding or order made by the National Biodiversity Authority as per these Rules shall, on a certificate issued by any officer of the National Biodiversity Authority in the same manner as a decree of a court.</p>	
	<p>21. Annual Report of National Biodiversity Authority. (1) The National Biodiversity Authority shall prepare, in such form and at such time each financial year as may be prescribed, its annual report, giving a full account of its activities relating to the traditional knowledge during the previous financial year and furnish, to the Central Government, before such date as may be prescribed, its audited copy of accounts together with auditors' report thereon.</p> <p>(2) The Central Government shall cause the annual report and auditor's report to be laid, as soon as may be after they are received, before each House of Parliament.</p>	
	<p>22. Power to make regulations. The National Biodiversity Authority may, with the previous approval of the Central Government, by notification in the Official Gazette, make regulations for implementing these Rules.</p>	

B3. General comments received on the draft TK Rules (Rules for Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity, 2009).

1. FICCI –IPR Division:

a. Legal uncertainty associated with access to TK and prior informed consent:

The procedure prescribed to obtain access to TK is quite complex involving many steps. Involvement of stakeholders at different levels makes the whole process time consuming and complicated. Therefore, any approval seeker will have to knock the doors of many fora/offices. At the same time the Authority shall dispose of the application within six months from date of receipt of application as per rule 14 of the Biological Diversity rules 2004. The procedures to obtain the approval should be made simple and user friendly. The procedure will have to be simplified so that the access to the TK is available for further research, investment and industrial growth.

The proposed rules even want public notification and participation and right to appeal the final decision. The rule even provides denial of access to the applicant in case the traditional communities express their unwillingness to participate in the consultation on prior informed consent. If such requirements are imposed as new conditions for obtaining access they may actually create hardships to the researchers and open new avenues for legal challenges.

The proposed regulation mechanism will cast a shadow upon the advantages and benefits envisaged under the Act such as conducting research, making money out of the research and thereafter meeting the obligation of equitable benefit sharing to the other party. Please note that the party seeking an approval for use/ research on the TK and genetic resources is investing time money and efforts. Even then, he is not sure whether his time, money and efforts will bear fruit or provide any benefits to him or others. It is an established fact that investing in these areas is extremely risky due to the inherent uncertainties and failures. In this context the benefit seekers/ beneficiaries should be reasonable and encouraging the efforts of the access seekers. If the procedure for obtaining access permit is made too tedious and time consuming, it shall ultimately discourage the researchers and they shall be forced to look for alternatives through the modern biotechnology techniques. This shift will eventually lead to extinction of huge knowledge base available with the traditional communities. This uncertainty will discourage investment in inventions utilizing TK and thereby reducing the opportunities for negotiating mutually agreed terms and for sharing of any resultant benefits. This is contrary to the interest of both the indigenous communities and communities of potential users of such TK. Please note that any system that increases the complexity and legal risk, carry a potential to discourage the use of natural genetic resources and TK under that system, and therefore reduces whatever equitable benefit to be shared.

We believe that procedure for obtaining access to TK and prior informed consent should be made simple, transparent and accessible to interested parties. Access to genetic resources should be facilitated at a

minimum cost and the procedure should be friendly for the access seeker. Further, the mutually agreed terms should be negotiated efficiently within a reasonable period of time with legal certainty and clarity.

b. Treatment of confidential information: The rules require the particulars of documents such as license to use, prior informed consent, assessment reports and the agreement between the parties to be published in the official Journal. However, no mechanism to ensure the confidentiality of the disclosed information has been provided in the proposed rules. Publication should be subject to some of the confidentiality involved in the nature of business of the approval seeker.

c. Need for a proper adjudication mechanism: There is a need for a proper adjudication mechanism to settle the disputes arising out of various proceedings under the proposed rules. We notice that an appeal from the order of the NBA under the rules may be filed in the Supreme court within thirty days from the date of communication to him which may be extended for another period of maximum sixty days. However, an appeal straightaway to Supreme Court by an aggrieved party is quite harsh on the aggrieved party. As per the due process of law and also based upon equity, aggrieved party should be given atleast an opportunity to file an appeal before approaching the Supreme Court. As you are aware that Supreme Court would decide only the question of law and not the fact and if there is any misrepresentation or omission in respect of interpreting/ considering the facts involved in the Judgment of the NBA then there has to be an opportunity of filing an appeal to consider even the factual issues involved in the case. Therefore, we suggest that if there is an appeal from the NBA located in Chennai then Chennai High court can have the jurisdiction to adjudicate this matter and thereafter an appeal to the divisional bench of the same High court and finally an appeal can be filed with the Supreme Court. The above procedure is in line with section 52 of the Biodiversity Act. This procedure will help even NBA for the reason that if the order passed by NBA is struck down by the Supreme Court as unreasonable (which can always be) they have no other option left.

2. Smt. Topi Basar, Professor Faculty of Law, University of Delhi.

Positive aspects of the Rule: i. TK is defined very broadly. It takes in to account all components of TK. It includes both oral and written TK. Emphasis is on collective nature of TK, having an inter-generational entity, held by traditional community /individual/including group of family. It also includes cultural TK such as folklore, dance and music among other forms of TK.

ii. Clear meaning and definition of the key elements as Traditional Community, Accessor, Misappropriation/ misuse, Prior-informed consent, Access and benefit sharing, etc.[3]

iii. Recognition of Traditional Representative Body to act on behalf of the Traditional Community. Access to TK cannot be allowed without the PIC of the Traditional Community. Also, permission is mandatory for registering their TK in the TK Register.

- iv. Creation of National Standing Committee and State Standing Committee is a good step.
- v. The Rules provide for creation of TK Register for the preservation and protection of various TK.
- vi. Establishment of TK Fund that shall be applied for the benefit of the traditional communities and in the protection, conservation and continued practice of traditional knowledge, by way of monetary and non-monetary as well as welfare based measures, etc.
- vii. To introduce TK education including local traditional knowledge in the formal and non-formal systems of education and shall involve knowledgeable members of traditional community for the same.
- viii. Notification of Traditional Knowledge Heritage Zones of areas of TK importance.
- ix. Contravention of these Rules is punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both.
- x. No application for access of any Traditional Knowledge shall be allowed if the said traditional knowledge is not registered in the Traditional Knowledge Register.
- xi. Any person, aggrieved by any proceeding or order of the NBA may file an appeal in the Supreme Court within thirty days.

Criticisms: The Rules are well balanced and finely drafted. The Traditional Community or holders of TK plays a significant role in the overall decision-making process through proper representation by its Representative Body. Infact the BMCs are also an important medium between the Traditional Community and the State Standing Committee and have been given important role in making of TK Register, TK Fund and in the ABS processes. As a whole it is a good attempt indeed.

But, it would have been more advisable to create a separate statutory authority for TK at the National, State and Local level. Instead the Rules have bestowed all the powers on NBA and SBB who are saddled with Biodiversity Act and Rules and putting more responsibility on them will over burden them. They will not be in a position to work with single-handed devotion on TK, which will in effect render the Rules ineffective and a mere paper Rule. The BMCs at the local level may remain the same as in the Biodiversity Act with additional powers and responsibilities pertaining to TK. TK is a very complex and crucial subject for the Nation. Only independent and separate machinery will be competent to deliver the desired objectives.

3. Association of Biotechnology Led Enterprises (ABLE)

- a. The proposed system, which requires potential accessors to negotiate prior informed consent, conditions of access and benefit sharing directly with traditional communities may not be workable or

efficient. Negotiations for accessing both knowledge and resources should take place between a potential accessor and a national governmental office or body which, in turn, can ensure that traditional communities are consulted, etc.

b. 2p discussion of misappropriation requires clarification as well. Misappropriation is simply the illegal appropriation of a GR. The draft can go on to define illegal, but it is not helpful to simply say "any form of appropriation . . ." that seems improper and then go on to list possibilities and include intellectual property.

4. Shri Bala Prasad, APCCF, Forest Dept, Manipur

- While evolving *sui generis* system for the protection of Traditional Knowledge following scenario may be kept in mind:
- Traditional Knowledge are available in form of documented, non-documented
- (passing one generation to other orally or folklore), partially documented.
- Non documented Traditional Knowledge may be owned by a community, group of individuals or specified individuals.
- Traditional Knowledge at times are trans –boundary in nature i.e. it may or may not coincide with well defined geographical boundary.
- Patents are being taken mostly by Indians settled in USA, Europe and Japan on Indian traditional medicinal Traditional Knowledge.
- There is serious situation as we may lose Traditional Knowledge fast as new generation is not finding indigenous medicinal systems attractive and going to other profession and medicinal Traditional Knowledge is being held by older people. Agri., TK is losing ground with accelerated pace due to high yielding varieties and focus on grow more food
- Traditional knowledge Digital Library is presently limited to Ayurveda, Unani, Sddha and Yoga. Moreover, TKDL is defensive mechanism. There is only one success story
- As soon as a TK comes in public domain, it can not be patented.
- Clinical trial takes approximately seven year

In view of above *sui generis* system for the protection of Traditional Knowledge may contain following as its components:

- Pro actively facilitating patents on Medicinal Traditional Knowledge, particularly belonging to indigenous communities by National Biodiversity Authority and State Biodiversity Board.
- Developing comprehensive Methodology for documentation of Medicinal Traditional Knowledge
- Amending Indian Patent Act / Biological Diversity Act so that knowledge of a community in public domain may be patented in favour of the community
- Helping individuals and group of individuals for taking patent on their Medicinal Traditional Knowledge
- In case of Medicinal Traditional Knowledge, in clinical trial on animals may be discarded.
- Revitalisation of Medicinal Traditional Knowledge through providing incentives, training
- Traditional knowledge Digital Library should also cover indigenous medicinal systems
- Legalising practicing of indigenous medicinal systems
- Preservation of TK associated with agro- biodiversity should be given priority in management of biodiversity by documenting, incentive for practice
- Private companies should be given incentives commercializing and sharing benefits with local people.

5. Shri S. Elumalai, School of Excellence in Law, Chennai

1. The provision relating to the definition of IPR (Sec.2(l)) must be enlarged so as to include plant breeders rights (PBR's) and confidential information/trade secrets, it is better to include the word 'the subject matter of Sec. 1 to 7 of Part II of TRIPS Agreement of WTO';
2. The provision relating to abuse, misuse and misappropriation must be exhaustively defined and should comply the requirements of the draft provisions of TK developed by the WIPO;
3. The definition relating to 'traditional community' should include the word 'Local Community or Similar People who are having access to traditional knowledge', so as to comply the CBD requirements. It is strongly suggested to provide an explanation clause to this definition. So as to make it clear that the word 'traditional community and local community' will be interchangeably used for the purposes of this Act.
4. In the provisions relating to the definition of 'traditional knowledge' it is better to remove the following elements covering folklore, copyright and other issues which are not strictly related with bio-resources relating TK;
5. It is strongly recommended that the aforesaid stated definitions must be incorporated in the Parent Act rather than in the Rules;
6. It is strongly recommended in the composition of National Standing Committee and State Standing Committee atleast one academicians relating to this field must be included;
7. It is constitutionally as well as legally mandatory to have a quasi-judicial authority to hear appeals arising out of various issues under the Act, because the access to the Supreme Court of India is not that much easier as envisaged by this Rules as an Appellate Tribunal, if the issue is left unaddressed this in turn will defeat the very basic object of the Act itself, i.e., (a) the TK holder and the common man may not have easy access to the apex court, (b) the Supreme Court cannot be reduced in to a mere appellate court;
8. The provisions relating to the Offences and Penalty clauses must be incorporated in the Parent Act, and not in the Rules;
9. The provisions relating to the action taken in good faith may be deleted because such provision is already existing in the Parent Act;
10. It is better to include in the definition clause relating to the following terms:
 - a. Technology;
 - b. Bio-Technology;
 - c. Alien Species;
 - d. Living Modified Organisms.

And try to incorporate the requirements of the Cartagena Protocol;

11. The provision relating to the access of TK in public domain, the word 'more than three States' have been used it should be brought down to more than 'one State';
12. In the absence of State Bio Diversity Boards more powers have to be given to N.B.A;
13. The N.B.A., must be given more regulatory powers in the form of administrative control.

6. M. S. University of Baroda, Vadodara

- To inform all the industries /firms/small entrepreneurs regarding rules and regulations of the National Biodiversity Authority (NBA).
- Awareness regarding NBA to local public at rural and urban level.
- Conveying the NBA rules regulation and benefit to the local people/ (localities) regarding their traditional Knowledge.
- Benefit of NBA for the protection of Natural reserve of High Significance.
- How you will scrutinize that the traditional knowledge has been used by the company
- The conflict that will arise between FDA approval and the NBA approval.
- What about if the Community traditional knowledge which is directly taped by the commercial community at their personal level.
- Preservation of aquatic ponds, estuaries, forest, non forest region (waste Land)
- Registration has to be renewed every three years. I don't think the businessman from Gujarat will get into such deals as the time span is very short. The period should be extended for minimum 10 years or 3 years with extension up to 10 years with due secrecy of the knowledge.
- Community other than the Govt. official should include professionals
- Raw material before exploiting from the forest should be reported to the Forest Authority concern and should be intimated to the NBA, Committee members.

7. Mr. Mayur Parekh, Advocate – Intellectual Management Consultant, Vadodara

- Stop Industries evolving in bio resources to access natural resources or take permission from concerned Government Authority.
- To preserve marine aquatic life of Gujarat Coastal Region and to stop Alang Port to eliminate waste from hazardous or toxic elements resulting from ship breaking.
- Use of Microorganism thoroughly for genetic bioproducts.
- Set up of forums at ground level.
- Proper utilization of funds.
- Wild life protection to regulate life cycle.
- Present enactments like wildlife act, forest act are not proper and non effective.
- Security of local people.
- Traditional Community definition is not explanatory.
- Tribunal Courts and separate courts.
- Agreements with foreign party before using our traditional knowledge.
- Awareness of IPR regime and laws.

8. Prof. M. P. Yadav

It is a matter of great satisfaction to learn that NBA is organising National consultations for the protection of Traditional Knowledge and conservation of bioresources for profit sharing. Among other benefits, this exercise will boost the efforts for conservation and IPR protection of our indigenous breeds of livestock. In this regard the Ranchi Declaration 2009 may also be taken into cognizance. NBAGR, Karnal may be of immense help.

9. Dr. (Mrs) Uma Melkania, G.B. Pant Nagar, Uttaranchal,

Several hypotheses have occurred about the global and regional pattern of biodiversity and Gradients of biodiversity and have shown significant effects. Combination of a variety of plant species in a forest resulted into considerable diversity in the timing and duration of phenophases and maximized the period of food availability to pollinators, frugivores and seed predators in return for their pollen transfer and seed dispersal services which are crucial for perpetuation of the system. It is generally noticed a decrease in species diversity from lower to higher altitudes on a mountain in terrestrial environments. A 1000 m increase in altitude results in a temperature drop of about 6.5⁰C. This drop in temperature and seasonal variability at higher altitudes are a major factor that reduces diversity. For every 100 cm increase in rainfall 50 tree species are added. Bird diversity increases with increase in vertical layering of the vegetation i.e. from grassland to forests which have herbs, shrubs, co-dominants and dominant trees. . More complex and heterogeneous the physical environment more complex and diverse will be flora and fauna. In view of the above several activities can be undertaken to attain the above mentioned points advertised by NBA for inviting suggestions/comments as below;

1. To establish Biodiversity Resource Database Centre for Uttarakhand

Objective:

- To standardize methodology manual for biodiversity survey,
- To find out details of biological resources and knowledge associated with it, viz., biological name, quantity, purpose, source, place of collection and uses etc.
- To prepare details on value addition potential and prospects on bioresource for Local, regional, national/ commercial use.

Methodology:

- Collection of literature from secondary sources, Govt. reports, Govt. and NGO'S sources, questionnaires, books, publications, unpublished reports, Ph.D, M.Sc., M.Phil thesis, traditional knowledge system, visits/ survey to various places of biodiversity interest, website.
- Characterization of various altitudinal zones for biodiversity survey in the state

Utility:

- Development of Uttarkhand state Biodiversity website for database, Activities, rules, Acts etc.
- Formulation of State Biodiversity rules.
- Publications.

2. To Standardize People's Biodiversity Register for Uttarakhand

- Survey of various altitudinal zones for classifying biodiversity resources.

- To work out ideal people's biodiversity register as per resource richness and traditional knowledge.
- To study biodiversity in cultivated and outside Protected Area Networks.

Materials and method:

- **Step 1-** Altitudinal division of biodiversity rich areas.
- **SubStep 1-** Division of every altitudinal zone to various sub-divisions as per topography, location, climate and anthropogenic level of disturbances.
- **Substep 2-** Survey of these areas to identify forest biodiversity, traditional crops, their varieties, landscape and ecotypes.

Utility:

- To assess the biodiversity potential of various resources and linking it with livelihood locally and with commercial use.
- To frame biodiversity rules.
- Identification of biodiversity rich areas outside Protected Area Network and cultivated areas.
- Helpful in benefit sharing.
- Help to protect traditional knowledge.
- Amendment in Biological Diversity rules 2004 keeping in view the altitudinal distribution of biodiversity.

3. Conservation, Maintenance and Consolidation of Memorial Biopark

- a. Survey and boundary consolidation of the Biopark.
- b. Conservation of biodiversity in the Biopark.
- c. Assessment, investigation and documentation of biodiversity including agrobiodiversity.
- d. Awareness and training for the stakeholders on biodiversity related issues.

Work Plan

- Survey of flora and fauna livestock, birds.
- Preparation of people's biodiversity register.
- Survey of traditional crops, varieties, landscape and ecotypes.
- Training and capacity building.
- Formulation of posters, hoardings, in the park.

4. To Establish Biodiversity Conservation and Awareness Programmes in Uttarakhand

To create awareness on biodiversity conservation, utilization and sustainable use through undertaking various programmes.

- Tree planting programme
 - Teachers training programme
 - Celebration of International Biodiversity Day
 - Celebration of World Environmental Day
 - Celebration of various day of environmental interest with NSS, Rotary club at Gram Panchayat level.
- To conduct village level mela to popularize Indian system of medicine, traditional knowledge on biodiversity, conservation and sustainable harvest yield, Bal-utsav, hoardings installation, posters, newsletters.

- Establishment of biodiversity conservation programmes through cultivation of bioresource of economic use through medicinal and herb park.
- National Regeneration Campaign, Essay writing competition on
- Agricultural biodiversity , Threats to biodiversity , Medicinal biodiversity
- Importance of biodiversity to man , Exhibition on biodiversity

10. Tulika Singh, Asst. Director, National Seed Association of India

NBA should devise proformas for those persons/organizations listed at Chapter-II, Clause-3(2) for accessing biological diversity for research or for commercial utilization, as current formats are too specific to collaborative research activities associated with traditional knowledge. Normally traded commodities including germplasm should be allowed to be exchanged freely within the organization across the globe and intra-institutional exchange under a SMTA. Institutions (public or private) should have freedom to enter into MTA for the exchange of normally traded commodities including germplasm.

11. Dr. Duggaraju Srinivasa Rao, Associate Professor of Zoology, Noble College

1. Please involve academic institutions in documenting the biodiversity of the area. One college in each district, where some amount of work on Biodiversity was already on, as a nodal centre for coordinating the schools and colleges in the district.

2. Teachers have confidence of students and local community who are holding the traditional information and knowledge about plants and animals and their use in human welfare and health.

3. It is my experience that most of the locals having knowledge on the medicinal use of plants are not sharing it because they don't have confidence on the Government machinery.