

**National Consultation on Access to Benefit Sharing (ABS)-
Comments received**

S.No	Name / Institution
1.	Ms. Sheetal Chopra, Deputy Director, IPR Division, FICCI
2.	Ms. Kanchi Kohli, Kalpavriksha, Environmental Action Group, Delhi
3.	Shri F.R. Daruwala, Juris Corp, Advocates& Solicitors, Mumbai
4.	Shri P. Vivekanandan, SEVA, Virattipathu, Madurai, Tamil Nadu
5.	Shri Bala Prasad, Additional Principal Chief Conservator of Forests, Forest Department, Imphal, Manipur
6.	Dr. R. S. Rana, Chairman, EC of NBA on ABS, New Delhi
7.	Shri Priyadarsanan Dharma Rajan, ATREE, Bangalore
8.	Shri S. Elumalai, Faculty of Law, The School of excellence in law, Chennai
9.	Shri Thamziharasu, District Environmental Co-ordinator, Kancheepuram

A2 – Specific Comments received on Draft Guidelines on ABS

Draft guidelines on ABS prepared by the Expert Consultant, NBA	comments
<p>I. Preliminary</p> <p>1. Objectives</p> <p>1.1 These Guidelines on Access and Benefit Sharing Regarding the Utilization of Biological Resources and knowledge associated thereto (hereinafter “the Guidelines”) provides an objective and non-discriminatory framework for granting approvals for access to Biological Resources and Knowledge associated thereto and the fair and equitable sharing of the benefits arising from their utilization, in conformity with the Biological Diversity Act 2002 (hereinafter “the Act”) and the Biological Diversity Rules 2004 (hereinafter “the Rules”).</p>	<p>FICCI: The following are not clear, need further explanation</p> <p>(a) <u>non-discriminatory framework</u> -is not clear, does it mean that it applies to all firms irrespective of them being a Section 3(2) organization as defined in the Act</p> <p>(b) <u>Framework for granting</u>-The aim of the guideline should be to promote the appropriate access to bio resources with minimum harm to the environment and not depriving access to such bioresources. Hence the term “granting” may be suitably explained or replaced with suitable statements to reflect this aspect and aim of the Act</p> <p>(c) <u>Definitions of terms “Biological Resources” and “Knowledge associated”</u>- this term needs to be defined clearly as it is not defined in the parent act or in the rules. If defining this term is difficult, suggest inclusion of a suitable explanation which can be included under section 2.1 definitions. This is required so as to avoid unnecessary confusion leading to possible issues including litigation</p> <p>(d) <u>Normally Traded as Commodities</u>: It is to be clearly stated that these Guidelines do not apply to the bioresources which are notified as “Normally Traded as Commodities under section 40 of Biodiversity Act. A statement need not be added in this section to state the same.</p>
<p>1.2 The Guidelines lay out the conditions under which access to Biological Resources and/or Knowledge associated thereto shall be granted and under which the sharing of benefits arising out of the utilization of Biological Resources and Knowledge associated thereto shall be qualified as fair and equitable.</p>	
<p>1.3 The CBD recognized the sovereign rights of States over the genetic resources within their jurisdiction and accordingly the Act requires that all Users of Biological Resources shall,</p>	<p>FICCI: Section 1.3 A saving clause need to be introduced to clearly articulate what way BR’s existing/known/present in countries other than India</p> <p>The guidelines oblige the user to seek the consent of the “State” prior to the access to Biological Resources.</p>

<p>unless otherwise provided in the Act, seek the consent of the appropriate authority under the Act prior to access to BR.</p>	<p><i>However, the guideline does not indicate as to which Department of the State would be the nodal agency.</i></p>
<p>Add</p>	<p><u>SEVA:</u> 1.4. <i>It will respect and recognize the continued access to natural resources by traditional communities and their customary practices towards sustainable use, conservation and management of resources.</i></p>
<p>2. Definitions 2.1 In these Guidelines, unless the context otherwise requires: a) <i>Access</i> means any access to the Biological Resources and/or knowledge associated thereto made under the Act</p>	<p><u>FICCI : Section 2.1</u> (a) More explanations is needed for the term ‘access’ such as to include “permission to collecting”, “obtaining”, or “otherwise acquiring bio-resources” etc.</p>
<p>b) <i>Net Profit</i> means profit after expenses have been deducted from gross revenue.</p>	<p><u>FICCI : Section 2.1(b)</u> a. The term “net profit” needs to be defined clearly related to product/products or services in which BR’s accessed and AK’s is used and form the basis for benefit claims. This should not be misunderstood and applied to the entire profits of the firm or profits of all brands in general. b. There is no further clarification as to the methodology of calculation of this net profit since it may vary vastly (and even be a loss) across different enterprises. In the alternative a small percentage of gross turnover in relation to the biological resource may be a better method to calculate and apportion benefits to the Providers. This is more so better, because accounting principles can be played around with to dampen profits, while not so, as regards sales.</p>
<p>c) <i>Provider</i> means any natural or legal person(s) which has the legal right of disposal over the Biological Resources and/or knowledge associated thereto being made available to the Users</p>	<p><u>FICCI: Section 2 .1(c)</u> a. It is requested that the term “Provider” is defined since in the field of agriculture, one doubts how many documents will exist? b. Further the guidelines should bring clarity in cases where the Provider is an individual/ tribe/ association/ villages etc. c. Also, the guidelines but does not provide any clarity on how the case would be dealt with in case the AK is in public domain say books, magazines, books of traditional knowledge, cultural notes, etc. The Guidelines need to sate the position on such bioresources and their AK.</p>

<p>d) <i>User</i> means any natural or legal person(s) which has requested for Access to Biological Resources and/or knowledge associated thereto under the Act.</p>	
<p>2.2 words and expressions used but not defined in these Guidelines and defined in the Act and/or Rules shall have the meaning respectively assigned to them in the Act and/or Rules.</p>	
<p>II. User Obligations 3. User Obligations Prior to Access</p> <p>3.1 The Users shall request for Access by using the appropriate Forms provided for in the Rules and shall, in addition to the details therein, disclose the following:</p> <p>3.1.A. Biological Resources which are Plants, their parts or Genetic Material</p> <ol style="list-style-type: none"> i. Whether cultivated or collected from natural areas ii. Whether BR procured from Private Land or Public Land iii. If Public Land, is it a protected Area, Forest, National Park etc iv. If the access is made directly from the source or there are Agents v. Whether the BR is endemic vi. Whether the BR is endangered species 	<p><u>FICCI 3.1(A)</u> It is requested that the meaning of "natural areas" is defined as every place on the earth is a natural area.</p> <p><u>Dr. R. S. Rana, Chairman, NBA-EC on ABS</u></p> <ul style="list-style-type: none"> • Specify the location/ area from where the BR is proposed to be collected. • Specify the quantity of the BR to be collected and also the season and duration of collecting. • Has the prior approval of the relevant SBB been obtained and attached? • Is the BR listed under EXIM Policy? • Is the BR a traditionally traded commodity? • Guidelines for conducting bio-survey for research/utilization? • Guidelines for sending abroad BR specimens for taxonomic identification? • Guidelines for sending abroad blood samples/ DNA for research purpose? • Provider Obligations under Third Party Transfer • Contracting Party is required to submit periodical reports to the NBA regarding fulfilling obligations under mutually agreed terms of the Agreement Contract. • Benefit sharing needs to be linked to gross revenue in place of net profit. • Certificate of Compliance to access under CBD will require a certificate from the NBA stating

<p>3.1.B. Biological Resources which are Animals, their parts or Genetic Material</p> <p>i. Whether domesticated or wild ii. Whether BR procured from Private owners or from Public Land iii. If Public Land, is it a protected Area, Forest, National Park etc iv. If the access is made directly from the source or there are Agents v. Whether the BR is endemic vi. Whether the BR is endangered species</p>	<p>that the access is based on PIC and Mutually Agreed Terms.</p> <ul style="list-style-type: none"> Provisions stated under Section IV are not clear and require rephrasing/ clarity. <p><u>Shri Thamziharasu, District Env. Co-ordinator</u></p> <p>The following items may be added as the third category</p> <p>(iii) Whether BR procured from gene bank (EX-Situ conservation of plant germplasm such as agricultural crops, horticultural crops and forestry plants).</p> <p>B. Biological resources, which are animals, their parts or genetic materials such as cattle animal semen, fish egg</p> <p>(iv) Whether BR procured from animal semen bank (EX-Situ conservation and fish egg).</p>
<p>3.1. (c): Biological Resources which are Micro Organisms, their parts or Genetic Material</p> <p>i. Whether developed/maintained in controlled or collected from natural areas ii. Whether BR procured from private areas or public areas iii. If public Area, is it a protected Area, Forest, Natural Park etc. iv. If the access is made directly from the source or there are agents (iv) Whether the BR is endemic (vi) Whether the BR is endangered species.</p>	<p><u>FICCI: Section 3.1.(C)</u></p> <p>The following issues may arise:</p> <p>a. What is the treatment if the microorganism is a subject matter of a patent (or patent application under the Patent Cooperation Treaty) and the relevant microorganism has been deposited with the approved depository under the Budapest Treaty.</p> <p>b. Are microorganisms only in their naturally occurring from covered by the guidelines? There is no mention of the treatment of microorganisms which are: Isolated, Mutated, Adapted, Recombinant.</p> <p>c. What is the treatment of a micro organism that may be patented as per the ruling in Diminaco AG case (1998)</p> <p>(d) What is the classification accorded to a virus and is it a biological resource for the purpose of these guidelines. A clarification in this regard is sought</p> <p><u>Juris Corp: Point 3.1(C)</u> In this context the following issues may arise:</p> <p>What is the treatment if the microorganism is a subject matter of a patent (or patent application under the</p>

	<p>Patent Cooperation Treaty) and the relevant microorganism has been deposited with the approved depository under the Budapest Treaty.</p> <p>Are microorganisms only in their naturally occurring form covered by the guidelines? There is no mention of the treatment of microorganisms which are Isolated, Mutated, Adapted and Recombinant</p> <p>What is the treatment of a micro organism that may be patented as per the ruling in Diminaco AG case (1998)</p> <p>What is the classification accorded to a virus and is it a biological resource for the purpose of these guidelines.</p>
<p>D. Knowledge associated with Biological Resources</p> <p>i. Whether the knowledge is owned by individual, family, group, organisation or a community</p> <p>ii. What BR is associated with the knowledge?</p> <p>iii. What Benefit Sharing is proposed by the owners?</p>	<p><u>FICCI 3.1(D)</u></p> <p>a. The user is obliged to indicate whether the knowledge associated with biological resources is owned by individual, family, group, organization or a community. We wish to highlight that it would be very difficult to identify this exactly. It is therefore requested that appropriate changes/clarifications may kindly be made.</p> <p>b. We wish to highlight that there may be cases when the BR is accessed via “traders/suppliers”. Traders & suppliers do not generally know, are able to provide exact place/location of collection? Most of them are not registered or covered under any law (except perhaps sales tax etc.) They are ignorant/totally unaware and do not agree to apply for ‘transfer of BR’ etc. It is therefore requested that the clarification may kindly be made in the guidelines to respond to such situations</p>
<p>3.2 The Users shall submit a report on the possible impact to environment that may be caused by their relevant activities prior to Access. The User shall continue to report changes to this report as an when the User identifies any such changes at any stage during or after the Access.</p> <p>Provided that in the event, the User reports a possibility of any adverse impact on environment, the report shall also mention the ameliorative measures in place and precautions taken to cause no damage to the environment or Biological Diversity. Any Access falling within this proviso will require the approval of the NBA</p>	<p><u>FICCI: Section 3.2</u></p> <p>a. Normally NBA will not give access to any bio-resources that have an adverse impact on the environment, as NBA will have such information with it. In such a scenario this clause may be redundant and may be deleted. However, if the intention of this clause is to provide a provision where NBA based on an impact assessment, and keeping in mind alternatives steps that are being put in place to reduce or manage the adverse impact, still grant conditional access ,then this clause may be retained but state the same for clarity.</p> <p>b. The user is required to submit a report on the possible impact to environment prior to access and shall keep the Authority updated about any such impact. In this regard, I would like to mention that it would be difficult for the user to provide and keep the Authority updated with such information. Moreover, every State has its own regional language.</p> <p>c. Further, usage of fertilizers and pesticides could also</p>

<p>prior to access and in the event the report is made during or after the Access, the User shall ensure that it shall stop any and all activities of Access.</p>	<p>affect the environment, so will this also be disallowed? Clarity in this regard is desired.</p>
<p>3.3 The users are encouraged to make an audio video recording of the negotiations with the Providers and in the event such a recording is made, a copy of the same shall be deposited with the concerned SBB or the NBA.</p>	
<p>4. User Obligations During and After Access 4.1 The Users shall after collecting the Biological Resources and Knowledge associated thereto, describe and record all relevant data and share the same with the nodal agency identified by NBA for the Purpose. Users shall respect customs, traditions and values of the Provider, if any during and after Access. 4.1. Provided that in the event of Knowledge associated with Biological Resources are accessed, the same shall be handled by the User in the manner requested by the Provider.</p>	<p><u>FICCI: Section 4.1</u> It is felt that the recording of all relevant data and sharing the same with nodal agency will have serious implications on its confidentiality. It may be good to specify the nature of data and info which needs to be shared and clearly articulate the same. Otherwise users who invest in research may feel this requirement as something that would deter them to become a user or invest in research. <u>FICCI: Section 4.1.</u> This may put undue restrictions, needs review.</p>
<p>4.2. Users shall utilize Biological Resources and Knowledge associated thereto strictly for the purposes for which the Access was made obtained. Any change in the purpose shall be notified to NBA and NBA shall at its sole discretion allow such use or direct fresh application to be made under the Act.</p>	<p><u>FICCI: Section 4.2.</u> The term “purposes” is not being defined “. Currently it is either used “for research or for commercial utilization”. What can be the other “purposes”? It is therefore desired that the list of such anticipated uses is adequately provided.</p>
<p>4.3. Users shall conduct scientific study on the Accessed Biological Resources to ensure the conservation and sustainable use of the Biological Resources. The Users shall ensure that this knowledge shall be transferred free of cost to the Providers.</p>	<p><u>FICCI: Section 4.3.</u> This section imposes obligatory duty on the users to transfer the knowledge free of cost to the providers. In such situation, what about the Intellectual Property creation? A clarification in this regard is sought.</p>

<p>III. Provider Obligations</p> <p>5. Provider Obligations</p> <p>5.1 Once the Access is approved by the NBA, the Providers shall ensure that the Access is facilitated within the prescribed time.</p>	
<p>5.2. If the Provider feels the need of professionals in assisting them with the negotiations with the Users, the Providers shall make a request for the same to the BMC, SBB or NBA and it shall be the responsibility of the BMC, SBB or the NBA as the case may be to provide the requested professionals to the Providers to assist them with the negotiations</p>	<p><u>FICCI - Section 5.2.</u> Clarity is desired with regard to how many Professionals one is obliged to employ? This will drain a lot of resources</p>
<p>5.3. The Providers shall record the advantages and disadvantages as informed to them by the Users while negotiating the terms for the Access to Biological Resources and Knowledge associated thereto. In the event the Providers are not in a position to record the same, the User shall notify the concerned BMC, SBB or the NBA and the BMC, SBB or the NBA as the case may be shall ensure the presence of a suitably qualified person who shall record the negotiations under this Clause.</p>	<p><u>FICCI - Section 5.3</u> Regarding recording the advantages and disadvantages while negotiating (Para 5.3), we wish to highlight that none of the Authorities in the world have done so. It is desired that the information may kindly be provided to the Industry regarding the purpose of such recordings.</p>
<p>5.4 Providers shall ensure the conservation and sustainable use of the Biological Resources and if need be request the Users to conduct further studies under clause 4.3 after reporting their findings to the Users to ensure the conservation and sustainable use of the Biological Resources.</p>	<p><u>FICCI – Section 5.4,</u> It is suggested to articulate provisions for those cases where there is no specific provider, but the BR is accessed through a trader or a cultivator and the AK is in public domain.</p>

<p>IV. NBA Approvals and Benefit Sharing principles</p> <p>6.1 Where the Access to Biological Resources is obtained for Commercial utilization from Providers who are owners of the same, the User shall ensure that the Access ensures Sustainable Livelihoods¹ to the Providers. The User shall further share with the Providers its knowledge of best practices to ensure conservation and sustainable use of the Biological Resources.</p>	
<p>6.2 Where the Access to Biological Resources is obtained for commercial utilization from local communities who collect the same from Public Land, the Users shall make fair payments² to the Providers and shall ensure ___% of the total price of the purchase towards welfare measures³ /NBF for the community. The User shall further share with the Providers its knowledge of best practices to ensure conservation and sustainable use of the Biological Resources.</p>	
<p>6.3 Where the Access is made for Research Purposes, the User shall ensure effective participation of Providers, wherever possible or collaborate with any research institution (collaborative Research) identified by the NBA.</p>	<p>Juris Corp: IV 6.3 There is no further clarification as to the methodology of calculation of this net profit since it may vary vastly (and even be a loss) across different enterprises. In the alternative a small percentage of gross turnovers in relation to the biological resource may be a better method to calculate and apportion benefits to the Providers. This is more so better, because accounting principles can be played around with to dampen profits, while not so, as regards sales.</p>
<p>6.3(A) In case of non commercial research</p> <p>i. The research shall ensure the participation of at least one researcher from a research institute designated by NBA and all results of research shall be shared freely with the government research institutions and any know how for production</p>	<p>FICCI: Section 6.3 (A) - The intention of this clause is not clear. There is always an issue of Confidentiality and possibility of an IPR at a later date than when the research is happening, and this clause does not recognize the same. Clarification in this regard is desired.</p>

<p>shall be passed to non commercial producers free of any costs.</p> <p>ii. Any IP rights sought shall have the name of a government research institute designated for this purpose as one of the inventors or co owners of the IP.</p>	<p>SEVA: 6.3 (A) ii. Any IP rights sought shall have the name of a government research institute designated along with communities for this purpose as one of the inventors or co owners of the IP.</p>
<p>6.3(B). In case of Collaborative Commercial Research</p> <p>i. Where the research is a Collaborative Research, any IP rights sought shall name the research institution involved as one of the inventors or co owners of the IP. Any know-how required for the production shall be transferred free of any costs if requested by the NBA for any use by government entities or if the products are required by the Government for Public good.</p> <p>ii. ___% of the Net Profit shall be paid to the National Biodiversity Fund and in the event of involvement of any community as Providers of the Biological Resources, the NBA may also direct the User to provide any of the non monetary benefit sharing measures provided for in Annexure I</p>	<p>FICCI:</p> <p>Section 6.3 (B): The person is entitled to be a “Co-owners of the IP if the person has made contribution to the knowledge/process/inventive steps. It is therefore desired that a clarification be made in the guidelines that the standard policies shall be applied in deciding the “authorship in scientific publications”.</p> <p>FICCI: Section 6.3(B): a. This percent of the net profit that is required to be paid to NBF or to the community or to the provider needs to be discussed with greater interactions. While it is appreciated that there are very few examples of such benefit sharing in monetary terms, it is to be recognized that a clearly defined, transparent and implementable guidelines on how the monetary terms would be arrived at will form a key to all concerned. Firms may be given options to declare at the time of BS discussions and decisions on what one or more non-commercial benefits sharing methods as per appendix I attached to the guidelines they will like to do, and give in writing about the same and a time plan for the same to be implemented. If there is a need for additional BS by way of monetary terms, then the provisions for the same need to clearly provided.</p> <p>b. Such a method while should be fair to the provider should also be easily computable by the industry and understood by anyone who looks at it. Industry will like to know the way the BS will be computed so that one can actually build it into the cost. Since the main part of all BS is expected to rotate around this monetary part, it is dealt and suggested below:</p> <p>Following situations need to be recognized before arriving at a method for computing the quantum of benefit sharing in monetary terms.</p> <ul style="list-style-type: none"> • A lot of marketing efforts in building the concept, brand, communication, product positioning, merchandising, distribution, trade commissions, below the line activities, all involve lot of investments and expenses to make products become successful financially. • It is known fact that most products do not make

	<p>profit for some time till it is established and goes through a build up phase which in some cases may take few years.</p> <ul style="list-style-type: none"> • In almost all cases, firms will not be able to put a figure on the sales or profit which may be asked for by NBA to compute the percentage of net profit. • The mere addition of one or more BR into any product does not mean high success in the product sales. • It would be also prudent that while computing the quantum of benefit to be shared a suitable off setting is provided to the actual/reasonable expenses the firm spends to establish the product. <p>c. It is desired that the variable methods of computation may kindly be provided to arrive at the %...of Net profit in following situations:</p> <ul style="list-style-type: none"> • In many cases the base product itself may be delivering the benefits and the addition of BR may provide either an additive effect or a synergistic effect or an incremental effect. In such case the addition of BR would be actually creating a new sub category or a sub brand or a variant. Industry in such cases would like to have the computation of the incremental sales that would be attributable to the addition of BR, and it is important to provide guidelines of such computation. Any example • There would be cases where a major point of benefit may be accruing from the BR usage which was part of the AK and part of the supportive data generated by way of research or human studies and the model for computation will need to be different in such cases. Any example • In another scenario the BR may be simply cultivated with new technologies developed by research and the output of such cultivation may simply be marketed at some premium cost. This would need a different way of computation of the BS quantum. Any example • There can be situations where the research on a BR may result in a totally new finding like a New Drug molecule for a known or a new indication, then the expectations form the results of such development are generally high. In such situations the Drug Development expenses are also very high to bring out a successful drug, and number of years of work needs to be done. BS in such case needs a
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	<p>different model for computation. Any example</p> <p>Similarly various other scenarios need to be collated from providers and users and appropriate models will need to be generated which will promote effective implementation of the BDA in spirit and in law.</p> <p><u>SEVA: 6.3(B) i.</u> Where the research is a Collaborative Research, any IP rights sought shall name the research institution involved <i>in addition to the communities</i> as one of the inventors or co owners of the IP.</p>
<p>6.3(C) In case of non Collaborative Commercial research</p> <p>i. Where results are shared in cases where the results of a non collaborative commercial research is shared with any designated Government Research Facilities, the User shall pay to the NBF ___% of the Net Profit and the NBA shall also direct the User to provide any of the non monetary benefit sharing measures provided for in Annexure I</p> <p>ii. Where Results are not shared</p> <p>In cases where the results of a non collaborative commercial research is not shared, the User shall pay to the NBF ___% of the Net Profit and the NBA shall also direct the User to provide any of the non monetary benefit sharing measures provided for in Annexure I</p>	<p><u>FICCI: 6.3 (C)</u></p> <p>a. It has been strongly feel that the conditions mentioned in section 6.3 is an undue restriction imposed on researchers. Why the research institute or a research team be forced to collaborate with a government institute or one of the researchers of the government institute should form a part of the research team. The government institute may not be interested in the kind of research that a private party may be doing and there may not be any researcher available in the government organization to collaborate and contribute anything in the area of research that the other party intended to conduct. These conditions would definitely hamper any further research and would be a stumbling block for getting new products and treatments etc.</p> <p>Please note that filing of patent or any IP pre-supposes strong commercial interest in the research. As regards deciding the status of inventor or co-applicant, it cannot be made by law rather the above status (inventorship/ applicant) is dictated by the efforts and contribution made by the parties doing the research, for example if a researcher contributes into the invention and qualifies to be an inventor then only the researcher can be termed as an inventor. Likewise, to be a co-applicant the applicant should contribute equally for creating the invention, obtaining protection, financing and taking it further to the market for commercialization. In the absence of such involvements, commitment and contribution in all aspects including financial intervention, the party cannot have a status of a co-applicant.</p> <p>Further, biological resources have been a part of public domain and TK associated with them has been in use/ practice and researched since time immemorial. Why such research should be curtailed by attaching government institutions and further imposing conditions such as involvement of one of the researchers/ scientists in the research work. In India research in all areas, except in space, atomic energy, defense have</p>

	<p>been liberalized and also there are incentives for doing that. The private researchers including private industries are doing lot of research to create huge quantum of knowledge and also product and processes. The Indian private companies file more number of patents than all the government institutes together. Therefore, the research using especially, the TK which is available in public domain for long and such knowledge is so far freely accessed, available, used extensively and researched. These privileges should not be now caged/ bound by attaching government institutions and like conditions. Private researchers should get approvals to access the biological resources and TK, wherever necessary and should be in a position to do research on their own.</p>
<p>6.4 Where the NBA approval is sought for seeking any Intellectual Property Rights under sec 6 of the Act, the following benefit sharing shall be qualified as fair:</p> <p>i. Where the IP is for non commercial use The User shall file an affidavit with the NBA stating that the IP is for non commercial use and the same shall be made available to the Government use free of cost. In the event the IP is later sought to be commercialized then sub clause (ii) of clause 6.4 shall be applicable.</p> <p>ii. Where IP is for commercial use The User shall pay to the NBF ___% of the Net Profit and the NBA shall also direct the User to provide any of the non monetary benefit sharing measures provided for in Annexure I</p>	
<p>6.5 Where the Access is made for knowledge associated with Biological resources</p> <p>The Benefit Sharing shall be in accordance with the terms and conditions negotiated between the Users and Providers and the NBA shall interfere only in the event of a gross inadequacies to the disadvantage of the Providers is found in the negotiated terms. The</p>	

<p>Benefit sharing may have a monetary part and any non monetary benefits that may be listed in Annexure I of these Guidelines or any legislation/mechanism made on TK.</p>	
<p>6.6 The NBA while determining the mode for the sharing of benefits shall consider the short, medium and long term interests of all stakeholders involved. NBA acknowledges that some modes of benefit sharing may become effective immediately, whereas others become effective only in the distant future due to the period of time needed for the benefits to arise.</p>	
<p>7. Certification of Compliance The NBA shall develop a system of certification and a certification mark will be provided for by the NBA that shall certify the compliance with the Act and highlight the fair and equitable benefit sharing.</p>	<p><u>FICCI: Section (7)</u> - Clarification is needed if such certification mark is on a sui generis basis under the Act or is it in pari material with a certification Trade Mark under the Trade Marks Act 1999. Further in case of biological resources which originate from particular specific geographic location only, methodology/guidelines for obtaining the status of a Geographical Indication “may also be incorporated into the guidelines</p> <p><u>Juris Corp:</u> Clarification is needed if such certification mark is on a sui generis basis under the Act or is it in pari material with a certification Trade Mark under the Trade Marks Act 1999. Further in case of biological resources which originate from a particular specific geographic location only, methodology/guidelines for obtaining the status of a Geographical Indication “may also be incorporated into the guidelines.</p>

A3. General comments on ABS Guidelines

I. Ms. Kanchi Kohli, Kalpavriksha Environmental Action Group, Delhi

FUNDAMENTAL ISSUES

1. **Conservation focus not upfront:** As we have brought to the notice of the NBA and the MoEF even before, the Biological Diversity (BD) Act, 2002 has increasingly played the role of an access legislation, with the conservation focus relatively diluted. If the NBA and MoEF is indeed serious about fulfilling the first objective of the law and the Convention on Biological Diversity (CBD), the country's ABS guidelines should upfront state that the primary objective of the BD Act is to address conservation and no application for access will be considered if it is coming in the way of this objective. This is both with reference to physical material and knowledge related to it.

2. **Communities not consulted:** As you would rightly be aware, many local communities have continued with their own systems of "sharing" benefits amongst themselves. It needs to be borne in mind that while these models and practices are conserved and built upon, new State guidelines do not come in the way of these existing models. The ABS Guidelines need to build in a clear space for this. It is evident that with no ABS guidelines in place, approvals given under the Biological Diversity Act, 2002 have gone without a larger and widespread determination of benefits and without any mandatory consultations with the BMCs (Section 41). There is no clarity in the draft Guidelines on how such instances will be dealt with. For instance, will the Guidelines have retrospective effect?

3. **Only monetary sharing of benefits:** The Biological Diversity Act in Section 21 clearly lays down the possibilities of monetary and nonmonetary mechanisms through which benefit sharing can be determined. Even within the existing limitations of the very concept of ABS, the legislation states that the "location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers." What is disappointing is that instead of broadening the scope of the various mechanisms of benefit sharing which could also include continued access to that particular resource or knowledge by communities, the draft guidelines only limit them into the box of monetised mechanisms of benefits which can be accrued.

4. **No Sui generis Options for Protection of Traditional Knowledge:** Prior to the issuance of any ABS guidelines, any domestic setup for grant of access should make it clear that no application for access or IPRs that interferes with the *sui generis* measures for protection of knowledge of local people relating to biological diversity, will be permitted. This needs to be a precursor to the ABS process.

DOMESTIC CONCERNS

1. **Approvals without ABS guidelines in violation of Section 21:** It is ironic that the NBA and its Committees have screened several applications and according to the NBA website the current status of applications approved are 325 with 269 related to IPRs. This has been without the existence of any procedures, notifications or guiding documents on how benefitsharing would be determined. The NBA has relied only on the user agencies on whether or not there would be any commercial utilization, whereby benefit sharing can be determined. In many instances the user agency has not stated this commercial purpose upfront, yet the approval has been granted. In a second instance, even where commercial purpose is cited, like in the case of a November 2007 approval to Novozymes Biologicals Inc. the agreement states, "*Royalty and benefit sharing will change on a case to case basis and will be regulated by the ABS guidelines*". In addition NBA has charged 5% annual royalty from the sale of the product derived from the biological resource.

2. **Onus on the User and Provider to carry out studies and compliance:** Throughout its seven pages, the draft Guidelines repeatedly put the onus to carry out assessments on the user and provider of the biological resource. There are a set of 5 sketchy questions which the NBA seeks responses too. Infact, the guidelines state that the "*users shall submit a report on the possible impact to environment that may be caused by their relevant activities prior to Access.*" The agency/individual which has the maximum stake in gaining access is to selfcertify the possible impacts on the environment. Such expectation of honesty would be both naive and unreal. Experiences with the process related to the Environment Impact Assessment (EIA) Notification and the approvals under the Genetic Engineering Approval Committee (GEAC) have over the years demonstrated that project authorities submit either misleading or insufficient data with the explicit purpose of gaining approvals. Yet, once the information is received there is absolutely no independent or open scrutiny to cross check if it is true or false. This has been a severe limitation of the way approvals have been granted till now and the same pattern has found its way into the draft guidelines. What is ironic is that key issue of compliance has

rendered itself to 3 lines at the fag end of the proposed guidelines and seeks only a certificate from the users.

3. **No possibilities of stringent monitoring or enforcement:** A critical limitation and lacunae with the approval process with the Biological Diversity Act, 2002 has been the fact that once agreements are signed there is absolutely no way to determine whether users of the material or knowledge are complying with the condition. Such a mechanism has failed to find its way into the law itself. The ABS guidelines could have plugged this gap by bringing on board a stringent monitoring mechanism following a far more rigorous approval process as mentioned in Point 1 above. The current draft ABS guidelines have this aspect completely missing.

4. **Non commercial research:** The country's own experience has shown that there is a substantial increase in public private partnerships or collaborations in sectors where biodiversity based resources are a critical component. This can be in the areas of agriculture, pharma, wildlife and energy. The NBA itself has granted approvals to seemingly non commercial research which have linkages with future commercial applications. We have brought to your attention instances of Dolphin Institute of Biomedical and Natural Sciences, Dehradun, transferring anaerobic fungi to Mascoma Corporation in the USA. The recent controversy around Bt brinjal research has also shown that what a seed MNC does as not for profit research, will eventually be for its commercial gain. Likewise, the US India Knowledge Initiative on Agriculture (KIA) has private sector giants like Monsanto, Walmart, on its Board. Thus there is a very thin line between commercial and not for profit research. However, the ABS guidelines draws this distinction without any substantiation on what is implied by noncommercial research. This is a very significant clarification which needs to emerge from any such guidelines prepared by the NBA or MoEF.

5. **Traditional Knowledge (TK) “protection” processes ongoing:** A TK Bill is also under preparation under the auspices of the Ministry of Commerce, which NBA is part of. It is reasonable to expect the objective of that wing of government to look at purely trade interests. The MOEF and the NBA is the only part of the government that can insist on biodiversity conservation and community concerns. Likewise, the link must be made between these Guidelines and the draft TK Rules. Just as the demand has been made at several international fora by indigenous peoples that traditional knowledge is a crosscutting issue with ABS discussions. Until TK is made safe and secure, ABS discussions should not be finalised. Even

in the international discussions indigenous peoples have highlighted the inseparability of TK and genetic resources.

II. Shri Priyadarsanan Dharma Rajan, ATREE, Bangalore

Benefit Sharing

In most cases it is difficult to attribute the right to knowledge to a particular community. So it is difficult to attribute the right over the traditional knowledge and share the benefit with any particular community. The argument of benefit sharing thus can lead to conflicts between communities and even between nations. For e.g. take the case of the pan tropic plant species *Dodonea viscosa*. The farmers of Sringeri (Karnataka) and Malayalee tribes, an indigenous community of Koli hills (Tamil Nadu) use the plant as biopesticide. The villagers of Chintamani (Andhra Pradesh) and Mayan tribes of Santa Cruz (Bolivia) use it as bone setters for cattle while it is used in Australia as a painkiller. Similarly the same species may be used for different purpose by different communities and the process and methods of usage also may vary among communities.

By excluding value added products from the purview of the act (Chapter 1 sect.2 (c)) the act restricts the benefit sharing to products developed on future patents mediated by the National Biodiversity Authority. Any new research may take several years to come out with any new product and it may take several more years to get a patent and market the product. Meanwhile the multinational companies are making huge profits out of traditional knowledge like Ayurveda, Unani etc and are outside the purview of the Act (Chapter 1 sect.2 (c) & Chapter IX Sect. 40). Even on the 6th year of establishing, there is not even a single case of benefit sharing NBA could facilitate. The majority of applications it received is not from the multinational companies but is from the Indian research institutions. This brings the country to the difficult situation of either

1). Forgo the notion of benefit sharing as it is not practical (to assign the ownership to any particular community or to share the benefits), and can create conflicts among various communities across the world as mentioned in the case of *Dodonea viscosa*. Or 2). If the benefit sharing need to be made realistic and the community/country has to make any benefit out of the TK, modify Sect.2 (c) to include all value added products based on traditional Knowledge (e.g. Ayurvedic drugs) and bring all corporate, including the Indian Corporates under the purview of Sect.3 (sub-sect.ii) of the Biological Diversity Act. In the best interest of the nation, we should forgo benefit sharing to facilitate free exchange of genetic resources. This is important to

safeguard our own food security as well as scientific and technological developments. The benefits of free exchange of biological resources far outweigh the 'benefits' of benefit sharing.

Knowledge and material: restrictions or openness

Quality research requires extensive collaboration and cooperation among specialists and institutions across continents. No country ever possessed sufficient expertise to identify nearly all the 1400 families of insects and 350-plus families of plants. So far the world taxonomists were addressing this problem by best using the tradition of collegiality and reciprocity existing in the taxonomic world, by sending specimens to experts across the world for identification. CBD and subsequent CoPs & conventions calls for encouraging partnerships among institutions in developed and developing countries to encourage research. Unfortunately the Biodiversity Act (Sect. 5) and subsequent legislations (Guidelines for Collaborative Research) seriously curtails the scientific freedom of individual Scientists by putting draconian regulations on the free exchange of specimens for research and threatens to strangulate biodiversity research.

Food security

The genetic limits of the native stock can be overcome only by incorporating genes from exotic genetic material. The provisions of the CBD that recognize the sovereign rights of nation states over their genetic resources, thrust up on humanity at the naïve insistence of India and other developing countries, undermine the role of sharing and distribution of genetic resources among human societies in supporting food production throughout the world. Restrictions on access and sharing of genetic resources across national boundaries will retard crop improvement programmes^{1,2}. Nationalization of biodiversity to counter corporate patenting is akin to setting the home on fire to kill the rat. Loss of biodiversity from the common heritage of mankind to the bureaucratic ownership of nation states will have adverse, unexpected impact on global food production. So India should take the lead in bringing the biodiversity back to the common heritage.

III. Prof. Elumalai, Law College

1. The word 'indigenous people' has been used, that should be avoided instead of that the word 'traditional community and local community' should be used;
2. The words 'obligations of traditional knowledge holders/providing parties have been used' it may be substituted with 'rights and obligations of providing parties'.

B. Comments on International Regime on ABS

I. Ms. Kanchi Kohli, Kalpavriksha:

1. No ABS worldwide: We are certain that the Government of India is acutely aware that in the history of the CBD no real case of “benefit sharing” has ever taken place post1993. The country's own experience since the grant of several hundred “approvals” for access by NBA will show that very few if at all benefit has “trickleddown” to local communities. Does the NBA perceive an overall improvement in the lives of the many directly resource dependent population since its “approvals”? Likewise, there is little evidence in the world where ABS is working for the wellbeing of ordinary peoples. The focus in the CBD's discussions has been on access to genes for research and commercialisation, and on setting a price for such access. We need to recognise that and the fact that ABS *per se* is not going to translate into poverty reduction of the millions in otherwise biorich countries. It is therefore not worthwhile to chase an illusion.

2. “Biopiracy” continues: When Megadiverse country governments say that an International Regime can end “biopiracy”, it means they are taking a purely legalistic view. The presumption is if access takes place as per national legislation, it is by definition not biopiracy. For NBA or MOEF an administrative system which makes it difficult or impossible to access and/or patent biological materials without government permission would indeed greatly reduce biopiracy, if not eliminate it. For common peoples and local communities unjust access by government institutions and other so called public institutions is often more commonplace than biopiracy by foreign corporations. And today as the biotech research in the country DOES show, public research institutions have been accessing and are doing so and that too more IN partnership with private corporations.

3. Trade agreements dominate: The GOI is signing and negotiating several free trade agreements with other countries, the provisions of IPR therein have a bearing on the subject. Even at the meeting of the Group of Technical and Legal Experts on Traditional Knowledge associated with Genetic Resources hosted by India in Hyderabad from 16 to 19 June 2009 many concerns from the floor on such Free Trade Agreements (FTAs) were not fully reflected in the official meeting minutes. And given that the International Regime on ABS will at most come out with global enforcement of national access legislation, we have to building our own safeguards in our laws before such (bio) trade oriented approach is put in place.

4. India's place on the global scene: India's place in the global scenario and the value of its experience having a ripple effect should not be underestimated. India can play a leadership role encouraging other developing countries to also design rules on biodiversity that are truly rooted in its own traditions and diverse cultures. This would be a true exercise of sovereignty that the CBD lays down. This would not only send a strong message to the “developed” countries and the life science corporations they foster, but also give strength to other developing countries and LDCs struggling with these issues. The time is ripe to forge a new South-South solidarity that is not motivated by economic interests alone.

5. Montreal Annex and Nagoya preparations: Based on the above set of considerations, it is the considered view of the Campaign members that the timeline or demands of the international processes should not determine the pace of our internal discussions. Instead it ought to be vice versa. It is a legitimate demand to make at international fora for instance, that we will first do a social and ecological review of the impact of the access approvals granted in the last five years and on that basis alone proceed further. Fast tracking decisions for a “Nagoya deadline” would go against the interests of the conservation and communities that the NBA is bound to protect. As you would be aware, the Montreal Annex – developed at the 8th Meeting of the Ad Hoc Open Ended WG on Access and Benefit sharing itself is a much bracketed text yet to be finalised and agreed upon. There is no apparent rush to already provide for its implementation. To start with, we urge that the NBA make the text of the Montreal Annex and the current draft guidelines (revised as Rules) available in different Indian languages to catalyse a discussion, rather than simple reproduction from the the Bonn Guidelines as in Annexure I of the draft ABS Guidelines. Several peoples' perspectives will surface that would assist the government work on this and also give both the moral, social and political grounding for putting forth its arguments even at the CBD.

We want to bring to your attention that it has been repeatedly pointed out that given India's realities there are severe limitations to web based processes of disclosure and seeking feedback. Yet authorities like the NBA continue to use this medium as the only face of public disclosure and that too only in English language.

The issue of Access and Benefit Sharing (ABS) has a far reaching impact and any process related to decision making around it demands a widespread and open debate prior to putting in place any policy or legal statements. Access to biological diversity and related traditional

knowledge cannot be allowed without such rigorous debate and bottom up deliberations. Until that happens, the only true operative thumb rule that should work as a guideline for benefit sharing should be:

a) Guaranteeing and safeguarding of full usage rights to the biological resources necessary for traditional community livelihoods, as well as the corresponding natural resource rights – as to land, water, etc. needed for their proper management. b) In the meantime no R&D activity based on our genetic resources and TK should foreclose by IPR the development of other models of collaboration and sharing. If we as a nation and society lose the BENEFIT of SHARING, any ACCESS is of no use. This we hope is also a line NBA will toe in the governmental discussions on developing the country's national innovation policy. We do hope that the MoEF and the NBA will take these issues on board and with that start a process of public debate in the country which has upto now not happened officially on this issue in the past.

II. Shri Bala Prasad, APCCF, Medicinal Plants and Biodiversity, Forest Department, Sanjenthong, Imphal, Manipur,

1. Trans boundary issues have been dealt in very superficial manner in A (13). As in case of genetic resources and associated TK these issues are one of major concern, they need to be addressed in comprehensive manner in International Regime on Access and Benefit Sharing.

2. International Regime on Access and Benefit Sharing should prescribe that every contracting party provide in their national legislation that while applying for patent the source of genetic resources and associated TK be categorically mentioned and mutually agreed term and prior consent be appended with the application.

3. In scope of International Regime on Access and Benefit Sharing Para 3(e-g) may be deleted. The regime must deal with marine biodiversity beyond territorial limit.

4.B1(7) regarding essentiality of national legislation in the host country for International Regime on Access and Benefit Sharing may not be accepted as it would be contrary to enabling environment for the implementation of the regime.

5. 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. The focus in the International Regime on Access and Benefit Sharing is on the TK, owned by the community, where as TK of individuals and group of individuals have not been adequately addressed.