

Ref	Clause	Clause or New insertion	IBHA Comments
2a	Substitution – "benefit claimers" means the conservers of biological resources, their byproducts, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application;	2(aa) "benefit claimers" means the conservers of biological resources, their by-products , creators or holders of associated traditional knowledge thereto (excluding codified traditional knowledge only for Indians) and information relating to the use of such biological resources, innovations and practices associated with such use and application;';	Change to " Means the conservers of biological resources and their by-products" What is traditional codified knowledge?
2ga	New insertion	(ga) "folk variety" means a cultivated variety of plant that was developed, grown and exchanged informally among farmers; (gb) "India" means the territory of India as referred to in article 1 of the Constitution, its territorial waters, seabed and sub-soil underlying such waters, continental shelf, exclusive economic zone or any other maritime zone as referred to in the Territorial Waters, Continental Shelf, Exclusive Economic Zone and other Maritime Zones Act, 1976, and the air space above its territory; (gc) "landrace" means primitive cultivar that was grown by ancient farmers and their successors;';	Change to "(ga) "folk variety" means a cultivated variety of plant that was locally developed, grown and exchanged informally among farmers
Section 3 (2) b	(ii) incorporated or registered in India under any law for the time being in force, which has any non-Indian participation in its share capital or management	(b) "foreign controlled company" means a foreign company within the meaning of clause (42) of section 2 of the Companies Act, 2013 which is under the control of a foreigner.	The definition of 'foreign company under Companies Act, 2013 Section 2(42) does not mention 'foreigner' and only covers those incorporated outside India: "foreign company" means any company or body corporate incorporated outside India which,— (a)

			has a place of business in India whether by itself or through an agent, physically or through electronic mode; and (b) conducts any business activity in India in any other manner.
Section 4 (substitution) Results of research not to be transferred to certain persons without approval of National Biodiversity Authority	No person shall, without the previous approval of the National Biodiversity Authority, transfer the results of any research relating to any biological resources occurring in, or obtained from, India for monetary consideration or otherwise to any person who is not a citizen of India or citizen of India who is non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961 or a body corporate or organization which is not registered or incorporated in India or which has any non-Indian participation in its share capital or management	No person or entity shall share or transfer any result of the research on any biological resource occurring in, or obtained or accessed from, India or associated traditional knowledge thereto, for monetary consideration or otherwise, to a person referred to in sub-section (2) of section 3, without the prior written approval of the National Biodiversity Authority, except the codified traditional knowledge which is only for Indians: Provided that the provisions of this section shall not apply if publication of research papers or dissemination of knowledge in any seminar or workshop involving financial benefit is as per the guidelines issued by the Central Government: Provided further that where the results of research are used for further research, then, the registration with National Biodiversity Authority shall be necessary: Provided also that if the results of research are used for commercial utilisation or for obtaining any intellectual property rights, within or outside India, prior approval of National Biodiversity Authority shall be required to be taken in accordance with the provisions of this Act.”.	It appears that Indians can share or transfer codified traditional knowledge without NBA approval. Further research on the results of research requires NBA registration. Further, there is no guidelines for such registration.
Section 6 subsection (1) amended	(1) No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:	(1) Any person or entity applying for an intellectual property right, <u>covered under sub-section (2) of section 3</u> , by whatever name called, in or outside India, for any invention based on any research or information on a biological resource which is accessed from India, <u>including those deposited in repositories outside India, or associated traditional knowledge thereto</u> , shall obtain prior approval of the National Biodiversity Authority before grant of such intellectual property rights.	This appears to be much clear interpretation requiring 3(2) entities to take prior intimation for IPR using bioresources, and Indians only requiring registration before NBA. The access

	<p>Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned: Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.</p>	<p>(1A) Any person applying for any intellectual property right, <u>covered under section 7</u>, by whatever name called, in or outside India, for any invention based on any research or information on a biological resource which is accessed from India, including those deposited in repositories outside India, or associated traditional knowledge thereto, shall register with the National Biodiversity Authority before grant of such intellectual property rights. (1B) Any person covered under section 7 who has obtained intellectual property right, by whatever name called, in or outside India, for any invention based on any research or information on a biological resource which is accessed from India, including those deposited in repositories outside India, or associated traditional knowledge thereto, shall obtain prior approval of the National Biodiversity Authority at the time of commercialisation.”.</p>	<p>prior permission for IPR commercialization becomes applicable for section 7 companies.</p>
<p>Section Clarified</p>	<p>7 No person, who is a citizen of India or a body corporate, association or organisation which is registered in India, shall obtain any biological resource for commercial utilisation, <u>or bio-survey and bio-utilisation for commercial utilisation</u> except after giving prior intimation to the State Biodiversity Board concerned: Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity, and v aids and hakims, who have been practicing indigenous medicine.</p>	<p>7. (1) No person, other than the person covered under sub-section (2) of section 3, shall access any biological resource and its associated knowledge for commercial utilisation, without giving prior intimation to the concerned State Biodiversity Board, subject to the provisions of clause (b) of section 23 and sub-section (2) of section 24: Provided that the provisions of this section shall not apply to the codified traditional knowledge, cultivated medicinal plants and its products, local people and communities of the area, including growers and cultivators of biodiversity, v aids, hakims and registered AYUSH practitioners who have been practicing indigenous medicines, including Indian systems of medicine for sustenance and livelihood.</p>	<p><i>This amendment is clearly focussed on medicinal plants and their stakeholders. Codified traditional knowledge should be part of Section 40 exemption, even if Ayush practitioners are specified here.</i></p>
<p>Substitution Section 8 Establishment of National</p>	<p>a) Chairperson, who shall be an eminent person having adequate knowledge and experience in the conservation and sustainable use of biological diversity and in</p>	<p>“(a) a Chairperson, who shall be an eminent person having adequate knowledge, expertise and experience in the conservation and sustainable use of biological diversity and in matters relating to fair and equitable sharing of benefits, to be appointed by the Central Government;</p>	<p>Propose to include representation from industry like FICCI/IBHA.</p>

<p>Biodiversity Authority</p>	<p>matters relating to equitable sharing of benefits, to be appointed by the Central Government;</p> <p>(b) three <i>ex officio</i> members to be appointed by the Central Government, one representing the Ministry dealing with Tribal Affairs and two representing the Ministry dealing with Environment and Forests of whom one shall be the Additional Director General of Forests or the Director General of Forests;</p> <p>(c) seven <i>ex officio</i> members to be appointed by the Central Government to represent respectively the Ministries of the Central Government dealing with –</p> <p>(i) Agricultural Research and Education;</p> <p>(ii) Biotechnology;</p> <p>(iii) Ocean Development;</p> <p>(iv) Agriculture and Cooperation;</p> <p>(v) Indian Systems of Medicine and Homoeopathy;</p> <p>(vi) Science and Technology;</p> <p>(vii) Scientific and Industrial Research</p>	<p>(b) sixteen <i>ex officio</i> members to be appointed by the Central Government, representing the Ministries dealing with—</p> <p>(i) Agricultural Research and Education;</p> <p>(ii) Agriculture and Farmers Welfare;</p> <p>(iii) Ayurveda, Unani, Siddha, Sowa Rigpa, Yoga and Naturopathy and Homoeopathy;</p> <p>(iv) Biotechnology;</p> <p>(v) Environment and Climate Change;</p> <p>(vi) Forests and Wildlife;</p> <p>(vii) Indian Council of Forestry Research and Education;</p> <p>(viii) Earth Sciences;</p> <p>(ix) Panchayati Raj;</p> <p>(x) Science and Technology;</p> <p>(xi) Scientific and Industrial Research;</p> <p>(xii) Tribal Affairs;</p> <p>(c) four representatives from State Biodiversity Boards on rotational basis;</p>	<p>Fair representation of members as per the area of application before the NBA should be considered</p> <p>Member secretary should be expert in biodiversity conservation as well as sustainable use. Preferable also in matters relating to fair and equitable sharing of benefits.</p> <p>A member from Finance ministry may also be considered to be included in the NBA for correct valuation of the Bioresource being used in any given product.</p>
<p>Section 18 clause (4) Action of NBA to oppose IPR outside India</p>	<p>(4) The National Biodiversity Authority may, on behalf of the Central Government, take any measures necessary to oppose the grant of intellectual property rights in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource which is derived from India</p>	<p>(4) The National Biodiversity Authority may, on behalf of the Central Government, take any measures necessary to oppose the grant of intellectual property rights in any country outside India on any biological resource which is found or brought from India, including those deposited in repositories outside India, or associated traditional knowledge thereto accessed.</p>	<p>The additional point with respect to ‘found in’ needs to be examined carefully as it does not specify Indian origin or not.</p>
<p>Section 19 4</p>	<p>The National Biodiversity Authority shall give public notice of every approval granted by it under this section.</p>	<p>The National Biodiversity Authority shall place in public domain details of every approval granted or rejected under this section.”.</p>	<p>Regulatory comments – Isn’t it in contradiction with IRCC declaration submitted along</p>

			with research application and Patent application? This will lead to loss of confidentiality. Especially for research applications. Can it be done for commercial utilisation. The amendment to this clause broadens the scope of the previously worded clause. There ought to be some provision for keeping the information confidential when requested by the Applicant.
Section 32 (2) (c)	The State Biodiversity Fund shall be applied for ... (c) conservation and promotion of biological resources;	The State Biodiversity Fund shall be applied for ... (c) conservation and <u>sustainability</u> of biological resources;	Could be revised as – (c) conservation and promotion of sustainable use of biological resources;
Section 36 A	New insertion	36A. The Central Government may authorise National Biodiversity Authority or any other organisation to take any measures necessary to monitor and regulate within the territory of India, the access and utilisation of <u>biological resources obtained from a foreign country</u> in order to meet the international obligations to which India is a signatory.	<i>This Section should become applicable only after the international obligation is notified in advance and also if there is reciprocal arrangement with said 'foreign country'.</i>
Section 40 Power of Central Government to exempt certain	Notwithstanding anything contained in this Act, the Central Government may, in consultation with the National Biodiversity Authority, by notification in the Official Gazette, declare that the provisions of this Act	40. Notwithstanding anything contained in this Act, the Central Government may, in consultation with the National Biodiversity Authority, by notification in the Official Gazette, declare that all or any of the provisions	Agri waste should not be limited to NTAC herbs only? Agri waste should be

<p>biological resources</p>	<p>shall not apply to any items, including biological resources normally traded as commodities.</p>	<p>of this Act shall not apply to biological resources when normally traded as commodities or to the items derived from them, including agricultural wastes, as notified and cultivated medicinal plants and their products for entities covered under section 7, registered as per the regulations made or as prescribed: Provided that no exemption shall be made for the activities referred to in sub-sections (1) and (2) of section 6.”.</p>	<p>completely exempted from section 4, Section 6, Section 7 and Section 19 of this act. Agri waste definition is not established, need clarification ?</p> <p><i>The amendments are not very clear, there should be further exemptions build in the section itself as to what is exempted such as the items which are commonly exported.</i></p>
<p>Section 62 2 Substitution Power of Central Government to make rules</p>	<p>(a) terms and conditions of service of the Chairperson and members under section 9; (b) powers and duties of the Chairperson under section 10; (c) procedure under sub-section (1) of section 12 in regard to transaction of business at meetings, (d) form of application and payment of fees for undertaking certain activities under sub-section (1) of section 19; (e) the form and manner of making an application under sub-section (2) of section 19;</p>	<p>“(a) the manner of issuing certificate of origin for cultivated medicinal plants under sub-section (2) of section 7; (aa) the terms and conditions of service of the Chairperson, Member-Secretary and other members under section 9;”; “(ba) the other functions to be performed by the Member-Secretary;”; “(ea) form of application and payment of fees under sub-section (1) of section 20;”; new insertion “(ja) the manner of holding inquiry by the adjudicating officer under section 55A; (jb) the other power under clause (e) of section 55B;”.</p>	<p>This is not yet clear in terms of usage of medicinal BR into cosmetics or ayurvedic products (Saundarya Prasadak)</p> <p>FAQ to be circulated with industry ?</p> <p><i>A new proposal of issuing certificate of origin for cultivated medicinal plants has been proposed as introduced in section 7. The reason for selecting the</i></p>

			<p><i>medicinal plants for issuance of such certificate cannot be understood. The NBA actions are for all bioresources and not just cultivated medicinal plants. The NBA should take such action without bias for all bioresources.</i></p>
--	--	--	---

The Proposed Bill fails to address several concerns of the stakeholder including:

- Mandate for Sustainable use- The main focus of the Act is PIC and ABS, however the third objective of Sustainable use seems to be lost. The focus and actions/incentives for sustainable use also need to be incorporated in the amendment bill.]
- Mutually Agreed terms: Except for mere mention in Section 21, MAT has not been discussed at all, leave aside the creation of process/platform for the NBA/SBB/BMCs to provide the applicant a fair negotiating platform to come to MAT before signing the Benefit Sharing Agreement.
- Broadening of NTAC list to incorporate actual commodity lists from the market, such as those being sold in retail stores, This will ensure sustainable use by different industry sectors.
- Acknowledgment of requirement of valuation of biological resource being used on a case to case basis. All access and use of bioresources cannot be considered as equivalent to 100% raw product e.g. like red sanders. A chemical product with fragrance from biological source cannot have same ABS calculation bracket.
- Certificate of Compliance may be proposed for the applicants who wish to streamline the process without annual hassles.
- Stakeholder consultations with diverse areas of work. A microbiologist work is very from a biotechnologist who may be using microorganisms. Thus taking views from several stakeholders, and from different states, is essential for this regulation to be effective.