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NATIONAL BIODIVERSITY AUTHORITY

PROCEEDINGS OF THE 45TH AUTHORITY MEETING

on

27th March, 2018

Venue

Committee Room- II,
Ground Floor, NASC Complex,
Near Todapur village, New Delhi

Proceedings of the 45th Authority Meeting of the National Biodiversity Authority held on 27.03.2018

The forty fifth meeting of the National Biodiversity Authority (NBA) was held on 27th March, 2018 at Committee Room- II, NASC Complex, New Delhi. Dr.B.Meenakumari, Chairperson, NBA chaired the meeting. The list of participants is placed as **Annex-I.**

2. At the outset, the Chairperson, NBA extended a warm welcome to the members. She briefed the members about (i) fifth Project Steering Committee (PSC) of the CEBPOL held on 1st February, 2018 chaired by Shri Arun Kumar Mehta, Additional Secretary, MoEFCC (ii) third meeting of the Expert Committee on Invasive Alien Species at NBA, Chennai (iii) the training organised by National Law School University of India, Bengaluru in association with UNEP–GEF on Global ABS Project (iv) the 3rd Global Conference of BioFin held from 6th to 8th March 2018 at Chennai in which 31 member countries shared experience on resources mobilisation for effective implementation of the objective of the CBD (v) preliminary discussions on the creation of awareness about the BD Act with Vigyan Prasar officials during their recent visit to NBA (vi) giving lecture by NBA on “Biodiversity Law - an interface with patent procedure” in the workshop on “Patent Drafting” organised by the Regional Patent office at Chennai and (vii) observance of National Science Day with college students with the support of the Eco-club and SRM University. She also informed the authority about the willingness expressed by NBA to the information from the Ministry to occupy the premises vacated by the AWBI, Chennai so that some activities of NBA could be relocated to those premises before the proposed acquisition of land from the Salt Pan Authority of India materialises.

3. The Secretary, NBA apprised about the status of the ABS applications received, trends in receipt of application and their disposals, the meetings of the Expert Committee on ABS and meetings conducted for the selection of India Biodiversity Awards-2018.

Thereafter, the agenda items were considered as under:

45.01: Confirmation of Proceedings of the 44th Authority meeting

The draft proceedings of the 44th meeting held on 25th January, 2018 sent to members on 05th March, 2018 has been confirmed incorporating comments of Dr Manoj Modi, DBT, Dr P.C.Bhattacharjee, NMPB and Dr Sujata Arora, Scientist 'G’, MoEF&CC.

Action: Secretary, NBA.

45.02: Action taken report of the 44th Authority meeting

Though considerable time is involved for finalizing the proceedings of 44th meeting, most of the decisions are being acted upon and will be updated by the next meeting of the authority.

Action: Secretary, NBA

45.03: To consider the Proceedings of the 47th meeting of Expert Committee on ABS held on 8th & 9th February, 2018.

Authority noted that 93 applications were placed before the Expert Committee in its 47th meeting on Access and Benefit Sharing held on 8th & 9th February, 2018. A total of five (5) representatives of applicants appeared before the EC and pleaded / clarified their stand on their pending applications.

2. The members of the authority noted the efforts put forth by NBA in bringing down the back log of pending applications.

3. The Secretary, NBA on a point raised by Dr. Yogesh Shouche clarified that BD Act does not differentiate between commercial and non-commercial research. Indian Scientists do not require approval to conduct research on biological resources obtained from India. But, the foreign user of the reference strain from Indian repository as well repository in outside India must seek prior approval of the NBA under the BD Act, 2002. The repository being the intermediary is obliged to inform the potential user of the reference strain to obtain approval of NBA for conducting research as guideline of the World Federation for Culture Collections states that expects its members to follow national legislation, rules or regulations, which take precedence (WFCC guidelines for the establishment and operation of collections of cultures of microorganisms No. 17.6).

4. In this context, Dr. Sujata Arora, Adviser, MoEFCC, referred to the provision in Article 8(a) of the Nagoya Protocol on Access and Benefit Sharing relating to access for research, and informed that during the negotiations of Nagoya Protocol on this issue, the developing countries including India did not support developed countries proposal to exempt non-commercial research. This is because there is a thin line separating non-commercial and commercial research, and very often the former leads to the latter. Accordingly, Article 8(a) of the Protocol provides for Parties to promote research including through simplified measures on access for non-commercial research. The members agreed that DBT's suggestion of simplifying procedures for non-commercial research may be sent to NBA in the form of a proposal to be considered by the Authority within the framework of the Act, and in line with the Nagoya Protocol.

5. During consideration of this agenda item, the Chairperson pointed out that large number of violation cases coming to the notice of NBA. More than 155 applications were found to be contravening the Act as per decisions of the Authority, out of which letters have been issued in 24 cases, and no communication has been sent to others. The members expressed that once the decision has been made by the Authority; the same should be communicated to the applicants. Dr Gunasekhran, Member suggested that in the instant case the rejection communications can be taken up year wise.

6. The Chairperson did not favour the proposal in view of advice pending from the Department of Legal Affairs and also foreseeing the prospect of multiple litigations which may arise involving avoidable heavy costs and time of the meagrely supported

manpower of NBA. She also felt that it is a denial of natural justice when a Committee which took the decision reaffirms its own orders after giving a personal representation / hearing in the case of applicants.

7. Secretary in his intervention stated that, this mandate has been given to EC on ABS by the Authority. He also observed that it is not an appeal on the decision taken by the EC on ABS but a procedure to give due representation to ensure natural justice before a final decision is taken on the matter by the Authority.

Decision:

a) The Authority approved the recommendations of the EC on ABS.

b) Authority directed the NBA to form an expert committee to identify the issues that need amendment in the Biological Diversity Rules 2004.

Action: Secretary, NBA

45.04: To consider the closure of application in Form-III (Appln.No. 298) filed by M/s Natural Remedies Pvt Ltd for seeking approval of NBA for obtaining IP rights

The members noted that the NBA was able to forward draft agreement for execution as late as 06th January 2012 for an approval granted by it in its 15th meeting held on 29th October, 2010 to M/s Natural Remedies Private limited for obtaining patent titled "A HERBAL ANTIMICROBIAL DERMATOLOGICAL DRUG" and that the applicant vide letter dated 29th May,2012 responded that the Patent no. 226999, dt. 31st December 2008 had already been granted for the drug.

2. The Members reviewed decisions in the 33rd, 35th and 36th meeting on rejection of such applications based on decision in the 41st Authority meeting held on 27th March, 2017 to exempt filing Form-III to applications prior to enactment of BD Rules 2004 i.e., 15.04.2004. Members agreed that the patent application in question having been filed in 1998 qualified for exemption from section 6 as per decision 41.09 of the Authority.

3. Dr. Dinesh Mishra wanted to know the steps to reduce the time lag in granting approval to patent applications. After listening the explanation of the Secretary, NBA on steps /stages involved in processing ABS applications the Authority directed NBA to clear online applications without any delay.

Decisions:

a) The Authority decided not to pursue the application of Natural Remedies considering decision of the 41st Authority meeting and wished the disposal of applications to be much quicker.

Action: Secretary, NBA

45.05: To seek guidance on applications of Access to Red Sanders wood

Recounting relaxation of ban by Directorate General of Foreign Trade (DGFT) on export of Red Sanders (RS) and simplification of procedures in the 32nd meeting held on 12th December 2014 the members took note that until the benefit sharing amount is credited into NBF and an Agreement executed with NBA/SBB, the RS wood should not qualify for CBEC permission for lifting from the site for export.

2. Out of 59 applications in Form-I NBA realized Rs.55 crores (approx.) as benefit sharing from the buyers.

3. The issue concerning the export of Red Sanders by four applicants without prior approval of the NBA in contravention of Sec.3 (1) of the BD Act was taken up with the Customs Department. The Asst. Commissioner, Customs, Thimmapur assured that necessary precautions will be taken in future to avoid such instances.

4. The members observed that the applicants had submitted applications with NBA in time seeking prior approval for exporting RS wood which were seized, confiscated and auctioned by DRI. The applicants had also paid 5% of the auctioned amount as BS to NBA as upfront payment. The RS wood was, however, exported to China with the approval of Customs and DRI before executing agreement with NBA. Further, as per the tender agreement (APFDC/DRI/STC/MMTC), the exporting agency does all activities on behalf of the applicant, including the transport of RS wood to the destination port.

5. A meeting with Customs, WCCB, DGFT is proposed in 3rd week of April in order to avoid lapses of this nature in future to establish the effective co-ordination among the different agencies while dealing the export of biological resources.

6. The Authority, therefore, decided to forgo the procedure for these four applications.

Decisions:

a) The Authority, in the instant case, decided to forgo the procedure for these four applicants from execution of agreement for accessing biological resources as they have filed the applications and paid the upfront payment as benefit sharing.

Action: Secretary, NBA

45.06: To consider the decisions of the Chairperson, NBA for granting exception to inventions which are Mechanical/Design improvements for ratification.

The members noted that mechanical/design improvements of inventions are not within the purview of Section 6 of the BD Act.

2. Pursuant to the decision of the 35th Authority meeting, the Chairperson, NBA granted exemption to only one such case *i.e Indian Oil Corporation* for the invention titled "Two-stage fluid catalytic cracking apparatus and process for production of different hydrocarbons".

Decisions:

a) The Authority ratified the exemption granted by to the sole Mechanical/Design improvement of invention.

Action: Secretary, NBA

45.07: To consider ratification of the decisions of the Chairperson, NBA for granting exception to inventions which make use of human genetic material

'Human genetic material' having been excluded from the definition of 'biological resource' as per Section 2(c) of BD Act, inventions based on human genetic material are not within the purview of Section 6 of the BD Act. Accordingly, No Objection Certificate has been issued to one (1) such case for the invention "A process for preparing stem cell based formulations".

Decisions:

a) The Authority ratified the issuance of NOC by the Chairperson, NBA for an invention based on research on human genetic material.

Action: Secretary, NBA

45.08: To consider the applications for access to Red Sanders wood approved by the Chairperson, NBA for ratification

Following the auction of Red Sanders by the Andhra Pradesh Forest Development Corporation NBA received one application from foreign buyer seeking access to Red Sanders wood. As per the procedure approved by the Authority in its 32nd (32.07) and 33rd (33.04) meetings, approval was accorded by the Chairperson after receiving benefit sharing component.

2. Pathanjali Ayurved Ltd.(PAL) paid Rs.207.90 crores to the APFDC and the foreign buyer paid Rs.206 crores. The same has been verified through the FOB value provided in the DGFT. Benefit sharing is not involved in the instant case as the price at which the consignment was bought by foreign buyer was less than the purchase price of Indian buyer.

Decision:

a) The Authority ratified the approval by the Chairperson, NBA on Form-I seeking approval.

Action: Secretary, NBA

45.09: To consider the Form-B applications disposed by the HQ for ratification

Decisions:

The Authority ratified the action taken on one Form-B applications by the NBA (HQ) and informed that the same may be hosted in the NBA website.

Action: Secretary, NBA

45.10: To consider the minutes of the 1st and 2nd Meeting of the Award Selection Committee for evaluation applications received for India Biodiversity Awards held on19th December 2017 and 22nd January 2018

The members were informed about the constitution of an Award Selection Committee for evaluation of the applications / nominations received by NBA towards India Biodiversity Awards in accordance with the decision taken by 41st Authority Meeting 27th March, 2017. The short listing of winners is in the final stage. Awards under "institutions" included Biodiversity Management Committees and "individuals" under four different categories. Since the cash prizes for institution and individual were found to be inadequate, the Committee recommended enhancement of cash prizes to 2 Lakhs for individuals and 5 Lakhs for institutions respectively.

2. After discussing the issue, the Members suggested that the recommendations of the Expert Committee may be communicated to the administrative Ministry for consideration.

Decisions:

a) The Authority directed the NBA to take up recommendations of the EC on enhancement of prize amounts with Ministry for consideration.

b) Authority also authorized the chairperson NBA to accept the recommendations of the Award Committee so that awards can be given during the celebrations of the International Day for Biological Diversity.

Action: Secretary, NBA

45.11: A report of the measures taken by NBA u/s 18(4) of the BD Act to oppose the grant of IPR outside India

The Secretary highlighted that objections raised to 8 foreign patents as per decisions in 35th and 44th meetings and the response received from WIPO, EPO, USPTO, Canada and Japan. He also clarified about European patent office response that since compliance with the applicable ABS legislation and regulatory requirements is the competence with the patentability requirement of the invention, observation cannot be taken in to account. The EPO also informed that the checking of PIC and MAT is the responsibility of the Competent National Authority and Focal point as designated by the EU member states. Thus, EPO does not act as check point as per the EU regulations, however, EPO encourages the applicant to include the information on the origin of the biological materials.

2. Dr. Sujata Arora appreciated the efforts made by NBA towards implementing Section 18(4) of the BD Act. Considering that all Parties to the Nagoya Protocol are required to take user country measures, she suggested that NBA may consider to include reference to Article 15(1), (2) and (3) of the Nagoya Protocol in the observations suitably. She informed that pursuant to the decision of the first meeting of the Conference of Parties to Nagoya Protocol, a Compliance

Committee has been set up of which an expert nominated by the Ministry (Dr. Luther Rangreji, Ministry of External Affairs) is a member. The Committee is scheduled to have its second meeting in April 2018, wherein one of the agenda is on Article 31 of the Protocol that relates to evaluating effectiveness of the Protocol four years after its entry into force. This review will be taken up by CoP-MoP in November 2018, for which Compliance Committee has to provide inputs.

3. In view of the above, she suggested that NBA may send a comprehensive note to the Ministry along with necessary documents so as to apprise the expert in the Compliance Committee. The Secretariat of the Convention of the Biological Diversity can also be consulted regarding taking up of the matter with the user countries.

Decisions:

a) Authority decided that NBA to communicate the detailed note and a letter to the Ministry for apprising the expert from India on the Compliance Committee of Nagoya Protocol, and for considering to consult the CBD Secretariat regarding taking up the matter with those countries.

b) Authority directed that the issue may also be brought to the notice of the Compliance Committee of Protocol as well as COP-MOP meet through MoEFCC.

Action: Secretary, NBA

45.12 To consider the applicants of Form B who have taken bio-resources outside India for study before approval of NBA against the Regulations 13 of the Guidelines of ABS Regulations, 2014.

1. The Secretary informed that Dr. Paltu Kumar Dhal (Application No: Form-B-52) Assistant Professor, Department of Life Sciences and Biotechnology, Jadavpur University had submitted Form-B seeking approval for carrying the sea water samples to Germany for conducting research. It was observed from the applicant's email dated 29th August, 2017 that the applicant carried the biological resources to Germany and completed the research work thereby contravening the Regulations 13 of the guidelines on ABS Regulations 2014.

2. Dr. Smitha Hegde, Professor, Centre for Science Education and Research, Nitte University, Mangalore (Appl.no; Form-B-59) had submitted Form B dated 1st June, 2017 and received by NBA on 03rd October, 2017 seeking approval for carrying 10 gm of *Pityrogramma calomelanos* (Silver back fern) leaf powder to Sophie University, Japan for conducting research, i.e. plastid developmental studies. It was learnt from the applicant's email dated 25th October, 2017 that applicant carried the biological resources to Japan as well as completed the research thereby contravening the Regulations 13 of the guidelines on ABS Regulations, 2014.

3. The Secretary clarified that no delegation by the authority exists to deal with the contravention of Regulations 13 of the ABS Regulations, 2014. The members observed that the Form-B was brought out through ABS Regulations, 2014 for speedy approval

and, therefore, initiating legal action at first instance may not be appropriate. The requirement being prior approval, post-facto approval is not permissible.

4. The members decided that a strong warning be sent to the Heads of organization of the applicants and thereafter the instant applications be treated as closed.

Decisions:

a) Authority directed the NBA to send a strong warning to the head of organizations of the applicants before treating the instant applications as closed.

Action: Secretary, NBA

45.13 Application submitted by M/s Evonik Industries AG Ltd in Form-I for access to fungal strains

M/s Evonik Industries AG Ltd (Applicant) made an Application in Form I on 25.06.2013 under Section 3(1) of the Biological Diversity Act, 2002 (BD Act) to NBA for access to two vials of permanent strain culture of *Schizochytrium limacinum- SC 1* from a company named M/s Avasthagen Limited Bangalore (Licensor), pursuant to the license agreement dated 28.12.2012. The Licensor is an entity falling under Section 3(2) of the BD Act which is required to obtain prior approval under the Act to access any biological resource from India for research. In the instant case the licensor obtained this biological resource without the prior approval under the Act. It was also observed that the licensor took patent on this invention without prior approval under Section 6 of the BD Act. Thus the licensor has violated Section 3 and 6 of the BD Act. Since the decision was taken in 17.04.2015 the Chairperson felt any rejection now, instead of the intended purpose, would only serve showing NBA in poor light on its lack of authority to enforce decisions and causing inordinate delays.

Decisions:

a) Authority directed the NBA to communicate the decision of rejection to the applicant (M/s Evonick) and treat the file as closed without further action/follow up.

Action: Secretary, NBA

45.14: Items for information

The Members took note of the activities carried out by the NBA such as comments / inputs offered on the draft CAMPA Rules, areas of cooperation with neighboring countries, etc.; activities / meetings undertaken by the UNEP-GEF-ABS project & its project states, fifth PSC meeting of the CEBPOL project and First PSC meeting of FAO-TCP Project as information.

45.15: Any other item(s) with the permission of the Chair

Annex-I

List of Participants

Official Members who participated			
1	**Dr (Mrs) B.Meenakumari** Chairperson, National Biodiversity Authority, Chennai	2	**Dr Sujata Arora** Adviser / Scientist 'G' Ministry of Environment, Forest and Climate Change Government of India Room No. V 235, Vayu Block, Second Floor Indira Paryavaran Bhawan Jor Bagh Road New Delhi-110 003
3	**Dr M. Gunasekaran,** Assistant Commissioner (Seeds), Department of Agriculture Co-operation & Farmers Welfare, Cabin no: 16, F-Wing, 2nd Floor, Shastri Bhawan, New Delhi-110 001	4	**Dr. Manoj Kumar Modi** Scientist- E/ Joint Director Department of Biotechnology Ministry of Science & Technology, Govt. of India, Block No:2, 6-8th Floor, CGO Complex, Block No. 2 Lodhi Road, New Delhi 110 003.
5	**Smt. Shyla Titus,** Deputy Secretary Ministry of Tribal Affairs, Room No. 736 A-Wing 7th Floor, Shastri Bhavan, New Delhi	6	**Shri S. Elamurugannan,** Assistant Inspector General of Forests, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhavan, Jor Bagh Road, New Delhi - 110 003
7	**Dr. Akhilesh Gupta,** Scientist G & Head SPLICE, Department of Science & Technology, New Mehrauli Road, New Delhi – 110 016	8	**Dr.R. Kirubagaran,** Scientist G, National Institute of Ocean Technology, Ministry of Earth Sciences, Velachery-Thambaram Main Road, Narayanapuram, Pallikaranai, Chennai – 600 100
9	**Shri. T. Rabikumar, IFS** Secretary,National Biodiversity Authority, Chennai –600 113.		
Non-Official Members who participated			
10	**Dr. Yogesh Shouche** Senior Microbiologist, National Centre for Cell Science Department of Biotechnology Lab, University of Pune Campus, University Road, Ganeshkhind, Pune, Maharashtra – 411 007	11	**Dr. Dinesh Misra,** No: 65, Sector 8 Gandhi Nagar, Gujarat - 382008
12	**Dr P C Bhattacharjee,** Retd., Professor & Head, Department of Zoology, A/3 Asiyana Housing Complex Maligon, Guwahati – 781011, Assam.	13	**Shri Darshan Shankar,** Chancellor, Trans Disciplinary University, C/o Foundation for Revitalization of Local Health Traditions (FRLHT), 74/2, Jarakabande Kaval, Post Attur via Yelahanka, Bangalore - 560 064
Members who did not participate			
14	**Dr. Sowmita Bhiswas** Chief Executive Officer, National Medicinal Plant Board Dept. of AYUSH, Ministry of Health & Family welfare, New Delhi	15	**Dr. Anand Kumar Singh**, Deputy Director General (Crop Science) (Additional Charge), Division of Crop Science, KrishiBhavan, Dr. Rajendra Prasad Road, New Delhi 110 001
16	**Prof. Umesh Rai** Director, Department of Zoology, South Campus, University of Delhi New Delhi- 110 007	17	**Dr. Sanjay Kumar**, Director, Institute of Himalayan Bio resource Technology P O No:6, Palampur, Himachal Pradesh:176061