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Wishing you a year full of happiness, good health, and endless blessings. Happy New Year 2025!



EDITORIAL

NATIONAL BIODIVERSITY AUTHORITY CALLS FOR PUBLIC COMMENTS ON ACCESS AND BENEFIT SHARING

NBA (NATIONAL BIODIVERSITY AUTHORITY) has called for views and comments on the process of revising the ABS (ACCESS AND BENEFIT SHARING) Regulations, 2014 in light of The Biological Diversity (Amendment) Act, 2023 and The Biological Diversity Rules, 2024. It was also announced that the Amended Act will come into force on April 1, 2024. The order passed by NGT (NATIONAL GREEN TRIBUNAL) on 20th December, 2023 in Dabur India Limited vs National Biodiversity Authority is also worth taking note of in this context.

The new Act of 2023 and the new Rules of 2024 need to be implemented through revised ABS guidelines in light of the provisions of the Nagoya Protocol, which came into effect in 2014.

All cases relating to NBA need to be handled in favor of Indian companies, entities, and Indian individuals in the context of amendments to Sections 3 to 7 of the Act.

The related publications and communications are reproduced below:

1. Notice inviting comments/suggestions for Revising Access and Benefit Sharing Regulations, 2014



National Biodiversity Authority

(An Autonomous and Statutory Body of Ministry of Environment, Forest and Climate Change)

Notice inviting comments / suggestions for Revising Access and Benefits Sharing Regulations, 2014

In light of the amendments to the Biological Diversity Act 2002 and Biological Diversity Rules 2004, the National Biodiversity Authority is in the process of revising the ABS Regulations, 2014. In this regard, it is invited to provide comments / suggestions to revise the ABS Regulations from the individuals / associations / entities / institutions and submit their views in writing on or before 17th December 2024 to the secretary@nba.nic.in, in respect of benefit sharing obligations related to their sectors for utilization of biological / genetic resources and / or associated knowledge / digital sequence information. For further information refer to www.nbaindia.org.

Dabur India Limited vs National Biodiversity Authority on 20 December, 2023.

The order of the respondent is usefully extracted below:

Sub: Execution of ABS Agreement under Application Form-I (4197)- Conveying the decision of 66th EC on ABS- reg.

Ref: Your letter dated 21.03.2022 received on 11.04.2022.

 This has reference to your letter cited above, wherein you have requested this office to consider the Access and Benefit sharing under Regulation 2 of the ABS Guidelines (Resource-Centric Approach). You have also claimed that the choice of paying the benefit sharing between Regulation 2 or 4 is vested with the applicant.

- 2. It is to inform that your application along your claims were examined by the Expert Committee on ABS (EC on ABS) in its 66th meeting held on 27th April, 2022. The EC observed that the applicant, being a Section 3(2) entity, had accessed the biological resources without obtaining the prior approval of NBA and thereby contravened the provisions of Biological Diversity Act, 2002. Hence, EC on ABS has not agreed to the claims made by you.
- 3. Accordingly, you are requested to pay the higher benefit component under Regulation 4 of the ABS guidelines 2014 (0.5% of annual gross ex-factory sale price of the product) from the date of commercial utilisation and submit the duly certified audited statement for the same.
- 4. You are requested to submit the duly signed

stamp paper agreement, as instructed by this office vide email dated 16.03.2022, within 15 days from the receipt of this communication.

46. The reasons recorded by the authority for arriving at the conclusions are not based on the remarks **NBA** bv or bv the recommendations of the Expert Committee. The impugned order referring to the access to biological resources by the appellant without obtaining the prior approval of NBA cannot be the reason to pay the higher benefit under Regulation 4 of the ABS Guidelines. 2014. Such non-speaking unreasoned or cryptic order passed without taking into account the relevant facts, evidence available are judicially recognised by the Courts normally. Mere mention of the provision of law without and relevant facts evidence cannot withstand the test of judicial scrutiny. The opinion expressed or conclusion arrived at in an order without recording the reasons is unjustifiable and such practice deprecated by the Courts. There are catena of decisions which reiterate that nonspeaking orders deserve to be quashed. The NBA in exercise of its quasi-judicial function must record reasons in support of the order. The order should have considered objections/submissions made the appellant and recorded the reasons. The failure on the part of the respondent to pass a speaking order vitiates the proceedings.

47. In the result, the Appeal is allowed and the impugned order is set aside. The matter is remitted back to the respondent for fresh

consideration of its order. Needless to say that the principle of natural justice shall be followed. Consequently, the Appeal is disposed of.

48. In view of the disposal of the Appeal, I.A. No. 170 of 2022 is also disposed of.

Smt. Justice Pushpa Sathyanarayana, JM Dr. Satyagopal Korlapati, EM Internet - Yes/No All India NGT Reporter - Yes/No Appeal No.54/2022 (SZ)& I.A. No. 170/2022(SZ) 20th December 2023. AM & MN.

Before the National Green Tribunal Southern Zone (Chennai) & Dabur India Limited Vs. National Biodiversity Authority & Anr.

Appeal No. 54/2022(SZ)& I.A. No. 170/2022(SZ) 20th December, 2023. (AM).

Pharmabiz Newsletter

NBA invites feedback on revising ABS

Regulations to strengthen ayurvedic biodiversity

conservation

Shardul Nautiyal, Mumbai
Thursday, December 19, 2024, 08:00 Hrs [IST]

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The National Biodiversity
Authority (NBA), an
autonomous and statutory
body under the ministry of
environment, forest and

climate change (MoEFCC), has called for public comments and suggestions regarding the revision of the Access and Benefit Sharing (ABS) Regulations, 2014 towards strengthening ayurvedic biodiversity conservation.

This initiative comes in light of the recent amendments to the Biological Diversity Act, 2002, and the Biological Diversity Rules, 2004. The public is invited to submit their views in writing to the NBA at secretary@nba.nic.in.

As per the MoEFCC notification on ABS, when the biological resources are accessed for commercial utilisation or the bio-survey and bio-utilisation leads to commercial utilisation, the applicant shall have the option to pay the benefit sharing ranging from 0.1 to 0.5 per cent at the following graded percentages of the annual gross ex-factory sale of the product which shall be worked out based on the annual gross ex-factory sale minus government taxes.

The NBA is seeking input from individuals, associations, entities, and institutions on the proposed revisions, with a focus on the benefit-sharing obligations related to the utilization of biological and genetic resources and/or associated knowledge and digital sequence information.

The NBA emphasizes the importance of stakeholder participation in ensuring that the revised ABS Regulations are comprehensive and aligned with the evolving landscape of biodiversity conservation, sustainable use, and equitable benefit sharing.

This move is part of the ongoing efforts by the NBA to refine and enhance India's framework for biodiversity governance, in accordance with

international obligations and national priorities for conservation and sustainable development.

NBA's call for input is expected to play a critical role in shaping future regulations related to biodiversity use and conservation, ensuring that the revised framework benefits all sectors involved while protecting India's rich natural heritage.

As per the ABS compliance, Ayush manufacturers are required to share benefits among concerned Biodiversity Management Committees (BMC) of the state for sustainable use of bio-resources as per Biological Diversity (BD) Act, 2002.

manufacturers Avurvedic have long been questioning the irrationality of the ABS notification saying that it is applicable to foreign companies only. It is not applicable to Indian manufacturers as most of the raw material is not commercially utilised. State Biodiversity Boards (SBBs) have however maintained that law exempts commonly traded commodities for general consumption and not commercial utilisation of bio-resource as stipulated in the November 21, 2014 ABS notification. MSBB has the mandate to collect ABS payment under the provisions of BD Act, 2002.

As per the BD Act, manufacturers are accountable to share details of the source from where raw material has been procured in Form I and further submission of the same to SBB. The NBA and central government are empowered to take legal action for the non-compliance of ABS.

CIPROM's Letter to NBA



CIPROM/209/24-25 21st December 2024

To,
Dr. B. Balaji, IFS.
The Secretary
National Biodiversity Authority
5th Floor, TICEL Biopark
CSIR Road, Taramani
Chennai – 600 113

Respected Sir,

Sub: Comments/Suggestions on proposal to revise the ABS Regulations

We are extremely happy to note that you have invited comments/suggestions for revising the ADS Regulations in light of the 2023 Amendments to Biodiversity Act, 2002 and the 2024 Amendments to Biodiversity Rules as well as the Gazette Notification that the revised Biological Diversity (Amendments) Act 2023 will come into effect from 01.04.2024 (as notified on 18th January 2024 through S.O.295E).

- 1. You are aware that the implementation of the Convention on Biological Diversity (CBD) should have been subject to the provisions of Nagoya Protocol, which has only been accredited by member countries and came into effect on 12th October 2014.
- 2. However, India had hastily notified and implemented the defectively drafted Biological Diversity Act 2002 [ex:- Sect 3 (e) (ii)] followed by badly drafted Biological Diversity Rules, 2004 and coercive provisions of the ABS guidelines and NGT rulings based on above irrational Acts and Rules.
- 3. Now that Nagoya Protocol is in force and the Act (2023) and Rules (2024) are amended more sensibly and practicably, the ABS guidelines should be notified in concurrence with Nagoya Protocol provisions and global practices.

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4. Most importantly, the Biological Diversity (Amendments) Act, 2023 requires as per provisions of the Rules, 2024, to file various Forms 1 to 16 for complying. The actions in response to filing of these Forms 1 to 16, must be time-bound. The proposed ABS guidelines must specify the precise timelines for responses, registrations and approvals in response to the applications in Form 1 to 16.

- 5. The ABS guidelines being notified may be ensured to be compliant to CBD and Nagoya Protocol and the implementation of the amended provisions of the new ABS guidelines may be made with retrospective effect from 2004.
- 6. It is humbly requested that the responses received late (after 18th December 2024) may also be taken on record for due attention and implementation.
- 7. It is further requested that all comments/suggestions/ representations received in response to your invitation, may please be published on the website of the NBA so that the public is aware and further duplication may be avoided.
- 8. We support and endorse the suggestions forwarded to you by FICCI dated 18th December 2024 (copy attached).
- 9. We support and endorse suggestions made by AMAM (Association of Manufacturers of Ayurvedic Medicines) dated 18/12/2024 (copy attached) and others.
- 10. While drafting the ABS guidelines, we request you to kindly ensure that indigenous research by Indian researchers are encouraged, the requests filed through various forms be responded positively in a timebound schedule.
- 11. A portal may please be opened on the NBA website to transparently make available to the public, all the applications received, actions and progress made on an ongoing basis.

We endorse the views expressed in attached documents.

Kindly process our above requests favorably.

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Yours faithfully,

For Centre for Intellectual Property Management

Dr. Gopakumar G. Nair

Hon. Chairman