



The e-newsletter for the Indian Biotech industry

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Amended Biodiversity Laws a welcome boost for our biotech industry



India's A Damocles Sword hanging over our industry in the last 10-15 years has been removed with the latest amendments approved by Parliament to the **Biological Diversity Act 2002**. The amendments that have come in the form of new **Biological Diversity (BD) Act 2023** is a great improvement over the original Act and is a welcome step by the government to help our BioEconomy that is now inching towards the \$ 100 billion mark.

I am happy to note that ABLE had been at the forefront of championing the need for these much-needed amendments to the BD Act for more than a decade. ABLE members were most affected more than 10 years ago when the many inadvertent provisions of the Act were put into action by the National Biodiversity Authority (NBA). ABLE members continuously knocked on the

doors of ministries involved, over the years to help the industry. However, some of the stringent provisions were hard-coded into the Act and only the Parliament could approve the changes suggested. This is what has happened over the last few years.

A draft legislation with most of the changes suggested by the industry was notified in December 2021 and a joint Parliamentary Committee further sought stakeholder suggestions and finally these amendments were incorporated into the Act and approved by both houses of our Parliament in July 2023. These changes will come into force as soon as it is notified by the government.

This newsletter has the highlights of the amendments that will help the industry, articulated by two foremost experts on this topic, Dr Malathi Lakshmikumaran and Mr Ravi Bhola. Decriminalization of minor violations, more clarity on definition of Indian and foreign companies that require multi-level permissions from the NBA, provision for adjudication for adverse rulings, monetary fines, ease of doing research without permission till commercialization are some of the key provisions. Both our experts answered a wide range of queries on this issue during the ABLE webinar on this topic on August 2023. The recording of this valuable discussion is available to members.

The Science and Technology Ministry is giving all the thrust for India taking a big role in global **biological manufacturing** opportunities. This is gathering momentum, pushed by the **DBT Secretary, Dr Rajesh Gokhale**. A series of stakeholder consultation meetings are going on across the country in recent weeks. ABLE facilitated one such meeting in collaboration with BIRAC @ In-Stem in Bengaluru in August. The summary of the suggestions is given in the news letters. Members who could not attend in person are requested to send their suggestions to ABLE at the earliest so that these could be incorporated in the final biological manufacturing framework.

A hectic season of biotech conferences are ahead of us. ABLE is playing a key role in two major events, the 1) The **26th edition of Bengaluru Technology Summit** in Bengaluru from November 29 to December 1, 2023, organized by the Government of Karnataka and 2) The next edition of the **Global Bio India 2023** scheduled to be held in New Delhi, from December 4-6, 2023, organized by the Department of Biotechnology, Government of India and BIRAC. ABLE is a key partner and this will be yet another great opportunity to show case our industry's capabilities to the Nation and the World.

I will be sharing more details. Please mark these dates in your calendar and participate in large numbers.

G S Krishnan
Hon. President | ABLE

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DBT & NSF Chiefs discuss biological manufacturing strategies @ ABLE-BIRAC joint meeting in Bengaluru

By Narayanan Suresh



ABLE in association with DBT-BIRAC organized a high-level Round Table with biotech industry leaders on August 23, 2023 in the presence of DBT (Department of Biotechnology) Secretary, Dr Rajesh S Gokhale and the visiting US National Science Foundation (NSF) Director, Dr Sethuraman Panchanathan. The meeting was held at the DBT-InStem facility in Bengaluru on August 23, 2023. The key topic was to promote Indo-US collaborations in biotech innovation and biological manufacturing opportunities to reach the target of \$ 100 billion biological manufacturing by 2030 from the current \$ 40 billion level.

Industry leaders suggested attention to the following areas during their discussion with the top government policy makers.

1. Scalable technologies to harness the power of tropical oceans to harness a wide range of industrial feed stock
2. Invest in increasing the talent pool of human resources in handling development and manufacture of a variety of biosimilar therapeutics products. This is more important than funding or building infrastructure. Industry needs large number of talented scientists to scale up
3. Simplified regulatory processes to encourage more biological manufacturing facilities
4. Encourage local manufacturing of high end analytical and other instrumentation required by industry to reduce overall capex costs
5. Use of more platform technologies to optimize manufacturing processes
6. Collaboration between domestic players to leverage strengths
7. Allow biological manufacturing investments to claim Productivity Linked Incentive (PLI) scheme benefits
8. Tweak climate change policies to encourage large scale use of low carbon emission

- manufacturing processes using biomass
9. Boost to manufacture of animal-free pharmaceutical ingredients that has huge global potential
 10. Tap demand for alternate milk proteins and other smart proteins by encouraging manufacture in the country to meet global demand
 11. PLI scheme should also incentivize manufacture of cell and gene therapy. Here large-scale volumes are not the criteria to be used
 12. Preferential buying of home-grown healthcare products in all sectors
 13. Circular economy sector has great potential and can feed the biomaterials needed in many industrial processes
 14. Low import duties on key raw materials needed to make high end oligonucleotides and other therapeutics for export markets
 15. A framework to encourage indigenous manufacture of fish meal and other ingredients in animal food sector using variety of insects
 16. Build infrastructure in the interface between incubators and large-scale manufacturing on the lines of Fraunhofer Institutes to provide affordable options for biotech startups to scale up into manufacturing

Earlier, inaugurating the round table, DBT Secretary, Dr Rajesh Gokhale outlined the efforts of BIRAC in the last 10+ years to catalyze the growth of the impressive innovation ecosystem in biotechnology. He thanked ABLE for being a partner in this endeavor. He said DBT has taken up the mission of increasing our country's biological manufacturing industry and it will include efforts in synthetic biology, artificial intelligence and every other modern tools available.

Dr Gokhale forecast that the food processing industry will change dramatically with the alternative processes available and could be in the forefront of the biological manufacturing sector. And materials biology too will undergo transformation. He gave the example of how societies are now grappling with the huge amounts of discarded clothes and how to have a meaningful tackling of these products through the entire life cycle. Huge biotech opportunities exist in finding beneficial solutions to this mounting waste problem.

Dr Panchanathan outlined the structure and impact of research projects funded by the NSF in the US and in other countries. He emphasized that India is a valuable partner to NSF and the collaboration in research sector between the world's two top democracies is gaining momentum due to the high level political leadership exchanges in recent years. NSF will collaborate with DBT to jointly fund many interesting research projects in biological manufacturing sector.

Earlier, Mr G S Krishnan, President, ABLE, welcomed the DBT Secretary and NSF Director and ABLE members. Dr Alka Sharma, senior advisor in DBT, briefed about the department's efforts to foster cooperation with top countries. Dr Jitendra Kumar, managing director of BIRAC shared the company's efforts to held the biotech innovation system. Dr P M Murali, President, ABLE Council of Presidents, moderated the discussions. Dr Dhananjay Tiwary, S&T Counsellor in Indian Embassy in Washington DC introduced the visiting NSF team. ABLE COO, Mr Narayanan Suresh, thanked DBT and the hosts In-Stem for the opportunity provided to the industry meet the government leaders and share their ideas to boost the country's biological manufacturing segment.

Amended Biodiversity laws are more biotech friendly now, say ABLE experts

By Narayanan Suresh

The graphic is a promotional poster for a webinar. On the left, under the heading 'SPEAKERS', are three circular portraits of the speakers: Mr. G S Krishnan (Hon. President ABLE), Dr. Malathi Lakshmikumar (Executive Director & Practice Head - Lakshmikumar & Sridharan Attorneys), and Mr. Ravi Bhola (Hon. General Secretary ABLE). The right side of the graphic features the 'k-tech' logo at the top right, followed by the text 'FREE WEBINAR ON', 'DECODING THE BIOLOGICAL DIVERSITY (AMENDMENT) ACT, 2023', and the date and time 'AUGUST 25, 2023 03:30 PM - 05:00 PM'. The background of the right side shows a globe and green foliage.

The government has listened to the concerns expressed by biotech industry and the latest amendments incorporated in the Biological Diversity Act by Parliament in July 2023 is very for the industry, commented two experts, Dr Malathi Lakshmikumar, top legal expert and partner in

Lakshmikumar & Associates, and Mr Ravi Bhola, Senior Partner, K&S Partners and secretary, ABLE.

They expressed these views while decoding the highlights of the newly amended biodiversity law at a webinar organized on this topic by ABLE on 25th August 2023. ABLE Chief Operating Officer, Mr Narayanan Suresh, recollected the 10-year long efforts of ABLE to highlight the need for these key amendments since 2013 to ensure smooth operations for companies in India to meaningfully commercialize the country's vast biological resources. ABLE President, Mr G S Krishnan, in his inaugural talk, mentioned the negative impact of some of the draconian provisions in the earlier Act that hindered investments by Indian and foreign companies.



Dr Malathi and Mr Ravi highlighted the 8 key amendments that will ease the way for doing biotech business in the country using natural resources.

These are:

1. Section 58 removed: offences are decriminalized

Violations under the Biological Diversity Act will now only attract stringent fines in most cases

2. Section 3(2) amended: More logical categorization of Indian and non-Indian entities under the Act now.

Earlier, there were vague definition that considered a company foreign even if there was a single foreign share holder, irrespective of the number of shares held. Now, there will be a more liberal interpretation of the “foreign” character of a company. Only if the majority shareholders are foreigners or if foreign holder has influential voting rights or right to appoint majority of directors in an Indian company only will be treated as foreign entity

3. Section 7 amended: More exceptions for Indian entities

- a. Codified Traditional Knowledge
- b. Cultivated Medicinal Plants and its products
- c. AYUSH Practitioners

Mr Ravi Bhola explained that Indian companies can now do research on all these products and no prior permission from the National Biodiversity Authority (NBA) is needed. When any such effort is commercialized, the NBA only needs to be informed about it.

4. Section 2 amended: Expanded definition of Biological Resources introduced

The experts explained that the Act has brought the term “derivative. Derivative means a naturally occurring biochemical compound or metabolism of biological resources, even if it does not contain functional units of heredity.

For example, coal, a naturally occurring material has no specific genetic material in it and hence it is not a biological resource. On the other hand, azdirachtin, extracted from neem will be treated as a “derivate”.

5. Section 6 related to Patents amended.

After the amendment, Indian entities do not need to take the NBA permission to file patent applications. This will lead to optimizing the work load at patent offices and reduce time to issue patents.

6. Section 59 amended: This means the biodiversity laws will not be applicable on Plant Varieties approved under the Plant Varieties Protection Act

7. Section 40 amended to expand the list of exemptions under the law

These include:

- a. Items derived from normally traded commodities
- b. Agricultural waste
- c. Commercially grown medicinal plants

Due to this, various obligations under the Biodiversity law kicks in only when commercialization process starts. No permission required to do research

- 8. Section 55 amended: More penalties and appointment of adjudication officer**
After removing prison terms, the law now prescribes a wide range of monetary fines to violators, ranging from Rs 1 lakh to Rs 50 lakh or event up to Rs 1 crore in exceptional cases for repeated offenders. There is also a provision to appoint an Adjudication officer with the powers of civil court to take up certain offences.

Overall, both the experts explained that thing will become easy now to use India's biological resources. The amendments have been approved by Parliament and will come into force when the Ministry of Environment and Forests officially notifies these changes in the original BD Act. Dr Malathi and Mr Ravi Bhola, answered a wide range of questions and provided clarifications to more than 100 members who tuned into the webinar.

Participate at BIO Hong Kong 2023

13-16 September 2023 | Hong Kong



We are excited to invite you to join us at BIOHK2023, taking place from September 13-16, 2023 at the Hong Kong Convention and Exhibition Centre, proudly hosted by Hong Kong Biotechnology Organization (HKBO). ABLE is a Global Partner for BIOHK2023.

BIOHK2023 is one of Asia's largest international biotechnology conventions where policymakers, industry, academia, research, investment and end users convene on behalf of cultivating biotechnology for the benefit of all. As a city with a rich history in industrial development and innovation, coined as "Asia's World City" for a reason. BIOHK's strategic positioning in Hong Kong aims to bring biotech companies from East and West together to foster collaboration.

BIOHK2023 Convention Theme KALEIDOSCOPE aims to bring the infinite possibilities of what one can accomplish in biotechnology. Join us at BIOHK2023 and explore the latest advancements and breakthroughs in biotechnology through the key themes: Cancer, Aging, Infectious Disease, and Chinese Medicine.

ABLE offers exclusive discounts to participate at BIO Hong Kong 2023. Connect to indrilas@ableindia.org.in for more details.

Visit the website to know more www.2023.bio-hk.com



ABLE is excited to announce 'voice for BT' & BEST program for college students



'voice for BT', an Inter-Collegiate Public Speaking Competition, is currently India's only public-speaking contest on biotechnology for college students. Organized by ABLE with the support from Novozymes South Asia, this event is conducted for Undergraduate Final Year B. Tech/ BE- Biotechnology, Food technology and Chemical engineering students or First Year Post graduate students. The contest is held in all the four zones in India where colleges can nominate ONE of student to represent their institution and participate in the 'voice for BT' 2023 contest.

Visit the website for more details www.ableindia.in/voicibt/

APPLY TODAY

Biotechnology Entrepreneurship Student Teams - BEST program is to encourage young graduate, post-graduate and doctoral students in developing their entrepreneurial skills by exposing them to issues involved in commercialization of biosciences and bringing out an idea to present in front of an eminent jury. Zonal rounds will be conducted followed by National finale. Form a Team of 3 & Shape your bright innovative business ideas into a Concept Note and send it to us.



Visit the website for more details www.ableindia.in/best/

REGIONAL ACADEMIC PARTNERS



KEY BIOTECH EVENTS

Winners Announced for the 3rd 'Women in Biotech' Awards



Golden Jubilee Biotech Park for Women along with the Association of Biotechnology Led Enterprises had started to set up the country's first National Awards to celebrate women entrepreneurs in Biotechnology – Women in Biotech awards to honor exceptional women leaders whose impactful contributions have reshaped the landscape of the biotech industry.

The 3rd Women in Biotech Awards ceremony took place in Taj Coromandel, Chennai. This year's award categories celebrated the remarkable achievements of women in various roles within the biotech industry. The winners were chosen by a distinguished panel of experts.



The Lifetime Achievement Award 2023 was bagged by Dr Deepanwita Chattopadhyay, Chairperson, IKP Knowledge Park.



Dr Ezhil Subbian, Co-founder & CEO of String Bio won the Women Entrepreneur of the Year 2023.



The Woman Scientist of the year 2023 was awarded to Dr Humira Sonah, Ramalingaswamy Fellow at DBT-National Agri-Food Biotechnology Institute (NABI), Mohali, Punjab.



Ms Vedavalli Sankaranarayanan, Founder & CEO of Plasmaart Resto won the Special Jury Award for the Most Innovative Woman Biotech Entrepreneur in Tamil Nadu.

ABLE member Sea6 Energy: Farming the ocean, and exploring the possibility of making crude oil from seaweed



India has a high dependence on crude oil—it's the third-highest importer in the world after the US and China. According to a July 25 report in the Economic Times, India imported \$31.4 billion worth of crude oil in the April-June quarter, about 60.1 million metric tonnes in volume.

There is no easy alternative to the versatile crude oil, which powers our industry and energy needs ranging from transportation to textile, but which also releases a huge amount of carbon dioxide that traps heat and contributes to global warming.

A Bengaluru-based startup launched by a biotechnology research veteran from Biocon and three engineering graduates from the Indian Institute of Technology (IIT)-Madras is contributing to the solution by farming the ocean. Sea6 Energy is developing a large-scale sustainable alternative feedstock of seaweed, which “can potentially replace everything that we do today with crude oil”, says Shrikumar Suryanarayan, co-founder and chairman.

In the past 13 years since the startup was founded, it has been working on two broad areas: First, large-scale seaweed production by developing automation, and second, converting this seaweed into useful products that have applications across various sectors.

Growing seaweed—which absorbs carbon dioxide as it grows, transforming it into biomass—is traditionally a labour-intensive process restricted to shallow waters, which makes it cost-ineffective. Sea6 has been inventing and scaling up machinery to counter these issues. It has a patent on a seaweed farming system, Suryanarayan says, which includes a tractor that automates the process of seaweed seeding and harvesting. There are also large-scale girds

that float on the ocean surface, which can withstand rough waves on which seaweed can be grown.

The first product made from seaweed that they have commercialised is a proprietary bio-stimulant, an extract, when sprayed in a small amount on a crop—like rice, maize, sugarcane, what have you—can drive the yield up by 10 to 30 percent depending on the crop that's grown, the inputs (fertilisers, irrigation) etc provided and the condition in which it is grown. "This is not a fertiliser by itself, but it improves the efficiency of how plants capture sunlight and use nutrients," says Suryanarayan. "This means, effectively, we have found a way to produce more food from the same land mass and, therefore, improve our food security."

Sea6 has a global patent on this product, which is exported to the US, Europe, Latin America, Japan and other countries in Southeast Asia. These bio-stimulants are manufactured both in India and Indonesia, though the bulk of the seaweed farming is done in the latter where Sea6 has a fully owned subsidiary because of the advanced maritime zoning and leasing regulations.

Sea6 is on track to earn about \$10 million this financial year largely on the back of the bio-stimulant, says Suryanarayan. He adds that they are working on how to make crude oil or fuel from seaweed, and have also published a scientific paper with IIT-Madras last year detailing how this could be possible. The startup, according to Tracxn, has raised a total funding of \$39.4 million from investors, including Tata Capital, BASF, Aqua Spark and Silverstrand, apart from a handful of angel investors, including Biocon CMD Kiran Mazumdar-Shaw. The Series B fundraise, which got in around \$18.5 million, came in July 2022, as per Tracxn.

The startup is yet to turn a profit, Suryanarayan says, because "expense on R&D is high" and the registration pathway required for commercialisation is long in different countries. "But once you get registration, sales are very rapid," he says. "The agricultural bio-stimulants are inherently profitable, and as the volumes build up, we expect to gain profitability in the next year or year and a half."

As they also scale up their farm technology, they have started doing research on how seaweed can be converted to biodegradable plastic. "Next year, we will be in a position to start rolling out some of these products, and we are positioning our next fundraising round, which is Series C, as a growth round," says Suryanarayan.

Vineet Chadha, partner, Tata Capital Innovations Fund, was one of the first to invest in Sea6 in 2015 and has been invested for the past eight years. According to him, the company has been consistently progressing and developing interesting products with seaweed, like, he says, water-soluble detergent pods, whose outer layer also dissolves as the clothes get washed.

Chadha believes that the beauty of Sea6 is the founding team's ability to innovate using simple, intuitive tools and technology and come up with large use cases and commercial applications. "They never complicate or over-engineer things. Their products, including the bio-stimulant, are testament to that. These guys think big, but simplistically. They have their science and their thought process very clear."

As an investor, the exit has taken longer than what he expected, partly because of Covid-19, Chadha says, but he is happy that they've been getting partial exits at regular intervals, one in 2020 and another in 2022. "The team is committed to give, and has been giving us liquidity, which is a good thing," he says.

Source: Forbes India

ABLE member Serum Institute's multivalent meningococcal meningitis vaccine gets WHO prequalification



MenFive[®], the first conjugate vaccine to protect against the five predominant causes of meningococcal meningitis in Africa, has been prequalified by the World Health Organization (WHO).

Developed through a 13-year collaboration between Serum Institute of India Pvt Ltd (SIPL) and PATH, with crucial funding from the UK government's Foreign,

Commonwealth and Development Office, MenFive[®] protects against meningococcal serogroups A, C, W, Y, and X and is designed to eliminate annual meningitis outbreaks and epidemics in the African meningitis belt—a string of 26 countries from Senegal and The Gambia in the west to Ethiopia in the east.

It is also the only vaccine that prevents meningitis caused by meningococcal group X, a pathogen increasingly implicated in meningitis outbreaks in Africa.

WHO prequalification was supported by extensive clinical studies in The Gambia, India, and Mali that demonstrated a high level of safety and immunogenicity. Importantly, prequalification allows MenFive[®] to be procured by United Nations agencies and Gavi, The Vaccine Alliance.

Adar Poonawalla, CEO, Serum Institute of India, said, "MenFive[®] is a game-changer vaccine developed through a powerful 13-year collaboration between SIPL, PATH, and vital support from the UK government, in the fight against meningococcal meningitis in Africa. As the first conjugate vaccine to safeguard against the five predominant causes of this deadly disease, MenFive[®] offers hope for a future free from annual outbreaks and epidemics in the African meningitis belt. It is a big moment as we, together, pave the way towards a healthier Africa, saving countless lives."

Meningococcal meningitis is a bacterial infection that sets in rapidly and can kill within hours. It can cause severe brain damage and sepsis leading to limb amputation and is fatal in 50 percent of cases if untreated. MenFive[®] is currently undergoing an additional Phase 3 study in healthy children between 9 and 15 months of age in Mali, to examine MenFive[®]'s safety and immunogenicity when administered alongside measles/rubella and yellow fever vaccine.

Source: BioSpectrum India

ABLE member Bugworks gets big funding for antibiotic development

Bengaluru-based startup Bugworks will receive funding and other support from the Global Antibiotic Research & Development Partnership (GARDP), a non-profit co-founded by the WHO, to develop a new antibiotic to treat drug-resistant bacterial infection.

The drug will be a new broad-spectrum antibiotic against bacterial infections that are becoming increasingly difficult to treat owing to antimicrobial resistance (AMR). Several Gram-negative bacteria such as *Klebsiella pneumoniae* are now resistant to most antibiotic treatments.

Bugworks' drug is currently in Phase I of clinical trials in Australia. The collaboration between GARDP and Bugworks will be formalised through an agreement by the end of this year, as per a press release.

"If our Phase I trials are successful, GARDP will commit funding of USD 20 million (over Rs 160 crore) for Phases II and III of the trials. This will be roughly 20% of the money needed to take the product to the market," Dr Anand Anandkumar, co-founder and CEO of Bugworks said.

Other than this, GARDP will facilitate clinical trials for Bugworks in low- and middle-income countries (LMIC) where AMR is a major challenge. "WHO also has licences for 140 LMICs, so it can facilitate the entry of our product to these countries as soon as it is ready," Dr Anandkumar said.

Other than support from the government, Bugworks has received investment from companies such as Biocon in India, along with investors abroad.

Source: Deccan Herald



Time for Science to
SHINE

Save the Date!

BIO International Convention
June 3-6, 2024
San Diego, CA



National Medical Devices Policy, 2023

Following the 'Approach Paper to National Medical Device Policy, 2022' published by the Ministry of Chemicals and Fertilizers (MCF) on May 10, 2022, which laid down a roadmap for accelerated growth of the medical devices sector while promoting safety and quality, the National Medical Devices Policy, 2023 ("Policy") was notified by the MCF on May 03, 2023.



The vision of the Policy is to help India emerge as a global leader in the manufacturing and innovation of medical devices by achieving a 10-12% share in the expanding global market.

The mission of the Policy inter alia includes:

- universal access to good quality medical devices
- ensuring affordability of medical devices
- focusing on quality of medical devices in order to enhance global positioning, acceptability and competitiveness
- enhancing the quality of care based on clinical outcomes and convenience of the patients;
- creating and evolving a modern eco-system; and
- facilitating skilled manpower.

Further, the government's strategies to promote medical device sector include:

- setting up a single window clearance system for facilitating licensing of medical devices
- enabling infrastructure - setting up large medical device parks, medium-sized medical devices clusters, enhancing the number of medical device testing laboratories in proximity to economic zones and centres of excellence in premier academic and research institutions
- facilitating R&D - promote innovation and Research and Development (R&D)
- attracting investments in the sector - promote indigenous manufacturing, build competitiveness and promote an ecosystem for manufacturing and leverage initiatives such as Public Procurement Policy (Make in India)
- human resource development - develop a skilling ecosystem, aligned to the Skill India Program, and ensure supply of a skilled work force such as scientists, regulators, health experts, managers, and technicians; and
- brand positioning and awareness creation - build global competitiveness by creation of a dedicated Export Promotion Council and promote additional forums for stakeholder knowledge sharing and awareness.

Introduction of this Policy by the Indian government is a vital and progressive step for the medical sector which would lead to easy access of best quality medical devices at competitive prices to consumers. The initiative will boost local manufacturing – a step much needed - and also end dependency on imports for critical life saving devices.

Source: Remfry & Sagar

FOCUS AREAS



ASSOCIATION OF BIOTECHNOLOGY LED ENTERPRISES (ABLE)

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