BIOTECHNOLOGY AND DEVELOPMENT REVIEW

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Asian Biotechnology and Development Review

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Editorial Introduction

Krishna Ravi Srinivas*

Welcome to the first issue of Volume 24. The response to the last issue, the Special Issue on Synthetic Biology was excellent. In this issue there are four articles and a book review.

In this issue we have four articles, two of them on biodiversity and two of them on synthetic biology. The article by Binay Panda and Pawan K Dhar, 'Running and managing shared resources for scientific research: A model from biofoundry' complements and supplements the article on Biofoundries published in the last issue (Thakur and Raghunathan 2021). They stress on the potential of biofoundries, identify the issues in realizing their potential and suggest a way forward in this. For a developing country like India biofoudries will be very relevant and given their immense potential in different sectors the case for a comprehensive policy. I consider this article as an important contribution to the emerging literature on biofoudaries and harnessing them for socio-economic development (e.g. Dixon, T.A., Freemont, P.S., Johnson, R.A. *et al.* 2022)

We have published many articles on Access and Benefit Sharing (ABS) of bioresources under the Convention on Biodiversity and respective national regulation. Deepak Kumar, S. Shanthakumar, Mrinalini Banerjee in Implementation of Access and Benefit Sharing (ABS) from Biological Resources in the State of Gujarat, provide a case study of implementation on ABS rules in Gujarat and make suggestions for effective implementation. Their recommendations are relevant and point out that the Biodiversity Management Committees (BMCs) need support and resources. Similarly they discuss that creation of Peoles' Biodiversity Registers needs to be prioritized. These suggestions although made in the context of Gujarat, they are applicable to many other states also. As they point out sharing of benefits from ABS is another contentious issue and in this also, the BMCs shares

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should be enhanced. Such case studies have valuable recommendations for policy makers.

Specific policies on Biodiversity are of recent origin as the idea/ concept of biodiversity itself is hardly four decades old. However given the importance of biodiversity for humanity's survival and sustenance policies on biodiversity attain critical importance. While the Global Biodiversity Frameworks and Targets are important and with goals they nudge the countries to care for biodiversity. But evolution of a biodiversity policy happens over decades and there are many factors that shape it. Science forms the basis for such policy making and the science-policy interface in biodiversity is important because while science provides the rationale for policy, it alone cannot make a policy.

Debanjana Dey in 'Biodiversity Science and Policy in India' traces the evolution of biodiversity policy in India and role of science and other factors in that. Highlighting recent initiatives in India and global developments she underscores the nexus between both. In this context she has given some suggestions and one of them is greater participation by local communities. Her observation 'The relationship between science and policy for biodiversity in India, which converges for increasing utility from natural resources and simultaneously increasing human wellbeing, needs to consider the system's heterogeneity and the ontology of biodiversity so as to promote development sustainably.' Is apt. However balancing multiple interests and maintaining ecological integrity of ecosystems on one hand, and, recognizing and dealing with different knowledge frameworks/systems is a challenge for any country. A compilation of best practices in this regard will be helpful.

The potential of emerging technologies to harm and help in biodiversity conservation and utilization is a matter of concern. The Parties to the Convention on Biological Diversity are discussing this as an important theme and other stakeholders are also working on them The technologies are inter alia, climate-related geoengineering, synthetic biology, digital sequence information and gene drives(Rabitz, F., Reynolds, J., & Tsioumani, E. (2022). Of these synthetic biology is of special concern on account of its potential for harm as well benefit. Even if we set aside fantasies and ideas about bringing back to extinct species, there are many issues that deserve attention. Synthetic Biology is a challenge because in both terms of theory and practice it is different from genetic engineering. Assessing the potential impacts of synthetic biology, beyond the realm of speculation needs good science and risk assessment. In their article 'Synthetic Biology and Biodiversity', Priya Sharma, Neeraj Verma, and Pawan K. Dhar provide an excellent discussion on these issues and suggest how policy makers and others can address them. As they point out synthetic biology poses a challenge to our perception and understanding of 'nature' and 'natural'. They offer a very relevant suggestion at the end by stating "The conservationists should seek out synthetic biologists, and the two should collaborate on broad discussions with scientists, communities, and regulatory bodies throughout the world. Our efforts at this critical intersection of biodiversity protection and technology might determine the destiny of nature.". Given the importance of this theme i.e. emerging technologies and biodiversity we intend to publish more articles on this in the future issues.

A review of 'Genetically Modified Democracy : Transgenic Crops in Contemporary India' by Manish Anand adds value to this issue. Your comments and suggestions are welcomes.

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Running and Managing Shared Resources for Scientific Research: A Model from Biofoundry

Binay Panda* and Pawan K Dhar*

Abstract: Biofoundry represents an excellent model for building and sustaining shared facilities for collaborative research and innovation. Biofoundry is a place where biological engineering meets automation. The biofoundry facility comprises many analytical instruments and precision robots to conduct experiments and automate at a large scale. Building, maintaining, and running a biofoundry requires adequate funding, skilled technicians and scientists, and a good business model. India does not have a long and successful history of building shared facilities for scientific research. However, Indian scientists will have to embrace the culture of sharing resources and facilities to conduct collaborative research to remain globally competitive. In this context, the challenges, and opportunities of biofoundry serve as a case in point for all future shared resources for scientific research and innovation. The unmet need of the nation is a policy framework for building large shared facilities leading to the optimal utilization of the technological and expertise resources, bring down the cost of doing science, and accelerate innovation.

Keywords: Engineering biology, Biofoundries Alliance, Public-Private-Partnership, Build-Operate-Transfer

Introduction

Hypothesis-driven science practiced by individual scientists is key to many fundamental discoveries. The fruits of fundamental science are often realized decades after experiments are conceived and reduced to practice. While individual investigator- and hypothesis-driven science will always remain important, the burden to provide significant community resources like genome sequencing information and production of a large amount of data has moved group and interdisciplinary science to the forefront. With the help of advanced scientific methods, scientists are increasingly joining with other scientists globally in pursuing collaborative team science as societal challenges have become more complex [1].

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The human genome project in the '90s [2] and the Laser Interferometer Gravitational- Wave Observatory (LIGO) project to detect cosmic gravitational waves in the 2000s [3] are successful examples of team science. Both have enabled thousands of researchers globally in their individual scientific goals. The economic reward of large investments in team science has also been significant. For example, a 5.6 billion US dollar investment from the United States Government in various human genome sequencing projects till 2010 generated an economic impact of \$796 billion between 1988 and 2010 [4]. Additionally, an updated report from the same agency noted that the government investment in genomics in the United States has helped generate nearly \$1 trillion in economic impacts till 2013 [5]. Large projects have become increasingly driven by international and large groups of scientists working separately yet joined by a common cause. The mega-science projects have created a need for large shared resources as they often require costly equipment and infrastructure hard to duplicate at multiple places. Expensive equipment requires a skilled workforce to run and maintain. Additionally, the throughput of many of the instruments in large shared resource facilities is large enough to cater to the need of multiple investigators across many different institutions.

Since independence, India has relied on individual talent to build institutions and excellence in science. In the early days, excellence in science mainly came from physical and theoretical sciences that are relatively inexpensive or require no equipment. As the nation moves to conduct large-scale team-science projects like genome sequencing, it is time that scientists learn to build large resources and share the facilities with other scientists in academia and industry. One such shared facility for biological sciences and engineering research is biofoundry. We describe below why biofoundry can be an example of a successfully shared resource and how other such facilities can learn and adopt the best practices of biofoundry.

What is a Biofoundry?

Biofoundry exists at the confluence of biomanufacturing and automation. The ability to develop tools and products in biomanufacturing is at the heart of biofoundries [6]. Biofoundries develop standardized protocols for various routines and subroutines at the level of biomolecules, networks, and cells, designing constructs, creating libraries, evaluating expressions, screening strains, generating mission-critical products and services. Low efficiency and failures in biomanufacturing frequently occur due to a lack of standardization in methodologies and the inability to deliver the right concentration at the right time. Achieving molecular precision, scale, and speed in a background of massively parallel contexts, extremely low volumes, and limited time windows demands increased workflow automation and the use of automation platforms that learn and adapt as the cellular conditions evolve.

In an ideal biofoundry setting, automation in the liquid handling, DNA sequence amplification, plate reading, high throughput DNA synthesis and transformation, genome edits, protein purification, flow cytometry, cell sorting, strain characterization, and enzymatic assays help achieve the desired results. The biofoundry workflow can accelerate the extensive scale screening of mutants to identify the suitable strains with an expected property [7].

Biofoundry applications may include key recurring lab activities that may be offered as a service e.g., workflow design, liquid handling, combinatorial plasmid design, cloning, sequencing, amplification, DNA editing, long DNA synthesis, plasmid construction, cell sorting, colony identification and extraction, peptide synthesis, protein purification, high throughput phenotyping, stain engineering, and so on.

On the applications side, biofoundry facilities are currently used globally to drive applications in health, biofuel, biodegradable plastics, agriculture, chemical industry, remediation, and environmental sensing.

Challenges in Running Shared Facilities in India

The main challenge of running a shared facility is its sustainability, both in human resources with long-term employment contracts and financial resources to run and maintain expensive equipment. Specific challenges in running and maintaining extensive shared resources like biofoundries are recently discussed [8]. In India, the extramural grant system primarily funds scientific projects or to initiates a facility but not towards maintaining or running the facility long-term. This means that the grants allow hiring scientific staff temporarily till a particular project is over. The only way to retain human resources or provide long-term employment contracts in a facility is for the host organization to absorb the staffing once the shortterm projects are over. However, this is not easy under the current system due to the following reasons:

Sanctions for permanent staffing require institutional authorization and additional funding from the government.

Although possible, hiring permanent staff to manage and oversee activities in a shared facility is not straightforward. In public universities and research institutes, any permanent position needs the approval of the University Grants Commission and the concerned government departments, respectively. When requested, this takes a long time with a requirement of multiple approvals.

The priority of Indian universities is not research but to teach and train students. Additionally, the universities are cash-starved, struggling to meet their need to pay salaries to their staff, maintain the buildings and other physical infrastructures and provide proper facilities.

Sustainable Financial and Business Model

What are the best business models to run and manage large shared facilities? Several innovative solutions can be tried to overcome the challenges. First, the universities and institutions can develop a system where a teaching/ research faculty, preferably at an assistant professor level, is given additional responsibility to run and manage a facility. The faculty member may be allowed to spare 20% of the time to run a shared facility. Additional responsibilities such as running and managing shared facilities must be recognized as academic contributions and counted towards promotions. Second, in research institutes, faculty members can be hired specifically to run, manage, and oversee large shared facilities, and be a part of other groups and large collaborative research projects. For example, a faculty explicitly hired to run a biofoundry can devote up to 70% of the time running and managing the facility and 30% of the time on individual or collaborative research programs. While doing so, the faculty member managing a facility cannot be evaluated based on the same metrics as any other faculty. There needs to be a separate mechanism and criteria of evaluation. Most importantly, there needs to be a system for the concerned faculty to get eventual promotion to the full professor level.

Finally, the shared facility can be given to a private entity to run on a

build-operate-transfer (BOT) model for a fixed number of years. This is common in public-private-partnership (PPP) projects and infrastructure projects like highways or airports. The academic institution needs to choose the private party through open, transparent, and competitive mode, especially choosing one with prior experience and expertise in running facilities. The BOT model will be an excellent model if certain pre-conditions are met. First, the government must provide space and money to build the infrastructure, including paying for the equipment's annual maintenance contract for the first 5yrs. The private party will not own the facility or space but will run and manage the facility for 5yrs by hiring staff on its payroll. Second, a certain percentage of equipment and staffing time is reserved for the host institution, and the rest can be used by the private party to sell its service to the broader community. A 50-50 model (50% of the equipment and human resources time reserved for the host institution and 50% for the private party) may be an excellent point to start with a profit-sharing model. A typical model may constitute a clause in the contract for the private party to share a part of the profit with the host institute. The private party can benefit from an academic institute pricing for reagents and a discount on the customs duty for import items. In return, the academic institution will have the facility run professionally, have the instruments utilized to a maximum and get a profit share. The private party is responsible for marketing and selling the services and ensuring that the facility is optimally used. The host institute needs to have the right to audit the usage and financial books of the private party.

This can be a win-win arrangement. The private party will get the space and equipment free of cost, for which it would have to spend a large sum of money to establish (a typical biofoundry may take up to 25-30 crore rupees to set up). On the other hand, the academic institution will get the facility run professionally with a guarantee of getting the highest quality service free and a share of the profit.

A Distributed Model of Doing Research

Traditional scientific collaborations, including involving people in different geographies, relied on scientists in the same area of research or with complementary skills and experience. Usually, scientists who know each other or have met and discussed ideas in a conference or a meeting tend

to collaborate. While yielding benefits to the community, such a process, especially in experimental science, has limitations. As resources at different locations, labs and universities differ significantly in terms of equipment and processes, and due to the lack of mutual agreements, they often are not shared. Therefore, what fits experimental science the best may not be the best model for theoretical and computational biology collaborations. Research in bioinformatics and computational analyses can include many students, scientists, and investigators worldwide, where sharing the same resources is easy. As more analysis is moving to the cloud, this makes it even more feasible. However, work that requires computational resources and data analyses does not have to abide by the above conditions. For example, ten or more biofoundries located at different geographical locations worldwide can be working on the same project without sharing or using any physical equipment. Each biofoundry can use software and computational tools to simulate individual parts of a biological pathway, automate processes, and experiment and pipeline that can be finally combined to produce a single biological pathway. The output, both computational tools, software, and bio-parts, of a biofoundry can be an input for the next biofoundry till a pathway gets assembled in a final biofoundry. Such a distributed model of doing research and unlike an automotive assembly line where the platforms are located physically at the exact location is a powerful model to massproduce synthetic biology products. Such a concept takes advantage of the competitive advantage of different locations, cost structures and can be highly productive. In one way, this is very similar to what the Airbus industry did to conceive, build and assemble various parts of the world's largest passenger aircraft, Airbus A380. They built various parts of the aircraft at separate locations and then transported them to a final location in Toulouse to assemble the aircraft. However, in biofoundries, sending software, computational tools, and individual gene sequences across other biofoundries are much more straightforward, cheaper, and less cumbersome. Large international consortia like the global Biofoundries Alliance (GBA) [9,10] and Genome Project- write (GP write) [11] can use a distributed model of building and testing bits of an entire process at different locations.

Conclusion

The concept of using and leveraging large shared facilities for research and innovation is new to India. Biofoundries provide an excellent model system to learn, run and implement processes to run shared facilities. At biofoundries, elementary processes are optimized through standardization and automation, accelerating innovation. India needs policy initiatives to establish national facilities for research using innovative models. The need of the hour is to tie funding proposals with national shared facilities with a model to hire permanent staff and sustain the facilities using an innovative model of build-operate-transfer model fulfilling the needs to bring academia and industry closer for innovation and entrepreneurship. This will speed up innovation, help researchers focus on their science rather than the management of facilities, and lower the cost of operation.

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Implementation of Access and Benefit Sharing (ABS) from Biological Resources in the State of Gujarat

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Abstract: Gujarat is one of India's most bio-diverse states and is very rich in biological diversity with regards to Asiatic lion, indigenous cow breeds (Gir), indigenous Kesar mango, microbes, insects, and bryophytes etc. Access and benefit sharing (ABS) clause through an additional CBD protocol known as the Nagoya Protocol for the Utilisation of Biological Resources and shared between users and providers for the protection of biological resources. In India, in line with this notion, the Biological Diversity Act, 2002 and Rules, 2004 were enacted by the Parliament of India. For this paper, data related to Biodiversity Management Committees (BMCs), People's Biodiversity Registers (PBRs), and the status of applications for access and benefit sharing in states was gathered and analysed for the status of the implementation of access and benefit sharing (ABS) from biological resources in Gujarat. Moreover, the level of awareness among the prominent users (industries) of biological resources related to access and benefit sharing (ABS) was assessed through the generation of a telephonic questionnaire survey of different sets of questions. The research discusses an outlook on access and benefit sharing (ABS) of biological resources in Gujarat State.

Keywords: Convention on Biological Diversity (CBD), Access and Benefit Sharing (ABS), Biological Resources, Biodiversity Management Committees (BMCs), People's Biodiversity Registers (PBRs), prior informed consent (PIC), technology commercialisation

Introduction

Biological diversity and genetic resources are estimated to be worth anywhere from US\$ 800 billion to US\$ 1 trillion, according to various estimations (Suneetha *et al.*, 2009). This potential, however, does not exist in a form that humans can immediately use; instead, it is founded on

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extensive genetic resource exploration for commodities, compounds, and services. Despite the fact that these genetic resources have been used in a number of ways, since the dawn of civilisation, since they are available in nature or under other varying situations, with the advancement of novel technology, researchers may now be able to increase the value of current biological diversification and genetic resources. These value additions have the potential to transform genetic resources into novel biotechnological foods, agricultural products and therapeutics, as well as other pharmaceutical items. But how to use genetic resources is one of the fundamental concerns of such utilisation and value addition. In this regard, the issues, including who has the right to access these biological resources, how the genetic resource access is granted, how the profits arise for the suppliers, how the profits are divided between the suppliers and the beneficiaries of the genetic resources, etc., are important.

The United Nations Convention on Biological Diversity (UN-CBD)

The United Nations Convention on Biological Diversity (CBD) is a key multilateral treaty to address these concerns. The CBD Act, which was approved at the 1992 Rio Earth Summit, is a legally binding international pact based on three goals (Balakrishna, 2015):

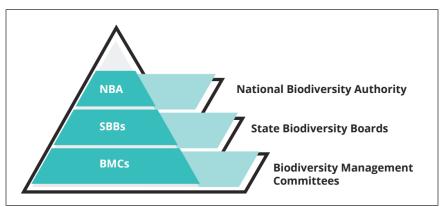
- Conservation of biological diversity,
- Use of its resources in a sustainable manner, and
- An equitable and fair distribution of the advantages derived from the exploitation of genetic resources.

The convention, adopted by 198 nations (along with India), recognised each country's sovereignty over its own genetic resources. This has supplanted the notion that biodiversity is a shared human legacy (resource). It recognises local and indigenous communities' contributions to conservation and sustainable use through traditional knowledge, practises, and innovations. It calls for an equitable distribution of the benefits derived from the use of these resources among these individuals. In 1994, India signed the CBD Treaty. The CBD has two protocols: (i) the Cartagena Protocol on Biosafety (2003) and (ii) the Nagoya Protocol on Access and Benefit Sharing (2014). In 2003, India ratified the Cartagena Protocol, and in 2014, it ratified the Nagoya Protocol.

The Biodiversity Act, 2002

Parliament passed the Biological Diversity Act in 2002 in response to India's CBD commitments. The Act governs access to biological resources and traditional knowledge associated with them. It establishes distinct regulatory frameworks for foreign and domestic entities. Both centralised and decentralised institutional mechanisms for biodiversity protection and sustainable access are included in the legislation. It establishes a three-tier regulatory structure: (i) a national biodiversity authority; (ii) state biodiversity boards; and (iii) local body biodiversity management committees. At the apex of the pyramid is the National Biodiversity Authority (NBA), with BMCs at the bottom and a State Biodiversity Board in the middle. The Act calls for benefits to be shared with biodiversity conservationists, as well as holders and creators of related knowledge. Benefits can be shared in a variety of ways, including monetary compensation, intellectual property rights sharing, and technology transfer. The intention of this fact sheet is to look at India's progress in implementing the Accessing and Benefit Sharing (ABS) framework under the BD Act, 2002, in order to meet the statute's third goal: efficient and reasonable sharing of benefits emerging from using genetic resources and related knowledge. This research paper focuses on the legal requirements that govern ABS, as well as the state of execution and the major challenges that arise.

Figure1: Three-tier institutional regulations are involved in the Biological Diversity Act 2002.



Source: Authors' own compilation.

The Biological Diversity (Amendment) Bill, 2021

In December 2021, the Biological Diversity (Amendment) Bill, 2021, was introduced in Lok Sabha and referred to a Joint Parliamentary Committee. The Bill proposes to amend the Biological Diversity Act of 2002 in order to: (i) promote the Indian system of medicine and the cultivation of wild medicinal plants, (ii) expedite processes for research, patent application, and transfer of research results, (iii) decriminalise offences, and (iv) encourage foreign investment in the sector. The bill also adds references to the Nagoya Protocol to the Act. The Bill modifies the Biological Diversity Act of 2002 to make compliance requirements for domestic businesses easier to meet. Users of codified traditional knowledge and AYUSH practitioners will be exempt from the obligation to share benefits with local communities. There are many changes as amendments incorporated in the Biological Diversity (Amendment) Bill, 2021 that are as follows:

The Biological Diversity Act, 2002	Changes proposed by the Bill, 2021
Approval required from NBA (for certain foreign entities)	Approval from NBA Entities: adds a new category for companies
Entities: (i) non-resident Indians, (ii) foreign individuals, (iii) companies not registered in India, and (iv) companies registered in India with non- Indian participation in share capital or management.	registered in India that are "foreign- controlled," as defined by the Companies Act of 2013.
Activities: acquiring biological resources found in India or related knowledge for: (I) research, (ii) commercial use, or (iii) bio- survey and bio-utilisation	

 Table 1. Approval/Intimation requirement for accessing biological resources or associated knowledge

Table 1 continued...

Table 1 continued ...

Prior intimation required to SBB (for certain domestic entities) Entities: (i) Indian citizens, and (ii) Indian-registered companies, excluding those that require NBA approval.	Exemptions: Exemptions are added for: (i) codified traditional knowledge, (ii) cultivated medicinal plants and their products, and (iii) AYUSH practitioners; the exception is limited to vaids and hakims and AYUSH practitioners for sustenance and livelihood.
Activities: obtaining biological resources occurring in India for commercial utilisation	
Exemptions: use by local people and communities, including biodiversity growers and cultivators, as well as vaids and hakims practising indigenous medicine.	

Source: https://prsindia.org/billtrack/the-biological-diversity-amendment-bill-2021

Access and Benefit Sharing: Nagoya Protocol

The terms "access and benefit sharing" relate to how genetic resources are made available to users or how the advantages that arise from their use are divided between them. The CBD established a global framework for the efficient allocation of the benefits gained from the utilisation of genetic resources. Supplier nations possess sovereign control over all genetic resources within their territory, as per Article 15 of the CBD, and the federal government has the power to exploit genetic resources and services based on national regulations. The Nagoya Protocol is a CBD additional agreement that offers a comprehensive legislative structure for ABS implementation in any nation.¹ According to national legislation, the exploitation of biological resources requires prior permission from the supplier nations' competent national authorities (CNAs) under Article 15 of the CBD and the Nagoya Protocol. CNAs are government-run organisations tasked with providing access to genetic resources.² Local communities (BMCs) may be able to negotiate access arrangements under a country's legal framework. This sort of permission is known as "Prior Informed Consent" (PIC). The PIC is calculated using the supplier's assessment of biological resources, their

geographical location, quantity, the intent of gathering and economic use to be obtained, the computation of profits that would arise from the use, and the proposed system for sharing these gains. Following the receipt of the PIC, the suppliers and consumers must create a benefit sharing agreement based on the use of biological resources (called "mutually agreed terms" or MAT). The terms of resource access and use, as well as the advantages to be shared, are all specified in the MAT.³

The Biological Diversity (BD) Act, 2002, in India, sets forth the framework for ABS enforcement, which is centred on Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), as defined by the CBD, an internationally legally enforceable accord. In light of these restrictions, the fate of ABS in India's provinces is examined in this report prepared. Due to its global regime, India's BD Act creates national and state-level regulatory authorities to regulate ABS (NBA and SBBs) with compulsory collaboration with legislative authorities at the grassroots level (known as BMCs)⁵. If a proposed ABS agreement is managed by NBA or SBB, it is determined by the organisation that it has equal rights and access to genetic resources and the objective of exploitation (Pauchard, 2017). The user organisation and the NBA or SBB sign a profit-sharing agreement when the NBA or SBB grants permission (after compulsory discussion with BMC)⁴. The cost of benefit sharing for the user organisation is then calculated using the ABS Guidelines, 2014. According to the guidelines, benefit sharing is dependent on the sale price of accessed biological resources as a product or the manufacturer's annual gross ex-factory sales (government taxes included and adjusted). Traders must contribute 1 to 3 per cent of the purchase price in benefit sharing, while producers must contribute 3 to 5 per cent. If benefit sharing is calculated based on the sales price, manufacturers must contribute between 0.1 and 0.5 percent. Benefit sharing is 0.1 percent for yearly gross ex-factory sales up to Rs. 10 million, 0.2 percent for sales between Rs. 10 million and Rs. 30 million, and 0.5 percent for sales above Rs. 30 million.^{4,5}

There have been a few documented incidents that demonstrate the effectiveness of the doctrine of Access and Benefit Sharing (Singh, 2021). In this case, before accessing the biological resources, the state government of Andhra Pradesh held a global tender for the sale of Red Sanders, having high economic potential value to bidders from India and abroad. The winning bidders had to pay the NBA or SBB 5%. 95 percent of all benefits were to be

distributed to BMCs. The Access and Benefit Sharing Agreement served the State well. It gave them a source of money and included them in decisionmaking, which could encourage them to use genetic resources sustainably. The auction would benefit individuals from all local communities at grassroot levels, including tribal, indigenous tenant, and forest resident. This unique approach to benefit sharing has altered how companies use genetic resources (Singh, 2021). Similarly, in 2007, PepsiCo signed an ABS agreement on behalf of the Tamil Nadu fishing community with the NBA for INR 37 lac. A total of 2000 metric tonnes of seaweed were shipped to Indonesia, Malaysia, and the Philippines by PepsiCo. This ABS agreement was implemented in four districts in Tamil Nadu. The corporation paid the NBA for access to genetic resources in Tamil Nadu's Gulf of Munnar (Singh, 2021). Moreover, Bio-India procured a total of 2000 kg of dried neem leaves (Value of \$55,035.00) from Amarchinta villagers of Andhra Pradesh through signing into an undertaking and export to Japan. To check for growth-stimulating activities in plants in the Malampuzha forest division in Kerala, it has signed an ABS agreement with the NBA. The bacterium sample would be used in a lab to promote lettuce, tomato, and rice crop productivity. Since 2004, the NBA has charged the corporation a 5 per cent annual fee for the sale of the biological resources (Singh, 2021). Furthermore, no mechanism for obtaining prior informed consent from local and indigenous communities is provided. This may be in contrast to the framework established by the Nagoya Protocol. The Nagoya Protocol requires signatory countries to obtain prior informed consent or approval, as well as the participation of indigenous and local communities, for access to genetic resources and traditional knowledge. In case of Divya Pharmacy vs Union of India (2018), the Uttarakhand High Court observed that the Nagoya Protocol's concept of fair and equitable benefit sharing is focused on the benefits for local and indigenous communities.¹⁶

The Draft ABS Guidelines, 2019

The draft ABS Regulations, 2019, are intended to replace the previous version and were made available for public comment earlier this year¹⁵. The regulations are proposed, *inter alia*, under Section 21(4) of the Biological Diversity Act of 2002 ("BDA"), which authorises the national biodiversity authority to frame "Guidelines" through regulations for the purposes of

determining equitable benefit sharing. Section 64 of the BDA gives the National Biodiversity Authority the authority to issue "Regulations." This power is distinct from the Central Government's/State Government's power to make "Rules" under Sections 62/63. In a nutshell, the regulations govern how benefit sharing obligations are determined and imposed by the authorities. For the sake of simplicity, the benefit sharing methods in the draft ABS Regulations, 2019, are elaborated as follows:

General Guidelines of Benefit-sharing (Draft Regulation 9)

- Monetary and/or non-monetary (list as Annex-II);
- Mandatory factors to consider: as commercial utilisation of the biological resource, stages of research and development, potential market for the research outcome, amount of investment already made for research and development, nature of technology used, time-lines and milestones from research initiation to product development, and risks involved in product commercialization;
- 'Minimal benefit sharing': technologies/innovations/products developed for epidemic/disease control, environmental pollution affecting human/ animal/plant health
- If contributing to non-monetary benefits, the monetary quantum shall be as reduced as determined by the NBA.

Biological Diversity of Gujarat State

Gujarat is one of India's most bio-diverse states, with the Tropic of Cancer passing through it. The state's notified forest area is 19,568 km², or about 10 per cent of the state's total geographical area of 1, 96024 km². There are 21 wildlife sanctuaries and four national parks in the state. It has the longest coastal line in India, at 1650 kilometres. Its natural habitat diversity includes deserts, sand deserts, mangroves, coral reefs, coasts, and forests. The forest types include dry deciduous, moist deciduous, thorny deciduous, and grassland. Moreover, Gujarat State is very rich in biological diversity⁶. Therefore, conserving the Gujarat State biological diversity, the Gujarat Biodiversity Board (GBB) was constituted by the Gujarat government in 2006 under section 22 of the Act, by notification number. GVN/2006/8/WLP/2003/177/G1 on dated 11/05/2006 (Rana *et al.*, 2015). The Board

is working hard to create Biodiversity Management Committees (BMCs) and PBRs at the state's local level. Biodiversity, its social significance and importance, be primarily understood by Gujarati people, and be realistically conserved, restored, maintained, valued, and continue to provide benefits to society at large on a long-term basis, while simultaneously retaining and fulfilling its eco-systemic functions, which are paramount (Vision 2025, Gujarat Biodiversity Board). Gujarat Biodiversity Board's (GBB) mission statement is as follows:⁷

- Ensure biological diversity conservation in Gujarat
- Biological resources and their components' exploitation in a sustainable manner, and
- Benefits from biodiversity use are shared fairly and equitably.

The creation of high-quality PBRs is critical for the preservation of our natural resources. The amount that BMCs would get as part of ABS would be highly dependent on the biological resources identified by the PBRs. As a result, it is very essential to create a high-quality PBR in the NBA-recommended format.⁸ Therefore, this research programme has been undertaken to analyse and compare the status of genetic diversity conservation and access and benefit sharing (ABS) through BMCs and PBRs, focusing on these facts and elements of concern to Gujarat State.

Living Organiam	Num	ber of Species
Living Organism	India	Gujarat
Angiosperms	17,500	2,198
Gymnosperms	64	01
Pteridophyta	1,100	16
Bryophyta	2,850	08
Algae	6,500	1,933
Fungi	164	164
Bacteria	850	
Viruses		
Total (Plants)	46,286	4,320

 Table 2. Plant and animal species found in Gujarat state and compared to those found elsewhere in India

Table 2 continued...

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Lower Animals	76,455	1,736
Fish	2,546	606 (487 Marine+119
F1511	2,540	Freshwater
Reptiles	485	107
Amphibians	206	19
Birds	1,228	479
Mammals	372	107
Total (Animals)	81,292	3,054
Grand Total	1 27 579	7,374
(Plants+ Animals)	1,27,578	7,574

Table 2 continued...

Source: Green Tribunal (https://greentribunal.gov.in/caseDetails DELHI/0701109001162016?page=order)

Research Methodology

Data Collection

For the present paper, data related to Biodiversity Management Committees (BMCs), People's Biodiversity Registers (PBRs), and the status of applications for ABS in states was gathered from the websites of the Gujarat Biodiversity Board, Gandhinagar), the National Biodiversity Authority (NBA), Chennai, and the National Green Tribunal, New Delhi respectively. 9, 10, 11, 12, 13

Comparative Analysis of the Status of the Progress of Biodiversity Management Committees (BMCs) and People's Biodiversity Registers (PBRs)

For the conservation of our biological resources, high-quality PBRs are necessary. The amount of money BMCs would get as part of ABS is heavily influenced by the biological resources identified by PBRs. As a result, creating a high-quality PBR in the NBA-recommended format is critical. The comparative status of BMCs formation and PBRs preparation in different states was analysed on the basis of the total number of local bodies, total BMCs constituted and PBRs constituted, and the status of completion (in percentage) in different states at different time intervals. The present report was prepared using data given in Orders (O.A. No. 347/2016) of the Hon'ble National Green Tribunal (NGT) as on dated 31/08/2020, the operationalisation status of Biodiversity Management Committees (BMCs) and People's Biodiversity Registers (PBRs) in states as on dated 04/01/2022 (National Biodiversity Authority, http://nbaindia.org/), and in different districts of Gujarat State as on dated 13/07/2021 (Gujarat Biodiversity Board, https://gsbb.gujarat.gov.in).The retrieved data was tabulated and analysed for a comparative study of the status of BMCs and PBRs in Gujarat State as well as in different states of India.¹³

Status of Applications: Access and Benefit Sharing (ABS) from Biological Resources

The National Biodiversity Authority (NBA) is responsible for regulating utilisation to genetic resources and/or related traditional knowledge for the purposes of biological survey, research, resources utilisation, commercial use, acquiring Intellectual Property Rights (IPR), and the exchange of research findings and retrieved biological resources. The data of ABS applications in Gujarat State was taken from the RTI (Right to Information Act) reply of the Gujarat Biodiversity Board (GBB) to lawyer Aditya Gujarathi working with the *Centre for Social Justice, Ahmedabad* on December 13, 2021 (Gujarathi, 2021).

Study the Current Level of Awareness of Access and Benefit Sharing (ABS) among Industries.

The Nagoya Protocol and the notion of access and benefit sharing (ABS) require widespread knowledge and education. In most cases, the current awareness initiatives of relevant government authorities are insufficient. The level of awareness among the prominent users of biological resources means industries have very limited documentation and that is not shared by the industries. Therefore, the level of awareness related to access and benefit sharing (ABS) was assessed through the generation of a telephonic questionnaire survey of different sets of questions that were as follows. The research methodology for presented work was adapted from the article of Alam and Arjjumend (2018). A total of fifty-two industries were taken for the study.

- 24 Asian Biotechnology and Development Review
- Industry type (Partnership/Ltd./Private Ltd./ LLP)
- Type of genetic resource
- Source of genetic resource
- Products developed from genetic resources
- IP protection of product
- Awareness about ABS
- Access and Benefit Sharing (Agreement)
- Licensing and regulatory authority pertaining to product mass production approval
- Quality and In-house R&D facilities availability
- Target market for sales of concerned product (domestic/ export)
- Each variable in the above study was calculated on a percentage basis among the total fifty industries.

Results and Discussion

The Status of Total BMCs Formed and PBRs Prepared in Different States

The status of BMCs' formation and PBRs' preparation in different states was comparatively analysed through progress reports filed by the National Biodiversity Authority before the Hon'ble National Green Tribunal, New Delhi (*in O.A. No. 347 of 2016, Chandra Bhal Singh vs. Union of India &Others*) at different time intervals⁵ (Table 2). According to the NGT Order, a total of 2,75,286 BMCs and PBRs should be constituted and prepared in the all states. As of August 31st, 2020, 96.52 per cent of BMCs and 71.20 per cent of PBRs had been formed based on inputs gathered from state biodiversity boards. As of January 4, 2020, the proportions of BMCs formed and PBRs prepared had increased by 98.33 per cent and 94.68 per cent, respectively (Table 3).

Table 3: Total BMCs constituted and PBRs prepared in different states at different times of the report filed by the National Biodiversity Authority (NBA)

Total	Details av	ailable	Details s	ubmitted	Details		Details	
BMCs	on the NE	BA	by States	and	submitted	l in	submitt	ed to
to be	site on da	ted	UTs befo	ore the	final repo	ort of	Hon'ble	e NGT
constituted	04/01/202	22	Hon'ble	NGT on	NBA bef	ore	by the I	NBA
and PBRs			dated 31/	/08/2020	Hon'ble l	NGT	on date	d
to be					on dated		26/07/2	016
prepared					31/02/202	20	(O.A. N	lo.347
in the							of 2016	
States	BMCs	PBRs	BMCs	PBRs	BMCs	PBRs	BMCs	PBRs
2,75,286	2,71,794	2,60,667	2,65,725	1,96,015	2,43,499	95,252	9,700	1,388

Source: Author's compilation.

Table 4. Status of completion (in percentage) of total BMCs and PBRs in different states at different times of the report filed by the National Biodiversity Authority (NBA)

Total	Details a	available	Details		Details s	ubmitted	Details	
BMCs	on the N	ΒA	submitte	d by	in final r	eport	submitt	ed
to be	site on d	lated	States an	ıd	of NBA	before	to Hon'	ble
constituted	04/01/20)22	UTs befo	ore	Hon'ble	NGT on	NGT by	y the
and PBRs			the Hon'	ble	dated 31	/02/2020	NBA or	n dated
to be			NGT on	dated			26/07/2	016
prepared			31/08/20	20			(O.A. N	lo.347 of
in the							2016	
States	BMCs	PBRs	BMCs	PBRs	BMCs	PBRs	BMCs	PBRs
2,75,286	98.73%	94.68%	96.52%	71.20%	88.45%	34.60%	3.52%	0.50%

Source: Author's compilation.

The changes in the status of completion of total BMCs and PBRs in all states were drastically increased because of an order of the principal Bench of the Hon'ble National Green Tribunal, New Delhi, dated March 18, 2020, in which the Hon'ble National Green Tribunal ordered the National Biodiversity Authority (NBA) to regularly conduct monthly review meetings with State Biodiversity Boards (SBBs) and Union Territories (UTs) for progress of BMCs and PBRs (*in O.A. No. 347 of 2016, Chandra Bhal Singh vs. Union of India & Others*).

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As of August 31, 2020, the BMC establishment and PBR preparation in fourteen states have been accomplished in every way: Assam, Goa, Kerala, Haryana, Jharkhand, Himachal Pradesh, Madhya Pradesh, Sikkim, Punjab, Telangana, Uttarakhand, Tamil Nadu, Uttar Pradesh, and Tripura. Moreover, Arunachal Pradesh, Chhattisgarh, Mizoram, Maharashtra and West Bengal were the five states where the BMC has been formed completely. The PBRs were in various stages of preparation in several states. More than 95 per cent of BMCs have been constituted in Andhra Pradesh, Karnataka, Odisha, and Rajasthan. The number of states in all aspects of complete BMC formation and PBR preparation has been increased to twenty-four in place of fourteen as of January 4, 2022.¹⁰ Because of the tough terrain, consistency in the supply of biological resources, and the small population in the villages, certain North Eastern states have told the Hon'ble National Green Tribunal that preparing PBRs for each hamlet may not be viable.

As a result, several states have opted to limit the number of PBRs prepared in their jurisdictions. The state Manipur, for example, has told the Hon'ble National Green Tribunal that they have planned to use a cluster strategy to create 199 PBRs under 2282 local bodies. The complete status of BMCs constituted and PBRs prepared at local bodies' levels (District Panchayat, Intermediate Panchayat, Village Panchayat, Traditional Panchayat, and Urban Bodies) in states is compiled in Tables 4 and 5.

The State Biodiversity Boards (SBBs) advise state governments on traditional knowledge and access to biological resources, while the BMCs carry out conservation work at the community level (district panchayats, intermediate panchayats, village panchayats, traditional panchayats, and municipalities). Every local body forms a BMC within its authority, as per Section 41 of the Act, with the goal of encouraging biological diversity conservation, sustainable use, and recordkeeping. BMCs are statutory bodies. The development of high-quality PBRs is crucial for the protection of our biological resources.⁸

Status of Completion of total BMCs and PBRs in Gujarat State

As per the progress report filed by the National Biodiversity Authority (NBA) and submitted to the Hon'ble National Green Tribunal, New Delhi on August 31, 2020, a total of 10819 BMCs were constituted and 1760 PBRs

Table 5: The status of BMCs constituted and PBRs prepared in different states at different times of the report filed by the National Biodiversity Authority (NBA)

		Number	BMCs constituted	PBRs	Status of completion (in percentage)	us of tion (in ntage)	BMCs constituted	PBRs prepared	Status of completi (in percentage)	Status of completion (in percentage)
No.	State	of local bodies	on dated on dated 04/01/2022 04/01/2022 NBA NBA website website	on dated 04/01/2022 NBA website	BMCs	PBRs	31/08/2020 OA. No. 347 of 2016)	on dated 31/08/2020 (OA. No. 347/2016)	BMCs	PBRs
1.	Andhra Pradesh	14216	14157	14157	100%	100%	13612	906	95.75%	0.67%
5	Arunachal Pradesh	1806	1806	1806	100%	100%	1806	906	100%	58.0%
ю.	Assam	2549	2549	2549	100%	100%	2549	2549	100%	100%
4	Bihar	9101	9101	9109	100%	100%	7141	0	78.46%	0.0%
5.	Chhattisgarh	11301	12004	3772	100%	33.37%	11301	1246	100%	11.0%
6.	Goa	205	205	205	100%	100%	205	205	100%	11.0%
7.	Gujarat	14713	14356	14716	97.57%	100%	10819	1760	73.53%	11.96%
8.	Haryana	6437	6435	6437	<i>96.66</i> %	100%	6435	6437	<i>96.96</i> %	100%
9.	Himachal Pradesh	3371	3371	3371	100%	100%	3371	3371	100%	100%
10.	Jharkhand	4690	4684	4684	99.87%	99.87%	4680	4680	99.78%	99.78%
11.	Karnataka	6554	6554	6554	100%	100%	6495	5081	99.0%	77.53%
12.	Kerala	1200	1200	1034	100%	86.16%	1200	1034	100%	86.16%

Implementation of Access and Benefit Sharing (ABS)

Table 5 continued...

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13.	Madhya Pradesh	23557	23557	23557	100%	100%	23557	23557	100%	100%
14.	Maharashtra	28649	28649	28649	100%	100%	28649	25255	100%	97.65%
15.	Manipur	2282	2260	199	99.03%	8.72%	1907	37	83.57%	1.94%
16.	Meghalaya	6471	6468	6468	99.95%	99.95%	4573	1050	70.67%	16.22%
17.	Mizoram	894	894	894	100%	100%	894	810	100%	90.60%
18.	Nagaland	1238	1238	1238	100%	100%	1096	1096	88.50%	88.50%
19.	Odisha	7256	7256	7256	100%	100%	7090	276	<i>%0L.</i> 70%	3.80%
20.	Punjab	13599	13599	13599	100%	100%	13599	13599	100%	100%
21.	Rajasthan	10406	11698	11168	100%	100%	10283	0	98.80%	0.0%
22.	Sikkim	196	196	196	100%	100%	196	196	100%	100%
23.	Tamil Nadu	13604	13604	13604	100%	100%	13604	13604	100%	100%
24.	Telangana	13461	13461	13461	100%	100%	13461	13461	100%	100%
25.	Tripura	1264	1264	1264	100%	100%	1264	1264	100%	100%
26.	Uttarakhand	7991	7991	7991	100%	100%	7991	7991	100%	100%
27.	Uttar Pradesh	59407	59407	59407	100%	100%	59407	59407	100%	100%
28.	West Bengal	3830	3830	3830	100%	100%	3830	3424	100%	89.40%
			2,71,794	260667			261015	196015		

Source: Author's compilation

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Table 5 continued...

were prepared. In Gujarat State, the percentage of total constituted BMCs was 73.53 per cent, and the percentage of prepared PBRs was 11.96 per cent, which was inadequate in comparison to other states such as Assam, Himachal Pradesh, Goa, Haryana, Jharkhand, Punjab, Madhya Pradesh, Sikkim, and Kerala, where all BMCs and PBRs were completed on time. Thereafter, the Gujarat State Biodiversity Board vigorously worked on BMC formation and PBR preparation in different local bodies of different districts of Gujarat State and, as a result, the total number of BMCs reached 14354 (97.57 per cent) and PBRs 14716 (100 per cent) as on January 4, 2022 (National Biodiversity Authority, http://nbaindia.org). The crucial positive change occurred in BMCs (24.04 per cent) creation and PBR preparation (88.04 per cent) between the different times of the report filed by the NBA (from 31/08/2020 to 04/01/2022). The details of the data are represented in the following Table 6.

Table 6: Status of completion (in percentage) of total BMCs and PBRs in Gujarat State at different times of the report filed by the National Biodiversity Authority (NBA)

Total BMCs to	Details submitte	ed by States	Details availab	le on	
be constituted	and UTs before	the Hon'ble	the NBA site o	n dated	
and PBRs to be	NGT on dated 3	1/08/2020	04/01/2022		
prepared in the	BMCs PBRs		BMCs	PBRs	
Gujarat State					
14713	10819	1760	14356,	14716	
	(73.53%)	(11.96%)	(97.57%)	(100.0%)	

Source: Author's compilation.

The growth in BMC formation and PBR creation was very prominent in Gujarat State during the pandemic COVID-19 compared to other states because some states informed the NBA during meetings conducted by the National Biodiversity Authority that the BMC establishment and PBR preparation had been hampered by the country-wide lockdown imposed by the COVID-19 pandemic, which prevented the movement of officials and people. Some states have stated that they are unable to prepare PBRs due to a lack of funds. The States have asked for the penalty imposed by the Hon'ble Tribunal in its Order dated 18/03/2020 to be waived and for an additional six months to finish the BMC creation and PBR preparation process¹³.

Status of BMCs Constituted in Different Districts of Gujarat State

Gujarat is very rich in biological diversity because of its geographic location and climatic conditions. On the basis of these ecological conditions, Gujarat is divided into five regions, namely North Gujarat, South Gujarat, Kutch, Saurashtra, and Central Gujarat. Gujarat has a total of thirty-three districts, which cover these five regions. The local bodies as Village Panchayats in all districts of Gujarat State are 14141, and along with District Panchayat, Intermediate Panchayat, Traditional Panchayat, and Urban Local Bodies are 14713, respectively. The maximum number of village panchayats, as local bodies, is situated in Banaskantha (877), Bhavnagar (662), Kutch (623), and Mehsana (608) districts, while the lowest is in Dang district (70) respectively. As per the progress report of BMCs and PBRs compiled by NBA, Gujarat State had only completed 73.53 per cent of BMCs and 11.96 per cent of PBRs as of August 31, 2020, in the order of the Hon'ble National Green Tribunal, New Delhi (in O.A. No. 347 of 2016, Chandra Bhal Singh vs. Union of India & Others) [38]. The number of total BMCs was increased rapidly in Gujarat State by the efforts of the Gujarat Biodiversity Boards in all districts. As a result, a total of twenty-three districts, namely Ahmedabad, Anand, Aravalli, Bharuch, Bhavnagar, Botad, Chhota-Udaipur, Dahod, Gir Somnath, Kheda, Mehsana, Morbi, Narmada, Navsari, Panchmahal, Sabarkantha, Rajkot, Porbandar, Surendranagar, and Valsad have successfully completed BMC formation. Furthermore, the remaining districts are in the final stage of completion of BMC formation, such as Kutch (99.05 per cent), Dang (98.57 per cent), Amreli (94.77 per cent), Banaskantha (97.14 per cent), Gandhinagar (94,05 per cent), Jamnagar (87.71 per cent), Devbhoomi Dwarka (87.44 per cent), and Vadodara (82.22 per cent) as on July 13, 2021 (Gujarat Biodiversity Board). The least performance in BMC formation occurred in the Mahisagar District and should be focused on by the Gujarat Biodiversity Board⁹. The complete details of BMCs formation in different district of Gujarat State are given in Table 7.

Table 7: The status of BMCs constituted in different districts of Gujarat State. The data was filed by the Gujarat Biodiversity Board (GBB) on its official website (as on dated 13/07/2021, https://gsbb. gujarat.gov.in/)

		Number of		Status of
Sr.	District	Local Bodies	BMCs	completion
No.	District	(Village	formed	-
		Panchayat)		(%)
1.	Ahmedabad	468	471	Completed
2.	Amreli	593	562	94.77%
3.	Anand	351	359	Completed
4.	Aravalli	318	371	Completed
5.	Banaskantha	877	852	97.14%
6.	Bharuch	547	561	Completed
7.	Bhavnagar	662	692	Completed
8.	Botad	180	196	Completed
9.	Chhota Udaipur	342	413	Completed
10.	Dahod	548	575	Completed
11.	Dang	70	69	98.57%
12.	Devbhoomi Dwarka	239	209	87.44%
13.	Gandhinagar	303	285	94.05%
14.	Gir Somnath	329	336	Completed
15.	Jamnagar	415	364	87.71%
16.	Junagarh	492	477	96.95%
17.	Kutch	632	626	99.05%
18.	Kheda	520	531	Completed
19.	Mahisagar	351	208	59.25%
20.	Mehsana	608	619	Completed
21.	Morbi	349	405	Completed
22.	Narmada	221	241	Completed
23.	Navsari	368	390	Completed
24.	Panchmahal	487	495	Completed
25.	Patan	470	494	Completed
26.	Porbandar	149	156	Completed
27.	Rajkot	517	517	Completed
28.	Sabarkantha	456	471	Completed
29.	Surat	572	594	Completed
30.	Surendra Nagar	542	560	Completed
31.	Тарі	291	308	Completed

Table 7 continued...

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32.	Vadodara	540	444	82.22%
33.	Valsad	383	388	Completed
	Total Village Panchayat	14141		
	Overall Total (along			
	with District Panchayat,			
	Intermediate Panchayat,	14713	14239	96.77%
	Traditional Panchayat,			
	Urban Local Bodies)			

Table 7 continued...

Source: Author's compilation.

Status of Applications for Access and Benefit Sharing (ABS) from Biological Resources

The National Biodiversity Authority (NBA) currently employs procedure to evaluate and approve ABS applications submitted via Forms I, II, III, and IV. Furthermore, the NBA assures that ABS applications are properly assessed on a case-by-case basis and that decision-making is done with care. As on December 15, 2021, the National Biodiversity Authority official website revealed that a total of 5675 applications were received under different categories (Form I, Form II, Form III, Form IV, and Form B) for access and benefit of genetic resources over a time period of 19 years (2003–04 to 2021-22). Out of these total 5675 applications, 2947 applications were granted approval and signed ABS agreements, which represented 51.97 per cent of the total applications submitted and remain pending with the applicant for the agreement's execution.¹² The comparative status of applications for ABS from biological resources at national levels is briefly elaborated in Table 8.

Table 8: Status of applications for access and benefit sharing (ABS)from biological resources at the national level (National Biodiversity
Authority, as on dated 15/12/2021)

1	Total Applications Received	granted and	Pending with Applicant for Agreement's Execution	Agreement Sent so far		Under Process Applications
	5675	2947	1546	4493	874	263

Source: Author's compilation.

As per the Gujarat Biodiversity Board's RTI response to Lawyer Aditya Gujarathi, under Section 7 of the Biodiversity Act, 2002, a total of 4500 industrial applications were received seeking consent for access of biological resources for commercial use up to February 2020 (Gujarathi, 2021). Moreover, only 68 applications were signed as ABS agreements for access and benefit sharing by the Gujarat Biodiversity Board. The percentage of signed ABS agreements was very limited, viz., 1.51 per cent, which is very painful for the Gujarat Biodiversity Management Committees (BMCs) that are working hard for benefit sharing at grassroot levels. The BMCs at the local body level are meant to collect 95 per cent of the benefit-sharing money paid by commercial users of bio-resources under Regulation 15(2) of the 2014 Regulations by the State Biodiversity Board. In the current situation, it is said that a BMC can't be accessed for benefit sharing. In that instance, the funds should be used to boost local people's livelihoods in places where biological resources are accessed, as well as to encourage sustainability of the ecosystem and the use of biological resources. In the case of Gujarat State, BMCs are not receiving any benefit-sharing amount from the State Biodiversity Board because of low levels of ABS agreement status for access and benefit-sharing from industries. The status of applications for ABS agreements is concluded in Table 9.

Table 9: Status of applications for access and benefit sharing (ABS)from biological resources in Gujarat State

Under Section 7 of the BDA, 2002, the total industrial application received to take consent for seeking access of biological resources for commercial use from Gujarat Biodiversity Board	Total agreement signed for Access to Benefit Sharing (ABS) by the GBB	Percentage of agreement signed for ABS
4500	68	1.51%

Source: Author's compilation

Note: As of February 2020, according to the Gujarat Biodiversity Board's RTI response to Aditya Gujarathi, a lawyer, https://www.newsclick.in).

Analysis of the Current Level of Awareness among Agro-inputs Producing Industries for Access and Benefit Sharing (ABS) from Biological Resources

A set of questions were prepared to structure the telephonic/ online interviews. The questions were related to industry type, types of products (microbial, plant and animal based genetic resources), supplier of genetic resources, IPR protection of product, awareness about ABS clause, ABS agreement for commercial use of biological resources, responsible licensing authority, facilities availability of quality control (QC) and research and development (R&D) and target market for biological resource-based product (domestic/international) respectively. The total 52 industrial respondents from agro-input producing industries were taken in presented study. The response of all questions was recorded in percentage basis and critically compiled in table 10.

- In study, total 52 industries were involved and out of which 26 companies were Partnership Firm, followed by Private Limited (20), Limited (3), and Limited Liability Partnership (LLP). Therefore, the maximum companies were from the partnership firm category.,
- All of the agro-input products (biofertilizers, biopesticides, growth promoters) produced by the targeted industries were microbial based (bacteria/fungi).,
- The sources of genetic resources were from both sectors: research institutes/universities (48.07 per cent), private sector (48.07 per cent), followed by individual supplier (3.86 per cent).
- The industries were producing majorly microbial biofertilizers (76.92 per cent), followed by biopesticides (19.23 per cent), growth promoters (3.85 per cent) respectively.
- In the study, no product was protected under patent protection, while trademark protected products were 48.08 per cent and followed by products without IPR protection (51.92 per cent).
- The ABS clause of the CBD Act and the Nagoya Protocol were unknown to all of the companies polled. Moreover, they never signed any agreements for biological resources for commercial utilization.

- Most of the genetic resource-based products (biofertilizers, 76.92 per cent) were regularised by the Fertilizer (Control) Order, 1985 through the Directorate of Agriculture, Gandhinagar, Gujarat (76.92 per cent) and other microbial products (biopesticides, 19.23 per cent) came under the regulations of CIB&RC Faridabad, with production permission from the Directorate of Agriculture, Gujarat.
- Most companies (75 per cent) were involved in third-party services for quality control (QC) and related R&D for concerned biological basedproducts and did not have the proper infrastructure for the same. Only 25 per cent of companies had a complete quality control and related R&D infrastructure for assessing biological control products.
- The majority of the companies (80.76 per cent) were selling biological resource-based products in the domestic market, while 19.24 per cent were exporting to other countries.

Table 10: Response of different agro-inputs producing industriesin Gujarat State on awareness about Access and Benefit Sharing(ABS) from biological resources

Questions of the		Industry Respondents			
telephonic/ online	Response (in parenthesis:		Response		
questionnaire survey	Tot	al number of	Percentage		
	res	pondents- 52)			
Organization/industry type	1.	Ltd	1. Ltd, 5.77%		
	2.	Pvt Ltd	(Total=3)		
	3.	Partnership Firm	2. Pvt Ltd. 38.46%		
	4.	LLP	(Total =20)		
			3.Partnership. 50.0%		
			(Total=26)		
			4. LLP, 5.77%		
			(Total=3)		
Which type of genetic	1.	Microbial based	1. 100% (Total =52)		
resource is used in product	2.	Wild plant based	2. 0.0%		
formulation/production?	3.	Animal based	3. 0.0%		
Which organization is the	1.	Individual	1. 3.86% (Total =2)		
source/supplier of genetic	2.	Private sector	2. 48.07% (Total		
resources?	3.	Public Sector	=25)		
	4.	Research Institute/	3.0.0% (Total = 0)		
		Universities	4. 48.07% (Total =		
			25)		

Table 10 continued ...

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Table 10 continued...

Which kind of product is developed from biological resources?	1. 2. 3. 4.	Biofertilizers Biopesticides Growth Promoters Enzymes/Organic Acids Parent	176.92% (Total =40) 2. 19.23% (Total = 10) 3. 3.85% (Total = 2) 4. 0.0% (Total = 0) 1 0.0% (Total =0)
based products protected under Intellectual Property Rights (IPR)?	2. 3.	Trademark Without IPR protection	2. 48.08% (Total = 25) 3. 51.92% (Total = 27)
Are you aware of the ABS clause (Article 15) of the CBD Act 1992 and the Nagoya Protocol, 2010?	1. 2.	Yes No	1. 0.0% (Total = 0) 2. 100% (Total =52)
Have you signed an ABS agreement with the Gujarat Biodiversity Board to access biological resources?	1.2.	Yes No	1. 0.0% (Total = 0) 2. 100% (Total = 52)
Who is the responsible licence/regulatory authority pertaining to bioresource-based-product mass production approval?		CIB&RC, Faridabad & Directorate of Agriculture (Plant Protection), Gandhinagar, Gujarat The Fertilizer (Control Order), 1985 and Directorate of Agriculture, Gujarat Without Approval	176.92% (Total = 40) 2. 19.23% (Total = 10) 3. 3.85% (Total =2)
Is the availability of facilities within the industry related to the quality and R&D of the concerned product?	1.2.	QC & R&D (Inhouse) QC & R&D (Third party, outsourcing)	1. 25.0% (Total = 13) 2. 75.0% (Total = 39)
What is the target market for the concerned product for sales?	1. 2.	Domestic International (Export)	1 80.76% (Total =42) 2. 19.24% (Total = 10)

Source: Author's compilation

Articles 21 and 22 of the Nagoya Protocol emphasise the need for stakeholder education and capacity building. "Each party should take measures to enhance awareness of the value of genetic resources and traditional knowledge linked with genetic resources, as well as related access and benefit-sharing aspects." The Nagoya Protocol advises states to educate their diverse stakeholders using a number of techniques. Indigenous communities/ or peoples in India and other countries were surveyed regarding their obligations under Articles 21 and 22 (Alam and Arjjumend, 2018). According to the NBA, India is committed to teaching the Nagoya protocol, ABS for native populations to local communities (ILCs), and their obligations in connection to genetic resources, indigenous practises, commercialisation of bioresources, and potential benefits.

Issues Related to ABS Agreement in Gujarat States

Gujarat State is the hub of the industrial sector where many industries are working on different genetic resources-based products for production and sales. The first major problem is that most companies do not have the knowledge of the CBD act and the Nagoya Protocol for access and benefit sharing. They have no idea about the concept of access to genetic resources and their commercialisation and benefit sharing with the state. It is the responsibility of the Gujarat State Biodiversity Board to tackle this issue and should organise Industry-Academia-Research Institute-Public Sector meetings at different time intervals to disseminate the knowledge of ABS. There is a very large gap between the different stakeholders of the ABS mechanism, and it is not easy for a single stakeholder.

The second aspect of ABS management is the regulation of biological resource-based products in the market. For example, in the case of bio-inputs (biofertilizers, biopesticides, growth promoters) being procured and sold in the market without the consent of the State Biodiversity Board. Most of the licences for mass production of microbial-based biofertilizers and biopesticides by the Directorate of Agriculture of the States are given without knowing the source of genetic resources. There is an urgent need for a no objection certificate (NOC) clause in the required perquisitions certificates for new licences under the Fertilizer (Control) Order, 1985 and CIB&RC Act when any applicant company wants to take a licence for such products for mass production. The more ABS agreements for product commercialisation

and IP protection that support revenue generation for the state biodiversity board and indirectly for Biodiversity Management Committees (BMCs) at the community level, the better. The flow of generated money from ABS from biological resources goes upwards to downwards, and it is very essential to run a successful BMC in the state.

Conclusion and Recommendations

The regulation and implementation of access and benefit sharing (ABS) from biological resources is a very complicated process for any user of industry. The question of access to genetic resources, whether the requirements of the Biodiversity Act are being fulfilled or not, if Prior Informed Consent (PIC) has been obtained from the users of the bioresource or related traditional knowledge, or mutually agreed terms (MAT) have already been completed by both the supplier and the users, is indeed very hard for tracking the traceability at different stages. The only solution to such an issue is sensitisation and awareness-raising. All departments and agencies working with bio resources must be aware of their legal obligations and begin cooperating with the National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs), and Biodiversity Management Committees (BMCs) in the execution of the Biodiversity Act, 2002, and the CBD regulations (Shah, 2022).

Though the country is slowly moving toward implementing the Convention on Biodiversity (CBD), diverse procedures, guidelines, and the Biological Diversity Act, 2002, the benefits to the local community or knowledge holders, as envisioned in the Convention on Biodiversity and the Biological Diversity Act, 2002 at grassroot level, have yet to materialise, and one of the reasons for this is the lack of a reliable market system for commercialisation. Several stakeholders participate in the value chain of any product until the genetic resource or information reaches the final user, and this lengthy value chain results in a lower rate of return. As a result, a value chain evaluation is required and both the user and the supplier must agree to a mutual understanding in order to successfully access and share genetic resources and relevant information.

Gujarat State is a prominent state in both biological diversity and industrial infrastructure for the valorisation of genetic resources in different

products for agriculture, food, herbal medicines, cosmetics, and industrial applications. But there is a need for a strong network of BMCs and documented PBRs in each district of Gujarat for researchers and industries so that more industries can enter into ABS agreements for biological resources for commercialisation. The Gujarat Biodiversity Board (GBB) should strengthen the BMCs and focus on PBRs because they generate revenue that changes the face of society at the community or grass root level. It is also helpful for grassroot innovations, IPR protection, and making Gujarat strong.

Endnotes

- ¹ Legal Initiative for Forest and Environment (2017). Access and Benefit Sharing. *Policy Paper*. No. 04-17: October 2017, 1-10
- ² Nagoya Protocol (2010): https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf
- ³ See Article 13 (2): National Focal Points and Competent National Authorities of Nagoya Protocol, 2010
- ⁴ Convention on Biological Diversity: Fact Sheets in ABS series: Produced by the Secretariat of the Convention on Biological Diversity: https://www.cbd.int/abs/infokit/ revised/web/all-files-en.pdf
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- ¹⁶ *Divya Pharmacy vs Union of India and Others*, Writ Petition No. 3437 of 2016, Uttarakhand High Court, December 21, 2018.

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Biodiversity Science and Policy in India

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Abstract: Science and policy are human constructs to understand biodiversity. This paper attempts to review the relationship between science and policy for biodiversity in India. It has been found that sciences and policies/programmes for biodiversity were shaped by national objectives and commitment to global and transnational goals for the planet's well-being, where biodiversity is an integral part of planetary well-being. The paper also shows how utilitarianism marked both research as well as policies and programmes with respect to biodiversity. Biodiversity conservation demands policies that are not just about economic gains within a plan period, but about larger conservation, threats to survival (species extinction), and inter-generational time scales. Given the global emphasis on biodiversity conservation particularly in the context of climate change and food security, country like India needs to balance multiple demands and multiple stakeholder's interests. The relationship between science and policy for biodiversity Post independence in India has converged for increasing utility from natural resources and simultaneously increasing human wellbeing. There is a need for biodiversity policy in the country to be fed by robust science and different knowledge forms where biodiversity is understood not only as a species or breed to be conserved but the system's heterogeneity and the ontology of biodiversity to ensure sustainability.

Keywords: Biodiversity, Conservation, science-policy, 2020 Global Biodiversity Framework, eco-system services.

Introduction

The concern for biodiversity among the global scientific and policy community came into force at the turn of the last century. Several studies indicated mass extinction and loss of world's biodiversity due to unprecedented levels of habitat destruction and anthropogenic activities (Wilson, 1988; Ehrlich and Wilson, 1991). This loss of living forms is directly or indirectly altering ecosystems functions and affecting human welfare (Loreau, 1991; Naeem *et al.*1994). The threat of losing living forms propelled the rise of biodiversity studies to better understand the

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interconnectedness of complex natural systems (Hooper et al. 2005; Hendry et al. 2009) and its relationship with human beings (Diaz et al, 2015). The loss of biodiversity is worrisome because an increase in the extinction rate of species will accelerate changes in the ecosystem (Naeem et al. 1994; Perrings, 2011) affecting the productivity and decomposition function of ecosystem (Hooper et al., 2012). Despite scientific evidences of why biodiversity matters, there has been a failure to stop or slower biodiversity loss with missed national and international goals like Aichi Biodiversity Targets of the CBD Strategic Plan for Biodiversity 2011–2020 (Secretariat of the Convention on Biological Diversity, 2020). The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), Global Assessment Report on Biodiversity and Ecosystem Services, 2019 provided scientific evidence about biodiversity loss and stated that over one million species are likely to disappear due to human actions (IPBES, 2019). There has been a call for urgent action by the Science Academies of the G7 nations to reverse the biodiversity loss by a more ambitious and reasoned approach for a transformational change at a local, regional and global level (The Royal Society, 2021). This requires understanding how science and policy interacts and what determines a policy decision. This paper attempts to review the relationship between science and policy for biodiversity in India. It describes the programmes/policies and scientific research components for biodiversity in India and reviews the interaction between science and policy.

Coined in 1986 the term biodiversity (Wilson, 1988), has remained major theme of several science disciplines (Loreau, 1991). However, the ambiguity with regards to its understanding (DeLong Jr, 1996) settled with the Convention on Biological Diversity (CBD)¹ defining it as, "the variability among living organisms from all sources including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems" (United Nations, 1992).

India exhibits a wide range of biodiversity in its forests, wetlands, mountains, desert and marine areas classified into ten bio-geographic zones across the country and the richness has been described in absolute numbers of species found (Rodgers and Panwar, 1988). The diversity within and between species has been described at all levels of ecological organization

and spatio-temporal scales, landscape that surrounds them (Bhagwat et al. 2005; Roy et al. 2012; Roy, Kushwaha, Murthy etal 2012) and community that governs them (Kothari, 2013; Alcorn, 1999). The Union Government has put in place several proactive policies and programmes for natural resources and their conservation. In the following section, the various policies and programmes for terrestrial biodiversity/natural resources and their conservation is highlighted in an historical context.

Policies and Programme for Biodiversity in India

In India, concerns about biodiversity and environment emerged in the 1980s. There were programmes (distinct policy instruments) formulated and implemented since independence for conservation/utilisation of natural resources. The objectives of the policies and programmes undertaken to conserve and utilize the biodiversity have evolved over several decades. Based on their core objectives and practical content, the programmes and policies for biodiversity and natural resources have been categorized into four phases.

Phase I - Utilisation of Natural Resource (1950-1969)

This phase immediately after independence marked utilisation of natural resources for growth and development. The first Five Year Plan stressed upon growth and all-round development of the country so as to increase (double) the per capita income of the people. Planning for utilisation and conservation of natural resources like forest, soil and minerals were carried out (GOI, 1952), of which forest drew the prominent attention. Each state was mandated by the Central Board of Forestry on the proportion of forest cover, based on nature of the terrain, land-use and national needs (GOI, 1952). The Forest Policy Resolution (FPR)² was legislated in 1952 which emphasised on the protective and productive role of forest with an objective of managing forest resources by extending and improving areas under forest cover.

However, with increased urbanization and developmental work for railways, construction, defense and industrial purpose, the need for continuous supply of timber and other forest produce escalated. So, to meet the demand new forest communications were developed to reach the inaccessible areas. On the other hand, to combat such destruction, afforestation like timber plantation of commercially and industrially important species like teak and matchwood were also carried out(GOI, 1956). But when economic concerns drive the utilization of natural resources, it gets more and more tied to economic development goals rather than conservation or protection goals, as exemplified by forestry where increased demand for timber and forest produce commoditized the production to facilitate timber for commercial purposes (Haeuber, 1993).

Conservation of flora and fauna as an integral part of forestry emerged gradually. Certain conservation methods like in-situ and ex-situ to conserve plants and animal genetic resource had been in practice since the colonial era (like the Reserve forests and the first national park - Corbett National Park built in 1935). Post-independence such methods were gradually strengthened. For conservation of wildlife, the Indian Board for Wildlife was constituted in 1952. During the Second Five Year Plan, 18 National Parks and game sanctuaries were established including the Zoological Park in Delhi (GOI, 1956). Since then, several national parks and wildlife sanctuaries have been set up.

Phase II - Environmental Protection (1970-1990)

The inaugural address by the then Prime Minister of India at the Tenth General Assembly of the International Union for Conservation of Nature (IUCN) on 24 November, 1969 for the first time reflected concerns about the environment problems related to air and water pollution, soil erosion, waste of natural resource, loss of wildlife etc. (Ramesh, 2017). As a result, environment was included in long term planning and development (GOI, 1970). But even this phase of environmental protection, though marked by a respect for nature, was 'always subjected to the greed' of people.

During this phase, environmental management became an important factor for national development goals and several initiatives like monitoring and control of air and water pollution; environmental impact assessment; natural living resource conservation; wildlife conservation projects, eco-development programmes, etc. were initiated (GOI, 1985). The Wildlife Protection Act, 1972 was enacted for the protection of wildlife. It prohibited 'hunting, poaching, smuggling and illegal trade of wildlife and derivatives' and had provisions for stringent punishment for violation of the act (GOI, 1972). A tiger conservation programme called 'Project Tiger' was launched in 1973 for the protection of Bengal tiger from extinction. It later expanded to the protection of the entire habitat of the tigers known as Tiger Reserves³. Along with tiger reserves, several National Parks (19) and Wildlife Sanctuaries (202) were set up till 1980 (GOI, 1981) for the protection of wildlife.

For forest conservation, stringent provisions were laid 'to stop diversion of forest land for any non-forest purposes' and the Forest (Conservation) Act was enacted in 1980. The act posed restrictions on all the states on 'dereservation of forests' without prior approval from the Union government (GOI, 1980). The Wildlife Protection Act, 1972 coupled with the Forest Act, 1980 reinforced the 'state-nature boundaries' with a centralizing nation state and control of Union government over forest and wildlife (Rangarajan, 2017). As a result of such measures, the extant of legalised deforestation came down from four million hectares in 1950-80 to a million hectare in the next two decades. Further for efficient "planning, promotion, co-ordination and overseeing the implementation of India's environmental and forestry policies and programmes" a dedicated department - Ministry of Environment and Forest (MoEF) was set up to act as a nodal agency of the Union government in 1985. For state level coordination of activities, dedicated state departments in each state acted as focal points for coordination with the centre. The Environment (Protection) Act was enacted in 1986 "for the protection and improvement of environment and for matters connected therewith" (GOI, 1986). The act also empowered the Union government to establish authorities to protect and improve the quality of environment and prevent, control and abate environmental pollution. All these acts armed the Union government with a comprehensive control over environment related activities.

Surveys and inventorisation of biological resources had been carried out since the colonial period, but the orientation of Botanical Survey of India (BSI) and Zoological Survey of India (ZSI) were restructured in the later part of 1980s. Their functions were restructured towards ecology and conservation by the inclusion of lower forms of plants and animals in their research mandate along with survey of living resources and ecological mapping (GOI, 1985). In this phase, policies meant specifically for protecting and safeguarding India's environment, mainly pollution abatement and conservation of forests, water and land resources. Also, the threat to the survival of some species did get attention and schemes were designed to protect those species. This was an important development in this phase.

Phase III - Conservation of Biodiversity (1991-2010)

Post-independence, there have been several policies and conservation efforts for natural resources like forest, wildlife, environment, but concerns for biodiversity surged after the formulation of CBD and India becoming a signatory to it in June 1992. The convention affirmed that the conservation of biodiversity was a common concern of mankind and each nation-state would be responsible for the conservation of the biological resources and their sustainable usage. Since biodiversity has been significantly reduced by human activities and large numbers of indigenous communities depend on biodiversity for their livelihood, the need to develop Science and Technology (S&T) and institutional capacities to understand biodiversity and implement appropriate policies was urgent (United Nations, 1992) and all the convening parties agreed to the terms laid by the convention. This phase marks the initiatives that were taken towards the fulfillment of the objectives of the convention.

The growth and development impetus which led to environmental degradation and decline of biodiversity was duly taken cognizance of. Accordingly, guidelines for 'National Conservation Strategy and Policy Statement on Environment and Development', 1992 was laid by the MOEF, Government of India to incorporate environmental considerations in the development process (GOI, 1992). Further emphases was laid on forest areas to prevent extinction of species and conserve biodiversity. *In situ* conservation practices within the protected areas (Sanctuaries, National Parks and Biosphere Reserves) were expanded gradually and institutional capacity for '*biodiversity utilization*' was also proposed in the Ninth Five Year Plan (GOI, 1997). Specific emphasis was laid on the species that had the potential of economic benefits such as medicinal plants. In addition to these, two major actions that were taken for the fulfillment of the objectives of CBD were the National Biodiversity Action Plan (NBAP) and the Biological Diversity Act (BDA).

According to the CBD, each contracting parties was directed to develop national strategies or plans for the conservation of biodiversity, sustainable use of the biological resources and equitable sharing of benefits arising from its use, so that the strategies could be implemented to bring about an impact on biodiversity. India was also committed to the preparation of National Biodiversity Strategy and Action Plan (NBSAP). For this, a decentralized and participatory approach was adopted. It involved inputs from village, district and state level actors, civil society organizations, scientist, academicians, farmers, fisherman, and different community members. Diverse methodologies like yatra, fairs, festivals, workshops were used to devise Biodiversity State Action Plans for 33 states, 10 ecoregions, 13 themes and 18 sub-state sites that resulted into a draft NBSAP.⁴ The NBSAP final report was submitted to MoEF in 2004, however it was not made public, instead the National Environment Policy (NEP) was implemented in 2006 (Kothari and Kohli, 2009). The NEP envisaged conservation of critical environmental resources to support livelihood, life support, economic growth and human wellbeing; intra and inter-generational equity; efficiency in resource use; and integration of environmental concerns in economic and social development (GOI, 2006). Later in 2008, the National Biodiversity Action Plan (NBAP) was released in conformity with the NEP. The action plan, which was supposed to be based on draft NBSAP, 2004 drew only one third of the strategies mentioned in the draft report (Kothari and Kohli, 2009).

To give effect to the provisions of CBD, for the first time a dedicated act for biodiversity -'Biological Diversity Act' (BDA) was enacted in 2002. The Act gave provisions to "conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto" (GOI, 2003). To implement the Act, organizational arrangements were made at different levels, national, state and local. The National Biodiversity Authority (NBA) was established in 2003. It facilitated the regulatory and advisory functions on issues of conservation, utilisation and equal distribution of benefits out of biological resources. Along with the NBA at a national level, a State Biodiversity Board (SBB) was set up in each state to advise the state government on any guidelines issued by the Union government and regulate the grant of approvals for commercial utilization of any biological resources. The procedure for accessing biological resources and traditional knowledge for any research or commercial utilization and criteria for equitable benefit sharing were laid down by the Biological Diversity Rules (BDR), 2004. The BDR also directed the setting up of Biodiversity Management Committees (BMC) at the local level with the assistance from SBBs to document information related to biodiversity. The information ranged from "preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms and chronicling of knowledge relating to biological diversity". These were to be documented in the form of Peoples' Biodiversity Register (PBR) (GOI, 2004). The PBRs would document knowledge of the indigenous community on the status, use and management of biological resources. Thus, biodiversity conservation encompassed identification and documentation of the resources for their utilization.

Phase IV- Commodifying Biodiversity (2011-2022)

This phase marked establishing Biodiversity Management Committees and preparing Peoples' Biodiversity Register across states and Union Territories. These two activities are termed as Key Performing Indicators to be achieved by 2024 under the "Enabler of Sustainable Business" Goal (GOI, 2021). Though the utilization of biological resources was checked by the 'Access and Benefit Sharing' (ABS) mechanism of the CBD which obliged foreign nationals and corporations to seek approval before obtaining any biological resources, at the national level the mechanism differed. In India, according to the Biodiversity Act, 2002, accessing any biological resource or associated knowledge for commercial utilization, research, bio-utilisation and biosurvey would require prior approval from NBA and concerned SBBs (GOI, 2004). Moreover, the benefit that would arise from such utilization had to be equitably shared as per NBA's directive. But for Indian nationals or corporate registered in India, a similar activity for obtaining any biological resources just requires intimation to the SBB. However, different SBBs have implemented different rules for Indian nationals for the access and utilization of biological resources and there has been no consensus among the states. In this process, the local communities have been left far behind without any scope for participation (Kohler-Rollefson and Meyer, 2014).

To ease out the ABS principle of CBD into practice, an international framework called 'Nagoya Protocol' was adopted by the Conference of the Parties to the CBD. This provided rules and measures to implement the 'fair and equitable sharing of the benefits arising out of the utilization of genetic resources' objective of the CBD. The Nagoya Protocol also mandated prior informed consent of the local and indigenous community for accessing the biological resources. India ratified the protocol and became a party to the protocol in October, 2014. However, creation and adoption of a national ABS system following Nagoya Protocols is yet to be in place. There is a need for an alternative framework on ABS, from an indigenous perspective by linking traditional knowledge commons and biocultural protocols to prevent exploitation (Srinivas, 2012).

The Union Government in 2021, introduced the Biological Diversity (Amendment) Bill, 2021 (which is being referred to the Joint Parliamentary Committee) to simplify the compliance procedure for domestic companies in accessing biological resources and to exempt registered AYUSH medical practitioners and people accessing codified traditional knowledge from giving prior intimation to SBBs for accessing biological resources (GOI, 2021). This amendment bill 2021 drew criticism from different environmentalists and academics with respect to misuse of biological resources and failing to meet the objective of 'sustainable use and conservation of biodiversity' (Koshy, 2022; Deccan Herald, 2022). The amendment bill may have significant implications for biodiversity governance and conservation in India as the permission granted to traditional medicine may be used by corporates (national and foreign) to access biological resources or associated traditional knowledge (Warrier, 2021).

That utilisation of natural resources for larger development goals and commercialization of natural resources for utilitarian objectives has been at the core of the National Biodiversity Act, an example from the Gujarat Biodiversity Board reinforces it.

Gujarat Biodiversity Board and People's Biodiversity Register - An Example

As per the Biological Diversity Act, 2002, the Gujarat Biodiversity Board (GBB) came into existence in 2006 to ensure conservation of state's biological resources, sustainable use of biological resources and fair and equitable sharing of benefits arising out of the use of biological resources. The board functions to regulate and grant or reject applications for commercial utilization of any biological resources of the state. The board has also constituted BMCs and provided technical support to them for the preparation of People's Biodiversity Register (PBR) in order to fulfill the provision of the act. The major policy implementation in terms of biodiversity was documentation of biodiversity in the form of PBR. In Gujarat, as of March 2021, a total of 13,437 BMCs was constituted in the district blocks. Their primary function was to prepare PBR in consultation with the local communities (GBB, 2021).

The process of PBR preparation in the villages of respective BMCs involve members of local communities to document agro-biodiversity, domesticated biodiversity, wild biodiversity, urban biodiversity and the indigenous knowledge related to biodiversity in agriculture, fishery and forestry. It also documented traditional knowledge, practices and strategies like controlling of insects and pest in agriculture and household, traditional method of preparation of bio pesticides, knowledge about local birds and animals, strategies to protect cattle from predators, strategies to fight natural disasters etc.

The objective it served was to capture the species richness of the country. The knowledge of the indigenous, pastoral, tribal communities about traditional medicines for common ailments, wild edible roots and tubers help to identify species that has immense market potentiality and valuation economically. Such PBR formulations would lead to utilization of the resources but with the condition of Access and Benefit Sharing as stipulated in the objective of the CBD. The GBB first signed the ABS agreement in 2015 with Aadi Aaushadi, an informal group engaged in production and selling of herbal and medicinal product (GBB, 2016). Aadi Aaushadi accessed traditional knowledge of herbal medicines from the tribes of Dediapara forest in South Gujarat and promoted cultivation of medicinal plants as the potential crop in the Dediapada district. Out of 250 potential plants, only 15 have been widely cultivated. By the ABS terms, the group would pay a sum of money for this access and would further pay in future

lead to proliferation and conservation of only these species that are valued in the market. This when profit increases. This dominance of market and economic valuation has been a part of global convergence of knowledge and policy. The United Nations Environment Progamme (UNEP)'s Global Environment Facility (GEF) project on ABS, was launched to 'understand the economic valuation of biological diversity for improved policy making' (GBB, 2016).

The evolution of India's biodiversity concerns, as evident in policies and programmes (mainly subsumed within environmental policy) brings us some key insights. The insights based on the account of policies and programmes for biodiversity has been summerised below,

- There is no policy for biodiversity per se in the country.
- There have been various acts and policies for biodiversity, for the conservation of diverse flora and fauna in place and these have been strengthened over the years through several initiatives.
- Biodiversity conservation is considered important because human livelihoods, economic development and well-being depend on natural resources/biodiversity and its usage.
- Continuous exchange and shaping of national biodiversity policy and programmes by transnational policies.

The following section discusses the sciences with respect to biodiversity conducted in the post-Independence period in India in order to enumerate how biodiversity science interacts with policies in India.

Biodiversity Science in India in the Post-Independence Era

Biodiversity science seeks to understand the variation within living forms in terms of origin, function and maintenance across spatio-temporal scales. It started in India during colonial period with taxonomic research for species identification and classification by British botanist and medicine practitioner. Owing to the rich diversity within Indian flora and also their medicinal importance, the 'Botanical Survey of India' was established in 1890 to explore "the plant resources of the country and plant species with economic virtue"⁵. The 'Zoological Survey of India' was established much later in 1916 "to explore, survey, inventorying and monitoring of the

rich faunal diversity in various states, ecosystems and Protected Areas of India".⁶ The information collected during colonial rule was mainly used by the colonial rulers to gain knowledge about the species and derive economic benefits out of them.

After independence, scientific research on natural resources got diversified into different disciplines from taxonomy to forestry, evolutionary biology, ecology, conservation biology, etc. The following table (Table 1) presents a snapshot of the domains of biodiversity research in India post-Independence and how it unfolded.

The attempt here is not to provide a review of scientific research that has been carried out in biodiversity but to understand the agenda which facilitated biodiversity research in the country. The major researches that were conducted in the plan periods have been categorized. It was found to correspond to the earlier categorization of policy evolution: Phase I – Utilisation of natural resource (1950-1969); Phase II – Environmental Protection (1970-1990); Phase III –Conservation of Biodiversity (1991-2022).

Phase	Objective	Research Areas
Phase 1	Forestry and	Logging methods, timber engineering, plant
1947 to	forest product	introduction, forest product research, silviculture,
1969	utilization in	timber utilisation in industries
	industries	
	Natural	Soil Survey to study land use pattern, soil
	Resource	characteristics, degree of erosion under different
	Conservation	condition of soil and climate,
		Shifting cultivation for conservation of soil and
		maintenance of soil productivity.
		Desert afforestation, pasture improvement,
		experimental plantation for stabilization of desert
	Taxonomy	Classification of plants, animals, fish, birds,
		insects etc.

Table 1: Phases of Biodiversity Research in India Post-Independence

Table 1 continued...

Table 1 continued ...

Phase 2 1970-1990	Environment	Environment Impact Assessment Environmental Quality monitoring using physical, chemical, biological, socio-economic indicators. Environmental Information System (ENVIS) to collect information relevant to toxic chemicals leading to pollution, mining, forestry, flora and fauna
	Ecology and Conservation	Ecosystem analysis of conservation Areas like Tiger Reserves, Biosphere Reserves, National Parks and selected sanctuaries to ascertain their actual biological content. Preparation of pollen, chromosome and seed atlas, Tissue banks for endangered plant species, compilation of national and state flora for Red data book Preparation of chromosome, morphological atlas of animal species, Red data book of threatened plants and animals, zoological collection and status survey of endangered species Identification of lesser known plant and animal species
Phase 3 1991-2022	Biodiversity status and conservation	Biodiversity mapping and status monitoring, construction of biodiversity database
	Biodiversity and human well-being	Integrating biodiversity, ecosystem services, climate change, agriculture, health, bio-economy and capacity building.

Source: Compiled from Five-year plan document (various years), Planning commission, Government of India, New Delhi.

From Table 1, it has been found that the research on natural resources after independence aligned with the focus and objective of the policies and programmes initiated for the natural resources and environment. With respect to biodiversity, the major studies that were carried out in the country included survey and inventorisation, with an explicit utilitarian interest. From the phases described in the Table, the first phase clearly revealed the development commitment of the newly independent nation. The second phase marked the drive for conservation of wildlife, forest and environment. The flora and fauna species of the country were being surveyed by the Botanical Survey of India (BSI) and the Zoological Survey of India (ZSI). They were responsible for exploration and documentation of the floral and faunal resources at national, state and selected ecosystem level; conducting taxonomic studies; status survey of the endangered species; and publishing the Red data book on endangered species (GOI, 2001). These surveys were also responsible for *ex-situ* conservation of critically threatened species in botanical gardens and zoological parks. However, biodiversity in India still remains to be fully known and their potentiality realized.

Also, to advance conservation plans for biodiversity, monitoring and inventorising was important. The third phase marked the research on status mapping and monitoring of life forms. One of the major challenges for conservation of biodiversity is the characterization, monitoring and quantification of biodiversity. Large number of species are still unknown to us and the pace of documentation is much slow than the rate of species loss (Roy et al., 2012). Though there have been several attempts to study species diversity but data on species ecology and distribution is limited or scattered among institutions or individuals (Vattakavenet al., 2016). There has been attempts to aggregate the data. Remote sensing technology has been applied to map and collect data about ecosystem and biodiversity. A national level coordinated research programme on 'Biodiversity charaterisation at landscape level using Remote Sensing and GIS' was launched by the Department of Biotechnology, Space Application Centre and National Remote Sensing Agency in collaboration with different research institutes (Pushpangadan and Nair, 2001). Studies were carried out to map resources and generate data for further research and conservation plans. For example, the study to map the flowering plant richness in forested landscapes has resulted in baseline spatial data on vegetation types, porosity, patchiness, interspersion, juxtaposition, fragmentation, disturbance regimes, ecosystem uniqueness, terrain complexity and the species richness (Roy et al., 2012).

Knowledge on species distribution, taxonomy, ecology and behavior are crucial to understand biodiversity dynamics in space and time (Vattakavenet *et al.*, 2016). So, a comprehensive biodiversity information system which

includes various aspects of biodiversity information at the species level, such as spatio-temporal distribution, taxonomic status, conservation status and ecological function were carried out for conservation of bioresources (Vattakavenetal, 2016; Gadgil, 2003). However, lack of coordination of research among institutes, common agenda and support for basic science disciplines has hindered taxonomic research in the country (Pushpangadan and Nair, 2001) and the progress on generation of comprehensive data on biodiversity. To increase the coordination among research, several biodiversity compilation portals have commenced to aggregate data for usage in research and commercial purposes. A number of databases were generated in Phase III to provide information for further research and to devise plans for conservation. An illustrative list of some databases which have recorded the biodiversity has been listed in Table 2.

Database	Information	Institute
NBRI-PADAP	Web-enabled database containing taxonomic and biodiversity information on algae, bryophytes, lichens, pteridophytes, gymnosperms and selected flowering plant taxa	CSIR-National Botanical Research Institute, Lucknow
National Wildlife Database	Geographic distribution of wildlife across the country	Wildlife Institute of India, Dehradun
Indian Bioresource Information Network (IBIN)	National interface to compile data on bio- resources such as plants, animals, marine, spatial distribution and microbial resources	Bio-resource Information Centres – University of Agricultural Sciences, Bangalore; National Remote Sensing Centre, Hyderabad. (Funded by Department of Biotechnology)

Table 2: List of Biodiversity Database in India

Table 2 continued...

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Indian Medicinal Plants Database	Indian medicinal plants duly linked to the specific botanical entities	Foundation for Revitalization of Local Health Traditions
IndiaA repository of information designed to harness and disseminate collective intelligence on the biodiversity of the Indian subcontinent		Consortium of institutes ⁷
India Biodiversity Information System	Based on citizen science and aspires to facilitate the participation of amateurs in gathering scientific data and building a free resource on Indian biodiversity	Foundation of Ecological Security, Gujarat

Table 2 continued...

Source: Compiled from the websites of the respective databases.

The India Biodiversity Portal aggregated biodiversity data of different kinds (for example distribution maps, temporal distribution or life history) in an integrated platform. It was the first of its kind in the country to compile data on the different species of flora and fauna found in the country. The database provided easy access and information to the researchers for further research and also for policy makers to refer for conservation actions. The India Biodiversity Portal was created in 2008 to provide open data on biodiversity in India. It was managed by a conglomerate of partners from research institutes, civil society organisation, information technology and legal domains.

A database known as PADAP for plant species was generated by CSIR-National Botanical Research Institute (CSIR-NBRI) based on the primary data and taxonomic expertise of the institute. The database acted as a repository of information collected by the institute and was also used for research and development purpose by ENVIS centre on Plant and pollution hosted by CSIR-NBRI. A bigger initiative was taken by the Department of Biotechnology (DBT) to create a network of existing databases and collate information on bioresources. The Indian Bio-resource Information Network was launched in 2012 to serve professionals involved in bio-prospecting, marketing, protecting and conservation of bioresources. Characterization of bioresources has been an essential component of biodiversity science in India. It is important because knowledge about the resources provides opportunity for further research, status monitoring and inputs to the policy makers to further plan for development actions or conservation of these resources. But the creation of database could also be an important first step to sell or commercially exploit resources and large tracts of forest lands or rural commons.

Here, we find that biodiversity research has produced information about natural resources by descriptive surveys and database formation and have also provided an explanation of how these resources were to be put to use in the production system. Further studies need to be conducted with respect to particular sector such as forestry, agriculture or bioenergy to delineate how the research trajectory in particular sector unfolded.

From the above description in section 2 and 3 economic estimation and association of economic value with biodiversity forms the major rationale. In such a model, the relationship between sciences and policy is presented as a linear causality emerging from the scientific facts about species and ecosystems, valued in monetary terms and enabling policy decisions for biodiversity conservation or as valued in terms of market. In such a model only, species which have a market value or utility will be promoted and conserved. It took 50 years since independence for the Government of India to promulgate the Biodiversity Act. As of now, there is no biodiversity policy in the country. In the absence of a policy for biodiversity, clearly, biodiversity was never a central concern in the country. The lack of an overarching policy for biodiversity also amounts to the absence of or relative insignificance of a set of stakeholders (conservationist, scientist and activist) and influence of corporates and economic actors with an agenda to promote biodiversity. It needs to be questioned whether such market dominated strategy to conserve or promote biodiversity is sustainable.

Discussion and Conclusion

Though there has been growing concerns for biodiversity among the researchers and policy makers, there is a lack of clarity about the relationship between biodiversity sciences and policies. Research conducted on biodiversity globally since 1980s, has been approached by different disciplines like taxonomy, evolutionary biology, ecology, conservation

biology, economics etc. and their results were limited to their respective disciplines without a unified 'common biodiversity agenda' (Loreau, 1991). Also, there exists a schism within the scientific community to understand biodiversity and to provide inputs or to communicate to the policy makers (Masood, 2018). Such lack of common agenda or schism cannot afford to persist because effect of species loss on ecosystem processes have been found to be comparable to other environmental crisis like ozone acidification, elevated carbon dioxide or pollution. Biodiversity science and policy interaction and effective action for biodiversity is yet to happen as that of climate science and policy (Hooper *et al.*, 2012).

More recently, there have been several efforts to foster biodiversity science and a unified agenda, and to strengthen the policy relevance of biodiversity research. The CBD (1992) and Aichi Biodiversity Targets 2020 did set the stage, as did the Rio and follow-up conferences (1992, 2012). But it was the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), Global Assessment Report on Biodiversity and Ecosystem Services, (IPBES, 2019) that directly confronted the task of providing scientific evidence about biodiversity loss to policy makers and stated that over one million species are likely to disappear due to human actions. The Dasgupta Review on the Economics of Biodiversity (Dasgupta, 2021) also emphasised on how our economies, livelihoods and well-being all depend on nature and our increasing demands from nature has far exceeded nature's capacity to regenerate, thereby endangering all life forms. The report calls for immediate policy measures to amend human actions and to acknowledge the fact that 'our economies are embedded within nature and not external to it'. But the report fails to question our relationship with nature and the offers little opportunity to transform our actions and thoughts so that the diversity and its dynamism is valued and conserved (Raina, 2021). To understand biodiversity, intense scientific investigations globally provided solutions to numerous problems, yet 'what determines species diversity?' has still been one of the top research question in all the disciplines of biological sciences (Chase, 2012). So, there lies much more beyond a species or breed to understand biodiversity. Moreover, biodiversity is a complex phenomenon. To interpret these complexities, its adaptive processes and its interaction with one another, an alternative approach is required, where both scientists and policy makers are open to different forms of knowledge.

In India, the National Mission on Biodiversity and Human Well-Being (NMBHWB) launched by the Principal Scientific Advisor to the Government of India is built on a framework that integrates biodiversity, ecosystem services, climate change, agriculture, health, bio-economy and capacity building in the realm of biodiversity science (Bawa *et al.*, 2021). To mainstream the concept of biodiversity, there is a need to recognize biodiversity as variety of life forms across species, genes and of ecosystem along with the varying landscapes, regions and habitats in which they exist.

It is now widely acknowledged that biodiversity is best understood and conserved by local communities and indigenous people. This is because of their deeply rooted knowledge and experience as typified by their practices, ideals, beliefs, cultures and emotions. The zero draft of the post 2020 Global Biodiversity Framework recognizes the urgent need for policy action globally, nationally and regionally to transform economic, social, and financial models so that the trends that have exacerbated biodiversity loss stabilise by 2030 and reverse the order with net improvements by 2050 to achieve the CBD's vision of 'living in harmony with nature by 2050' (IISD, 2020). Given the global emphasis on biodiversity conservation particularly in the context of climate change and food security, country like India needs to balance multiple demands and multiple stakeholder's interests. This would require building partnership with organizations at the global, national, and local levels for immediate actions with active participation of indigenous peoples and local communities. The relationship between science and policy for biodiversity in India, which converges for increasing utility from natural resources and simultaneously increasing human wellbeing, needs to consider the system's heterogeneity and the ontology of biodiversity so as to promote development sustainably.

Endnotes

¹ Convention on Biological Diversity (CBD) is an international legal instrument developed by an Ad Hoc Working Group of Technical and Legal Experts, convened by the United Nations Environment Programme, with the main objective of "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resourcesCBD was adopted on 22nd May 1992 at the United Nations Conference on Environment and Development at Rio de Janeiro. (See Convention on Biological Diversity https://www.cbd.int/history)

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- ² FPR was legislated as a measure against the exploitative Indian Forest Act, 1927, legislated under the colonial rule to increase the control of government (states) over access to the forest and use of forest produce and restrict the rights of the common people (traditional user right) over the forests (Haeuber, 1993).
- ³ Tiger Reserves were constituted on a 'core-buffer strategy' where the core areas had the legal status of a National Park or a Sanctuary, and the buffer or peripheral areas were a combination of forest and non-forest land. The Project Tiger aimed "to foster an exclusive tiger agenda in the core areas of tiger reserves, with an inclusive people oriented agenda in the buffer" (Seehttps://projecttiger.nic.in/content/107_1_Background. aspx)
- ⁴ The NBSAP project was coordinated by Kalpavriksh, a Civil Society Organisation based in Pune for technical execution of the project and the implementation was coordinated by Biotech Consortium India Limited. The project Directorate was based at MoEF and the project Director being Joint Secretary, MoEF, all the decisions regarding the project and finalization of the report rested with the ministry. See Biotech Consortium India Limited.
- ⁵ See Botanical Survey of India Brief History (https://bsi.gov.in/content/3_1_ BriefHistory.aspx)
- ⁶ See Zoological Survey of India Objective(http://zsi.gov.in/App/content.aspx?link=154)
- ⁷ Asian Biodiversity Conservation Trust; Azim Premji University; Ashoka Trust for Research in Ecology and the Environment; Bombay Natural History Society; Care Earth; Foundation for Ecological Research Advocacy and Learning; Foundation for Ecological Security; Foundation for Revitalisation of Local Health Traditions; French Institute of Pondicherry; Hornbill Foundation; Indian Foundation for Butterflies; Keystone Foundation; Madras Crocodile Bank Trust; National Centre for Biological Sciences; OSGeo; Salim Ali Centre for Ornithology and Natural History; Strand Life Sciences; WWF India; Zoo Outreach Organisation.

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Synthetic Biology and Biodiversity

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Abstract: Anthropogenic activities such as land usage, over-exploitation of natural resources, species introduction, climate change all have greatly impacted the Earth's ecosystem and biodiversity. Synthetic biology is advancing at a breakneck pace, with far-reaching ramifications for food security, agriculture, trade, health, etc affecting global biodiversity in numerous unknown ways. Depending on how they are built and targeted, synthetic biology applications have significant positive and negative consequences for biodiversity conservation. However, there is no consensus on the current state of synthetic biology and its implications for conservation, much alone the possibilities for future improvements. The potential advantages vary from the protection of vulnerable species to the development of synthetic substitutes for wildlife goods. Changes in the ecological functions of target organisms, as well as negative effects on the lives of indigenous and local populations who rely heavily on biodiversity, are examples of potential negative effects. There is an urgent need for authoritative action that may assist the conservation community, governments, and businesses in reaching an agreement on the hazards and potentially linked with synthetic biology and how they should be addressed. The application of synthetic biology must also be informed by case-by-case evaluations, guided by scientific facts, and decision-making must incorporate traditional knowledge, religious and ethical values.

Keywords: Synthetic Biology, biodiversity, food security, agriculture, trade, health

A brief introduction to Biodiversity

CBD (Convention on Biological Diversity) has defined Biodiversity as "the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems".

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The global biodiversity of life on this planet is a huge repository of nucleic acids, proteins, cells, tissues and organisms creating food chains and servicing the environment. For example, material goods such as food, timber and medicines, key functions like flood management, temperature regulation, nutrient cycling, and nonmaterial advantages such as recreation. Biodiversity contributes to agriculture (Hooper *et al*, 2012), enables the carbon cycle, and sustains human health (Barton and Pretty, 2010). It provides resilience to environmental change and provides social and economic benefits (Nicola *et al*, 2009; TEEB, 2009).

Human activities have altered ecosystems (Foley *et al*, 2005), converting natural landscapes into cement jungles, introducing non-native species, and destroying wildlife (Kilpatrick *et al*, 2017). Though efforts are going on to restore this balance, yet biodiversity continues to decline at various rates across the planet.

The question is: which approach or combination of approaches is suitable to restore the ecological balance and enable sustainable economic development. Conservation is already a unifying discipline with efforts like strengthening protected areas, advancing state policy on natural resources and so on.

Potential impacts of synthetic biology on biodiversity (risk & rewards)

Synthetic biology can be defined as "a further development and new dimension of modern biotechnology that combines science, technology, and engineering to facilitate and accelerate the understanding, design, redesign, manufacture, and/or modification of genetic materials, living organisms, and biological systems," (according to the definition by UN CBD, 2017).

New technological advancements have increased the possibility of using Synthetic Biology towards ecological conservation, complementing and reinforcing existing conservation techniques. New synthetic biology-based technologies may be capable of decreasing biodiversity loss by minimising the effects of anthropogenic hazards. For instance, it may reduce the hazards caused due to habitat destruction. The sea and land habitats are not available to wildlife due to the commercial utilisation of such areas by humans. For example, the area invested for energy installations can be saved by using alternative sources of energy such as microbial fuel cells (Redford *et al*, 2014).

The undeniable fact is that emerging capabilities of synthetic biology, when used for biodiversity conservation, have the capabilities to transform the conservation sector in unforeseen ways, either good or bad, and over unpredictable timescales.

Of the 170 animal extinctions, invasive alien species are responsible for 20% (solely) and 54% (partly) (Clavero and García-Berthou, 2005). Invasive alien species have largely affected about 1352 amphibians, reptiles, birds and mammal species worldwide (Bellard *et al*, 2016). Synthetic biology offers ingenious alternatives against invasive alien species as well as eradication of new alien invasive species which may pose risk to biodiversity. The consequent profile whether helpful or deleterious of anticipated synthetic biology techniques applied for control of "invasive alien species" will thus be variable depending on targeted species or population, purpose and application scale.

Invasive species control. Gene drive is a process in which a gene has a property to be transmitted at a frequency even higher than the typical 50 per cent by replicating itself as well as selectively eradicating competing elements (Burt and Trivers, 2009; Marshall, 2009). This results in the spread of gene drive elements across populations even if the individuals carrying the elements do not benefit from a fitness advantage, while a fitness penalty will delay and perhaps block spread. Many distinct forms of gene drive may be found in nature. Certain gene drive elements, both natural and manufactured, are projected to spread to the majority of target animal populations (Noble et al, 2018; Hoffman et al, 2011). Other gene drive systems are naturally limited owing to frequency dependence; intended local drive systems, like non-driving genes, are not anticipated to propagate much beyond the targeted populations (Marshall and Hay, 2012; Basalova et al, 2018). Scientists want to harness gene drive by either exploiting naturally existing systems or by synthesizing synthetic analogues known as "engineered gene drives," which might be exploited to propagate engineered alterations across many generations of wild populations Teem et al, 2020). Some invasive species control tactics may allow invasive species populations to be decreased by restricting the fertility of organisms inheriting two altered copies or by changing the sex ratio (IUCN SSC, 2016).

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Restoration of extinct species. Some synthetic biology applications in conservation have been grabbing eyeballs. For instance, "de-extinction" - an act of generating an organism that is once an extinct species or acts as a substitute restoring the ecological value of their extinct counterparts - (IUCN SSC, 2016). The application of synthetic biology-based tools to restore extinct species is an intriguing concept that has captured the public interest. Additionally, media interest in resurrecting extinct species such as mammoths, top-level events and channels (e.g., National Geographic, TEDx,), and well-funded projects like the passenger pigeon project¹ added more curiosity and derived lots of attraction towards the topic. It is quite probable that some of these projects will be executed since the efforts will draw financing, and serve as an example of synthetic species made on public demands. It is feasible that a market centred on the public display of lost species will arise, either in the private sector (amusement parks like "Jurassic Parks") or as commercial zoos. The appeal of species restoration for conservation purposes may be obvious, but there are compelling reasons to be worried about. For instance, in quest of generating an ultimate "diva species" (Sandbrook, 2012), de-extinction may take funds diverted from other more important conservation issues as well as may lead to other unknown long-term consequences (Novak, 2018). Thus, extinction may no longer be permanent considering ongoing efforts of rebuilding endangered species using synthetic biology technologies. Woolly mammoths, passenger pigeons, and thylacines are among them. Such experiments are going to be very highly expensive, but as predictions suggest prices may fall in future and such restoration and re-creations may become ubiquitous and economically viable. But again, the most important questions remain unanswered: if the resurrection of extinct species become successful, will such species be referred to as a substitute for extinct forefather's species or they may become invasives from the past posing threat to present species. On what grounds, decisions will be made about which species is to be saved or restored and which not. What will be the consequence of restoring extinct species if the ecosystem formerly housing them no longer exist? What if our efforts to protect naturally occurring biodiversity are compromised in course of resurrecting extinct species (Norton, 2010).

Disease resistance. Talking on chronic threats, Synthetic biology might potentially give possibilities for engineering resistance to fungal

infections, which are currently posing a danger to a variety of species and plants (Fisher *et al*, 2012) such as, bats found in North America are highly infected with "white-nose syndrome", an illness caused by a fungus (Whitenose Syndrome). Being insectivorous and aiding in plant fertilisation, bats are projected to provide USD 23 billion to US farmers each year (Gruner, 2013). The mass killing of bats has greatly impacted agriculture. Reduction or eradication of the impact of the white-nose syndrome would benefit both biodiversity and human wellbeing. Synthetic biology could be utilized to counteract the given problem by either attacking the disease-causing fungus or interfering with its mode of infection. Certain applications, such as the engineering of microorganisms to biosynthesize chemicals supplied from imperilled species. For example, a therapeutically useful molecule isolated from the horseshoe crab's blood, are already in the works (Maloney, Phelen and Simmons, 2018).

Habitat restoration. Synthetic biology is able to actively help in habitat restoration, particularly by removing contaminants, eliminating invasive diseases or competitive species, or increasing decomposition rates (Kumar and Singh, 2020). However, the concept of restoration must be carefully managed so that it does not undermine people's enthusiasm to protect the ecosystems (Caro *et al*, 2012). Biological clean-up of the Gulf of Mexico oil spill (2010) occurred faster than planned, but the large deep-water leak caused significant and ongoing harm (Redford *et al*, 2019). To assist in the management of such disasters, it is plausible to imagine employing synthetic biology to generate and alter microorganisms with greater capacity to digest spilled hydrocarbons.

The beliefs that underpin public debate over the utilisation of synthetic biology-based products raise several social, philosophical, ethical, political and moral concerns. One recurring concern is that interventions of synthetic biology are comparable to "playing God" (Dabrock, 2009; Heather *et al*, 2017), including actions which ought not to be taken either because of the threat of irreversibly disrupting complex natural systems which are currently beyond humanity's control or because of one's own faith and values. Such values are likely most visible when it comes to concerns of species extinction (Sandler, 2012). This is especially significant for problems concerning the construction of substitutes for extinct species (IUCN, 2016). De-extinction

has been called "a fascinating but dumb idea" since it has the potential to draw resources away from endangered species conservation.

Some scientists and ethicists recommend a utilitarian approach to synthetic biology in which ethical concerns about the use of synthetic biology are weighed against the potential benefits to humanity (Smith, 2013). In the instance of employing a gene drive to combat malaria, for example, ethicists balanced the moral grounds against changing a mosquito species against the moral justifications for inventing a new instrument that may lower clinical malarial illness caseloads (Zoloth, 2016).

It is not difficult to envisage several conservation problems associated with the use of synthetic biology technology. These include new creatures escaping from confinement and establishing themselves in open environments. Such species (eg: derived from recombinant DNA technology, synthetic biology, or conventional breeding will possibly alter existing ecosystems negatively and if they transfer genetic material with wild species, they will change the existing biodiversity via decreasing viability (Ket et al, 2008). There's also a chance that these new synthetic biology derived organisms will become invasive, competing or replacing current species that will imposes a particular risk to species that are endangered or rare (Jeschke et al, 2013);. Hybrids and transgenics that has been developed from genetic combinations with their wild types (e.g., genetically modified Atlantic salmon) (Oke et al, 2013). Such risks are also associated with the introduction of novel species for conservation reasons (e.g., to aid in the restoration of contaminated or damaged ecosystems), and these scenarios will necessitate thorough investigation and analysis, as well as a careful balance of potential risks versus gains.

Convention on Biological Diversity

The advancements in synthetic biology, like in other science and technology governance systems, is influenced by discussion at international, national, and private-sector-driven perspectives and interests. Several worldwide, legally enforceable environmental conventions and treaties that give direction on the fate of technological developments like synthetic biology must be considered by nations. Several international processes are now examining possibilities for dealing with synthetic biology products and organism development and deployment.

Several international organisations and treaties are now investigating the effects of synthetic biology technologies and products on their respective agreements. The need to limit the human effect on biological diversity has gained widespread political support. The "United Nations Convention on Biological Diversity" (CBD), is one of the world's most frequently recognised treaties. Since 2002, 196 nations CBD parties have pledged that by 2010 the rate of biodiversity loss needs to reduced significantly; To facilitate its work, the parties agreed to form an "Ad Hoc Technical Expert Group" (AHTEG) and organise a monitored, open-ended online discussion. The AHTEG has developed an integrative framework for synthetic biology, which will serve as a good starting point for future discussion. Parties agreed that frequent horizon-scanning of the most current technological breakthroughs is necessary for analysing new information on synthetic biology's possible impacts. There is a growing number of international, national and regional policy frameworks that target biodiversity conservation; such as, 87 per cent of CBD signatories have now developed on "National Biodiversity Strategies" and "Action Plans", providing strategies for addressing biodiversity loss at the national level7. The method is specifically applied to synthetic biology in CBD COP Decision XI/11, which states:

"Recognising the development of technologies associated with synthetic biology, synthetic cells or genomes, and the scientific uncertainties of their potential impact on the conservation and sustainable use of biological diversity urges Parties and invites other Governments to take a precautionary approach, under the preamble of the Convention and with Article 14, when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology, following domestic legislation and other relevant international obligations."

Case by case risk assessment and monitoring regimes

Synthetic biology applications for products and organism developments are subject to case by case or staged monitoring and control at various levels, ranging from the laboratory scale to field trials or organism's deployments.

The CBD COP14 expanded the AHTEG and emphasised the importance of case-by-case risk evaluations before organisms harbouring modified

gene drives are released into the environment, as well as the possibility of comprehensive risk assessment recommendations. [COP/14/L.31 para 9(a), 10].

The risk assessment approach has a basic framework across nations but varies slightly concerning depth and breadth of study (Claudia *et al*, 2008) . The EU Environmental Risk Assessment approach is one of the most extensive examples. The majority of risk evaluation approaches are relying on two basic components: (1) Assessments of planned and unintentional consequences, including the likelihood and possible importance of the impacts; and (2) Comparison of the changed product with current equivalents (Claudia *et al*, 2008). When analysing prospective consequences, decision-makers may consider information on gene transfer, persistence, and toxicity, as well as possible intended and unforeseen effects on targeted and nontargeted populations, as well as respective socio-cultural implications²⁸.

Legislation may provide provisions for monitoring regulated activity. Multiple authorities in the United States have post-market monitoring power over biotechnology goods. The FDA mandates producers to disclose and conduct market risk analysis and safety assessments on foods, pharmaceuticals and biotechnology goods (NASEM, 2017). The EPA is obligated for re-evaluation of pesticides in every 15 years, but in fact, it has only done so every 5–6 years. Genetically modified organisms that potentially behave as plant pests are possibly deregulated in this case minimal monitoring or supervision is required (NASEM, 2017).

Systems biology, molecular biology, bioinformatics, plant virology and microbial ecology are all areas related to synthetic biology that comes under one umbrella. When conservation is concerned, each product, tool, and technique produced from the fields of synthetic biology needs to be assessed based on the evidence of the negative and positive consequences they are anticipated to have on any particular conservation target. In all circumstances, the evolutionist must thoroughly evaluate the impact of the synthetic biology method on the whole spectrum of conservation goals for all affected species. Only then may well-informed choices be made. Such studies would compile a knowledge base to aid decision-makers in understanding the vast range of synthetic biology applications available, as well as the considerations that should be made concerning their impact on the conservation of biodiversity.

Environmental governance is riddled with scientific ambiguity. The precautionary method, often known as the precautionary principle, is a decision-making technique for dealing with uncertainty (Peterson, 2006; Wiener and Rogers, 2002). According to the Rio Declaration, "when there are concerns of significant or permanent harm, lack of complete scientific knowledge must not be used as a justification for delaying cost-effective steps to avert environmental deterioration." [Principle 15 of the Rio Declaration]

Synthetic biology applications include the risk that is unclear and potentially unratifiable, necessitating the use of the precautionary approach or methodology. There is no agreement on what this entails with respect to regulatory actions. Some supporters of synthetic biology argue that certain or all of the new technologies needs to be free from present GMO regulation, Others say that all methods should be subject to executive monitoring, which might lead to certain procedures being streamlined. (ENSSER, 2017). According to certain social and scientific organisations, the precautionary approach or strategy mandate a "moratorium on the release and commercial usage of synthetic organisms, cells, and tissues." Others contend that a synthetic biology moratorium will damage the field and stifle potentially positive developments, but a more nuanced understanding of the concept that allows for limited, well-regulated risk might assist to manage the conflict between a need for caution about intervention risks and worry about non-intervention hazards (Wareham and Nardini, 2015).

Different methods are used by national regulatory regimes for addressing the extent of application. These techniques are frequently described in terms of "product" or "process" principles. A "product" method means that supervision is triggered by particular qualities of goods that are regarded to be risky, regardless of how they were created, whereas a "process" method means that the goods that are subject to supervision are described by the process by which it was generated (Kuzma, 2016). In practice, productbased regulatory methods frequently rely on process-based distinctions, whereas process approaches frequently evaluate a combination of "product and process" based characteristics (Bergeson, Dolan and Engler, 2015).

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Under the Plant Protection Act (PPA), the Federal Insecticide, Fungicide, and Rodenticide Act, the Toxic Substances Control Act, the Federal Food, Drug, and Cosmetics Act. the United States employs what is commonly referred to as a product approach ((Bergeson, Dolan and Engler, 2015). However, in rare circumstances, authorities may consider procedure while making decisions. Applications for licences to introduce genetically engineered plant pests, for example, need a full explanation of biology of the system at the molecular level (e.g., donor-recipient-vector) that will be employed to create the regulated commodity" [US 7 CFR 340].4] (Keiper and Atanassova, 2020).

Conservation and Sustainable Use of Biodiversity

Synthetic biology offers both potential advantages and drawbacks that might impact resource management and economic growth today and, in the future. The sustainable development is defined as "the development that meets the demands of the present without jeopardising future generations" and ability to satisfy their own needs" (WCED, 1987). It recognises the interdependence of economical and societal growth and environmental protection (Rio Declaration, Principle 4).

Discussing the possible consequences of synthetic biology for biological diversity conservation and sustainable usage requires a review of current policy frameworks and the specific governance difficulties posed by synthetic biologies, such as designed gene drive technology (Kumar, 2012).

Several synthetic biology applications are designed to give a path to achieving sustainable development goals. Such as applications addressing "invasive species" could help to achieve the goals of conservation of terrestrial and marine biodiversity [SDGs 14 and 15], whereas some synthetic biology applications which address vectors that cause diseases in humans such as "mosquitos" help to achieve the goals related to human health and as well as poverty alleviation [SDGs 1 and 3]. Simultaneously, some of the hazards connected with synthetic biology may have a different impact on achieving these aims.

Civil Societies, Conservationists, Synthetic Biologists Under one Umbrella

Now is the moment to assess if synthetic biology is an evil solution, causing its issues, some of them may be undesired or even unacceptable in terms of conservation of biodiversity.

Extinction may not be permanent if synthetic biologists and others scientists follow their proposals to utilise modern genetic-engineering technologies such as genome engineering to preserve endangered species and bring extinct ones back to life (Piaggio *et al*, 2017). This is the most apparent example of a broad collaboration between the synthetic biologist and the biodiversity conservationist that should take place. The broad collaboration between the synthetic biologist and the potential to transform the connection between people and the natural world.

Currently, synthetic biology and the biodiversity conservation have progressed individually. The experts and the scientists that practise them differ not just in apparent aspects, such as scientific practise and training, but also in subtle ways, such as world views, attitudes to risk and uncertainity, and value systems. Despite these contrasts, there is a growing feeling that synthetic biology and conservation will merge, or, as some fear, clash, in the coming years. New approaches to apparently intractable issues using scalable technology provide a slew of new and unexpected obstacles. It is widely acknowledged that an established and active discussion may limit the potential risk of synthetic biology products being created for diverse objectives and maximise their value for nature conservation (Marris and Jefferson, 2013).

Synthetic biology's emergence has sparked debate among conservationists throughout the world, as well as a emerging recognition of the importance of detailed and more significant collaboration between current synthetic biology and conservation organisations (Garfinkel *et al*, 2007).

Many developing-country governments, native leaders, and regional groups have also expressed worry about how synthetic biology emergence may harm their traditions, rights, and livings. The optimism and scepticism around the use of synthetic biology in conservation are concerned because biodiversity loss continues although having the sophisticated framework of conservation science and policy; and the realisation by all levels of government organisations, and the society, that human well-being is dependent on a healthy natural environment.

Decision Making and Regulations

Good governance procedures apply to "decision-making" that affects or may influence wildlife and the natural habitat. "Access to information", "public participation" in decision-making, and "access to justice" are three critical components of good governance procedural rules. (SDG 16; Rio Declaration Principle 10).

Synthetic biology decision-making may jeopardise native peoples and the community's rights to natural resources and culture. The right to manage natural resources and wealth is included in the notion of people's self-determination, which is recognised in the "United Nations Charter", the "International Covenant on Economic", "International Covenant on Civil and Social, and Cultural Rights". (UN Charter art. 55; ICCPR art. 1; ICESCR art. 1).

According to AHTEG, the development of synthetic biology techniques and applications must be complemented by the effective engagement of native peoples and local communities. In 2018, the CBD COP urged Parties and other government organisations to obtain consent or approval, that should be, free, prior informed, as well as the participation of potentially affected indigenous peoples and local communities before implementation of engineered gene drives into the field (COP/14/L.31 para. 9, 11).

The confinement of modified organisms is a crucial issue for the conservation of biological diversity. Existing 'laboratory' and 'field' classifications are ambiguous and may preclude the safety of new and existing species. There is knowledge of invasive species that can be applied to new creatures. It may be feasible to build genetic technology to prevent synthetic creatures from escaping inadvertently. At the same time some applications such as white-nose syndrome or environmental clean-up, necessitate the spread of new species rather than their confinement. In circumstances like these, how might safety considerations be incorporated? (Dudley, 2011).

The significance of public opinions and comprehension cannot be overstated. The degree of public acceptance in synthetic biology solutions for biodiversity conservation will influence the policies, financing, and regulatory frameworks. We must think carefully about how problems, risks and rewards are portrayed in the media, and we should consider cooperation with communication specialists and social scientists to understand and articulate from diverse points of view, as well as to help in developing effective narratives. The majority of media coverage on synthetic biology and biodiversity is currently influenced by sensational headlines of endangerment and extinctions, disregarding the potential benefits of synthetic biology in addressing conservation issues, and largely avoiding the governance, moral, and social issues that required discussions (Novossiolova, 2016).

New cooperative studies between research scholars, civilians, and other sectors of society are required to overcome the information shortages and the differences between how practitioners in the two professions think today. Perhaps properly planned and controlled experimental work might help us to gain a better grasp on the use of synthetic biology for conservational purposes. Such projects might help to strengthen personal and disciplinary bonds, as well as provide ideas for adjusting to a changing climate.

The evolution of synthetic life is underway. The rapid emergence of synthetic life arises several questions such as ; How will synthetic life interact with the natural one, and how well can such interactions anticipate using present ecological knowledge of interspecies interactions? or will they be safe and utilised for repairing damaged or polluted habitats or solving other ecological and environmental problems that have previously proved difficult to solve? Is it possible that the introduction of synthetic organisms into ecosystems would have a beneficial effect? Will they be evaluated as having higher value if they increase the living variety of the ecosystems in which they are embedded, or will they be judged as degraded if they lose their authenticity (Kaebnick, 2011)? Will the "garage biology" regulatory environment be generally approved, or will national governments attempt to build separate regimes, and how will national and international perspectives on the issue be considered (Schmidt, 2010)?

The definition of "natural" as we know it now is no longer valid. Mostly conservation is dependent on preserving ecosystems that have evolved through time via evolution and ecological successions, sometimes revealing intricate webs of interdependence that are difficult to recover if broken. Will the interactions between synthetic organisms/cells with their natural counterpart to be easy to form, or may their very different origins have a big influence on natural communities? What influence would this have on common perceptions of "natural," and the concept of evolution as a process regardless of human creation? Will new technologies, as in other contexts, call into question the ethical concern for conservation ((Kaebnick, 2011)? How will we assess organisms developed through unique nucleotides as a part of their genetic code "xenobiology products"? (Schmidt, 2010.

Conclusion

Several synthetic biology technologies and applications, if properly designed and well addressed, can benefit the conservation of biological diversity. The majority of technological advancements attempts have been taken to eliminate or suppress invasive alien species. To date, no design or technology is ready for field trials or implementation for biodiversity conservation. The field's applicability and effectiveness of proposed synthetic biology technologies are anticipated to face several challenges that will need more study, or may even prove to be insurmountable obstacles for beneficial applications. Any proposed trial designs and field sites should be evaluated based on every different case. Gaining a better understanding of stakeholder interests concerning any potent application and product of synthetic biology for conservation would need social science research and stakeholder interaction. Humanity should bear the responsibility of decreasing the rate of biodiversity loss. Integrated strategies are required for this. It's high time for conservationists to think about the aplications of synthetic biology and other new genetic technologies. Engagement is critical, and should be founded on a set of guiding principles and a solid decision-making framework to comprehend the advantages and drawbacks based on existing and emerging information to maximise biodiversity benefits while minimising biodiversity loss. The conservationists should seek out synthetic biologists, and the two should collaborate on broad discussions with scientists, communities, and regulatory bodies throughout

the world. Our efforts at this critical intersection of biodiversity protection and technology might determine the destiny of nature.

Endnote

¹ Revive & restore. 2013. Http://longnow.org/revive

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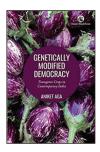
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Book Review

Genetically Modified Democracy – Transgenic Crops in Contemporary India

Author: Aniket Aga Publisher: Orient BlackSwan Year: 2022 ISBN: 978-93-5442-107-5 Pages: 309



Debates and discussions around GM crops in a democracy ought to have contestations with diverse viewpoints from different associated stakeholders, particularly when there are uncertainties and lack of knowledge about its long term impacts and consequences for the environmental and human health. The contestations in different country contexts is being shaped by the institutional contexts, scientific capability, actors involved in its research and development, adoption and implementation, and its governance and the political will to engage with such technologies. Scholars (Hajer, 2003; MacNaghten and Carro-Ripalda, 2015) have talked about 'institutional void' in the governance of agricultural biotechnology as a focus on the risks dimension offers little scope for deliberation and reflection on the social, cultural and institutional dimensions and the purposes of science and innovation. Different frameworks, as a way forward to overcome this deficit in the governance of GM technology, have been put forward by scholars (discussed in MacNaghten and Carro-Ripalda, 2015) such as, responsible innovation which seeks to incorporate and align aspects of values and ethics in the technological innovation discourse focusing on 'governance of innovation' rather than traditional approaches of 'governance of risk' (von Schomberg, 2013); the pathways to sustainability approach positing emphasising on the importance of framing and narratives in analysing dominant pathways to sustainability and opening up alternative and marginalised pathways (STEPS Centre, 2010); and, a culture-sensitive approach viewing technology not merely from an instrumental perspective but embodying distinctive social, political and ethical values and histories (Winner, 1986).

The book Genetically Modified Democracy, authored by Aniket Aga, frames GM (genetically modified) crops as a problem for science and democracy and reflects on the governance of GM technology in the Indian context. The publication building upon the diverse and extensive research and stakeholder engagement exercise undertaken by the author contextualises the issues in GM debate with reference to India with a thickly textured description of its trajectory in a holistic manner. The book is in three parts with two chapters in each part. Part I traces the histories of biotechnology in India as a state led initiative in comparison to the venture capital mode of evolution in the context of the United States. The author has highlighted that the evolution of biotechnology in India that occurred alongside the Green Revolution was marked by conflicts among plant sciences and that the development of this technology since its beginning stayed aloof from agriculture. Examining the institutional development of biotechnology in India with the setting up of Department of Biotechnology in 1986 the author delves into the importance being accorded to the technology at a time when there were no start-ups and universities in the country working in this domain. The administrative separation of biotechnology from agriculture, environment and health, according to the author, laid the foundation for the state being unable to frame long-term policies which in due course gave rise to the GM debate in the 1990s.

Part II focuses on the controversies surrounding GM crop policy making and regulatory aspects. Using the concept of *public* which allows for accommodating coalition of actors to deliberate on issues surrounding technologies, the author locates epistemologies of making claims in the GM debate in two modes of documentation - scientific and legal-administrative and demonstrates how the dynamics between the claims made by these two modes stimulates the regulatory design for GMOs and the significant challenges. The author claims that the regulatory regimes for GM crops offered no space for deliberative discourse on whether to engage with this technology or how best to harness it the agricultural context. The book maps the landscape of anti-GM movements in India and their role in broadening and deepening the battle over GM food and highlight the inherent characteristics of the movement in India. The anchoring of different campaigns against GM crops in India was done on the terrain of regulatory science rather than on the ground of ethics and political economy. A singular and narrow focus on GM crops enabled diverse and antagonistic segments

to come together and thus providing the desired strength and agility to the movement.

The final part of the book provides a grounded perspective into the GM debate highlighting the context and characteristics of agribusiness and farming in India. The book makes an observation that the three industries, viz. agricultural machinery, seeds, and agrochemicals developed separately in India in contrast to the United Stated where chemical companies have horizontally integrated seeds allowing for synergies between the chemicals and the seeds businesses. Looking at the structure of the private agribusiness industry in India, the Indian seed industry has followed a different trajectory from that in the West. Unlike in the United States, the private seed industry in India, owing to the lack of capacity to directly provide farmers with seeds, did not compete with the public sector but looked at capturing value through multiplication and bulk-production of public sector varieties and hybrids. These divergences which are attributed to the historical pathways to innovation and development in the agricultural domain generate friction in terms of opportunities and constraints for domestic and transnational firms. The book further delves into the aspect of farmers' engagement with new technologies via the node of retailer of seeds and agrochemicals with a fieldwork based case study in western Maharashtra. The author designates retailers as 'merchants of knowledge' since farmers rely on them for seeking advice related to farming practices and troubleshooting farming related challenges. The author highlights that the lack of state extension service for providing technical support to the farmers and the knowledge deficit among farmers enables the retailer to push products of his choice. The book attempts to draw reader's attention to the fact that historical trajectories of development and differentiation in agriculture and agribusiness should be taken into account. It reiterates that "the gambles of agriculture are too deep to be resolved by a technological package alone".

The concluding chapter of the book reflecting on the interplay of science and politics calls for broader ways of thinking about science and politics in the context of debate over GM food crops in India. The author states that the Indian case of involving legislature and the judiciary when the parameters of a problems are themselves up for debate, represents an expansion of democratic oversight, and this holds valuable lessons for democratic politics around the world.

This book through its thorough insight into the GM debate in multiple, heterogeneous theaters of action in a democracy spanning legislature, executive, judiciary as well as law, science and collectives and mobilisations, provides an opportunity to reflect on essential features that need to be considered in order to advance more responsible form of agricultural biotechnology governance. As a future-oriented endeavor the emergence of latest advances in biotechnology related tools, such as gene editing and the CRISPR/Cas9 method also raises a set of concerns pertaining to its social and ethical implications as well as the development of suitable regulatory apparatus and framework. There are various challenges posed by the need to reconcile multiple objectives-that of technology development, risk regulation and taking care of socio-economic implications, the scientific uncertainty and the limits in capabilities of the various players. Therefore, a governance framework characterised by increased participation and cooperation between the different players and stakeholders is the need of the hour.

The conclusions and evidence from the book provide insights on how the issues of GM debate need to be looked from the perspective of different actors and at various levels. This also provides important cue into evolving a governance approach which reconciles the need to provide a nurturing environment for the development of the technology and maximise societal benefits, while addressing the risks and socio-economic implications. The framework would, thus, ideally include a range of institutions - research bodies, promotional agencies, planning bodies, nodal ministries, other ministries, regulatory agencies, implementing agencies and actors in the public and private sphere performing different functions. As a way forward in developing a responsible and inclusive governance structure, it is essential to broaden the scope of the government's role from command and control to that of coordination, steering and networking and identify the roles for different actors and stakeholders. This would ensure that such emerging technologies are being engaged and governed in way that square with the public's value.

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- 3. Use 's' in '-ise' '-isation' words; e.g., 'civilise', 'organisation'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'.
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This issue carries four articles, while the first one is on the importance of biofoundaries and strategies needed to harness them, the second one is a case study on Access and Benefit Sharing in Gujarat State, the third explores the evolution of biodiversity policy and science-policy interface in India and the fourth is issues related to synthetic biology and biodiversity, including conservation of biodiversity. A book review is also published in this issue.



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