**India’s submission on synthetic biology in response to CBD Notification No. 86375 dated 16 March, 2017**

**(a) Research, cooperation and activities noted in subparagraphs (a) through (c) in the CBD Notification.**

**(b)      Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention.**

**(c)     Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks.**

In India, synthetic biology is presently being undertaken by only a few research institutes. Further, as synthetic biology itself is in initial stages in India, there is not much activity in terms of industry or investments. Very few industries are venturing into this and these are mostly into R&D. As research itself is in infancy, technology development and transfer is still some time away, though current initiatives in neem and biofuels using synthetic biology offer potential for industrial applications.

There is no firm that offers products based on synthetic biology. Private sector involvement is limited to a few companies working on for example vanilla synthesis, and production of saffron using yeast system.

While data on venture capital in biotechnology is available for the country, there is no data on venture capital in synthetic biology. The lack of any data on synthetic biology could possibly be because presently the area of synthetic biology is quite defused with conventional genetic engineering. It is therefore likely that those working on synthetic biology may be categorising it under some other category.

In view of the above, to be able to conduct research on the benefits and adverse effects of organisms, components and products of synthetic biology on biodiversity, it is necessary to first construct a database landscaping all synthetic biology activities in India.

As a part of the five year planning process that was still very recently (till 2012-2017) being undertaken for the country, the erstwhile Planning body of the government had set up a Task Force on Systems Biology and Synthetic Biology Research needs.

The Task Force while taking into account the situation on synthetic biology in India as well as the global scenario, has acknowledged the potential and gone into the need for promoting synthetic biology along with the challenges ahead. The key applications identified were biofuels, bioremediation, biosensors, food and health. The Task Force recommendations on capacity building have gone beyond conventional approaches by underscoring the need to promote large scale transdisciplinary discourse, giving due importance also to developing human resources and innovative funding options for research. The Task Force report while recognising ethical, legal and social issues in synthetic biology, gives much emphasis on public acceptance, funding research on public discourse and policy issues and addressing biosafety, biosecurity and ethical issues and developing a regulatory framework for synthetic biology.

Although the Task Force had made a strong case for a push, it has not yet come through. As a result, synthetic biology in India continues to be in initial stages, though some initiatives have been launched by departments such as Department of Biotechnology and Department of Scientific and Industrial Research.

Some of the synthetic biology activities that may be directly relevant to the objectives of the Convention and its Protocols include the following:

* Crisper-mediated deletion or insertion, which leads to a product that may impact the objectives of the Convention and its Protocols when released to the environment. Those products which are not intended to be released in the environment should be considered under this topic.
* Genome engineering designed to transmit the trait from one species to another when released in the environment.
* Complex pathway and/or circuits integration, which may lead to changes in the behaviour of the organism and such organism are intended to be released in the environment.
* Applications that are aimed at altering and replacing natural populations (for example, gene drive systems).
* Application of synthetic biology leading to an increased pathogenic potential of organism and risk associated with it when released into the environment.
* Application of synthetic biology leading to enhanced gene flow in the environment.

**(d)** **Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology.**

**(e)      Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology.**

In India, biosafety regulations have been in place since 1989, and are fairly well developed. The Rules notified in 1989 under Environment (Protection) Act, 1986, lay down the rules and procedures for research manufacture, import, use, and release of genetically modified organisms and their products. There are various authorities set up for enforcing the Rules 1989: (a) Recombinant DNA Advisory Committee (RDAC), (b) Institutional Biosafety Committees 21 (IBSCs), (c) Review Committee on Genetic Manipulation (RCGM), and (d) Genetic Engineering Appraisal Committee (GEAC). Further, the Indian Council of Agricultural Research conducts biosecurity evaluation of agricultural products, and the Drug Controller General of India is involved in the biosecurity clearance of medical products. It is also mandatory to establish State Biosafety Coordination Committees (SBCCs) and District Level Committees (DLCs), to supervise compliance of statutory biosafety requirements. This current biosafety regulatory framework may be applicable for synthetic biology research and applications as well. There may however be a need to look at the linkages between risk and potential consequences of this emerging technology for environment and health, while also keeping in mind the provisions in relevant international agreements including CBD and its protocols.

**(f) Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology.**

The Preamble of the Convention recognizes the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components. Many indigenous peoples and local communities with long attachment to their traditional territories (lands and waters) are living proof of lifestyles in harmony with nature. At the same time these communities have shaped and often enhanced biodiversity, ecosystems and land and seascapes to create enduring and resilient biocultural systems.

In the context of the above, with a view to gain knowledge, experience and perspectives of indigenous peoples and local communities in understanding of the potential benefits and adverse effects of synthetic biology, the indigenous peoples and local communities may be involved in deliberations relating to synthetic biology.

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