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Synthetic Biology in India: Issues in Risk, Power and Governance*

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Abstract: Synthetic biology is an emerging technology that can facilitate 'design' and 'creation' of micro-organisms which may not be found in nature. Synthetic biology is considered as an amalgamation of principles of engineering and biology. Globally synthetic biology has advanced rapidly in the last decade; however, in India it is in nascent stages. In this discussion paper, the status of synthetic biology in India and debates in India on synthetic biology are discussed and the discourses on synthetic biology in India are also analysed. While synthetic biology is yet to get a big push in India, initiatives on biofuels and setting up of research centers indicate that it can grow rapidly in India. The Task Force set up by the Planning Commission examined the various issues including regulatory issues and suggested a way forward for synthetic biology in India. The concerns about dual use, absence of governance structures and need for regulation are not unique to India. Given the potential of synthetic biology in biomedicine, agriculture, energy and other sectors it is important that synthetic biology gets the priority it deserves. The paper also examines the potential pathways for synthetic biology in India and points out that adequate support in terms of funding and addressing regulatory, ethical, legal and social issues is necessary to reap the benefits of synthetic biology.

Keywords: Synthetic biology, genetic engineering, dual use, twelfth five year plan, governance, intellectual property rights, risk discourse

1. Synthetic Biology: Trends and Issues

Synthetic biology can be considered as an emerging technology, an amalgamation of the principles of engineering and biology. The core engineering principles invoked in synthetic biology are *abstraction, modularity, standardisation and quantification* (Schyfter *et al.* 2013).

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It is a platform technology that has wide applications. Synthetic biology is different from genetic engineering and other approaches of genetic modification. Thanks to the genome mapping exercises, developments in bioinformatics and falling costs of genetic sequencing and annotation scientists are now in a better position to understand the finer aspects of the genetic code. Synthetic biology builds upon on this and brings in an engineering approach to biology.

The global trends and developments indicate that synthetic biology is making headway and the US and Europe are leading while China is taking major initiatives in synthetic biology. Medicine is an important area of R&D among biological system designers/ manufacturers conducting research in synthetic biology. Home and personal care products are a priority in specialty/fine chemical applications globally and biofuels are key topics of research among the applied R&D groups. Projected value of global synthetic biology market by end user is expected to be US$ 10838.6 million in 2016 of which diagnostics/pharmaceuticals will be US$ 5373.3 (Clarke 2013).

While the potential of synthetic biology has been acknowledged widely in the UK and US, others are also moving ahead with specific plans and goals in synthetic biology (National Academy of Engineering and National Research Council 2013). Interestingly, the concept of Responsible Innovation is being integrated into synthetic biology research in the UK and the National Roadmap calls for 'responsible acceleration' of technologies to market while the Technology Strategy Board of the UK is requesting that applicants should apprise of potential social, ethical, legal, regulatory and environmental issues. It has developed a Responsible Innovation Framework for assessing applications of synthetic biology. Synthetic biology is also seen as important for solving global health problems. For example, the call for proposals by Gates Foundation attracted more than 700 applications and developing novel diagnostics, biosensors, and vaccines using synthetic biology were specified by many applicants (Rooke 2013). In the South Asian context, the multivalent oral vaccines developed using

synthetic biology could drastically reduce deaths in children under five years on account of diarrhoea (Vohra and Blakely 2013). There are many challenges in applying synthetic biology to solve global health problems, and this includes issues in regulation, intellectual property, and commercialisation (Douglas and Stemerding 2013). Recently, a sociologist cautioned against over-optimistic projection of benefits of synthetic biology (Marris 2013). The Inter Academy Panel – a global network of science academies – has acknowledged the potential of synthetic biology and suggested that "we must collectively ensure that policy development worldwide is sufficiently flexible to encourage research and manage innovation, including those applications not yet envisaged, while suggesting sensible practices to mitigate any risks" (IAP 2014). From a public policy perspective the important issues to be addressed are: R&D investment and commercialisation, biosecurity and biosafety, public perception, capacity building and regulation (OECD 2014). Many of them are receiving attention at different levels; for example, the Convention on Biodiversity is addressing issues related to impacts of synthetic biology on biodiversity and genetic resources. Governance and regulation of synthetic biology has been discussed in many reports.[1]

As synthetic biology enables creation of novel organisms with features not present in natural organisms and as these are very different from typical genetically modified organisms, biosecurity and biosafety issues have major ramifications for Biological Weapons Convention. Given the nature of this technology, it is obvious that while national efforts are important, global initiatives in governance and regulation are equally important. As synthetic biology differs from genomics and biotechnology in many ways, regulatory regimes for synthetic biology have to be different although lessons learnt from biotechnology regulation are relevant. Since synthetic biology is an emerging technology how to promote and incentivise R&D in synthetic biology is an important issue and some of the governments are promoting it through explicit programmes and by identifying priorities. Intellectual property rights in synthetic

biology is emerging as an important issue and broadly speaking, there are two trends; while one is steering towards patenting, and the other is in favour of using open source and common approaches instead of relying on patents (Nelson 2014). However, the reality is more complex and IPR developments in synthetic biology cannot be simply classified into two approaches and standardisation is emerging as an important issue (Minssen and Wested 2013).

Do It Yourself (DIY) communities are playing an important role in innovating novel and cheap alternatives and are trying to develop socially useful and affordable applications from synthetic biology (Landrain *et al.* 2013). Although synthetic biology is in initial stage and much has not been done in terms of commercialisation, it is gaining increasing attention because of the potentials and the opportunities it creates in solving some important problems. For developed nations investing in synthetic biology is important to keep up their position in S&T and to help their industries in maintaining the competitive edge. But developing countries have to consider synthetic biology as an emerging technology with immense potential and give more importance to capacity building. The S&T policy and strategy thus have to build upon the available capacity in biotechnology and facilitate inter-disciplinary R&D so that they can utilise synthetic biology. Further, it is also important that they address issues in technology governance and respond to global developments in governance of synthetic biology so that their response is adequate and can address issues in biosecurity and biosafety.

Many countries are promoting synthetic biology and have adopted different approaches in funding, promotion and regulation. Among developing countries China and South Korea are emerging as important players in synthetic biology. In some countries, like the UK and the US, road maps have been prepared to identify potential pathways of the technology and its trajectories. In case of Europe, a road map was prepared through an EU Project and this road map was published in 2009. In April 2014, ERASynBio, a project supported

by the European Commission, published a report on a strategy for Synthetic Biology in Europe. This report suggested the following as key recommendations: (1) Invest in innovative, transnational and networked synthetic biology research. (2) Develop and implement synthetic biology in a responsible and inclusive manner. (3) Build a networked, multidisciplinary and transnational research and policy making community. (4) Support the future of synthetic biology by providing a skilled, creative and interconnected workforce. (5) Utilise open, cutting-edge data and underpinning technologies (ERASynBio 2014).

In France the Stratégie Nationale de Recherche et d'Innovation (SNRI) published the French National Research and Innovation Strategy, outlined by the Ministry of Higher Education and Research and defined synthetic biology as a priority challenge. While subsequent reports have outlined the challenges before developing synthetic biology, France has established an Observatory for Synthetic Biology and the idea of Responsible Innovation has had its impacts on debates on Synthetic Biology in France (Meyer 2013).

China has drawn an ambitious road map for synthetic biology and through research projects it is enhancing its capacity. The targets in the road map are set over 5, 10 and 20 years. It is envisaged that by the final stage China would have the capacity to integrate technology platforms for designing, modelling and validation of biosystems. As there are not many private players, the Chinese Government is taking major steps. In 2008, a dedicated research funding scheme was proposed but it has been delayed (OECD 2014). In case of the UK, the road maps in synthetic biology are linked with development of bio-economy and maintaining the leading edge. The map draws a plan for synthetic biology till 2030. In case of the US, many initiatives in universities like Berkeley, Stanford, Harvard and MIT are related to synthetic biology and the Synthetic Biology Engineering Research Center (SynBERC) sponsored by the National Science Foundation, have integrated research on ethical and legal issues with its scientific

and technology work. The Department of Energy is a major sponsor of research in synthetic biology.

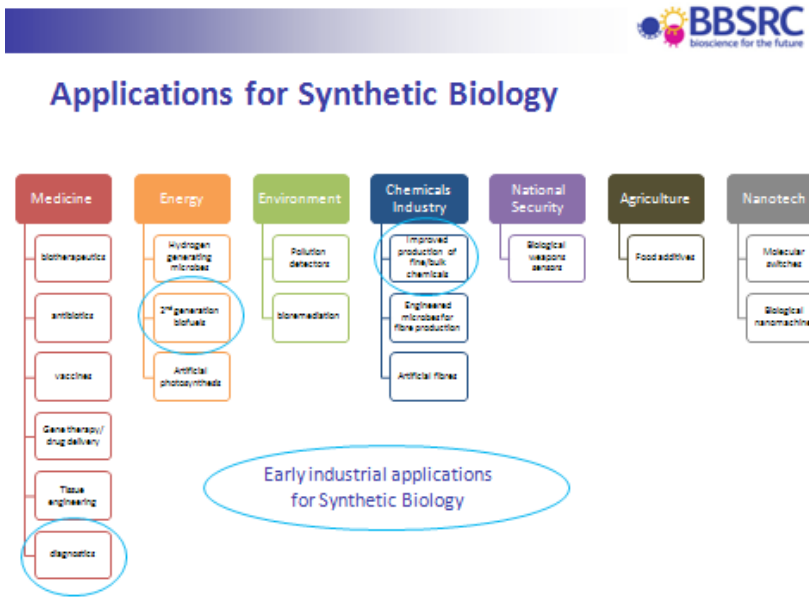
As in the case of other emerging technologies the US and Europe are leading in basic and applied research in synthetic biology. Although not all countries have come out with road maps and plans, it is becoming clear that countries will continue to invest in this technology, building upon their expertise in biotechnology and related fields.

2. Major Applications of Synthetic Biology

A much cited definition given by Royal Academy of Engineering states: "Synthetic Biology aims to design and engineer biologically-based parts, novel devices and systems as well as redesigning existing, natural biological systems" (Royal Academy of Engineering 2009). De Lorenzo and Danchin (2008) describe synthetic biology as an ''inclusive theoretical and technical framework in which to approach biological systems with the conceptual tools and language imported from electrical circuitry and mechanical manufacturing'' to pursue ''the rational combination of standardised biological parts that are decoupled from their natural context''. Figure 1 lists the major applications for synthetic biology.

In industrial biotechnology synthetic biology is expected to contribute significantly in the chemical and energy sectors, particularly in biofuels. Using synthetic biology and metabolic engineering for production of industrial materials like bio-isoprene is expected to result in cost savings and shorter innovation cycle in R&D and production. In case of biofuels, producing alagal biofuels through synthetic biology is considered as a major application. However, as of now most of the work in this area is in R&D stage and commercialisation is yet to take place. Yet this area has attracted much attention from private sector and governments as it could provide an alternative route in production of petroleum based products. In environmental applications, the synthetic biology is likely to play an important role in bioremediation and in

Figure 1: Major Applications for Synthetic Biology



Source: Boyce (2012).

environmental sensing. For example, it can result in better biosensors that can detect toxics like arsenic in water. Such applications are important for developing countries. In health and medical applications, it is estimated that synthetic biology will play an important role in drug discovery and development of vaccines, and diagnostic kits. Although examples like production of Artemissinin and taxol have been cited in the literature, they have not been commercialised. In case of agriculture, synthetic biology is likely to result in technologies that would enhance efficiency and productivity besides being useful in developing varieties that are resistant to diseases, resistant to drought and abiotic stresses and crops that would require less fertiliser and pesticide (OECD 2014). At the same time these developments also raise questions about governance. For example, synthetic biology based biosensors have the potential for use in medical diagnostics but issues relating biosafety have to be addressed while standardisation of parts and their safety has implications for commercialisation (Bhatia and Chugh 2013).

Thus, it is possible to use synthetic biology to address some of the major challenges like climate change, environmental protection and enhancing agricultural productivity besides improving health through cheaper diagnostic kits. However, to what extent the potential will be realised depends on many factors. But there are many challenges in this, and, scientific and technical challenges are significant. For example, in a review article on Synthetic Biology Way *et al.* (2014) point out the major challenges in translating current approaches to solving problems through synthetic biology.

3. Synthetic Biology in India

Synthetic biology in India is largely confined to few institutes and groups when compared tothe number of institutes and groups working in life sciences and biotechnology. Given the interdisciplinary nature of synthetic biology, it could be expected that India would have some centers specialising in synthetic biology or interdisciplinary groups working in it across institutes. But this has not happened. At present, there is only one center that calls itself as Center for Systems and Synthetic Biology, based in University of Kerala, Trivandrum. The special interest Group on Synthetic Biology in India, Synjeevani is based at Jawaharlal Nehru University, New Delhi. There are individual scientists and groups working on different aspects of synthetic biology in some institutes including the Indian Institutes of Technology (IITs), National Centre for Biological Sciences (NCBS), Council of Scientific and Industrial Research (CSIR) laboratories and Central Universities like Jawaharlal Nehru University. For promoting India-Finland joint research in synthetic biology, the Department of Biotechnology (DBT) had called for proposals for this.

In terms of synthetic biology industry not much is happening except for a few dedicated firms that are venturing into this; the reasons for this are obvious. Although the commercial potential of synthetic biology is much discussed in the literature even in the US, the number of firms that have succeeded in synthetic biology is limited so far. In case of India, as the research itself is in infancy

technology development, transfer to industry or setting up an industry based on the research in laboratories will take time. But there is scope for companies specialising in niche areas; hence India may witness birth of small firms working in niche areas in synthetic biology in years to come. On the other hand, some of the current initiatives in neem and biofuels using synthetic biology offer much potential for industrial applications. Bioenergy constitute the thrust area in synthetic biology and a large number of groups are working in this area. The following are some of the groups/initiatives in this area: Department of Biotechnolgy-Institute of Chemical Technology (DBT-ICT), Center for Energy BioSciences at ICT Mumbai; synthesis of Drop-In Biofuels: synthesising pathways for production of higher alcohols, fatty acids and hydrocarbons in E. coli and yeast; synthesis of aminoacids, biobutanol; synthesis of furanics from biomass; Indian Oil Corporation's R&D Center at Faridabad, supported by the DBT; Metabolic Engineering of E.coli for biobutanol; Metabolic Engineering of Saccharomyces cerevisiae for co-fermentation of glucose and xylose; Madurai-Kamaraj University Group led by Dr. P. Gunasekaran working on Levansucrase mutant of Z.mobilis for ethanol production; Osmania University, Hyderabad Group led by Dr. Chand Basha working in ethanol fermentation using bioresources including rice straw; and research is being done on engineering microbes for sugar fermentation, consolidated bioprocessing, butanol production and hydrocarbon production; and engineering algae for growth improvement and lipid improvement at the International Centre for Genetic Engineering and Biotechnology (ICGEB) in New Delhi. Regarding bilateral collaboration, the DBT and Academy of Finland have jointly launched a programme, *viz.* FINSynBio to promote India-Finland research in synthetic biology.

As synthetic biology itself is in initial stages in India, there is not much activity in terms of industry or investments. The number of firms working in synthetic biology is less than ten and almost all of them are in R&D or offering services. Thus, there is no firm that offers products based on synthetic biology. The private sector

involvement is limited to a few companies like Evolvo Biotech (P) Ltd. and Sea6 Company. The former is working on vanilla synthesis and production of saffron using yeast system while the latter is developing technology to convert seaweeds to biofuels (Singh and Dhar 2013). Sea6 entered into an agreement with Novozymes regarding converting seaweed carbohydrates into sugar. It seems to have applied for patents in synthetic biology. Suryakiran Bioinformatics based in Tiruvanathapuram, Kerala is developing synthetic biology applications using bioinformatics.

As part of the Twelfth Five Year (2012-2017) Plan a Task Force on Synthetic Biology and Systems Biology Resource Network was constituted. The Task Force lists only a few firms including Cell Works.

While data on venture capital in biotechnology is available, there is no data on venture capital in synthetic biology in India. Another issue in data relating to synthetic biology is that of classification. It is likely that even those working in synthetic biology may not be categorising it under that category. For example, the R&D in biofuels in synthetic biology can be categorised under other categories including metabolic engineering. Similarly, the process related R&D can be categorised as research on bioenergy than as research in synthetic biology.

In terms of publications, it is estimated that publications in synthetic biology from India are less than thirty. One reason is that the number of institutions working in this area is very limited, a fact that is acknowledged by a study done by Woodrow Wilson Center (2013). It points out that in Asia, Japan and China lead in synthetic biology with 15 and 11 entities, respectively. A study on citation landscape puts India in the 16th place (Oldham, Burton and Hall 2012).

As mentioned above, in the context of Twelfth Five Year Plan a Task Force on Systems Biology and Synthetic Biology Research Needs was set up. This perhaps is the first group that has gone into

the need for promoting synthetic biology in India and the challenges ahead in developing synthetic biology in India. The Task Force took into account the situation in India as well as the global scenario and proposed a way forward for systems biology and synthetic biology in India (Planning Commission 2012). The Task Force argued that the timing is ripe for a well supported 'push' into synthetic biology in India. The immediate goal should be to build a base of research expertise and infrastructure. The human resources potential is untapped and a competition like iGEM may be relevant in India. The broad undergraduate education over narrow technical training related to synthetic biology should be prioritised. Similarly, broad based engineering curriculum that helps students to maintain their basic engineering and quantitative skills and exposure to new directions in biology is important. India should use open source biological platforms so that the legal environment is conducive to the growth of small biotechnology players. This route can be helpful in creating desired niches. With many recommendations to augment the capacity in synthetic biology, the Task Force suggested a budget of Rs. 1970 crore in the Twelfth Five Year Plan period (2012-2017) and envisaged that the CSIR, which as champion of synthetic biology will give specific shape to this and direct this.

The Task Force identified biofuels, bioremediation, biosensors, food and health as key applications for systems and synthetic biology and identified synthetic biology to play an important role in solving problems in this sector. It rightly identified the technological issues in synthetic biology (moving beyond individual cells, moving beyond small groups of genes through genome scale engineering and moving beyond predictive design cycles by selecting and evolving synthetic constructs). The Task Force took the position that India is fully capable of applying synthetic biology and suggested that it needed a push. It identified the following as immediate goals: (1) increasing the number of synthetic biology groups and consortia at research institutes and universities; (2) supporting the growth of enabling technologies and platforms including whole-genome techniques; and (3) nurturing

a new generation of students with strong basic skills in sciences, engineering, computation and mathematics and engaged in bio-engineering. The Task Force notes that while Indian participation in iGEM has been increasing it is not adequate and points out that in 2011 only four teams were from India. The Task Force invokes innovation discourse but tempers it with public acceptance and cautions against naïve optimism about the outcomes of technological innovations. It correctly points out that too much emphasis on biofuels puts food crops against fuel crops, although alternative approaches such as using algae and cynobacteria will be useful in overcoming this issue. This has implications for food security.

Although the Task Force does not mention Responsible Research and Innovation, it takes an important position on public acceptance and transparency. The Task Force's recommendations on capacity building underscore the need to promote large scale transdisciplinary discourse. The recommendations it has made on capacity building indicate that it has gone beyond conventional approaches and is sensitive to emerging trends. It has suggested setting up new institutions in both physical and virtual mode. It suggests enabling open innovation and crowd source approaches to problem handling, and, participatory technology development with industry. It gives importance to development of human resources. Regarding innovative funding options, it suggested tax holidays to promote research, providing seed money for research, fast track funding for researchers, and funds for research and public discourse on various policy issues.

In the report innovation discourse and risk discourse are linked by its perception that for realising the potential of synthetic biology emphasis on benefits and its application in solving problems in different sectors alone are not sufficient. Rather public acceptance, funding research on public discourse and policy issues and addressing biosafety, bio-security and ethical issues and developing a regulatory framework for synthetic biology are equally important. The Task Force does not mention anticipatory governance of technology, nor

elaborates public engagement in synthetic biology but its emphasis on ethical, social and legal issues which indicates that it is willing to take broad view on promoting and regulating technology. It recognises that these issues have to be addressed upfront instead of focusing on technological development alone as the top most priority. Even as it discusses the importance of innovation, it cautions against placing too much emphasis on biofuels and thereby its sensitivity to dilemmas in applying technologies is made evident. It is important to note that given its mandate the Task Force has considered these to be important and it indicates the growing awareness among scientists and policymakers on these issues, although it may not be reflected uniformly in all official reports and plans.

The innovation discourse of the Task Force recognises the changing profile of biotechnology industry in India, particularly in health biotechnology. It specifies the leveraging of industries through systems and synthetic biology in different sectors. The report points out that India missed the bus in genomics and should not repeat it in systems and synthetic biology. With that objective in view it has proposed many initiatives and has made suggestions on various aspects including capacity building.

To sum up, the Task Force Report, though brief, recognises the ethical, legal and social issues in synthetic biology without elaborately discussing them. It gives them the importance they deserve. Though the innovation discourse and the power of the technology are the dominant discourses in the report, they are tempered by risk discourse and due attention that needs to be given to socio-economic issues. Hence, this report can be read as a document that strikes a balance between the discourses with emphasis on synthetic biology meeting the developmental needs of India. Although the task force made a strong case for giving a push and also came out with specific plans for capacity building and detailed estimates for various activities in the Twelfth Plan period, the push it favoured did not come through. Instead the outcome has been a fragmented approach to synthetic

biology by different agencies and hence there is no central plan or mission that is devoted to synthetic biology. Instead different departments and agencies are going ahead with their respective plans in synthetic biology, with emphasis on building upon earlier initiatives in synthetic biology. In the absence of a single document from these agencies and departments devoted to synthetic biology, it is not possible to identify the discourses in them. As there is no big push or coordinating agency on synthetic biology, development of a coherent regulatory framework or addressing of ethical, legal and social (ELS) issues uniformly may not happen. Instead each agency and department is likely to address them on its own.

As part of the planning process for Twelfth Five Year Plan (2012-2017) a working group of the Department of Biotechnology (DBT) was established to identify the thrust areas and for allocation of resources in biotechnology. The Working Group of DBT for Twelfth Plan identified using synthetic biology for developing next generation biofuels as an important application and suggested including this under various programmes such as Grand Challenge Programme and translational research projects. Although the Group recognised the importance of synthetic biology under different applications, programmes and initiatives, it did not suggest any specific initiative or project with the sole focus on synthetic biology. In other words, synthetic biology was considered as one of the key technologies that could be applied across and used in different programmes cutting across various projects being undertaken by the DBT for different objectives ranging from capacity building to promoting enterprises in biotechnology.

Under the major new initiatives of the DBT in the Twelfth Plan, Synthetic Biology and Metabolic Engineering are listed as such initiativies and according to the DBT, "Synthetic biology thus in many ways can be said to be the science of the future of energy and material industry, besides making important contributions in healthcare. Most chemicals and fuels in not very distant future will be result of advances in synthetic biology". However, it does not elaborate any

specific initiative in health biotechnology using synthetic biology. As indicated earlier, major focus is on energy bioscience and under this the scope for synthetic biology is obvious.

The Department of Scientific and Industrial Research (DSIR) plan for the Twelfth Five Year Plan emphasised its ongoing work in synthetic biology, metabolic engineering in Azadirachtin (neem) and Vinca alkaloid biosynthetic pathways and recommended developing this further. The Twelfth plan document proposes, "Biosciences with chemical sciences and synthetic biology for next-generation biofuels" as examples of proposed connectivity under inter-disciplinary translational research.

According to the Twelfth Five Year Plan, the following initiatives will be made during the plan period: (1) Under the Department of Biotechnology as part of the the initiative on 'connecting and augmenting existing competences across institutions and universities for bio-economy and social impact', biosciences with chemical sciences and synthetic biology for next-generation biofuels will be supported. (2) In the proposal to establish DBT Grant-in-Aid or partnership research and translational centres through long-term support in 10 best universities/institutions in at least 10 areas of interest, chemical biology and synthetic biology have been included. (3) Similarly, in translational and strategic research in which about 50 projects/networks are to be launched, projects/networks in synthetic biology will be included. (4) The Council of Scientific & Industrial Research (CSIR) Institute of Synthetic and Systems Biology is to be established. The Department of Scientific and Industrial Research (DSIR) document for the Twelfth plan estimates the budget for this as Rs. 800 crore.

These are initiatives launched under the respective departments/ CSIR and there is no proposal to establish a mission type programme in synthetic biology. The focus is more on biofuels and other application oriented research while projects in health sector on synthetic biology

are not mentioned in the Twelfth Five Year Plan Document. As there is no separate programme on synthetic biology that integrates various projects under different ministries and agencies, it is difficult to get exact information on the proposed activities in synthetic biology in India. The report of the DBT working group is focused more on innovation and potential of technology, i.e. biotechnology and synthetic biology is situated within this context. It neither recognises the challenges posed by synthetic biology in terms of biosafety, biosecurity and ethical issues, nor does it give a special consideration in regulatory issues. This reflects a business as usual approach and synthetic biology is considered as yet another technology/application within the broad field of biotechnology. Since the Working Group's Report does not even give much importance to ELS and regulatory issues in biotechnology or for that matter on public perception and public engagement with biotechnology, the absence of any discussion on synthetic biology and the ELS issues is not surprising. Even in biotechnology the report's orientation is more towards educating the public on biotechnology and on communication than on public engagement with technology or public participation in technology assessment.

The innovation discourse in synthetic biology is a dominant discourse and even within that the priorities are more towards applications related to synthetic biofuels. The innovation discourse, as evident in the Task Force Report and DBT working group, stresses the need to harness the potential of synthetic biology although neither offers a road map to achieve this objective. Nor the linkages between the National Innovation System in biosciences and life sciences in India, and the biotechnology industry and synthetic biology are identified and mapped by them. In that sense the discourse lacks a focused strategy and as the number of actors is limited the discourse is yet to be debated or challenged by others. While the global discourse on innovation is expanding and is backed by strategies in some countries in India the discourse on innovation is yet to reach the critical mass to spur interventions in the policy making. Thus, it

can be concluded that while this is the dominant discourse it has not yet emerged as a powerful discourse that could impact the policy making and regulation.

It is obvious that synthetic biology in India is very much in the initial stages. The synthetic biology community in India is small and is based on few institutes. Given the fact that India has a dynamic biotechnology industry and lot of research and teaching activities are happening in biotechnology in India the situation is ripe for growth of synthetic biology. But this is not happening on account of many factors. Some of these are: (1) Synthetic biology needs interdisciplinary approach and such a milieu may not be available in institutions. (2) Absence of a push from the government in terms of mission mode in supporting synthetic biology or support through special programmes in synthetic biology could be a factor. (3) The technology itself is evolving and is yet to reach the stage in which its utility has been proven and products have been developed and accepted by public. (4) Narrow focus of departments and agencies is not conducive to development of a broad inter-disciplinary approach. (5) There is lack of sufficient number of engineers trained in biosciences and bioscientists working on applying engineering approaches in biology. This does not mean that synthetic biology will remain at the current level. The possible pathways are:

1. Synthetic biology gets more support from government on account of international developments resulting in a specific mission on synthetic biology or special projects in synthetic biology supported by departments and agencies with one agency/department coordinating it. The research on biofuels results in significant breakthroughs and thereby synthetic biology gains acceptability and this results in more attention and funding.
2. Synthetic biology may continue to grow at slow speed with few groups spread across institutes working on various issues. Some applications (e.g. biofuels) get more support,

industry funding and gain prominence while research in other areas languishes for want of support.

3. Synthetic biology gathers momentum through various means including Indian participation in iGEM, funding from major international agencies in health R&D and broad support from the DBT, without resulting in spectacular growth.
4. International developments adversely impact growth of synthetic biology in the world and this affects synthetic biology in India also.

Synthetic biology in India lacks a strong champion who could convince the government about its importance and secure funding for it. In case of nanotechnology mission there was funding even before the founding of Nanotechnology Mission was possible because some scientists including Prof. C.N.R. Rao played an important role in convincing the government. The origins of DBT can be traced to similar initiative taken by Prof. P.M. Bhargva. In case of synthetic biology, if a prominent scientist or policy maker supports it and pushes for it, it might get the much needed big push from the government. A well thought out regulatory regime should be developed so that when synthetic biology makes rapid strides in India issues related to regulation do not result in unsavory controversies and litigations. Incorporating sustainability considerations in developing synthetic biology is necessary (Wiek *et al.* 2012).

In a recent article G. Padmanaban (2014), an eminent scientist has suggested that interdisciplinary research teams and a new institute for synthetic biology should be set up so that India does not miss the boat in this emerging technology. He has pointed out that Indian participation in iGEM is low when compared with other countries.

But as synthetic biology is an inter-disciplinary techno-science, capacity in more than one discipline and building teams that could work on such projects is important. One of the scientists working in synthetic biology in India pointed out that more than infrastructure

and budgetary allocations the capacity of institutions to foster such research and building teams of scientists from different disciplines to work in a project will be the determining factor in applying synthetic biology successfully (interview conducted in 2013).

Over the last two decades India has built up good capacity in biotechnology. This has happened because of funding from the Government of India and has also helped in the growth of a vibrant industry in agri-biotech and health biotech sectors. India has many research centers doing cutting edge work in biotechnology and life sciences. India's expertise in bioinformatics and information and communications technology (ICT) field is globally recognised. Besides a strong industry that has global skills, there are many research centers that are working on bioinformatics and companies like Strand Genomics have been built upon the linkages between academics and industry. These two, i.e. capacity in biotechnology and bioinformatics combined with ICT, should be used to build synthetic biology in India. Some of the proposed initiatives like the CSIR Center on Synthetic Biology are necessary but not sufficient, given the rapid pace with which the field is growing. Hence, there is a need to develop a strong programme in synthetic biology so that during the Twelfth Five Year Plan a firm foundation would be laid. It is suggested that the DBT can first create exclusive initiative on synthetic biology to assess the field and develop a strategic plan. Based on that, later a separate entity which could be a Technology Mission or Special Programme can be set up.

Since synthetic biology is an emerging technology supporting it through venture capital is important. The DBT can envisage special programmes to facilitate academic-industry partnerships in synthetic biology. To sum up, India should capitalise on its strengths in biotechnology to give synthetic biology a push and combine the capacities in biotechnology and ICT to take the emerging technology forward. At a later stage a Mission on Synthetic Biology can be established with specific goals. As the current level of activity in

synthetic biology in India is limited, it is difficult to identify dominant discourses and the values. Still one can state that innovation discourse is the main discourse and as the technology is yet to be supported in a major way in terms of funding or through a Mission on synthetic biology, power and control discourse is yet to emerge strongly. The discourse now is largely driven by a few scientists, who are working in this field, while official bodies have recognised the potential of this technology. There is awareness, although limited, on socio-ethical issues including regulation and biosafety.

Developing a road map for Synthetic Biology (e.g., a road map for Synthetic Biology in India till 2030) can give a fillip to this technology in India. Such a road map can be prepared by a group with representatives from stakeholders and can identify potential areas for prioritisation and suggest steps to realise the potential in India.

4. Synthetic Biology in India – Risk, Power and Governance

Krishnan *et al.* (2010) point out that most scientists working in synthetic biology in India are of the view that the Government of India should devise a new policy that covers, *inter alia*, biosafety and biosecurity issues emerging from research in synthetic biology. Although it is acknowledged that biosafety regulations in India are well developed and research using biotechnology is regulated, the need for taking into account developments in synthetic biology for revising and updating the regulations and guidelines is also voiced, particularly in the context of dual use research. India has an elaborate system for biosafety in research and applications of living modified organisms and for regulating research from a biosafety perspective as part of the biotechnology regulatory framework. The rules of 1989 of Environment (Protection) Act 1986 lay down the rules and procedures for manufacture, import, use, research and release of genetically engineered organisms and their products. At the national level there are four authorities for enforcing the rules of 1989: (a) Recombinant DNA Advisory Committee (RDAC), (b) Institutional Biosafety Committees

(IBSCs), (c) Review Committee on Genetic Manipulation (RCGM), and (d) Genetic Engineering Approval Committee (GEAC).

Of these, the RDAC and the RCGM are under the Department of Biotechnology and the GEAC is with the Ministry of Environment and Forests. All the Committees have representatives from stakeholders and the scientific community. The RDAC reviews national and international developments in biotechnology to advise the government on policy imperatives. At the level of institutions engaged in research and/or activities that are governed by the rules of 1989 it is mandatory to have an IBSC. In fact, the IBSC is the first level regulator and monitor of biosafety. IBSCs are mandated to follow 'Recombinant DNA Safety Guidelines, 1990' and the 'Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998'.

The RCGM is empowered to give biosecurity clearance on the recommendation of the ISBC. The Indian Council of Agricultural Research conducts biosecurity evaluation of agricultural products and the Drug Controller General of India being the Central Drug Regulatory Authority is involved in the biosecurity clearance of medical products. Further, it is mandatory to establish State Biosafety Coordination Committees (SBCCs) and District Level Committees (DLCs), to supervise compliance of statutory biosafety requirements. Thus, the current regulatory framework is applicable for synthetic biology research and applications. Given the India's vast network of institutions and industry dealing with modern biotechnology it is time to review the regulations taking into account developments like synthetic biology and concerns regarding Dual Use Research.

An important concern regarding using synthetic biology is the issue of dual use and applying synthetic biology to develop potentially dangerous/toxic life organisms. Another issue is that of biosafety and implementing rules to prevent accidental release/escape and protection

of human health and environment. According to Dhar (2013), although synthetic biology community in India is small and is operating within a reasonable regulatory environment, the regulatory framework can be further strengthened. Reviewing the global trends and initiatives in Europe, the US and China, Jain *et al.* (2013) pointed out that given the potential commercial prospects India should develop legislation and policies to regulate synthetic biology. India has initiated steps to evolve Code of Conduct for Scientists who might be engaged in Dual Use Research or research that would be directly relevant for provisions of Biological and Toxin Weapons Convention (BTWC).[2]

As mentioned earlier, the Planning Commission Task Force identified bio-security, bio-safety and ethical issues which need to be addressed. It pointed out that biohackers can misuse synthetic biology and there is also the threat of unintentional release of synthetic habitats to natural habitats which can cause adverse consequences to environment and human health. With reference to regulatory framework it pointed out the need to develop it in conjunction with international agreements like Trade Related Intellectual Property Rights Agreement (TRIPS), Cartagena Protocol on Biosafety (CPB) and Convention on Biological Diversity (CBD), etc.

The risk discourse, as evident in the Task Force Report, reflects broadly the concerns expressed about synthetic biology and the need for effective regulation. The Report devotes hardly a page to this but manages to map the issues and underscores the issues in safe and efficient promotion of synthetic biology. The very fact that it looks beyond a typical lab oriented biosafety perspective and understands the relevance of international agreements in developing a regulatory framework indicates that the Task Force is well aware of the complexity in developing a regulatory regime. Similarly, it acknowledges that synthetic biology raises important moral and ethical concerns.

The risk discourse spelt out by the Task Force neither exaggerates the issues of risk nor reduces them as scientific and technical issues to

be resolved by experts alone. Its recognition that interfering life in its natural form is opposed by some stakeholders indicates its sensitivity to such opposition. Although it does not elaborate steps to address these issues, it does underscore the fact these are global concerns that need to be addressed.

The risk discourse in India emerges primarily out of the concern for enhancing the regulations to match the global standards in regulating, particularly the biosafety aspects in synthetic biology. The Task Force rightly points out linkages between risk and potential consequences for environment and health. India's policy on these issues and using synthetic biology is yet to crystallise in terms of national strategy or action plan for synthetic biology. Although risk discourse is visible and some of the concerns are widely shared, it has not made much impact on policy making or on revising the regulatory framework.

Synthetic biology is often associated with Playing God image or with a technology that could result in un-natural and novel organisms that could go out of control. But in India in the discourses on synthetic biology, which is confined to few circles, these imageries are not found. Instead the power and control discourse is over shadowed by innovation and risk discourse. One reason could be absence of networks in synthetic biology that have emerged elsewhere (Hodgson and Meyer 2009). Another factor could be that innovation discourse in India underscores implicitly the power and control aspects in synthetic biology by recognising its potential in different sectors without elaborating the scope for exercising power and control in future.

With reference to control through Intellectual Property Rights, the Task Force pointed out the controversies in IP issues and the two contrasting approaches in open access initiatives and those oriented towards proprietary knowledge. But as there have not been many controversies over patents related to synthetic biology in India this has not emerged as a matter of concern that gets reflected in discourses.

There is hardly any activity related to BioBricks in India. Hence, Power and Control discourse is not strong in India.

In early 2013, a Delphi study on future of synthetic biology in India in different time horizons was conducted. The study was done in two rounds and the respondents were mostly either working in biotechnology or life sciences in industry/academia. While their experience and educational qualifications ranged from students to senior academics/scientists, the respondents who were not scientists or had no technical/scientific knowledge could not answer questions that demanded such knowledge. Hence, in the second round only 25 respondents were targeted. While the respondents considered that majority of the objectives are likely to be plausible within the next decade only the two objectives of a protocol specific to synthetic biology and integrating synthetic biology in curriculum are expected to be achieved by 2020. Other objectives like complete genome cloning experiments in laboratories and development of international protocol to govern synthetic biology are expected to be achieved on a longer time scale while majority of the 26 listed objectives are likely to be achieved within 2020-2030. The study, which is first of its kind in India, needs to be supplemented with studies on public perception, studies on stakeholders' perception on regulation and application of synthetic biology and studies on coverage of synthetic biology in media.

It is interesting to note that while the Task Force recognises the potential of synthetic biology it also points out that synthetic biology research should be supported when it happens in an atmosphere of 'public acceptance and transparency' and efforts to minimise the large negative consequences should be made. It points out that premature push to bio-fuels has resulted in controversies and takes the position that "unless public brought on board the potential of large-scale beneficial outcomes to synthetic biology will be limited". Even as it recognises the enormous potential of biotechnology, it points out that there are other issues that could limit the benefits being realised by the 'broadest possible population'.

The controversies over synthetic production of Artemsemin and potential negative impacts on account of synthetic vanilla indicate that the socio-economic issues will play an important role in the legitimacy and acceptability of synthetic biology. In case of biofuels, the applications that do not exacerbate the demand for vast quantities of fertile lands are likely to be less controversial. India, in fact, should prioritise health sector as an important sector doing R&D in synthetic biology as it can achieve two objectives, i.e. developing affordable vaccines, diagnostics and sensors and building capacity by this. In case of biofuels also, it should try to attempt a socio-economic assessment of the technology in terms of its social costs and benefits, particularly the impacts on livelihoods and demand for land.

Civil society at present does not seem to be interested in synthetic biology, perhaps because there is not much happening in India. But Vandana Shiva, who is well known for her opposition to GMOs in agriculture and Green Revolution, has already criticised synthetic biology and linked that with the opposition to biotechnology in agriculture.[3] Since many NGOs in India reflect the position taken by Friends of Earth, Greenpeace and ETC Group in such issues such a stand is not surprising. Another contentious issue that could emerge in future is the diversion of land for biofuels and utilisation of synthetic biology for the same. For those NGOs, which are opposed to GMOs and agricultural biotechnology extending the same arguments to oppose synthetic biology is not difficult. As public awareness in synthetic biology is lacking they can play on the fear of the unknown technology aspect and try to convince public that synthetic biology will exacerbate problems caused by agricultural biotechnology. The DBT and other agencies should take a proactive stand on public engagement in synthetic biology and address emerging issues in regulation, biosafety and biosecurity lest they become controversial issues that could constrain development of synthetic biology and diffusion of products derived from that. One approach could be that they identify potential issues of contention and controversy and be prepared with initiatives in public communication and engagement.

The Task Force Report takes into account socio-economic issues and in fact takes the position that science plays only a small role in ensuring that solutions reach the broadest possible public and other factors play an important role in distribution and production. Its caution against pushing biofuels at the cost of food crops and emphasis on public acceptance and transparency indicate that it recognises the importance of socio-economic issues. In case of synthetic biology, globally socio-economic issues have not received much attention when compared to issues related to regulation, risk and ethics. One reason for that is that synthetic biology is in nascent stages and so far the products based on synthetic biology have no significant socio-economic impacts. In fact it is estimated that many products will be commercialised after a decade or so than in the near future. A survey of literature shows that synthetic biology has good potential to address socio-economic issues but so far there has been no demonstrated effect to vouch for this (National Academy of Engineering and National Research Council 2013). While the UK has allotted money for research on synthetic biology applications in water purifications, surprisingly such an application has not been funded in India. As synthetic biology is yet to make a headway in India, it is time to identify socio-economic issues and direct the innovation process in such a way that synthetic biology can be harnessed effectively. For example, India can prioritise vaccine development, developing diagnostic kits and other applications that are more relevant in the context of developing nations.

5. Conclusion

Synthetic biology is in preliminary stages in India. Its potential is acknowledged in official documents and is also considered as an important technology by the DBT. But in terms of funding, there are no special plans or support through mission mode. While the Task Force came up with an ambitious plan for synthetic biology envisaging significant investments in capacity building and emphasis on human resource development, it also acknowledged the ethical issues and the risks and social acceptability of synthetic biology.

But such a perception is absent in other official documents which do not give synthetic biology any special attention. Whether the talk on realising the potential will be matched with support and investments, is a big question. But as India is not a significant player in the global Synthetic Biology developments, it may not have much impact on global trends. On the other hand, trends and debates on issues related to Synthetic Biology like biosecurity, biosafety, impacts on environment/biodiversity have significant implications for India. Hence, it is essential that policy makers in India pay attention to this emerging technology and its potential impacts.

Endnotes

1 For example, see report by Presidential Commission for the Study of Bioethical Issues (2010), and Zhang *et al.* (2011).

2 BWC/MSP/2005/MX/WP.23 (2005)

3 See http://www.policymattersjournal.org/2/post/2013/09/-synthetic-biology-an-emperor-with-no-clothes.html

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