Ethics Debates on Synthetic Biology in the Three Regions

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Chapter 1

Summary discourses on synthetic biology in Europe

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1. Introduction

Ever since the emergence of synthetic biology (SynBio) in the United States, the field immediately gained attention of European scientists and policy makers. In contrast to the U.S. earlier biotechnology has stumbled upon fierce public resistence in Europe, which made a crucial impact on its development. Similarly, the reception of SynBio by European societies will have a crucial impact on the development of the field in Europe. Currently, this story is starting to unfold, as the European debate on SynBio is starting to take form. The further development of SynBio in Europe is therefore at a crucial stage. In the previous deliverable *'Discourses on synthetic biology in Europe'* (D5.1) the Rathenau Instituut aimed to provide an overview of the current state-of-affairs in the SynBio debate. To this end, we analyzed a collection of reports on SynBio, stemming from a broad variety of actors that have started expressing their expectations of the field. In the following we will briefly recapitulate these findings.

In order to conduct our analysis we used five discourses as searchlights, including discourses on *innovation, risk,* and *power & control*. In addition, we focused on *lay morality*: what expectations and issues have been raised concerning SynBio by voices from civil society and the broader public? Finally, we addressed the way in which European *reflective ethics* voices engaged with SynBio.

2. Innovation discourse

Why is SynBio important? What can the field deliver? What are the opportunities? What is needed to let SynBio mature into an industrially relevant and socially robust discipline? These are the central questions of an innovation discourse. In Europe, certainly voices can be heard, mainly stemming from the scientific community and industry, which emphasize the opportunities SynBio might bring for society. According to these voices, SynBio could revolutionize the biological and biotechnology industries and maybe even biology as a science. Moreover, SynBio is expected to contribute to smart and sustainable growth (resource efficient, green) and competiveness, aims which relate to European values of *sustainability* and *market freedoms.* SynBio applications are envisioned in the fields of biomedicine, sustainable chemical industry, environmental remediation, energy and materials production. Correspondingly, in Europe several support actions have been established, like funding research (e.g. NEST Pathfinder initiative 2004-2008, and the funding schemes in the 6th and 7th European Framework programs), strategy development (e.g. the TESSY roadmap 2008), knowledge transfer between industry and academia, and integration of scientific disciplines, also including policymakers & stakeholders early on. In sum, the European innovation discourse on SynBio is *strongly developed* and as a result the field has been gaining momentum through government investments, scientific capacity building and mobilization of stakeholders, especially on the European level.

3. Risk discourse

Similar to the innovation discourse, the European risk discourse is also *strongly developed*. It is rather multifaceted and several types of actors are involved: the scientific community, government, but also civil society organizations (CSOs) are making their mark. Biosafety (potential unintended consequences) and biosecurity (potential misuse in terms of terrorism and state warfare) have been raised as especially important concerns with regard to SynBio. In response to such concerns, there is a broadly supported call for monitoring whether established regulations and risk assessment procedures are still adequate. In this context, some scientists view SynBio as the ultimate safety tool, since it will allow for more 'safety by design' than earlier biotechnology. CSOs are not convinced by such viewpoints. Particularily concerned with *citizen's rights* and *sustainability* as important European values, they call for strong application of the precautionary principle.

4. Power and control discourse

Developments in synthetic biology will enable scientists to put 'nature' and 'life' more and more on the drawing board. On the one hand, this allows for many opportunities to address grand challenges society is facing, such as health, energy and sustainability challenges. On the other hand, this gives rise to risks and ethical questions. So who gets to decide how SynBio should develop and under what conditions? Who is responsible? In Europe, SynBio arrives at a time where science's role and position in society face increased public scrutiny. Can these issues be left to governments and experts or should other stakeholders, or even the broader public be actively involved as well? In other words: the emerging European debate on SynBio raises particulary challenging questions of *power and control*, including the adequateness of current regulatory regimes, the balance between self-regulation and governmental oversight, and the balance between forward looking regulation on the one hand and room for innovation on the other. In this context, government and (social) scientists call for early involvement of stakeholders and the broader public in the governance of SynBio. Besides, there are more disctinct and critical views, stemming from internationally operating CSOs. According to these voices, there is a need for specific ethical and legal mechanisms – no soft governance but rather 'hard' government – to constrain an overly market-driven development of SynBio. In the European power & control discourse, these issues converge in the overall theme of *responsible research and innovation*, bringing in interests and values from technology developers, industry, government, stakeholder groups and involving the broader public. While the development of SynBio is still predominately confined to a laboratory context, the governance landscape of SynBio already comprises of a large number of actors and issues, adding up to a rather complex picture.

5. Lay morality

Public reception is crucial for the course of development a technology. To put it bluntly: it can make or break a technology. Public concerns may involve potential physical harms, but to a large extent also relate to *non-physical harms,* i.e. boundaries that should not be overstepped, that are related to our values and culture. GEST intends to examine the impact of this so-called *lay morality* on the emerging SynBio debate. In the case of SynBio this is however not an easy task, since the development of SynBio as such is at a rather early stage. Correspondingly, even the sole awareness of SynBio among the public is rather low. Therefore, there is no real public debate on SynBio in

Europe so far. However, attitudes can be gauged from surveys and organized public debates. From European surveys and organized debates it appears that members of the public perceive several opportunities, such as: greening economy, addressing climate change and health needs. In this sense, also a risk of inaction is perceived. On the other hand, there are concerns relating to biosafety and biosecurity and there is also a more general skepticism about quick 'technical fixes'. In addition, some European CSOs have started voicing opposition against SynBio. Next to worries about physical risks, their concerns relate to commercial monopolization and increasing global inequalities. When we try to understand these issues from the perspective of values we will actually see that these issues relate to a broad spectrum of values: sustainability, justice, solidarity, equality, citizen's rights and market freedoms. In conclusion, public discourse concerning SynBio is so far *weakly developed*, but surveys among the general public show a large degree of pluralism; there are lot of issues and values involved, which might be difficult to reconcile. This will be a serious challenge for the European governance of SynBio.

6. Reflective ethics

In addition to *lay morality,* morality is reflected upon by professional *reflective ethics* voices. Such voices may either stem from academia, or ethics advisory bodies (including technology assessment and ELSI community). In Europe such voices have attended SynBio from its early beginnings. Supported by EU funding, the (formally institutionalized) ELSI and TA community actively engaged with SynBio and also ethics scholars in academia engaged with SynBio shortly after the emergence of the field. Their work entails a comprehensive discussion of positive and negative aspects of SynBio, including issues of biosafety, biosecurity, intellectual property and governance. Reflective ethics also further broadens the debate by addressing concerns about 'Playing God', instrumentalization of life and intergenerational justice, also explicitly relating these concerns to the European values system and human rights framework. Broadly speaking we can identify four different roles *reflective ethics* voices have been playing in the emerging SynBio debate: (1) articulation of values and issues, (2) highlighting (hidden) tensions between values, (3) enriching the debate with more fundamental considerations[1], (4) translating these issues and values to the S&T policy making arena.

7. Conclusion

In our analysis we have mapped emerging discourses on SynBio and have shown how these discourses are shaped by values expressing established value systems in European society. We have summarized the result of our analysis in the discourse/values table below. On the basis of this table we can distinguish three different perspectives in terms of which we can understand the three different SynBio discourses and tensions between them.

[1] A good example hereof is how the EU-project SYNTH-ETHICS has conducted an in-depth analysis of the notion of "Playing God" by means of SynBio, which so far has not led to controversy, but is considered as a potential issue, since such concerns have been voiced regarding earlier biotechnology is well.

		Innovation	Risk	Power & Control
Public Good / Market	**Freedoms**	Competitiveness Intellectual property		Culture of responsibility Self-governance Monopolization
	Sustainability	Smart/sustainable growth Social benefits	Risk of inaction	
	Justice	Monopolization	Exploitation	
	Solidarity	Disadvantaging populations	Depletion of resources	
	Equality	Openness Sharing	Increasing inequalities	Incorporation of the public
Protection	**Dignity**		Unnaturalness Unease about total control	
	Citizens' Rights	Social responsibility	Minimizing risks Precaution	Governmental oversight Right of the public

Firstly, we can understand these discourses from an *actor perspective*, focusing on the issues (in red) that are debated in these discourses. Secondly, we can understand these discourses from a *reflective perspective*, focusing on the values (in grey) that are expressed in these debates. Thirdly, we can understand these discourses from a *governance perspective*, focusing on three central aims for science and technology policy making: market innovation, the public good and protection of individual rights (in green). The table shows that – in spite of the emergent nature of SynBio – a fundamental European debate on the field is taking shape, and so far a variety of positive and negative viewpoints has been brought into debate, by several actors. Moreover, we have found significant tensions between several of these viewpoints and the values to which they relate. How the European SynBio debate exactly will evolve in the future, yet remains to be seen. In any case, prioritizing and reconciling the different viewpoints we have mapped is likely to prove a major challenge and have a significant impact on the development of SynBio in Europe.

Chapter 2

Discourses on Synthetic Biology in China

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1. Background

With the rapid development of synthetic biology in some developed countries since the beginning of the 21st century, the research and application prospect of synthetic biology have attracted the attention of Chinese scientists and the Chinese government. Be it scientific research or industry development, China has given a great support to the modern biotechnology as a national strategy. This provides an excellent environment and great opportunities for the development of synthetic biology in China.

1.1 China sees emergence of a new technology evolution dominated by the biotechnology and a new industrial revolution dominated by the biological economy worldwide and thinks that this presents a rare opportunity for China to achieve the leap-forward development of its economy.

Chinese minister of science and technology Wan Gang said in an article : biotechnology is one of the most promising new technologies today and the new scientific and technological revolution led by the biotechnology is taking shape at an accelerated pace; the scientific and technological revolution driven by the biotechnology is speeding up the formation of the biological economy; worldwide, the biotechnology has become a strategic priority in the R&D activities in countries and the biological industry has become an important driving force of the world economic development; the biotechnology is becoming a new source driving economic growth following the Internet economy; the industrial development promoted by the new scientific and technological revolution presents a historical opportunity for a country to achieve a leap-forward development and will lend itself favourably to China's effort to protect public health, promote economic development and safeguard national security; China must grasp this opportunity to develop the biotechnology by leaps and bounds, which will make an important contribution to the great rejuvenation of the Chinese nation.[1]

In the book, *China's Biological Economy: Biotechnology and Bio-industry Innovation from the Perspective of International Comparison*[2], compiled by China National Center for Biotechnology Development under the Ministry of Science and Technology of China, the new scientific and technological revolution is described as follows: a new scientific and technological revolution led by the biotechnology as well as a new situation where the biotechnology is a leading force in the new round of technology and industrial revolution is taking shape, as evidenced by the following facts: 1) as the agro-biotechnology drives the second green revolution, a series of GMOs are put into application; 2) as the pharmaceutical biotechnology drives the fourth medical revolution following

[1] Wan Gang (2010), Preface to *China's Biological Economy: Biotechnology and Bio-industry Innovation from the Perspective of International Comparison*, compiled by China National Center for Biotechnology Development, China Agricultural Science and Technology Press, Beijing.

[2] This book was compiled by China National Center for Biotechnology Development under the Chinese Ministry of Science and Technology and published in 2010. The views in the book can be considered to represent the science and technology authority of China.

the public health system, anaesthetics and anaesthetic techniques, and vaccines and antibiotics, new drugs have emerged in an endless stream; 3) as the industrial biotechnology promotes the third industrial revolution, an all-new safe and sustainable manufacturing industry is taking shape; 4) Breakthroughs in the energy biotechnology will greatly facilitate the R&D of new energies; 5) environmental biotechnology will become one of the most effective means to solve complicated environmental pollutions; 6) the biotechnology will fuels the development of biological resources and foster a series of emerging industries; 7) Biosafety is an important part of national security, economic security and homeland security; and 8) the biological industry has entered into the stage of technological take-off from the stage of technological accumulation. The biotechnological development will bring about comprehensive economic and social changes and usher the humankind into a new social state from the agricultural society and the industrial society; the new scientific and technological revolution presents a rare historical opportunity for China. In this backdrop, China should make strategic deployments and play an active role in the new scientific and technological revolution, trying to be a major participant and leader in it and a substantial beneficiary of the new economy rather than an onlooker and lagger as it was in the period of the industrial revolution.

The idea about the new scientific and technological revolution is supported by most Chinese scientists. In May 2011, the China Center for Modernization Research, CAS, conducted an opinion survey among the CAS and CAE academicians concerning the components, issues and strategies of the new scientific and technological revolution. The research report subsequently published, entitled Strategic Opportunities on the Sixth Revolution of Science and Technology , stated that over the past five hundred years, two scientific revolutions and three technological revolutions took place in the world, that China missed the first four scientific and technological revolutions and performed averagely in the fifth scientific and technological revolution, and that as the sixth scientific and technological revolution emerges in the 21st century, China must make the most of this opportunity. The feedback from the 108 academicians showed that they were highly supportive of the relevant contents about the 6th technological evolution, with 46-72% holding a positive attitude while only 0-6% holding a negative attitude towards the main body of the sixth scientific and technological and 36-81% holding a positive attitude while 0-4% holding a negative attitude towards the extended and peripheral parts of the sixth scientific and technological (ChuanQi He. 2011).[3]

1.2 The biotechnology is one of China's strategic emerging industries and receives great encouragement and support from the Chinese government

Developing strategic emerging industries and fostering new drivers of economic growth is an important measure of China to maintain economic growth and adjust its economic structure, and it is also a major strategic measure for China to maintain long-term economic prosperity. Biotechnology has been strongly supported by the Chinese government as a strategic emerging industry. Former state leaders Hu Jintao and Wen Jiabao mentioned on many occasions that priority would be given to the development of biotechnology and the biological industry. At the National Science and Technology Conference in 2006[4] , Hu Jintao said that "the biotechnology should be

[3] Chuanqi He, *Strategic Opportunities on the Sixth Revolution of Science and Technology,* 2011, Science Press, Beijing.

[4] This conference, convened by the CPC Central Committee and the State Council, is the highest meeting

prioritized in the effort to develop high technologies and efforts will be made to strengthen the application of the biotechnology in agriculture, industry, population and health". China's basic approach to developing biotechnology and the biological industry can be summarized in two points. The first is to develop the biotechnology, introduce the biological economy, and accelerate China's pace to become a large and strong country in biotechnology and the biological industry. The second is to develop the pharmaceutical technology and build China into a strong pharmaceutical country. For this purpose, China has released a series of policy documents to promote the biological industry. In June 2009, the General Office of the State Council issued the Several Policies on Promoting the Biological Industry, which explicitly stated that "[efforts will be made to] accelerate the fostering of the biological industry into a pillar industry and national strategic emerging industry in the high-tech field". In October 2010, the State Council promulgated the Decision on Accelerating the Fostering and Development of Strategic Emerging Industries (GUO FA 2010 No. 32) in which the biological industry was included in the seven strategic emerging industries for prioritized fostering and development. The 12th Five-Year Plan for National Economic and Social Development released in 2010 also mentioned the "project for innovative development of strategic emerging industries" which includes the biological industry.

In China, developing the biotechnology and the biological industry is not merely a slogan but also practiced by the central government and the local governments at all levels. China has formulated a series of related documents, including the 11th Five-year Plan for the Biological Industry, the 12th Five-year Plan for the Biological Industry, the 12th Five-year Plan for the Development of the Biotechnology, and the National Plan for the Development of Human Resources in Biotechnology in the Medium to Long Term (2010-2020). In the 11th Five-year Plan for the Biological Industry formulated at the initiative of the National Development and Reform Commission[5], a number of fields including vaccines, diagnostic reagents, innovative drugs and biomedical engineering were earmarked for prioritized support, with multiple supporting policies released accordingly. During the 11th Five-year Plan period (2005-2010), the National Development and Reform Commission designated 22 national biological industrial bases whose combined output value accounted for more than 60% of the output value of the entire biological industry in China. In addition to continuing and expanding the original fields for prioritized support, the 12th Five-year Plan for the Development of the Biological Industry further increases the support for innovative pharmaceutical fields including innovative vaccines, monoclonal antibody and genetically engineered drugs, which will receive even more taxation benefits, more national financing and more technical support.

The 12th Five-year Plan for the Development of the Biotechnology formulated at the initiative of the Ministry of Science and Technology in 2011 stated that efforts would be made to prioritize the development of bio- pharmacy, bio-agriculture, biomass energy, bio-manufacturing, bio-environmental protection and bio-service, make breakthroughs in a number of key technologies, try

China's science and technology development. Since the founding of the P.R. China, a total of four national science and technology conferences have been held, with the previous three held in 1956, 1978 and 1995. Every conference has produced important national science and technology development plans or documents.

[5] The National Development and Reform Commission is a macro control department under the State Council that is responsible for comprehensively researching and formulating economic and social development policies, performing gross balance, and guiding China's overall economic reforms.

to establish China's position in the international frontier studies of biotechnology, and scale to the commanding height in a number of international biotechnological studies. In this plan, the synthetic biology features as one of the 12 key technologies where breakthroughs are needed in the 12th Five-year Plan period. Efforts will be made step by step to explore the application of the synthetic biology in the pharmaceutical and energy fields.

In July 2012, the State Council[6] issued the 12th Five-year National Plan for the Development of Strategic Emerging Industries which gives priority to the development of a number of industries including the bio-pharmacy, biomedical engineering, bio-agriculture and bio-manufacturing during the 12th Five-year Plan period, during which the size of the biological industry is expected to grow at more than 20% every year. For this purpose, efforts will be made to 1) tap the great needs in public health, agricultural development and resource and environmental protection; 2) strengthen the R&D of key generic technologies and processes such as biological resource utilization, genetic engineering, biosynthesis, antibody engineering and bioreactors; 3) strengthen biosafety research and administration and develop a national gene resource information database; 4) improve the capabilities in biopharmaceutical R&D, develop new drugs, and accelerate the development of biomedical engineering technologies and products; and 5) develop biological breeding, promote the bio-manufacturing industry, accelerate the establishment of an internationally advanced modern biological industry and the R&D and industrialization of the marine biotechnology and related products.

The biological industry is also strongly supported in most Chinese provinces as a strategic emerging industry. Some provinces released their 12th five-year plan for the biological industry and relevant policies to support the development of the industry. In 2010, for example, Beijing initiated the G20 Project for the leap-forward development of the biomedical industry which, through the first phase from 2010 to 2012 and the second phase in the subsequent five years after that, aims to increase the contribution of the biomedical industry to Beijing's industrial added value to more than 5% and make Beijing a center of innovation in biomedical innovation with major impact in the Asian-Pacific region.

1.3 China's biological industry grows fast and has strong market opportunities.

Since the 1990s, China's biomedical industry has maintained an average annual growth of 15-30%, recording an average annual growth of 25% from 2006 to 2009, being far higher than the global average annual growth (less than 10%). [7]In 2012, the size of China's biomedical industry reached RMB 1800 billion, up more than 15% year on year,[8] as a result of the strong rigid demand and the

[6] The State Council of the P.R. China, i.e. the Central Government, is the executive body of the supreme organ of state power; it is the supreme organ of state administration. The State Council is composed of the Premier, the Vice-Premiers, the State Councilors, the Ministers in charge of ministries, the Ministers in charge of commissions, the Auditor-General, and the Secretary-General. The Premier assumes overall responsibility for the work of the State Council. The ministers assume overall responsibility for the work of the ministries and commissions.

[7] Department of S&T for Social Development under the Ministry of Science and Technology of China and China National Center for Biotechnology Development, *China Biotechnological Development Report 2010*, 2011, Science Press, Beijing, pp. 23-24.

[8] Department of S&T for Social Development under the Ministry of Science and Technology of China and China National Center for Biotechnology Development, *China Biotechnological Development Report 2012*, 2013,

spur of policies. Compared to the 9th Five-year Plan period, the 10th Five-year Plan period (2001-2005) saw the output value of China's biomedical industry double, the R&D budget in the industry quadruple, and the formation of more than ten biological industrial clusters in Beijing, Shanghai, Tianjin and other cities and biological industrial bases and biotechnology parks of varying sizes across China. According to the prediction of the 12th Five-year Plan for the Biological Industry, the output value of China's biological industry will hit RMB 3.6 trillion by 2015, more than doubling the amount of RMB 1.5 trillion in 2011. Efforts will be made to increase the output value of China's biomedical industry to RMB 6 trillion by 2020.

The rapid development of China's biological industry was both the result of China's policy push and dependent on strong rigid social demand. China has an aging population of 1.3 billion. As the people have an increasing demand for life quality in China's drive to build a moderately prosperous society, there is a growing demand for medical and health resources. In the past decade, consumer spending in medical care in China has been constantly increasing, with the per capita spending on drugs growing at 19.7% annually, far higher than the growth of the per capita consumer spending (10.8%), and there is an urgent need for new drugs and new medical technologies. On the other hand, China is in a stage of accelerated industrialization and urbanization, facing a huge pressure from energy, resources and the ecological environment and the heavy task to improve the living standards of all citizens. In China's drive to identify new drivers of economic growth and transform its economic structure in implementing its natural strategy of sustainable development, there is a strong need for new technologies. This provides an excellent development environment and market opportunities for developing the biotechnology. In 2009, China consumed approximately 50% of the world's total production of steel and cement, and 18% of the world's total production of energy, with its emission of carbon dioxide and sulfur dioxide topping the world, but its GDP only accounts for approximately 8% of the world total. [9]

In the long term, there are a strong demand and huge market opportunities for China to develop the biotechnology and the biological industry which, coupled with continued supportive policies and strong demand, will usher China's biological industry and related technologies into a period of high growth. In this backdrop, the development of synthetic biology will have a bright prospect in China.

1.4 The synthetic biology research started rather late and is still in its early stage in China.

The study of synthetic biology started rather late in China, and it was from 2006-2007 that China began to be gradually involved in related international activities. In 2006, IGEM (International Genetically Engineered Machine Competition) ambassadors Patrick Cai and John Cumbers visited Tianjin University where they introduced the teachers and students to the synthetic biology and IGEM. In 2007, Chinese university students took part in IGEM for the first time and performed excellently. Their good performance has continued in the subsequent IGEM competitions. In April and June 2007, Tianjin University held two symposiums on synthetic biology, which invited the

Science Press, Beijing, pp. 215.

[9] Department of S&T for Social Development under the Ministry of Science and Technology of China and China National Center for Biotechnology Development, *China Biotechnological Development Report 2010*, 2011, Science Press, Beijing, pp. 6-20.

founder of the synthetic biology in the U.S. and promoted the publicity of synthetic biology in China.[10]In 2007, Edinburgh -Tianjin Joint Research Centre for Systems Biology and Synthetic Biology jointly established by the University of Edinburg and Tianjin University was launched in 2007 and opened a course entitled "Introduction to Synthetic Biology" to undergraduates in the second half of 2008. In December 2008, China established its first national research base of synthetic biology - Shanghai Institutes for Biological Sciences (SIBS), CAS. With the technical support of this laboratory, SIBS established the Shanghai Research and Development Center of Industrial Biotechnology which specializes in the development and industrialization of related technologies. In addition to these two institutes, there are several other research institutes which are engaged in the research of synthetic biology, including Tsinghua University Center for Synthetic and Systems Biology, Hunan Engineering Research Center of Combinatorial Biosynthesis and Natural Product Drug Discovery, the Qingdao Institute of Bioenergy and Bioprocess Technology (QIBEBT), etc.

Although China started late and is behind developed countries in the study of synthetic biology, with the great encouragement and support of the Chinese government in biosynthetic biology research since 2000, this field of study has been on track of rapid development. Recent years, the research in synthetic biology has been financed by a series of programs including the 863 program[11], the 973 program[12], the National Natural Science Foundation [13]and the Ministry of Science and Technology, with the funds of researchers mainly coming from related programs under the Ministry of Science and Technology and the National Natural Science Foundation and partially from research programs at provincial and municipal levels. In the 973 Program, for example, two synthetic biology research projects were launched in each of 2010 and 2011. The research projects under the 973 Program in this field include "cell factory", "photosynthesis and artificial leaf", "high-efficient drug synthesis systems", "standard cells, modules and databases", and the application of synthetic biology in industry and agriculture.

China's synthetic biology research has been fully geared to catch up with the developed countries and actively involved in international exchange and cooperation in SynBio, with a strong research force having been established. Three annual symposiums on synthetic biology attended by academicians from six academies (academies of sciences and academies of engineering) in China,

[10] The research of synthetic biology has just started in China. In a bid to promote Chinese college students' participation in the International Genetically Engineered Machine Competition (iGEM for short), Tianjin University hosted a iGEM symposium on April 16, 2007, which was attended by teacher and student representatives from Peking University, Tsinghua University, Tianjin University and the University of Science and Technology of China. During the symposium, Drew Endy, a famous synthetic biologist from MIT, and C. Smolke from California Institute of Technology gave lectures on synthetic biology. From June 16 to 17, 2007, Tianjin University held an iGEM training class for group teachers in the Asia Pacific region, which was attended by relevant teachers from Australia, Japan, Taiwan and Hong Kong in addition to the abovementioned four universities in the Chinese mainland. The main lecturers include iGEM founders Tom Knight and Randy Rettberg from MIT, and K. Haynes from Davidson College, the designer and creator of E. coli computer.

[11]The 863 Program, National High-tech R&D Program, was approved in 1986 to promote high technology R&D in China. Biotechnology is listed as one of its eight priority fields.

[12] 973 program, National Basic Research Program of China, was approved in 1997 to support basic science and technology research. It promotes research and innovation in major frontier fields of far-reaching and strategic importance, such a life science.

[13] The National Natural Science Foundation of China (NSFC) was established in 1986 to support basic science research through internationally accepted mechanism. Some biotech related research has been funded though the General Program, Key Program, or Major Program of NSFC.

the UK and the U.S. were held from 2010 through 2012.[14] A Sino-U.S. joint research on synthetic yeast genome is under way. A search by the present author on domestically published papers (including papers in learned journals, doctoral dissertations, master's theses, papers read at important domestic academic meetings and international academic meetings) at the CNKI literature retrieval platform using the keyword “synthetic biology” found 121 articles from 2004 to August 2013 (see Fig 1), with the annual number of papers published being below 10 in 2010 and before and more than 30 in 2011 and 2012. These articles, however, are mostly surveys and introductions. According to relevant international statistics, China ranked sixth in terms of the number of articles published in international synthetic biology journals, following the U.S., UK, Germany, France and Switzerland (see Fig 2). The Chinese Academy of Sciences ranked 17th among international research institutions in terms of the number of papers published in this field. It can be said that there is a significant gap in the understanding and research of synthetic biology in China. There are few major findings or breakthroughs in synthetic biology in the world made by Chinese, especially in original innovations.

[14] To strengthen the exchange between the sciences and engineering academies of China, Britain and the United States in synthetic biology as an emerging discipline, discuss together future trends of development, and promote policy coordination and R&D cooperation, the sciences and engineering academies of the three countries agreed in 2010 to jointly organize a series of international symposiums on synthetic biology. The first three-country six-party meeting on synthetic biology took place in London in Britain in 2010, where attendees had comprehensive discussions about synthetic biology. The second meeting was held in Shanghai in China, which focused on related S&T issues. The third meeting, convened in the United States, focused on next-generation tools, platforms and facilities in synthetic biology and related policies. The third meeting was attended by scientists from the sciences and engineering academies of China, United States and Britain, and official and entrepreneur representatives from the three countries, who had an in-depth discussion about a series of subjects including “future development of synthetic biology”, “challenges facing the world”, “research in key applied fields”, “problems in basic biology”, “organizational strategies for supporting the development of synthetic biology” and “national strategies in advanced synthetic biology”. Mr. Zhang Xian'en, Director-General of Department of Basic Research, the Chinese Ministry of Science and Technology, had a speech entitled “Outlook of Synthetic Biology in China”, covering such aspects as technological evolution of bio-manufacturing, progress of research in synthetic biology in China, development roadmap, challenge and response, etc.

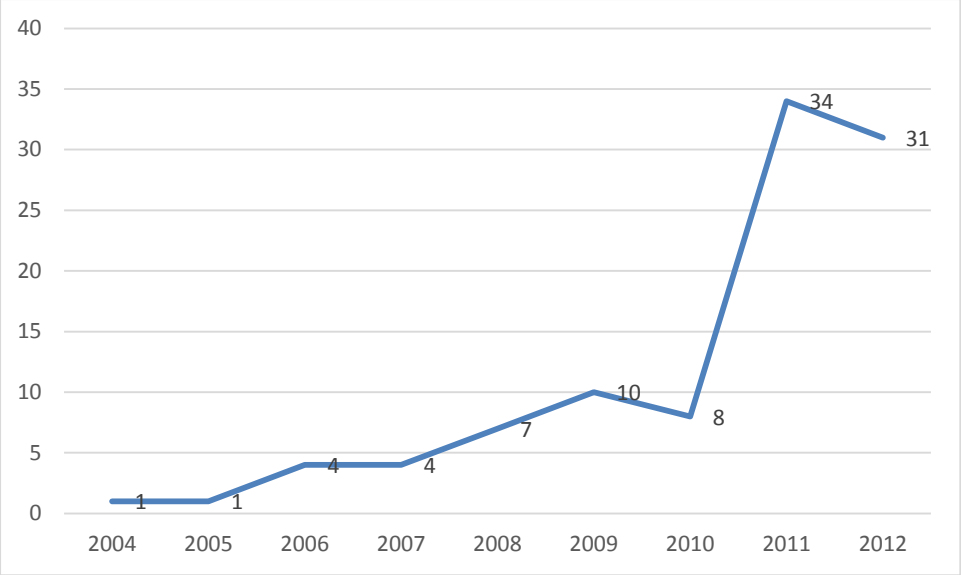
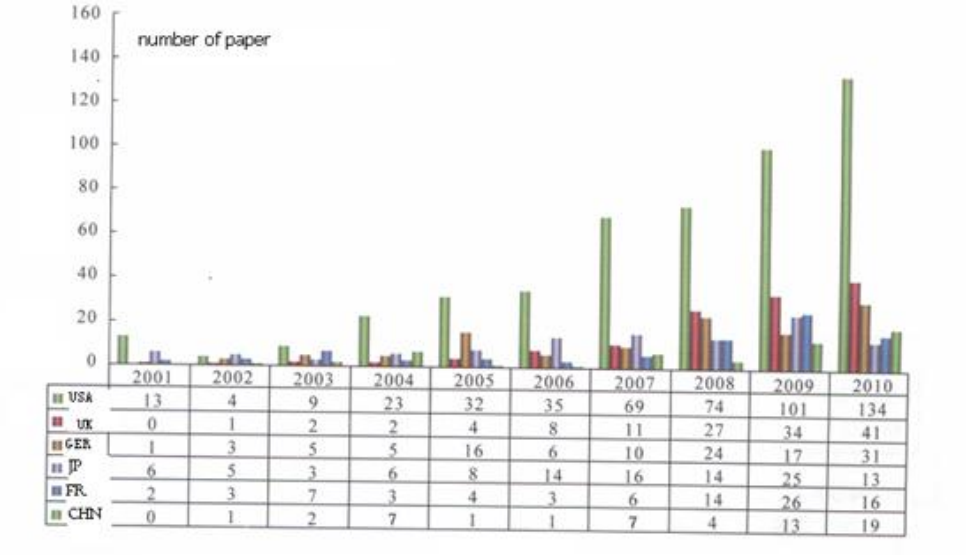


Fig 1: Number of papers in synthetic biology published in China



	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
USA	13	4	9	23	32	35	69	74	101	134
UK	0	1	2	2	4	8	11	27	34	41
GER	1	3	5	5	16	6	10	24	17	31
JP	6	5	3	6	8	14	16	14	25	13
FR	2	3	7	3	4	3	6	14	26	16
CHN	0	1	2	7	1	1	7	4	13	19

Fig 2: Papers in synthetic biology published from 2001 to 2010 in the world[15]

2. SynBio Innovation Discourse in China

Encouraged by the findings in synthetic biology in the world, Chinese researchers have shown a strong interest in and optimistic attitude towards the development and application prospect of synthetic biology. Discourses on innovation in synthetic biology are found extensively in the annual *China Biotechnological Development Report* compiled by the Ministry of Science and Technology of China, China's official Xiangshan Science Conference sessions[16], and symposiums organized by China

[15] Cited from Xiong Yan et al, Now and Outlook of Synthetic Biology, *Life Science*, No. 9, 2010

[16] The Xiangshan Science Conferences was initiated by the former State Science and Technology Commission, now the Ministry of Science and Technology of China (MOST). It was officially inaugurated in 1993 under the joint sponsorship of MOST and the Chinese Academy of Sciences (CAS). It also draws support from the National

Association for Science and Technology (CAST)[17]. In these discussions, synthetic biology is considered by Chinese Biologists as one of the great frontiers of the modern biotechnology. Chinese Biologists have called on many occasions for government support for the development of synthetic biology and the advancement of related researches.

2.1 Synthetic biology is deemed by Chinese scientists as a frontier and trend of the modern biotechnology and one of the main symbols of the new scientific and technological revolution.

As stated in the above, the Chinese government and many scientists think that the world is embracing a new scientific and technological revolution led by the biotechnology. As an important part and powerful driver of this revolution, synthetic biology represents the direction of the biotechnology in the 21st century. Just as stated in the official China Biotechnology Development Report, synthetic biology, as an important part of the biotechnology, is a key technology where breakthroughs are needed, and it will help break the barriers in biology to form a new biological system and powerfully promote the development of such fields as pharmaceuticals, energy, chemicals, material and environment. Synthetic biology is one of the 12 core key technologies for prioritized development during the 12th Five-year Plan period (2010-2015) in the 12th Five-year Plan for Biotechnological Development formulated at the initiative of the Ministry of Science and Technology. The plan determined the main direction of the development of the synthetic biotechnology: develop high-throughput low-cost DNA synthetic technology and high-efficient gene segment recombination, analysis, directional design and synthesis of protein structure, construction of standard biological parts and functional modules, establish the application of synthetic biology in prodrugs, midbody, bio-energy and bio-based chemicals, and gradually explore the application of synthetic biology in the pharmaceutical and energy fields.

The view that synthetic biology is a leading technology in the new scientific and technological revolution has been supported by most scientists. A 2011 opinion survey of academicians by the China Center for Modernization Research, CAS, found that concerning what are the main symbols of the sixth scientific and technological revolution, transcriber and human body regeneration are supported by 72% and 69% of the respondents, followed by synthetic life (39%), new biology (34%), and personality information packet (29%), all of which are more supported than opposed. “Synthetic life and synthetic biology” is one of the four basic scientific issues among the 22 strategic scientific

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Natural Science Foundation of China, the Academic Divisions of CAS, the Chinese Academy of Engineering, the Ministry of Education of China, the General Armament Department of the People's Liberation Army, the former State Commission of Science, Technology & Industry for National Defense, China Association for Science and Technology, and the Ministry of Health. The thematic topics of Xiangshan Science Conference sessions mainly cover cutting-edge issues in basic science and the scientific problems from key engineering and technological fields, with a focus on discussing frontier science issues, forecasting future trends, conferring about latest scientific breakthroughs, sharing new academic thoughts and methodologies, and analyzing new academic offshoots and new interdisciplinary issues.

[17] The China Association for Science and Technology (CAST) is a non-profit, non-governmental organization of Chinese scientists and engineers, which is composed of national professional societies, associations, institutes and local science and technology associations, covering the overwhelming majority of natural science disciplines and most industries and sectors. Currently it has 167 national professional societies, 31 provincial science and technology associations, and extensive local and grassroots science and technology organizations, with more than 4.3 million members.

and technological issues that will impact China's modernization put forward by the Chinese Academy of Sciences in a report entitled Science & Technology in China (A Roadmap to 2050) released on June 2009. (Chuan Qi He. 2011)

The Xiangshan Science Conference is a national academic forum on state-of-the-art issues in basic research and scientific issues in major engineering fields initiated by the Ministry of Science and Technology and financed and supported by nine government departments including the National Natural Science Foundation, Chinese Academy of Sciences and the Ministry of Education. At the 322th Xiangshan Science Conference with the theme of "synthetic biology" in May 2008, the attending scientists showed their overall support for the synthetic biology and called for more government support for strengthening SynBio research. A representative view was aired by Zhang Chunting, a CAS academician, who stated at the conference that "Compared to such technologies as gene transfer and genetic engineering, synthetic biology is a next-generation biotechnology". At the 6th China Summit forum on Industrial Biotechnology Development in October 2012, CAS academician Zhao Guoping pointed out that the tremendous amount of gene information and high-throughput genome technology brought by genomics will usher scientific research into the era of systems biology and synthetic biology and revolutionize the industrial biotechnology and that synthetic biology, at a highly interdisciplinary scientific frontier which incubates new thoughts, new strategies and new methods in frontier issues including the origin of life, biological evolution and organism structure, will help humankind meet strategic challenges in energy, chemicals, environment, medical care, etc.

China Biotechnological Development Report 2012 stated that the synthetic biology research in China is still in its early stage and mainly confined to bioengineering-related fields such as microbiology, genetics and industrial application science and the Subfield of SynBio covered Genetic circuits (based on genetic engineering but using real engineering principles), Minimal genomes (or minimal cells), Protocells (or synthetic cells), Chemical synthetic biology (or xenobiology), DNA synthesis (or synthetic genomics). They suggested that China should make the most of the important opportunities in the early stage of the research by conducting research activities with priorities. From knowledge accumulation to technological methods, China has laid the foundation for SynBio studies. The challenge that is imperative to meet is to integrate the existing researches, grasp core scientific issues by starting with major products in such industries as *pharmaceutical*, energy and the environment, create new synthesis-controlled function-oriented metabolic networks and organisms, and lead original researches and independent innovations in synthetic biology in China[18].

2.2 Synthetic biology attracts wide attention to its application in economic and social development and is expected to address bottlenecks faced by China in such issues as energy and the environment.

Chinese scientists are very optimistic about the prospect of synthetic biology, which optimism is largely based on the possible application of synthetic biology. A report compiled by China National Center for Biotechnology Development, China's authority for the development of biotechnology,

[18] Department of S&T for Social Development under the Ministry of Science and Technology of China and China National Center for Biotechnology Development, *China Biotechnological Development Report 2010*, 2011, Science Press, Beijing, pp. 23-24.

believes that in the coming years, synthetic biology will develop faster than the recombinant DNA technology. It will also promote the development of metabolic engineering, enzyme engineering and genetic engineering and has a very bright prospect of application in a number of fields including chemical production, energy generation, environmental protection, vaccine development and medical care. Therefore, it has a great economic and social significance. The focus and direction of China's synthetic biology development is to promote its application in the biomedical and healthcare fields first, solve practical problems and catch up with and overtake developed countries. The main efforts include: 1) establishing a highly-efficient gene/genome synthesis platform; 2) creating new genetically engineered microorganisms to lay the foundation for the R&D of biological drugs; and 3) establishing a new technological platform for the R&D of innovative drugs and improved drugs. There is also a view that efforts should be made to give full play to the potential application of new biotechnologies in industrial development, especially the role of synthetic biology in promoting multiple fields, and establish a comprehensive and scientific biological industrial system where synthetic biology serves as an important technical means. This is thought to be an important way for China to address the serious challenges it faces in such fields as environmental protection, energy and health. Therefore, synthetic biology should be prioritized strategically in China's applied biotechnological research. [19]

The broad prospect of application of synthetic biology is recognized by the Chinese government. As the official Report on Biological Industry in China (2010), synthetic biology has a broad prospect of application, boasts huge social benefits and economic value, and will be widely applied in many fields including energy, environmental protection, chemicals, materials and pharmaceuticals, especially in new bioenergy development, environmental pollution monitoring and treatment, drug development and disease treatment. China has an urgent need to develop the SynBio industry. China's overall approach to synthetic biology is to achieve its application in such fields as industry, agriculture, treatment of major diseases and environmental monitoring and treatment through basic technological research, thus solving a series of problems in traditional fermentation and emerging bio-refinery industry improvement, green agriculture and marginal land utilization, monitoring and treatment of major diseases, and environmental protection. Synthetic biology is seen as bringing to China a new driver of and opportunities for economic growth.

2.3 Chinese scientists advocate that the government should strongly support and promote synthetic biology research in order not to miss this important historical opportunity.

In recent years, there is a growing attention and advocacy from Chinese scientists for the development of synthetic biology. The announcement by a J. Craig Venter Institute research group in May 2010 about the creation of the first synthetic life cell in the world, in particular, drew great interest from Chinese scientists and government. Judging from the speeches of experts at Xiangshan Science Conference sessions and CAST symposiums on synthetic biology, there is a crisis awareness among many Chinese scientists who think that the development of synthetic biology in foreign countries poses a serious challenge to China's biosafety and that if the present opportunity is not

[19] MOST China National Center for Biotechnology Development, Preface to *China's Biological Economy: Biotechnology and Bio-industry Innovation from the Perspective of International Comparison*, China Agricultural Science and Technology Press (CASTP), Beijing, pp. 131-135.

grasped to catch up with the foreign countries, China will be thrown into a very passive situation in this field and the gap with developed countries will grow even wider. Some scientists have advocated on many occasions that the government should seize this major opportunity in synthetic biology by strongly supporting its deployment and making early plans and deployments. At the 322th Xiangshan Science Conference on synthetic biology in May 2008, more than 40 scholars from home and abroad expressed their advocacy for the government to elevate synthetic biology to strategic height as a core technology that will have a far-reaching impact on China's national economic development. At a symposium on "Synthetic Biology: Ethical Issues and Biosafety" organized by CAST in June 2010[20], some scholars pointed out that synthetic biology, as a technology bearing on the scientific and technological revolution and China's national economic development, present a rare opportunity which should be strategically seized so that China can establish its position in the upcoming biotechnological revolution; other scholars stated that the development of synthetic biology should be approached from the perspective of national security, that synthetic biology is about whether China will secure its place in a field of strategic importance, that synthetic biotechnology is a deterrent force by itself, and that, therefore, adequate attention and strong support should be given for its development; some academicians also said that China should take immediate actions to be actively involved in the field of artificial life research and try at least not to fall behind the United States in the field.

To sum up, at present, Chinese scientists and government have formed a consensus that synthetic biology is an emerging field of research with a huge potential, that it has a great significance for China's economic and social development and national security to develop synthetic biotechnological research and products, that it presents a rare opportunity for China to overtake the West scientifically, that China should approach synthetic biology from a strategic height and seize the opportunity to enhance China's strengths in the field of research. The Chinese government is already taking active efforts to promote synthetic biology research. Zhang Xian'en, director of the Basic Research Division of the Ministry of Science and Technology, said on several occasions that synthetic biology is an emerging interdisciplinary subject with a huge scientific and applied potential and that efforts will be made to promote the development of synthetic biology in China. China's science and technology programs and National Natural Science Foundation have all stepped up financing for biotechnological research in recent years. At present, China MOST is formulating its roadmap for the development of synthetic biology to clarify the main tasks and direct and coordinate related domestic researches.

[20] This meeting was the 40th session of the New Viewpoint Academic Salon organized by China Association of Science and Technology. It was chaired by Yang Huanming, researcher at Beijing Institute of Genomics, Chinese Academy of Sciences, and attended by more than 30 experts from universities, institute and news media from across the country and relevant government officials. The thematic topics of this meeting included: 1) What on earth are the objects of research of synthetic biology? 2) What on earth are the benefits of synthetic biology? Is it appropriate for China to vigorously develop synthetic biology in the present stage? How can the relevant research projects by Chinese scientists get the support from the government? 3) What ethical challenges will the development of synthetic biology encounter? How to regulate research activities in synthetic biology and prevent against related risks? (4) What are the respective roles of the media, the public and the government in the development of synthetic biology? What can the academic community do to answer the worries among the public?

3. SynBio Risk Discourse in China

There is an international view that the development of synthetic biology may pose unpredictable risks to humankind, other species, natural ecology, the environment, and national security and that particular attention must be given to the biosafety risks. This view is also echoed by some Chinese scholars (including biotechnology researchers and social researchers) who put forward at symposiums and in their academic papers the necessity to prevent ethical and other risks posed by synthetic biology. From Xiangshan Science Conference sessions, CAST symposiums on biological ethics and safety, and the annual MOST China Biotechnological Development Report mentioned in the above, we can see discussions about the risks and standardization issues related to synthetic biology, though these discussions are rather generic and lack specificity. However, the mainstream view is that synthetic biology is a double-edged sword with both social benefits and risks, and that while China should take measures to prevent the ethical and other risks, those risks should not become an obstacle and barrier to the development of synthetic biology in China.

3.1 Some experts advocate a cautiously optimistic attitude towards the development of synthetic biology.

At the academic symposium on the ethical issues and biosafety about synthetic biology organized by the China Association for Science and Technology in June 2010, some experts called for a cautiously optimistic attitude towards the development of synthetic biology and thought that while strengthening synthetic biology research, efforts should be made to fully investigate and discuss important issues related to society, ethics, ecology and economy to work out appropriate solutions and measures and develop appropriate standards and effective regulatory mechanisms, in order to transform the latest achievements in synthetic biology research into actual beneficial social productivity. Other scholars pointed out that, from the international perspective, China needs to pay attention to the ethical and safety issues of synthetic biology, as is expected of China as a responsible large country and that with the development of synthetic biology, it is important to establish a number of systems to monitor the relevant links and avoid possible hazards.

3.2 More experts believe that it is not advisable to consider ethical and other risks too early because it will hinder progress.

At the abovementioned conference, some experts pointed out that the ethical and safety issues related to synthetic biology, while they do exist, yet should not be exaggerated, and cautioned that China should not be swayed by the media in the developed countries about the risks and ethical challenges of synthetic biology. According to them, the synthetic biotechnology is still in its infancy and is a far cry from the creation of artificial lives. In this backdrop, therefore, it is not necessary to formulate too many restrictive measures which may be developed gradually after the development of synthetic biology reaches a certain stage. They added that biosafety related to synthetic biology is not necessarily a real challenge, because as far as the present technological development is concerned, there is still a long way to go before creating a fully functional life. In contrast, a look at the biotechnological development, international patents and innovative technologies in the world will show that what is needed the most in China at the present stage is strong government support

for catching up with developed countries in synthetic biology research, which is the key to China's success in this field. CAS academician Yang Huanming pointed out, in particular, that biosafety control should not be hyped up, that stem cell research and gene transfer are basically held in the negative light in the developed countries, which has had a very serious misleading effect on China, the removal of which effect will take a lot of efforts, and that China should not recommit the same error in synthetic biology research. According to him, China should have the faith that technological development will bring new opportunities, adding that China can follow the example of the U.S., where the development of synthetic research is both encouraged and regulated with detailed effective measures. Some scholars believed that national security is more urgent than biosafety because the U.S. Department of Defense has established a research institute related to synthetic biology, putting synthetic biology on par with atomic and hydrogen weapons in terms of importance and that, therefore, China should attach importance to synthetic biology even from the perspective of national defense.

It can be seen that on the issue of risks and safety, Chinese scientists largely hold a proactionary attitude, many believing that China's synthetic biology research is still in its preliminary stage where more encouragement and support, rather than restriction on ethical grounds which will only hinder progress, is needed, and that regulatory measures should be developed as the research progresses.

3.3 Some experts call attention to the influence of the media of developed countries on China and the need to make positive publicity of synthetic biology.

Some experts (academician Yang Huanming, for instance) expressed their worry about the influence of the ethical discussion in the western media and the public opinion. According to them, the discussion of the ethics of modern scientific development started in the developed countries and though developing countries discuss largely the same theme, it may lead to different results; the development of synthetic biology is a good thing per se, and the public opinion will hinder China's progress in synthetic biology and further increase the gap between developed countries and developing countries. Therefore, first of all, China should strengthen positive publicity about synthetic biology and make its positive promotion the predominant trend;[21] secondly, as advocated by Dr. Du Lin, efforts need to be made to form the consensus that the discussion of ethical and biosafety issues related to synthetic biology should not become a hindrance to synthetic biology research in China and that the discussion of such issues should serve the purpose of responding to future international opposition rather than hindering China's development in this field of research.[22]

Some experts hold that a major problem faced by China in the development of synthetic biology is how to make positive publicity which it is very necessary to strengthen through more commitments and explanations. Synthetic biology should be correctly interpreted and put across to the public in an easy-to-understand manner to avoid blind ignorance-induced fear on the part of the public and its negative impact on the government's decision-making about this field of research. China should not

[21] Yang Huanming, "Actively Promote the Development of Synthetic Biology", *Ethical Issues of Synthetic Biology and Biosafety*, compiled by the Academic Division of China Association of Science and Technology, China Science and Technology Press, 2011, pp. 18-21

[22] Du Li, "Ethical Issues and Biosafety Goals of Synthetic Biology Explained", *Ethical Issues of Synthetic Biology and Biosafety*, compiled by the Academic Division of China Association of Science and Technology, China Science and Technology Press, 2011, pp. 26-28

be swayed by misinformation and misconceptions and should encourage the development of industries related to this field.

3.4 A minority of experts think that it is necessary to take preventive measures and strengthen safety management.

Some experts proposed specific measures in response, which include strengthening and popularizing risk awareness among researchers, making positive publicity about the field to dispel blind panic, developing detailed correct product safety manuals for synthetic biological parts and organisms, etc. A few experts pointed out that China must make early preparations for the launch of a necessary regulatory system governing biosafety, ethics and intellectual property rights, that legal documents about synthetic biology research activities should be prepared to forestall possible biosafety problems, that only by making adequate necessary preparations in such aspects as public awareness (public acceptance), technical guarantee and legal regulation can the synthetic biology research embark on the path of sound development.

Some scholars make suggestions in their papers. Liu Xiao and Tang Hongling wrote that the risks of synthetic biology involve three parties, including research institutes and researchers, enterprises and their employees, and the government, and that the biosafety regulatory measures should be made accordingly. Among them, the government is at the most important link in promoting and implementing biosafety regulation and its duties and obligations include 1) attaching high importance to biosafety, strengthening the formulation and implementation of relevant policies and regulations and their operability; 2) establishing a biosafety regulatory body to impose qualification review and administration of institutes and personas involved in relevant researches and put in place a sound safety review system; 3) introducing a biosafety rating of biosafety issues related to synthetic biology research institutes and releasing mandatory or instructional policies for related researches; 4) providing policy and funding support for conducting special research projects and related symposiums and popularizing relevant knowledge among the public; 5) establishing an information and data exchange platform about agencies and departments related to synthetic biosafety and integrating related monitoring networks; 6) establishing channels for effective communication between regulatory bodies and the public, building a modern information dissemination network to enhance two-way information exchange, and giving the public the right of participation and supervision by, for examples, creating a public-oriented biosafety website, providing contact information such as email and telephone number; and 7) establishing effective contacts with international safety regulatory organizations, strengthening research on applicable international treaties and the synthetic biosafety laws of foreign countries, and achieving the exchange and sharing of safety information.[23]

In fact, the risks and safety issues of synthetic biology have caught the attention of relevant government departments and the relevant safety supervision policies are already under discussion. In addition to sponsoring academic symposiums on synthetic biology-related ethical and biosafety issues, China National Natural Science Foundation launched a special research project in 2008 to

[23] Liu Xiao, Tang Hongling, "Synthetic Biology and Biosafety Supervision", Chemistry of Life, No. 6, Vol. 32, 2012

jointly research synthetic biology-related biosafety issues with the Austrian Science Fund and held two symposiums on the synthetic biology-related biosafety and risk assessment in January 2010 and October 2011. [24]

To sum up, although synthetic biology has drawn the attention of Chinese scholars and the Chinese government to its possible impact in many fields including social ethics, biosafety and intellectual property rights, there is still a lack of detailed systematic researches and the discussion of the ethnical and other risks of synthetic biology in China is still mainly confined to general introduction and citing of foreign views, lacking unique thoughts and systematic reflections and specific survey of social acceptance of related issues in China and failing to demonstrate the characteristics and peculiarities of ethical researches in China. From the Chinese government to Chinese scientists, it is generally believed that the benefits of developing synthetic biology in China outweigh the risks and that China both have the favourable conditions to develop synthetic biology and should not miss this rare development opportunity.

4. SynBio Power and Control Discourse in China

Judging from existing materials, the administration and regulation of synthetic biology research has not been put within the Chinese government's decision-making agenda and policy framework. China has neither set up a biological ethics committee nor made any official declaration on the ethics and risks related to synthetic biology. It can be said that China does not think it has entered the stage where a related control system should be put in place.

At present, Chinese authorities including the Ministry of Health has set up the Transgenic Ethics Committee and the Stem Cell Ethics Committee in the biotechnological field, but even with the presence of these committees, the implementation of relevant policies still has various problems. Some experts think that this is a very dangerous practical problem. In fact, China learned a lesson before. After the promulgation of the Ethical Guiding Principles for the Research of Human Embryonic Stem Cell jointly formulated by the Ministry of Science and Technology and the Ministry of Health, a number of competent government departments including the Ministry of Science and Technology, the Chinese Academy of Sciences and the China National Natural Science Foundation

[24] The meeting was part of the China-Austria Research Project on Biosafety of Synthetic Biology jointly funded by the National Science Foundation of China and Austrian Science Fund and held for the purpose of identifying new needs of biosafety management in the research of synthetic biology and promoting China-EU cooperation. The meeting was sponsored by the Institute of Botany of the Chinese Academy of Sciences and Austrian Organization for International Dialog and Conflict Management (IDC) and assisted by Key Laboratory of Synthetic Biology of the Chinese Academy of Sciences. The second symposium focused on four thematic topics: 1) safety management and regulation of synthetic biology research bases, main social challenges facing synthetic biology research in China, and the establishment of a regulatory system and administration rules governing synthetic biology; 2) contrast between synthetic biology and genetic engineering in biosafety assessment; 3) biosafety of synthetic biology and related biosafety protection and ethical issues; 4) and development and publicity of synthetic biology. Through discussion, the parties reached the following consensus: the safety assessment in synthetic biology can draw upon and make improvement on the relevant practices of transgenic biosafety assessment; the biosafety of synthetic biology has uncertainties and should be addressed with prudence; to promote the development of synthetic biology, it is necessary to strengthen communication with the public and attach importance to popularization of scientific knowledge; to ensure safety, it is important to emphasize the moral statue of researchers; and laboratories of synthetic biology should have adequate safety measures and reach a considerable safety level.

formed the first National Committee for the Guidance and Coordination of Stem Cell Research in October 2011, but the research and application of the stem cell technology was still in a mess. Many hospitals, in defiance of existing regulations, used stem cells in treatment without approval, which brought many problems. Relevant officials at the Ministry of Science and Technology admitted that it is imperative to enact laws to regulate the ethical and safety issues of synthetic biology.

Our opinion in this respect is that it is not yet the time for China to consider the ethical issues and risks of synthetic biology, that there is not any strong advocacy for this from the public or academia, and that at the present stage, even with the presence of those laws, their implementation will remain problematic.

5. SynBio, values and lay morality in China

According to the GEST report on China's value system, contemporary China's value system is a complicated and diversified value system that blends traditional Chinese values (the Confucianism-dominated traditional culture combining Confucianism, Buddhism and Taoism which emphasizes family and collective interests and empathy), imported values introduced since the modern times (Marxism, science, liberty, democracy and equality), and value criteria emerging from new social situations (economic development orientation/developmentalism, common prosperity, national rejuvenation, catching up with and surpassing the western world, sustainable development, etc.). This value system can be summed up in several keywords: progress/development, affluence, peace and safety, harmony, and sustainable development. These value orientations have also had a bearing on the above three discourses on synthetic biology in China.

5.1 Innovation, values and lay morality

In the discussion about innovation in synthetic biology in China, the most frequently used phrases are “frontier technology”, “leap-forward development”, “opportunity for overtaking”, and “huge potential value”. In the official China Biotechnological Development Report 2008, synthetic biology was thus described: “The emergence and rapid development of synthetic biology show a new trend of biotechnological development, i.e. breaking biological means through biotechnological means to form new biological systems and achieve expected industrial application.…It is expected that biotechnology will see a galloping development in the coming years with extensive applications in energy, environment, chemicals, materials and medicine and create massive social and economic benefits….It is necessary to leverage the potential of application of new biotechnologies in industrial development, especially the role of synthetic biotechnologies in driving technological development in many fields, in order to put in place a scientific and comprehensive bio-industrial system strongly supported by synthetic biology. This is an important way to deal with the serious situations faced by China in such fields as environmental protection, energy and health.”[25] An almost the same description was also found China Biotechnological Development Report 2012: “Synthetic biology represents a new opportunity in the development of biotechnology and an leap-forward

[25] Department of S&T for Social Development under the Ministry of Science and Technology of China and China National Center for Biotechnology Development, *China Biotechnological Development Report 2008*, 2009, Science Press, Beijing, pp. 128-130.

development of the traditional biotechnologies. It makes it possible to break through existing biological systems to create new life systems, thus spawning a new generation of biotechnologies and leading to new productive forces driving the leap-forward development of the biotechnological industry."

Among Chinese scientists, synthetic biology is to a considerable extent discussed with an emphasis on its potential value of application in biomedicine, energy and environmental protection and its role in strengthening China's national security and securing an advantageous position in the new round of scientific and technological revolution. Indeed, synthetic biology is considered by Chinese scientists to represent a rare opportunity of development for China which hopefully will bring a new breakthrough in China's future economic development. It can be seen that the expectation of synthetic biology in China, from the top to the bottom, has been underscored by its application and economic value, reflecting the strong aspiration and pursuit of the Chinese government, Chinese scientists and the Chinese public for the rapid progress of the country and the national rejuvenation, prosperity and sustainable development.

5.2 Risk, values and lay morality

In the risk discourse, the Chinese government and scientists are mainly concerned with three issues: 1) biosafety and prevention matters in the process of the development of synthetic biology, such as laboratory safety and biological terrorism; 2) the impact on the Chinese public from foreign media's reporting of and negative attitude toward synthetic biology in connection with its risks and ethical challenges. Experts are worried that this impact may be negative because it may mislead the Chinese public and give rise to a wave of fear and opposition among the public, thus hindering the progress of synthetic biology. 3) the challenges from developed countries' patent monopoly and IPR competition, which may lead to China's backwardness in the research and development of synthetic biology.

There is little discussion and attention dedicated to issues like "Playing God" which are often mentioned in foreign discussions about synthetic biology's risks and ethical issues. According to the results of the Chinese Citizen Science Knowledge Survey[26] in 2007, only 16% of the respondents agreed that "We have relied on science too much to the neglect to faith", far lower than the percentage in the EU (In an EU survey in 2010, 38% of the respondents agreed and 34% disagreed with the statement that "We have relied on science too much to the neglect of faith"). It can be inferred that the Chinese public are less concerned about the faith and ethical challenges posed by synthetic biology as the public in the EU are.

Overall, the main concerns of the Chinese government and scientists about synthetic biology relate to China's national security and development. Rather than such issues as the ethical predicament, ecological risks and human rights problems that may be brought in the process of the development of synthetic biology, what concerns the Chinese government and scientists the most is what China should do in the face of the obstacles in its effort to develop synthetic biology and how China can catch up in this field. In their opinion, the biggest risk and challenge facing China will be its backwardness in the development of synthetic biology, which would mean the loss of another

[26] Ren Fujun et al. *China Citizen Science Knowledge Report* (Vol. 1), 2010. Beijing: Popular Science Press; Ren Fujun, *China Citizen Science Knowledge Report* (Vol. 2), 2011. Beijing: Popular Science Press.

important opportunity of development. In the discussions about the related risks in China, we can see at work a national crisis awareness developed since the modern times about "backwardness means vulnerability to attack" and China's pursuit of such values of development, affluence and peace (safety).

5.3 Power& control, values and lay morality

Science is always held in high esteem by the Chinese public. According to the results of the Chinese Citizen Science Knowledge Survey, a higher percentage of Chinese public have a positive attitude toward science than the EU public. In spite of a more prudent and objective turn in the Chinese public's attitude toward science, this attitude is far from the fear and misgiving expressed by the EU public. In this context, there is no much concern among the Chinese scientists, government and public about the control and management of synthetic biology as a new technology. In the eye of the Chinese public, science is an important tool for transforming the world. With a general high esteem held about science in China, there is little concern about the risks and ethical challenges that may be posed by synthetic biology. In the statement, "Science and technology make our life healthier and more convenient and comfortable", for example, was agreed by as high as 94% of the respondents of the 2001 survey on Chinese citizens' science knowledge.[27] In 2010, the percentage was still high at 89% in China, versus 66% in the EU in the same year. In the same 2010 survey in China, 85% of the respondents agreed that "Science and technology provide more opportunities of development for our posterity". A comparison of such surveys between China and the EU, a consistently higher percentage of the Chinese public are positive toward science than the EU public. When asked about the statement, "Scientists in possession of the knowledge and abilities to change the world will become very horrible", only 14% of the Chinese respondents in 2007 expressed their agreement, which was far lower than the 53% in the EU. This underscores a major difference between the Chinese public and the EU public. It can be concluded that given their consistently dominant positive attitude toward science, the Chinese public have a low awareness of the risks and negative effect relating to science, which is far from translating into a worry and fear about science and technology.

Judging from the discussions about the management and control of synthetic biology, at present the Chinese scientists and public don't have much demand for the control of synthetic biology, and the Chinese authorities have not put the policy formulation for such management on their agenda, either. This reflects the effect of China's value system. In China, where pragmatism and developmentalism always prevail, the pursuit of progress, development and affluence has priority over potential risks as long as the latter have not materialized as actual threats.

6. Chinese Reflective Ethics

Existing materials available indicate that in contrast to the advocacy made on various occasions for the government to attach importance to and support the R&D of synthetic biology, Chinese scientists lack in-depth research, systematic reflection and conscious participation in the ethical

[27] The statement in surveys before 2010 read: "Overall, scientists' work has made our life simpler and more comfortable".

issues of synthetic biology. A search on CNKI using the key words “synthetic biology” and “ethics” only returned one paper, which showed the seriousness of the problem.

Only a few scholars in ethics made introductions and analyses on the ethical issues related to synthetic biology. An influential effort was made by Zhai Xiaomei and Qiu Renzong in 2010, who stated that with respect to the ethical issues in synthetic biology, the following issues need to be addressed: 1) authenticating and assessing the potential risks of synthetic biology, including physical and non-physical harms; 2) authenticating and assessing the beneficial and harmful consequences of synthetic biology to human wellbeing; 3) surveying the philosophical and cultural factors which make non-physical risks important or unimportant in making public policies concerning synthetic biology; 4) analysing whether the existing regulatory framework of the synthetic biology is appropriate or not; and 5) establishing the ethical framework of synthetic biology research and application. They pointed out that ethical issues of synthetic biology can be divided into two categories: the first category is conceptual ethical issues which concern the justification for the creation of living organisms, and the second category is non-conceptual ethical issues which concern the assessment of benefits and risks. With respect to the issue of the assessment of the benefits and risks of synthetic biology, there are two views, one proactionary and the other precautionary. The proactionary view holds that the biggest risk to the state is the failure to achieve rapid technological development and seize a key opportunity for public wellbeing improvement, industrial development and economic growth. Those embracing this view tend to advocate the minimum control and public education. The precautionary view holds that any new substance or technology shall be deemed to be dangerous before there is evidence showing that it is safe. Those who take the view tend to require more control and public participation. At present, the proactionary view on the risks and ethical issues of synthetic biology prevails, but those holding this view think that a precautionary view should be taken on the synthetic biology by conducting researches on related ethical, legal and safety issues of synthetic biology at the early stage and on the upstream links of research in order to forestall possible risks.

7. Conclusion and Outlook

In conclusion, synthetic biology research is still in its preliminary stage in China. There is a strong advocacy for the government to encourage and support the development of synthetic biology. As for its ethical issues and risks, they have not become anything of a “problem” which needs to be addressed for the academia, the public and the government alike. This situation has come about due to China’s development pattern and actual needs as a “developing country” and has also to do with the potential effect of China’s social value system, as shown in the table below:

	Innovation	Risk	Power & Control
progress/development	Application and interests Science and industry competitiveness Intellectual property Leap-forward development National development strategy proaction	Risk of inaction Backwardness Lost opportunity	Government's support Prioritized fields Positive publicity
Affluence	Patents and IPRs Industrialization	Monopolization	Strategic emerging industry of national strategic importance
Peace and safety	security	Biosafety National security Biological terrorist weapons Minimizing risks	Laboratory management Responsibility Precaution
Harmony and Sustainability	Means for solving energy and environmental problems sustainable growth Social benefits		

To sum up, synthetic biology's management and public involvement in China take on the following characteristics and have a long way to go.

(1) Synthetic biology is still in its preliminary stage in China and has a very limited impact among the public.

At present, there are only a small number of ordinary citizens and even scientists with a good knowledge of synthetic biology, and the discussion of its risks and ethical issues has neither entered into the public domain nor led to any collective civil action of opinion expression. Although there has been some discussion on the justification of synthetic biology and related biosafety issues in the media, it has not raised drawn much attention from the public. In recent years, Chinese media have published a number of articles introducing the progress and achievements of synthetic biology in foreign countries. As soon as there was a major discovery or progress in the field, Chinese media would immediately report on it and introduce related ethical and biosafety issues discussed in the foreign countries, but these reports were mostly introductory and largely meant to attract eyeballs. There have been only a few interviews with experts in the biological field, but no public survey or discussion on synthetic biology has been found.

(2) There is no cultural resistance to the development of synthetic biology in China

Judging from China's social values and social development environment, synthetic biology research does not face much resistance in China. On the one hand, most Chinese are unreligious, and the religious forces are not strong enough to influence policymaking. The conflict between synthetic biology research and religious faiths commonly seen in the foreign countries basically does not exist in China. On the other hand, the utilitarian approach to science and technology determines that synthetic biology generally will not meet strong resistance in China. For example, the research and promotion of the relatively mature stem cell technology has not met strong resistance in China. Although the unauthorized use of stem cell technology in treatment has brought many problems, they have not led to any public outcry about the risks and ethical issues of stem cell research and application.

(3) The influence from outside and the social influence of domestic leftist forces should not be underestimated.

Even though there is not inherent resistance in Chinese society against the development of synthetic biology, the influence from outside and the social mobilization capacity of some interest groups should not be underestimated, and there are many uncertainties about the public attitude towards and public participation in synthetic biology. It cannot be excluded that synthetic biology in China will not be subject to the huge influence of external forces and some environmental organizations as the transgenic technology has been. As in the case of the transgenic technology, the opposition to synthetic biology in China may likely mainly come from outside and be used by some groups not satisfied with the existing politics as a cause to accuse the government of omission. This may influence some citizens and to a large extent influence the opinion on and acceptance of synthetic biology in Chinese society. Therefore, scholar Lei Pei pointed out that the lesson from what the transgenic technology experience should be drawn by having timely communication with the public and enabling them to better understand the synthetic biotechnology.

(4) China faces both opportunities and challenges in the future development of synthetic biology

Looking forward, the development of synthetic biology in China enjoys a lot of favourable conditions. The first is China's liberal social and cultural environment, where ethical and religious issues do not pose a major challenge to the development of synthetic biology. The second is the support from governments at all levels. The Chinese government has attached great importance to the development of synthetic biology, with a series of factors from national science and technology programs and research infrastructure development to supportive industry policies and bio-industrial bases all providing favourable conditions for the development of synthetic biology. The third is the fact that China has had a good foundation in terms of theoretical knowledge accumulation and necessary technological equipment. China has established a number of synthetic biology research institutes, with this field of study having attracted many young researchers. The International Genetically Engineered Machine Competition (IGEM), in which Chinese college students participated in 2007 for the first time and have performed excellently since then, has been very popular in China. All these make possible the rapid development of synthetic biology in China. The fourth is a huge market and demand. China has a population of 1.3 billion. With the reform of China's medical care

system, there will be a growing demand for advanced medical care, especially for new drugs and medical technologies. In China's drive to transform its economic structure, there is a strong need to find new drivers of economic growth. And the prominent environmental and resource pressure that China faces also calls for new technological means for solution.

However, it should be noted that the development of synthetic biology also faces a series of challenges in China. The first is the inadequacy of investment and the lack of channels of investment. China's venture capital industry is not very developed because there is not a tradition or custom for people or industries to finance scientific research. And enterprises tend to lack enthusiasm for basic research and a long-term vision. The second is that there is a lack of the pioneering spirit in the academia, with few original achievements and a significant gap with the internationally advanced level. The third is that the government lacks risk control awareness and leaves much to be desired in its governance capacity. The lack of necessary laws and regulations may lead to some problems in the process of the development of the synthetic biology industry. The related patent system may also be unfavourable to China. China needs to respond to these problems and challenges and actively develop synthetic biology. In this respect, both Chinese scientists and the Chinese government have a tall task and a long way to go.

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Chapter 3

The Status of Synthetic Biology in India

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1. Synthetic Biology and Innovation Discourse

Synthetic biology can be considered as an emerging technology, an amalgamation of the principles of engineering and biology. De Lorenzo and Danchin 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 standardized biological parts that are decoupled from their natural context''.[1]

The global trends and developments indicate that synthetic biology is making headway and USA and Europe are leading while China is taking major initiatives in synthetic biology. Medicine is an important area of R&D in synthetic biology among Biological System Designers/Manufacturers conducting research in synthetic biology, while home and personal care products are a priority in specialty/fine chemical applications globally. Among the applied R&D groups biofuels is a key topic of research. The projected value of global synthetic biology market by end user is expected to be $10838.6 million in 2016 of which diagnostics/pharmaceuticals will be 5373.3[2]. While the potential of synthetic biology has been acknowledged widely in the UK, USA, others are also moving ahead with specific plans and goals in synthetic biology.[3] Interestingly the concept of Responsible Innovation is being integrated into synthetic biology research in UK and the National Roadmap calls for 'Responsible acceleration' of technologies to market, while the Technology Strategy Board of 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. Interest is being evinced in the relevance of synthetic biology for solving global health problems, as for example the call for proposals by Gates Foundation attracted more than 700 applications and developing novel diagnostics, biosensors, vaccines using synthetic biology was specified by many applicants.[4] In the South Asian context multivalent oral vaccines developed using synthetic biology could drastically reduce deaths in children under 5 years on account of diarrhoea.[5] There are many challenges in applying synthetic biology to solve global health problems, and this includes issues in regulation, intellectual property, and commercialization.[6] Recently a sociologist cautioned against over-optimistic projection of benefits of synthetic biology.[7]

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[1] de Lorenzo V, Danchin A (2008) Synthetic biology: discovering new worlds and new words - The new and not so new aspects of this emerging research field. EMBO Reports 9: 822–827.
[2] Cited in Clarke (2013).
[3] National Academies Press (2013).
[4] Rooke (2013).
[5] Vohra, Blakely (2013).
[6] Douglas, Stemerding (2013).
[7] http://www.scidev.net/global/biotechnology/opinion/synthetic-biology-s-malaria-promises-could-backfire.html

Synthetic biology in India is largely confined to few institutes and groups when compared to the 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 few centers specializing 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. In addition, there is a special interest Group on Synthetic biology in India Synjeevani based at Jawaharlal Nehru University, New Delhi. There are individual scientists and groups working on different aspects on synthetic biology in some institutes including IITs, NCBS, CSIR laboratories and Central Universities like JNU. For promoting India-Finland joint research in synthetic biology, the Department of Biotechnology issued a call for proposals. India does not seem have a DIY community in synthetic biology although such 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.[8]

In terms of synthetic biology industry not much is happening except few dedicated firms that are venturing into this. The reasons for this are obvious and although the commercial potential of synthetic biology is much discussed in the literature, even in USA the number of firms that have succeeded in synthetic biology is limited so far. In the case of India as the research itself is in infancy, technology development and transfer to industry or setting up an industry based on the research in laboratories will take time. But the scope for companies specializing in niche areas is present and hence India may witness birth of small firm working in niche areas in synthetic biology in years to come. On the other hand, some of the current initiatives regarding the use of neem for biofuels production offer much potential for industrial applications.

Biofuels and bioenergy constitute the thrust area in synthetic biology and large number of groups are working in this area. The following are some of the groups/initiatives in this area:

- DBT-ICT Center for Energy BioSciences at ICT Mumbai
- Synthesis of Drop-In Biofuels- Synthesizing pathways for production of higher alcohols, fatty acids and hydrocarbons in E.Coli and yeast
- Synthesis of amino acids
- Biobutanol
- Synthesis of furanics from biomass
- Indian Oil Corporation – R&D Center at Faridabad- supported by 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
- 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
- ICGEB, New Delhi research is being done on engineering microbes for sugar fermentation, consolidated bioprocessing, butanol production and hydrocarbon production; Engineering algae for growth improvement and lipid improvement.

[8] Landrain et.al (2013).

- Regarding bilateral collaboration DBT and Academy of Finland have jointly launched a program 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 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.[9] In terms of publications the number is 29.[10]

As part of the 12th Five Year (2012-2017) Planning process a Task Force (Task Force on Synthetic Biology and Systems Biology Resource Network) was constituted. The Task Force lists only few firms including Cell Works while other sources indicate few more including the recently founded Sea6 a start-up based in IIT Madras. Sea6 is working on developing technologies to convert seaweeds into biofuels and has 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.

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 categorizing it under that category. For example, the R&D in biofuels in synthetic biology can be categorized under other categories including metabolic engineering. Similarly process related R&D can be categorized 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 which points out that in Asia Japan and China lead in synthetic biology with 15 and 11 entities respectively.[11] A study on citing landscape puts India in the 16th place.[12]

In the context of 12th 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, the global scenario and proposed a way forward for systems biology and synthetic biology in India.[13] The Task Force argued that the timing is ripe for a well-supported 'push' into synthetic biology in India. The immediate goal should be build a base of research expertise and infrastructure. The human resources potential is untapped and a competition

[9] Deepak Singh, Pawan K Dhar Exploring the future of synthetic biology in India and its Probable Pathways from Infancy to Maturity Current Synthetic and Systems Biology Vol 1 No 1 1-11 (2013)
[10] Ibid.
[11] Woodrow Wilson Center (2013).
[12] Oldham, Burton and Hall (2012).
[13] Report of the Planning Commission Constituted Task Force on Synthetic Biology and Systems Biology Resource Network (2012).

like iGEM may be relevant in India. The broad undergraduate education over narrow technical training related to synthetic biology should be prioritized. Similarly a broad based engineering curriculum that helps students to maintain their basic engineering and quantitative skills and exposures 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 Crores in the XIIth Five Plan Period (2012 -2017) and envisaged that CSIR, which is a champion of synthetic biology will give specific shape and direction.

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

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 the 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.

The Task Force Reports Innovation Discourse and Risk Discourse are linked by its perception that for realizing the potential of synthetic biology in India, emphasis on benefits and its application in solving problems in different sectors alone is 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 indicates that it is willing to take broad view on promoting and regulating technology. It recognizes 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 indicates the growing awareness among scientists and policy makers on these issues although it may not be reflected uniformly in all official reports and plans.

The innovation discourse of the Task Force recognizes 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 it has proposed many initiatives and has made suggestions on various aspects including capacity building.

To sum up, the Task Force Report though brief recognizes the ethical, legal and social issues in synthetic biology without elaborately discussing them. It gives them the importance they deserve. With the innovation discourse and the power of the technology are the dominant discourses in the report, they are tempered by risk discourse and attention to socio-economic issues. Hence this report can be read as a report that strikes a balance between the discourses with emphasis on putting synthetic biology to meet 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 XIIth 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 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 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 12th Five Year Plan (2012-2017) a working group of the Department of Biotechnology (DBT) was established to identify the thrust areas and allocation of resources in biotechnology. The Working Group of DBT for the 12th Plan identified using synthetic biology for developing next generation biofuels as an important application and suggested including this under various programs including Grand Challenge Program and translational research projects. Although the Group recognized the importance of synthetic biology under different applications,

programs 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 programs cutting across various projects being undertaken by the DBT for different objectives ranging from capacity building to promoting enterprises in biotechnology.

The DSIR (Department of Scientific and Industrial Research) plan for 12th Five Year Plan emphasized its on-going work in synthetic biology, Metabolic engineering in Azadirachtin (Neem) and Vinca alkaloid biosynthetic pathways and recommended developing this further. Under the major new initiatives of DBT in 12th Plan Synthetic Biology & Metabolic Engineering are listed as one such initiative and according to 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 XII th plan document proposes 'Biosciences with chemical sciences and synthetic biology for next-generation biofuels" as an example of proposed connectivity under inter-disciplinary translational research.

Synthetic Biology in the XIIth Plan

According to the XIIth Five Year Plan the following initiatives will be made during the plan period:

1. Under Department of Biotechnology in 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 e*stablish 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) CSIR Institute of Synthetic and Systems Biology is to be established . The DSIR document for XIIth plan estimates the budget for this as Rs 800 crores

These are initiatives launched under the respective departments/CSIR and there is no proposal to establish a Mission type program 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 12th five year plan document. The emphasis on innovation and application of synthetic biology along with emerging technologies within the broad objectives of the five year plan.

As there is no separate program 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

recognizes the challenges posed by synthetic biology in terms of biosafety, biosecurity and ethical issues, nor gives it 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 a 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, DBT working group stress the need to harness the potential of synthetic biology although neither offer a road map to achieve this objective. Nor the linkages between National Innovation System in biosciences and life sciences in India, 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. So it can be concluded that while this is the dominant discourse it is not yet emerged as a powerful discourse that could impact policy making and regulation.

2. Risk Discourse

Remya Krishnan *et al.* point out that most scientists working in synthetic biology in India are of the view that Government of India should devise a new policy that covers, inter alia, biosafety and biosecurity issues emerging from research in synthetic biology.[14] 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, as below:

a) Recombinant DNA Advisory Committee (RDAC)
b) Institutional Biosafety Committees (IBSC),
c) Review Committee on Genetic Manipulation (RCGM), and
d) Genetic Engineering Approval Committee (GEAC).

Of these 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

[14] Krishnan, R. et.al (2010) at 240.

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 IBSC is the first level regulator and monitor of biosafety. IBSC's 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'. Issued by Department of Biotechnology. 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 biosecurity clearance of medical products. Furthermore, 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. The regulatory framework is to be replaced by an Authority if the BRAI Bill is enacted. Given the India' 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 Pawan Dhar although synthetic biology community in India is small and is operating within a reasonable regulatory environment, the regulatory framework can be further strengthened.[15] Reviewing the global trends and initiatives in Europe, USA and China, Jain, Bhatia and Chugh point out that given the potential commercial prospects India should develop legislation and policies to regulate synthetic biology.[16] India has initiated steps to evolve a Code of Conduct for Scientists who might be engaged in Dual Use Research or Research that would be directly relevant for provisions of BTWC. [17]

The earlier mentioned Task Force identified bio-security issues, bio-safety issues and ethical issues as issues that need to be addressed. It pointed out that potential for misuse by biohackers was there and also the threat of unintentional release of synthetic habitats to natural habitats and the consequences for environment and 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).

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

[15] Dhar P.K (2013).
[16] Jain A., Bhatia P., Chugh, A. (2012).
[17] BWC/MSP/2005/MX/WP.23 (2005).

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 not reduces them as scientific and technical issues to be resolved by experts alone. Its recognition that interfering life in its natural form is opposed indicates its sensitivity to such opposition by different stakeholders. Although it does not elaborate steps to address these issues it underscores the fact these are global concerns (also).

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 crystallize in terms of a national strategy or action plan for synthetic biology. Hence, although risk discourse is visible and some of the concerns are widely shared it has not made much impact in policy making or in revising the regulatory framework.

3. Power and Control Discourse

Synthetic Biology is often associated with the 'Playing God' image or with a technology that could result in unnatural and novel organisms that could go out of control. But in India in the discourses on synthetic biology, which are confined to few circles these imageries not found. Instead the power and control discourse is overshadowed by the innovation and risk discourse. One reason could be absence of networks in synthetic biology that have emerged elsewhere.[18] Another factor could be that the innovation discourse in India underscores implicitly the power and control aspects in synthetic biology by recognizing 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 that 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 so far, 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, the Power and Control discourse is not strong in India.

4. Lay Morality and Public Discourse

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 expertise were not able to answer questions that demanded such a knowledge. Hence in the second round only 25 respondents were targeted. While the respondents considered that the majority of the objectives are likely to be plausible within the next

[18] Cf Susan Molyneux-Hodgson, Morgan Meyer Tales of Emergence—Synthetic Biology as a Scientific Community in the Making BioSocieties 4, 2-3 (2009) 129-145.

decade, only two objectives are expected to be achieved by 2020: a protocol specific to synthetic biology and integrating synthetic biology in curriculum. 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 a majority of the 26 listed objectives are likely to be achieved within 2020-2030. The study – while 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 recognizes` the potential of synthetic biology, it also points out that while synthetic biology research should be supported, this should happen in an atmosphere of 'public acceptance and transparency' and efforts to minimize the large negative consequences should be made. It points out that a 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 recognizes the enormous potential of biotechnology it points out that there are other issues that could limit the benefits being realized by the 'broadest possible population'.

The controversies over synthetic production of Artemisinin and potential negative impacts on account of synthetic vanilla indicate that socio-economic issues will play an important role in legitimacy and acceptability of synthetic biology. In case of biofuels applications that do not exacerbate the demand for fertile lands and vast quantities of land are likely to be less controversial. India in fact should prioritize 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 conduct 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 criticized synthetic biology and linked it with the opposition to biotechnology in agriculture.[19] Since many NGOs in India reflect the position taken by Friends of Earth, Greenpeace and the 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 utilization of synthetic biology for the same. However, research in synthetic biology aimed at developing biofuels from agricultural wastes and other sources that do not need extensive diversion of land should be encouraged. For those NGOs which are opposed to GMOs and agricultural biotechnology, extending the same arguments to oppose synthetic biology is not difficult. Given the lack of public awareness concerning synthetic biology, they can play on the fear of the unknown technology aspect to try to convince public that synthetic biology will exacerbate problems caused by agricultural biotechnology. DBT and other agencies should take a proactive stand on public engagement in synthetic biology and should address emerging issues in regulation, biosafety and biosecurity lest they become controversial issues that could constrain development of synthetic

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

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

5. Socio-Economic Issues Discourse

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 recognizes the importance of socio-economic issues. In the 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 is that synthetic biology is in nascent stages and so far the products based on synthetic biology have not been products that have significant socio-economic impacts. In fact it is estimated that many products will be commercialized 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.[20] 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 prioritize vaccine development, developing diagnostic kits and other applications that are more relevant in the context of developing nations. 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.

Thus the socio-economic discourse is yet to emerge as a loud voice in the discourses on synthetic biology in India.

6. Synthetic biology in India – Pathways and Issues

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. Within that research on biofuels gets top most priority. The sheer absence of health research in synthetic biology indicates that synthetic biology has long way to go in India. Given the fact that India has a dynamic biotechnology industry and lot of research and teaching activity happening in biotechnology in India the situation is ripe for growth of synthetic biology. But this is not happening on account of many factors:

1. Synthetic biology needs interdisciplinary approach and such a milieu may not be available in institutions

[20] National Academies Press (2013).

2. Absence of a push from the government in terms of mission mode in supporting synthetic biology or support through special programs 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 are accepted by public
4. Narrow focus of departments and agencies is not conducive to development of a broad inter-disciplinary approach
5. 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 as below:

   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
   2. The research on biofuels results in significant breakthroughs and thereby synthetic biology gains acceptability and this results in more attention and funding
   3. Synthetic biology may continue to grow at slow speed with few groups spread across institutes working on various issues
   4. Some applications (e.g. biofuels) get more support, industry funding and gain prominence while research in other areas languishes for want of support
   5. 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 DBT, without resulting in spectacular growth.
   6. International developments adversely impact the 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 the Indian Nanotechnology Mission – while there was funding even earlier – the founding of Nanotechnology Mission was possible because some scientists including 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 are necessary.[21]

Over the last two decades India has built up good capacity in biotechnology thanks to the funding from Government of India and this has helped in the growth 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 ICT field are globally recognized. 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 elements, i.e. capacity in biotechnology and bioinformatics combined with ICT, should be used to build synthetic biology in India. As of now there is no special program or exclusive funding scheme for synthetic biology. Some of the proposed initiatives like the CSIR Center on Synthetic Biology are necessary but not sufficient, given the rapid pace in which the field in growing and the availability of the capacity in India. Hence there is a need to develop a strong program in synthetic biology so that during the XIIth five year plan a firm foundation would be laid. It is suggested that DBT can first create an exclusive initiative on synthetic biology to assess the field and develop a strategic plan. Based hereon, in a later stage a separate entity which could be Technology Mission or Special Program can be set up. Since synthetic biology is an emerging technology supporting it through venture capital is important. DBT can envisage special programs to facilitate academic-industry partnerships in synthetic biology. To sum up, India should capitalize 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 the 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 for synthetic biology, power and control discourse is yet to emerge strongly. The discourse now is largely driven by few scientists who are working in this field, while official bodies have recognized the potential of this technology. There is an awareness although limited, on socio-ethical issues including regulation and biosafety.

7. 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 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. Hence the discourses in synthetic biology in India are yet to evolve and only feeble voices are heard now. Whether the talk on realizing the potential will be matched with support and investments is a big question.

[21] Wiek et.al. (2012).

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Chapter 4

Concluding comparative analysis – Executive summary

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1. Introduction

Ever since the unravelling of the DNA molecule in 1953 by Watson and Crick, developments in biotechnology have come a long way. After cloning and genetic modification, synthetic biology (SynBio) is expected to mark the new phase in the development of biotechnology. Synthetic biologists are gaining more and more control over the fundamental building blocks of life. This allows them to 'design' and 'create' micro-organisms that may perform a variety of useful tasks, but at the same time become increasingly more estranged from organisms we may find in nature. Given SynBio's potential to contribute to addressing important challenges, such as regarding health, sustainability, scarcity of resources and energy security, it is no surprise that this new discipline has been embraced by scientists all over the globe. On the other hand, like any other science and technology (S&T) SynBio also gives rise to (potential) risks. In addition, SynBio may raise moral questions and concerns, since it allows mankind to put 'life' and 'nature' on the drawing board in an unprecedented manner.

On overall, SynBio may thus – once more like any other S&T – also lead to *tensions* (and even conflict) and therefore: debate. First, we aim to understand the *role of ethics* in articulating, anticipating and (perhaps) reconciling these tensions in the evolving debate on SynBio. The nature and dynamics of these tensions and debates are however, not solely informed by the character of a particular S&T; they are rather highly informed by the socio-economic condition, culture and values of the specific region, which will be taken into account. Furthermore, we consider that SynBio is a global endeavour, contributing to an increased *global interconnectedness*. This is for instance expressed by increasing international (scientific) cooperation, but also by the potential risks that will not be constrained by state borders. Last, as we previously mentioned moral concerns may certainly lead to tension *within* a specific region, but also *between* different regions. Consider for instance, the international debate sparked by the cloning of the sheep 'Dolly' and the breeding of 'Herman the bull' the world's first genetically modified bovine.

Against the backdrop of these region-specific traits and global interconnectedness, in the following we will summarize and compare how SynBio has been debated so far in China, the European Union (EU) and India. In order to conduct this analysis we will use five discourses as searching lights, namely discourses on *innovation, risk,* and *power & control*. In addition, we will focus on *lay morality*: what expectations and issues have been raised concerning SynBio by voices from civil society and the broader public? Last, we will address the way *reflective ethics* voices engaged with SynBio in the three regions. We will examine the nature and weight per discourse, i.e. what kind of issues are discussed and to what values do they relate? What kind of actors take part in the discussion? Furthermore, we will consider whether certain discourses are more dominant than others. This will allow us to make a comparative analysis of the three regions, in which we will consider differences and similarities. Throughout this endeavour we will pay specific attention to the role of the region-specific values – as defined in earlier GEST deliverables – in informing the debate.

We will start off however, by briefly describing the state-of-the-art of SynBio in the three regions, since the degree of development is highly likely to be one of the core parameters for the nature (and even emergence) of the different discourses in the three regions.

2. State of the art of the development of SynBio in the three regions

The development of SynBio in the three regions differs quite strongly, varying from rather advanced to still starting up. In the following we will provide a brief state-of-the-art of the development of SynBio, to serve as a backcloth for our comparative analysis. First, it should be mentioned that the general development of SynBio is for the moment still very much confined to laboratory settings, and has only recently begun to find its way to being applied in industrial settings.

The development of SynBio in Europe is not quite as advanced in the United States, but still very much at the forefront. Ever since the emergence of SynBio in the United States, SynBio was almost immediately embraced by the European scientific community. Correspondingly, the European Union (and several individual EU member states) also felt the need not to miss the bus and started investing in SynBio rapidly as well. By 2014 we can see that SynBio is slowly being applied in industrial settings. Although not as early as in Europe, SynBio has raised the attention of Chinese researchers and also the Chinese government started funding SynBio research from about 2008, and ever since the field has attracted only more support from the Chinese government. The development of SynBio in China is therefore not as advanced as in Europe, but by now fully equipped to catch up with countries at the forefront. In sharp contrast, SynBio has so far only gained little attention in India, and as yet largely confined to few institutes and groups when compared to the number of Indian groups working in life sciences and biotechnology. Also the interest from the Indian government and industry is limited so far. Our discussion of the discourses on SynBio in India will therefore be primarily based on the findings of a Task Force (made up by members stemming from government and academia), installed by the government to examine the opportunities of SynBio and systems biology.

3. Comparing discourses on synthetic biology in the three regions

- *Discourses on innovation*

Why is SynBio important? What can the field deliver? What are the opportunities? What is needed to let SynBio mature into an industrially relevant and socially robust discipline? These are the central questions of an innovation discourse. In all three regions voices are heard on the opportunities SynBio might bring for society. SynBio is perceived as a potential powerful scientific domain and its applications might help addressing challenges that all three regions face. Such challenges may relate to solving problems regarding (public) health, sustainability, energy sources. When compared to the Indian discourse, the European and Chinese innovation discourse are both much stronger developed, and also reveal several support actions, such as funding research, and capacity and community building. Contrary to China, in Europe however, a need is felt to go beyond such techno-scientific support actions in order to make SynBio successful, such as addressing ethical and regulatory concerns early on. Interestingly, similar points are also raised by the Indian Task Force. In terms of values we find that the European discourse is predominately informed by values of

(market) freedoms and *sustainability.* Turning to China, we see that the innovation discourse – and the goals pursued by supporting SynBio – next to its socio-economic status, is very much informed by the total spectrum of Chinese values: protecting public health (*harmony*), promoting economic development (*progress*), safeguarding national security and coping with an aging and growing population (*peace)*, and last, addressing resource and environmental needs (*sustainability).* This demonstrates, that while not institutionalized in the same manner as in EU or the US for example, *ethics* certainly has a place in directing the course of SynBio in China. Also when we look at the findings of the Indian Task Force, we find a strong link between SynBio's goals and needs ranging from energy security, to improvements in agriculture and health, which strongly relate to values of *access* and *equity.*

- *Discourses on risk*

Like any other technology SynBio offers benefits but also gives rise to risks. What type of risks are perceived? By whom? What is the weight they assign to the risks in the face of the benefits? How should be dealt with the (potential) risks? The potential risks of SynBio make up for an important part of the evolving storyline on SynBio, and issues like *biosecurity* and *biosafety* are raised in all three regions. This is also no surprise, since EU member states, India and China are all member of several international conventions, such as the Cartagena Protocol and the Biological Weapons Convention, that call for addressing such issues as well. Strikingly, in China the aforementioned issues are indeed considered as a risk, but hampering innovation and missing out on the opportunities of SynBio is perceived as a much bigger risk by government and the scientific community. *Progress* therefore seems to be dominant value in the Chinese risk discourse. In Europe there is a more or less commonly shared attention for potential physical harm, relating to *citizen's rights*. Contrary to the other regions, also civil society has entered the European risk discourse, bringing in the perspective of *justice, solidarity* and *equality* in the discourse. Strikingly, we also find that *sustainability* is also invoked in the risk discourse as well. In the innovation discourse SynBio is understood in its potential contribute to a greener economy. In the risk discourse however, SynBio is also being challenged by CSO's for its potential harmful effects on the environment, i.e. its detrimental effect on *sustainability.*

- *Discourses on power & control*

On the one hand, SynBio allows for many opportunities to address grand challenges mankind is facing, including challenges relating to health, energy and sustainability. On the other hand, SynBio may give rise to risks and ethical concerns. So, who gets to decide on where to SynBio should develop and under what conditions? Who is responsible? In addition, SynBio arrives at a time where science's role and position in society face increased public scrutiny. Can these issues be left to government and experts or should other stakeholders, or even the broader public be actively involved as well? In other words: who gets to exercise the *power and control* of synthetic biology? Turning to our case studies, we find that only in Europe we can see a strongly developed discourse hereon. The main actors are government and the scientific community, but also civil society is making its mark. Largely inspired by earlier bad experiences with public reception of technologies, a need is perceived to involve stakeholders and the broader public early on in the development of SynBio. The aim is that such involvement and addressing ethical, legal and social issues early on, allow SynBio to be better embedded in society. Furthermore, we can identify several challenges that

require delicate balancing, such as devising forward-looking regulation, without stifling innovation, and balancing between self-regulation and state-driven regulation and coercion. This latter form of hard-government is particularly advocated by (internationally operating) NGO's such as Friends of the Earth and the ETC Group. In any case, the European governance landscape of SynBio is therefore already rather complex, even while SynBio is still predominantly confined to the lab. Turning to the Indian case, the Indian Task Force, also recommends to address ELSI issues and map public opinion upfront, rather than only stimulating technological development alone as a top priority. To substantiate this claim it refers to the premature push of biofuels and the negative consequences thereof. In addition, the Task Force raises the tension between open source initiatives and rigid intellectual property approaches, relating to the Indian values of *access, equity* and *inclusion*. The Chinese discourse shows a different picture, namely that the development of SynBio is largely in the hands of the government and the scientific community, and is considered as being sufficient so far.

- *Synthetic biology and lay morality*

Public reception is crucial for the course of development a technology. To put it bluntly: it can make or break a technology. Concerns of members of the public may involve potential physical harms, but to a large extent also relate to *non-physical issues,* i.e. boundaries that should not be overstepped, that are related to our values and culture. However, given the state of development SynBio has not (yet) led to significant *public debates*, which can be examined. In fact, even the sole awareness of SynBio is rather low. Correspondingly, in none of the regions do we see an active public debate on SynBio. In China science is held in high esteem by the public, and there is trust in governmental management SynBio. This stance reflects the effect of the Chinese value system, where pragmatism and developmentalism prevail in the pursuit of *affluence* over potential risks as long as the latter have not materialized as actual threats. In Europe there is also no real active debate so far (in spite of a small number of NGO's), but surveys among the general public demonstrate a large degree of pluralism, i.e. there are lot of (earlier mentioned) issues and values involved. Such issues include monopolization, concerns regarding biosafety and biosecurity, increasing global inequalitie and, freedom of research, relating to a broad spectrum of values, such as *sustainability, justice, solidarity, equality, citizen's rights and market freedoms.* These issues and values will prove to be difficult to reconcile. This will become a serious challenge for the governance of SynBio, given the aspirations to include a wide array of actors and addressing the issues they put forward. Unsurprisingly, in the Indian case we also will not find a public debate on SynBio. However, a couple of environmental groups, that have been concerned with GMO's, have spoken out against SynBio. For instance, well-known GMO-opponent Vandana Shiva recently voiced critique on SynBio. The raised concerns broadly relate to socio-economic considerations and values such as *equity* and *access*.

- *Synthetic biology and reflective ethics*

In addition to *lay morality,* morality is reflected upon by professional *reflective ethics* voices. Such voices may either stem from academia, or ethics advisory bodies (including technology assessment and ELSI community). Are such voices heard so far in the emerging SynBio debate? If so, do they make an impact on S&T policy-making and development? In China some reflective ethics voices from academia are heard, but on overall systematic reflection on the moral aspects of SynBio is lacking. In fact, ethical reflection has so far mainly been limited to general introduction, and citing of foreign

views, instead of formulating authentic thoughts. The voices heard do call for authenticating both physical and non-physical harms, as well as benefits, the need for reviewing cultural and philosophical factors which may relate to non-physical harm, justification of creating new organisms (conceptual issue). In spite of this perceived knowledge gap, so far there is little cultural resistance expected (such as concerns regarding 'playing God'). Only in the European case we see strong involvement of *Reflective Ethics* voices so far. The TA, and ELSI community, as well as academia have engaged with SynBio early on and have made broad contributions to debate in terms of examining potential benefits, risks and other issue. Furthermore, efforts are made to make sure that such issues are addressed by government and politics. Broadly speaking we can identify four different roles *reflective ethics* is playing in in the emerging debate on SynBio: (1) articulation of values and issues, (2) highlighting (hidden) tensions between values, (3) enriching debate[1], (4) translation to S&T policy making arena. It is perhaps not surprising that such efforts are made in Europe, since earlier biotechnologies have led to serious sensibilities. In India we will not find *Reflective Ethics* so far, but the aforementioned Taskforce recommends ethical reflection, given the potential sensibilities.

Overview development of SynBio and SynBio discourses in China, Europe and India

	Development of SynBio	**Innovation**	**Risk**	**Power & Control**	**Public (Lay morality)**	**Reflective ethics**
China						
Europe						
India						

Darkness of cell = degree of development

4. Conclusion and discussion

In the preceding we aimed to map the evolving debates on SynBio in China, the EU and India. Put in comparison, all three emerging debates show distinct features and positions on the pros and cons of SynBio. On the one hand they are informed by the differences in the state-of-art of SynBio in the respective regions. On the other, they are informed by the region-specific socio-economic condition, culture and value system. In the 20th century biotechnology has been the subject of international debate on numerous occasions. We recall the the international debate sparked by the cloning of 'Dolly the sheep' and the breeding of 'Herman the bull'. Two events that for some constitute moments of scientific triumph, but for others create a grave sense of uneasiness. In any case, the whole of mankind needs to relate to such events, since they cannot be ignored and force us to (re)define mankind's desired relationship with (and potential power of) nature and life itself. To paraphrase organic chemistry pioneer Friedrich Wohler such events constitute 'ugly facts' and slay romantic ideas of life and nature. Given the large scale support and enthusiasm for SynBio, it is likely that this new frontier of biotechnology will also confront mankind with events and facts the whole of mankind needs to relate to.

[1] A good example hereof is how the EU-project SYNTH-ETHICS has conducted an in-depth analysis of the notion of "Playing God" by means of SynBio, which so far has not led to controversy, but is considered as a potential issue, since such concerns have been voiced regarding earlier biotechnology is well.

Therefore, we call for the strengthening of a true *global ethics* in science and technology. By this we certainly do not mean that there is a need to develop a single global *morality*, but rather that – given the increasing interconnectedness of regions – there is a need for stronger systematic ethical reflection and dialogue among different regions. We consider two important stepping stones to achieve such interregional ethical reflection and dialogue.

First there is a need for a proper forum in which such exchange of ethical thoughts can take place. It is interesting to see that such fora are in place for *risks* related to biotechnology. In all three regions for instance serious attention is paid to biosafety and biosecurity. This is not surprisingly since China, EU member states and India are all party to the Cartagena Protocol on Biosafety and the Biological Weapons Convention. Given the increasing global interconnectedness the creation of a forum in which common ground on risks can be searched for, is an important achievement. However, how to deal with risks of S&T does not *per se* tell us a lot about how different regions appreciate S&T in general. Finding common ground in terms of *morality* is likely to be more challenging. For all regions certainly share concerns regarding safety and security. *Moral* concerns are however, far more related to the distinct culture, values and beliefs of a specific region. Therefore moral concerns may differ strongly between regions. In spite hereof, dialogue and searching for common ground is called for, since different moral concerns may lead to tensions *amongst* regions, just as they raise tensions within a certain region. We therefore call for a proper forum for a global ethics discourse in which such different viewpoints can be discussed, next to the fora which are in place for a risk discourse. The General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) pioneered in this regard by acclamation of the *Universal Declaration on Bioethics and Human Rights* in 2005. This might be an excellent opportunity to build further upon.

Last, for a proper global ethical dialogue, we consider it is crucial for each region to formulate an autonomous moral identity. For we have seen that for instance in China, the moral response to SynBio is primarily based on reacting to (and evading) moral concerns stemming from the West, rather than formulating an autonomous moral position on SynBio. Institutionalization of *reflective ethics* and *public participation* (similar to the EU and sometimes called for in the case of India) might be one way to facilitate such a process, but certainly is not the only option. For example, in the Chinese case we found an implicit – yet strong – connection between the Chinese value system and the motivations for stimulating SynBio. Strengthening the formulation of a moral identity towards S&T may thus also be achieved by explicating such hidden reflection on morality and S&T. In any event, according to us only if such autonomous formulation of a moral identity takes place, will we be genuinely able to exchange thoughts on how we as mankind should relate to the world of possibilities that SynBio has to offer.