RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 23, No.3, pp 101-112

Regulating Risks in Synthetic Biology

Sachin Sathyarajan[*], Balakrishna Pisupati[**] , Neeraj Verma, Pawan K. Dhar[***]

Abstract: Synthetic Biology is considered as a key emerging technology. Globally regulating risks in Synthetic Biology is a contentious issue. Discussions on regulating Synthetic Biology and it's relevance for various treaties, conventions and protocols are on going in many fora, convened under, inter alia, Convention on Biological Diversity. Given it's ramifications, such discussions are inevitable. Regulating biosafety and biosecurity, and, liability for harm are key themes on which discussions are being held. This article describes these developments and their importance. In India the XII th Five Year Plan considered harnessing synthetic biology for national development and regulating it. India has a biotechnology regulatory regime. But develop a robust policy for synthetic biology, foresight and analysis are needed. The global developments on regulating synthetic biology are relevant for development and regulation of synthetic biology in India.

Keywords: Convention on Biological Diversity, Biosafety, Harm and Liability, risk assessment

Brief Introduction

Synthetic biology is one of the top ten breakthrough technologies as part of the "forth industrial revolution" that are "most likely to change the world" (Brownsword, 2008). Synthetic biology aims to build new organisms with functions that might not exist in nature (Boldt and Müller, 2008). Where previous genetic technology served as a tool of manipulating existing organisms, synthetic biology aims to create new life, sometimes from scratch.

[*]Faculty of Law, Jindal Global Law School, Sonipat.
[**] United Nations Environment Programme, Nairobi, Kenya (formerly FLEDGE, Chennai).
E-mail: pisupatibalakrishna@gmail.com (*Corresponding author*)
[***]Synthetic Biology group, School of Biotechnology, Jawaharlal Nehru University, New Delhi.

It is important to understand that any technology cannot advance without some freedom in research and development. The objective for a national legal framework is to leverage its anticipated benefits while guarding against its potential risks. The laws and regulations framework governing traditional tools and products of biotechnology can be applicable to this relatively nascent field in some ways, but most often it fails to fully adapt to the evolving possibilities of synthetic biology.

Synthetic biology organisms are able to self-replicate and spread rapidly and evolve on their own. We cannot be sure of how it will play out in the future, so all countries including India has to develop a framework for anticipatory governance. There are key areas of national interest pertaining to biosecurity, biosafety, liability, intellectual property, trade and ownership which warrants great attention in designing an effective governmental policy and regulatory framework (Wiek *et al*. 2012).

Initiatives from India

There are complex challenges for a country like India which has a rich biodiversity and is increasingly adopting the technology. As part of the 12th five year plan, India has set up a Task Force on systems biology and synthetic biology research in 2011[1]. The country has informed international bodies that the technology is still at its infancy in the country.

The Task Force came up with a report and has acknowledged the potential with regards to key applications in biofuels, bioremediation, biosensors, food and health. The Task Force had made a strong case for a push for the technology, and few initiatives have been launched by departments such as Department of Biotechnology and Department of Scientific and Industrial Research[2]. Initiatives include the Indian Biological Engineering Competition and the DBT training program[3].

The report had emphasized that India has the opportunity to be a world leader as a protector and supporter of "open-source biological platforms"[4]. This requires a supportive legal and regulatory environment in which small biotechnology players can also participate. Recently, the DBT funded policy and research planning for synthetic biology (JNU and FLEDGE collaborative program) and recommendations were submitted.

Policy Aspects

A policy framework related to technology lays down the objective, the scope of legislation on a particular subject and its relationship to existing international and national frameworks. The policy framework focuses on why, how and when a technology is developed and deployed. International law requires state parties to the respective treaty regimes to take measures at the national level, to achieve common stated objectives in the manner it has been collectively agreed.

Subsequent laws and regulations provide tools for effective national policy implementation, backed by enforcement, as well as detailed procedures for the redress of damages[5]. Section 4 discusses the various international developments and related treaty frameworks which is directly applicable to designing a synthetic biology policy framework for India.

Global Policy Initiatives

Synthetic biology is impacted by discussions at international, regional and private-sector driven positions and interests. Various international treaties and organisations are currently examining the impacts of synthetic biology and engineered gene drive systems on their respective agreements. India is a party to all the international governance bodies discussed below

i. Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD) has been ratified by 196 states. The United States of America (US) is a non-party to the convention. Synthetic biology is a new and emerging issue in the context of realizing the objectives of convention.

The twelfth Conference of the Parties (COP12) and COP13 produced decisions seeking a more robust assessment of synthetic biology against the Convention's new and emerging criteria[6]. The Parties decided to establish an Ad Hoc Technical Expert Group (AHTEG) and convened a moderated online forum[7].

The AHTEG has produced multiple reports and recommendations but is yet to come up with a robust assessment against the new and emerging criteria as mandated by the COP[8]. At the COP 14, Parties agreed on a need for regular horizon-scanning of the most recent technological developments

for reviewing new information regarding potential impacts of synthetic biology[9].

a. The Cartagena Protocol on Biosafety

The CBD COP extended the AHTEG on synthetic biology, taking into account the work under risk assessment under the Cartagena protocol on Biosafety[13]. Current deliberations are also considering whether any living organism developed thus far through new developments in synthetic biology fell or could potentially fall outside the definition of a living modified organism (LMO) and thus be subject to the risk assessment requirements of the Cartagena Protocol on Biosafety[10].

b. The Nagoya Protocol on Access and Benefit Sharing

In 2017, the Secretariat of the CBD commissioned a report examining the impacts of digital sequence information (DSI) as it relates to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS) to the Convention on Biological Diversity (Wynberg and Laird, 2018). An Ad Hoc Technical Expert Group (AHTEG) was also established to provide recommendations for member states on those impacts and a draft decision was submitted with vast disagreements[11].

ii. Food and Agricultural(FAO)

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) report commissioned in 2017 examined the impacts of synthetic biology and digital sequence information (DSI) on the Plant Treaty (Welch *et al*, 2017). The report addresses the phenomenon of "dematerialisation", which suggests that "the information and knowledge content of genetic material extracted, processed and exchanged in its own right, detached from the physical exchange of the plant genetic material". It included the scientific and technological changes affecting the Treaty and the broader legal considerations and opportunities for benefit sharing within the ITPGRFA framework[12].

iii. Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

CITES has been engaged in discussion on the question of synthetic products that are indistinguishable from products from listed specimens and the status of modified organisms and products under the Convention[13]. Seventieth meeting of the CITES Standing Committee in October 2018 adopted a report on the "Specimens Produced from Synthetic and Cultured DNA"[14]. The study notes that regulation under the treaty becomes challenging since synthetic biology specimens may be extremely difficult to differentiate from that of wild specimens by visual or analytical means.

iv. International Union for the Conservation of Nature (IUCN)

IUCN Members adopted Resolution titled "Development of IUCN policy on biodiversity conservation and synthetic biology" to map the impacts on conservation and sustainable use of biodiversity[15]. In early 2018, an IUCN Synthetic Biology and Biodiversity Conservation Task Force, was created to oversee the implementation of the Resolution and to develop policy recommendations before the 2020 World Conservation Congress.

v. Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The focus under TRIPS, on issues related to synthetic biology, pertains to the intellectual property rights issues. The results of current synthetic biology research that is focused on modifying existing "natural" genomes could qualify for the "breeder's right" under the International Union for the Protection of New Varieties of Plants (UPOV Convention) If in the future, there are new plant varieties developed as a result of the production of entirely novel genomes, protection under breeder's rights is being discussed.

vi. UN Convention on the Law of the Sea (UNCLOS)

UNCLOS includes activities and resources beyond national jurisdiction. In relation to a new treaty under negotiation that includes marine genetic resources in areas beyond national jurisdiction (ABNJ), including sharing of benefits synthetic biology and its impact on ocean governance is being discussed.

Regulatory Aspects

Regulation refers to interventions that are put in place by relevant agencies "*to control and channel conduct in the desired way*" (Brownsword, 2010). Regulation is designed to implement the specifics of a policy or legislation. Regulations are to be authorized by the governmental agencies that hold the designated authority. Synthetic biology is not insulated from the highly polarized debates that are surrounding the use and management of the new wave of fourth industrial revolution technologies.

The rapid pace of scientific research and irregularities about the specific benefits of synthetic biology create complex challenges for national regulation. Synthetic biology can also pose risks such as bioterrorism, loss of trade opportunities, environmental damage, and transboundary harm.

Considering the multifarious applications of synthetic biology like energy, agriculture and biofuels, there is always a perceived threat of components releasing into the open environment. Risk and uncertainty give rise to synthetic biology's major governance challenges. On a spectrum we are looking at an intentional bioterrorist attack on one hand to accidental damage to the environment on the other. There is a difference between risk and uncertainty. Risk refers to an event that can be estimated using theory or experience or both but uncertainty cannot be estimated by either methods.

Biosafety addresses the "inherent risks of a biological agent or material to cause unintentional harm to human health and the environment".[16] In contrast, **biosecurity** concerns itself with the intentional uses of a biologic agent or material through loss, theft, diversion, release, or inadvertent research results that have security implications.[17] Intention is the key difference between both the two concepts and biosafety mostly refers to accidental events. National biosafety regulations like that of India[18] may provide that certain activities require prior authorisation or notification, containment procedures or other forms of administrative oversight.

Risk Assessment- Biosafety and Biosecurity

The World Trade Organization's 1995 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the 2000 Convention on Biological Diversity's Cartagena Biosafety Protocol seem inadequate to deal with biosafety issues posed by synthetic biology. The WTO's SPS measures

limit the space for member states to introduce trade restrictions based on considerations of food safety, and plant and animal health.

The Cartagena Protocol deals with import and export (transboundary movement) of LMOs, including illegal and unintentional transboundary movements. It enables import of certain living modified organisms subject to an Advanced Informed Agreement procedure.[19] The traditional biosafety framework was created in response to the issues raised by the recombinant DNA technology. Agricultural biotechnology can cause GM crops outperforming non-modified species and create undesired gene transfer. There are additional questions of safety of GM food for consumption.

The CBD Cartagena Protocol applies to all "Living modified organism" (LMO) which are "living organisms that possesses a novel combination of genetic material obtained through the use of modern biotechnology".[20] The scope can extend to animals, plants, food, pharmaceuticals and insects. Most countries have designed national regulatory frameworks for risk assessment and management in relation to LMOs.

The Cartagena Protocol[21] requires Parties to "establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks" connected with the use, handling and transboundary movement of living modified organisms (LMOs) This includes "possible adverse effects of LMOs on the conservation and sustainable use of biological diversity" The terminology "modern biotechnology" according to the Protocol drafted in 2000 does not include techniques like genome editing.[22] The Protocol does not concern itself with constituent parts like DNA under Article of the Protocol.

The 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (usually referred to as the Biological Weapons Convention) was the first multilateral undertaking prohibiting the development or acquiring of biological agents or weapons for hostile purposes or armed conflict. The scenario is not adapted for the conduct of non-state actors apart from governments becoming biosecurity threats.[23]

The increased securitisation of public health is bringing increased focus on both intentional and unintentional release of biohazardous organisms. The World Health Organization revised International Health Regulations (IHRs)

in 2005 to ensure States notify the organisation in case of an unexpected or unusual public health event within its territory.[24] Proposals for screening customers who are ordering material which could be weaponised are made to commercial providers of synthetic DNA.

National Biosafety Regulations

The Cartagena Protocol currently ratified by 171 Parties, but is yet to be ratified by several countries active in the application of biotechnology. Major biotechnology players such as the US, Canada and Argentina are not Parties to the Protocol. Many countries have biosafety regimes in place that fully or partially follows the risk assessment framework outlined in the Protocol.[25]

The 1989 Rules for manufacture, use, import, export and storage of hazardous microorganisms/genetically engineered organisms or cells is jointly implemented by the Ministry of Environment and Forests (MoEF) and the Department of Biotechnology in India. The 1989 Rules regulate research, development and large-scale commercialisation of GM crops as well as post- approval monitoring and compliance in accordance with the treaty obligations of India.[26]

The scope of applicability of the Cartagena Protocol to synthetic biology is a contested topic. CBD Parties during the Mexico COP13 in 2016 noted that it is not clear whether SYNTHETIC BIOLOGY organisms would fall under the definition of LMO[27]. In 2017, the CBD AHTEG concluded that most living organisms developed through techniques of synthetic biology, including organisms containing engineered gene drives, fell within the definition for LMOs.[28] In November 2018, CBD COP14 emphasised the need for case-by-case risk assessments and specific guidance on such risk assessment could be useful.[29]

Regulatory Stages and Requirements

Biotechnology applications are subject to step-by-step regulation and monitoring at various levels in different jurisdictions. Most countries require some sort of authorisation system depending on the risk associated. In Canada, the release of GM plants with "novel traits" has to pass through various stages including import, contained use in a laboratory or greenhouse, unconfined release and commercialisation.

The proposed Biotechnology Regulatory Authority of India Bill is pending approval in the Parliament since 2013.[30] Various stages of regulatory approval include the manufacture, use, sale, import, export and storage of GMOs.[31] The Indian regulatory system also comprises of other legal instruments including the Drugs and Cosmetics Rules – 1988, Protection of Plant Varieties and Farmers' Rights Act, 2001, Biological Diversity Act, 2002.[32]

There is a three-tier system of approval for GMOs as well as their products under Rules 1989. The initial assessment of applications begins at the institutional level itself by the IBSCs, where the proposals are evaluated and recommended to the RCGM (Choudhary *et al*, 2014). After an in-depth evaluation of the forwarded proposals, the RCGM sends its recommendations to the GEAC.

In 2014, a ten-year moratorium was imposed on commercialisation and release of BT Brinjal. Several State governments like Andhra Pradesh, Maharashtra and Karnataka have approved field trials for few crops including food crops. Within the EU, member states have powers to "opt-out" and close areas and even the state borders to release GM plants.[33]

Liability for International Harm

The international legal principle of state responsibility for international harm provides for liability for possible damages attributable to synthetic biology. The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress [Supplementary Protocol] to the Cartagena Protocol provides for states to establish national frameworks for liability in cases of environmental harm.

The Supplementary Protocol has 42 parties to date and there are no binding obligations for establishing civil liability. The national frameworks can provide for rules and procedures that address damage, including civil liability, but they do not have a binding obligation for the operator to take appropriate action. Some states have adopted a non- state liability approach while others opt for a fault based liability.

EU legal instruments apply a principle of strict liability, or no-fault liability, for any damage to the environment resulting from dangerous activities.[34] The European Convention on Civil Liability for Damage

Resulting from Activities Dangerous to the Environment (The Lugano Convention) covers the production, storage, use disposal or release of GMOs.

Fault-based liability may be difficult to prove in the context of synthetic biology. There may not be a sufficiently close causal link between the activity and the damage to show liability. Strict liability is typically reserved for acutely dangerous activities or activities delineated in national legislation.[35]

Conclusion

This compilation is intended to provide a foresight for further developing a national policy framework for India. it is important to consider the international developments and global initiatives while developing the national policy for India, especially since the science and regulatory framework related to use of the science is driven by global considerations. It is time for India to consolidate its stand on the science of synthetic biology and communicate its interests and aspirations in relevant international fora with clarity and should avoid conflicting stands on science on one hand and regulation on the other.

Endnotes

1 Report of The Planning Commission Constituted Task Force on Synthetic and Systems Biology Resource Network, 2011.

2 Report Of The Planning Commission Constituted Task Force On Synthetic And Systems Biology Resource Network https://dst.gov.in/yearsplan/synthetic-and-system-biology-resource-network-ssynthetic biologyrn

3 As a precursor event to the iGEM competition https://syntheticbioindia.weebly.com/ibec-2016-description.html

4 Report Of The Planning Commission Constituted Task Force On Synthetic And Systems Biology Resource Network https://dst.gov.in/yearsplan/synthetic-and-system-biology-resource-network-ssynthetic biologyrn

5 https://www.who.int/heli/tools/legis_regul/en/

6 https://bch.cbd.int/synbio/

7 Ad Hoc Technical Expert Groups on Synthetic Biology, 2015, 2018

8 Ad Hoc Technical Expert Groups on Synthetic Biology, 2015, 2018

9 CBD COP decision 14/19

10 Report of The Ad Hoc Technical Expert Group On Synthetic Biology Montreal, Canada, 4-7 June 2019 at https://www.cbd.int/doc/c/b2bb/cf58/b09729bb00be6abf72325a1a/synbio-ahteg-2019-01-03-en.pdf

11 Recommendation Adopted by The Subsidiary Body on Scientific, Technical and Technological Advice CBD/SYNTHETIC BIOLOGYSTTA/22/ CRP.10, 2018 at https://www.cbd.int/doc/recommendations/synthetic biologystta-22/synthetic biologystta-22-rec-10-en.pdf

12 Decisions 17.89 to 17.91, 2016; SC69 Doc. 35, 2017

13 Seventieth meeting of the Standing Committee Rosa Khutor, Sochi (Russian Federation), CITES, 1-5 October 2018 at https://cites.org/sites/default/files/eng/com/sc/70/E-SC70-33.pdf

14 Resolution 6.086

15 https://legal.un.org/ilc/reports/2019/english/chp5.pdf

16 Biotech Consortium India Limited and Ministry of Environment, Forest and Climate Change, Regulatory Framework for Genetically Engineered Plants in India, https://biotech.co.in/sites/default/files/2020-01/Regulatory-framework-for-GE-plants.pdf

17 Biotech Consortium India Limited and Ministry of Environment, Forest and Climate Change, Regulatory Framework for Genetically Engineered Plants in India, https://biotech.co.in/sites/default/files/2020-01/Regulatory-framework-for-GE-plants.pdf

18 Alexander Kelle. 2009. Security Issues Related to Synthetic Biology, in Synthetic Biology: The Technoscience And Its Societal Consequences 101, 102 (Schmidt et al. Eds.)

19 Regulatory Gaps and Synthetic Biology, 'Policy Brief Regulatory Gaps in the Global Governnace of Synthetic Biology '.(2014)

20 Article 3, Cartagena Protocol on Biosafety to the Convention on Biological Diversity

21 Cartagena Protocol on Biosafety to the Convention on Biological Diversity, https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf

22 "Modern biotechnology" is defined in the Cartagena Protocol as: "The application of: a. In vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection"

23 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction 10 April 1972

24 IHRs Article 7

25 Biotech Consortium India Limited and Ministry of Environment, Forest and Climate Change, Regulatory Framework for Genetically Engineered Plants in India, https://biotech.co.in/sites/default/files/2020-01/Regulatory-framework-for-GE-plants.pdf

26 Sheetal Menon and Shishir Kumar Jha (2016) National biosafety system for regulating agricultural biotechnology in India

27 CBD COP13 Decision 17, para. 6

28 CBD COP decision 13/17, para 7

29 CBD COP decision 14/L.31para 9.

30 https://www.prsindia.org/sites/default/files/bill_files/Brief-_BRAI_Bill_2013.pdf

31 Biotech Consortium India Limited and Ministry of Environment, Forest and Climate Change, Regulatory Framework for Genetically Engineered Plants in India, https://biotech.co.in/sites/default/files/2020-01/Regulatory-framework-for-GE-plants.pdf

[32] RCGM Secretariat https://ibkp.dbtindia.gov.in/Content/Rules?AspxAutoDetectCookieSupport=1

[33] 2001/18/EC Art. 26b Winter, G., Cultivation Restrictions for Genetically Modified Plants: On Variety of Risk Governance in European and International Trade Law; https://www.cambridge.org/core/journals/european-journal-of-risk-regulation/article/cultivation-restrictions-for-genetically-modified-plants/0F6C85FACA0779560A06D37EADB826BB (2017)

[34] Lugano Convention

[35] United Republic of Tanzania. 2009. The Environmental Management (Biosafety) Regulations. http://tz.chm-cbd.net/biosafety/nationalimplementation/national-biosafety-framework/tanzania-biosafety-regulations-2009.pdf

References

Boldt, J. and O. Müller. 2008. "Newtons of the leaves of grass". Nat Biotechnol 26, 387–389.

Brownsword, R. 2008. Rights, Regulation and the Technology Revolution. Oxford Scholarship.

Choudhary, B., Gheysen, G., Buysse, J., Meer, P.v. and S. Burssens. 2014. "Regulatory options for genetically modified crops in India". Plant Biotechnology Journal. Vol. 12, pp.135–146.

Welch, E., Bagley, M., Kuiken, T. and S. Louafi. 2017. Potential implications of new synthetic biology and genomic research trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA or 'Treaty').

Wiek, Arnim, et al. 2012. "Sustainability and Anticipatory Governance in Synthetic Biology." IJSESD vol.3, no.2: pp.25-38. http://doi.org/10.4018/jsesd.2012040103

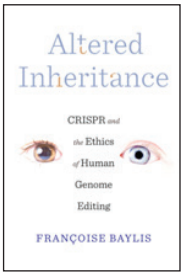
Wynberg, R. and S. A. Laird. 2018. 'Fast Science and Sluggish Policy: The Herculean Task of Regulating Biodiscovery'. Trends in Biotechnology.

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 23, No.3, pp 113-116

Book Review

Altered Inheritance: CRISPR and the Ethics of Human Genome Editing



Author: Françoise Baylis

Publisher: Harvard University Press

Year: 2019

ISBN: 978-0674976719

Pages: 304; Price: INR 1548.00

The book analyses scientific, ethical, societal and political aspects of the early history of the human genome editing. Not limiting the discussions about the future use of technology within the "scientific, medical, political, corporate, or other elites", author firmly puts forth the need for societal consensus in shaping the way forward for best harnessing the potential of genome editing for humankind. Thus, bringing together "all of us" in deciding if human genome editing is a boon or a threat. The author, Françoise Baylis has worked extensively on heritable human genome modification, bioethics, assisted human reproduction, women and public health, polices and ethics. She is Professor at Dalhousie University, Canada and was a member of the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing.

For this book, Françoise received the PROSE Award in Clinical Medicine in 2020. During the same year, Emmanuelle Charpentier and Jennifer Doudna were awarded the Nobel Prize in Chemistry for the development of the revolutionary gene manipulating technology 'Clustered Regularly Interspaced Short Palindromic Repeats' in association with the Cas9 DNA-cutting enzyme (CRISPR/Cas9 genetic scissors). Often seen as a 'double edged sword', scientists have raised numerous scientific, societal, governance and ethical issues associated with CRISPR. In September 2020, detailed 'consensus' study report on the Heritable Human Genome Editing (HHGE) came up with several recommendations, including extensive

societal dialogue before pre-clinical use of HHGE in any country. Françoise was invited to share her reactions on the report. While acknowledging report's emphasis on the need to involve society in discussion around HHGE's (im)permissibility, she pointed that there was no mention of societal consensus (which is also the fulcrum of her book).

The book is lucidly written, comprehendible and aims to empower discussion on governance and ethics of HHGE. She presents useful timelines on science and social relations of human genetics during 1880 and 2018 and science policies of human genome editing during 2015-2018. The proponents put forth the compelling medical need and benefits of somatic cell gene editing in correcting faulty genes and curing Huntington's disease, and preventing genetic diseases in future generations. However, germline editing could cause heritable permanent changes and expose genetically modified babies to long-term untold harms. The potential harms, concerns of accessibility and shift from "health-related to non-health-related genetic modifications" were discussed, along with simpler and safer alternatives to HHGE. It is important to discuss and deliberate responsibly to forsee "potential biological, societal, and cultural consequences". The book delves into various ethical debates around complicated design projects of "better babies". With greater use and normalization of genetic and reproductive technologies there are risks of exposure to harmful and "oppressive acts of discrimination, stigmatization, and marginalization".

The author neither firmly advocates nor strongly opposes HHGE, giving a well-balanced assessment and evaluation of potential benefits and harms, ethical and societal risks and challenges of these HHGE developments. She underlines that some "underscore the importance of public dialogue and seek to position themselves as knowledgeable contributors to this dialogue." The book argues for a "broad societal consensus" which according to her "is a process that involves seeding global dialogue, engaging in a respectful exchange of divergent views and values, building trust, and exploiting collective intelligence on how best to use science and technology to create a better world."

The author emphasizes on adopting "slow science" that advocates scientists to slow down, take time and think how their work could help achieve societal goals. In contrast with the present culture of "fast science"

that is largely fueled by personal and commercial interests, often directed by market forces and profits. She underlines that it is the social responsibility of science and scientists to contribute to public policy for common good. An important aspect of this is making scientific accessible to policy makers, public as well as science diplomats. At this stage, she asserts that repeated calls by scientists, professional science organizations, national ethics and transnational governance for time-bound prohibitions is crucial and will provide scope for science diplomats to work with civil societies and ethicists to deliberate on policy choices to promote "common good for the commonweal". She underlines critical 'roles' played by bioethicists in the HHGE debates to situate science in the larger socio-cultural context and ensure wider representation of values, interests and beliefs, towards - "all of us" shaping the way forward for "us all".

Calling for action towards an equitable and just world, the book focuses on maximum participation towards collective informed decision making for "our biological and social future." The author has very well placed all aspects of the HHGE developments, potential benefits and risks, including "designer babies". The book caters to a wide range of audience, and very strongly puts forth the need for "broad social consensus" which is a very timely, significant and thought-provoking intervention into the ongoing debates around HHGE, which will shape our informed actions to understand what are the gains and loss for the future. The book adequately explores and identifies various 'participants' of the multi-stakeholder discussions and deliberations. Thus, paving the way forward for evaluating/assessing/weighing the technology's potentialities and harms, which will be very useful in developing both national and international regulatory frameworks.

Sneha Sinha
Consultant, RIS
Email: sneha.sinha@ris.org.in

References

Angrist, Misha & Barrangou, Rodolphe & Baylis, Françoise & Brokowski, Carolyn & Mathews, Debra. 2020. Reactions to the National Academies/Royal Society Report on Heritable Human Genome Editing. The CRISPR Journal. 3. 333-349.

Association of American Publishers Award. 2020. 2020 Prose Awards Category Excellence Winners. Retreived from https://publishers.org/wp-content/uploads/2020/02/2020-PROSE-CATEGORY-WINNERS-LIST-for-Press-Release.pdf.

Shwartz, Mark. 2018. "Target, delete, repair - CRISPR is a revolutionary gene-editing tool, but it's not without risk". Retrieved from https://stanmed.stanford.edu/2.

The National Academy of Medicine, National Academy of Sciences and The Royal Society. 2020. "Consensus Study Report: Heritable Human Gene Editing". Retrieved from https://www.nap.edu/catalog/25665/heritable-human-genome-editing.

The Royal Swedish Academy of Sciences. 2020. "Press release on the Nobel Prize in Chemistry 2020". Retrieved from https://www.nobelprize.org/prizes/chemistry/2020/press-release/

Guidelines for Contributors

1. ABDR is a refereed multi-disciplinary international journal. Manuscripts can be sent, preferably as email attachment, in MS-Word to the Managing Editor, Asian Biotechnology and Development Review, Research and Information System for Developing Countries (RIS), Core 4B 4th Floor, India Habitat Centre, Lodhi Road, New Delhi 110003, India (Email: editor.abdr@ris.org.in; Tel. +91-11-24682177-80; Fax: +91-11-24682173/74). Submissions should contain institutional affiliation and complete mailing address of author(s). All submissions will be acknowledged on receipt.
2. Manuscripts should be prepared using double spacing. The text of manuscripts should not ordinarily exceed 7,000 words. Manuscripts should contain a 200 word abstract, and key words up to six.
3. Use 's' in '-ise' '-isation' words; e.g., 'civilise', 'organisation'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'.
4. Use figures (rather than word) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old, etc.). In general descriptions, numbers below 10 should be spelt out in words. Use thousands, millions, billions, not lakhs and crores. Use fuller forms for numbers and dates— for example 1980-88, pp. 200-202 and pp. 178-84.
5. Specific dates should be cited in the form June 2, 2004. Decades and centuries may be spelt out, for example 'the eighties', 'the twentieth century', etc.

References: A list of references cited in the paper and prepared as per the style specified below should be appended at the end of the paper. References must be typed in double space, and should be arranged in alphabetical order by the surname of the first author. In case more than one work by the same author(s) is cited, then arrange them chronologically by year of publication.

All references should be embedded in the text in the anthropological style–for example '(Hirschman 1961)' or '(Lakshman 1989:125)' (Note: Page numbers in the text are necessary only if the cited portion is a direct quote).

Citation should be first alphabetical and then chronological–for example 'Rao 1999a, 1999b'.

More than one reference of the same date for one author should be cited as 'Shand 1999a, 1999b'.

The following examples illustrate the detailed style of referencing:

(a) Books:

Hirschman, A. O. 1961. *Strategy of Economic Development*. New Haven: Yale University Press.

(b) Edited volumes:

Shand, Ric (ed.). 1999. *Economic Liberalisation in South Asia.* Delhi: Macmillan.

(c) Articles from edited volumes:

Lakshman, W. D. 1989. "Lineages of Dependent Development: From State Control to the Open Economy in Sri Lanka" in Ponna Wignaraja and Akmal Hussain (eds) *The Challenge in South Asia: Development, Democracy and Regional Cooperation*, pp. 105-63. New Delhi: Sage.

(d) Articles from Journals:

Rao, M.G., K. P. Kalirajan and R. T. Shand. 1999. "Convergence of Income across Indian States: A Divergent View". *Economic and Political Weekly,* 34(13): pp. 769-78.

(e) Unpublished Work:

Sandee, H. 1995. "Innovations in Production". Unpublished Ph.D thesis. Amsterdam: Free University.

(f) Online Reference:

World Health Organisation. 2000. "Development of National Policy on Traditional Medicine". Retrieved on March 31, 2011 from http://www.wpro.who.int/sites/trm/documents/Development+of+National+Policy+on+Traditional+Medicine.htm

Asian Biotechnology and Development Review (ABDR) is a peer reviewed, international journal on socio-economic development, public policy, ethical and regulatory aspects of biotechnology, with a focus on developing countries. ABDR is published three times a year by Research and Information System for Developing Countries (RIS), a New Delhi based autonomous think-tank, envisioned as a forum for fostering effective policy dialogue among developing countries.

Synthetic Biology (SB) is an emerging technology that has much potential and there are concerns about risk and governance in SB. In this special issue on SB there are six articles that deal with different aspects of synthetic biology ranging from introducing SB to relevance of biofoundries for a developing country like India. Given the international dimension of risk and regulation in SB, articles discuss them in detail giving an international perspective and describing the regulation in India. Similarly Access and Benefit Sharing (ABS) and SB is explored in an article in the context of genetic resources. This special issue is part of RIS's research and publications on SB, which is a component of RIS's work on emerging technologies.

RIS
Research and Information System for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Core IV-B, Fourth Floor
India Habitat Centre
Lodhi Road, New Delhi-110 003
Tel. 91-11-24682177-80
Fax: 91-11-24682173-74
Email: dgoffice@ris.org.in
Website: www.ris.org.in

/risindia @RIS_NewDelhi /RISNewDelhi