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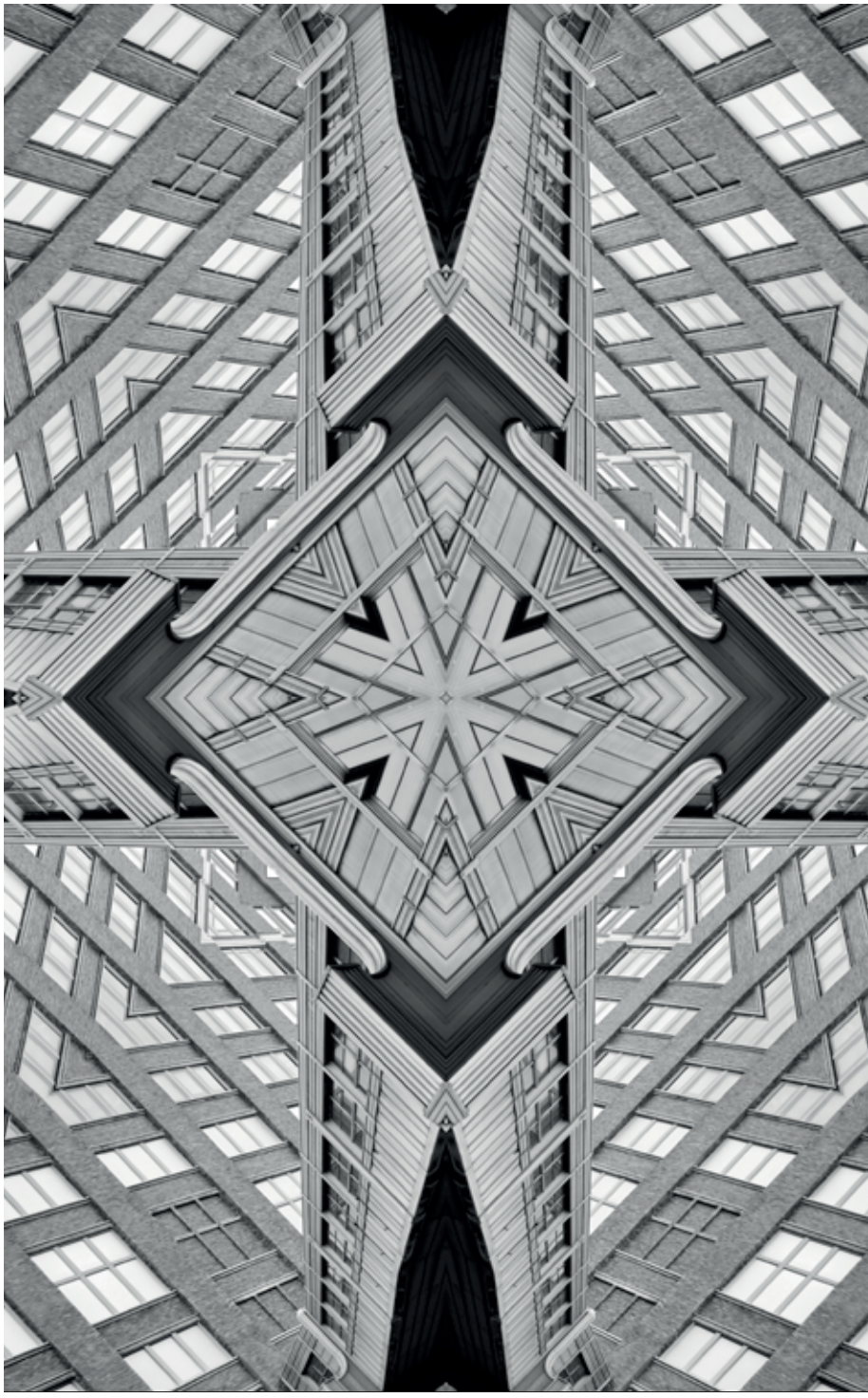

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Innovation in Biotechnology: Ethical and Regulatory Challenges

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Abstract

This brief analyses the regulatory, security and ethical challenges facing states and the international community regarding emerging technologies in biotechnology, focusing on the CRISPR/Cas9 gene editing system and artificial gene synthesis. It highlights the inadequacy of current mechanisms such as export control regimes to regulate these emerging technologies because of a fundamental shift in the nature of challenges posed and an altered global landscape. The brief also underlines the need for an inclusive mechanism to facilitate discussions on the ethical issues, and suggests possible solutions to the manifold dilemma.

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Introduction

Emerging technologies can be categorised as either new, or continuing advancement of existing ones that may be widely available within a few years. Globally, the rapid growth in the field of biotechnology has led to the emergence of newer technologies that have the potential to impact various aspects of people's lives. Technologies such as gene therapy, gene editing, synthetic biology, and nanobiotechnology are being used to address a variety of challenges such as treating genetic disorders, eliminating tropical diseases like malaria, and using targeted medicine to treat cancer.[1] At the same time, however, these technologies present unique regulatory and bioethical conundrums.

Emerging technologies usually undergo a period of familiarisation and experimentation during which scientists test their limits and develop promising new applications. During this course of technological maturity, these technologies often challenge existing ethical and regulatory norms, primarily due to their novelty. It is difficult to regulate them at this stage, because their broader implications on health, the environment, and national security are yet to be fully understood. Regulatory apparatuses eventually catch up and a new equilibrium is established. However, adequate caution must be exercised in this intervening maturity period which, for some emerging technologies may last several years.

This brief examines two of the most promising advances in the field of biotechnology: the CRISPR/Cas9 gene-editing system, and artificial gene synthesis technology. These technologies illustrate how regulatory and ethical grey-areas can be exploited in ways that are detrimental to both science and society. Past experience with emerging technologies can help create an understanding of the effectiveness of traditional regulatory approaches and explore alternatives better suited for the current challenges.

> "It is difficult to regulate emerging technologies during the period of experimentation as their implications on health, the environment, and national security are not fully known."

CRISPR/Cas9 Gene Editing Technology

Developments in biotechnology are facilitating significant innovation across the globe, especially in the fields of medicine, environment, and agriculture. One with plenty of potential is the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR/Cas9) system.[2] It is a gene editing technology which was invented just about a decade ago but has revolutionised the field of medical research and biotechnology owing to its simplicity, efficiency, and cost-effectiveness.

The essence of CRISPR/Cas9 gene-editing system is simple enough: It finds the target DNA sequence in the cell and performs desired edits to the gene sequence, all by itself. This functionality can also be used to turn segments of genes on or off without altering the target DNA sequence. As compared to other gene editing techniques, CRISPR is quick, easy, and extraordinarily cost-efficient. This technique can be applied directly in embryo as well, reducing the time required to modify target genes as compared to the traditional method of using embryonic stem (ES) cells.

CRISPR is already being used in a variety of ways to address contemporary challenges. Some of its applications include development of custom-made gene drives in wild-type mosquito populations with potential to eliminate deadly tropical diseases such as malaria;[3] making newborns free of disease by editing out dangerous mutations at the embryonic stage that cause genetic disorders such as Down syndrome and Huntington's disease;[4] and improving the efficiency and production of biofuels by creating strains of algae that produce twice as much fat, which are then used to produce biofuels.[5]

To be sure, CRISPR-Cas9 can revolutionise the fields of immunotherapy and gene therapy, among others. However, its simplicity and cost-effectiveness could also enable its use for potentially unethical research, especially as it currently falls in an ethical and regulatory grey-area. In 2018, Chinese scientist, He Jiankui, announced the birth of the world's first-ever 'CRISPR twins'.[6] He used CRISPR technology to edit the genome of human embryos and remove undesirable mutations in the CCR5 gene that makes the cell susceptible to Human Immunodeficiency Virus (HIV).[7] It was a surprising and concerning development because CRISPR technology is still at an experimental stage and germline editing has not been approved in humans.[a] The second- and third order-effects of such genetic edits, that too in genomes of live humans, are unpredictable.

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a In germline editing, edited genome of an individual becomes heritable. This contrasts with somatic cell editing where only the patient being treated is affected. Regulatory agencies in many countries allow somatic gene editing but not germline editing in humans.

What concerned the global scientific community further was that such a consequential experiment was conducted clandestinely, and the result was publicly announced only after the babies were born.[8] Even experiments involving mosquito gene drives that seek to eliminate malaria are being done under controlled conditions precisely because their potential impact on the environment is unknown. The birth of the 'CRISPR twins' lays bare the deficiencies in oversight procedures, both at the global and Chinese-government level that allowed such an experiment to be conducted in the first place.[9]

Artificial Gene Synthesis

Artificial gene synthesis is the production of gene-length double-stranded DNA fragments through chemical synthesis of oligonucleotides. Unlike natural DNA synthesis in living cells, artificial gene synthesis does not require a template DNA, allowing almost any sequence to be synthesised.[10] The technology makes it possible to produce DNA molecules that do not exist naturally in living organisms. Gene synthesis is not a new technology, and DNA fragments have been synthesised in laboratories since the 1970s. However, earlier methods were time-consuming, prohibitive, and prone to errors. Commercial gene-synthesis services available today have shorter turnaround times, are cost-effective, and are virtually error-free. This is fast becoming an enabling technology for modern molecular biology.

This technology provides several advantages during the research and development process. Gene synthesis is used to make custom plasmids,[b] optimise gene expression,[c] produce recombinant antibodies,[d] study mutant genes and even design and synthesise DNA vaccines. It provides greater flexibility to scientists in choosing target sequences for their experiments. However, as is the case with many emerging technologies, artificial gene synthesis, if unregulated, can become a national security and public health risk.

The accessibility and advantages of this technology makes it a potentially attractive instrument, for example, for bioterrorism. In accordance with international treaties such as the Biological Weapons Convention (BWC), several microbiological agents, including specific strains of bacteria and viruses are strictly regulated due to their potential to be used as ingredients of biological weapons. These include causative agents of deadly diseases such as tuberculosis, anthrax, rinderpest, and botulism. To mitigate the possibility of non-state and malicious actors using these strains for a biological attack, their use in biomedical

b Plasmids are small, circular pieces of DNA mainly found in bacteria. They are used in genetic engineering to amplify copies of certain genes and in molecular cloning, they are used to transport foreign genetic material from one cell to another.

c Gene expression is the process through which the instructions in DNA are converted into a functional product, such as a protein.

d Recombinant antibodies are antibodies that are generated in a laboratory using synthetic genes.

research is tightly regulated by countries.[11] However, availability of low-cost gene-synthesis services is testing the limits of this regulatory approach.

Many of the specific virulent or infectious strains restricted under the BWC have their non-lethal, non-infectious and commonly found counterparts. For example, several strains of *E. coli* can be found in the typical human gut—they are harmless, and exist in a symbiotic state in our large intestines providing resistance against pathogenic organisms. However, a specific strain of *E. coli* such as the Shiga-toxin producing one, can cause bloody diarrhoea and kidney failure. It has the potential to create a public health scare or disrupt agricultural supply chains. Most worrying is that only a few specific genes determine whether an *E. coli* will be harmless and harmful: this could be exploited by a trained biologist to convert a commonly available variant into a virulent one. While such risks have existed in theory for several decades, traditional gene synthesis methods in use were prohibitive and not considered as cause of concern. However, recent advancements in gene editing technologies along with cheap, commercially available gene-synthesis services[e] have converted a once theoretical threat into a real one.[12]

In 2017, David Evans and his team at the University of Alberta announced that they used synthetic biology tools to recreate the extinct *horsepox* virus, which is closely related to the *variola* virus that causes smallpox.[13] They purchased multiple overlapping DNA fragments from a commercial German gene-synthesis company and stitched together a functional 212,000-base-pair horsepox virus genome in their laboratory. Furthermore, they were able to grow, sequence and characterise the synthetic sequence along the lines of predicted natural sequence. This led to concern among the scientific community that this experiment could also be replicated to synthetically recreate the variola virus, given its close relation with *horsepox*.[14]

More recently, there have been concerns raised by several governments, scientists and national security experts regarding the origin of the SARS-CoV-2 virus that causes Covid-19. The theories include an accidental leak of a synthetic coronavirus, and a genetically-edited coronavirus that 'escaped' from a laboratory.[15] Investigations into the origins of SARS-CoV-2 are still ongoing and are fraught with geopolitical implications of their own.[f] However, the pandemic experience highlights that existing regulatory procedures at the national and international level are inadequate to address the emerging biosafety and biosecurity risks posed by emerging technologies.

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e Gene synthesis services are available in several major countries (indirectly in India too). Upon order, they are manufactured in US, EU, China, Japan or wherever the company is located, and cold chain shipping effectively ensures it can be shipped anywhere.

f China has repeatedly refuted the accidental leak theory. It will suffer significant reputational damage if it is determined that origin of SARS-CoV-2 virus was indeed an accidental leak from a laboratory. This revelation will only exacerbate the geopolitical realignment currently underway in response to China's rise.

Balancing Alarmism and Regulation

Historically, emerging technologies can be developed with either beneficial or harmful intent. The challenge for the global community is to develop regulations that do not stifle innovation and protect scientific freedom, while ensuring enough checks and balances to minimise risks posed by the misuse of such advancements. The potential for technologies such as CRISPR/Cas9 and synthetic biology to benefit humanity far exceeds the risks their misuse may pose. Both these technologies have also been at the forefront of tackling the Covid-19 pandemic. Several vaccines that have either been developed or are under development, including mRNA vaccines have used both of these technologies in their vaccine development process.[16] Furthermore, extensive collaboration between scientists from across the globe would not have been possible without the free flow of information. Extremely restrictive regulations would have added more months to the vaccine development process—something that the world could not afford.

However, information asymmetry between the scientific community and the general public, along with the role of media, often leads to alarmism and impulsive policymaking. This is true as well for emerging technologies. The scientific community bears a unique responsibility to uphold the highest standards of biosafety and ethical probity because a few isolated incidents of misuse and negligence can negatively affect public perception and hamper growth prospects of the emerging technology. The 1999 case of Jesse Gelsinger from United States is quite instructive in this regard. Gelsinger was the first person to be publicly identified as having died in a clinical trial for gene therapy.[17] He had a rare genetic liver disease and participated in a gene therapy trial for the same disease at the University of Pennsylvania. He died at the age of 18, of complications from an inflammatory response triggered by his body shortly after receiving a dose of the experimental adenovirus vector. The investigation conducted by United States Food and Drug Administration (USFDA) concluded that the scientists involved in the trial broke certain rules of conduct. This was a grave setback for the gene-therapy technology. Following the incident, all gene therapy trials in the United States were halted for some time. Funding for gene therapy research dried up and deep scepticism developed among the public and policymakers regarding the technology.[18] Indeed, it took more than a decade for the field to recover from this setback.[19]

Given the complicated, technical, and unpredictable nature of scientific experimentation, better regulatory mechanisms should be devised to tackle contemporary challenges. At the same time, these measures should not stifle scientific freedom nor cause unnecessary alarm among the public or policymakers.

Current Regulatory Landscape

Global

National governments tend to enact domestic regulations when emerging technologies reach a desired threshold for use, adoption or commercial viability. Similarly, as global health, biosecurity, and ethical implications of certain emerging technologies start becoming apparent, calls for multilateral regulatory frameworks also strengthen.

Historically, technologies with potential national security implications have been subjected to regulations aimed at limiting their spread and monitoring their use. This has been attempted by institutionalising export control regimes and through legislative or executive actions at the level of individual states. For example, the Australia Group (AG) is an export-control organisation that compiles a list of technologies, equipment, and pathogens with the capability to be used for chemical or biological weapons development. This list is used by nations to harmonise their own export-control regulations. Similarly, there are international treaties such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity that govern movement of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. But countries still retain significant freedom to formulate their own regulations.

Ethical standards for research and development (R&D) activities are usually enforced through legislations or guidelines issued by national governments. There is no global multilateral institution that issues binding guidelines on the ethical aspects of innovation, although some international conventions detail broad bioethical principles that countries can use as a template to frame their own guidelines. For example, UNESCO's Universal Declaration on Bioethics and Human Rights (2005) as adopted by the United Nations General Assembly (UNGA) outlines "universal standards in the field of bioethics with due regard for human dignity and human rights and freedoms, in the spirit of cultural pluralism inherent in bioethics."[20] Furthermore, inter-governmental organisations such as the UN Inter-Agency Committee on Bioethics (UNIACB) have been constituted to facilitate discussions on bioethics.

It is incumbent upon national governments to regulate these emerging technologies through domestic legislations or guidelines. Several countries[g] have already issued detailed guidelines that can regulate emerging technologies in the biotechnology field, including regulations and guidelines on bioethics.

g Regulatory authorities in India, European Union, United States, United Kingdom among others have issued domestic guidelines on bioethics.

India

In India, the Ministry of Environment, Forest, and Climate Change (MoEFCC), Ministry of Science and Technology (MoST) and Ministry of Health and Family Welfare (MoHFW) are responsible for regulating different aspects of R&D in biotechnology. For R&D of genetically modified organisms (GMOs), the overarching regulatory framework has been notified under the Environment (Protection) Act, 1986 through 'Rules for manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989.' These rules are to be jointly implemented by MoEFCC, Department of Biotechnology (DBT) under MoST and respective state governments. As per these rules, six committees have been constituted (See Table 1).

Table 1
Regulatory Committees

Regulatory Committee	Function
Recombinant DNA Advisory Committee (RDAC)	An advisory body that takes note of developments in field of biotechnology at national and international level
Institutional Biosafety Committee (IBSC)	Any institution that intends to engage in research activity that involves genetic manipulation of microorganisms, plants or animals is mandated to constitute an IBSC. It also ensures that necessary guidelines are properly implemented within the research institution.
Review Committee on Genetic Manipulation (RCGM)	A regulatory body that monitors safety related aspects of research projects involving genetically engineered organisms.
Genetic Engineering Appraisal Committee (GEAC)	The apex regulatory body housed under the MoEFCC. It approves activities involving large scale use of hazardous microorganisms and recombinant products such as commercial introduction of GMO crop varieties.
State Biotechnology Coordination Committee (SBCC)	Acts as monitoring body that ensures compliance of relevant guidelines by research institutions at the state level and coordinates with DLCs within its jurisdiction.
District Level Committees (DLC)	Acts as monitoring body that ensures compliance of relevant guidelines by research institutions at the district level.

Source: BMC Proceedings[21]

Current Regulatory Landscape

For research involving human participants and clinical trials, a separate framework by the Central Drugs Standard Control Organization (CDSCO) under the MoHFW is applicable. The Drugs and Cosmetics Act, 1940 is the governing legislation under which Indian Good Clinical Practice Guidelines for Clinical Trials, 2001 and New Drugs and Clinical Trials Rules, 2019[22] have been notified. CDSCO has mandated that clinical trials should be registered online in Clinical Trials Registry–India (CTR-I), a national public record system for registration of clinical trials. The guidelines also mandate that each research institution establish an Institutional Ethics Committee (IEC). More than 1200 Ethics Committees have already been established by various institutions and registered with CDSCO.[23]

The National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) is constituted by MoHFW to oversee the activities in the field of stem cell research in India. The committee examines the scientific, technical, ethical, legal and social issues involving stem cell research and therapy. All institutions carrying out research on human stem cells are mandated to constitute an Institutional Committee for Stem Cell Research (IC-SCR) and register it with the NAC-SCRT.

The Indian Council of Medical Research (ICMR) along with Department of Biotechnology (DBT) has also published National Guidelines for Stem Cell Research, 2017. The guidelines restrict genome modification including gene editing by CRISPR-Cas9 technology of stem cells, germ-line stem cells or gamete and human embryos to in-vitro studies only.[24] The guidelines also prohibit culturing of genome modified human embryos beyond 14 days of fertilization. Furthermore, ICMR has also published National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. These are applicable to all biomedical, social, and behavioural science research for health conducted in India involving human participants, their biological material, and data. At the global level, India is signatory to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and India's domestic export control regulations are fully aligned with guidelines of the Australia Group (AG). However, there is need for better coordination and collaboration between countries at regional and global level regarding these guidelines.

Challenges with Current Regulatory Mechanisms

The transnational nature of biotechnology research makes it increasingly difficult for both scientists and companies to adhere to different regulatory norms in different countries. Countries such as Germany, the UK and the US have a well-developed biotechnology sector with the capability to manufacture cutting-edge laboratory equipment such as gene sequencers, gene synthesisers, advanced experimental kits, and reagents. Meanwhile, countries like India, Israel and many in Asia, Africa and South America have to rely exclusively on imports of such equipment. Collaborations between scientists of different countries have also increased due to the decentralised nature of biomedical research. Given the bioethical and national security implications of many emerging technologies, it is imperative that a multilateral regulatory system is developed.

Traditionally, export control regimes have regulated technologies with implications on global and national security. Export control regimes are multilateral institutions that seek to prevent proliferation of technologies that may be used to develop nuclear, chemical, or biological weapons. These institutions have played an important role in regulating cross-border flow of potentially dangerous dual-use technologies. However, there are significant challenges involved in regulating emerging technologies in biotechnology through export controls.

First, it is difficult to regulate the global flow of information relating to these technologies due to the open and collaborative nature of scientific research. Many of these techniques use commonly available reagents and laboratory equipment that would be practically impossible to regulate through export controls. Furthermore, tight export control regulation would only contribute to stifling research and development (R&D) activities as these technologies are fast becoming the cornerstone of biomedical research across various fields. For example, the CRISPR technology is essentially a variant of natural self-defence mechanism in bacteria that has been tweaked for use as a gene editing tool. The biological principle underpinning the technology is public knowledge and a trained biologist would face little difficulty in conducting experiments using CRISPR anywhere in the world. Furthermore, commercially available CRISPR kits have only simplified the experimental process. It makes it harder to formulate a specific criterion to label certain technologies as dual use and recommend their inclusion in the export control lists.

Second, in stark contrast to the period between 1960s-1980s when the first export control regimes were established, cutting-edge R&D activities are no longer the exclusive domain of select few industrialised or advanced economies. This complicates efforts to regulate emerging technologies using export controls. For example, only a handful of countries or private corporations could afford

to invest in nuclear technology—this constraint reduced the risk of widespread proliferation once these countries agreed to cooperate on non-proliferation measures. In biomedical research, however, its trans-national nature presents a unique challenge. The heightened role of non-state actors and rogue individuals in spreading terrorism is another factor complicating regulation through export controls.

Finally, for any export control regulations to be effective, they would need to command support from the key geopolitical players of the day and from countries with significant industrial and scientific base. For example, crucial players in the biotechnology sector such as Russia, China and Israel are not members of the Australia Group (AG). This implies that any efforts at regulation under the aegis of AG would be ineffective. Furthermore, export control regimes are seen by non-members as a means to deny them access to advanced technologies. Therefore, export controls are unlikely to become the framework to regulate currently emerging technologies in the field of biotechnology.

The role of geopolitics

No aspect of contemporary world is immune from the reach of global geopolitics and regulation of emerging technologies is no exception. Historically, developed nations like the US, Russia and the European Union have been the dominant force in institutionalising global regulations. Through their technological and economic prowess, they have ensured that the world adopted their standards of regulation, and often keeping in mind their country's parochial interests. However, as a more multi-polar world takes shape, this equilibrium has started to shift: there is significant lack of trust between governments, especially between biotechnology powerhouses such as the US and China. This trend has been further accelerated by the geopolitical fallout of the Covid-19 pandemic.

Similarly, regional powers such as India and the countries of Association of Southeast Asian Nations (ASEAN) along with other developing countries are also asserting themselves and asking for a seat at the regulatory high-table. This has led to a churn at several international institutions including export control organisations and the UN, especially on matters concerning emerging technologies. One recent example is the success of India in getting its own 5G standard known as '5Gi' approved for final evaluation to become part of global 5G standards set to be approved by International Telecommunications Union (ITU) in 2021.[25]

Challenges with Current Regulatory Mechanisms

Given the trans-national nature of biotechnological research, both in terms of cutting-edge research and manufacturing of laboratory equipment, geopolitics would certainly gain prominence during discussions seeking to regulate this field. According to a realist approach to geopolitics, countries with significant edge in the biotechnology industry would prefer regulations that maintain their technological lead while preventing other countries from catching up. To prevent itself from being at the receiving end of this geopolitical dynamic, India should cooperate with its partners and participate in international discussions or working groups as an advocate for its interests along with those of the developing world.

International institutions are under strain, and building a broad consensus on emerging technology regulation would be a massive challenge. There is an urgent need to develop an alternate deliberative approach that is both more inclusive than export controls and less fragmented than individual national regulations.

“Given the trans-national nature of biotech research, geopolitics would certainly gain prominence in discussions seeking to regulate the field.”

A Way Forward

The UN remains the most representative forum for discussion involving all relevant stakeholders. Therefore, an Open-ended Working Group (OEWG) created under the resolution of the UN General Assembly (UNGA) can be considered as a potential forum for discussions on this issue. An OEWG set up by UNGA in 2018 is already deliberating another globally contentious issue: the application of international law in cyberspace. It has been able to successfully conduct several rounds of discussions. A similar mechanism can be devised to discuss other globally contentious issues such as the regulatory aspects of emerging technologies in biotechnology.

An OEWG is the least restrictive and most deliberative option to facilitate discussions among civil society members, NGOs, and subject-matter experts in addition to representatives from UN member states. The proposed OEWG can choose to start deliberations based on the background paper released by 'Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing' set up by the World Health Organization (WHO) in 2019 to provide an overview of governance issues around human genome editing.[26] Similarly, the 2015 report submitted by 'The Independent Advisory Group on Public Health Implications of Synthetic Biology Technology Related to Smallpox' to the Director-General of WHO can act as a basis for broader deliberations on dual-use aspects of synthetic biology.[27]

Discussions at the global level often takes time to materialise into relevant conventions, treaties, or guidelines. It may take several additional years across jurisdictions to develop adequate procedures to regulate emerging technologies. In the meantime, the scientific community and private enterprise should step in to fill in the global regulatory gap. There are several precedents for the same.

In 1975, the Asilomar Conference on Recombinant DNA was convened in California that included lawyers, journalists, government officials, and scientists from different parts of the world. The participants considered the issue of regulation of biotechnology and formulated voluntary guidelines to ensure the safety of recombinant DNA technology which was as revolutionary and novel a technology then, as CRISPR is now. These guidelines served as a template for subsequent guidelines issued by the National Institutes of Health and other regulatory bodies.[28] The initiative by the scientific community to self-regulate in response to a revolutionary yet unpredictable technology can serve as a template for present times.

The global scientific community should consider stringent self-regulation regarding controversial aspects of emerging technologies such as human genome editing using CRISPR until a broader consensus can be developed. There have been some encouraging efforts in this regard: UNESCO's International Bioethics Committee (IBC) in 2015 updated its guidelines on the Human Genome and Human Rights. Workshops and discussions related to bioethics have been organised at International Summit on Human Gene Editing in 2015 and 2018. The He Jiankui incident highlighted the importance and urgency of such initiatives and the need to encourage all members of the global scientific community to adhere to these guidelines. It is significant to note that after international backlash, including at the 2018 International Summit on Human Gene Editing, Chinese regulators proposed legislative changes and issued fresh guidelines to prevent a repeat of such incidents.[29]

The private sector has also tried to self-regulate the use of potential dual-use technology in the absence of multilateral guidelines. For example, several multinational companies providing commercial gene-synthesis services have formed the International Gene Synthesis Consortium (IGSC). IGSC members together represent 80 percent of the world's commercial gene synthesis capacity. The organisation has published its own Harmonised Screening Protocol (HSP) to screen gene synthesis orders across jurisdictions for sequences that have dual-use potential or are restricted under national or export-control regulations.[30] The protocol also encourages IGSC members to coordinate with and share information with local and national law enforcement and intelligence authorities to prevent the potential misuse of synthetic genes. This system is based on guidelines issued by the US Department of Health and Human Services (DoHHS) that mandate gene synthesis companies to undertake comprehensive screening of the customer, the sequence ordered to be synthesised and do a follow-up screening to verify the legitimacy of the customer.[31]

Initiatives taken by gene-synthesis companies can become a template for other multinational corporations across countries to formulate a common reporting mechanism for their sector to be used by manufacturers, exporters, and importers of sensitive and potential dual-use technologies to keep a record and verify credentials of customers. They can also work with willing national regulators to further refine this mechanism.

Conclusion

Saurabh Todi *tracks emerging technologies, non-proliferation issues, and the emerging geopolitical dynamics between India, China, and the US.*

Over time, the increasing pace of technological innovation ensures that newer and better technologies continue to be developed. Often, it is the regulators that must play catch-up with scientific and technological developments. Advancements in technology are happening at a much faster pace today than almost any other time in human history. Increased global literacy, globalisation, rapid growth in information technology services, automation, and artificial intelligence are all contributing to the accelerated the pace of innovation.

In the initial onslaught of the Covid-19 pandemic, governments around the world significantly increased investments in healthcare, with corresponding investments by the private sector as well. This would certainly provide an impetus to R&D, spur innovation, and help the evolution of existing technologies. Instead of playing catch-up with technological developments of the day, a proactive approach by governments is a much better alternative to address contemporary challenges. This approach should involve regular deliberations between scientists, civil society, and the private sector, and can be more beneficial than resorting to ad-hoc regulatory arrangements.ORF

“Often, it is the regulators that must play catch-up with scientific and technological developments.”

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