Bulletin of Chinese Academy of Sciences

Volume 36 | Issue 11 Article 4

11-20-2021

China's Strategies for Governance of Biotechnological Changes and New Ethical Challenges

Yaojin PENG
Institute of Zoology, Chinese Academy of Sciences, Beijing 100101, China University of Chinese Academy of Sciences, Beijing 100049, China Beijing Institute for Stem Cell and Regenerative Medicine, Beijing 100101, China, yaojin.peng@ioz.ac.cn

See next page for additional authors

Recommended Citation

PENG, Yaojin and QI, Zhou (2021) "China's Strategies for Governance of Biotechnological Changes and New Ethical Challenges," *Bulletin of Chinese Academy of Sciences (Chin*
Vol. 36 : Iss. 11 , Article 4.
DOI: https://doi.org/10.16418/j.issn.1000-3045.20210823001
Available at: https://bulletinofcas.researchcommons.org/journal/vol36/iss11/4

China's Strategies for Governance of Biotechnological Changes and New Ethical Challenges

Abstract

Biotechnology is changing greatly over recent years, providing huge benefits to human society. However, the ethics, safety, and negative externalities of biotechnology have become increasingly prominent. Currently, biotechnology is still in the early stage of development, and full of high uncertainty. Technological changes in this field have the characteristics of stronger subversiveness, complexity, and social relevance. The world is facing a process of great development of biotechnology, new outbreaks of ethical challenges, and ethical governance reforms. China should take this opportunity to promote the high-quality development of biotechnology on the one hand, and on the other hand, adopt a multi-pronged approach to achieve comprehensive, flexible, and sustainable governance of ethical issues by conducting forward-looking ethical risk research and judgment, improving regulatory system, encouraging the participation of multiple stakeholders, and taking part in global governance, etc.

Keywords

biotechnology; ethics governance

Authors

Yaojin PENG and Zhou QI

Citation: PENG Yaojin, ZHOU Qi. China's Strategies for Governance of Biotechnological Changes and New Ethical Challenges [J]. Bulletin of Chinese Academy of Sciences, 2021 (11): 1288–1297.

China's Strategies for Governance of Biotechnological Changes and New Ethical Challenges

PENG Yaojin[1,2,3], ZHOU Qi[4]

1. Institute of Zoology, Chinese Academy of Sciences, Beijing 100101, China;
2. University of Chinese Academy of Sciences, Beijing 100049, China;
3. Beijing Institute for Stem Cell and Regenerative Medicine, Beijing 100101, China;
4. Chinese Academy of Sciences, Beijing 100864, China

Abstract: Biotechnology is changing greatly over recent years, providing huge benefits to human society. However, the ethics, safety, and negative externalities of biotechnology have become increasingly prominent. Currently, biotechnology is still in the early stage of development and full of high uncertainty. Technological changes in this field have the characteristics of strong subversiveness, complexity, and social relevance. The world is facing a process of great development of biotechnology, new outbreaks of ethical challenges, and ethical governance reforms. China should take this opportunity to promote the high-quality development of biotechnology on the one hand, and on the other hand, adopt a multi-pronged approach to achieve comprehensive, flexible, and sustainable governance of ethical issues by conducting forward-looking ethical risk research and judgment, improving regulatory system, encouraging the participation of multiple stakeholders, and taking part in global governance, etc. **DOI:** 10.16418/j.issn.1000-3045.20210823001-en

Keywords: biotechnology; ethics; governance

The world is experiencing the profound changes unseen in a century, with a new round of scientific and technological revolution and China's transformation of its development mode. As one of the cutting-edge and booming research fields in the 21st century, biotechnology is changing rapidly and has become an important engine of this scientific and technological revolution. The development of biotechnology will subversively change scientific research, public health, agriculture, energy, and environmental protection, bringing huge benefits to the human society and altering the global scientific and technological, political, economic patterns. Moreover, it may even affect the process of human beings.

However, as the relationship between science and technology and the society is experiencing a paradigm shift [1], ethics, safety, and negative externalities accompanying the development of biotechnology have become increasingly prominent. Learning from history, we should realize that any science and technology that promotes the progress of human society, changes the course of the world, and triggers fundamental changes in human life requires effective governance and compliance with ethical norms. The currently great changes in biotechnology provide China with not only a key opportunity to boost the high-quality development of biotechnology but also a rare strategic condition to shape the innovation ideas, advance the modernization of the national ethical governance system and capacity, and participate in the global governance on ethics of biotechnology.

1 Development and trend of biotechnology

The booming of biotechnology has expanded the scope of bio-economy to many fields in recent years and will gradually lead to the development of global economy in the future [2]. In particular, the frontier fields such as stem cells, synthetic biology, and gene editing have developed rapidly. The research papers in the three fields have been increasing rapidly since 2000 (Figure 1). Specifically, the number of annually published papers focusing on stem cell research has exceeded 20 000 by 2016 and remained stable in the following years. The number of papers concerning synthetic biology has grown greatly since 2010. The number of papers regarding the research and application of gene editing technology has raised sharply after the emergence of CRISPR-Cas9 in 2012 and is still growing rapidly.

The progress in new general technologies such as single-cell sequencing, high-resolution imaging, and gene editing has fostered new breakthroughs in stem cell research. Moreover, the integration of stem cell research with new biomaterials, 3D printing and other new technologies has given birth to new fields such as organ-on-a-chip, organoids,

Received: 2021-11-03
Supported by: Research Ethics Project of the Academic Divisions of the Chinese Academy of Sciences (XBKJLL2019001); Strategic Priority Research Program of the Chinese Academy of Sciences (XDA16040503)
Corresponding author: ZHOU Qi, E-mail: zhouqi@ioz.ac.cn

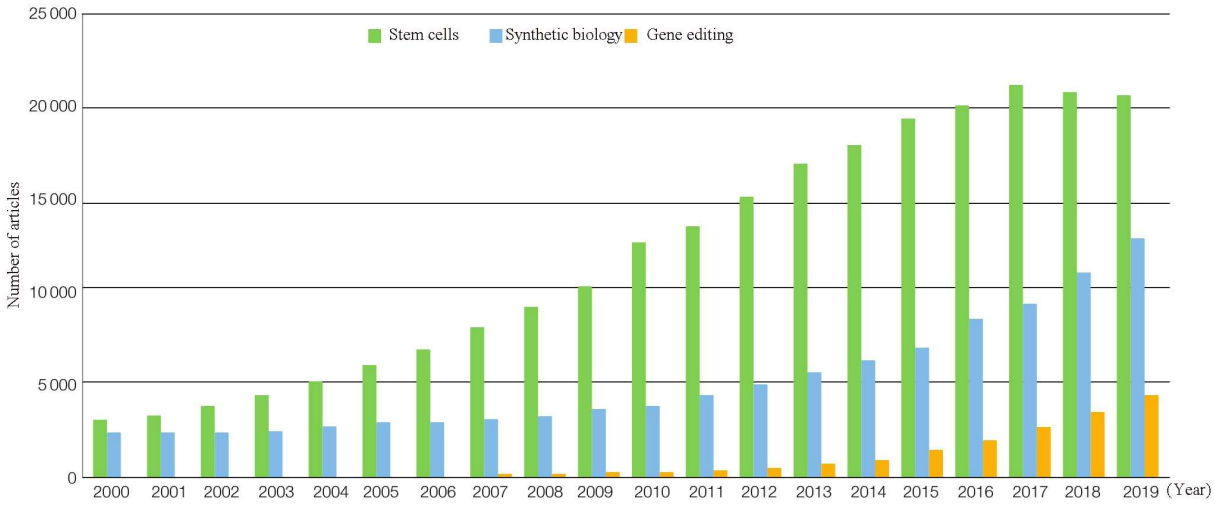

Figure 1 Number of articles related to stem cells, synthetic biology, and gene editing from 2000 to 2019

Database: Web of Science. Search time: Oct.15, 2020. Database update time: Oct.14, 2020. Search keywords: genome edit, gene edit, CRISPR, TALEN, ZFN; Stem cell; artificial life, synthetic biology. Document type: article + review.

and chimeras. In the field of stem cells, the United States, China, Germany, Japan, and the United Kingdom published a large number of papers from 2010 to 2019. Specifically, the United States published 62 159 relevant papers, which accounted for 34.76% of the global total volume, much more than those in other countries. Since 2010, the number of annually published papers associated with stem cells in China has surpassed that of developed countries such as the United Kingdom and Germany, rising to the second in the world, with the growth rate significantly higher than that of other countries in the following 10 years (Figure 2a). In the field of synthetic biology, the annual growth rate of papers published globally was above 10% from 2010 to 2019 (Figure 2b). Specifically, the number of papers published in the United States reached 26 138, accounting for 35.46% of the global total volume; China ranked second in the world with 18 388 papers and a high growth rate. In 2019, China surpassed the United States in the number of papers related to synthetic biology, ranking first in the world (Figure 2b). In the field of gene editing, the United States published 7 751 papers during this 10-year period, which accounted for 47.51% of the global total volume; China ranked second with a total of 3 732 papers (Figure 2c). In the past five years, China's average growth rate of the papers concerning gene editing has exceeded 50%, being similar to that in the United States.

In general, global biotechnology is booming and the frontiers are still in the early stage of development. Compared with developed countries, China starts late in the development of biotechnology, which is thus characterized by overall weak strength and unsound system construction. However, with the substantial investment of the government in recent years, China's biotechnology has developed rapidly and caught up with developed countries. In some cutting-edge fields such as stem cell, regenerative medicine, and synthetic

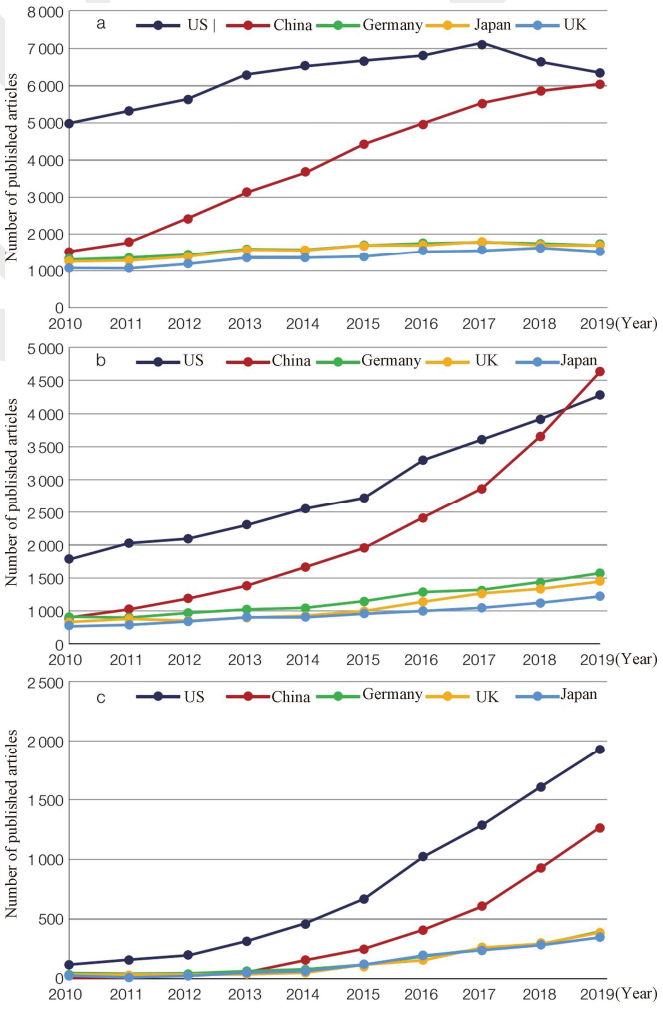

Figure 2 Number of published articles in the top five countries in the fields of stem cells (a), synthetic biology (b), and gene editing (c) from 2010 to 2019

biology, China is now in a world-class or even leading position as it does not lag behind the developed countries in the beginning. It can be said that in some fields, China and other technologically developed countries have stepped into the frontier or no-man's land.

2 Development characteristics of biotechnology

Biotechnology, especially the frontiers, is making robust progress, while the technological development path and direction, application mode, and scenarios are highly uncertain. At the same time, biotechnology is being integrated with other emerging fields such as big data, artificial intelligence, and nanotechnology rather than developing solitarily, which is thus experiencing accelerated iteration. More importantly, compared with traditional biotechnologies, the state-of-the-art biotechnologies have strong subversiveness, complexity, and social relevance.

(1) Subversiveness. In the 21st century, the accuracy, efficiency, simplicity, and cost of biotechnological fields such as CRISPR-Cas and synthetic biotechnology have been greatly improved, which has promoted the civilianization and accessibility of knowledge and technology in the fields [3]. Such development has gradually altered the situation that biological research can only be conducted in large laboratories and enterprises and spawned a variety of small laboratories and workshop-style research fields such as garage biology. In this way, such technologies can be extended to other fields like medicine, pharmacy, chemical industry, energy, and environmental protection in a very short period of time, which may rapidly and profoundly reshape the development paths and industrial structures in these fields.

(2) Complexity. The complexity here is reflected in the following three aspects. ① The knowledge and technology of biotechnology are difficult for ordinary people to understand and master. As the field is being subdivided, even biologists have difficulty in judging subdivisions they are unfamiliar with, let alone policy makers and the public. This feature makes the decision logic underlying the technologies in this field difficult to understand, predict, and evaluate. ② The design and manufacture of biotech products are separated. For example, synthetic biology, which studies biological systems by engineering, is facing the separation of analysis, system design, and manufacturing processes, i.e., the steps in the design-build-test (DBT) cycle [4]. The aggravation of such separation will make potential ethical issues more complicated and governance more difficult while improving the accessibility of technology [5]. ③ Biotechnology is developing from a linear model to an open networked model. It is experiencing the integration of multidisciplinary concepts and knowledge, while its materials, data, and methods are more open and shared. Biotechnology has attracted more experts or "hobbyists" from other fields and it is no longer just the domain of biologists, which has increased the personnel complexity in the field.

(3) Social relevance. Traditional biological research mainly observes and explains life, so there is usually a large gap between basic research and application. However, modern biotechnology is closely related to human life and has been put into application since its emergence, producing huge social influence. At present, biotechnology has been deeply integrated into all fields of the society. Moreover, cutting-edge biotechnologies such as gene editing and synthetic biology have the ability to change the occurrence and evolution of life including human beings at the genetic level, and can transform or even create life. These technologies hit the root of life, human nature, and self-identification, arousing concerns of the public. Therefore, modern biotechnology has stronger social relevance than traditional biotechnology.

3 Ethical issues and new challenges of biotechnology

From the history of biotechnology in the past 40 years, we can see that the birth and application of emerging biotechnologies, from test-tube babies to pre-implantation diagnosis and screening, from stem cell research to cloning technology, and from synthetic biology to gene-edited embryos, have caused extensive and repeated social concerns and ethical controversies. These emerging biotechnologies stem from the huge demand for scientific and technological progress in social development. At the same time, they impact social culture and ethical values and promote the change in relevant rules and the rearrangement of the system. Importantly, biotechnology is gradually becoming networked and open and has been considered an emerging technology field spanning multiple industries and sciences. Therefore, the ethical risks it brings may vary widely in different domains.

3.1 Frontier ethical disputes in the development of stem cell technology

Traditional ethical disputes in the field of stem cells mainly focus on human embryonic stem cell research and human cloning. Human embryonic stem cell research involves the extraction of stem cells from early embryos (5–7 days after sperm-egg binding) and the establishment of cell lines for reuse. Therefore, the core of the ethical controversy is the ethical status of embryos. To be specific, whether the embryos are human and whether they can be used for research. However, because of the differences in technological development and the diversity of cultural and social concepts, how to define human and embryo varies, and the relevant laws and policies also vary among different countries. The currently adopted international rule, namely, the "14-day rule" [6], has been adopted for almost 40 years. In addition, regarding therapeutic cloning and reproductive cloning, the international community has basically reached a consensus

on prohibiting human reproductive cloning, whereas the ethics of therapeutic cloning is still in debate [7].

The above-mentioned ethical controversies in the early 2000s seem to have come to an end. However, with the maturity and application of biotechnology platforms such as gene editing, large-scale culture, and biomanufacturing in recent years, stem cell-related technologies have advanced from the molecular level to the tissue level and from basic research to practical application. The two cutting-edge research directions, chimera and organoids, based on stem cells have reignited the ethical controversy about what is an embryo and what is a human being, and also spawned more new ethical challenges. For example, chimera research involves the chimerism between human and non-human animal bodies or embryos. Accordingly, the ethical disputes are not limited to stem cell and embryo research, instead, they gradually extend to the boundary between humans and animals [8], the implications of the potential use of chimeras, and the possibility of conferring human status on animals [9]. In addition, the research and application of chimeras induces a series of controversies such as the risks of violating human dignity, violating animal welfare and rights, causing the uneven allocation of medical resources, and transmitting the disease from animals to humans [10]. This has completely gone beyond the traditional ethical debate over the status of embryos.

In the research on organoids, controversies are aroused in the fields like the possibility of brain organoids being "conscious" [11], how to define consciousness [12], and the limitations or special censorship of specific studies [13]. In addition, stem cell-based embryo model research also faces disputes on consciousness and self-knowledge, and research in this field involves the ethical risk of crossing the "14-day rule" [14]. These ethical disputes not only are rich in profound philosophical connotations but also have profound legal and social influences, going far beyond traditional ethical disputes on stem cells. The development and reform of stem cell technology lead to the rekindling and spreading of ethical disputes in this field.

3.2 New ethical and safety challenges for synthetic biology

Although synthetic biology emerged in the 1960s, it has only gradually developed in the past ten years. As an emerging technology, synthetic biology has also raised many ethical controversies. Specifically, synthetic biology aims to use the ideas of engineering to modify or create biological systems or organisms with special purposes, so the new ethical challenges it poses are special, involving both conceptual and non-conceptual ones [15]. The conceptual new ethical challenges mainly focus on the debate over concepts such as life and nature, such as the critical ethical analysis of the concepts like "life" and "non-life", and "natural" and "artificial". This involves issues such as whether synthetic life challenges the traditional concept, value, and meaning of life. The non-conceptual new ethical challenges focus on the potential application of synthetic biology in different fields, mainly involving biosafety, biosecurity, as well as the fairness and justice of resource allocation in the application of this technology.

Biosafety and biosecurity are key ethical concerns arising from the latest progress in synthetic biology. Biosafety is a general issue concerning the risks of synthetic biology to human health and the eco-environment, mainly covering three issues: biological error, accidental exposure of synthetic organisms, and accidental release of synthetic organisms to the environment [5]. The concerns of the latter two issues are greater. A more controversial ethical concern in synthetic biology is biosecurity [16]. This issue involves the abuse of biological agents, materials or technologies, like the theft, diversion, or deliberate release of biological agents or materials to endanger human health or the eco-environment. In particular, the biological weapons and terrorism threats have attracted much attention. From a technical standpoint, scientists have been able to create or reanimate deadly viruses such as poliovirus [17], 1918 Spanish influenza pandemic virus [18], horsepox virus [19], and Ebola virus [20] in the laboratory. As a result, people will worry about that the development of synthetic biology provides more possibilities for the upgrading of biological weapons, and the barriers for malicious actors to acquire and use biological weapons will be correspondingly weakened or eliminated [21]. This may guide countries to utilize synthetic biology to develop biological weapons, and terrorists can use this technology to create bioterrorism. Like computer hackers, biohackers may also try to create viruses out of curiosity or to demonstrate their technical prowess [22], thereby causing unprecedented harm to humans.

3.3 New ethical concerns in the application of gene editing technology

Gene editing, especially CRISPR-Cas, is a disruptive biotechnology developed in recent years. Compared with traditional gene editing technologies such as zinc finger nucleases (ZFNs) and transcription activator-like effector nucleases (TALENs), CRISPR-Cas is characterized by easy operation, low cost, and high efficiency. However, just like the "gene-edited babies" incident at the end of 2018, the potential application of gene editing to human body has caused unprecedented ethical concerns. These concerns focus primarily on alterations to the human germline genome in three dimensions.

In the individual dimension, ethical concerns are mainly about the safety of technology application. The current gene editing technology has defects such as off-target effect, which may lead to unintended editing with unknown consequences. In human germline gene editing, the potential risk of off-target or unintended consequences cannot be determined at present.

In the family dimension, the widespread application of human germline gene editing may lead to changes in the family structure, as well as the natural emotions and perceptions

between parents and children [23]. If some genetic diseases or traits can be easily changed by gene editing, parents will be more likely to perceive but more difficult to tolerate the imperfections of their children, and the parents' instinct to unconditionally accept their children will be impacted. In addition, the application of human germline gene editing may alter the consistency of interests between parents and children, which poses a challenge to the protection of children autonomy in the future.

In the society dimension, human germline gene editing first arouses eugenic concerns. Because of the popularity of this technology, some people will specifically breed offspring with preferred genetic characteristics, which will increase social prejudice and discrimination [24]. In addition, attention should also be paid to the potential social fairness and justice in the application of this technology. People worry that the application of this technology will become the "patent" of the rich, which will further solidify the existing injustice in the society and aggravate the differentiation of social classes. Other ethical concerns include the commercialization of "designed babies", human augmentation, and moral decline [25].

In addition to the above-mentioned applications to the human body, gene editing is increasingly applied to non-human animals, such as the improvement of domestic animals, the construction of laboratory animal models, the control of invasive species/diseases, the construction of chimeras, and the recovery of endangered and extinct species. The research and applications of non-human animal gene editing also raise social and ethical challenges to food safety, biosafety, justification for creating laboratory animal models, animal welfare and rights, and public trust in scientific research. Compared with that of human germline gene editing, the research and application of animal gene editing may impose greater ethical challenges, so the scientific community, policy makers, and regulators need to maintain high attention.

4 China's exploration in the ethical governance of biotechnology

Biotechnology is developing and will develop rapidly. The technological changes in this field will inevitably bring an impact on social morality, values, legal rules, and even politics and economy. At the same time, the uncertainties, subversiveness, and complexity of biotechnology development make the ethical risks in this field increasingly complex and unpredictable. To avoid the occurrence of the ethical events such as Black Swan and Gray Rhino, ethical governance is in urgent need. In 2019, the 4th plenary session of the 19th Central Committee of the Communist Party of China (CPC) passed the Decision of the CPC Central Committee on Some Major Issues Concerning Upholding and Improving Socialism with Chinese Characteristics and Modernizing National Governance System and Capacity, which specified to improve the ethical governance mechanism for science and technology. The Outline of the 14th Five-Year Plan for Economic and Social Development (2021–2025) and Long-Range Objectives through the Year 2035 of the People's Republic of China also emphasized the improvement of the ethical governance system. Compared with improving the ethical governance mechanism, the word "system" reflects China's higher and comprehensive requirements for the ethical governance of science and technology.

The ethical governance of science and technology may have two problems. Insufficient governance will lead to excessive or unknown ethical risks and weaken public confidence, while excessive governance will limit the development of cutting-edge biotechnology. The enormous potential benefits and uncertain ethical risks pose unique and huge challenges to the governance in today's society [26]. Faced with this emerging field, especially the fact that ethical disputes vary in different fields and gradually spread with the development of biotechnology, ethical governance should not be handled with a fixed process or framework. According to the nature, characteristics, development trend, and application fields of specific biotechnology, flexible governance should be carried out. The traditional linear process from the public and expert opinion to policy formulation is also no longer feasible, and a parallel, predictive, forward-looking process will be more practical. In general, China's main strategic orientation to strengthen the ethical governance of biotechnology should include the following six aspects.

(1) Conducting forward-looking research and judgment on the ethical risks of biotechnology and deepening the research on China's governance system and structure to improve China's ethical governance plan. At present, countries around the world lack sufficient experience in ethical governance of cutting-edge biotechnology. While strengthening the practice of forward-looking research and judgment on the ethical risks of biotechnology, China is committed to promoting the innovation of ethical governance strategies. It keeps pace with the development of cutting-edge sub-fields, identifies technical characteristics, evaluates development laws and trends, and conceives application scenarios to promote the discussion and research of ethical issues in the context of Chinese culture and technological development. China should collect and develop available data and information as much as possible in an environment with constantly changing knowledge, identify the ethical risks based on the latest data, assess expected impacts, and measure knowledge gaps to seek solutions. With the National Ethics Committee for Science and Technology at the core, China's ethical governance should aim to cultivate a team of talents for research and management, deepen the research on the governance system and structure, and give full play to its strategic research and decision-making consulting role, so as to improve the national capacities in the judgment and the decision-making regarding ethical risks in science and technology.

(2) Constructing the national legal system and regulatory system to consolidate the foundation of China's ethical governance in biotechnology. On the whole, China's legislation in this field is still lagging behind with unsound system. The new ethical challenges of cutting-edge biotechnology have overturned the traditional legal assumptions to a certain extent and affected the existing legal basis, framework, and even some legal principles [27]. Therefore, China needs to intensify efforts to build a legislative mechanism that adapts to the characteristics of biotechnology development, improve the quality of legislation, and form a rational and forward-looking legal system [28]. In addition, China should combine abstract legal principles, specific legal rules, and flexible regulatory policy tools together based on the current status and differences in biotechnology development in China and abroad, and flexibly adjust governance according to the evolution of ethical risks or hazards in subdivided fields [29]. The role of the National Ethics Committee for Science and Technology should be given full play to the decision-making and regulatory consultation of ethical governance. Through the coordination of the committee, the existing decentralized ethics supervision system should be modified to improve the coordination of the actions and analysis abilities among and within regulatory agencies [29] and overcome the uncertainties and risks of biotechnology with limited resources.

(3) Giving full play to the supervision and management roles of research institutions as the main body and improving the business capabilities of ethics review committees. Ethical issues run through the entire research and application cycle of biotechnology. Research institutions are the best subjects for ethical supervision of research projects, playing an increasingly prominent role [30,31]. China should strive to build an institutional ethics supervision system that is compatible with its own legislative supervision system and cultural tradition and basically symmetrical with scientific and technological development and ethical governance. At present, China should improve the ethical review system and effectively review the ethical issues during the design and implementation of the research projects involving biotechnology. Efforts should be made to strengthen the review capacity building of members in ethics committees at all levels across the country, and improve the professional review level of the committees. In the construction of the ethical review system, special ethics committees or procedures can be established for specific fields to reduce potential ethical risks and improve China's ability to manage ethical risks of special biotechnologies.

(4) Steadily promoting the self-discipline construction of the scientific and technological community by proposing and implementing the Chinese plan for the autonomy of the scientific and technological community. China must deeply realize that the ethical governance of science and technology cannot rely solely on "top-down" supervision, but should involve the participation of multiple stakeholders including scientists and enterprises through various types of autonomy or self-discipline. It is suggested to improve the education and training on the ethics of scientific research, help relevant personnel improve their ethics and legal awareness and skills, and foster correct values on life, safety, fairness, and justice, so as to create a basic environment for responsible innovation [32]. In addition, incentive measures from the aspects of economy, public relations, and legal system should be taken to encourage the development of biotechnology industry in a socially responsible way. The industrial associations, societies, top research institutions, and leading companies should formulate behavioral guidelines and standards and establish ethical norms to maintain public confidence in the development of China's biotechnology.

(5) Strengthening the publicity and education of the ethics of science and technology to promote public participation in building a new ecology of benign ethical governance of science and technology. China should establish an effective dialogue mechanism among stakeholders, and strengthen the education of popular biological science and ethics of science and technology, especially for the fields that have local special ethical concerns and targeted sub-fields, so as to improve the understanding of the public on the ethical issues in the research of biotechnology [33]. On one hand, it is necessary to establish appropriate mechanisms to monitor and identify social ethical concerns, and encourage the public participation in extensive discussions and exchanges [34]. On the other hand, it is suggested to pay attention to the popularization of biotechnology for the public by innovating communication methods and ensuring the accuracy of the communication content, and improving the public's rational understanding of the complexity and uncertainty of this field, so as to gain the understanding and support of the public.

(6) Promoting global collaboration on the governance of ethical issues of biotechnology in terms of the top-level design and contributing Chinese wisdom. Ethical issues of biotechnology are transnational and cross-cultural, and they are common problems faced by all mankind. The ethical governance of biotechnology in China must take into account international concerns, in which parallel efforts and international consultation and cooperation are crucial. China should maintain an active dialogue with the international community (states and international organizations) and play a role in the global governance of biotechnological ethics. In some advantageous fields, we should vigorously promote the construction of a dialogue mechanism and an international institutional framework for ethical governance, and strive for China's discourse and initiative in global ethical governance of biotechnology. China should seize the opportunities of current development and reform of biotechnology, continue to promote international cooperation in biotechnology research, deeply participate in global governance on biotechnological ethics, so as to accumulate experience and lay a solid strategic foundation for the development and ethical governance of biotechnology.

5 Conclusion

The new wave reform of biotechnology governance focuses on ethics and safety, which involves not only technology development, international competition, and national interests, but also differences in cultural values and conflict of rules. The ethical issues of biotechnology have gradually expanded from traditional disputes to frontier disputes with the technological iterations. In addition, the integration of biotechnology with information technology, artificial intelligence, big data, and other technologies have posed new ethical challenges which have shaken the existing ethical governance rules and systems for biotechnology, driving the adjustment of science and technology governance in various countries and promoting the arrival of the era of biotechnology development and ethical governance reform. As the cornerstone of the national biotechnology strategy, the development and promotion of biotechnology should be conducted in a manner consistent with Chinese values and ethical conduct. Adhering to the principle of sustainable governance and considering the current advancement of science and technology, China should promote the high-quality development of biotechnology on the one hand, and on the other hand, adopt a multi-pronged approach to achieve comprehensive, flexible, and sustainable governance of ethical issues by conducting forward-looking ethical risk research and judgment, improving regulatory system (with the supervision department at the core), encouraging the participation of multiple stakeholders (e.g., institutions, industries, and the public), and taking part in global governance.

References

1 Mejlgaard N, Bloch C. Science in society in Europe. Science and Public Policy, 2012, 39 (6): 695–700.
2 National Academies of Sciences. Engineering, and Medicine. Safeguarding the Bioeconomy. Washington DC: The National Academies Press, 2020.
3 Zettler P J, Guerrini C J, Sherkow J S. Regulating genetic biohacking. Science, 2019, 365: 34–36.
4 Peng Y J. The Era of Synthetic Biology: Biosafety, Biosecurity and Governance. Journal of International Security Studies, 2020, 38 (5): 29–57 (in Chinese).
5 National Academies of Sciences, Engineering, and Medicine, Division on Earth and Life Studies, Board on Chemical Sciences and Technology, et al. Biodefense in the Age of Synthetic Biology. Washington DC: National Academies Press, 2018.
6 Hyun I, Wilkerson A, Johnston J. Embryology policy: Revisit the 14-day rule. Nature, 2016, 533: 169–171.
7 Langlois A. The global governance of human cloning: The case of UNESCO. Palgrave Communications, 2017, 3: 17019.
8 Robert J S, Baylis F. Crossing species boundaries. The American Journal of Bioethics, 2003, 3 (3): 1–13.
9 Streiffer R. At the edge of humanity: Human stem cells, chimeras, and moral status. Kennedy Institute of Ethics Journal, 2005, 15 (4): 347–370.
10 Peng Y J, Li W. Ethical issues and governance of life science and technology: A case study on human-animal chimeras. Science & Technology Review, 2020, 38 (5): 42–49 (in Chinese).
11 Chen H I, Wolf J A, Blue R, et al. Transplantation of human brain organoids: Revisiting the science and ethics of brain chimeras. Cell Stem Cell, 2019, 25 (4): 462–472.
12 Koplin J J, Savulescu J. Moral limits of brain organoid research. The Journal of Law, Medicine & Ethics, 2019, 47 (4): 760–767.
13 Hyun I, Scharf-Deering J C, Lunshof J E. Ethical issues related to brain organoid research. Brain Research, 2020, 1732: 146653.
14 Aach J, Lunshof J, Iyer E, et al. Correction: Addressing the ethical issues raised by synthetic human entities with embryo-like features. eLife, 2017, 6: e20674.
15 European Group on Ethics in Science and New Technologies (European Commission). The ethics of synthetic biology. (2009–11–17). https://op.europa.eu/en/publication-detail/-/publication/c9b00815-2268-4ba7-bdfe-59d96dfb1f5d.
16 Cho M K, Magnus D, Caplan A L, et al. Ethical considerations in synthesizing a minimal genome. Science, 1999, 286: 2087–2090.
17 Cello J, Paul A V, Wimmer E. Chemical synthesis of poliovirus cDNA: Generation of infectious virus in the absence of natural template. Science, 2002, 297: 1016–1018.
18 Tumpey T M, Basler C F, Aguilar P V et al. Characterization of the reconstructed 1918 Spanish influenza pandemic virus. Science, 2005, 310: 77–80.
19 Noyce R S, Lederman S, Evans D H. Construction of an in-19 Noyce R S, Lederman S, Evans D H. Construction of an fectious horsepox virus vaccine from chemically synthesized DNA fragments. PLoS One, 2018, 13 (1): e0188453.
20 Sylvia P W. Ebola virus could be synthesized. New Scientist (2002–07–17). https://www. newscientist.com/article/dn2555-ebola-virus-could-be-synthesised/.
21 Dando M. The impact of the development of modern biology and medicine on the evolution of offensive biological warfare programs in the twentieth century. Defense Analysis, 1999, 15 (1): 43–62.
22 Tucker J B, Zilinskas R A. The promise and perils of synthetic biology. The Atlantis News, 2006, 12: 29–45.
23 Mulvihill J J, Capps B, Joly Y, et al. Ethical issues of CRISPR technology and gene editing through the lens of solidarity. British Medical Bulletin, 2017, 122 (1): 17–29.
24 Sonia S M. A brave new world of designer babies? Berkeley Technology Law Journal, 2007, 27: 897.
25 Nuffield Council on Bioethics. Genome Editing and Human Reproduction: Social and Ethical Issues. London: Nuffield Council on Bioethics, 2018.
26 Gregory M. Nanotechnology governance. Alabama Law Review, 2008, 59 (5): 1323–1384.
27 Xue L, Zhao J. Toward agile governance: The pattern of emerging industry development and regulation. Chinese Public Administration, 2019, (8): 28–34 (in Chinese).
28 Liu Y L. Research on the regulation of biotechnology in the United States. Peking University Law Journal, 2016, 28 (2): 462–485 (in Chinese).
29 Mandal G N. Gaps, inexperience, inconsistencies, and overlaps: Crisis in the regulation of genetically modified plants and animals. William and Mary Law Review, 2004, 45 (5): 2167–2259.
30 Hurley E A, Hull D, Shriver S P. The next phase of human gene-therapy oversight. The New England Journal of Medicine, 2018, 379: 1393–1395.
31 US Department of Health and Human Services. United States government policy for institutional oversight of life sciences dual use research of concern. (2014–09–24). https://www.phe.gov/s3/dualuse/documents/oversight-durc.pdf.
32 Fan C L, Zhang X Q, Chen Q. A study on the bioethical governance mechansim in China. China Soft Science, 2008, (8): 58–65 (in Chinese).
33 Li Z F. Public scientific literacy and contemporary science and technology governance. Studies on Science Popularization, 2020, 15 (1): 5–10 (in Chinese).
34 Chen H D. Ethical debates and governance of science and technology: Case studies of embryo and stem cell research in the United Kingdom. Journal of Dialectics of Nature, 2019, 41 (12): 40–46 (in Chinese).

PENG Yaojin, Associate Professor of the Institute of Zoology (IOZ), Chinese Academy of Sciences (CAS); Zhiyi Professor at Beijing Institute for Stem Cell and Regenerative Medicine (BISCRM); Director of the Centre for Ethics of Science and Technology (CEST, BISCRM). Dr. Peng holds a Bachelor's degree in life science, and PhD at the Faculty of Law, Maastricht University, the Netherlands. His research focuses on legal and ethical issues in the fields of biotechnology and medicine, intellectual property law and standards, policy and management of S&T, etc. E-mail: yaojin.peng@ioz.ac.cn

ZHOU Qi, corresponding author, Vice President of Chinese Academy of Sciences (CAS), and President of Beijing Institute for Stem Cell and Regenerative Medicine. Academician of CAS, and Fellow of the World Academy of Sciences for the advancement of science in developing countries (TWAS). As an expert in stem cell and developmental biology, Dr. Zhou has contributed significantly to the basic research on stem cell, reproductive and developmental biology, as well as to the application of stem cells to clinical use. E-mail: zhouqi@ioz.ac.cn