

THE CRIMINAL LAW REGULATORY LOGIC AND FUTURE PATHWAYS OF GENE EDITING TECHNOLOGY IN CHINA: SEVEN YEARS AFTER “GENE-EDITED BABIES”

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Abstract: The 2018 “gene-edited babies” incident marked a critical turning point in China’s criminal regulation of gene editing. Before the incident, China largely relied on administrative rules and ethical guidelines to govern gene-editing activities, without a systematic criminal legal framework or comprehensive regulatory mechanisms. In the aftermath, China intensified its efforts to establish stronger legal controls over gene-editing technology. This study examines the regulatory landscape seven years after the event, integrating empirical data on public awareness and perceptions of gene editing with a literature-based legal analysis of the current legislative framework and its deficiencies. Through this dual approach, the paper aims to deepen understanding of the evolution of China’s criminal regulation of gene editing and to provide policy insights for China and other developing countries seeking to strike a balance between scientific innovation and ethical as well as legal accountability.

Keywords: gene editing technology, criminal regulation, ethical issues, China

La lógica reguladora del Derecho Penal y las perspectivas futuras de la tecnología de edición genética en China: siete años después de los “bebés editados genéticamente”

Resumen: El incidente de los “bebés editados genéticamente” en 2018 marcó un punto de inflexión crucial en la regulación penal de la edición genética en China. Antes del incidente, China dependía en gran medida de normas administrativas y directrices éticas para regular las actividades de edición genética, sin un marco legal penal sistemático ni mecanismos regulatorios integrales. Tras el incidente, intensificó sus esfuerzos para establecer controles legales más estrictos sobre la tecnología de edición genética. Este estudio examina el panorama regulatorio siete años después del incidente, integrando datos empíricos sobre la concienciación pública y las percepciones de la edición genética con un análisis legal basado en la literatura del marco legislativo actual y sus deficiencias. A través de este doble enfoque, el artículo busca profundizar en la comprensión de la evolución de la regulación penal de la edición genética en China y proporcionar perspectivas políticas para China y otros países en desarrollo que buscan lograr un equilibrio entre la innovación científica y la responsabilidad ética y legal.

Palabras clave: tecnología de edición genética, regulación penal, cuestiones éticas, China

A lógica regulatória do direito penal e os caminhos futuros da tecnologia de edição genética na China: sete anos após os “bebés geneticamente modificados”

Resumo: O incidente “bebês geneticamente modificados” marcou um ponto de virada na regulação penal da China sobre edição genética. Antes do incidente, a China dependia em grande parte de regras administrativas e diretrizes éticas para controlar atividades de edição genética, sem um arcabouço legal penal sistemático ou mecanismos regulatórios abrangentes. Após o ocorrido, a China intensificou seus esforços para estabelecer controles legais mais fortes sobre a tecnologia de edição genética. Esse estudo examina o cenário regulatório sete anos após o evento, integrando dados empíricos sobre conscientização e percepções do público em relação à edição genética com análise legal baseada na literatura do arcabouço legislativo atual e suas deficiências. Através dessa abordagem dual, esse artigo objetiva aprofundar a compreensão da evolução da regulação penal da China sobre edição genética e fornecer insights sobre políticas para a China e outros países em desenvolvimento buscando encontrar um equilíbrio entre inovação científica e a responsabilidade ética e legal.

Palavras chave: tecnologia de edição genética, regulação penal, questões éticas, China

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1. Introduction

The emergence of gene editing technology is widely regarded as a revolutionary breakthrough in the field of life sciences. It not only brings new hope for overcoming genetic diseases, improving treatment outcomes, and enhancing overall human health, but also opens up broad prospects for agricultural improvement and pharmaceutical development (1). With the advancement of AI, the integration of gene editing and intelligent algorithms is expected to significantly enhance research efficiency and accelerate profound transformations in medicine and life sciences (2). However, technological innovation often comes with risks. While benefiting humanity, it may also give rise to ethical dilemmas and safety concerns. For example, any error in germline gene editing could be transmitted across generations through heredity, leading to irreversible consequences, whereas human cloning and interspecies genetic chimeras could challenge the very foundations of human identity and ethical boundaries (3).

In China, the development of gene editing technology has also aroused widespread concern. The exposure of the “gene-edited babies” incident in 2018 not only shocked the academic community and the public at home and abroad but also pushed the conflict between the frontiers of life sciences and ethical boundaries to the center of public debate(4). In the aftermath, the Chinese government quickly took steps to strengthen criminal regulation, as it became increasingly clear that ethical review and administrative regulations alone were insufficient to provide effective constraints, and that criminal law should extend its reach to the domain of human gene editing(5). In response to public concerns, the *Amendment (XI) to the Criminal Law of the People’s Republic of China* urgently introduced two offenses related to human genetic science—the crime of illegally carrying out human gene editing, cloning, and other reproductive medical activities, and the crime of illegally collecting or providing human genes, embryos, and other resources—thereby, to a certain extent, filling the legal gap in the criminal regulation of the abuse of human genetic technologies(6).

Time flies—seven years have passed since the

“Gene-Edited Babies” incident. This study seeks to address several key questions: What insights can empirical research on gene-editing technology, particularly in relation to the “Gene-Edited Babies” incident, provide? What is the current state of China’s legislative framework on gene editing, especially in terms of criminal regulation? And what deficiencies persist within the existing legal system governing gene-editing technology? The paper will systematically explore and analyze these issues to contribute to a deeper understanding of the legal and ethical governance of gene-editing in China.

2. Exploring the Reasons for the Criminalization of Gene Editing Technology

2.1 Gene Editing Technology Holds a Pivotal Strategic Position in China

Gene editing technology, as a revolutionary tool in the life sciences, has been assigned a highly strategic position in China. It is not only a core area of competition in cutting-edge science and technology but is also regarded as a key means to drive medical revolutions, ensure food security, and enhance the competitiveness of the bioeconomy (7). In 2016, the *National Innovation-Driven Development Strategy Outline* first proposed achieving breakthroughs in fields such as genomics and precision medicine(8). In 2020, *Biosecurity Law* further emphasized the safe governance and regulated development of biotechnology, including gene editing(9). In 2021, the Chinese central government, through top-level designs such as the *14th Five-Year Plan for Bioeconomy Development*, explicitly identified gene editing as a strategic scientific and technological direction and allocated substantial resources, aiming to achieve high-level technological self-reliance and secure a commanding position for future development(10). It can be seen that China’s strategic positioning is reflected in three main aspects:

- Treating gene editing as a critical technology for safeguarding national health and food security.
- Using it as an important driver of the bioeconomy and emerging industries.

- Leveraging it as a crucial asset for participating in global science and technology governance and Regulation formulation.

2.2 The application of gene editing technology has been advancing by leaps and bounds

China has taken a leading role in gene editing applications across multiple fields. In medicine, it launched the world's first human CRISPR clinical trial in 2016 and has since advanced both basic research and clinical trials, from studying cancer and genetic disorders to testing therapies for leukemia, lymphoma, B-thalassemia, and Duchenne muscular dystrophy (11). In agriculture, researchers use gene editing to improve rice, wheat, and corn for pest resistance, drought tolerance, and soil adaptability, while also enhancing livestock such as pigs resistant to African swine fever (12). In the industry, biomedical companies are rapidly investing in gene and cell therapies as well as molecular diagnostics, accelerating the commercialization of research and strengthening China's position in the global biomedical sector.

2.3 The Ethical Controversies Brought by Gene Editing Cannot Be Ignored

2.3.1 Hidden Genetic Discrimination

According to statistics, between 2000 and 2011, Chinese courts heard a total of 92 cases involving anti-discrimination claims, which were mainly concentrated in several categories. Among them, cases of discrimination against hepatitis B virus carriers were the most numerous, with 41 cases, accounting for 44.6% (13). This was followed by 9 cases of disability discrimination (9.8%), 8 cases of gender discrimination (8.7%), and 7 cases each of discrimination based on social origin and health status (7.6% each). In addition, there were 5 cases each of height discrimination and childbirth discrimination (5.4%), 4 cases of discrimination against HIV carriers (4.3%), 2 cases each of age discrimination and appearance-based discrimination (2.1%), as well as 1 case of regional discrimination and 1 case of employment discrimination caused by carrying pathogenic genes. Overall, discrimination against hepatitis B carriers dominated anti-discrimination cases, while genetic discrimination, though appearing

in only one case, already reflected the emergence of a new type of discrimination. Although there was just a single case of employment discrimination caused by carrying pathogenic genes among the 92 anti-discrimination cases, its significance goes far beyond the number itself. It not only reveals the potential of genetic information to become a new tool of discrimination but also reflects the lag in legal responses to emerging social risks brought about by technological development. As a concealed and forward-looking form of discrimination, genetic discrimination is gradually becoming a key area that future anti-discrimination law needs to address.

Gene-editing technology, while driving medical progress and disease prevention, also carries the potential risk of intensifying genetic discrimination (14). On the one hand, advances in gene editing have made genetic testing more sophisticated, making access to personal genetic information increasingly convenient. The misuse of such information could lead employers, insurance companies, or even educational institutions to treat individuals differently based on whether they carry certain genetic defects or have undergone genetic editing interventions, thereby infringing upon their rights to equality and privacy (15). On the other hand, the notion of "optimizing humanity" promoted by gene editing may fuel an excessive societal pursuit of "healthy" or "perfect" genes, which in turn could marginalize individuals who have not undergone genetic editing or who carry particular mutations. This not only reinforces inequalities in the distribution of social resources but may also, in subtle ways, create new forms of social stratification and discrimination.

2.3.2 Erosion of Social Equity and Fair Resource Distribution

Social equity represents an important value orientation of governance modernization in China, yet the development of gene editing technology may pose challenges to this goal. First, as a frontier technology with high costs and significant technical barriers, gene editing—if primarily controlled by a small group of elites or high-income classes—will lead to inequality in access and application (16). Such inequality is not only reflected in disparities in treatment opportunities but may also

generate intergenerational advantages through “genetic optimization,” thereby creating a “genetic divide.” Second, once this divide becomes entrenched, it may intensify existing social stratification and run counter to China’s current policy orientation of “common prosperity” (17). More seriously, if gene editing exerts implicit influences in areas such as education, employment, and social security, social stratification may acquire “technological” characteristics, resulting in entrenched and irreversible institutional inequality.

2.3.3 Risks to Ethnic Unity

The development of gene editing technology may provide individuals or groups with opportunities for “genetic optimization” based on hereditary traits (18). However, if access to this technology is distributed unequally, there is a risk of discrimination against specific groups or “non-optimized” individuals, thereby invisibly exacerbating inequalities both within and between ethnic groups. In China, ethnic unity and social harmony are regarded as fundamental pillars of national development. If gene editing is misused to promote evaluations of genetic “superiority” or to prioritize certain ethnic traits, it could not only undermine a sense of national identity but also weaken social cohesion, ultimately generating profound social and ethical challenges.

3. Empirical Analysis Regulatory Framework of Gene Editing Technology, and Exposed Issues

The year 2018 marked a pivotal point in the legal regulation of gene editing in China. In that year, He Jiankui announced the birth of the world’s first gene-edited babies, triggering widespread attention and ethical controversy both domestically and internationally, and exposing the existing legal gaps and regulatory deficiencies in China’s gene editing field (19). Therefore, this paragraph takes 2018 as a key node to examine the changes in relevant legislation before and after that year, and analyzes, based on survey data, the issues that still exist in the current application of gene editing technology in China.

3.1 Empirical Analysis on Public

A total of 1,200 questionnaires were distributed in this study, of which 1.08K(N=1080) were deemed valid, resulting in a valid response rate of 90%. The gender distribution was evenly balanced, with 540 males (50%) and 540 females (50%). Regarding educational attainment, Figure 1 presents that 216 participants (20%) had a high school education or below, 270 (25%) held an associate degree, 432 (40%) possessed a bachelor’s degree, and 162 (15%) had a master’s degree or above. This diverse sample composition ensures representativeness across gender and educational backgrounds, thereby providing a robust basis for analyzing variations in public awareness and attitudes toward gene-editing technology and related ethical and legal issues.

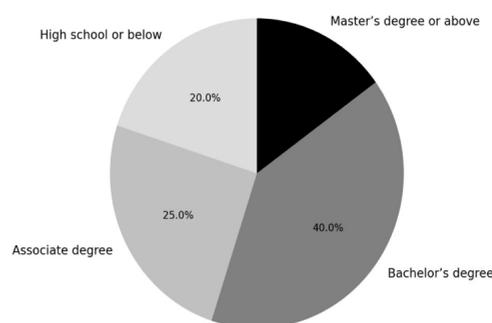


Figure 1: Educational Attainment of Respondents (N=1080)

To further verify this Correlation, data from Figure 2 demonstrate a clear upward trend in awareness with increasing education level. Specifically, only 30% of respondents with a high school education or below had heard of gene editing technology, compared with 40% among junior college graduates, 50% among those with a bachelor’s degree, and as high as 93% among master’s degree holders. Similarly, awareness of the He Jiankui gene-edited babies incident increased from 12% in the lowest education group to 44% in the highest. These results indicate that education level is a key determinant of public understanding of scientific and ethical issues: individuals with higher education not only possess greater exposure to scientific information but also

tend to adopt more rational and balanced attitudes toward emerging biotechnologies. Therefore, strengthening bioethics and science communication—particularly among groups with lower educational attainment—remains essential for fostering informed social dialogue and responsible public engagement.

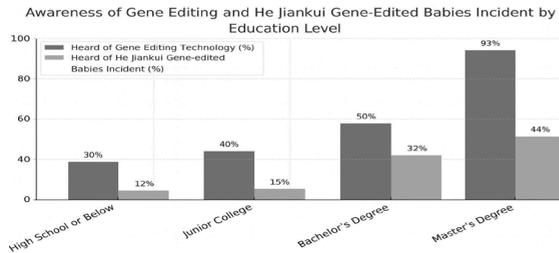


Figure 2: Empirical Research Data on Gene Editing Technology and the Gene-Edited Babies Incident

3.2 Legislative Changes Regarding Gene Editing Technology

Before 2018, China primarily relied on administrative regulations and ethical guidelines in the field of gene editing, such as the *Interim Measures for the Administration of Human Genetic Resources* (1998) and the *Ethical Guidelines for Human Embryonic Stem Cell Research* (2003), lacking clear criminal liability and a systematic regulatory framework². The He Jiankui gene-edited babies incident prompted the advancement of criminal legislation on gene editing in China, namely the *Criminal Law Amendment (XI)*(20). There are currently two offenses in Chinese criminal law related to human genetic technology: first, the crime of illegally collecting human genetic resources or smuggling human genetic material; and second, the crime of illegally implanting gene-edited or cloned embryos (21).

However, despite the criminal law clearly defining the scope of punishment and legal responsibility, numerous problems remain (22). First, the legal provisions do not fully keep pace with the rapid development of gene-editing technologies (23). New experiments such as CRISPR are constantly emerging, while the law's revision cycle is relatively

long, making certain behaviors difficult to clearly define (24). Second, the connection between criminal law and ethical review is insufficient. Overreliance on criminal sanctions may stifle scientific innovation, while ethical review alone is often inadequate to effectively prevent high-risk activities. Third, enforcement and judicial application face significant challenges. Gene editing involves highly specialized experiments and data, making evidence collection difficult, and the dispersed oversight by multiple departments can lead to regulatory gaps or duplicate penalties. Finally, there are obstacles to international coordination and cross-border governance. China's criminalization standards differ from countries that primarily rely on administrative and ethical oversight, which may increase legal risks for international scientific cooperation.

3.3 Exposed Issues

While the rapid development of gene-editing technology in China has promoted medical progress, it has also exposed numerous issues in legal and social governance. From the perspective of criminal regulation, current criminal law mainly addresses acts such as the illegal collection of human genetic resources and the unlawful implantation of gene-edited embryos. However, with the continuous emergence of new technologies like CRISPR, existing legal provisions have lagged, making certain behaviors difficult to clearly define (25). At the same time, ethical review exerts limited binding force in scientific research, and the connection between law and ethics is insufficient, with reliance on criminal penalties potentially inhibiting scientific innovation. Moreover, relevant regulations are dispersed across various laws and administrative documents, supervisory responsibilities overlap, coordination is inadequate, and alignment with international standards remains insufficient. At the public level, although some groups have a basic understanding of gene-editing technology, awareness of specific events remains low, particularly among individuals with lower educational attainment, reflecting uneven scientific literacy. Meanwhile, gene editing may lead to hidden discrimination and social fairness issues, and inadequate legal protection further heightens public concern over potential risks. In summary, the development of gene-editing

² Table 1: Key Legislative and Regulatory Frameworks for Gene Editing Technology in China.

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| Date | laws and regulations | Ministry |
|-------------|--|---|
| 1993 | Administrative Measures for the Safety of Genetic Engineering | Science and Technology Committee |
| 1998 | Interim Measures for the Administration of Human Genetic Resources | Ministry of Science and Technology & Ministry of Health |
| 2003 | Ethical Guidelines for Research on Human Embryonic Stem Cells | Ministry of Science and Technology & Ministry of Health |
| 2015 | Administrative Measures for Clinical Research on Stem Cells (Trial) | National Health and Family Planning Commission & State Food and Drug Administration |
| 2016 | Measures for Ethical Review of Biomedical Research Involving Human Subjects | National Health and Family Planning Commission |
| 2020 | Safety Management Measures for Biotechnology Research and Development | Ministry of Science and Technology |
| 2021 | Civil Code of the People's Republic of China | National People's Congress |
| 2021 | Measures for Ethical Review of Life Sciences and Medical Research Involving Humans (Draft for Comment) | National Health Commission |

technology exposes problems such as lagging legislation, weakened ethical constraints, fragmented regulation, and insufficient public awareness, necessitating responses through systematic legislation, strengthened ethics and public education, improved regulatory systems, and closer alignment with international standards.

4. Future Pathways for Improvement of Gene Editing Technology

4.1 Strengthening Public Participation

In the governance of gene editing technology, strengthening public participation is an essential approach to alleviating ethical controversies. At present, China's regulation of gene editing mainly relies on experts and administrative authorities, while the public often remains absent, resulting in insufficient social trust and information asymmetry. It is necessary to establish multi-level platforms for public communication, enabling diverse groups to express opinions in policymaking, ethical review of research, and risk assessment.

For example, public representatives could be introduced into the ethical review process of major scientific projects, or public awareness could be enhanced through science popularization and open hearings to ensure the right to know and participate. Public participation not only increases the transparency and legitimacy of decision-making but also helps achieve risk-sharing and balance of interests in a value-pluralistic society, thereby promoting the sustainable development of gene editing (26).

4.2 Improving the Legal and Regulatory Framework

Improving the legal and regulatory framework is a fundamental step to addressing ethical controversies. Although China has already amended the Criminal Law, introduced administrative regulations, and issued ethical guidelines to regulate illegal human gene editing activities, problems remain, including vague legal provisions, fragmented regulatory standards, and insufficient

enforcement (27). It is necessary to further refine legislation by clearly defining the boundaries of gene editing research and applications, particularly by setting strict prohibitions in areas involving human germ cells and embryos (28). At the same time, a coordinated regulatory mechanism should be established to ensure information sharing and joint enforcement among science, health, and judicial authorities, thereby enhancing regulatory effectiveness. By strengthening the legal framework and improving institutional enforcement, it is possible to safeguard scientific innovation while effectively preventing ethical and social risks.

4.3 Promoting Ethical Education and Scientific Self-Regulation

Promoting ethical education and scientific self-regulation is another important approach to addressing the ethical controversies surrounding gene editing. At present, some researchers, in their pursuit of academic breakthroughs and international competitiveness, tend to overlook a comprehensive assessment of ethical risks. To address this, bioethics education should be strengthened within the training system for researchers, making ethical competence an integral part of scientific capability. At the same time, research institutions should establish robust self-regulatory mechanisms, including internal rules, academic norms, and disciplinary measures, to create a system of clear responsibilities and effective accountability (29). The scientific community should also foster an academic culture that regards ethics as a fundamental bottom line, promoting both self-supervision and peer oversight to cultivate moral consciousness beyond institutional constraints. Only by emphasizing both ethical education and scientific self-regulation can scientific progress be advanced while avoiding the recurrence of ethical misconduct.

4.4 Promoting International Cooperation and Aligning with Global Standards

Promoting international cooperation and aligning with global standards is a necessary pathway for enhancing the governance of gene editing (30). Gene editing technology is highly transnational and shared, and relying solely on the regu-

lation of a single country is insufficient to comprehensively address potential ethical and safety risks. Therefore, China should actively participate in the development of international ethical guidelines and technical standards, fostering global consensus and coordinated mechanisms. At the same time, cross-border scientific collaborations require strengthened compliance review and risk assessment to prevent the emergence of “ethical loopholes,” where research circumvents ethical constraints due to regulatory differences. Aligning with international norms can not only enhance the legitimacy and credibility of domestic research but also promote innovation steadily in global scientific competition while upholding ethical standards and social responsibility.

5. Conclusion

Gene editing technologies, exemplified by CRISPR-Cas9, offer transformative scientific potential while simultaneously presenting profound legal and ethical challenges. The 2018 “gene-edited babies” incident in China exposed serious deficiencies in regulatory oversight, ethical governance, and public participation, highlighting the urgent need for a multidimensional governance framework. Such a framework should integrate robust legal regulation, transparent ethical review mechanisms, active public engagement, professional self-discipline within the scientific community, and strengthened international cooperation. Through this comprehensive approach, China can balance innovation with accountability, prevent unethical experimentation, and promote the responsible and sustainable development of gene editing technology. Future research should further explore public attitudes through empirical methods, assess comparative governance experiences across jurisdictions, and develop mechanisms to enhance compliance and ethical awareness, thereby contributing to the establishment of a more coherent, evidence-based, and globally harmonized governance system for emerging biotechnologies.

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