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Review

Biotechnology Innovation in Do-It-Yourself (DIY) Gene Editing: A Call for a New Regulatory Framework

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Abstract

The expansion of do-it-yourself (DIY) gene editing, facilitated by Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology, has catalyzed a significant shift in scientific research and biotechnology innovation. This movement is propelled by a community-driven approach that challenges the traditional confines of scientific exploration, allowing amateur scientists to perform sophisticated biological experiments. While this democratization fosters inclusivity and accelerates innovation, it simultaneously introduces significant biosecurity risks. The possibility of unregulated gene editing leading to the unintentional creation of harmful organisms or the deliberate engineering of pathogens underscores the need for a new regulatory framework. This paper explores the implications of DIY biology within the context of public health, environmental safety, and biosecurity, highlighting the urgency for adaptive policies that balance scientific freedom with security. It proposes integrating community-driven regulatory practices with formal oversight mechanisms by examining biosecurity implications, ethical considerations, and the potential for misuse. Additionally, the role of decentralized autonomous organizations (DAOs) is explored as a novel approach to transforming governance within the domain of DIY gene editing, particularly in the context of CRISPR research.

Keywords
Biosecurity; biodefense; biotechnology innovation; CRISPR technology; DIY gene editing; public health and regulatory framework

1. The Emergence of DIY Biology

The emergence of DIY biology represents a significant shift in the landscape of scientific research and innovation, particularly in gene editing. This movement is characterized by a growing community of amateur scientists and enthusiasts who engage in biological experimentation outside traditional laboratory settings. DIY biologists (or "biohackers") are "individuals who conduct biological experiments as an avocation rather than a vocation" [1]. They often operate with limited resources and in less controlled environments than professional labs, yet they demonstrate a remarkable ability to innovate and contribute to the field.

The roots of DIY biology can be traced back to a confluence of factors. The rise of the internet and open-source culture has played an important role, enabling the sharing knowledge and techniques among a global online community. Online platforms, forums, and local meetups play a pivotal role in facilitating the exchange of ideas, methodologies, and results [2]. This collaborative spirit empowers individuals to learn from each other, build upon each other's work, and collectively push the boundaries of what is possible in scientific research. DIY biology enriches the scientific process by allowing a more comprehensive range of voices and ideas, fostering innovative solutions to complex problems that might be overlooked in more conventional settings [3]. For instance, a group of seven individuals with a specific genetic variant collaborated using DIYgenomics.org to study the effects of various vitamin regimens on their homocysteine levels [4]. Another example is patients with amyotrophic lateral sclerosis (ALS) who met through Patients Like Me and worked together to test the impact of lithium carbonate on their symptoms [5]. These examples underscore the power of internet-facilitated collaborations in advancing personal and community-driven scientific inquiries.

In 2008, the formation of DIYbio.org marked a significant milestone in organizing the global DIY biology community [6]. This platform serves as a hub for individuals seeking to explore and conduct science outside the confines of traditional institutions. Early achievements of the group include organizing congresses that led to the development of ethical codes for DIY biologists, signifying the community's commitment to responsible and ethical scientific practice. More recently, DIYbio.org launched DIY biosphere, a platform for sharing information about projects, organizations, and events, further knitting the global DIY biology community together. This approach challenges the traditional notion that meaningful scientific research is exclusive to well-funded institutions like universities and corporate labs. DIY biologists, hobbyists, students, artists, and entrepreneurs advocate for a more inclusive scientific community where individuals from various backgrounds can contribute, irrespective of their access to formal scientific training or resources [7].

The introduction of CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) technology has further propelled the DIY biology movement. CRISPR is a gene-editing tool that has revolutionized genetic engineering. Its ease of use, efficiency, and affordability have made it accessible to professional scientists, amateur biologists, and enthusiasts. With CRISPR, individuals

can perform sophisticated genetic modifications that were once only possible in well-funded laboratories.

DIY biologists typically operate in two types of settings: private and communal. On the one hand, Private settings include homes, garages, or personal spaces where individuals set up their labs. These private labs can range from basic to highly sophisticated, depending on the resources and expertise of the individual. The equipment used in these labs is often acquired second-hand from platforms like eBay or Craigslist or even self-manufactured utilizing open-source 3D printing technologies and protocols available online. Biological materials can be sourced from suppliers or shared among the DIY biology community [2].

Communal settings, on the other hand, are shared spaces where individuals with a common interest in DIY biology come together. These community labs provide a collaborative environment where members can share resources, knowledge, and experience. They often offer educational programs and workshops, particularly in popular areas like CRISPR. Community labs can be seen as incubators for innovation and learning, providing a supportive space for experimentation and discovery. Platforms like YouTube host various scientific lectures, while online course providers like edX and Coursera offer structured courses. Additionally, platforms such as Open Wet Ware and repositories such as Sci-Hub and bioRxiv provide access to scientific protocols and manuscripts, further enriching the resources available for learning and experimentation.

In parallel with the community-driven, collaborative environment of DIY biology labs, there is a need to address biosecurity concerns. The widespread availability and simplicity of CRISPR technology mean that advanced techniques in genetic engineering, once confined to the secure environment of professional laboratories, are now accessible to the broader public. This accessibility allows experimentation in less regulated or informal settings such as homes, garages, or community labs, potentially increasing the risk of unintended consequences or misuse [8]. Therefore, there is a pressing need for frameworks that can keep pace with the speed of innovation, ensuring that all biohacking activities are conducted responsibly. This includes addressing the potential for accidentally releasing genetically modified organisms into the environment or deliberately misusing gene editing tools. It is essential to create guidelines that foster a culture of safety and accountability within the DIY biology community without stifling the innovation that drives it. The challenge lies in making rules and enforcing them in a way that respects the independent nature of DIY biology. The task is complex: it involves education, community engagement, and the development of easy-to-follow safety protocols. It is a delicate balance between encouraging scientific curiosity and maintaining public health and safety.

2. Methodology

This review paper aims to provide a comprehensive overview of the biotechnology field, specifically focusing on the new method of biotechnology innovation - the emergence of DIY gene editing and its intersection with recent policies and regulatory frameworks within public health, environmental safety, and biosecurity. The methodology employed in this study encompasses a systematic review and analysis of academic literature, regulatory documents, official declarations, and news items on the revolution of DIY gene editing technology.

A thorough review of existing literature was conducted using academic databases such as Scopus, Web of Science, PubMed, and Google Scholar. Keywords searched in the database included

"biotechnology innovation", "biosecurity", "biodefense", "bioterrorism", "CRISPR technology" and "DIY gene editing", in association with "environmental safety", "ethics", "public health", "legal challenges" and "regulatory framework" were examined to identify relevant academic articles, review papers, and information from public sources such as global DIY biology communities, news article, media reports, online platforms, and forums.

Case studies, real-world examples, and expert opinions of DIY gene editing projects were also reviewed to explain the motivations, methods, and results of DIY gene editing projects and the scientific, ethical, legal, and regulatory challenges faced by individuals or groups involved in such undertakings. This also facilitated an understanding of public opinions, media coverage, policy development and regulatory actions, risk management strategies, and critical trends in DIY gene editing.

Further analysis of different legal documents and guidelines issued by government agencies, scientific organizations, and bioethics committees was undertaken to describe the changing regulatory environment related to DIY gene editing. This included a review of legislative measures and regulatory agencies at the national and international levels, such as the Food and Drug Administration (FDA), the Federal Food, Drug, and Cosmetic Act (FDCA), the Public Health Security and Bioterrorism Preparedness and Response Act and the 'Food Safety Modernization Act'. Recent amendments and proposed regulations were assessed to discern the regulatory and ethical frameworks and safety standards governing DIY gene editing technologies for effective governance and oversight.

3. CRISPR and the Gene Editing Revolution

The CRISPR-Cas9 system represents one of the most groundbreaking advances in biotechnology, offering unparalleled precision in gene editing [9]. This system, derived from a natural defense mechanism in bacteria, has been engineered to allow for precise modifications in the DNA of virtually any organism, including humans [10]. The implications of this technology are vast and varied, ranging from the potential to cure genetic diseases to the more controversial prospects of enhancing human abilities or altering ecosystems.

CRISPR-Cas9 works by utilizing a Cas protein, most notably Cas9, with a guide RNA (gRNA) to induce double-stranded breaks at specific locations within the genome. The cell's natural repair mechanisms then kick in to fix these breaks, allowing for gene addition, alteration, or disruption. This process, while powerful, is not without its complexities and ethical concerns, especially when it comes to applications in humans.

In human medicine, CRISPR can potentially treat many diseases previously thought to be untreatable [11]. It has been particularly promising in addressing monogenic disorders-diseases caused by a mutation in a single gene-such as sickle cell disease and cystic fibrosis. Clinical trials are already underway to test CRISPR' s efficacy in treating these conditions. Beyond therapeutic uses, CRISPR also has applications in basic scientific research, allowing for the exploration of gene function and the development of new models for studying complex diseases.

However, using CRISPR in germline editing-modifying the DNA of sperm, eggs, or embryos- brings forward profound ethical questions. Edits made at the germline level are heritable, meaning they will be passed on to future generations [12]. This raises the possibility of permanent changes to the human gene pool, which may have unforeseen consequences. The debate around germline editing

peaked when a Chinese scientist announced the birth of the first CRISPR-edited babies in 2018, an act that was widely condemned by the scientific community for its ethical and safety transgressions [13].

The ethical considerations do not stop at germline editing. There is also the potential for CRISPR to be used for non-therapeutic enhancements, such as increasing intelligence or physical strength, leading to concerns about creating inequalities and the concept of 'designer babies'. Moreover, there is a fear that these technologies could be misused for nefarious purposes, including bioterrorism [14].

As CRISPR technology matures, the legal and ethical frameworks surrounding its use must evolve. The international community has been engaged in ongoing discussions to establish guidelines and regulations to ensure CRISPR is used responsibly. This includes the work of organizations like the National Academies of Sciences, Engineering, and Medicine, which has provided extensive analysis and recommendations on human genome editing [15].

4. Biosecurity Implications of DIY Gene Editing

The democratization of gene editing, originated by the CRISPR revolution, raises profound biosecurity concerns. The ability for individuals to edit genomes outside regulated environments introduces risks of unintentional harm to public health, agriculture, and ecosystems. There is a possibility of creating organisms with the potential to disrupt natural biological systems or inadvertently engineer pathogens [16].

Biosecurity is not merely about the involuntary effects; it also encompasses the deliberate misuse of gene editing technology. While malicious applications by state actors often dominate the discourse, the simplicity of CRISPR makes it a potential tool for bio-terrorism, even at an individual level. The regulatory gap is evident: existing laws and frameworks were not designed to govern individuals or small groups capable of manipulating life's building blocks [17].

The public health implications of DIY gene editing are particularly alarming due to the possibility of releasing engineered pathogens. The risks are heightened in an unregulated environment where amateur scientists may not fully understand the virulence or transmissibility of the organisms they manipulate. The infamous case of the engineered influenza strain, deemed too hazardous to share publicly, underscores the catastrophic potential of such pathogens escaping the confines of a controlled setting. This incident is a cautionary tale, prompting the scientific community to reconsider the boundaries of research openness concerning public safety [18]. It also illustrates the urgent need for a robust framework to preemptively address the biosecurity risks associated with DIY gene editing, ensuring that public health is safeguarded against the unintended consequences of well-intentioned scientific curiosity. For DIY biology, the challenge is to maintain this balance without stifling biotechnology innovation [19].

The environmental risks are equally pressing. Gene drives, a CRISPR application, have the potential to alter entire species, and their release into the wild could have irreversible impacts. Current environmental protections may not account for such rapid technological advancements, necessitating an urgent re-evaluation. Gene drives can spread genetic modifications rapidly through a population, potentially altering entire ecosystems [20]. One concern is the potential for gene drives to unintentionally disrupt the balance of interdependent species within the ecosystem. For

instance, modifying a pest species might seem beneficial, but if that pest is a food source for a predator, the effects could cascade through the food chain [21].

Deploying gene drives in DIY gene editing could precipitate complex interlinked environmental risks. Notably, the unintentional crossing of borders by gene drives could disrupt ecosystems and biodiversity in regions where such interventions have not been sanctioned or anticipated, potentially leading to international ecological and political conflicts [22]. Complicating this scenario is the risk that target organisms might evolve resistance to these gene drives, a dilemma paralleling the challenge of antibiotic resistance, which could give rise to a new ecological quandary. Furthermore, the prospect of gene drives being weaponized for environmental terrorism adds a grave dimension to these concerns, necessitating a unified approach to governance and a robust international dialogue on biosecurity.

The possibility of modifying harmless microorganisms into harmful ones, capable of releasing toxins or altering the human immune system or microbiome, presents additional risks. This could result in entirely new pathogens with unpredictable effects on humans. The emergence of gene editing technologies, particularly CRISPR, has added a layer of complexity to bioterrorism. These tools could potentially be exploited to resurrect extinct viruses or create antibiotic-resistant strains of bacteria, complicating the task of biodefense. Nations and groups have recognized the destructive potential of bioweapons as a cheaper alternative to other forms of mass destruction, and their use could provoke severe international repercussions. The difficulty in detecting such attacks and the potential for unattributed acts of terror heightens the risk they pose [23].

The U.S. has invested substantially in biodefense, focusing on healthcare provider education and developing countermeasures against the most threatening agents in response to these threats. Legislative measures, such as the Public Health Security and Bioterrorism Preparedness and Response Act, have been enacted to safeguard food supplies. The ‘Public Health Security and Bioterrorism Preparedness and Response Act’ of 2002 and the ‘Food Safety Modernization Act’ of 2010 were enacted to prevent bioterrorism. These laws protect food supplies from pathogens. Under these acts, facilities involved with food production for humans or animals in the United States must register with the FDA, which has the authority to halt food production and distribution if there is credible evidence or information indicating a threat to human or animal health [24].

5. Centralized Biosecurity Measures in the Age of CRISPR

Regulatory bodies are tasked with the complex challenge of revising existing laws to reflect the nuances of gene editing technologies, creating flexible oversight mechanisms that can rapidly adapt to new scientific developments. The FDA plays a fundamental role in regulating medical technologies, including the emerging field of DIY CRISPR gene editing [2]. The FDA’s jurisdiction over CRISPR materials hinges on the “intended use” of these materials [25]. This concept is central to understanding what constitutes a biological drug product under the FDCA. The Act broadly defines drugs as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals, or those intended to affect the structure or function of the body [26]. Consequently, any use of CRISPR for human applications potentially classifies these materials as biological drug products, subject to rigorous regulatory requirements. The determination of “intended use” extends beyond public statements by manufacturers, encompassing any relevant evidence, including how consumers might use the product. This broad interpretation allows the FDA

to regulate a wide array of CRISPR materials, even those not explicitly intended for human use, based on the potential for such use inferred through various means [27].

The FDA's authority to regulate DIY CRISPR materials and kits also relies on the principle of interstate commerce. The jurisdiction of the FDA extends to products that move in interstate commerce or incorporate components that do. This aspect of the law ensures that the FDA's regulatory reach is extensive, given the complexity of modern supply chains where products and components frequently cross state and national boundaries. Even DIY CRISPR products distributed freely or used in a non-commercial context can fall under FDA jurisdiction if they, or any of their components, have traversed state lines. This wide-ranging interpretation of interstate commerce significantly expands the FDA's capacity to oversee CRISPR materials and kits, encompassing virtually all products that enter the market in the United States [28].

Despite its broad jurisdiction, the FDA faces significant challenges in enforcing its regulations on DIY CRISPR activities. The agency's enforcement discretion means that not all products or activities may be subject to oversight, particularly if they do not pose a clear public health risk or if proving their status as biological drugs is difficult. Additionally, there are explicit gaps in the FDA's oversight capabilities [29]. For instance, the FDA cannot regulate the self-administration of CRISPR interventions created and used by individuals without commercial products, nor can it regulate the dissemination of instructions for such activities if they are not directly tied to a commercial product. This leaves a notable gap in regulatory oversight for certain DIY CRISPR activities, highlighting a nuanced landscape where regulatory authority and practical enforcement capabilities may not fully align.

Alongside the U.S. regulatory framework governed by the FDA, the European Union offers a contrasting approach to managing DIY genome editing, highlighted by stringent enforcement and clear legislative directives. EU Directive 2009/41/EC mandates that genome editing must be conducted in licensed laboratories, effectively prohibiting most DIY applications. This directive is complemented by Directive 2001/18/EC, which emphasizes the need for controlled environments when dealing with genetically modified organisms to prevent their unintentional release. Adding to this regulatory environment, in 2017, the European Centre for Disease Prevention and Control urged national authorities to scrutinize the authorization of commercial DIY gene editing kits, highlighting potential biosecurity risks [30]. In this regard, a communication from the European Commission outlined an action plan to enhance preparedness against biological risks, specifically noting the security threats posed by commercially available DIY bio-kits which could facilitate the creation of modified pathogens [31]. These proactive measures reflect a comprehensive approach aimed at minimizing the public health and environmental risks associated with emerging biotechnologies.

6. Decentralized Oversight in Gene Editing

In response to these regulatory gaps, the DIY CRISPR community has developed its own mechanisms of self-regulation to address ethical and safety concerns. These self-regulatory practices include the establishment of community norms and ethical codes, adherence to biosafety standards, and the formation of informal review boards to assess the ethical implications of projects [32].

Ethical conduct stands as a cornerstone within the DIY biology community. The early efforts of organizations such as DIYbio.org, which convened congresses to develop an ethical framework,

highlight the community's commitment to operating within a set of moral guidelines. These guidelines, embodied in distinct codes of ethics for North America and Europe, prioritize transparency and peaceful purposes among other values. At a more granular level, community laboratories and individual projects often adopt their own ethical statements, demonstrating a localized commitment to these broader principles. However, translating these ethical values into the oversight of specific projects presents challenges, especially in the absence of traditional Institutional Review Boards (IRBs) that review federally funded or supported research. DIY biologists, navigating a landscape where federal IRB regulations typically do not apply, have explored alternative forms of ethical review, including self-constituted ethics boards or consultations with independent entities, though these remain uncommon practices.

It is also important to note that the DIY biology community widely acknowledges the importance of adhering to established biosafety standards, particularly those outlined in the "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) by the NIH and CDC. The BMBL guidelines, which detail safety practices across four levels of containment, serve as the benchmark for biosafety in the United States. Community laboratories, often designating themselves as operating at biosafety levels 1 or 2, adopt these guidelines to manage risks associated with handling biological agents. Safety policies within these laboratories outline protective measures, handling procedures, and restrictions on certain types of research, ensuring a base level of safety compliance. Additionally, some community laboratories implement project review processes to further ensure safety before any research begins.

The effectiveness of these safety policies and practices hinges on their enforcement, which varies across different settings. Community laboratories often require members to demonstrate their understanding of safety protocols through tests or classes. The design of these laboratories as open, collaborative spaces also facilitates peer support and monitoring, further reinforcing a culture of safety and open innovation [33]. Moreover, agreements or contracts stipulate member responsibilities and the consequences of unsafe or prohibited activities, though enforcement actions appear to be rare, reflecting a community where safety is a shared priority.

Despite these structured approaches to ethics and safety within community settings, DIY biologists operating in private settings face a different set of challenges. Absent formal oversight mechanisms, these individuals often rely on informal networks and social media platforms to discuss safety issues, share knowledge, and, occasionally, enforce community norms through social shaming. This informal system, while lacking the authority of traditional regulatory bodies, plays a crucial role in promoting safe practices and ethical conduct within the broader DIY biology community.

7. The Future of DIY Gene Editing: DAOs, Innovation, and Community-Driven Science

The evolving landscape of DIY gene editing necessitates a forward-looking approach to biosecurity policy. Future directives must address the dual-use nature of gene editing technologies, ensuring their application in a manner that promotes public health, environmental preservation, and national security [34]. The development of adaptive biosecurity frameworks is imperative to establish guidelines for safe practices that can evolve with the rapid pace of technological advancement. Such frameworks must provide for the responsible dissemination of research findings and foster international collaboration for the development of global standards.

Enhancing detection capabilities through improved surveillance systems, including the integration of rapid diagnostic tools and artificial intelligence, is essential for the early identification and mitigation of potential threats. Furthermore, the scientific community must cultivate a culture of responsible communication that balances the openness necessary for progress with the security measures required to prevent misuse [35].

In parallel with enhancing biosecurity measures, the rise of Decentralized Autonomous Organizations (DAOs) introduces a transformative approach to governance in the context of DIY gene editing. As a central aspect of the Decentralized Science (DeSci) movement, these entities offer a departure from traditional centralized control, laying the groundwork for an innovative, collective framework that oversees scientific exploration and advancement. The autonomous nature of DAOs, characterized by decision-making through smart contracts and the absence of centralized authority, resonates with the broader shift towards transparent, consensus-based operations within blockchain technology's scope [36, 37]. As DAOs are meticulously designed on blockchain platforms like Ethereum, they allow for the creation of tokens and the establishment of governance models that are both transparent and adaptable [38]. This fosters a culture of transparency and accountability in research governance, which is critical for the responsible development of gene editing technologies. By leveraging smart contracts, DAOs offer an innovative framework that not only streamlines scientific inquiry but also integrates advanced biosecurity protocols, ensuring the safety and ethical integrity of the research process [39]. This emergent model of community oversight could play a central role in establishing a secure yet progressive landscape for CRISPR and other gene editing technologies.

One of the primary benefits of DAOs in the context of CRISPR research is the democratization of funding. Traditional funding models are often criticized for being opaque and biased, favoring established researchers and institutions. DAOs can distribute financial resources based on community votes, ensuring a fairer and more diverse allocation that reflects the collective interest of the community. This approach could empower a wider range of scientists, including those from underrepresented regions or institutions, to pursue ambitious CRISPR projects that might otherwise be overlooked.

DAOs can also facilitate open-source science, where researchers share their findings freely and collaborate without the restrictions of patents and paywalls. This could lead to a surge in CRISPR innovation as researchers build on each other’s work in real-time, fostering an environment where knowledge and tools are accessible to anyone with the interest and capacity to contribute. The open-source nature of DAOs aligns well with the principles of the CRISPR technology itself, which was initially shared openly by its discoverers [40]. Additionally, DAOs can enhance peer review and reproducibility in CRISPR research. By incentivizing peer review through token rewards, DAOs encourage thorough and timely evaluations of scientific work. This could improve the quality and reliability of research outputs, addressing the reproducibility crisis that affects modern science [41]. The transparent and immutable record-keeping inherent to blockchain technology, which underpins DAOs, ensures that experimental methods and data are accessible and verifiable, promoting rigorous scientific standards.

The use of DAOs in CRISPR research also holds promise for public engagement and education. Educational initiatives should be broadened to improve awareness of ethical and safety considerations related to gene editing, especially within the DIY biology community. As decentralized communities, DAOs can engage non-scientists in the research process, educating the

public about the potential and risks of CRISPR technology. This engagement could lead to better-informed public discourse and policy-making around biotechnological advancements, aligning scientific progress with societal values and ethics.

Author Contributions

Alessandro Stasi: Conceptualization; Data curation; Formal analysis; Validation; Writing - original draft; Onnida Thongpravati: Conceptualization; Investigation; Formal analysis; Validation; Writing - review & editing. All authors have read and agreed to the published version of the manuscript. Authorship has been limited to those who have contributed to the work reported.

Competing Interests

The authors have declared that no competing interests exist.

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