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A Study on Synthetic Biology Risks and Response Strategies in legal, ethical, and societal frameworks

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ABSTRACT

Synthetic biology has emerged as a transformative field at the intersection of molecular biology, genetic engineering, digital design, and artificial intelligence. Enabled by breakthroughs such as next-generation sequencing (NGS), low-cost DNA synthesis, and advanced gene-editing platforms like CRISPR–Cas9, synthetic biology allows researchers to design, redesign, and construct biological systems with unprecedented precision. These developments have generated substantial scientific and socioeconomic benefits, including novel therapeutics, mRNA vaccines, gene-drive applications for vector-borne disease control, and opportunities for biodiversity restoration. However, these technologies also pose profound challenges, raising concerns about biosafety, biosecurity, and bioethics.

Biosafety risks encompass the unpredictable ecological and human-health consequences of releasing synthetic organisms—including genetically modified plants, animals, and microorganisms—into natural ecosystems.

These concerns reflect broader issues inherent to a "risk society," in which uncertain, high-impact scientific risks challenge traditional legal frameworks. Accordingly, this article argues for applying risk-law principles—particularly precautions—to synthetic biology governance. Effective regulation requires systematic risk assessment, proportional risk management, and transparent risk communication. As scientific uncertainty increases, democratic participation becomes essential. Decisions about emerging biotechnologies cannot remain the exclusive domain of experts or government agencies.

Ultimately, synthetic biology offers significant promise but also unprecedented uncertainty. Addressing its risks requires an integrated governance approach grounded in precaution, democratic accountability, and interdisciplinary oversight. This paper highlights the dual nature of synthetic biology and underscores the need for robust legal, ethical, and societal frameworks

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to guide its future applications.

1. Introduction

Since the beginning of the twenty-first century, human society has been developing genetic information network systems, which open new possibilities for understanding the principles behind the mystery of life. This progress was largely driven by the Human Genome Project, launched in 1990, which decoded the human genome in 2003 with 99.9% accuracy (NHGRI, 2003). The cost of sequencing genomes has decreased exponentially since then (Wetterstrand, 2023). Thus, we now live in a "post-genome era" where individuals can theoretically access their complete genetic information. Amid these advances, synthetic biology has become a key field in the life sciences.

Klaus Schwab considers biotechnologies—especially synthetic biology—one of the main drivers of the Fourth Industrial Revolution (Schwab, 2016). Synthetic biology combines advanced technologies from molecular biology, genetic engineering, mathematics, digital design, and artificial intelligence (Boles & Singh, 2021). Its growth has been accelerated by the development of precise and efficient gene-editing tools. For example, the development of mRNA-based COVID-19 vaccines is considered a representative achievement of synthetic biology (Liu, 2022). Furthermore, synthetic biology is expected to generate new jobs across various industries in the era of the Fourth Industrial Revolution (OECD, 2014).

However, legal disputes over synthetic biology have become a significant issue in the bioindustry. This article examines the concept and dual nature of synthetic biology. By analyzing its potential risks and legal policy implications, it explores key legal issues and challenges in addressing synthetic biology risks. Finally, it argues that the responsibility for managing these risks does not rest solely with scientists but must be shared among multiple stakeholders, including society, lawmakers, and the judiciary.

2. The Concept and Dual Nature of Synthetic Biology

Synthetic biology involves the technical creation of genetic information and the reorganization of biological systems. It was enabled by two major technological advances. First, considerable progress has been made in DNA synthesis, starting from fundamental components of DNA such as nucleobases, sugars, phosphates, and nucleotides. These are linked to form synthetic genes (Hughes, 2017). The cost of this process has decreased substantially. Second, since 2007, the rapid advancement of next-generation sequencing (NGS) technologies has led to a dramatic reduction in the cost of decoding DNA sequences (Carlson, 2009). Now, entire genomes can be read quickly and accurately. Consequently, the genomes of many organisms have been sequenced. As this data has grown, the types of genes necessary for designing living organisms

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have become clearer. As biology has merged with biotechnology, information technology, and nanotechnology, synthetic biology has emerged and become a mainstream discipline in the life sciences.

Although a universal definition has not yet been agreed upon, in 2010 the U.S. Presidential Commission for the Study of Bioethical Issues (PCSBI) defined synthetic biology as "a field of research that involves the construction of novel biological entities such as designed proteins, genetic circuits, and cells, or the redesign of existing biological systems" (PCSBI, 2010). In addition, the Ad Hoc Technical Expert Group on Synthetic Biology (AHTEG) of the Convention on Biological Diversity (CBD) provided a working definition of synthetic biology in 2015: "an additional development and a new dimension of modern biotechnology that combines science, technology, and engineering to facilitate and accelerate the understanding, design, redesign, manufacture, and/or modification of genetic materials, living organisms, and biological systems." (CBD, 2015).

A key driver in the rise of synthetic biology has been the advent of gene-editing technologies, especially the third-generation CRISPR–Cas9 system (Li et al., 2023). CRISPR–Cas9, utilizing the Cas9 endonuclease, has improved the precision and efficiency of gene editing. Guide RNA identifies the target DNA sequence, and Cas9 then cuts the DNA at the specified site (Li et al., 2023). CRISPR technology has been widely used to develop gene therapies and other new drugs; research genetic diseases such as cancer, Alzheimer's, and anemia; and study human stem cells (Chehelgerdi et al., 2024). It is also used in plant gene editing to create genetically modified foods (GMOs), to address food security and to assist in the restoration of endangered species. Synthetic biology and gene-editing technologies have both positive and negative aspects. On the positive side, synthetic biology may help combat the biodiversity crisis by enabling the revival of endangered species. Animals like mice and dogs have been cloned using these technologies and efforts are underway to extend these methods to larger species. In the future, synthetic biology might be used to resurrect extinct species or protect those on the verge of extinction.

Furthermore, synthetic biology can be used in disease treatment and drug development. For example, the application of CRISPR-based gene editing to gene drive technology[15] has led to strategies for controlling malaria-carrying mosquitoes (Abraham et al., 2025). Genetically modified (GM) mosquitoes can be developed to reduce the burden of malaria. Similar approaches could be used to block the Zika virus, which causes microcephaly. Synthetic biology and CRISPR technology also play a significant role in gene therapy by replacing harmful genes with normal ones, and they are crucial for developing new cell-based treatments (Zhang et al., 2024).

While synthetic biology has solved some pressing human problems and may solve others in the

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future, it also has negative implications. The emergence of new synthetic organisms raises concerns about biodiversity loss, biosecurity threats such as bioterrorism and "biohackers," and bioethical issues, including the possibility of "designer babies." These concerns highlight the risk that synthetic biology could threaten human survival or cause ethical harm (Uddin, 2020). Societal awareness of these risks and decisions on how best to respond to them are closely tied to people's attitudes toward potential dangers that are not yet fully realized. These issues will be discussed in the next section.

3. Potential Risks of Synthetic Biology and Legal–Policy Implications

As synthetic biology rapidly advances, "uncertain risks" are increasingly likely to become "certain risks" and "potential risks" are more apt to turn into concrete dangers (Zeng et al., 2022). These risks in synthetic biology can be divided into three areas: biosafety, biosecurity, and bioethics (Hewett et al., 2016). First, biosafety concerns stem from uncertainty about how newly created synthetic organisms—such as GM plants and GM animals produced through synthetic biology and gene-editing—might affect human health and natural ecosystems (Gómez-Tatay, 2019). Traditional GMO development relied on random mutation or conventional breeding, which involved lengthy periods and generally limited ecological impacts when such organisms were released (Wolt et al., 2016). The same was mostly true for invasive alien species (Snow et al., 2005). Existing legal and policy frameworks were usually sufficient to manage these issues (Wolt et al., 2016).

In contrast, advances in synthetic biology are creating a wide range of new organisms across many fields. Synthetic biology and gene-editing technologies have expanded beyond GM crops to include GM mosquitoes, GM salmon, GM pigs, and GM cattle (Wang and Zhang, 2019). Many of these organisms have been developed in laboratories (Gómez-Tatay, 2019). The biosafety risks stem from the fact that once synthetic organisms escape from labs or are released into the environment, their behavior becomes largely unpredictable (Hoffmann et al., 2023). They could proliferate abnormally in the wild, threaten biodiversity, or hybridize with native species, creating unforeseen new organisms (Wang and Zhang, 2019). Additionally, if synthetic organisms are commercialized and consumed, their potential negative impacts on human health represent a hidden risk (Gómez-Tatay, 2019).

Second, synthetic biology's potential risks can pose biosecurity threats, including biological or bioterrorist attacks (Millett, 2020). Today, anyone with internet access can obtain viral genome sequences (Holm, 2017). Using synthetic biology techniques, it is possible to recreate lethal viruses in laboratories (Holm, 2017; Zeng et al., 2022). This means synthetic biology could be misused to produce biological weapons (Millett, 2020). The recent rise of the "biohacker" movement also poses significant risks (Sandberg and Cassidy, 2020).

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Historically, most outbreaks and spread of infectious diseases caused by bacteria or viruses were natural (Garfinkel et al., 2007). However, humans have begun intentionally using these agents for experimentation or warfare (Wright, 2011). Notably, the 1995 sarin gas attack on the Tokyo subway by Aum Shinrikyo and the 2001 anthrax attacks in the U.S. heightened fears of bioterrorism (Tucker, 2000). Since the 2000s, rapid advances in genomics have made it easier to genetically manipulate bacteria and viruses, thereby increasing the risk of malicious use (Garfinkel et al., 2007). Although major nations emphasize biosecurity risks linked to synthetic biology, research in this area remains insufficient (Zeng et al., 2022).

Third, synthetic biology raises serious bioethical issues. In 2015, a team at Sun Yat-sen University in China reported editing human embryos using CRISPR technology (Liang et al., 2015). In 2018, a professor at the Southern University of Science and Technology in China shocked the world by claiming to have edited embryos. He stated that he had created twin babies resistant to HIV (Cyranoski, 2019). These events sparked global debate over the potential for "designer babies" and raised questions about the adequacy of legal regulations concerning bioethics (Baylis, 2019). Overall, the dual nature of synthetic biology makes it more likely that society will face risks once thought impossible (Hewett et al., 2016). As science progresses, we now have powerful tools like synthetic biology and gene-editing, and it is crucial to determine how to use them responsibly (Zeng et al., 2022). As concerns about biosafety, biosecurity, and bioethics grow, establishing legal and policy frameworks to address these risks becomes an urgent priority (Hoffmann et al., 2023). The next section explores key legal issues related to this.

4. Legal Issues and Tasks in Responding to Synthetic Biology Risks

4.1. The Need for a Risk-Law-Based Approach

Debates about risk have traditionally been developed within administrative law, especially environmental law, and the precautionary principle (a risk-management approach) has become codified as a guiding rule in environmental legislation (Cousy, 1996). Today, theoretical and policy discussions on risk are also active in public health and science and technology law. According to traditional German risk theory, risk is understood as danger (Gefahr), risk (Risiko), and residual risk (Restrisiko) (Huber, 2009). "Risk" refers to a lower or more uncertain probability of harm whereas "danger" implies a high probability of harm. Under this framework, measures to prevent dangers are justified under police law, while risks call for precautionary measures based on the precautionary principle (Huber, 2009). "Residual risk" involves minimal or acceptable probability and/or harm. The general public must tolerate residual risks (Veinla, 2018). Risk can also be expressed as a function of the probability of occurrence and the severity of harm. That is, it depends on: (1) the likelihood that an event will happen and cause damage, and (2) the reasonably foreseeable extent of that damage. The "risk domain" lies

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between danger (high probability and/or severe harm) and residual risk (minimal or acceptable probability and/or harm).

Risk analysis generally involves three components: risk assessment, risk management, and risk communication. First, risk assessment is the process of determining the nature and extent of the hazard posed by a harmful substance or situation to human health. It must be carried out objectively and scientifically. Second, risk management refers to the process by which, after risk assessment, decision-makers decide whether to regulate a risk and, if so, how much. A key question is when and under what circumstances the law should intervene and how far that intervention should go. The precautionary principle offers criteria and conditions for answering these questions (Sadeleer, 2002). Third, risk communication involves exchanging information and opinions about risks among risk assessors, risk managers, consumers, and stakeholders. It provides the public with more information, enhances participation in risk management, and promotes rational decision-making by ensuring transparency and sharing information. Based on this risk framework, addressing risks from synthetic biology can be understood as a process that assesses and manages harms to humans, ecosystems, states, and societies caused by synthetic biology; selects the most appropriate response measures; and supplements and finalizes decisions through risk communication among members of society.

Currently, the pace of technological innovation in synthetic biology far exceeds public awareness and existing legal frameworks. It raises concerns about the risks it entails. For example, it is unclear what might happen after the release of GM mosquitoes designed to eliminate diseases, whether easy access to genetic information and DIY gene-editing kits will increase the risk of bioterrorism, or what genetic defects or harms could occur for individuals and their descendants if embryos are edited to resist HIV. These individual risk scenarios in biosafety, biosecurity, and bioethics collectively form the broader category of synthetic biology risk. From a legal perspective, risk theory and risk law provide useful tools for developing responses. Traditional legal systems focus on clearly identifiable and present dangers, which makes it difficult to manage potential risks from synthetic biology (Cousy, 1996). In contrast, risk law has established specific doctrines to address risks arising from scientific advances, technological progress, and industrialization, and it is closely linked to the precautionary principle (Sadeleer, 2002). The core idea of the precautionary principle is that precautionary measures can be taken — even amidst scientific uncertainty — when certain conditions are met. This principle has been recognized and embedded across different fields, and the synthetic biology sector must also incorporate and regulate it in its risk-management strategies. Because risk inherently involves uncertainty, risk management varies depending on the likelihood of harm. When scientific uncertainty is reduced (i.e., the likelihood of harm is higher), risk assessments can rely heavily on solid scientific data to estimate risks and choose effective countermeasures. Conversely, when uncertainty is significant (low probability and poorly understood risks), scientific data have limited use, and political, ethical, and social values become more influential in shaping responses and guiding social decisions. As a frontier of advanced science and technology, synthetic biology poses challenges for assessing the existence and scale of risks. Uncertainty remains notably high. For this reason, political and social factors, ethical norms, and societal values are important in risk governance. Effective risk management relies heavily on risk communication. This will be further explored in relation to synthetic biology and democracy (Veinla, 2018).

4.2. Synthetic Biology and Democracy

The principle of democracy is one of the fundamental constitutional principles and a core community value. Democracy, often summarized as "government of the people, by the people, for the people," means that citizens are sovereign. This principle extends to science and technology (Góni, 2025). In modern society, where scientification, technologization, and specialization are prominent, major public decisions are often made by experts based on technocratic reasoning (Cotton, 2012). This expert dominance can create tension with democratic values. When scientists, engineers, and policymakers control decision-making on critical issues in science and technology, their dominance conflicts with the democratic principle that citizens have the right to participate in decisions affecting their lives and futures (Góni, 2025). Ensuring public participation is therefore crucial in managing science and technology.

In the context of synthetic biology, not only should citizens be included in discussions on the use of synthetic biology technologies and related policymaking, but institutions must also guarantee public participation in these processes (Habets, 2021). Synthetic biology involves designing, synthesizing, and constructing life. It is linked to issues of biosafety, biosecurity, and bioethics. Because synthetic biology affects living beings, including humans, it has profound ethical and societal implications. As such, scientists, policymakers, and ordinary citizens must be able to understand and discuss synthetic biology and its potential impacts.

Compared to traditional risk domains such as environmental pollution, chemical substances, and nuclear power, synthetic biology risks differ in several ways, including the likelihood and predictability of harm, the public's ability to access and understand complex knowledge, and the asymmetry and limitations of the information available to society (Cotton, 2012).

Therefore, risk communication must be emphasized as a key tool for realizing democratic principles in responding to synthetic biology risks. Effective risk communication provides citizens with comprehensive information about risks, encourages their participation in risk management, and promotes rational decision-making by sharing relevant information (Todd, 2018). It is essential for synthetic biology risk governance. Such communication requires

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providing balanced information about both benefits and risks, evaluating potential harms, and establishing mechanisms for information exchange and public deliberation (Fuchs, 2023). Citizens need detailed information about the nature of risks, methods for measuring and evaluating risks, strategies for reducing risks, and available response options.

Although synthetic biology is highly specialized and expert knowledge is limited, decisions regarding its future are the responsibility and right of all members of society, not just a small group of experts. Citizens should be able to participate in public discussions about the future of synthetic biology, voice their opinions, and be involved—either directly or indirectly—in shaping policies and making decisions (Góni, 2025). Democratic processes must also ensure that synthetic biology technologies and related policies are not monopolized by governments or corporations but are guided by social development and the public good (Habets, 2021). To keep synthetic biology a "beneficial technology," its social and public character must be emphasized. Given its significant implications for the community's future, allowing only a small group of scientists or policymakers to control these decisions would undermine democratic values (Góni, 2025). Today, synthetic biology technologies and their consequences are shifting from perceived "residual risk" to recognized "risk," and in some cases, into the realm of "danger." The monopolization of synthetic biology could increase these risks as a broader social issue. Therefore, appropriate mechanisms for managing and controlling the risks are essential, and careful consideration of who should oversee them and how they should do that is needed (Habets, 2021).

5. Who Controls Synthetic Biology Risks?

Traditionally, the primary responsibility for risk control has rested with the executive branch (Tanimura, 2013). Today, however, civil society, the legislature, and the judiciary play important roles.

(1) Civil Society. The role of civil society has become increasingly significant. Decisions about how much uncertain risk society is willing to accept should not be left solely to experts. Collective reflection and democratic deliberation on the risks and benefits of synthetic biology are essential, and such processes must be supported by open and participatory mechanisms (Stirling, 2018). Calls for the social control of science and technology through citizen participation have been persistent. One basis for this is the public nature of science and technology. Although this public aspect has been weakened by the industrialization of science and technology, the broad societal impact of scientific advances and the fact that large-scale research and development projects are often funded by taxpayers emphasize the need to reaffirm the public character of science and technology (Goñi, 2025). Particularly in fields with strong public implications, mechanisms must be put in place to enable citizens to participate.

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Another foundation for citizen participation is the increasing demand for technological citizenship. Technological citizenship reflects the characteristics of a high-tech society and relates to citizens' rights to participate in decisions about science and technology policy. It includes the right to access knowledge and information, the right to participate in decision-making on science and technology, the right to demand that decisions be based on consensus, and the right to restrict technologies that could harm individuals or groups (Grigoletto, 2023). In the context of synthetic biology risk control, social regulation through citizen participation, grounded in the public nature of science and technology and in technological citizenship, is crucial (Fuchs, 2023). Expanding citizen participation in synthetic biology policy also boosts the legitimacy of related policies and the likelihood of effective implementation.

(2) The Executive Branch. Generally, risk control is conducted by competent state authorities through precautionary measures or cost–benefit analyses. Historically, the executive has played a central role (Tanimura, 2013). Unlike receiving expert knowledge, risk assessment and management involve professional and formative judgments by policy-making bodies. Therefore, the executive has the authority and responsibility to act before the judiciary. Today, the executive remains the main actor in risk governance while the judiciary intervenes when necessary. In practice, managing synthetic biology risks will involve regulatory administration by executive agencies. It is essential to develop risk response strategies that reflect the specific characteristics of biosafety, biosecurity, and bioethics. Detailed standards and requirements should also be established to justify precautionary measures in each area (IRGC, 2018). Administrative authorities can control risks by imposing precautionary measures on risk creators. Therefore, clear criteria are needed to determine when such measures can be triggered. Under the precautionary principle, precautionary measures are permitted when: (a) scientific uncertainty exists; (b) there is at least some scientific evidence; (c) a recognizable risk is present; (d) the risk is socially intolerable; (e) potential harm is serious and irreversible; and (f) the measures align with the principle of proportionality (EC SCENIHR, 2014). Of these, the principle of proportionality is central. Precautionary measures require careful evaluation of the interests involved and a balanced assessment of those interests. The structure of this balancing varies depending on the nature of the risk and the domain of administration. Moreover, the interests of current and future generations must be considered when adopting precautionary measures, as both are entitled to protection from risk (Coppens et al., 2024). To strengthen expertise, legal stability, and neutrality in administrative oversight of synthetic biology risks, establishing a separation between risk assessment and risk management bodies could be beneficial. Competent agencies responsible for biosafety, biosecurity, and bioethics would handle risk management within their legal mandates, while independent expert groups could conduct risk assessment. Experts involved in risk assessment must remain neutral and independent, with institutional

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guarantees ensuring diversity, transparency, and openness.

(3) The Judiciary. While the executive generally has primary authority over risk control, courts also have a role. The relationship between the executive and the judiciary in risk governance varies across civil law and common law systems (Kuzma, 2015). Civil law countries tend to have broad administrative discretion regarding when and how to respond to uncertain risks. In contrast, courts in common law countries are more likely to review administrative decisions on risk. This difference reflects the extent to which courts defer to precautionary regulatory measures and who effectively controls risk. As seen in cases involving GMOs, European courts have applied the precautionary principle and have shown considerable deference to EU health and safety measures. They have recognized broad EU discretion based not only on scientific evidence but also on social, economic, traditional, ethical, and environmental considerations (EC SCENIHR, 2014).

6. Conclusion: Proposals for Responding to Synthetic Biology Risks

Synthetic biology has the potential to bring significant benefits and prosperity, but it may introduce unforeseen risks into society (Ou et al., 2023). Ongoing attention and continuous effort are necessary to develop appropriate responses to the risks posed by synthetic biology (Wang & Zhang, 2019). First, in the field of biosafety, a detailed review of the concept and scope of biosafety, along with how developments in synthetic biology influence it, is essential (SCENIHR et al., 2015). It is also critical to evaluate the comprehensiveness and effectiveness of biosafety policies across countries and to understand current trends in biosafety regulation within international organizations (Sasani, 2024). In particular, gene drive systems—genetic mechanisms that favor the inheritance of specific genes—have significant impacts, offering substantial advantages for disease control but raising serious concerns about the potential for uncontrollable ecological damage (turn0academia12 Reed et al., 2018). Until effective safeguards are in place to regulate gene drives, their use in natural ecosystems should be delayed, and measures should be implemented to prevent gene drive organisms from being released into the environment (SCENIHR et al., 2015).

Second, regarding biosecurity, response strategies must be tailored to address biological weapons used in warfare, bioterrorism by individuals or non-state actors with political or religious motives, and biocrimes committed for financial gain (Wagener, 2013; Kurtoğlu, 2024). Systematic responses require coordinated research on the concepts, characteristics, and trends of bioterrorism, its links to human and national security, and broader global security perspectives (Gronvall, 2018). Third, in terms of bioethics, the limitations and potential improvements of the Bioethics and Safety Act must be considered. This Act aims to prevent violations of human dignity and harm to the human body in research involving humans or human-derived materials,

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as well as in work involving embryos or genes (Ou et al., 2023). Many countries prohibit the implantation of genetically modified embryos into humans. However, since detailed standards for embryo gene editing are not explicitly outlined, legal gaps may occur. Additionally, questions remain about the conditions under which synthetic biology technologies affecting human life and health should be permitted and regulated (Kurtoğlu, 2024). Addressing these issues requires legislative reform.

In conclusion, to manage the risks of synthetic biology, we must refine biosafety, biosecurity, and bioethics frameworks; adopt risk law and the precautionary principle appropriately; promote democratic participation and effective risk communication; and clarify the roles of civil society, the executive branch, and the judiciary in risk governance (Millett, 2021). Through these multidimensional efforts, society can harness synthetic biology as a public-oriented, beneficial technology while minimizing potential harms (Ou et al., 2023).

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