Editing Biosecurity:

Needs and Strategies for Governing Genome Editing

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Executive Summary

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Stanford | CISAC Center for International Security and Cooperation

FSI Freeman Spogli Institute for International Studies

STUDY OVERVIEW

In 2017, researchers from George Mason University and Stanford University initiated a two-year multidisciplinary study, *Editing Biosecurity,* to explore critical biosecurity issues related to CRISPR and related genome editing technologies. The overarching goal of the study was to present governance options and recommendations to key stakeholders, and to identify broader trends in the life sciences that may alter the security landscape. In characterizing the landscape, and in the design of these options and recommendations, the research team focused on how to manage the often-competing demands of promoting innovation and preventing misuse, and how to adapt current, or create new, governance mechanisms to achieve these objectives.

The four study leads and seven research assistants for *Editing Biosecurity* were assisted by a core research group of fourteen subject-matter experts with backgrounds in security, the life sciences, policy, industry, and, ethics. The centerpiece of the study was three invitation-only workshops that brought together the study leads and the core research group for structured discussions of the benefits, risks, and governance options for genome editing. To support these workshops and the final report, the study leads prepared two working papers on risk assessment and governance, respectively, and commissioned five issue briefs on key topics.

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This report is open for peer review and comment until December 31, 2018. All comments can be sent to: editingbioproject@gmail.com. Following incorporation of peer review comments, a final version will be released in January 2019.

The views and opinions expressed in this report are those of the authors. They do not represent their institutions, nor do they represent the views of the workshop participants, or the organization that funded the study. The authors assume full responsibility for the report and any errors or omissions.

ISSUE BRIEFS AND WORKING PAPERS

Perello E. *CRISPR Genome Editing: A Technical and Policy Primer*. Editing Biosecurity Issue Brief No. 1. Arlington, VA: George Mason University; December 2018.

Carter SR. *Genome Editing, the Bioeconomy, and Biosecurity*. Editing Biosecurity Issue Brief No 2. Arlington, VA: George Mason University; December 2018.

Watters K. *Genome Editing and Global Health Security*. Editing Biosecurity Issue Brief No 3. Arlington, VA: George Mason University; December 2018.

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Koblentz GD, Kirkpatrick J, Palmer MJ, Denton SW, Tiu B, and Gloss K. *Biotechnology Risk Assessment: State of the Field*. Editing Biosecurity Working Paper No 1. Arlington, VA: George Mason University; December 2017.

Kirkpatrick J, Koblentz GD, Palmer M, Denton SW, and Tiu. *Biotechnology Governance: Landscape and Options*. Editing Biosecurity Working Paper No 2. Arlington, VA: George Mason University; March 2018.

The working papers and issue briefs are available at the project's website:

https://editingbiosecurity.org/

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IN BRIEF

Editing Biosecurity: Needs and Strategies for Governing Genome Editing

Genome editing has the potential to improve the human condition.

— Genome editing is poised to make major beneficial contributions to basic research, medicine, public health, agriculture, and the biomanufacturing industry that could reduce suffering, strengthen food security, and protect the environment.

Genome editing is disruptive to the biosecurity landscape.

— The threat landscape may expand to include new means of disrupting or manipulating biological systems and processes in humans, plants, and animals.

— Genome editing could be used to create new types of biological weapons.

— The "democratization of biotechnology" may dramatically increase the number and type of individuals and groups capable of misusing genome editing.

CRISPR illuminates broader trends and the challenges of an evolving security landscape.

— Scientific, technological, economic, and social trends are increasing the range of potential biological hazards, diversifying the sources of these hazards, multiplying the routes of exposure, expanding the populations that may be exposed, and increasing the population's level of susceptibility. An approach to biosecurity that accounts for these trends, and encompasses risks posed by deliberate, accidental, and reckless misuse, can help navigate the complex and evolving security landscape.

Take the technology seriously.

— A thorough, informed, and accessible analysis of any emerging technology is crucial to considering the impact that it may have on the security landscape.

Key stakeholders must be engaged.

— Stakeholders in the genome editing field encompass a more diverse array of actors than those involved in previous biosecurity discussions. The engagement of new communities of actors is required.

Applied research is needed to create and implement innovative and effective policies.

— Applied research is necessary to continue the process of modifying existing governance measures, and adapting new ones, as new genome editing technologies and applications are developed, new stakeholders emerge, and new pathways for misuse are identified.

EXECUTIVE SUMMARY

Study Approach

This study's purpose was to highlight the changing safety and security landscape engendered by the emergence of new genome editing technologies, help policy-makers and other stakeholders navigate this space, and illuminate broader trends in the life sciences that may impact the biosecurity landscape.

The two-year *Editing Biosecurity* study was led by four researchers from George Mason University and Stanford University. The centerpiece of the study was three invitation-only workshops that brought together the study leads and the core research group for structured discussions of the benefits, risks, and governance options for genome editing. The study leads and research assistants prepared two working papers to frame the workshop discussions. The first working paper reviewed past studies that assessed the risks posed by emerging dual-use technologies. The goal of this working paper was to provide a baseline for understanding the security implications of genome editing and to identify best practices in risk assessment. The second working paper provided an overview of the current governance landscape for biotechnology and a framework for evaluating governance measures. Each workshop included a range of scientific, policy, ethics, and security experts. The study leads gathered additional information from subject-matter experts in the form of five commissioned issue briefs. Several of the study's experts served as discussants who critically engaged the content of the issue briefs through iterative commentary and feedback.

The study leads and core research group have backgrounds in various disciplines, including the life sciences, social sciences, and the humanities, an approach designed to ensure a rigorous research process underpinned by the inclusion of a variety of perspectives, and further complemented by numerous areas of expertise. The study and its products relied on unclassified, open, and publicly accessible information. The study was an independent academic work in which the charge and scope were determined by the research team. In combination, these factors were motivated by the team's goal of producing open and accessible research outputs that can assist stakeholders in crafting more effective and informed policies.

Introduction

In 2012 scientists discovered that an obscure bacterial defense mechanism called Clustered Regularly Interspaced Short Palindromic Repeats (**CRISPR**) could be used more widely to make precise cuts in DNA. Less than a year later, CRISPR was used to edit the genome of mammalian cells. In combination, these two developments launched a revolution in the field of genome editing that has transformed the life sciences research enterprise.

While the capability to modify the genomes of living organisms is over four decades old, CRISPR is the most significant recent advance and most publicly visible example of genome editing technology. CRISPR allows scientists to add, delete, or modify multiple genes simultaneously with a high degree of precision. Genome editing is poised to make major contributions to basic research, medicine, public health, agriculture, and the biomanufacturing industry, thereby reducing widespread suffering and improving the human condition.

There are risks associated with intentional, reckless, or accidental misuse of genome editing. Genome editing enables new discoveries about how microbes, humans, animals, and plants work, and it provides new tools for manipulating these biological processes. As a result, the threat landscape may be expanded to include new means of disrupting or manipulating biological systems and processes in humans, plants, and animals that are in addition to future threats coming from edited pathogens. The number of potential vectors, targets, and effects will grow rapidly as genome editing is used to explore and exploit biology. Genome editing could be used to create new types of biological weapons, such as those able to target the microbiome and the immune and nervous systems. Further, the “democratization of biotechnology” may dramatically increase the number and type of individuals and groups capable of misusing genome editing. In effect, the versatility, flexibility, and precision offered by new genome editing techniques, such as CRISPR, increases the attack surface, which encompasses the number, accessibility, and severity of vulnerabilities that could be exploited to cause harm, either deliberately, accidentally, or recklessly.

As the biotechnology landscape evolves, so too will the attack surface.

Genome Editing

Genome editing has emerged as a lively discipline of genetic engineering, making use of successive generations of increasingly simple and flexible tools that allow a modern molecular biologist to perform an almost unlimited range of alterations to the genomic makeup of an organism.

One can view genome editing from four perspectives.

- Genome editing ***tools*** are the specific molecular methods that are used to alter an organism's DNA. They may be used in conjunction with other tools, and as part of larger processes. The most well-known of these tools is called CRISPR.
- Genome editing ***capabilities*** refer to the molecular alterations and outcomes that these tools allow scientists to achieve.
- Genome editing ***processes*** are the technologies and procedures, not limited to the genome editing tools themselves, that are essential for planning, executing, and measuring the outcome of a genome editing activity.
- The genome editing ***field*** comprises the entire set of activities, technologies, cultural norms, economics, and ecosystems of developers and users associated with these techniques.

Box 1. Four perspectives from which to view genome editing.

Genome editing tools are typically composed of three components: the payload, the guidance module, and the delivery system. The payload is a nuclease protein that can cut DNA or RNA, effectively removing or crippling a specific gene in an organism. Additional protein, DNA, or RNA can be added to the payload to insert new DNA at a cut site, or modulate the expression of a specific gene. The payload is guided to its target by either a customized binding domain or, in the case of CRISPR, guide RNAs—programmable elements that act as a guidance molecule. Finally, these components are assembled and delivered into cells using a genome editing vector.

CRISPR

CRISPR is the most significant recent advance and most publicly visible example of precision genome editing technology.

CRISPR allows scientists to add, delete, or modify multiple genes simultaneously, and with a high degree of precision. Consequently, CRISPR has launched a revolution in the field of genome editing that is having a transformative effect on the entire life sciences research enterprise.

How CRISPR Works

The introduction of CRISPR as a genome engineering technique occurred between 2012 and 2013. CRISPR-Cas9 was the first in a rapidly expanding suite of RNA-guided endonuclease (RGEN) tools. The core of the CRISPR RGEN system (see Figure A) is a CRISPR-associated or Cas nuclease protein, with multiple functions, one of which is to bind to nucleic acids (double-stranded DNA, in the case of Cas9), unwind it, and introduce a break at a target site. A guide RNA binds to the Cas protein and provides a molecular targeting function, which can be programmed to ensure the nuclease cuts at the intended target. The operation to assemble a new CRISPR RGEN that is suitable for use in a cell can be as short as a few hours to days. CRISPR can be delivered via numerous types of vectors including plasmids, messenger RNA, viruses, and synthetic ribonucleoproteins. The major drawback associated with CRISPR is its lower level of specificity resulting in a higher likelihood of off-target effects compared to other genome editing tools, although this depends on the specific combination of editors and targets. However, this drawback is largely offset by the relative simplicity of the CRISPR system.

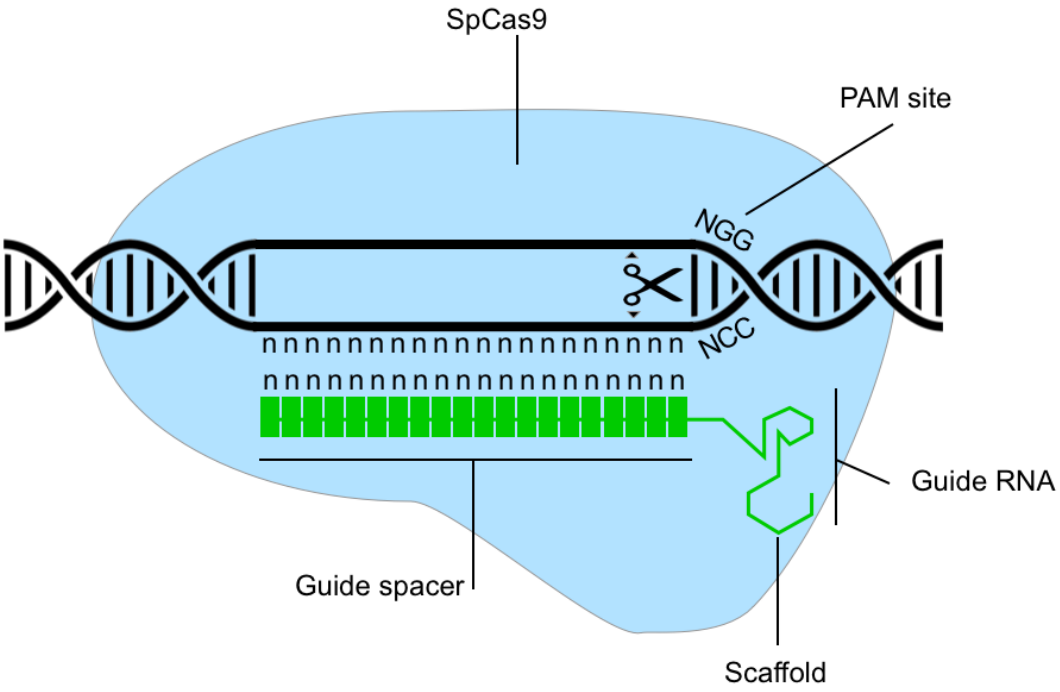


Figure A. The Cas9 nuclease unwinds double-stranded genomic DNA at a PAM site—a specific DNA motif with an NGG sequence—and cuts at the site where guide RNA spacer matches one strand of the DNA. Source: Adapted from Figure E in Perello E. CRISPR Genome Editing: A Technical Policy Primer. Editing Biosecurity Issue Brief No. 1. Arlington, VA: George Mason University; December 2018. Available from: www.editingbiosecurity.org.

CRISPR has been compared to a Swiss Army knife because of its versatility in applications. Yet genome editing with CRISPR is not simply the act of cutting and repairing the target DNA. It includes several events leading up to, and beyond, those moments. Genome editing is thus not a discrete activity, but rather a generalizable process.

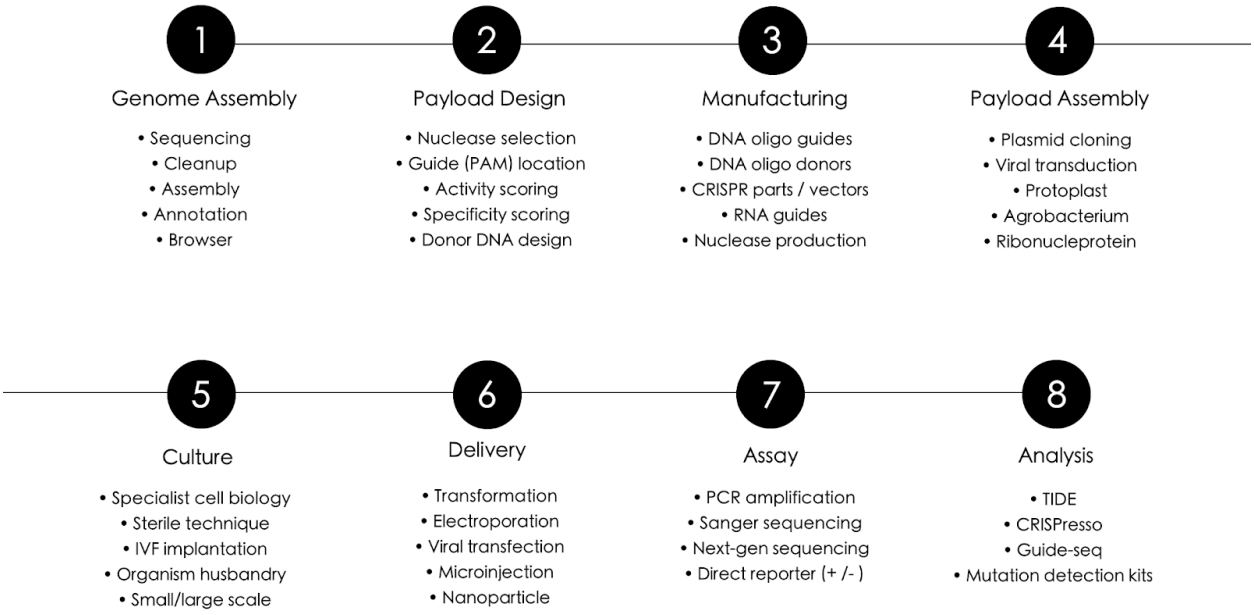


Figure B. An idealized CRISPR process with each step representing a distinct component of a typical genome editing experiment. Source: Figure M in Perello E. *CRISPR Genome Editing: A Technical and Policy Primer*. Editing Biosecurity Issue Brief No. 1. Arlington, VA: George Mason University; December 2018. Available from: www.editingbiosecurity.org.

Many variants of the generalized genome editing process exist to meet different technical or experimental goals. Successful execution of each step can be challenging without the correct skills, and to this extent, CRISPR technology users must be familiar with a distinct range of laboratory tools and techniques, be comfortable using molecular tools and delivery techniques, maintaining viable cells or organisms over extended timeframes, and using various assays, bioinformatic design tools, or analysis packages. The connection of steps within the entire genome editing process is not always a simple affair, and a user may encounter problems that will need to be troubleshot. Depending on project complexity, either an individual or a team will take on one or more of these steps, each requiring some specialist training and technology access.

The Benefits and Risks of Genome Editing

Benefits

Genome editing is a powerful technology that promises a wide range of benefits across a number of domains, but there are technical and social obstacles to realizing these benefits. Over the long-term this realization will also depend on society's ability to facilitate beneficial research and prevent, or if necessary mitigate, the potential risks posed by the technology.

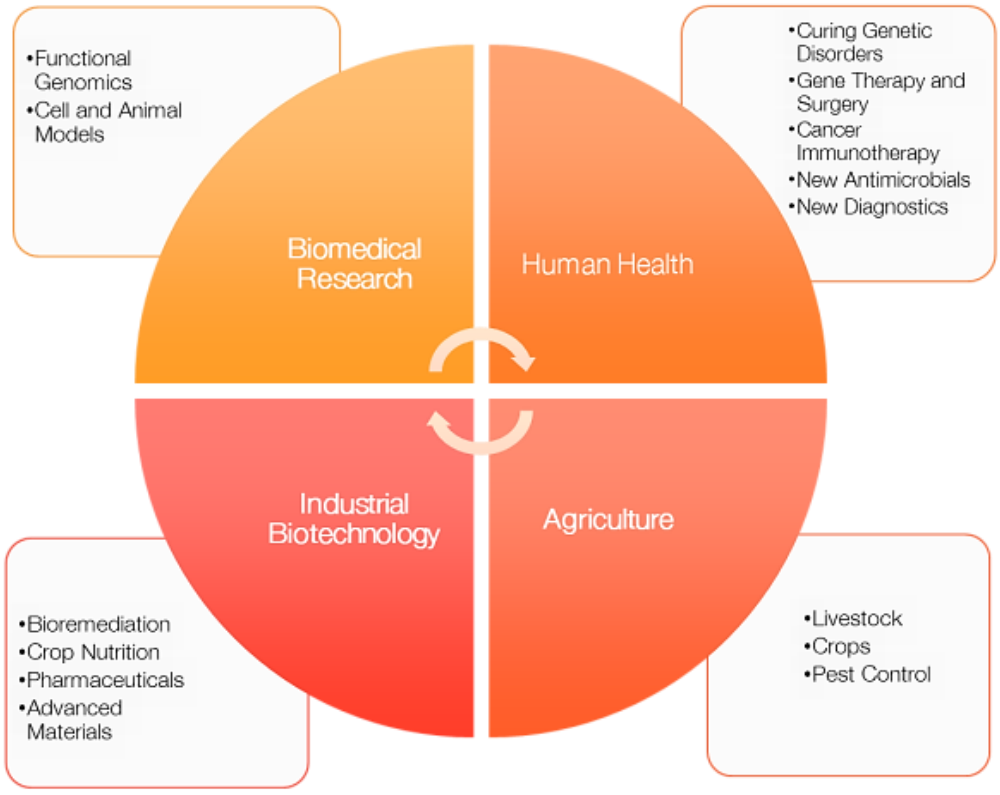


Figure C. Four broad domains of benefits and example applications facilitated by CRISPR.

Available indicators point to a rapid acceleration of technological capability, economic investment, and product development in genome editing that will have significant economic impact. The market for genome editing is expected to exceed $3.5 billion by 2019, but a security incident, biosafety lapse, or significant regulatory uncertainty could hamper this growth.

Risks

The growth of the attack surface has expanded dramatically due the open source nature of the life sciences research enterprise, the globalization of its innovators and users, and the increasing integration of biotechnology into the economy. In addition, developments in genome editing have created new potential attack vectors and the means for rapidly identifying novel ones. Indeed, many of these new attack vectors do not involve actual pathogens, but instead relate to genetic constructs and associated means of delivery. Since the current biodefense paradigm is oriented around developing defenses against a short list of pathogens and most defenses are agent-specific, these new attack vectors have the potential to circumvent current defenses. These new attack vectors also raise new attribution challenges. Since 2001, the United States has invested heavily in microbial forensics, but again, these capabilities are geared towards the analysis and characterization of traditional biothreat pathogens. Genome editing, and CRISPR in particular, pose a new set of challenges to biosafety, biodefense, and biosecurity, thereby altering the security landscape. The landscape of risks can be viewed as comprised of four security domains, illustrated in figure D.

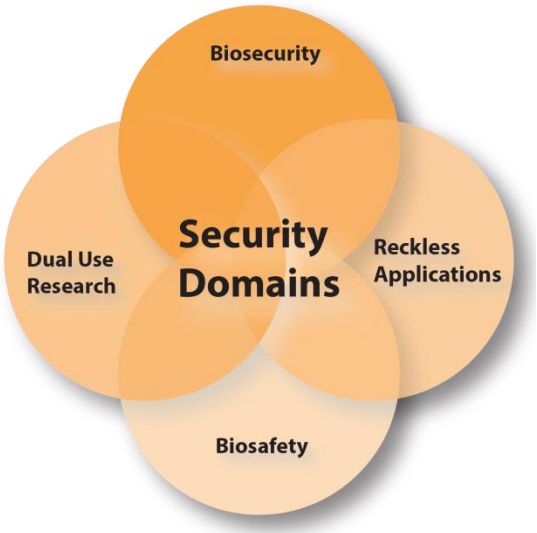
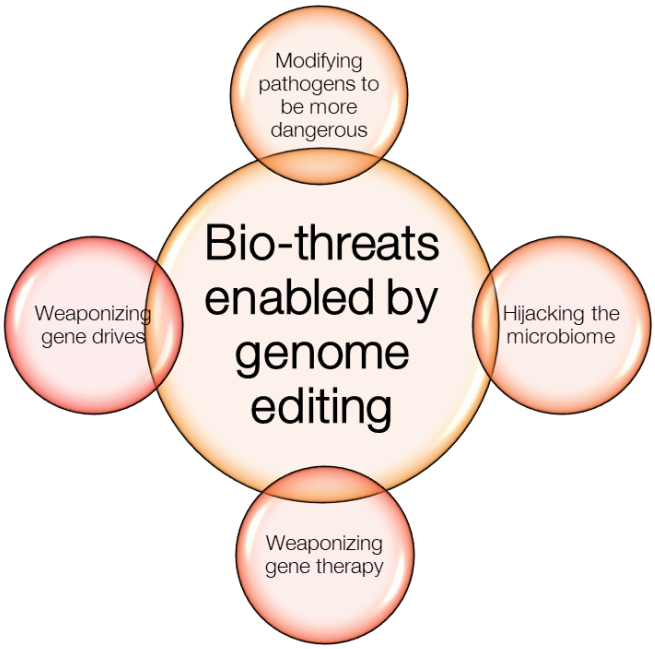


Figure D. Security domains and the landscape of risks.

Scientific, technical, economic, and social trends are increasing the range of potential biological hazards, diversifying the sources of these hazards, multiplying the routes of exposure, expanding the populations that may be exposed, and increasing these populations' level of susceptibility. The rapid diffusion of versatile genome editing tools to a broad range of users has increased the attack surface that must be defended against deliberate, accidental, or reckless misuse of genome editing technology.

CRISPR has all the hallmarks of a generative technology.

Generative technologies are versatile platforms that can be reprogrammed by developers with a range of motivations, objectives, and skills to accomplish a variety of tasks. The open source nature of the technology encourages experimentation, the development of a wide range of applications, their adoption by a diverse user-developer base, and the formation of knowledge-sharing networks and cultures which feeds further innovation. Understanding CRISPR as a generative technology helps shed light on why this technique has come to dominate the field of genome editing, the technology's implications for biosecurity, and the challenges that policy-makers face in formulating and implementing governance measures that promote innovation and reduce risks.



We identify four examples of biological threats enabled by genome editing that populate the risk landscape.

Figure E. Examples of biological threats enabled by genome editing.

Despite the potential risks, there remain significant barriers to misuse of genome editing in the near-term for states, in the medium-term for skilled groups, and in the longer-term for skilled individuals.

Scenarios, Takeaways, and Governance Options

The full report illustrates governance gaps and options across four categories. Provided within each of these categories are scenarios that were developed by drawing upon the study's workshops, input from subject matter experts, and supplemental research and analysis. The scenarios have been grouped across these four main categories, but elements of each could appear in other categories. The scenarios are structured around concrete, yet hypothetical, examples. Mindful of potential information hazards, they have been written to be plausible, but not capable of directly enabling misuse.

Advances in genome editing have illuminated the need to examine the current state of biotechnology governance, identify gaps and areas for improvement, and provide new governance options, while ensuring the appropriate balance between promoting safety, security, and innovation.

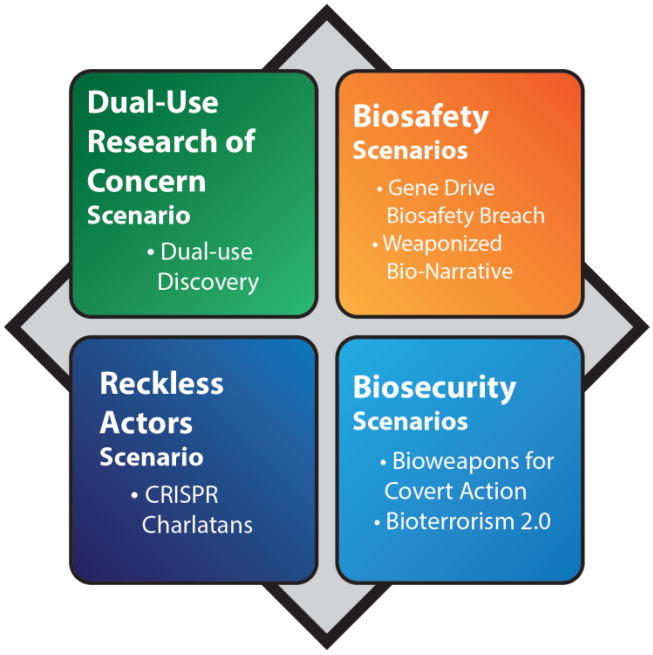


Figure F. Areas of security concern and corresponding scenarios.

The scenarios illustrate the complexity of vulnerabilities and risks, gaps in current policy and practice, and the ecosystem of actors that must be involved to manage the changing security landscape. The scenarios do not represent a comprehensive list of concerns, nor are they necessarily the most important, and they are not intended to be predictive. Instead, they are tools for illustrating gaps between current biosecurity policies and the challenges that emerging genome editing capabilities may pose in the near future.

Each scenario is coupled with examples of policy options that illustrate a range of representative approaches that could address these identified governance gaps. The options presented outline a set of approaches that could be taken to help fill some of the gaps; the approaches are not wholly conclusive, nor do they preclude other options for governance or actors who could implement such options. Finally, the scenarios offer background and context that is intended to display how the discussion and debate around genome editing, and CRISPR in particular, illuminates broader strategic, technological, and policy changes that are shaping the security landscape.

Abridged Example Scenario

Scenario Description: Bioterrorism 2.0

The scenario illuminates biodefense vulnerabilities that can emerge from an increasingly complex global ecosystem of materials and service providers for biotechnology research. It involves a terrorist group that takes advantages of commercially available resources and a lack of customer screening to use genome editing to convert a non-pathogenic bacteria into a biological weapon.

The New Dawn is a white supremacist and millenarian group dedicated to purifying society of "undesirable" elements. Instead of engaging in random acts of violence or symbolic acts of terrorism, New Dawn is pursuing an alternative method to achieving their goal of a white ethno-state. The leaders of New Dawn prey on talented, lonely individuals, particularly PhD students and post-doctoral researchers, whose social and professional achievements have not lived up to their expectations and who hold strong grievances against minority groups or society in general.

The group decides to combine their members' limited expertise with CRISPR, and an easily acquired non-pathogenic bacteria, to create a new biological weapon. The group orders what they need to set up a rudimentary but functional lab from a variety of domestic and overseas suppliers. The backbone of their biological weapon is the innocuous *E. coli* bacteria, which can be found in the environment and the gut of humans and animals. *E. coli*'s hardiness, versatility, and ease of handling have made it a favorite microbial model organism for biologists and a workhorse for the biotech and pharmaceutical industries. These same properties also make the bacteria well-suited for the purposes of New Dawn. At first, the group tries to use CRISPR to modify a lab strain of *E. coli* to produce botulinum toxin, the most lethal toxin known to humans. One of the group's members is able to obtain a synthetic copy of the gene coding for the toxin from a DNA synthesis firm in Asia that does not conduct sequence or customer screening. Nonetheless, this effort is unsuccessful due to the difficulty of engineering a new metabolic pathway for the bacteria to produce the toxin.

The group's next attempt to develop a biological weapon is to engineer a different strain of *E. coli*, called O157:H7. While most strains of *E. coli* are harmless, a few can produce toxins. Due to their low infectious dose and their ability to spread through contaminated food and water, these strains can cause outbreaks of food poisoning. *E. coli* O157:H7 is one the more dangerous strains of the bacteria since it produces the shiga toxin, which can cause severe food poisoning with a lethality rate of 5-10%. The group hopes to engineer 0157:H7's existing metabolic pathway with the help of bacterial protein expression kits purchased online to increase the amount of shiga toxin produced by the bacteria. The group plans on disseminating its super-toxin producing bacteria, which should induce high fatality rates in those who consume contaminated food and beverages, in restaurants and grocery stores in predominantly minority neighborhoods.

Takeaways

- **Increasingly Complex Global Industry:** There is an increasing number and diversity of providers of materials and services supporting biotechnology research.
- **Inconsistent Oversight Standards:** Customer and order oversight and screening standards exist in some cases, but these do not cover the full global market. Other suppliers in the industry, such as genome editing software or reagent suppliers, or companies that provide on-demand biological engineering services, often lack any screening standards.
- **Experiments Evading Oversight:** Using genome editing to modify non-pathogenic bacteria to be more dangerous can circumvent oversight under the Federal Select Agent Program because the bacteria do not appear on the select agents list.

Options for Improving Oversight of Biotechnology Goods and Services

- **Industry Oversight Standards:** The U.S. government could work with providers of biotechnology goods and services to establish voluntary guidelines that include "know your customer" standards, especially for items that pose a higher risk of misuse, and systems for advice and reporting. The U.S. government could also encourage the genome editing industry to adopt a standard to use only goods and services provided by companies that adhere to customer screening standards.
- **Funding Incentives for Industry Oversight**: The U.S. could require recipients of government funding for life sciences research to purchase from companies that demonstrate a specified level of customer and order screening. Private funding bodies could, as a condition of funding, also require similar standards for researchers to purchase screened DNA.
- **Industry and International Engagement:** The U.S. government could work with other countries with large biotechnology industries, such as China, to co-develop standards, possibly via support for an international standards consortium.
- **Incentives for Research Organizations:** Journals and professional societies could only publish, or accept for presentation, research that has met screening standards.
- **Applied Security Research:** The U.S. government could continue and expand sponsored research on methods to increase the effectiveness and reduce the cost of screening. One option for DNA synthesis screening is to develop a curated database of "sequences of concern." Another is to explore a sequence screening upgrade that utilizes one-way encryption to screen sequence fragments through an international network of cloud-based servers.

Context and Background: Synthetic DNA Screening

The International Gene Synthesis Consortium (IGSC) is comprised of leading DNA synthesis firms who voluntarily screen customers and their ordered sequences.

Synthetic DNA Screening

The field of synthetic biology is characterized by a mix of governance measures. In 2009, a group of leading DNA synthesis firms formed the International Gene Synthesis Consortium and announced that they were voluntarily adopting customer and sequence screening standards. The IGSC is comprised of 12 DNA providers, and it collectively accounts for 80% of the global market in DNA synthesis. As part of the screening process, orders are compared against a database of nationally and internationally regulated pathogens and toxins to determine if any ordered sequence poses a security risk. If the automated screening system detects a close match between an ordered sequence and a regulated agent, the order and the customer are scrutinized manually. Based on this manual analysis, the order can be filled, the company can contact the customer for more information, the order can be cancelled, or the company can contact government authorities. As the cost of DNA synthesis continues to decrease, and screening costs remain relatively stable at present, manual screening will constitute an increasingly heavy burden on the members of IGSC.

Members of the IGSC share information on a regular basis within the confines imposed by the need to safeguard proprietary business information. Implementation of the IGSC's standards, however, are at the discretion of each company, and there is no mechanism for the consortium or its members to assess the degree to which members are complying with the consortium's standards.

A gap in the standards that IGSC has yet to address is the potential for non-pathogenic coding DNA sequences, which are not covered by current screening methods, to be synthesized and used nefariously. For instance, genes relating to ecosystem niche habitat preference for a harmless organism could be ordered from a DNA provider. Using CRISPR, the genes could then be inserted into an esoteric pest species to modify or expand its range. This could result in potentially serious economic or ecological effects. This gap is especially important in the context of target selection for gene drives.

In parallel with the industry's development of codes of conduct, the U.S. Department of Health and Human Services (HHS) crafted voluntary guidelines for U.S.-based DNA synthesis providers that were published in 2010. These guidelines detail customer screening measures, standards for sequence screening, and the process for raising concerns with the appropriate government authorities. HHS recommendations only cover double-stranded DNA longer than 200 base pairs; they do not cover short oligonucleotides (single-string DNA). In addition, there is no mechanism for assessing whether companies, based in the United States or elsewhere, follow the HHS guidance.

Conclusion

The genome editing field is near an inflection point. While still a relatively new field in the annals of science, it has been six years since the publication of the seminal paper that first identified the potential of CRISPR-Cas9 to make precise edits to DNA. Because CRISPR has proven to be so versatile, it has unlocked a much broader array of capabilities that enable a wider range of actors to modify a diverse array of organisms in a multitude of ways.

Designing effective safety and security governance measures for a generative technology such as genome editing is challenging. The accessibility of the technology, in terms of acquiring the necessary material and skills to use it, makes it attractive to a wide range of actors with diverse motives and objectives. The versatility of the technology enables these actors to develop a variety of products in a number of disparate fields. The current system for governing the safety and security dimensions of biotechnology is fragmented and based on a patchwork of laws, regulations, policies, and voluntary measures at the national and international levels.

Many of the issues identified here are representative of broader systemic challenges created by advances in the life sciences and biotechnology—challenges that will grow only more complex over the long-term. Unless the process of modernizing existing governance measures to ensure the safe, secure, and responsible use of biology begins today, the scientific and policy communities will find it even more difficult to take effective action in the future.

At a minimum, existing governance measures need to be updated to consider the growing capabilities offered by genome editing in the fields of agriculture, biomedical research, human health, and the bioeconomy. In some cases, these updates will be minor and incremental. In other cases, governance measures may have to be radically revised in order to achieve the objectives for which they were designed. There may also be cases where brand-new initiatives at the national or international level are needed to fill a critical gap in the governance architecture.

Lead Contributors

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Prior to arriving at George Mason, Dr. Koblentz was a visiting assistant professor in the School of Foreign Service and Department of Government at Georgetown University. He has also worked for the Executive Session on Domestic Preparedness at the John F. Kennedy School of Government at Harvard University and the Nuclear Non-Proliferation Project at the Carnegie Endowment for International Peace. Dr. Koblentz is the author of Strategic Stability in the Second Nuclear Age (Council on Foreign Relations, 2014) and Living Weapons: Biological Warfare and International Security (Cornell University Press, 2009) and co-author of Tracking Nuclear Proliferation: A Guide in Maps and Charts (Carnegie Endowment for International Peace, 1998). His research and teaching focus on international security and weapons of mass destruction. He received a PhD in political science from the Massachusetts Institute of Technology and a MPP from the John F. Kennedy School of Government at Harvard University.

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Dr. Megan J. Palmer is a Senior Research Scholar at the Center for International Security and Cooperation (CISAC) at Stanford University. She leads a research program on the governance of biotechnology development with a focus on how security is conceived and managed. Her current projects focus on assessing strategies for governing dual use research, analyzing the international diffusion of biosafety and biosecurity norms and practices, and understanding the security implications of alternative technology design decisions. Dr. Palmer has also created and led many programs aimed promoting the responsible development of biotechnology. She leads programs in responsible innovation for the international Genetically Engineered Machine (iGEM) competition, which last year involved over 5000 students in 340 teams from 48 countries. She also founded and serves as Executive Director of the Synthetic Biology Leadership Excellence Accelerator Program (LEAP), an international fellowship program in biotechnology leadership. Previously, Dr. Palmer spent 5 years directing the policy-related research program for the Synthetic Biology Engineering Research Center (Synberc), a multi-university research center in synthetic biology. She has also held positions as the William J. Perry Fellow in International Security at CISAC, a research scientist at the California Center for Quantitative Bioscience at the University of California Berkeley and a postdoctoral scholar in the Bioengineering Department at Stanford University. Dr. Palmer holds a Ph.D. in Biological Engineering from MIT and a B.Sc.E. in Engineering Chemistry from Queen's University, Canada.

Edward Perello, Research Fellow, Institute for Philosophy and Public Policy, George Mason University

Edward Perello is the Principal Researcher for Arkurity, a boutique consulting firm conducting research on public policy challenges in synthetic biology, conservation biotech, and biosecurity. Edward's research interests include the oversight of human genome editing, state and non-state actor development of biological capabilities, and the application of synthetic biology to ecological challenges. He is a Research Fellow at George Mason University, where he works on security policy for genome editing tools. He currently serves on the IUCN Task Force on Synthetic Biology and Biodiversity Conservation, and is working with conservation groups to realise new opportunities for biotechnology in ecosystem restoration. He previously founded Desktop Genetics, a CRISPR biotechnology company, and served as Chief Business Officer for six years. Edward co-chaired the iGEM software committee for two years and is an alumnus of the ELBI biosecurity and SynBio LEAP fellowships.

David A. Relman, Thomas C. and Joan M. Merigan Professor in Medicine, and Professor of Microbiology and Immunology, and Senior Fellow, Freeman Spogli Institute for International Studies at Stanford University. Chief of Infectious Diseases, Veterans Affairs Palo Alto Health Care System

David A. Relman is the Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology & Immunology at Stanford University, and Chief of Infectious Diseases at the Veterans Affairs Palo Alto Health Care System. He is also Senior Fellow at the Freeman Spogli Institute for International Studies (FSI), and served as science Co-Director at the Center for International Security and Cooperation (2013-2017), at Stanford. He is currently director of a new Biosecurity Initiative at FSI. Relman trained at MIT and then Harvard Medical School, followed by clinical training in internal medicine and infectious diseases at the Massachusetts General Hospital in Boston, and then a postdoctoral fellowship in microbiology at Stanford.

Relman was an early pioneer in the modern study of the human indigenous microbiota (microbiome). A landmark paper in 2005 was one of the first to describe the human gut microbiota with molecular methods. Most recently, his work has focused on human microbial community assembly, and community stability and resilience. Principles of disturbance and landscape ecology are tested in clinical studies of the human microbiome. Previous work included the development of methods for pathogen discovery, and the identification of several historically important and novel microbial disease agents. One of those papers was selected as “one of the 50 most important publications of the past century” by the American Society for Microbiology.

Among policy-relevant activities in health and biological security, Relman served as vice-chair of the National Research Council Committee that reviewed the science performed for the FBI 2001 Anthrax Letters investigation, chair of the Forum on Microbial Threats (2007-2017), a member of the Committee on Science, Technology & Law (2012-2015), and is currently a member of the Intelligence Community Studies Board (2016-), all at the U.S. National Academies of Science. He was a founding member of the National Science Advisory Board on Biosecurity (2005-2014), a member of the Working Group on Biodefense for the President’s Council of Advisors on Science and Technology (The White House) (2016), and served as President of the Infectious Diseases Society of America (2012-2013). He is currently chair of the Board of Scientific Counselors at NCBI/NIH. He was a recipient of NIH Pioneer and Transformative Research Awards, and was elected to the National Academy of Medicine in 2011.

Sarah W. Denton, Research Fellow, Institute for Philosophy and Public Policy, George Mason University

Sarah W. Denton is a Research Fellow with the Institute for Philosophy and Public Policy at George Mason University. Her research focuses on the ethical, legal, and social impacts of emerging technologies, such as artificial intelligence, lethal autonomous weapons, and advances in the life sciences. She also serves as a research consultant to Eleonore Pauwels, Research Fellow on Emerging Cybertechnologies at United Nations University Centre for Policy Research, on projects grappling with international governance strategies for artificial intelligence. Sarah holds an M.A. in Philosophy from George Mason University.

Disclosures

Gregory D. Koblentz has agreed to serve as a volunteer advisor to DARPA's PREPARE program on the ethical, legal, and social implications of using genome editing technology to develop defenses against chemical, biological, and radiological hazards.

Megan J. Palmer receives general support for her position at Stanford University from the Open Philanthropy Project. She serves as a volunteer director of the Human Practices program and as a volunteer member of the Safety & Security Executive Committee of the international Genetically Engineered Machine (iGEM) Competition. Dr. Palmer is also an academic member of the National Science Foundation (NSF)-supported Engineering Biology Research Consortium (EBRC) and serves as an advisor to the NSF Center for Cellular Construction. She serves as a pro bono member of the Board of Directors of Revive & Restore.