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Biological risk assessment and management

Approaches to Risk and Benefit Assessment for Advances in the Life Sciences

Submitted by the United States of America

Summary

This paper considers approaches to risk and benefit assessment that could be applied to advances in the life sciences with possible "dual-use" implications for bioweapons development. The paper describes the components of scientific risk assessment and outlines existing risk assessment tools of particular relevance to the Biological Weapons Convention, including those developed by the U.S. National Science Advisory Board for Biosecurity (NSABB), Jonathan B. Tucker, and the U.S. National Academy of Sciences. Finally, it highlights additional risk management tools and discusses approaches to weighing benefits.

I. Introduction

1. In 2018, the States Parties to the Biological Weapons Convention (BWC) assessed a series of biotechnology developments for their potential misuse for bioweapons development (i.e., "dual-use" potential). These technical capabilities included gene editing, gene synthesis, gene drives, and metabolic pathway engineering. The use of these tools continues to spread in life sciences research for legitimate and beneficial applications in public health and medicine, agriculture and the environment, and other civil sectors. However, these tools also have the potential to change the landscape for biological weapons threats, in light of their accessibility, their rapid development, and their convergence with advances in other fields.

2. These emerging capabilities can present challenges to BWC States Parties. However, science-based assessment tools can help to analyze potential risks and benefits from these technological capabilities, allowing States Parties to focus attention and resources on the most likely or concerning threats. When combined with additional tools, such as biorisk management and social awareness, risk assessment tools provide the basis for management options that reduce the risk of misuse of advances in the life sciences. The 2019 BWC

Meeting of Experts on Science and Technology offers a timely opportunity to examine such risk and benefit assessment frameworks and to determine which approaches may be most useful for States Parties. The 2019 Experts discussions will provide a foundation for future discussion of management options.

II. Risk Assessment Tools

A. Defining Risk Assessment

3. Analysts often use scenario-based frameworks to assess emerging technology risks and to explore potential outcomes or mitigations. While informative, these analyses tend to be hampered by a lack of evidence-based case studies and excessive imagination not calibrated to likelihood; one can envision an almost limitless list of bad things that might happen, however unlikely. Given the rapid pace of innovation in the life sciences, the seemingly limitless possibilities create a high level of concern as to which dual-use risks are most likely and worthy of attention, resources, and governance. In this rapidly developing field, full knowledge is not possible and risk should be assessed by a "weight of evidence" approach based on science and data. Moreover, the biological sciences are hallmarked by a culture of openness and information sharing to advance both scientific discovery and the practical application of those discoveries. Solutions to this dual-use dilemma traditionally rely on self-governance within the scientific community and on imposed institutional controls within the biological sciences, along with national and international agreements, such as the BWC, for the responsible use of biology globally. Such self-governance and existing oversight is further strengthened by focused scientific risk/benefit assessment to systematically evaluate the uncertainty of the risks of newly emerging technological capabilities.

4. Risk assessment is used to determine the 'acceptable level of risk' associated with a potential future event. Risk assessments feature two parts: an analysis to provide features and characteristics of the risk being assessed and an evaluation to place that risk within the context of other influencing factors. The Royal Society noted in 2009 that risk assessment can be used in the face of uncertainty and a changing landscape of emerging biological capabilities[1]. They emphasized technical expert assessment across a spectrum of events, from naturally occurring occurrences or accidental releases to deliberate misuse. They further urged the "net assessment of countermeasures" that could be used to mitigate risks and the consideration of socioeconomic factors.

B. Risk Assessment Frameworks for Biological Dual-Use Technologies

5. The specific challenges of biological dual-use technologies were examined by the U.S. National Science Advisory Board for Biosecurity (NSABB), which developed a "Proposed Framework for the Oversight of Dual-use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information" in 2007[2]. The document clarifies criteria for identifying what it terms "dual-use research of concern," or DURC, narrowing the expansive field of "dual-use" to specific areas which may be directly misapplied to pose

[1] New Approaches to Biological Risk assessment. The Royal Society, 2009. https://royalsociety.org//media/Royal_Society_Content/policy/publications/2009/7860.pdf

[2] https://www.ncbi.nlm.nih.gov/books/NBK305027/, incorporated as Annex 4 into the WHO's 2010 guidance document Responsible life sciences research for global health security, accessed here: https://www.ncbi.nlm.nih.gov/books/NBK305040/pdf/Bookshelf_NBK305040.pdf. The United States incorporated these recommendations into dual-use research of concern policies: https://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf; https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf; https://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf; https://www.phe.gov/s3/dualuse/Pages/GainOfFunction.aspx; https://www.phe.gov/s3/dualuse/Pages/ppp-oversight-recommendations.aspx

a threat. The NSABB framework examines the nature of the threat, whether there are current countermeasures, the level of technical skill and sophistication to use the technology, and the scope of the threat, as well as the potential benefits of the particular technology/information. The NSABB framework also delineates the responsibilities for individual researchers, research institutions, and funders pursuing dual-use research, as well as for publishers in communicating information that may be misused. In an appendix, the report suggests points to consider in performing biological risk assessment and management of DURC.

6. Building on this discussion, Jonathan B. Tucker created an adaptable framework[3] in 2012, which aimed to develop a tool to assess the risk that individual emerging technologies might be misused for hostile purposes and to develop tailored governance strategies. Three interconnected processes were needed to create Tucker's framework:

(a) Technology monitoring to detect dual-use innovations that may be misused;

(b) Technology assessment to determine the likelihood of misuse and feasibility of regulation;

(c) Selection of governance measures based on the technology assessment and a cost-benefit analysis.

7. Calculation of risk was based on the technology's accessibility, ease of misuse, the magnitude of harm, and imminence of misuse. However, decisions on how to manage that risk were driven by assessment of the "governability" of the technology, that is, the extent to which the technology is susceptible to various types of governance measures that would mitigate the risk of misuse. Governability was determined based on whether the technology was more tangible or information-based, qualities of maturity and convergence with other technologies, the rate of advance, and the level of international diffusion.

8. Most recently, a committee formed by the U.S. National Academy of Sciences (NAS) developed a framework for assessing risks posed by synthetic biology[4]. The NAS framework's factors for assessing the capability for malicious use of a biotechnology included:

(a) The nature and capability of the technology itself, including: its ease of use, rate of development, existing barriers to use, and convergence with other technologies;

(b) The potential for use as a weapon, i.e., how feasibly it could be weaponized, its scope of damage or impact, and certainty of achieving desired results;

(c) The attributes of actors who could command such a capability, including access to expertise and resources, and size of the organizational footprint required.

9. The framework evaluates these features against influencing factors, which include:

(a) The ability to deter and prevent misuse of the technology;

(b) The ability to recognize that a bioweapons attack has occurred using the technology;

(c) The ability to attribute an attack to the perpetrator misusing the technology;

(d) The ability to provide for consequence management and recovery—strong public health infrastructures and their capacity can determine outcomes, since regardless of the nature of a biological event (natural, accidental or intentional), these capabilities will mitigate harm.

[3] Jonathan B. Tucker, ed., Innovation, Dual Use, and Security: Managing the Risks of Emerging Biological and Chemical Technologies (Cambridge: MIT Press, 2012).

[4] National Academies of Sciences, Engineering, and Medicine. 2018. Biodefense in the Age of Synthetic Biology. Washington, DC: The National Academies Press. https://doi.org/10.17226/24890.

C. Risk Assessment Informs Governance Options

10. These considerations provide contextual insight and rationality into emerging biotechnology risk assessment. Further, as biotechnology expands beyond medicine and agriculture to materials and energy, they can be readily adapted to those sectors to ensure awareness of novel biological threats.

11. Such scientific risk-based frameworks are fully compatible with institutional oversight or self-governance within the scientific community and could be useful in the consideration and development of national laws and regulations. Each framework recommends technology monitoring to detect emerging dual-use innovations with a potential risk of misuse (also known as 'horizon scanning') and technology assessment to determine the likelihood of misuse – including accessibility, costs, and ease of use. These features provide the foundation to determine governability, or the feasibility and effectiveness of governance measures based on the technology assessment. The Tucker framework, which includes examining case studies, determined that governability did not correlate well with the function of the technology itself; rather, the risk assessment drove which, if any, existing policies or regulations could mitigate the risk of misuse. It also recommended that cost-benefit analysis of potential oversight be included, to ensure that application of any governance anticipates potential detrimental costs, or unintended negative effects on reaping the benefits of research.

III. Additional Tools Can Maximize Effectiveness: Building a "Toolkit"

12. Risk assessments can be supplemented by sensible biological risk management tools, which add a layer of preparedness and operational risk reduction on a situational basis. For example, very useful discussions have taken place during the BWC intersessional program regarding pathogen security and biosecurity practices that would serve to advance national and international security.

13. Progress has been made on coordinating best practices in laboratory safety and biorisk management,[5] which can have a role in confidence building[6]. Biosecurity "checklists" for use in laboratories were developed to minimize accidental or deliberate release of harmful agents[7]. An international working group compiled resources and best practices of such efforts in a single training and information guide[8]. Similarly, the World Health Organization (WHO) is updating its Laboratory Biosafety Manual, in which risk assessment informs which risk management tools could be applied to the safe use, transport, and disposal of harmful laboratory agents[9]. All of these efforts contribute to a collection of biological risk management tools, which may be applied to prevent misuse. Importantly, these practices are frequently adopted across industry, a growing component of global biotechnology.

14. Social attitudes are also becoming more important with respect to the advancement of emerging biotechnologies. The Societal Risk Evaluation Scheme (SRES)[10] was one of the

[5] December 2018 ISO standards for biorisk management https://www.iso.org/obp/ui/#iso:std:iso:35001:dis:ed-1:v1:en

[6] Gary Burns and Toon De Kesel "Can Biorisk Management Standards Contribute to Non-Proliferation of Biological Weapons" in "Setting A Standard For Stakeholdership Industry Contribution to a Strengthened Biological and Toxin Weapons Convention" Egmont Series December 2011 Edited by Jean Pascal Zanders.

[7] Brizee, et al. Development of a Biosecurity Checklist for Laboratory Assessment and Monitoring. ABSA international. 2019. DOI: 10.1177/1535676019838077 journals.sagepub.com/home/apb

[8] A Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences. International Working Group [formerly known as the Federal Experts Security Advisory Panel (FESAP) Working Group] 2019.

[9] WHO Laboratory Biosafety Manual, 4th Edition. https://egfolperbprom.files.wordpress.com/2015/08/who-laboratory-biosafety-manual-fourth-edition.pdf

[10] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0168564

first attempts to assess risks of emerging biological applications, by directly considering society's attitude and the anticipated level of concern toward a potentially adverse event outcome caused by misuse of biotechnology. Since then, the European Union has developed tools within 'Responsible Research and Innovation'[11] which attempts to better align the research process with the values, needs, and expectations of society. The new WHO Laboratory Biosafety Manual will also include "legal, cultural, socioeconomic, public perception" considerations of the biotechnology in assessing risk.

15. By incorporating non-scientists citizens, businesses, and policy makers into the discussion of societal outcomes for particular emerging technologies, risk assessment can be more influential, bolster expectations of responsibility, and support international norms around novel biotechnologies. This inclusive conversation is crucial as biotechnology grows beyond traditional biological disciplines into engineering and manufacturing, where non-biologists are using advanced biotechnological tools. Studies demonstrate trends in attitudes towards particular technologies such as genome editing[12,13,] and these trends further support global ethical norms aligned with BWC goals.

IV. Weighing Benefits

16. Assessments of risks of biotechnologies must be weighed against their potential benefits. Biotechnologies have a strong track record of enabling breakthroughs for medicine, public health, and agricultural productivity. New, emerging biotechnologies may not only advance and improve upon these capabilities for a growing global population, but also offer opportunities to develop novel materials and energy sources, evidenced by a growing global interest in sustainable biological manufacturing[14.] Many countries have developed national strategies for harnessing the power of biotechnology to create "circular bioeconomies," hallmarked by a lowered energy and carbon footprint and a reduction of harmful waste in the production of everyday goods and products. Additionally, emerging biotechnologies can enable medical countermeasures that combat the consequences of accidental release or intentional misuse of biological agents as well as naturally-occurring pathogens or viruses.

17. While optimism for the future is high, rational assessment of benefits in this arena is essential for weighing relative risks and benefits. The advent of biological manufacturing appears to be following the typical technology "hype cycle"[15]. For example, initial enthusiasm that biology can "make anything," led to large investments between 2006-2012 in chemicals and fuels that have not met expectations. The economic returns on biotechnology products intended to cost less than goods produced by traditional methods have yet to out-compete the low prices of petroleum-based products. Industries are now pivoting towards chemicals and materials that are more profitable and are in the midst of adopting more realistic strategies and platforms. As industry evolves, it will be important to track which biotechnologies are likely to be successful and publicly adopted. As the global bioeconomy grows, there is both the opportunity for economic benefits and for non-tangible benefits to the whole of society, like improving the quality of life.

18. Early efforts to evaluate the nature of bioeconomy benefits are already underway, both in the U.S.[16] and globally[17.] Although there are robust, matured processes for benefits analysis at the technology application stage particularly in medicine and in agriculture benefits assessment in the early stages of technology development lag behind methods for risk

[11] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation
[12] http://www.globaltimes.cn/content/1126725.shtml
[13] https://science.sciencemag.org/content/357/6351/553.full
[14] Global Bioeconomy Summit Conference Report: Innovation in the Global Bioeconomy for Sustainable and Inclusive Transformation and Wellbeing. https://gbs2018.com/fileadmin/gbs2018/GBS_2018_Report_web.pdf
[15] https://www.gartner.com/en/research/methodologies/gartner-hype-cycle
[16] Safeguarding the Bioeconomy: Finding Strategies for Understanding, Evaluating, and Protecting the Bioeconomy while Sustaining Innovation and Growth. National Academies of Sciences. 2019 http://nas-sites.org/dels/studies/bioeconomy/
[17] https://gbs2018.com/workshops/policy-measuring-and-monitoring/

assessment. The sort of questions needed to assess potential benefits tangibly in this space include: how humans, animals, plants or the environment can benefit from biotechnology; how broadly applicable the technology is and in what time frame; and finally, whether the research or development of technology can benefit national security and stability?

V. Conclusion

19. In the coming years, it is certain that there will be remarkable biotechnology research advances with dual-use potential. Science-based assessment and evaluation tools can help to assess potential risks and benefits and to direct oversight attention and resources towards the most likely or concerning threats. When combined with additional tools like biorisk management and social awareness, these risk assessment and evaluation tools can help reduce the risk of misuse of biology. While there is no single solution for risk management that fits all countries or situations, these frameworks offer adaptable options that could supplement self-governance and oversight measures.