Chapter 6
Addressing Emerging Synthetic Biology Threats: The Role of Education and Outreach in Fostering Effective Bottom-Up Grassroots Governance

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6.1 Introduction

In the run-up to the Seventh Review Conference of the Biological and Toxin Weapons Convention (BTWC) – the principal international agreement that outlaws the development, production, stockpiling, acquisition, and retention of biological and toxin weapons – the US National Research Council published a report which

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highlighted three trends in science and technology that affect the scope and operation of the BTWC:

- The rapid pace of change in the life sciences and related fields;
- The increasing diffusion of life sciences research capacity and its applications, both geographically and outside traditional research environments; and
- The extent to which scientific and technical (engineering) disciplines beyond biology are increasingly involved in life sciences research and innovation.[1]

The advancement of synthetic biology over the past two decades epitomises these three trends and underscores the need to develop and implement effective mechanisms for safeguarding all life sciences activities against accidental or deliberate misuse.

Synthetic biology is a fast-growing interdisciplinary field that combines the principles of engineering with the knowledge in biology to generate technologies and products with applications in agriculture, healthcare, foods, materials science, and more by enabling the design, redesign, manufacture and/or modification of genetic material, living organisms, and biological (eco)systems.[2] Such enabling capabilities are inherently dual-use: on the one hand, they can benefit the advancement of life science R&D, but on the other, they might also be misused to cause harm to humans, animals, or the environment (e.g. through the development of biological weapons). The biosafety and biosecurity implications of synthetic biology are being considered within the framework of different international agreements, such as the Convention on Biological Diversity (CBD), Chemical Weapons Convention (CWC), the International Health Regulations (IHRs), and the BTWC. In 2014, the Conference of the Parties to the Convention on Biological Diversity, recognising the potential

[1] National Research Council, *Life Sciences and Related Fields: Trends Relevant to the Biological Weapons Convention*. Washington, DC: The National Academies Press, 2011, available at https://doi.org/10.17226/13130. See also J.A. Carrera, A.J. Castiglioni, P.M. Heine, 'Chemical and Biological Contract Manufacturing Services: Potential Proliferation Concerns and Impacts on Strategic Trade Controls', *Strategic Trade Review*, Vol. 3:4, Spring 2017. pp 25–46, available at http://www.str.ulg.ac.be/wp-content/uploads/2017/04/Chemical-and-Biological-Contract-Manufacturing-Services-Potential-Proliferation-Concerns-and-Impacts-on-Strategic-Trade-Controls.pdf.

[2] A. Nouri and S. Seyedin-Noor, 'Synthetic Biology: A Call for a New Culture of Responsibility', *Bulletin of Atomic Scientists,* 7 December 2018, available at https://thebulletin.org/2018/12/synthetic-biology-a-call-for-a-new-culture-of-responsibility/; CBD Ad Hoc Technical Expert Group on Synthetic Biology, *Report of the Ad Hoc Technical Expert Group on Synthetic Biology,* UNEP/CBD/SYNBIO/AHTEG/2015/1/3, 7 October 2015, Montreal, Canada, available at https://www.cbd.int/doc/meetings/synbio/synbioahteg-2015-01/official/synbioahteg-2015-01-03-en.pdf; NASEM, *Biodefense in the Age of Synthetic Biology*, National Academies Press, Washington DC, 2018; J. Zhang et al., *The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-Borderness, and the 'Art' of Governance,* BIOS Working Paper No. 4, 2011, BIOS, London School of Economics and Political Science, London. Available at https://royalsociety.org/~/media/Royal_Society_Content/policy/publications/2011/4294977685.pdf; R. Carlson, *Biology is Technology: The Promise, Peril, and New Business of Engineering Life,* Harvard University Press, Cambridge MA, 2010.

impact that technologies with synthetic life, cells or genomes can have on the conservation and sustainable use of biological diversity, decided to establish an Ad Hoc Technical Expert Group on Synthetic Biology.[3] The mandate of the AHTEG includes, *inter alia,* the identification of the potential benefits and risks of organisms, components, and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity, as well as any related human health and socioeconomic impacts relevant to the Convention and its Protocols.[4] The work of the AHTEG is directly pertinent to the functioning of the Cartagena Protocol on Biosafety to the CBD. The Cartagena Protocol aims to ensure the safe handling, transport, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.[5] The convergence of chemistry and biology and its implications for the Chemical Weapons Convention – the principal international agreement that outlaws the development, production, and use of chemical weapons – are being reviewed by the Scientific Advisory Board (SAB) of the Organisation for the Prohibition of Chemical Weapons (OPCW).[6] The benefits and risks of recent life science advances such as genome editing have been considered during the BTWC proceedings, in order to ensure that related knowledge, materials, and techniques are utilised only for peaceful, protective, and prophylactic purposes.[7] Synthetic biology has also been addressed in the context of global health security, particularly with regard to the need for strengthening laboratory biosafety and biosecurity norms and fostering a culture of responsibility in the life sciences.[8]

Despite the growing recognition of the dual-use potential of synthetic biology, developing viable mechanisms for mitigating biosafety and biosecurity concerns

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[3] Conference of the Parties to the Convention on Biological Diversity, *Decision XII/24. New and emerging issues: synthetic biology,* UNEP/CBD/COP/DEC/XII/24, 17 October 2014, Pyeongchang, Republic of Korea, available at https://www.cbd.int/doc/decisions/cop-12/cop-12-dec-24-en.pdf.

[4] Conference of the Parties to the Convention on Biological Diversity, *Decision XII/24. New and emerging issues: synthetic biology,* UNEP/CBD/COP/DEC/XII/24, 17 October 2014, Pyeongchang, Republic of Korea, available at https://www.cbd.int/doc/decisions/cop-12/cop-12-dec-24-en.pdf.

[5] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 11 September 2003, available at http://bch.cbd.int/protocol.

[6] OPCW Scientific Advisory Board, *Report of the Scientific Advisory Board on Developments in Science and Technology for the Fourth Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention,* RC-4/DG.1, 30 April 2018, The Hague, The Netherlands, available at https://www.opcw.org/sites/default/files/documents/CSP/RC-4/en/rc4dg01_e_.pdf.

[7] See, for example, BTWC Meeting of Experts on Review of developments in the field of science and technology related to the Convention, Report of the 2018 Meeting of Experts on review of developments in the field of science and technology related to the Convention, BWC/MSP/2018/MX.2/3, 12 November 2018, Geneva, Switzerland, available at https://undocs.org/BWC/MSP/2018/MX.2/3.

[8] World Health Organisation, *Responsible Life Sciences Research for Global Health Security: A Guidance Document,* 2010, Geneva, Switzerland, available at https://www.who.int/csr/resources/publications/HSE_GAR_BDP_2010_2/en/.

without significantly impeding research and innovation remains a challenge. This is largely due to the fact that under international law dual-use research *per se* is not illicit, as long as it meets the general purpose criterion enshrined in Article I of the BTWC:

> "Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
>
> (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and quantities that have no justification for prophylactic, protective, or other peaceful purposes. Biological and Toxin Weapons Convention, https://www.un.org/disarmament/biological-weapons/."

The general purpose criterion is intended as a comprehensive prohibition of biological and toxin weapons. However, as the negotiations on the development of an international verification protocol to the BTWC have demonstrated, devising a technical system for compliance with the provisions of the Convention has significant limitations, which, unless fully addressed run the risk of undermining the effectiveness of the biological prohibition regime and compromising its integrity. Upholding the general purpose criterion thus requires an integrated set of policies, initiatives, and measures that are flexible and accommodating of the interests and goals of the different stakeholders. In other words, it requires the in-depth implementation of the existing international biosafety and biosecurity regulations, in order to promote, foster, and sustain a strong and viable culture of biosafety, biosecurity, and responsible conduct of science. Such a culture manifests itself in shared beliefs, attitudes, and patterns of behaviour of individuals and organisations that can support, complement or enhance operating procedures, rules, and practices, as well as professional standards and ethics designed to prevent the unintentional (accidental) or intentional release of biological agents and toxins.[9] A robust safety and security culture is an integral element of high reliability organisations and an essential prerequisite for mitigating the risk of 'normal accidents' associated with advanced technology.[10] The Eighth Review Conference of the BTWC in 2016 acknowledged the essential contribution that the life science community can make to promoting and sustaining such a culture. When considering the national implementation of the Convention, the Conference agreed on the value of measures to:

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[9] International Working Group, *A Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences,* 2019, available at https://absa.org/wp-content/uploads/2019/04/CULTURE_TRAINING_CATALOGUE.pdf.

[10] K. Roberts, 'New Challenges in Organisational Research: High Reliability Organisations', *Organizations and Environment,* vol. 3:2 (1989), pp. 111–125; G. Rochlin, 'Reliable Organisations: Present Research and Future Directions', *Journal of Contingencies and Crisis Management,* vol. 4:2 (1996), pp. 55–59; Ch. Perrow, *Normal Accidents: Living with High-Risk Technologies* (New Jersey: Princeton University Press, 1999); N. Goodman, *Shifting the Blame: Literature, Law, and the Theory of Accidents in Nineteenth-Century America*, (Princeton, NJ: Princeton University Press, 1998); Tim Trevan 'Biological Research: Rethink Biosafety', *Nature,* 11 November 2015.

(a) implement voluntary management standards on biosafety and biosecurity;
(b) encourage the consideration of development of appropriate arrangements to promote awareness among relevant professionals in the private and public sectors and throughout relevant scientific and administrative activities;
(c) promote amongst those working in the biological sciences awareness of the obligations of States Parties under the Convention, as well as relevant national legislation and guidelines;
(d) promote the development of training and education programmes for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins;
(e) encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct.[11]

The purpose of this chapter is to examine the role of the synthetic biology community in strengthening biosafety and biosecurity and safeguarding synthetic biology against accidental and deliberate misuse. The chapter argues that biosafety and biosecurity education, awareness-raising, and outreach are essential for fostering effective bottom-up (self-governance) approaches for biosafety and biosecurity risk management. Section 6.2 provides an overview of the structure of the synthetic biology community underscoring its complexity in terms of (1) professional interdisciplinarity, (2) diversity of stakeholders, and (3) dynamic landscape with professional and non-professional actors moving from one context to another over time. Section 6.3 then examines the prevalent perceptions and framing of biosafety and biosecurity risks within the synthetic biology community, in order to identify options for enhancing stakeholder engagement and leveraging the diversity of expertise within the synthetic biology community for promoting responsible research and innovation practices (Sect. 6.4). The conclusion (Sect. 6.5) outlines a summary of the key findings in this chapter.

6.2 Structure of the Synthetic Biology Community

Synthetic biology has developed as a result of the convergence of knowledge, techniques, and tools of different scientific disciplines such as systems biology, genetic engineering, mechanical and electrical engineering, information technology, physics, chemistry, nanotechnologies, and computer modelling.[12] The Lego analogy is commonly used to illustrate the potential of synthetic biology: just as Lego bricks of different colour, shape, and size can be combined together to build new

[11] Eighth Review Conference of the States Parties of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final Document,* BWC/CONF.VIII/4, 11 January 2017, Geneva, Switzerland, available at https://undocs.org/BWC/CONF.VIII/4.

[12] United Nations Interregional Crime and Justice Research Institute (UNICRI), *Security Implications of Synthetic Biology and Nanobiotechnology: A Risk and Response Assessment of Advances in Biotechnology* (Turin: UNICRI, 2012), http://www.unicri.it/special_topics/nanobiotechnology/security_report/.

structures, so can genes and proteins be used as building blocks to create new kinds of cells and new biological functions for cells.[13] In some respects, the evolution of synthetic biology follows the consolidation of molecular biology throughout the 1930s, which facilitated the characterisation of the structure of the DNA molecule and culminated in the emergence of gene splicing experiments in the early 1970s. As noted in the National Research Council 2009 report, 'A New Biology for the 21st Century':

> Biology is at a point of inflection. Years of research have generated detailed information about the components of the complex systems that characterize life – genes, cells, organisms, ecosystems – and this knowledge has begun to fuse into greater understanding of how all those components work together as systems. Powerful tools are allowing biologists to probe complex systems in ever-greater detail, from molecular events in individual cells to global biogeochemical cycles. Integration within biology and increasingly fruitful collaboration with physical, earth, and computational scientists, mathematicians and engineers are making it possible to predict and control the activities of biological systems in ever greater detail. [14]

Within this context, synthetic biology could be considered a game-changing technology, rather than just a novel scientific discipline.[15] For one thing, it allows an unprecedented access to cutting-edge tools, techniques, and methods for manipulating biological and biochemical systems to an increasingly diverse range of practitioners outside traditional life science domains. This is manifested in the horizontal interdisciplinary diversity across the synthetic biology community which includes engineers, computer and materials scientists, and chemists. Synthetic biology has further attracted the interest of designers and artists, as well as given rise to a fast-growing global 'do-it-yourself' (DIY) movement of 'amateur/garage' biologists, some having little or no formal science education or research credentials.[16]

The synthetic biology community is heterogeneous in terms of stakeholders, too. As far as academic research and teaching are concerned, relevant courses are embedded within the formal curricula of universities at undergraduate and postgraduate level around the world. There are specialised synthetic biology academic research centres, institutes, and ad-hoc societies for advancing innovation and scholarship. A case in point is the BioBricks Foundation, a not-for-profit organisation set up in 2006, in order to promote the use of standardized biological parts that

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[13] J. Collins, 'Synthetic Biology: Bits and Pieces Come to Life', *Nature,* vol. 483 (2012), pp. S8–S10.

[14] National Research Council, *A New Biology for the 21st Century* (Washington DC: National Academies Press, 2009), available at https://www.nap.edu/catalog/12764/a-new-biology-for-the-21st-century.

[15] R. Carlson, Biology is Technology: The Promise, Peril, and New Business of Engineering Life, Harvard University Press, Cambridge MA, 2010.

[16] R. Sleator, 'Synthetic Biology: From Mainstream to Counterculture', *Archives in Microbiology,* vol. 198 (2016), pp. 711–713, https://link.springer.com/article/10.1007/s00203-016-1257-x.

are safe, ethical, cost effective and openly accessible.[17] National science academies, individually and collectively carry out periodic monitoring of the state of science in the field, organise meetings and events, and conduct high-level assessments of the social, economic, environmental, or security impact of novel scientific and technological advances.[18]

Synthetic biology finds a wide-ranging application in the biotechnology industry, particularly in the field of drug development, plant breeding, food production, and as an alternative to petrochemical manufacturing. The commercial sector further includes gene synthesis companies – firms that sell synthetic DNA – as well as start-up companies, social entrepreneurs, and bio-incubators – organisations and spaces that help projects and startups develop into mature and sustainable businesses.[19]

Professional associations within industry and academia play an important role in developing standardised approaches and practices, promoting competence and excellence, and recognising and rewarding positive behaviour. They can also act as interlocutors during policy- and decision-making processes.

R&D in the area of synthetic biology benefits from public and private funding from a variety of sources, including government agencies, private foundations and charities, venture philanthropies, and investors. Government agencies are further involved in the administration and regulation of science and research activities.

Science publishers and mass media, including social networks constitute another critical stakeholder, not least because of their role in shaping public opinion and their responsibility to ensure rigorous and ethical reporting and dissemination of information.

The availability of kits, affordable equipment, and commercial services has facilitated the emergence of community-style laboratories effectively turning the practice of biology into a leisure activity open to individuals from all walks of life.[20] Through their activities, non-traditional actors interested in the life sciences, such as Do-It-Yourself (DIY) biologists, designers, and artists seek to promote a better understanding of biotechnology and ultimately uncover new creative ways of resolving societal challenges.

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[17] BioBricks Foundation, 2020, available at https://web.archive.org/web/20151113084040/http://biobricks.org/about-foundation/.

[18] See, for example, European Academies Science Advisory Council, *Synthetic Biology: An Introduction,* (Brussels: EASAC, 2011), available at https://easac.eu/publications/details/synthetic-biology-an-introduction/; Organisation for Economic Cooperation and Development and the Royal Society, *Symposium on Opportunities and Challenges in the Emerging Field of Synthetic Biology,* (OECD, Royal Society, 2010), available at https://sites.nationalacademies.org/pga/stl/PGA_050738.

[19] For more information about bio-incubators, see https://sphere.diybio.org/.

[20] National Research Council, *Life Sciences and Related Fields: Trends Relevant to the Biological Weapons Convention*, (Washington, DC: The National Academies Press, 2011), available at https://doi.org/10.17226/13130; L. Scheifele and T. Burkett, 'The First Three Years of a Community Lab: Lessons Learned and Ways Forward', *Journal of Microbiology and Biology Education,* vol. 17:1 (2016), pp. 81–85.

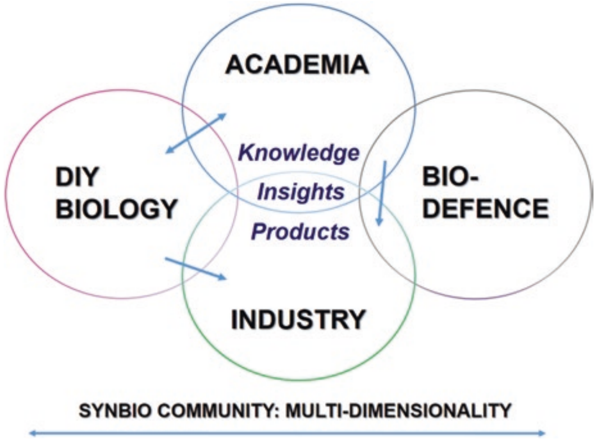

Fig. 6.1 Structure of the synthetic biology professional community (Source: Authors)

The general public is the primary beneficiary and end-user of the materials and products generated as a result of the progress of synthetic biology. Ensuring R&D integrity, safety, security, and reliability are essential requirements for maintaining public trust in science.

The field of synthetic biology is very dynamic, allowing practitioners to frequently change jobs and professional settings. It is possible, for instance, to move from academic research to industry and vice versa; to take up biology as a hobby with the prospect of becoming a social entrepreneur; or to start one's own business during or after formal schooling. This means that professionals often get exposed to different professional cultures, which in turn, enables them to develop a range of transferrable skills and increase their capacity for professional adaptation (Fig. 6.1).

6.3 Perceptions of Risks Within the Synthetic Biology Community

Risks associated with synthetic biology generally fall into two overarching categories: biosafety risks that result from accidents or negligent behaviour; and biosecurity risks that result from the deliberate misuse of knowledge, information, or materials. The term 'biosafety' is defined differently by stakeholders. For the purposes of the present chapter, two definitions of 'biosafety' are considered, namely the definition of the World Health Organisation and the definition accepted under the Convention on Biological Diversity. The World Health Organisation defines biosafety as the set of 'containment principles, technologies, and practices that are implemented to prevent the unintentional exposure to biological agents or their inadvertent release'.[21] Within the context of the CBD, 'biosafety' is understood as the 'safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity and human health'. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 11 September 2003, available at http://bch.cbd.int/protocol. Taken together, these two definitions encompass the spectre of measures, technologies, and procedures that are required to ensure occupational health and safety throughout the research process, as well as the safe handling of research results and products.

The importance of safe laboratory practice is recognised as an essential condition for conducting work in the area of synthetic biology. Following the first genetic engineering experiments in the 1970s which led scientists developing the technology to call for a research moratorium, heated debates on the future of work involving recombinant DNA (rDNA) resulted in an international consensus that research should continue but under stringent restrictions.[22] The pinnacle of these debates was the Asilomar Conference convened in 1975 which brought together some 140 participants including scientists, lawyers, journalists, and government officials. The recommendations of the conference largely informed the development of the official US guidelines for research involving rDNA molecules that were published a year later and, to date, are regularly updated.[23]

The issue of laboratory and environmental safety is explicitly acknowledged in the guide 'Doing Global Science: A Guide to Responsible Conduct in the Global Research Enterprise' that the Inter-Academy Partnership (IAP) published in 2016.[24] The guide defines the professional responsibilities of scientists and is intended as an essential tool for fostering the norms and principles of research integrity. Biosafety professional associations make a significant contribution to promoting safe work with biological materials through advocacy and capacity building, professional certification, and networking. For example, the International Federation of Biosafety Associations (IFBA) administers a Professional Certification Programme in different technical disciplines related to the management of biological risks and a Global Mentorship Programme that seeks to facilitate peer learning and experience sharing among practitioners. IFBA has also established a Biosafety Hero award, in order to celebrate the personal achievement of dedicated biosafety professionals and identify role models.[25]

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[21] World Health Organisation, *Laboratory Biosafety Manual,* 4th ed., (Geneva: World Health Organisation, 2020), https://www.who.int/publications/i/item/9789240011311.

[22] P. Berg, 'Asilomar 1975: DNA Modification Secured', *Nature,* vol. 455 (2008), pp. 290–291, available at https://www.nature.com/articles/455290a.

[23] US National Institutes of Health, Biosafety and Recombinant DNA Policy, https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/.

[24] Inter-Academy Partnership, *Doing Global Science: A Guide to Responsible Conduct in the Global Research Enterprise* (Princeton NJ: Princeton University Press, 2016), available at https://www.interacademies.org/33345/Doing-Global-Science-A-Guide-to-Responsible-Conduct-in-the-Global-Research-Enterprise.

[25] For information about the activities of the International Federation of Biosafety Associations, see https://internationalbiosafety.org/.

Developing safe and good quality products is among the key priorities and responsibilities of any industry. In 2007, the Biotechnology Innovation Organisation (BIO) – the largest trade association representing private and public enterprises and academic institutions across the US and in over 30 other nations – launched the 'Excellence through Stewardship' (ETS) Programme, the first industry-coordinated effort to address product stewardship and quality management.[26] A year later, the programme evolved into a non-profit organisation which currently has over 50 members, including sector research institutions, technology providers, seed producers, and biotechnology associations from around the world.[27] The overriding goal of ETS is to enable enterprises to ensure effective compliance with the regulations that are applicable to their operations. To this end, ETS seeks to promote the universal adoption of quality management systems for the full life cycle of agricultural technology products through the articulation of relevant guiding principles and management practices; the development of training resources and programmes; and the administration of audit processes.

Contrary to common perceptions, the 'do-it-yourself' biology community has strived to internalise biosafety procedures and practices and ensure that these are tailored to the specific setting within which DIY biologists operate. As a result of a series of workshops and gatherings that brought together DIY practitioners from around the world, codes of conduct were developed in 2011 (Box 6.1).[28] These codes define a set of guiding principles by which practitioners agree to abide. Community laboratories have their own advisory boards comprising of technical experts who review project proposals and assist in addressing potential safety concerns. It is also possible for DIY biologists to seek advice and guidance from biosafety professionals via designated online portals.[29]

Similar to biosafety, the term 'biosecurity' has multiple definitions. The World Health Organisation considers biosecurity within the laboratory setting and defines laboratory biosecurity as the protection control and accountability for biological materials within laboratories, in order to prevent their unauthorised access, loss, theft, misuse, diversion, or intentional release.[30] More generally, biosecurity refers to the successful minimising of the risks that the biological sciences might be

[26] Biotechnology Innovation Organisation, 'BIO Launches the Excellence Through Stewardship Program Initiative Introduces Best Practices for Quality Management of Plant Biotechnology Products', *Press Release,* 25 July 2007, available at https://archive.bio.org/media/press-release/bio-launches-excellence-through-stewardship-program-initiative-introduces-best-p. See also Biotechnology Innovation Organisation, 'BIO Statement of BIO Ethical Principles', https://www.bio.org/articles/bio-statement-of-bio-ethical-principles.

[27] For information about the Excellence through Stewardship Organisation, see https://www.excellencethroughstewardship.org/.

[28] For information about the DIY biology codes of conduct, see https://diybio.org/codes/.

[29] T. Kuiken, 'Learn from DIY Biologists', *Nature,* vol. 531 (2016), available at https://www.nature.com/news/governance-learn-from-diy-biologists-1.19507; T. Landrain et al. 'Do-It-Yourself Biology: Challenges and Promises for an Open Science and Technology Movement', *Systems and Synthetic Biology,* vol. 7 (2013), pp. 115–126.

[30] World Health Organisation, *Biorisk Management: Laboratory Biosecurity Guidance* (Geneva: World Health Organisation, 2006), available at https://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6/en/.

Box 6.1 DIYbio Codes of Ethics

European Congress: Draft DIYbio code of ethics	North American Congress: Draft DIYbio code of ethics
Transparency Emphasize transparency and the sharing of ideas, knowledge, data and results.	**Open Access** Promote citizen science and decentralized access to biotechnology.
Safety Adopt safe practices.	**Transparency** Emphasize transparency, the sharing of ideas, knowledge and data.
Open Access Promote citizen science and decentralized access to biotechnology.	**Education** Engage the public about biology, biotechnology and their possibilities.
Education Help educate the public about biotechnology, its benefits and implications.	**Safety** Adopt safe practices.
Modesty Know you don't know everything.	**Environment** Respect the environment.
Community Carefully listen to any concerns and questions and respond honestly.	**Peaceful Purposes** Biotechnology should only be used for peaceful purposes.
Peaceful Purposes Biotechnology must only be used for peaceful purposes.	**Tinkering** Tinkering with biology leads to insight; insight leads to innovation.
Respect Respect humans and all living systems.	
Responsibility Recognize the complexity and dynamics of living systems and our responsibility towards them.	
Accountability Remain accountable for your actions and for upholding this code.	

accidentally or deliberately misused in a way that causes harm to humans, animals, plants, or the environment.[31] This includes the risk of bioterrorism, bio-crimes, and development of biological weapons.

Biosecurity risks have attracted considerable attention over the past two decades, particularly in the light of rapid global diffusion of enabling capabilities with dual-use potential. The accidental discovery of a method for enhancing the virulence of the Mousepox virus, the artificial synthesis of the polio virus, the recreation of the

[31] S. Whitby et al. eds. *Preventing Biological Weapons: What You Can Do* (Bradford: University of Bradford, 2015), available at https://bradscholars.brad.ac.uk/handle/10454/7821.

Spanish Influenza virus, and the creation of a novel synthetic life form are among the early studies which have underscored the need for a careful assessment of the broader social, ethical, and legal implications of synthetic biology.[32] Two high-level reports published by the US National Research Council in 2004 and 2006, respectively have made recommendations in this regard. The Fink Committee report titled 'Biotechnology Research in an Age of Terrorism' defines seven types of experiments that require review by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail. These include experiments that:

1. Would demonstrate how to render a vaccine ineffective.
2. Would confer resistance to therapeutically useful antibiotics or antiviral agents.
3. Would enhance the virulence of a pathogen or render a non-pathogen virulent.
4. Would increase transmissibility of a pathogen.
5. Would alter the host range of a pathogen.
6. Would enable the evasion of diagnostic/detection modalities.
7. Would enable the weaponisation of a biological agent or toxin.[33]

The proposed criteria could serve as the backbone of an oversight system for minimising potential biosecurity concerns. However, as noted by the Committee, (1) the scope of the criteria is limited, since they address only microbial threats and (2) in the future, the proposed categories need to be expanded to cover a significantly wider range of potential threats.[34] The Lemon-Relman Committee report titled 'Globalisation, Biosecurity, and the Future of Life Sciences' has proposed a conceptual framework for assessing the potential for beneficial and disruptive

[32] See S. Whitby and M. Dando, 'Biosecurity Awareness-Raising and Education for Life Scientists: What Should Be Done Now?' in B. Rappert, ed. *Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons* (Canberra: ANU Press, 2010), pp. 179–196, available at https://press.anu.edu.au/publications/series/practical-ethics-public-policy/education-and-ethics-life-sciences. On examples of dual-use research, see M.Selgelid and L. Weir, 'The Mousepox Experience', *EMBO Reports,* vol. 11:1 (2010), pp. 18–24, available at https://www.embopress.org/doi/10.1038/embor.2009.270; E. Wimmer, 'The Test-Tube Synthesis of a Chemical Called Poliovirus: The Simple Synthesis of a Virus Has Far-Reaching Societal Implications', *EMBO Reports,* vol. 7: Spec No (2006), pp. S3–S9, available at https://www.embopress.org/doi/10.1038/sj.embor.7400728; J van Aken, 'Ethics of Reconstructing Spanish Flu: Is it Wise to Resurrect a Deadly Virus', *Heredity,* vol. 98 (2007), pp. 1–2, available at https://www.nature.com/articles/6800911; A. Katsnelson, 'Researchers Start Up Cell with Synthetic Genome', *Nature,* 20 May 2010, available athttps://www.nature.com/news/2010/100520/full/news.2010.253.html; 'Sizing up the "Synthetic Cell"', *Nature,* 20 May 2010, available at https://www.nature.com/news/2010/100520/full/news.2010.255.html.

[33] National Research Council, *Biotechnology Research in an Age of Terrorism* (Washington DC: National Academies Press, 2004), available at https://www.nap.edu/catalog/10827/biotechnology-research-in-an-age-of-terrorism.

[34] National Research Council, *Biotechnology Research in an Age of Terrorism* (Washington DC: National Academies Press, 2004), available at https://www.nap.edu/catalog/10827/biotechnology-research-in-an-age-of-terrorism.

applications of the novel life science advances. [35] The Committee has developed a system of classification comprising of four thematic groupings, namely:

1. Technologies that seek to acquire novel biological or molecular diversity;
2. Technologies that seek to generate novel but pre-determined and specific biological or molecular entities through directed design;
3. Technologies that seek to understand and manipulate biological systems in a more comprehensive and effective manner;
4. Technologies that seek to enhance production, delivery, and "packaging" of biologically active materials.

The report has recommended that a broader perspective on the 'threat spectrum' is adopted by focusing on trends in life science advances that can facilitate hostile misuse.[36]

Unlike biosafety considerations, by and large, biosecurity risks may not be immediately evident to life science stakeholders. A case in point in this regard is the multifaceted international controversy that spurred as a result of the creation of a mammalian-transmissible H5N1 virus in 2011.[37] The two studies conducted independently in the Netherlands and the USA met several of the criteria for experiments of concern as defined by the Fink Committee. In 2005, the Inter-Academy Panel published a Statement on Biosecurity which acknowledged the special responsibility of scientists regarding problems of dual use and the misuse of science and technology and the duty to be aware and foresee the possible consequences of their own activities.[38] One of the lead scientists of the Dutch research team had participated in the focus group established to support the development of the Code of Conduct on Biosecurity that the Royal Netherlands Academy of Arts and Sciences had adopted 4 years earlier (Box 6.2).[39] Nevertheless, biosecurity issues were only considered after the editorial boards of *Science* and *Nature* decided to defer the publication of the manuscripts and the papers were subject to additional review.[40] The publication of the two studies was preceded by a protracted global debate on

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[35] National Research Council, *Globalisation, Biosecurity, and the Future of Life Sciences* (Washington DC: National Academies Press, 2006), available at https://www.nap.edu/catalog/11567/globalization-biosecurity-and-the-future-of-the-life-sciences.

[36] National Research Council, *Globalisation, Biosecurity, and the Future of Life Sciences* (Washington DC: National Academies Press, 2006), available at https://www.nap.edu/catalog/11567/globalization-biosecurity-and-the-future-of-the-life-sciences.

[37] On the H5N1 controversy, see *Nature* Special Collection, available at https://www.nature.com/collections/wntqfnjrxb.

[38] Inter-Academy Panel, *IAP Statement on Biosecurity,* 2005, available at https://www.interacademies.org/13912/IAP-Statement-on-Biosecurity.

[39] Royal Netherlands Academy of Arts and Sciences (KNAW), *A Code of Conduct for Biosecurity* (Amsterdam: Royal Netherlands Academy of Arts and Sciences, 2008), available at https://www.knaw.nl/en/news/publications/a-code-of-conduct-for-biosecurity.

[40] For a review of editorial policies regarding the publication of dual-use research of concern, see D. Patrone et al. 'Biosecurity and the Review and Publication of Dual-Use Research of Concern', *Biosecurity and Bioterrorism,* vol. 10:3 (2012), pp. 290–298, available at https://www.liebertpub.

how the risks and benefits of life science research should be balanced has demonstrated that, by and large, biosecurity issues tend to be considered mainly within the context of laboratory practice, whereby priority is given to the physical security of biological materials and information, including through access control and vetting of research personnel. The debate has further shown that concerns of dual use and science misuse are rarely considered and addressed at the different stages of research process.

In its 2016 publication, 'Doing Global Science: A Guide to Responsible Conduct in the Global Research Enterprise', the IAP has noted that preventing the misuse of life science research is likely to challenge researchers and the broader research enterprise in future which is why researchers need to participate in discussions about the possible consequences of their work, including harmful consequences, when planning research projects.[41] More recently, the World Health Organisation has sought to provide additional guidance on the governance of dual-use research of concern (DURC) in the life sciences – "research that, based on current understanding, has the potential to provide knowledge, information, products or technologies that could be directly misapplied to create a significant threat with potential consequences to public health and safety, agricultural species and other plants, animals, and the environment".[42] According to WHO, the recommended approach for DURC management is "laboratory and medical-scientific self-governance" underpinned by regulatory oversight and "an enhanced culture of trust, personal responsibility, accountability and transparency in laboratories, a culture which comes from strong leadership and a commitment to championing ethics in the workplace".[43]

com/doi/10.1089/bsp.2012.0011. Both the Dutch and US research papers were eventually published in 2012, see S. Herfst et al. 'Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets', *Science,* vol. 336:6088 (2012), pp. 1534–1541, DOI: https://doi.org/10.1126/science.1213362; M. Imai et al. 'Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets', *Nature,* vol. 486 (2012), pp. 420–428, https://www.nature.com/articles/nature10831.

[41] Inter-Academy Partnership, *Doing Global Science: A Guide to Responsible Conduct in the Global Research Enterprise* (Princeton NJ: Princeton University Press, 2016), available at https://www.interacademies.org/33345/Doing-Global-Science-A-Guide-to-Responsible-Conduct-in-the-Global-Research-Enterprise.

[42] World Health Organisation, *Laboratory Biosafety Manual,* 4th ed. (Geneva: World Health Organisation, 2020), https://www.who.int/publications/i/item/9789240011311.

[43] World Health Organisation, *WHO Guidance on Implementing Regulatory Requirements for Biosafety and Biosecurity in Biomedical Laboratories – A Stepwise Approach* (Geneva: World Health Organisation, 2020), https://www.who.int/publications/i/item/who-guidance-on-implementing-regulatory-requirements-for-biosafety-and-biosecurity-in-biomedical-laboratories%2D%2Da-stepwise-approach.

Box 6.2 The Dutch Code of Conduct for Biosecurity [Emphases Added]
In 2007, the Royal Netherlands Academy of Arts and Sciences (KNAW) adopted a 'A Code of Conduct for Biosecurity'.[44] The Code aims to **prevent** life sciences research or its application from **directly or indirectly** contributing to the development, production or stockpiling of biological weapons, as described in the **BTWC**, or to any other **misuse** of biological agents and toxins. It targets different groups of stakeholders and defines six basic principles of biosecurity including:

- Raising awareness.
- Research and publication policy.
- Accountability and oversight.
- Internal and external communication.
- Accessibility.
- Shipment and transport.[45]

Following the H5N1 controversy, in 2013, the Royal Netherlands Academy of Arts and Sciences published a report titled 'Improving Biosecurity: Assessment of Dual-Use Research' which underscored that '**the primary responsibility for dealing with potential dual-use risks of life science research lies with the researchers and parties in the knowledge chain**'.[46]

The report outlined a biosecurity assessment framework noting that 'when determining whether a study should be regarded as dual use from the perspective of biosecurity, both the **biological** and the **contextual** factors must be considered. […]. The question then is not only **whether** a research project is dual use within the context of biosecurity, but in particular **what consequences** this should have.'

The report further recommended the establishment of a Biosecurity Advisory Committee in the Life Sciences. The proposed Advisory Committee would fulfil both **case-specific tasks**, such as advising on specific research proposals, reviewing reports by whistle-blowers about projects and

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[44] Royal Netherlands Academy of Arts and Sciences (KNAW), *A Code of Conduct for Biosecurity* (Amsterdam: Royal Netherlands Academy of Arts and Sciences, 2008), available at https://www.knaw.nl/en/news/publications/a-code-of-conduct-for-biosecurity.

[45] Royal Netherlands Academy of Arts and Sciences (KNAW), *A Code of Conduct for Biosecurity* (Amsterdam: Royal Netherlands Academy of Arts and Sciences, 2008), available at https://www.knaw.nl/en/news/publications/a-code-of-conduct-for-biosecurity.

[46] Royal Netherlands Academy of Arts and Sciences, Biosecurity Committee, *Improving Biosecurity: Assessment of Dual Use Research* (Amsterdam: Royal Netherlands Academy of Arts and Sciences, 2013), available at https://www.knaw.nl/en/news/publications/improving-biosecurity.

Box 6.2 (continued)
researchers, and reporting, as well as **system-based tasks**, such as keeping track of scientific, technological and policy-related trends and developments, maintaining contacts with research institutions, international networking, facilitating public engagement, communication, and accountability.

Finally, the report highlighted that the 'Code of Conduct for Biosecurity **should be an ongoing topic of interest in education and researcher training** and for research team heads and funding bodies'.[47]

6.4 Enhancing Stakeholder Interaction in the Field of Biosafety and Biosecurity

The professional diversity within the synthetic biology community presupposes a multitude of professional cultures, each characterised by its own system of values, shared meanings, established practices, and routines. These cultures are constantly in flux and being conditioned by the larger national cultures within which they exist and operate. Each professional culture is a manifestation of the prevalent priorities and objectives that different stakeholders set and pursue. The ways in which the concepts of risks and benefits are framed by different stakeholders inevitably vary, not least because these concepts are expressions of the dominant common understandings and interests that each professional group considers important. A robust biosafety and biosecurity culture entails the existence of mechanisms, practices, procedures, and attitudes which ensure that risks and concerns are raised, tackled, and effectively managed throughout the full research and innovation cycle.[48] Active interaction among stakeholders is crucial for finding a common ground for constructive dialogue and identifying viable avenues for reconciling competing interests among different professional cultures. Cooperation is key in order to develop and implement adequate and sustainable approaches for risk mitigation which do not hinder research and innovation.

Education and training are key elements of the process of sensitising prospective and practising scientists to the values of research integrity, responsible conduct, and professionalism. Science classes are meant to encourage curiosity and desire to learn and aspire. They also provide an opportunity to foster an understanding of the social responsibility of scientists to be aware of the broader implications of their work and carry out an informed assessment of the risks and benefits involved (Box 6.3).

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[47] Royal Netherlands Academy of Arts and Sciences, Biosecurity Committee, *Improving Biosecurity: Assessment of Dual Use Research* (Amsterdam: Royal Netherlands Academy of Arts and Sciences, 2013), available at https://www.knaw.nl/en/news/publications/improving-biosecurity.

[48] National Academies of Sciences, Engineering, and Medicine, *Governance of Dual-Use Research in the Life Sciences: Advancing Global Consensus on Research Oversight* (Washington DC: National Academies Press, 2018), available at https://www.nap.edu/catalog/25154/governance-of-dual-use-research-in-the-life-sciences-advancing.

Box 6.3 International Recognition of the Need for Responsible Science Education

NRC (US), *Biotechnology Research in an Age of Terrorism,* 2004:[49]

Recommendation 1: Educating the Scientific Community

The Committee has recommended that 'national and international professional societies and related organizations and institutions create programs to educate scientists about the nature of the dual use dilemma in biotechnology and their responsibilities to mitigate its risks.'

NRC (US), *Globalisation, Biosecurity, and the Future of the Life Sciences,* 2006:[50]

Recommendation 4: The committee recommends the adoption and promotion of a common culture of awareness and a shared sense of responsibility within the global community of life scientists.

4a. 'Recognize the value of formal international treaties and conventions, including the 1972 Biological and Toxin Weapons Convention (BWC) and the 1993 Chemical Weapons Convention (CWC).
4b. Develop explicit national and international codes of ethics and conduct for life scientists.
4c. Support programs promoting beneficial uses of technology in developing countries.
4d. Establish globally distributed, decentralized, and adaptive mechanisms with the capacity for surveillance and intervention in the event of malevolent applications of tools and technologies derived from the life sciences.'

German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, 2014:[51]

Recommendation 1: Raising the level of awareness for questions of biosecurity in the scientific community

'In view of the potential for misuse of dual use research in the life sciences, there is a need to increase the degree of awareness amongst members of the

(continued)

[49] National Research Council, *Biotechnology Research in an Age of Terrorism* (Washington DC: National Academies Press, 2004), available at https://www.nap.edu/catalog/10827/biotechnology-research-in-an-age-ofterrorism.

[50] National Research Council, *Globalisation, Biosecurity, and the Future of Life Sciences* (Washington DC: National Academies Press, 2006), available at https://www.nap.edu/catalog/11567/globalization-biosecurity-andthe-future-of-the-life-sciences.

[51] German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, German Ethics Council, 2014, available at https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-biosecurity.pdf.

Box 6.3 (continued)

scientific community for these issues and to promote an underlying culture of responsibility.'

Swiss Academies of Arts and Sciences, *Misuse Potential and Biosecurity in Life Sciences Research*, 2017:[52]

'**Education** and **training** in **biosecurity** are among the most effective strategies to anticipate and prevent misuse of life science research. […] Other important measures to prevent misuse include fostering **responsible** research practices and **scientific integrity** more generally and cultivating an atmosphere of **trust** at research institutions and in research groups.'

Continued professional development training allows practising researchers to keep up to date with relevant policy and legislative developments and ensure that institutional procedures and practices are aligned with national regulations. It is important that biosafety and biosecurity issues are given equal attention during education and training and that the complementary role of biosafety and biosecurity in the governance of science and technology is elucidated. A case in point is the Professional Certification Programme of the International Federation of Biosafety Association which features Biosecurity as a technical discipline. The Biosecurity certification exam covers six topic areas:

(1) Biosecurity Conventions, Guidelines and Standards;
(2) Biosecurity Risk Assessment and Programme Management;
(3) Physical Biosecurity Measures;
(4) Pathogen Accountability;
(5) Personnel Reliability;
(6) Dual-use and Bioethics.[53]

Those willing to sit the exam need to hold a valid certification in Biorisk Management which covers basic laboratory biosafety concepts, among other things. The Biosecurity Professional Certification aims to promote biosecurity learning and competence among practising researchers, so that they can subsequently apply the acquired skills and knowledge on their workplace, for example, by helping introduce biosecurity concepts into the existing institutional oversight policies and staff development training schemes.

When implementing biosafety and biosecurity education and awareness-raising programmes, attention needs to be given both to the content and mode of its

[52] Swiss Academies of Arts and Sciences, *Misuse Potential and Biosecurity in Life Sciences Research: A Discussion Basis for Scientists on How to Address the Dual Use Dilemma of Biological Research* (Swiss Academies Report: 2017), available at https://naturalsciences.ch/organisations/geneticresearch/topics/biosecurity

[53] For information about the IFBA Professional Certification in Biosecurity, 2020, see https://internationalbiosafety.org/wp-content/uploads/2019/02/3.2-Professional-Certification-in-Biosecurity-Exam-Content-English.pdf. See also R. Moritz et al. 'Promoting Biosecurity by Professionalizing Biosecurity', *Science*, vol. 367:6480 (2020), pp. 856–858, https://science.sciencemag.org/content/367/6480/856https://science.sciencemag.org/content/367/6480/856.

delivery. Teaching and training methods need to be carefully selected, in order to maximise learning impact and facilitate the application of relevant knowledge to everyday science practice.[54] Active learning techniques such as simulations and scenario-based exercises encourage critical reflection and self-assessment, and contribute to an enhanced understanding of biosafety and biosecurity risks. This in turn enables stakeholders to be proactive in the process of risk governance and develop a sense of ownership. An in-depth shared understanding of the risks posed by advances in synthetic biology among stakeholders is essential, in order to ensure consistency and coherence across the implemented mechanisms and approaches.

Examples of initiatives that seek to promote responsible innovation in the field of synthetic biology include the Engineering Biology Research Consortium (EBRC) and the International Genetically Engineered Machine (iGEM) Competition. EBRC is a non-profit, public-private partnership dedicated to advancing engineering biology.[55] EBRC administers a programme on improving security considerations that is designed to facilitate education and dialogue on security issues among stakeholders through workshops, awareness-raising, and development of training material. Launched in 2004, the iGEM Competition is an annual event that brings together interdisciplinary teams of university and high school students, DIY biologists, and more from around the world and provides them with the opportunity to push the boundaries of synthetic biology by tackling everyday social and environmental challenges.[56] iGEM has a dedicated biosafety and biosecurity program which operates throughout the life cycle of projects – from inception to future applications – allowing risks and concerns to be identified, flagged up, and addressed in a timely manner (Box 6.4).[57] iGEM participants also have at their disposal the 'iGEMers Guide to the Future' which is an online resource designed to provide iGEM participants with a space, process, and tools for facilitating project development and responsible design and innovation.[58] The Guide has been developed as a result of a EU-funded collaborative initiative titled 'Synthetic Biology – Engaging with New and Emerging Science and Technology in Responsible Governance of the Science and Society Relationship' (SYNENERGENE), designed to establish an open dialogue among stakeholders on the potential benefits and risks of synthetic biology.[59]

[54] T. Novossiolova et al. 'Altering an Appreciative System: Lessons from Incorporating Dual-Use Concerns into the Responsible Science Education of Biotechnologists', *Futures,* vol. 108 (2019), pp. 53–60, available at https://www.sciencedirect.com/science/article/abs/pii/S001632871830466X.

[55] For information about the Engineering Biology Research Consortium, 2020, see https://ebrc.org/.

[56] For information about the International Genetically Engineered Machine Competition, 2020, see https://igem.org/Main_Page.

[57] P. Millet et al. 'Developing a Comprehensive, Adaptive, and International Biosafety and Biosecurity Program for Advanced Biotechnology: The iGEM Experience', *Applied Biosafety,* vol. 24:2 (2019), pp. 64–71, available at https://journals.sagepub.com/doi/full/10.1177/1535676019838075.

[58] The 'iGEMers Guide to the Future' is available at https://live.flatland.agency/12290417/rathenau-igem/.

[59] The SYNENERGENE project was carried out between July 2013 and June 2017 as part of the FP 7 funding scheme of the European Commission. Further information about the initiative is available at https://www.synenergene.eu/index.html.

Box 6.4 iGEM Biosafety and Biosecurity Programme[60]

iGEM's biosafety and biosecurity programme is forward-leaning, in that it addresses both traditional (pathogen-based) and emerging risks both in terms of new technologies and new risks. It is integrated into the technical work of the competition – with clearly described roles and responsibilities for all members of the community. The program makes use of both incentives (such as through a Safety and Security Award for excellence and human practices components of its medals) and penalties for noncompliance (up to and including disqualification).

As all biological lab work, even simple experiments, carries some risk, teams must follow a set of safety and security rules:

- Teams must be in full compliance with iGEM's safety and security policies.
- Teams must use the competition's forms to provide information on any risks from their project and steps taken to manage them.
- The Safety and Security Committee must have approved (a) check-in forms before a team uses parts and organisms not on the white list and (b) animal use forms before teams use vertebrates and some invertebrates.
- Instructors must sign off relevant forms.
- All deadlines for providing safety and security information must be met.
- Teams must follow all relevant international, regional, national, local, or institutional laws, rules, regulations, or policies, including national or institutional biosafety and biosecurity rules. If conducting any experiment with human subjects (including noninvasive experiments, such as surveys), teams must comply with all rules governing experiments with human subjects.
- Teams must work in the biosafety level appropriate for their project.
- Teams cannot conduct work with risk group 3 or 4 organisms, parts from a risk group 4 organism, or work in a safety level 3 or 4 laboratory.
- Teams must follow iGEM shipment requirements when submitting samples.
- Teams cannot release or deploy their project outside of the laboratory (including putting them in people) at any time during the competition or at the Giant Jamboree.

Similar to iGEM, DIY biology community labs have been recognised as potential catalysts for promoting responsible innovation.[61] 'Patient-led research' or 'citizen-driven biomedical research' is a new form of research where citizens and patients are the primary *producers* and *mobilizers* or *instigators* of knowledge

[60] This text box is based on Piers Millet et al. 'Developing a Comprehensive, Adaptive, and International Biosafety and Biosecurity Program for Advanced Biotechnology: The iGEM Experience', *Applied Biosafety,* vol. 24:2 (2019), pp. 1–8.

[61] E. Pauwels and S. Denton, *The Rise of the Bio-Citizen,* Wilson Center, January 2018, available at https://www.wilsoncenter.org/article/the-rise-the-new-bio-citizen.

pursuing a range of activities from analyses of genomic data for diagnosing rare diseases, identification of potential therapeutic drugs, organization and crowdfunding of clinical trials' cohorts, and even self-surveillance or self-experimentation.[62] Collectively the DIYbio community have adapted and adopted biosafety standards to meet their needs as well as worked with ABSA International to develop a biosafety boot-camp training program in order to promote mentorship regarding the risks and benefits of emerging technologies.[63]

6.5 Conclusion

This chapter has sought to examine the role that the synthetic biology community can play in addressing the security implications of their work and thus contribute to the efforts to ensure that the life sciences are used only for peaceful purposes. The interconnectedness of the following three points is of particular importance in this regard:

- Identifying, assessing, and mitigating biosafety and biosecurity risks related to emerging life science advances (e.g. synthetic biology) requires the active engagement of all science stakeholders, including professional and amateur science practitioners.
- There is a need for institutionalised early and recurring training in responsible conduct of research, biosafety, and biosecurity for prospective and practising scientists and engineers, in order to foster a shared understanding of the potential risks and how they can be addressed. Equally, it is important that DIY biology communities internalise the requirements for biosafety and biosecurity awareness and practices.
- Stakeholder interaction, experience sharing, and collaboration among the different professional and non-professional communities engaged in synthetic biology is vital to strengthening the concepts of stewardship, responsibility, and accountability, in order to safeguard research and innovation against accidental or deliberate misuse.

[62] E. Pauwels and S. Denton, *The Rise of the Bio-Citizen,* Wilson Center, January 2018, available at https://www.wilsoncenter.org/article/the-rise-the-new-bio-citizen.

[63] Lim, Y. B., *Checking Ourselves Before Wrecking Ourselves:Co-Evolving Innovation and Safety in the DIYBio Community*, BUGSS, September 2019, available at https://bugssonline.org/community/diybio-biosafety/. See also L. Sundaram, 'Biosafety in DIY-Bio Laboratories: From Hype to Policy', *EMBO Reports*, e52506 (2021), available at https://www.embopress.org/doi/abs/10.15252/embr.202152506

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