Creating International Governance for Synthetic Biology: Identifying the Principles and Players

By Erin Tanimura

Abstract: Synthetic biology brings significant potential to mitigate pollution, combat climate change, increase manufacturing efficiency, improve agricultural production, and provide many other societal benefits. But these benefits come with equally significant risks and uncertainties. Current international biosafety and biosecurity regimes cannot adequately regulate synthetic biology. This paper discusses the process by which international actors should create a new system of governance for synthetic biology. Five principles should govern the creation of an international system of oversight: the precautionary approach, transparency of process, flexibility and adaptability, assurances of benefits sharing, and respect for ethical concerns. Given these guiding principles, various international actors — including the synthetic biology industry, state-level governments, citizen groups, and non-governmental organizations — should participate in developing this governance scheme. Finally, the paper briefly discusses how these international actors may come together to begin creating an effective system of synthetic biology governance.

Introduction

Synthetic biology encompasses both the "design and construction of new biological parts, devices[,] and systems" and the "re-design of existing natural systems."[1] Scientists distinguish synthetic biology from other fields within the broad biology umbrella by its emphasis on engineering; practitioners in this field hope to literally build novel organisms from genetic building blocks.[2] Synthetic biology breaks down into various subfields and approaches, including: bioengineering, synthetic genomics, protocell synthetic biology, unnatural molecular biology, and *in silico* synthetic biology.[3] Each branch brings scientific advantages as well as health, safety, and security risks. Often, the exact risks are uncertain.

Synthetic biology brings technological advancements promising improvements for agriculture, pollution remediation and mitigation, fuel efficiency, and other environmental concerns.[4] "Synthetic microorganisms" may help to digest or neutralize hazardous pollutants, such as heavy metals, in the environment.[5] Engineered cells may help combat climate change through more efficient production of carbon-neutral

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[1] Joyce Tait, *Governing Synthetic Biology: Processes and Outcomes*, in SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 141, 143 (Markus Schmidt et al. eds. 2009); *see* Markus Schmidt, *Do I Understand What I Can Create?*, in SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES, *supra*, at 81, 83 (describing this as the most popular definition); *see also* Anna Deplazes, *Viewpoint: Piecing Together a Puzzle: An Exposition of Synthetic Biology*, 10 EUROPEAN MOLECULAR BIOLOGY ORG. REP. 428, 429 (2009) (stating four different but related definitions of synthetic biology).

[2] *See* Tait, *supra* note 1, at 143.

[3] Deplazes, *supra* note 1, at 428; *see also* Schmidt, *supra* note 1, at 83 (explaining that synthetic biology includes (1) engineering DNA based on biological circuits, by using biological parts: (2) finding the minimal genome; (3) constructing protocells; (4) chemical synthetic biology and creating orthogonal biological systems based on biochemistry not invented by evolution).

[4] Jennifer Kuzma & Todd Tanji, *Unpackaging Synthetic Biology: Identification of Oversight Policy Problems and Options*, 4 REG. & GOVERNANCE 92, 93 (2010).

[5] *Id.*

biofuels.[6] New and improved synthesized pesticides could improve agricultural production.[7] Synthetic biology research continuously adds to this array of environmental improvements.

But synthetic biology poses a substantial threat to the environment as well. In one report analyzing risks to traditional areas of regulatory concern, both "environmental application" and "food and agriculture production" face substantial IP, biosecurity, biosafety, and ethical concerns from almost all synthetic biology sectors.[8] Given these threats, a coalition of nongovernment public interest organizations recently called for a full "moratorium on the release and commercial use of synthetic organisms, cells, [and] genomes" for the time being.[9] A full moratorium is unlikely because of the technological advancement and the economic growth thus far.[10] However, synthetic biology's high risks and uncertainties indicate that something must be done to combat the field's potential negative consequences.

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[6] *Id.*
[7] *Id.*
[8] *Id.* at 97-98 (analyzing human health, consumer products, energy, food and agriculture production, chemical production, and environmental application).
[9] FRIENDS OF THE EARTH ET AL., THE PRINCIPLES FOR THE OVERSIGHT OF SYNTHETIC BIOLOGY (2012), *available at* http://libcloud.s3.amazonaws.com/93/ae/9/2287/1/Principles_for_the_oversight_of_synthetic_biology.pdf (listing various endorsing organizations) [hereinafter FRIENDS OF THE EARTH, PRINCIPLES FOR OVERSIGHT]; *see also* FRIENDS OF THE EARTH, SYNTHETIC BIOLOGY 101, *available at* http://libcloud.s3.amazonaws.com/93/41/1/971/Issue_brief_-_Synthetic_biology_101.pdf; FRIENDS OF THE EARTH, SYNTHETIC SOLUTIONS TO THE CLIMATE CRISIS: THE DANGERS OF SYNTHETIC BIOLOGY FOR BIOFUELS PRODUCTION, *available at* https://www.cbd.int/doc/emerging-issues/foe-synthetic-biology-for-biofuels-2011-013-en.pdf.
[10] Gary E. Marchant, *The Growing Gap Between Emerging Technologies and the Law*, *in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT 19, 19-20 (Gary E. Marchant et al. eds. 2011) ("History indicates that [banning an emerging technology] is highly unlikely, especially with technologies that have significant economic, psychological, or military value."); Gautam Mukunda et al., *What Rough Beast?*, POL. & LIFE SCI., Sept. 2009, at 2, 18 (2009) ("An outright ban in one country would accomplish little except to hamper that nation's technological development and economic growth.").

Further, synthetic biology is outpacing regulatory regimes. Within the United States, federal agencies regulate emerging technologies based on the product type and usage rather than the process by which they were created.[11] For example, the Environmental Protection Agency, Food and Drug Administration, and Department of Agriculture regulate genetically modified organisms (GMOs) under various acts relating to food, drugs, and pesticides.[12] A limited treaty regime regulates some of these GMOs on the international stage.[13] These oversight mechanisms take time to create and implement — more time than scientific progress allows. Some form of governance, oversight, or regulation is necessary to combat synthetic biology's threats and potential threats. Fast-paced scientific developments, combined with "worldwide proliferation of life science research," hinder "traditional approaches of devising formal rules and regulations."[14] Traditional governing bodies and regulatory mechanisms simply cannot keep pace with synthetic biology's scientific progress.[15] Synthetic biology may require the international community to turn away from traditional regulatory regimes to a more flexible, workable, and practical system of governance.

This paper will discuss the process by which international actors should create this system of governance. Part I will discuss the characteristics of synthetic biology that make the field and its products both unique and exceptionally risky. These risks

[11] Kuzma & Tanji, *supra* note 4, at 96.
[12] *Id.*
[13] Convention on Biological Diversity of the United Nations Conference on Environment and Development, *opened for signature* June 5, 1992, 31 I.L.M. 818 (entered into force Dec. 29, 1993) [hereinafter Convention on Biological Diversity].
[14] Brian Rappert, *Pacing Science and Technology with Codes of Conduct: Rethinking What Works*, *in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT, *supra* note 10, at 109, 110.
[15] Marchant, *supra* note 10, at 25; Tait, *supra* note 1, at 148.

exacerbate traditional biosafety, biosecurity, intellectual property, and ethical concerns. Part II will explain why current international biosafety and biosecurity regimes cannot adequately regulate synthetic biology. Part III will offer guiding principles to govern the creation of an international system for synthetic biology oversight. Part IV will discuss which international actors should participate in creating an international system of governance. Given the guiding principles, the oversight development process should include the synthetic biology industry, international governments, nongovernment organizations, and citizen groups. Part V will briefly discuss how these international actors may come together to begin creating a synthetic biology governance scheme.

I. Risks of Synthetic Biology

A. Characteristics of Synthetic Biology

Synthetic biology comes with unique characteristics that ultimately exacerbate concerns common to emerging technologies. First, synthetic biology presents a dual-use dilemma, as products may be used for beneficial or harmful purposes. Second, newly synthesized organisms are entirely novel and able to self-replicate, exacerbating concerns of potential release into the environment. Finally, synthetic biology's modular nature and standardized processes make synthetic biology available to amateurs.

1. Dual Use

Synthetic biology faces a dual-use dilemma: legitimate and beneficial synthetic biology research may be "misapplied for malicious purposes."[16] "[N]efarious actors" may use synthetic biology research and products to create dangerous pathogens or bioweapons

[16] Kavita Marfatia Berger, PhD, *The Role of Science in Preparedness and Response*, 6 U. ST. THOMAS L.J. 622, 633 (2009).

of mass destruction.[17] Synthetic biology's dual-use potential creates significant biosafety concerns and exacerbates potential threats arising from "open source" databases.

The National Science Advisory Board for Biosecurity advises the scientific community to address the dual use concern by "rais[ing] awareness of the issue and strengthen[ing] the culture of understanding within the scientific community and public."[18] Further, a recent report sponsored by the Synthetic Biology Engineering Research Center notes that some of synthetic biology's positive uses can "directly counteract potential abuses."[19] For example, accelerated vaccine production and the development and production of new antibodies can quickly counteract new and harmful pathogens and diseases.[20] Despite these reassurances, synthetic biology's dual-use potential substantially impacts risk assessment and aggravates safety and security concerns.

2. Risk Associated with Synthetic Biology Products

Scientists do not know how synthetic biology products will behave and interact with non-laboratory environments. Synthetically engineered microorganisms are "radically different" from GMOs and other biological predecessors.[21] Synthetic biology boasts a greater degree of genetic transfer than conventional genetic engineering.[22] Thus, new synthetic creations may show "unpredictable and emergent properties" that make

[17] *Id.*
[18] Kuzma & Tanji, *supra* note 4, at 100-01.
[19] Mukunda et al., *supra* note 10, at 11-12.
[20] *Id.*
[21] Tait, *supra* note 1, at 145.
[22] Kuzma & Tanji, *supra* note 4, at 95.

risk assessment difficult.[23] These differences limit the applicability of current GMO oversight mechanisms to synthetic biology.[24]

Further, synthetically produced organisms differ from other emerging technologies, such as new chemical technologies, because synthetic biology products are "alive" and thus capable of self-replication.[25] The ability to multiply, combined with unpredictable characteristics associated with the high level of genetic transfer, make an intentional or accidental release of synthetic biology products especially risky and potentially uncontrollable.

3. Modular Nature and Standardized Processes Make Synthetic Biology Available to Amateurs

Increased modularity and streamlined synthetic biology procedures allow unskilled and amateur biologists to participate in synthetic biology. Conventional genetic engineering inserts new genetic material into an existing genome; the resulting gene interactions may cause unanticipated effects or functions.[26] To combat these unexpected effects, synthetic biologists create "standardized modular biological parts" that can be pieced together to create novel organisms.[27] With fewer or no unexpected gene interactions, it is hoped that new synthetic biology creations will have minimal unexpected effects. Along with increased modularity, synthetic biologists replace "*ad hoc* experimental design" with increasingly routine, standardized, and reliable synthetic

[23] Tait, *supra* note 1, at 145.
[24] *See* discussion *infra* Part II.A.
[25] Schmidt, *supra* note 1, at 92; Deplazes, *supra* note 1, at 432. This general observation has limitations, however, as software and computer viruses may be technically capable of self-replication. Schmidt, *supra* note 1, at 92.
[26] Mukunda et al., *supra* note 10, at 14.
[27] *Id.*

biology procedures.[28] Modularity and streamlined procedures decrease the "tacit knowledge" needed participate in synthetic biology and allow amateurs heightened access to experimentation.[29]

Academic institutions and the synthetic biology industry encourage this "deskilling" and expanded access to synthetic biology experimentation. Researchers advocating open access to synthetic biology parts created "BioBricks" — functional, interchangeable DNA segments designed to easily assemble into a larger structure.[30] MIT's Registry of Standard Biological Parts provides public access to BioBricks and design methodologies, making experimentation widely available to unskilled biologists.[31] This and other databases provide "a toolbox to design biological systems" without the hassle of extensive research.[32] Academic institutions further encourage aspiring bioengineers with competitions such as the annual iGEM (International Genetically Engineered Machines) competition.[33] The iGEM competition helps students develop basic synthetic biology skills while "acquiring self-confidence and enthusiasm about their ability to engineer organisms."[34]

These features making synthetic biology simple, inexpensive, and widely accessible also create a community of amateur "do-it-yourself" (DIY) biologists and

[28] *Id.* at 7; *see* Tait, *supra* note 1, at 145.
[29] Mukunda et al., *supra* note 10, at 14 ("Synthetic biology is unique, however, in the extent to which it is explicitly devoted to the minimization of the importance of tacit knowledge.").
[30] *Id.* at 7 (analogizing BioBricks to interchangeable parts that served as a "a cornerstone of the industrial revolution").
[31] Kuzma & Tanji, *supra* note 4, at 96; Mukunda et al., *supra* note 10, at 7.
[32] Schmidt, *supra* note 1, at 95.
[33] Mukunda et al., *supra* note 10, at 15.
[34] *Id.*

"biohackers."[35] DIY biologist — unskilled amateurs — may soon create novel biological systems in the comforts of their own homes.[36] The benefits and risks of a garage biotechnology industry exacerbate synthetic biology's dual-use dilemma.[37] While some scientists are excited for a DIY community,[38] all acknowledge that DIY projects may put amateurs, their communities, and the local environment at "unprecedented risk."[39] Scientists and policymakers further fear "garage biohackers" may one day pose a threat similar to that of computer hackers who steal information from closed sources for malicious purposes.[40] Thus, while synthetic biology's unique characteristics have benefits, they also create extensive concerns that policymakers must address while creating a synthetic biology governance scheme.

B. Synthetic Biology Characteristics Create Biosafety, Biosecurity, Intellectual Property, and Ethical Concerns

Synthetic biology's unique characteristics exacerbate traditional biosafety, biosecurity, intellectual property, and ethical concerns.

1. Biosafety

Synthetic biology exacerbates biosafety concerns. Also known as "bioerror,"[41] biosafety concerns include laboratory accidents and the unintentional exposure to — and release of — pathogens and toxins.[42] Scientists must additionally account for biosafety

[35] Schmidt, *supra* note 1, at 95.
[36] *See id.*; Mukunda et al., *supra* note 10, at 15.
[37] *See* Mukunda et al., *supra* note 10, at 15.
[38] *Id.*
[39] Schmidt, *supra* note 1, at 95.
[40] Mukunda et al., *supra* note 10, at 15.
[41] Thomas H. Murray, Ph.D., *What Synthetic Genomes Mean for Our Future: Technology, Ethics, and Law, Interests and Identities*, 45 VAL. U. L. REV. 1315, 1324 (2011).
[42] *See* Schmidt, *supra* note 1, at 82.

concerns arising from synthetic biology's unique characteristics: potential horizontal gene transfer between synthesized and organic organisms, and the ability of synthesized organisms to self-replicate, evolve, and adapt in new environments.[43]

Generally, biosafety measures are forward-looking, created to prevent unintentional contact between humans and the environment.[44] Synthetic biology calls for carefully crafted biosafety measures designed to combat concerns arising from synthesized organisms' unique characteristics. For example, some scientists advocate using "terminator" or "suicide genes" programmed to force a synthesized organisms to self-destruct if unintentionally released into the wild.[45] While careful genetic programming will alleviate some biosafety concerns regarding organisms' ability to self-replicate, it is insufficient to fully address all biosafety concerns.

2. Biosecurity

Synthetic biology's unique characteristics create biosecurity concerns. Synthetic biology's increased modularity and the corresponding rise of DIY biologists present one strain of biosecurity concerns. Further, synthetic biology often implicates national and international security concerns arising from the potential to construct bioweapons.[46] Generally, biosecurity measures aim to prevent "loss, theft, misuse, diversion, [and]

[43] *Cf.* Murray, *supra* note 41, at 1324 (discussing biosafety concerns of genetically modified organisms).
[44] *See* Schmidt, *supra* note 1, at 82.
[45] PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGY 63 (2010), *available at* http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf.
[46] *See generally* Katia Moskvitch, *UN: 'More Should be done' to prevent bio-terrorism*, BBC NEWS (Sept. 27, 2012), http://www.bbc.co.uk/news/technology-19745045; Rachel Oswald, *Synthetic Biology Industry Poses Security Challenges, Experts Say*, NUCLEAR THREAT INITIATIVE (Feb. 11, 2011), http://www.nti.org/gsn/article/synthetic-biology-industry-poses-security-challenges-experts-say/; *U.N. Official Calls For Stronger International Monitoring of Synthetic Biology*, NUCLEAR THREAT INITIATIVE (Sept. 28, 2012), http://www.nti.org/gsn/article/un-official-calls-stronger-intl-monitoring-synthetic-biology/.

intentional release pathogens and toxins."[47] But synthetic biology's heightened biosecurity concerns indicate that policymakers will face difficulties constructing and implementing workable biosecurity measures.

Increased modularity and the corresponding rise of DIY biologists combine with expanded scientific knowledge and openness to create significant biosecurity risks. Synthetic biology's heightened modularity, leading to the advent of inexpensive and widely available BioBricks, increase access to the building blocks of potentially dangerous bioweapons.[48] Using these genetic parts, amateur biologists broaden the pool of individuals with the ability "to alter agents in ways useful to potential attackers."[49] Further, many scientists and academics advocate for the open sharing of biological information — including pathogen genomics. Open knowledge could potentially give DIY biologists easy access to the blueprints for lethal pandemics or plagues.[50] For example, scientists recently released the genome for the 1918 influenza virus. A New York Times opinion piece describes this move as "extremely foolish," essentially publishing "the design of a weapon of mass destruction."[51]

Amateur biologists present biosafety concerns arising from increased access to genetic material and information. While these "garage biohackers" and DIY biologists

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[47] Schmidt, *supra* note 1, at 82.
[48] *See generally* Mukunda et al., *supra* note 10, at 3 ("Yet even at this relatively early stage of development, concerns over the security implications of DNA synthesis and synthetic biology are driven by a belief that their continued advance will improve the effectiveness of biological weapons while reducing impediments to their acquisition and utilization by state and non-state actors alike.").
[49] *Id.* at 16.
[50] Kuzma & Tanji, *supra* note 4, at 100; *see* JEZ LITTLEWOOD, MANAGING THE BIOLOGICAL WEAPONS PROBLEM: FROM THE INDIVIDUAL TO THE INTERNATIONAL 4 (2006) (arguing that "knowledge which has both legitimate peaceful and (illegitimate) hostile applications" may affect biological weapons production), *available at* www.un.org/disarmament/education/wmdcommission/files/no14.pdf.
[51] Ray Kurzweil & Bill Joy, Op-Ed., *Recipe for Destruction*, N.Y. TIMES (Oct. 17 2005) http://www.nytimes.com/2005/10/17/opinion/17kurzweiljoy.html?_r=1&.

may not immediately conjure images of bioterrorist organizations, perhaps they should. On a larger scale, the biosecurity concerns discussed above easily amount to national and international security threats from bioterrorism.[52]

At the extreme, synthetic biology's potential to create bioweapons may suggest state-sponsored biowarfare or a bioweapons arms race. One report argues that serious biosecurity risks are unlikely in the near future.[53] But it concedes that customized biological weapons are likely a threat in the long term that will prompt state action.[54] An increased bioweapon threat would likely incentivize states to research "offensive biological weapons" on the grounds that the research is "purely defensive."[55] This "research" may lead to an arms race among technologically advanced states.[56] Though far off, these projections illustrate synthetic biology's potential for harm.

Planning and implementing a sufficient biosecurity regime will be difficult, especially since synthetic biology poses dual use concerns. Policymakers attempting to alleviate synthetic biology's biosecurity concerns must understand the complex problems posed by the new technology.[57] They must be willing to "go well beyond the traditional arms control/disarmament paradigm" and commit to on-going and permanent management.[58] On the international stage, such planning and implementation may require collaboration with other nations to integrate new biosecurity strategies into international

[52] Murray, *supra* note 41, at 1324.
[53] Mukunda et al., *supra* note 10, at 10.
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *See* LITTLEWOOD, *supra* note 50, at 4.
[58] *Id.*

agreements, such as the 1972 Biological Weapons Convention.[59] New domestic and international infrastructure will be difficult to implement, but necessary to combat synthetic biology's biosecurity threats.[60]

3. Intellectual Property

Synthetic biology raises intellectual property concerns: intellectual property attorneys struggle to extend existing technology protections to synthetic biology. Synthetic biology operates "at the intersection of biotechnology, software[,] and electronics."[61] Because it utilizes advances from these various fields, patent and copyright issues in each sector further complicate synthetic biology's intellectual property issues.[62] Synthetic biology's emphasis on modularity exacerbates this confusion. The "parts agenda" suggests that intellectual property rights will be difficult to identify, as they are "fragmented across many owners and sometimes overly broad."[63] Because of this confusion, intellectually property laws surrounding synthetic biology are still in flux.[64]

But arguably synthetic biology's "open source" approach presents the field's largest intellectual property concern. Many of the field's early proponents argued for "open source" databases to house "portfolios of technological building blocks" — such as

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[59] *See id.*
[60] *See generally* ANDREAS PERSBO & ANGELA WOODWARD, NATIONAL MEASURES TO IMPLEMENT WMD TREATIES AND NORMS: THE NEED FOR INTERNATIONAL STANDARDS AND TECHNICAL ASSISTANCE (2005), *available at* www.un.org/disarmament/education/wmdcommission/files/No32.pdf.
[61] Tait, *supra* note 1, at 146.
[62] *See* Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting A Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 112-13 (2007); *see also* Mike May, *Engineering a New Business*, 27 NATURE BIOTECHNOLOGY 1102, 1120 (2009) (discussing synthetic biology's legal and regulatory challenges involving patents).
[63] Joachim Henkel & Stephen M. Maurer, *Parts, Property & Sharing*, 27 NATURE BIOTECHNOLOGY 1095, 1095 (2009).
[64] Tait, *supra* note 1, at 146.

BioBricks — and the corresponding blueprints to create organisms.[65] Theoretically, this would create a "commons" of genetic knowledge.[66] Open source advocates argue that data sharing is essential to grow the synthetic biology community.[67] But others suggest that synthetic biology advancements require stringent intellectual property protection to incentivize scientists and industry to continue researching and creating.[68] Ultimately, the intellectual property regime chosen for synthetic biology will affect information sharing, the distribution of wealth, and other equity issues. These concerns indicate that — in addition to biosafety and biosecurity concerns — policymakers must be sensitive to the intellectual property ramifications of an international synthetic biology governance scheme.

4. Ethics

Synthetic biology raises bioethical concerns. Scientists may use synthetic biology to re-engineer existing organisms and, ultimately, create novel life forms. The field's critics argue that this is not morally responsible.[69] Critics and supporters alike urge policymakers to look into the "implications of these new manipulative possibilities for the human future[.]"[70] National and international policymakers must examine how synthetic biology's advances will affect the nature and scope of the "human experience

[65] Katherine J. Strandburg, *Evolving Innovation Paradigms and the Global Intellectual Property Regime*, 41 CONN. L. REV. 861, 879 (2009).
[66] *Id.*
[67] Kuzma & Tanji, *supra* note 4, at 99-100.
[68] *Id.*; Tait, *supra* note 1, at 147.
[69] Tait, *supra* note 1, at 145.
[70] Nigel M. de S. Cameron & Arthur Caplan, *Our Synthetic Future*, 27 NATURE BIOTECHNOLOGY 1103, 1104 (2009).

and lifespan."[71] While synthetic biology raises significant ethical concerns, the extent to which these concerns should inform policy decisions is unclear.

II. Legal Background: Current International Biosafety and Biosecurity Regimes Cannot Adequately Regulate Synthetic Biology

Current international biosafety and biosecurity regimes cannot sufficiently govern synthetic biology. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity addresses some biosafety concerns posed by "living modified organisms" when moved across borders.[72] The Biological Weapons Convention provides a framework to address international biosecurity threats.[73] But many synthetic biology threats fall outside the scope of these regimes.

A. Biosafety: The 1992 Convention on Biological Diversity and the Cartagena Protocol

Current biosafety regimes cannot comprehensively address synthetic biology's unique biosafety risks and leave substantial regulatory gaps. The Convention on Biological Diversity (CBD) opened for signature in 1992 and entered into force in 1993.[74] The CBD encourages the conservation of biodiversity and includes provisions on benefits sharing and intellectual property.[75] The CBD's three main goals are to promote the conservation of biodiversity, the sustainable use of its components, and the fair and

[71] *Id.* MIT's Registry of Standard Biological Parts registers BioBricks and illustrates this concept. Mukunda et al., *supra* note 10, at 7; Tait, *supra* note 1, at 147.
[72] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *opened for signature* Jan. 29, 2000, 39 I.L.M. 1027, 1027 (entered into force Sept. 11, 2003) [hereinafter Cartagena Protocol].
[73] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *opened for signature* April 10, 1972, 26 U.S.T. 583, T.I.A.S. No. 8062, 1015 U.N.T.S. 163 (entered into force Mar. 26, 1975) [hereinafter Biological Weapons Convention].
[74] *History of the Convention*, CONVENTION ON BIOLOGICAL DIVERSITY, http://www.cbd.int/history/ (last visited Mar. 4, 3013).
[75] *See generally* Convention on Biological Diversity, *supra* note 13.

equitable sharing of benefits arising out of the use of genetic resources.[76] The CBD's drafters likely did not contemplate synthetically engineered microorganisms when crafting the CBD. This emergent technology brings new biodiversity threats and equity concerns and thus complicate the CBD's three main goals.

In 2000, the international community adopted the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol) as a supplement to the CBD.[77] The Cartagena Protocol governs the safe transfer, handling, and use of "living modified organisms" (LMOs).[78] LMOs include "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[79] The Cartagena Protocol only applies to the "transboundary movement, transit, handling[,] and use" of living modified organisms;[80] it does not directly regulate their research or production within countries.

Whether synthetic biology parts and products generally fall within the definition of LMOs is debatable. The International Civil Society Working Group on Synthetic Biology (ICSWG) assumes that the Cartagena definition of "LMO" includes synthesized

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[76] *See* Convention on Biological Diversity art. 1, *supra* note 13, at 823 (discussing objectives); *A Brief Introduction to the Convention on Biological Diversity*, IISD LINKAGES, http://www.iisd.ca/biodiv/cbdintro.html (last updated Feb. 18, 2000).

[77] *About the Protocol*, BIOSAFETY CLEARING-HOUSE, http://bch.cbd.int/protocol/background/ (last visited Feb. 25, 2013); *see also* Ruth Makenzie et al., *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN ENVIRONMENTAL POLICY LAW PAPER NO. 46 (2003); *Frequently Asked Questions about the Cartagena Protocol on Biosafety*, COMISIÓN NACIONAL DE RECURSOS FITOGENÉTICOS, http://www.conarefi.ucr.ac.cr/Bioseguridad1.htm (last visited Mar. 1, 2013). The Cartagena Protocol entered into force in 2003. *About the Protocol*, *supra*.

[78] Cartagena Protocol art. 2, *supra* note 72, at 1028 (discussing general provisions).

[79] Cartagena Protocol art. 3, *supra* note 72, at 1028. The Cartagena Protocol further defines "living organism" as "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids." *Id.*

[80] Cartagena Protocol art. 4, *supra* note 72, at 1029.

microorganisms.[81] But even if we accept that the Cartagena Protocol governs the transboundary movement of synthetically engineered organisms, the protocol cannot adequately regulate synthetic biology.

Many synthetic biology processes and transactions fall outside the scope of the Cartagena Protocol. First, the Cartagena Protocol only applies to physical transfer; it does not apply to the virtual (digital) transfer of LMO genetic material.[82] Second, the protocol covers whole living organisms and cannot regulate ready-to-assemble constituent genetic parts.[83] Finally, the Cartagena Protocol has a limited scope and cannot apply to research, creation and synthesis of biological parts, or the end use of the products.

But even if the Cartagena Protocol could apply to most synthetic biology parts and transactions, should it? Conventional genetic engineering and synthetic biology differ substantially in processes and products. Synthetic biology allows the transfer of whole systems, potentially including "hundreds or thousands of traits (genes/parts) from different donor organisms."[84] While GMOs are not without risks, the extent of genetic transfer is much more limited in conventional genetic engineering.[85] Given these differences, it may be unwise to extend the Cartagena Protocol to synthetically produced organisms. Synthetic biology's high engineering complexity, systems scope, and novel life forms suggest that a novel governance regime is necessary.

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[81] INTERNATIONAL CIVIL SOCIETY WORKING GROUP ON SYNTHETIC BIOLOGY, A SUBMISSION TO THE CONVENTION ON BIOLOGICAL DIVERSITY'S SUBSIDIARY BODY ON SCIENTIFIC, TECHNICAL AND TECHNOLOGICAL ADVICE (SBSTTA) ON THE POTENTIAL IMPACTS OF SYNTHETIC BIOLOGY ON THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY 24 (2011) [hereinafter ICSWG].
[82] *Id.* at 24-25.
[83] *Id.* at 25; *see also* discussion *supra* Part I.A.3 (discussing the high degree of modularity).
[84] Schmidt, *supra* note 1, at 87.
[85] *Id.*

B. Biosecurity: The 1972 Biological Weapons Convention

Current biosecurity measures also cannot fully address synthetic biology's risks and characteristics. In 1972, the international community confronted growing bioweapon concerns with the Biological Weapons Convention (BWC).[86] The multinational disarmament treaty builds on the Geneva Protocol of 1925, which prohibited the use but not production of biological and chemical weapons.[87] The BWC bans development, production, stockpiling, acquisition, and retention of toxins and biological agents "of types and in quantities" that lack "protective or other peaceful purposes."[88] Parties to the convention may not assist in producing, "directly or indirectly" transfer, or otherwise acquire bioweapons.[89] Further, parties must take necessary measures to implement the BWC provisions domestically.[90] The BWC broadly applies to bioweapons and thus theoretically governs synthetic biology products used for nefarious purposes.

The BWC addresses general biosecurity concerns, but the broad framework does not address problems specific to synthetic biology. First, the BWC — and perhaps any treaty designed solely to lessen biosecurity concerns — cannot account for synthetic biology's dual-use dilemma. The heart of synthetic biology is legitimate research used to bring positive societal advancements, but ill-willed actors may use its achievements for

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[86] *Disarmament: Disarmament in Geneva*, UNITED NATIONS OFFICE AT GENEVA, http://www.unog.ch/80256EE600585943/%28httpHomepages%29/$first?OpenDocument (last visited Aug. 18, 2013). The convention's full title is: Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction.

[87] *See* Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571, 94 L.N.T.S. 65. The agreement is commonly called the "Geneva Protocol."

[88] Biological Weapons Convention arts. I, IV, *supra* note 73.

[89] *Id.* art. III.

[90] *Id.* art. IV.

malicious purposes.[91] The international community could list and ban the most dangerous synthetic biology products (i.e., the most likely to be used as bioweapons), but this would not be an easy task. While synthetic biology parts and processes may become weaponized in the wrong hands, they are not inherently "weapons" and would be difficult to classify. Further, Article IV directs parties to implement the BWC's objectives domestically. There is no international consensus to guide parties in creating domestic regulations. A new international governance scheme for synthetic biology must address the shortcomings of both the BWC and the CBD, discussed above.

III. Guiding Principles

Nations share the high risks of synthetic biology across borders. A governance system should similarly cross borders and provide an international solution. To better bring about this system, this section urges policymakers to take a precautionary approach, ensure transparency of process, create a regime that can adapt to changing technology, address benefits sharing and other equity concerns, and respect ethical concerns.

A. Precautionary Approach

An international governance regime should employ the "precautionary approach" or "precautionary principle" to account for synthetic biology's substantial risks and uncertainties. Emerging technology oversight may be promotional, permissive, precautionary, or preventative in approach.[92] Promotional policies hasten the development and spread of technology, while preventative policies do the opposite and

[91] *See* discussion *supra* Part I.A.1.
[92] Kuzma & Tanji, *supra* note 4, at 106.

block or ban new technology.[93] Permissive oversight does not aim to promote or prohibit but is instead neutral toward emergent technology.[94] The precautionary approach falls between permissive and full preventative oversight, effectively slowing the dispersal of emergent technology.[95]

Under the precautionary principle, policymakers may not avoid or postpone "cost-effective" environmental protection measures for "lack of scientific certainty."[96] Rather, the principle encourages policymakers to anticipate and act against "threats of serious or irreversible damage,"[97] especially when faced with high risks and uncertainties.[98] On the international stage, States apply the precautionary approach "according to their capabilities."[99] The precautionary principle's application and scope are debatable. Critics of the principle's modern application contend that policymakers take "precaution" to the extreme, stifling trade and scientific and economic development.[100] For example, one biotech crop advocate argues that the European Union's "erroneous adoption" of the principle "ignores the benefits of biotech crops in favor of testing commodity imports for every possible trace of an unapproved variety."[101]

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[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] United Nations Conference on Environment and Development, Rio de Janiero, Braz., June 3-14, 1992, *Rio Declaration on Environment and Development*, princ. 15, U.N. Doc. A/CONF.151/26 (Vol.1), Annex I (Aug. 12, 1992) [hereinafter Rio Declaration], *available at* http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm. This definition is the most widely accepted articulation of the precautionary approach. DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 478 (4th ed. 2011).
[97] Rio Declaration, *supra* note 96, at princ. 15.
[98] DANIEL BODANSKY, THE ART AND CRAFT OF INTERNATIONAL ENVIRONMENTAL LAW 32 (2010).
[99] Rio Declaration, *supra* note 96, princ. 15.
[100] Kimball Nill et al., *The "Low Level" or "Adventitious" Presence of Biotech Crops-Potential Adverse Impacts on U.S. Grain Exports*, ABA AGRIC. MGMT. COMMITTEE NEWSL., April 2012, at 12.
[101] *Id.*

The precautionary principle is a widely accepted principle of international law.[102] The 1992 Rio Declaration on Environment and Development advocates for the international community to employ the precautionary approach to prevent environmental degradation.[103] Produced at the United Nations' "Earth Summit," the Rio Declaration early established that the international community should take anticipatory action to combat environmental threats.[104] Further, the Cartagena Protocol explicitly advocates for a precautionary approach to regulate LMOs.[105] International policymakers should similarly apply the precautionary principle when creating an international governance scheme for synthetic biology and other emergent technologies.

Life science research and high-risk emerging technologies call for a greater degree of precaution, so governing bodies should employ substantial precaution in synthetic biology oversight. Life science research comes with a "presumption of regulation . . . on a precautionary basis and at very early stages in research and innovation[.]"[106] Synthetic biology's ability to create and manipulate novel biological systems suggests that policymakers apply this presumption of precautionary regulation.[107]

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[102] In the international arena, "hard law" includes treaties, customs, and general principles. *See generally* BODANSKY, *supra* note 98, at 98 (citing Article 38 of the Statute of the International Court of Justice). Though accepted by many academics, the precautionary principle is perhaps not a principle that rises to the authority level of "general principles" or customary law. *See generally id.* at 199-203 (discussing the duty to prevent transboundary pollution and the precautionary principle).
[103] Rio Declaration, *supra* note 96, princ.15. One should note that the Rio Declaration, while an international document, is a declaration and thus a form of "soft law."
[104] *See generally* DAVID HUNTER ET AL., *supra* note 96.
[105] Cartagena Protocol, *supra* note 72, at 1028 (art. 1).
[106] Tait, *supra* note 1, at 148.
[107] Kuzma & Tanji, *supra* note 4, at 96.

Further, both living and nonliving emerging technologies with higher risks call for a greater degree of precaution.[108] This correlation relates to the uncertainty of emerging technology. An approach based entirely on risk assessment may be inadequate because knowledge of the risks is incomplete. A risk assessment approach could under-project risk or misinterpret risk calculations, ultimately causing harm. Nano-biotechnology illustrates this; the field has greater perceived risks, even by admission of its own scientists, than other areas of nanotechnology development.[109] Nano-biotechnology research correlates with a greater need for "earlier-stage, more precautionary approaches to regulation."[110] Likewise, synthetic biology brings substantial risks and uncertainties — environmental, social, and others[111] — that mandate a precautionary approach.

B. Transparency of Process

International actors should be transparent in their efforts, motives, and goals while creating a synthetic biology regulatory regime. As will be discussed later, synthetic biology includes a wide array of stakeholders. Scientists, companies producing standardized parts, state governments, community groups, and indigenous peoples have various interests in how synthetic biology will be regulated.[112] Synthetic biology's

[108] Tait, *supra* note 1, at 149 (discussing nanotechnology).
[109] *Id.*
[110] *Id.* at 148 (conceding that this claimed need may not be justified in this area, as much biotechnology falls within general nanotechnology governance).
[111] *See* discussion *supra* Part I (discussing synthetic biology's risks); *see also* Kenneth W. Abbott, *An International Framework Agreement on Scientific and Technological Innovation*, *in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT, *supra* note 10, at 127, 133-34 (discussing technical, normative, and political uncertainties).
[112] *See* discussion *infra* Part IV.

oversight development process requires transparency for these diverse groups to trust and "buy into" the international system of governance.[113]

Private industry codes of conduct for synthetic biology screening procedures provide examples of transparent and nontransparent processes. The private synthetic biology industry produced two codes, one by the International Association of Synthetic Biology (IASB) and the other by the International Gene Synthesis Consortium (IGSC).[114] Similar in substance, both codes require human experts to investigate customer orders resembling pathogen or toxin gene sequences.[115] But the synthetic biology codes differ in "openness."[116] While the IASB wrote its code with a great deal of transparency, the more exclusive IGSC completed its protocol behind closed doors.[117] Scholarship advocates wider adoption of the IASB code because its creation was more transparent and, relatedly, more trusted by industry and inclusive of stakeholders.[118] These two industry codes and the academic response to each illustrate the need for transparency — albeit in larger scale oversight than simply screening procedures.

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[113] Kuzma & Tanji, *supra* note 4, at 94.
[114] Markus Fischer & Stephen M. Maurer, *Harmonizing Biosecurity Oversight for Gene Synthesis*, 28 NATURE BIOTECHNOLOGY 20, 20 (2010) [hereinafter Fischer & Maurer, *Harmonizing Biosecurity Oversight*]. For the IASB code, see INTERNATIONAL ASSOCIATION SYNTHETIC BIOLOGY, IASB CODE OF CONDUCT FOR BEST PRACTICES IN SYNTHETIC BIOLOGY (2009), *available at* http://www.ia-sb.eu/tasks/sites/synthetic-biology/assets/File/pdf/iasb_code_of_conduct_final.pdf; and see also *Code of Conduct for Best Practices in Gene Synthesis*, International Association Synthetic Biology, http://www.ia-sb.eu/go/synthetic-biology/synthetic-biology/code-of-conduct-for-best-practices-in-gene-synthesis/ (last visited Mar. 4, 2013). For the IGSC code, see INTERNATIONAL GENE SYNTHESIS CONSORTIUM, HARMONIZED SCREENING PROTOCOL (2009), *available at* http://www.genesynthesisconsortium.org/wp-content/uploads/2012/02/IGSC-Harmonized-Screening-Protocol1.pdf.
[115] Fischer & Maurer, *Harmonizing Biosecurity Oversight*, *supra* note 114, at 21.
[116] *Id.*; *see* Stephen M. Maurer, *Beyond Treaties and Regulation: Using Market Forces to Control Dual Use Technologies* 3 (Goldman Sch. of Pub. Policy, Working Paper No. GSPP10-010, 2010) [hereinafter Maurer, *Beyond Treaties*], *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1705630.
[117] Fischer & Maurer, *Harmonizing Biosecurity Oversight*, *supra* note 114, at 20; *see also* Maurer, *Beyond Treaties*, *supra* note 116, at 3-5.
[118] *See* Fischer & Maurer, *Harmonizing Biosecurity Oversight*, *supra* note 114, at 21-22.

C. Flexibility and Adaptability

Synthetic biology governance must be flexible and able to adapt to the field's continuous advancements. Like many emerging technologies, synthetic biology faces a pacing problem: scientific advancement outpaces regulatory regimes.[119] This pacing problem has multiple dimensions.[120] First, existing legal frameworks often lack workable flexibility mechanisms, ignoring the "dynamic view of society and technology."[121] For example, the United States Clean Air Act tied air pollution requirements to the existing ozone standard with "no flexibility or anticipation that the [Environmental Protection Agency] ozone standard may change."[122] Second, courts, legislatures, and administrative agencies do not have the capacity to keep up with changing technologies.[123] Legal institutions and existing legal frameworks simply cannot adapt to synthetic biology's research and development advances, especially at the international level. Thus, any future system of governance must consider the drawbacks of traditional frameworks and institutions.

The same risks and uncertainties that make synthetic biology oversight necessary also mandate that any successful oversight scheme contain flexibility mechanisms. Extensive unknown risks suggest that policymakers cannot know with certainty "what would constitute an optimum regulatory system."[124] Further, inflexible regulation risks "long term rigidity of innovation systems" and would likely hinder future synthetic

[119] *See* Marchant, *supra* note 10, at 19.
[120] *Id.* at 23.
[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] Tait, *supra* note 1, at 144.

biology research and development.[125] Some scientists argue that regulation for developing technology, such as nanotechnology, is thus premature.[126] But these uncertainties more likely indicate that policymakers should avoid rigid, inflexible systems. Flexible systems can safely allow technological advancement and avoid regulations that "inappropriately 'lock in' inferior technology choices."[127]

Emerging technology oversight proposals highlight the need for flexibility. Kenneth Abbott advocates an international framework convention for emerging technologies, emphasizing its "particularly flexible" nature.[128] The proposed convention would not include strict substantive requirements.[129] Rather, it would promote "*objectives*, *principles*[,] and *general commitments* to guide national and collective action."[130] Gary Marchant suggests oversight by independent international institutions.[131] These institutions' expertise and independent status would allow quick, effective policy adjustments in response to technological developments.[132] Bioethics leader Thomas Murray comments on various recommendations' abilities to address risk assessment and cost-benefit concerns.[133] He advises that any oversight approach — whether self-governance or top-down control mechanisms — should extend to the private sector and be "flexible enough to deal with an evolving technology."[134] These proposals and

[125] *Id.*
[126] Marchant, *supra* note 10, at 27.
[127] *Id.*
[128] Abbott, *supra* note 111, at 129.
[129] *Id.* at 136.
[130] *Id.*
[131] Marchant, *supra* note 10, at 29-30 (citing the Internet Corporation for Assigned Names and Numbers (ICANN) as a successful example).
[132] *Id.*
[133] Murray, *supra* note 41, at 1328.
[134] *Id.*

commentaries highlight the need for an adaptable and flexible governance scheme able to keep pace with synthetic biology developments.

D. Assurances of Benefits Sharing and Other Equity Concerns

A synthetic biology governance regime should address benefits sharing and other equity concerns. The International Civil Society Working Group on Synthetic Biology (ICSWG) identified various social and equity concerns in its 2011 report to the CBD Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA).[135] Synthetic biology will have wide-ranging social impacts, especially in the developing world. Synthesized products and the growing "bioeconomy" may help developing economies to access and implement environmental sustainability practices.[136] These new developments may also help agricultural and industrial productivity.[137] A synthetic biology governance regime should help developing economies to have safe access to these benefits.

But these advancements come at a price. First, new synthesized organisms pose a substantial risk to existing ecosystems. Scientists do not know how the novel genomes will interact with existing organisms and systems. Second, synthetic biology developments may negatively impact food and livelihood security as synthetic substitutes replace natural products, adversely impacting traditional commodity markets.[138] Many natural compounds of economic importance, such as natural oils and aroma chemicals,

[135] ICSWG, *supra* note 81, at 28-32. The SBSTTA listened to these concerns and discussed them in SBSTTA 16, Recommendation XVI/12, *available at* http://www.cbd.int/recommendation/sbstta/default.shtml?id=13061.
[136] ICSWG, *supra* note 81, at 28.
[137] *Id.*
[138] *Id.* at 30.

originate in the global South.[139] Synthetic biologists often work to replace these "high-value ingredients and commodities" with cheaper compounds produced by microorganisms.[140] If successful, synthetic biology's commercial applications will destabilize developing economies, disrupt trade and markets, and displace workers.[141] Finally, synthetic biology may negatively and inequitably impact global biodiversity.[142] Agricultural and industrial processes will become more efficient as a result of synthetic biology's advances in "metabolic pathway engineering."[143] These efficient processes require significantly greater biomass to run.[144] The ICSWG fears that industrial and agriculture groups will turn to the species- and biomass-rich tropics and subtropics for biomass supplies.[145] Businesses in need of biomass already turn to developing countries in these areas.[146] Thus, synthetic biology's efficiency measures may cause further harm to biodiversity—especially in the tropics and subtropics.[147]

Past treaties and protocols address benefits sharing and other equity concerns, indicating the international community's willingness to address such social justice concerns on the international stage. Beginning in 1992, the CBD attempted to address these concerns through its third major goal: to promote "the fair and equitable sharing of

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[139] *Id.*
[140] *Id.*
[141] *Id.* at 30-32.
[142] *Id.* at 28.
[143] *Id.*
[144] *Id.*
[145] *Id.*
[146] *Id.* ("With an estimated 86% of global biomass stored in the tropics or subtropics, developing countries are already being tapped as the major source of biomass to supply industrial-scale feedstock for fermentation tanks and biorefineries[.]")
[147] *Id.*

the benefits" arising from genetic resources.[148] The Cartagena Protocol added to this broad framework with provisions for "information sharing" and a "Biosafety Clearing-House."[149] It was not until 2010 that the international community earnestly addressed the CBD and Cartagena Protocol's shortcomings through the Nagoya Protocol.[150] The Nagoya Protocol aimed to fulfill the CBD's third goal through the "appropriate access to genetic resources" and by the "appropriate transfer of relevant technologies."[151] It includes a provision on financial mechanisms to help developing countries with "capacity-building and development requirements" to implement the protocol.[152] Unfortunately, though the Nagoya Protocol has 92 signatories, only sixteen countries have ratified it.[153]

These past attempts suggest that any new system of governance should similarly address benefits sharing and other equity concerns — and early in the creation process. Further, the international community's long road to Nagoya indicates that a workable scheme of equitable sharing takes time, effort, and determination. A synthetic biology governance scheme should address benefits sharing and equity concerns early in the planning process.

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[148] Convention on Biological Diversity, *supra* note 13, at 823 (art. 1) (discussing objectives).
[149] Cartagena Protocol, *supra* note 72, at 1036 (art. 20).
[150] *See generally* Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, COP Decision X/1 (Oct. 29, 2010) [hereinafter Nagoya Protocol], *available at* https://www.cbd.int/decision/cop/default.shtml?id=12267; *see also The Nagoya Protocol on Access and Benefit-sharing*, CONVENTION ON BIOLOGICAL DIVERSITY, http://www.cbd.int/abs/ (last visited Mar. 4, 2013).
[151] Nagoya Protocol, *supra* note 150, at art. 1 (discussing the objective).
[152] *Id.* at art. 25 (discussing "Financial Mechanisms and Resources").
[153] *List of Parties: Nagoya Protocol*, Convention on Biological Diversity (last visited Apr. 28, 2013), *available at* https://www.cbd.int/convention/parties/list/default.shtml#tab=2.

Synthetic biology's international governance scheme should address multiple components of this new field's equity issues. First, it should address access issues, including access to "open source" databases and, more broadly, the new synthetic biology technology. Increased access potentially brings both positive and negative ramifications: while new technology can help developing countries become more efficient producers and manufacturers, it can also harm existing economies. Further, policymakers should consider what mechanisms are necessary to combat the negative secondary effects from benefits in the global North.

E. Respect for Ethical Concerns

The international community should acknowledge and discuss ethical concerns, but the extent to which ethical concerns should inform policy decisions is widely debated. Academics widely acknowledge ethical concerns related to synthetic biology. Many individuals and citizen groups oppose the creation and use of novel life forms;[154] some also oppose "ownership" of life under intellectual property laws.[155] Some groups may cite religious or moral grounds for these ethical concerns.[156]

However, academics do not discuss the extent to which ethical concerns should contribute to synthetic biology oversight — if at all. Respect for and discussion of ethical concerns may facilitate public participation and increase transparency of the process. An earnest effort to address ethical concerns may also increase widespread international acceptance of the finished product. But these benefits may be true of increased respect

[154] *See* Kuzma & Tanji, *supra* note 4, at 94; Tait, *supra* note 1, at 148.
[155] *See* Tait, *supra* note 1, at 148.
[156] Kuzma & Tanji, *supra* note 4, at 94.

and discussion generally. Perhaps ethical concerns should receive heightened acknowledgement simply because they evoke such harsh criticism from groups normally skeptical of environmental concerns, on the grounds that it implicates creating "life."[157] Respect for and discussion of ethical concerns, combined with the prior four process principles, will help the international community to create an effective system of synthetic biology governance.

IV. Actors

Synthetic biology requires some sort of cohesive, uniform, international governance system. Further, the actors involved in creating this governance scheme should work to ensure the five process principles discussed above. But the international community faces a dilemma: who should create a system of governance for synthetic biology? Implicit in this question are others: Who is best able to analyze and regulate synthetic biology's unique but substantial risks?[158] Who is best able to adapt to the field's ever-increasing advancements? What actors would give a scheme international legitimacy and encourage broad participation? And more broadly, what level of stakeholder involvement must be achieved to set a positive, workable precedent for future emerging technologies? This section argues for the involvement of three broad stakeholder groups: the synthetic biology industry, national governments acting on the international stage, and nongovernmental organizations (NGOs) and citizen groups.

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[157] *See generally* Dan M. Kahan et al., *Risk and Culture: Is Synthetic Biology Different?*, 3 (Cultural Cognition Project, Working Paper No. 29, 2009) (discussing the cultural inversion theory), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1347165; *infra* text accompanying notes 208-210.
[158] *See generally* Murray, *supra* note 41, at 1328.

A. Synthetic Biology Industry

The synthetic biology industry must participate in creating a synthetic biology governance regime. This category of stakeholders includes two subgroups: scientists engaged in synthetic biology research and development and science- and technology-based business firms. DIY synthetic biologists sit at the intersection of scientists and citizens groups. Though DIY biologists are difficult to identify, a potential governance scheme should still discuss and address their concerns. Many members of the synthetic biology industry advocate heavily for DIY biology and, theoretically, should advocate for their interests as well. But this process may reveal that the different risks associated with DIY biology correlate with a different set of interests. In that case, DIY interests should be considered a citizen group interest, which will be discussed later.[159]

Three factors suggest that synthetic biology industry actors must play a significant role in creating a synthetic biology governance regime. First, synthetic biology scientists and businesses have expertise on this new technology.[160] Second, and related to their expertise, they must respond to and implement any new legal regime.[161] Finally, these actors created and drove forward the synthetic biology market — a market that may transform significant sections of the world economy.

Scientists and businesses have expertise in the field and are most knowledgeable about synthetic biology's risks and potential future developments.[162] Their intimate

[159] NGO and citizen group interests will be discussed *infra* Part IV.C.
[160] *See* Abbott, *supra* note 111, at 130.
[161] *Id.*
[162] *Id.*

knowledge of synthetic biology gives them legitimacy and authority within the field.[163] This expertise will help the international community assess risks, which in turn will allow policymaking bodies to determine necessary precautionary measures in line with the precautionary approach.[164] The industry's knowledge will also help the international community to identify where a synthetic biology governance scheme must include flexibility mechanisms.

Additionally, the synthetic biology industry must respond to any new legal regime and implement its provisions in laboratories and businesses.[165] Scientists and business firms have the "authority, access[,] and information to produce meaningful compliance with legal rules on a day-to-day basis in the lab or factory."[166] As the regulated actors, they provide valuable input concerning what regulation is practical and feasible. Their input further relates to transparency of process: the more the regulated parties participate in creating an international governance scheme, the more likely they are to commit to the finished product.

Finally, synthetic biology scientists and businesses created a market for synthetic biology parts and services.[167] Modular genomic parts may become a market of their own, and the ability to modify biological systems impacts agriculture production, industrial

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[163] *Cf.* Ching-Fu Lin, *Global Food Safety: Exploring Key Elements for an International Regulatory Strategy*, 51 VA. J. INT'L L. 637, 662 (2011) (discussing private actors' "scientific and technical expertise," and thus advantage in setting food safety standards).
[164] This does not take into account the industry's biases against the precautionary approach; more accurate knowledge of the risks does not automatically indicate precautionary measures.
[165] *See* Abbott, *supra* note 111, at 130.
[166] *Id.*
[167] *See generally* May, *supra* note 62 (discussing biosafety concerns of the new market).

efficiency, and commodity manufacturing worldwide.[168] The synthetic biology market may thus "[transform] significant sections of the world economy."[169] Further, regulation affects investments in emerging technologies. Venture capitalists and other biotechnology investors need a clear idea of an emerging technology regulatory system before investing in its development.[170] Regulation determines "pay-back time" on investments, reassures investors of an "eventual market for emerging products," helps determine ultimate profitability.[171] These market concerns support the industry's participation in oversight development: not only are scientists and businesses important stakeholders, but they are also the force driving a powerful, growing market.

Regardless of whether the international community turns to the synthetic biology industry for guidance, the industry will likely participate in governance.[172] Industry responded to the growing call for synthetic biology oversight and made strides toward self-governance in the absence of state-level regulation, discussing codes of conduct as early as 2003.[173] As discussed above, these codes illustrate the need for transparency of process. Codes provide further benefits to the international community. A form of soft law, codes take less time to develop compared to formal oversight.[174] They allow interested parties with intimate knowledge of the field to customize regulations and best

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[168] *See generally* Mukunda et al., *supra* note 10, at 7.
[169] *Id.*
[170] Tait, *supra* note 1, at 144.
[171] *Id.*
[172] *See id.* at 102 ("Regardless, the [synthetic biology] community seems to be taking a self-regulatory path similar to the Asilomar Conference.")
[173] Stephen M. Maurer, *End of the Beginning or Beginning of the End? Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It*, 45 VAL. U. L. REV. 1387, 1416 (2011).
[174] Gary E. Marchant et al., *International Governance of Autonomous Military Robots*, 12 COLUM. SCI. & TECH. L. REV. 272, 310 (2011) [hereinafter Marchant et al., *International Governance*]

address synthetic biology's unique risks.[175] Further, codes are "adept enough to keep pace" with science and technology developments.

But allowing the synthetic biology industry to be the only source of international oversight is problematic. Private industry lacks the infrastructure, support, and legitimacy necessary for sufficient international oversight.[176] Comprehensive oversight — encompassing more than screening codes — would require more administrative infrastructure than private companies can currently provide. Adequate planning and administration would be expensive and time consuming. A scheme addressing all synthetic biology concerns and considering all process principles would likely produce more costs than benefits to the synthetic biology industry.[177] Even if the industry could create an adequate system of self-governance, questions would arise about its authority and legitimacy. Synthetic biology codes of conduct illustrate this concept. When multiple codes vie for acceptance, it is unclear which takes precedent.[178] In these situations of ambiguous legitimacy, effective monitoring and enforcement may be difficult.[179]

Oversight by the synthetic biology industry may also have negative implications for the growing synthetic biology market. At the extreme, this market could lead to powerful actors within the synthetic biology industry gaining exclusive control over the creation of life through licenses and patents. Allowing the same actors to regulate synthetic biology may create a dangerous monopoly on the creation and manipulation of

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[175] *Id.*
[176] *Cf.* Lin, *supra* note 163, at 663 (discussing food safety governance and its major shortcomings, including: "conflicts of interest, legitimacy deficits, and lack of institutional capacity").
[177] *See generally* Murray, *supra* note 41, at 1328.
[178] Marchant et al., *International Governance*, *supra* note 174, at 310.
[179] *See generally* Murray, *supra* note 41, at 1328 ("If risk were addressed largely as a matter of self-governance, then questions arise about how self-governance should be monitored or enforced.").

life.[180] Further, allowing only a few key actors within synthetic biology to dominate discussions silences the concerns of smaller firms and those new to the industry.[181] Regulatory compliance is difficult for companies new to the sector; these companies must turn to and support "the strategies of the multinational companies" to survive.[182] This further increases the risk of a monopoly. Thus, biologists and synthetic biology firms should help create a system of governance, but they should not be the only actors involved.

B. Government (State-Level) Involvement

National governments must participate in creating an international system of governance. State involvement legitimizes regulatory efforts and provides leadership, infrastructure, and international accountability mechanisms. This legitimacy and leadership may ultimately help ensure the process principles discussed above. International legitimacy can further bring the "broad normative coherence" necessary for successful emerging technology oversight on the international stage.[183]

At the very least, actors with state-level authority and legitimacy should address areas of heightened risk outside of private sector control. Private industry self-regulation may provide successful oversight for some synthetic biology practices.[184] But the synthetic biology industry cannot account for all risks — especially those outside of

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[180] Tait, *supra* note 1, at 147 ("Craig Venter's team has filed for a patent on the smallest genome needed for a living organism, . . . [and it] has received considerable media attention because it has been interpreted as a patent on the essence of life itself.").
[181] *Id.* at 144.
[182] *See id.*
[183] *Cf.* Thomas A. Faunce, *Nanotechnology in Global Medicine and Human Biosecurity: Private Interests, Policy Dilemmas, and the Calibration of Public Health Law*, 35 J.L. MED. & ETHICS 629, 636 (2007) (discussing international oversight for nanotechnology).
[184] *See* discussion *supra* Part IV.A.

private sector control. First, governments should monitor synthetic biology's "open source" information banks. While open databases can have positive equity ramifications, broad sharing and lack of barriers create biosecurity risks.[185] The National Science Advisory Board for Biosecurity suggests "review by institutional and federal oversight systems" for potentially dangerous categories of experimentation.[186] Further, governments should address risks posed by DIY biologists to themselves and their communities.[187] Government-sponsored emergency assistance and other emergency safety mechanisms would help combat risks by garage biologists. Finally, governments should have authority to quickly check and restrain potentially dangerous experiments. For example, some academics suggest that the United States government adopt a "'safety hold' norm similar to that used by Air Traffic Control (ATC) systems."[188] Under a government-enforced "safety hold," any member of the scientific community may halt an experiment based on safety or security concerns.[189] Advocates presented the "safety hold" idea to the synthetic biology community in 2007 at the international "Synthetic Biology 3.0" conference;[190] whether it could work in practice is unclear. Though it would provide valuable emergency support, scientists could also use this as a tool to slow

[185] *See* discussion *supra* Part I.B.2.
[186] Kuzma & Tanji, *supra* note 4, at 101 (including "increasing virulence or resistance of pathogens" in the categories of experiment to be reviewed).
[187] *See generally* Schmidt, *supra* note 1, at 95 ("A scenario where amateur biologists would design and construct their own pet bugs in their garage would certainly put the health of the amateur, the community around him or her and the environment under unprecedented risk.").
[188] Mukunda et al., *supra* note 10, at 18.
[189] *Id.*
[190] Gautam Makunda of MIT and Scott Mohr of Boston University presented this novel idea at Synthetic Biology 3.0 on June 25, 2007, in Switzerland. Their presentation can be downloaded online at http://www.docstoc.com/docs/48399173/Synthetic-Biology-30-DNA-Synthesis-Synthetic-Biology-and. Unfortunately, the presentation does not provide details of the mechanisms involved.

competitors' work and force members of the biology community underground. Despite its obvious drawbacks, the "safety hold" illustrates one manner in which the government can restrain potentially dangerous experiments in emergencies. These situations illustrate that government involvement is necessary to address these risks outside of private sector control.

This call for state-level government participation implies international cooperation. Nations working alone leave regulatory gaps through which ill-willed actors may bypass biosafety and biosecurity measures.[191] International cooperation promotes a uniform, standardized system and prevents a "leaky" international regime.[192] Further, early international cooperation facilitates positive information sharing by which states may later discuss and update international governance measures. Coordination facilitates information sharing among states and societal actors, and between actors working at different stages of synthetic biology development.[193] It also improves the quality of information shared by "increasing the comparability of information and assessments from varied sources."[194] Effective, open channels of communication will enable the international community to assess an international governance regime and respond to any governance implemented — creating a positive feedback system.

State-level participation may come in many forms. Direct international regulation is possible but unrealistic.[195] Rather, national governments will likely facilitate action on

[191] *See* Mukunda et al., *supra* note 10, at 18.
[192] *See id.* ("[T]he only way to prevent a 'leaky' system would be to implement international agreements where all parties accept the same standards and sanctions.").
[193] Abbott, *supra* note 111, at 130.
[194] *Id.*
[195] *Id.* at 127 (explaining that legal institutions are relatively weak on the international stage).

the international stage, or support, supplement, and legitimize actions by private industry and other non-governmental organizations. Abbott suggests that state-level governments can take the lead in creating an international framework convention, implemented through a top-down approach.[196] Under this proposal, a state-created framework would provide the broad outlines of oversight.[197] But international institutions, separate from any individual state, would oversee implementation and enforcement of national regulatory actions.[198] Alternately, state governments could look to recommendations from the synthetic biology industry and independent institutions. Stephen Maurer argues that strong self-governance by private industry is feasible, desirable, and the "last, best chance for improved security."[199] He urges state governments to support and encourage synthetic biology codes of conduct. [200]

These alternatives to direct state-level governance illustrate why governments should not be the only decisionmakers in creating a synthetic biology governance system. Direct oversight is not feasible. States must either garner support for a top-down international framework, or throw support behind non-government regulation. These options mandate that states cooperate not only with other states on the international stage, but also societal actors, including scientists, private industry, citizen groups, and other community organizations.

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[196] *Id.* at 137-38 (suggesting this approach for emergent technologies generally).
[197] *Id.*
[198] *Id.* at 139-42.
[199] Stephen M. Maurer, *Taking Self-Governance Seriously: Synthetic Biology's Last, Best Chance to Improve Security* 13 (Goldman Sch. of Pub. Policy, Working Paper No. GSPP12-003, 2012), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2183306.
[200] *Id.*

C. Nongovernment Organizations, Citizen Groups, and Indigenous Communities

Besides governments and the synthetic biology industry, stakeholders include those affected by synthetic biology innovations and those "concerned with [its] social, cultural[,] and ethical implications."[201] Synthetic biology's novelty and potential social impacts suggest the need for increased public engagement, dialogue, and access to "relevant information" prior to and during oversight development.[202] The increased engagement and dialogue should continue throughout oversight implementation.[203] Public participation will help guarantee that oversight development includes the five process principles discussed above.

First, nongovernment organizations (NGOs) and citizen groups provide a check on industry and government power and discretion, often in line with the precautionary principle. NGOs such as the ETC Group, Greenpeace, and Friends of the Earth object to synthetic biology self-governance on the grounds that it does not provide adequate comprehensive oversight.[204] These groups go so far as to argue for a "moratorium on release and commercialization of synthetic organisms, cells, or genomes" until government bodies have developed a comprehensive regulatory scheme.[205] Further, states whose industries compete in the international synthetic biology market may face

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[201] Abbott, *supra* note 111, at 130.
[202] Kuzma & Tanji, *supra* note 4, at 104; *see also* Abbott, *supra* note 111, at 134 (explaining that an "international arrangement . . . should encourage the participation and engagement of stakeholders, relevant epistemic communities and civil society, both within states and transnationally").
[203] Kuzma & Tanji, *supra* note 4, at 104.
[204] *Id.* at 102-03. *See generally* FRIENDS OF THE EARTH, PRINCIPLES FOR OVERSIGHT, *supra* note 9.
[205] FRIENDS OF THE EARTH, PRINCIPLES FOR OVERSIGHT, *supra* note 9, at 3. A full moratorium is unlikely. *See supra* note 10 and accompanying text.

incentives to "*under*-regulate" for competitive reasons.[206] As NGOs and citizen groups gain worldwide support and visibility, they force the international community to hear their concerns.

As broad public engagement provides a check on industry and state-level governments, it also protects equity and ethical concerns overlooked by those same groups. Synthetic biology's promise of new living systems has far-reaching societal impacts.[207] These impacts, real and perceived, provoke concerns based on morality, religion, culture, and other societal values. For example, ethics and risk perception overlap in the "cultural inversion" hypothesis.[208] In normal cultural profiles, hierarchical, cultural, and highly religious individuals are generally least concerned and most skeptical about environmental and technological risks.[209] But synthetic biology inverts this cultural profile: those individuals normally least concerned with environmental risks are most concerned about synthetic biology's risks.[210] The cultural inversion hypothesis illustrates that synthetic biology faces new and unique ethical concerns. Broad public engagement should help to ensure that the international community hears synthetic biology's equity and ethical concerns by promoting discussions and common understanding.

Further, public engagement assures transparency of process and preempts later backlash. Public engagement and transparency are necessary for the oversight development process,[211] especially where risks and uncertainties are substantial.

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[206] Abbott, *supra* note 111, at 131.
[207] *See* Kuzma & Tanji, *supra* note 4, at 94.
[208] Dan M. Kahan et al., *supra* note 157, at 3.
[209] *Id.*
[210] *Id.*
[211] Kuzma & Tanji, *supra* note 4, at 94.

Synthetic biology's uncertainty and risks cause substantial fear and produce "sharp reactions, if not overreactions, to potential threats."[212] This "normative uncertainty," combined with uncertainty of the technology's future, creates "political uncertainty."[213] When faced with political uncertainty, policymakers cannot know what oversight scheme is most effective against the potential risks.[214] In this situation of high risks and uncertainty, public engagement is necessary for an effective oversight development process.[215] Public engagement helps policymakers combat political uncertainty and promotes discussion to combat normative uncertainty. It further promotes transparency, which ultimately increases stakeholder acceptance of the final governance scheme. Academics reference early GMO regulation as a system lacking public engagement and advise against a similar failure with synthetic biology.[216]

In the United States and countries with similar legislative processes, public engagement comes with a drawback. Legislatures can only address a certain number of concerns at a time and often address those concerns slowly. NGOs and citizen groups push federal and state legislatures to address concerns of "perceived political urgency and expediency." This can be a benefit: issues important to the general public receive attention first. On the other hand, this is a downside to broad public engagement. The public has the ability to "elevate [an] issue to the front of the priority line" based on

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[212] Mukunda et al., *supra* note 10, at 16.
[213] Abbott, *supra* note 111, at 133-34. In normative uncertainty, "[A]t least some individuals find it difficult to reconcile what they know of a technology with personal values or prevailing social norms." *Id.* These individuals "may even find it difficult to determine which values and norms should apply." *Id.*
[214] *Id.* at 134 (explaining that an "international arrangement . . . should encourage the participation and engagement of stakeholders, relevant epistemic communities and civil society, both within states and transnationally").
[215] *See* Kuzma & Tanji, *supra* note 4, at 94.
[216] *See, e.g.*, *id.* at 104; Tait, *supra* note 1, at 151.

perceived, not actual, risks. Applying this principle to synthetic biology, NGOs and citizen groups have substantial power to force legislative action in one area while ignoring substantial but less well-known concerns. Allowing NGOs and citizen groups this authority over synthetic biology's agenda could negatively impact the field's long-term governance scheme. Despite this potential drawback, however, NGO and citizen group involvement is necessary to creating an effective system of international governance.

V. Coming Together

After identifying five process principles and three stakeholder groups important to creating a synthetic biology governance scheme, we must ask: what comes next? Is it possible for any single governance scheme to adequately ensure each process principle and facilitate participation by each stakeholder group? Though we lack a well-fitting, workable model for this ambitious governance scheme, it may be possible to achieve.

This paper advocates a broad, standard international system of governance for synthetic biology. States should look toward an international system as a goal, but a feasible starting point may require a more humble approach. A single governing body — from a domestic agency to an international organization — could bring together a workgroup to discuss a synthetic biology agenda. While called together by policymakers, the workgroup could encourage broad stakeholder participation by reserving seats for members of the synthetic biology community, NGOs, and citizen groups.

Various governing bodies lend themselves to the role of bringing together a synthetic biology workgroup. At the domestic level, the United States Department of

Homeland Security or the Federal Bureau of Investigation could call together a workgroup focusing on synthetic biology's biosecurity and dual use concerns.[217] The United States is a developed country and world superpower. These agencies' involvement would certainly showcase synthetic biology as a potential national and international security threat that must be taken seriously. But the country has shied away from other international environmental governance schemes, such as the Kyoto Protocol to the United Nations Framework Convention on Climate Change. Whether the United States would facilitate such an international scheme scheme now — even for international security reasons — is unclear.

Alternately, an international institution could facilitate a synthetic biology workgroup. The United Nations Security Council, another security-related governing body, would be a fitting candidate and could take up the issue as part of its counter-terrorism efforts.[218] The European Union, frequently assessing and discussing international risks,[219] is also a desirable forum. The European Union's executive arm has already hosted workshops to discuss synthetic biology's challenges,[220] indicating a

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[217] For information on a workshop that may indicate their interest in this role, see generally *Dual Use Research: Implications for Security*, COUNCIL ON FOREIGN RELATIONS http://www.cfr.org/projects/world/dual-use-research-repercussions-for-security/pr1637 (last visited Apr. 28, 2013).

[218] *See generally United Nations Security Council Resolution 1540 (2004)*, UN.ORG http://www.un.org/en/sc/1540/ (last visited Apr. 28, 2013). Of course, the United States is a permanent member of the U.N. Security Council and could block the Council's efforts. For a list of the current members of the United Nations Security Council, see *Current Members*, UN.ORG, http://www.un.org/en/sc/members/ (last visited Aug. 19, 2013).

[219] *See generally International Risk Assessment Dialogue*, European Commission: Public Health, http://ec.europa.eu/health/dialogue_collaboration/international_dialogue/index_en.htm (last visited Apr. 28, 2013).

[220] *See* Yojana Sharma, *Developing countries face up to synthetic biology challenges*, SCIDEV.NET (Apr. 27, 2012), *available at* http://www.scidev.net/en/agriculture-and-environment/environmental-policy/features/developing-countries-face-up-to-synthetic-biology-challenges-1.html.

willingness to address the issues. These domestic and international examples illustrate potential governing bodies that could bring together a synthetic biology workgroup.

The governing body should reach out to the synthetic biology industry, scientists, NGOs, and citizen groups to serve in the workgroup. Both industry and civil society would likely be willing to participate in a synthetic biology workgroup. Over the past decade, members of the synthetic biology community have discussed and advocated for a standard, international system of governance.[221] Scientists and other members of the synthetic biology industry held multiple international meetings on synthetic biology in 2004 and 2006. Held at UC Berkeley in 2006, "Synthetic Biology 2.0: The Second International Meeting on Synthetic Biology" outlined a set of goals and guidelines for synthetic biology procedures.[222] Synthetic biology businesses similarly recognized the need for multi-national governance and created private codes of conduct for screening through the IASB and IGSC. While the IASB and IGSC codes only address screening procedures, they indicate the industry actors' willingness to create and implement a workable self-governance scheme. National governments and international organizations have not yet adopted a single set of codes or guidelines. The synthetic biology industry's work thus far suggests that members would be willing to participate in a workgroup with government oversight — especially if the governing body showed willingness to ultimately endorse or adopt industry codes of conduct.

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[221] For a list of past events at which the synthetic biology community discussed a system of international governance, see *Upcoming Events*, SYNTHETICBIOLOGY.ORG, http://syntheticbiology.org/Conferences.html (last visited Apr. 28, 2013).

[222] *See Biosecurity Resolutions*, SYNTHETICBIOLOGY.ORG, http://syntheticbiology.org/SB2.0/Biosecurity_resolutions.html (last visited Apr. 28, 2013).

A synthetic biology workgroup should also facilitate civil society participation by reserving seats for members of NGOs and other citizen groups. NGOs and citizen groups helped place synthetic biology on the international agenda; they identified biosafety and biosecurity threats and responded vociferously with calls for greater oversight.[223] NGOs, including the ETC Group and Friends of the Earth, already came together in the ICSWG to submit governance recommendations to the CBD's Subsidiary Body on Scientific, Technical and Technological Advice.[224] Their concerns and past involvement indicate that NGOs and citizens groups would willingly participate in a synthetic biology workgroup.

The governing body could set an agenda for the workgroup to discuss areas in need of governance. These are numerous and include: research, licensing of materials to conduct synthesis,[225] screening orders,[226] shipping orders (implicating both domestic and transboundary movement), oversight for end uses,[227] and emergency assistance. The workgroup could create codes or guidelines for proposed government adoption.

Ultimately, the workgroup model could grow into a system of networked international governance.[228] Synthetic biology policymakers could work toward creating an international scientific advisory body, much like the Intergovernmental Panel on

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[223] *See e.g.*, FRIENDS OF THE EARTH, PRINCIPLES FOR OVERSIGHT, *supra* note 9.
[224] *See* Sharma, *supra* note 220.
[225] GEORGE CHURCH & ED REGIS, REGENESIS: HOW SYNTHETIC BIOLOGY WILL REINVENT NATURE AND OURSELVES 235 (2012).
[226] *See* discussion *supra* Parts III.B and IV.A (discussing the IASB and IGSC codes of conduct).
[227] CHURCH & REGIS, supra note 228, at 236.
[228] *See generally* Liliana B. Andonova, *Public-Private Partnerships for the Earth: Politics and Patterns of Hybrid Authority in the Multilateral System*, GLOBAL ENVTL. POL., May 2010, at 25, 26 (2010) (noting that the environmental arena is "particularly conducive" to collaborative systems of governance).

Climate Change.[229] Or it could help to facilitate a public-private partnership between private synthetic biology actors and one or more governing bodies.[230] The format of the end governance system, however, need not be fully clear; at this point policymakers should prioritize bringing stakeholders together to discuss these issues.

Conclusion

Synthetic biology brings significant potential to mitigate pollution, combat climate change, increase manufacturing efficiency, improve agricultural production, and provide many other societal benefits. But these benefits come with equally significant risks and uncertainties. The international community clamors for a system of governance, but none has yet materialized. Governing bodies must come together soon to create an international system; this system should include the five process principles discussed above and facilitate participation from various stakeholder groups. Assuring these principles and wide stakeholder participation should bring about an effective system of international governance for synthetic biology.

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[229] See generally *Organization*, INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, www.ipcc.ch/organization/organization.shtml (last visited Apr. 28, 2013).

[230] *Cf.* Marian Garcia Martinez et al., *Co-Regulation As a Possible Model for Food Safety Governance: Opportunities for Public–Private Partnerships*, 32 FOOD POL. 299, 302 (2007) ("An essential element of a co-regulatory approach to governance of food safety is cooperation between the public and private sectors in the process of creating new rules."). *See generally* Andonova, *supra* note 228, at 26 (defining public private partnerships as "agreements for collaborative governance between public actors . . . and nonstate actors"); Karin Bäckstrand, *Accountability of Networked Climate Governance: The Rise of Transnational Climate Partnerships*, GLOBAL ENVTL. POL., Aug. 2008, at 74; Ingrid J. Visseren-Hamakers et al., *Interaction Management by Partnerships: The Case of Biodiversity and Climate Change*, GLOBAL ENVTL. POL., Nov. 2011, at 89, 91 ("Partnerships represent a prominent form of new governance mechanisms, which enable collaboration among the different societal sectors, government, market and civil society.").