

**TEMPLATE FOR PEER REVIEW COMMENTS  
TECHNICAL SERIES ON SYNTHETIC BIOLOGY**

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## Peer Review of First Draft of "Updated CBD Technical Series 82 Synthetic Biology"

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In Notification SCBD/CPU/DC/WM/MAQ/MW/8958, the Secretariat calls for peer reviews of the First Draft of the "Updated CBD Technical Series 82 on Synthetic Biology", hereafter the "Draft Report". The call restricts the format to a three-column template even though narrative better elicits the desired "focus on substantive matters rather than on editorial issues". In the columns to the left, to what page and line in the Draft Report should this paragraph be ascribed? I will answer my own question: page 0 line 0. This and the paragraphs to follow will be one long General Comment.

Elision is deliberate omission. Absent from the 183-page Draft Report are three issues: regulatory capture, mandatory financial security and bounded openness over natural information. Inasmuch as all three greatly concern the implications of the Convention on Biological Diversity (CBD) and Nagoya Protocol (NP) for Synthetic Biology (Synbio), any continued absence in the revised report would be purposeful. Addressing regulatory capture, mandatory financial security and bounded openness requires formal economics, which is applied in the parallel Draft Study on "Article 10 of the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress and decision CP-9/15", hereafter the "Draft Study on NKLSP". Thus two closely related texts are now being vetted, with deadlines of 15 and 26 June 2021. The corresponding sets of peer reviews risk being "silo-ed", which is also the criticism of international regimes in the Conclusion of the Draft Report (p. 133). The sets should be integrated. This review of the Draft Report will integrate not only with that forthcoming of the Draft Study but also with previous reviews of the five commissioned studies on DSI and that of the study on transboundary situations [1]. When the studies and reviews are removed from the silos, the foundational flaws of the CBD and NP become evident and cross-cutting.

### Regulatory Capture

A literature exists on "regulatory capture" for which George Stigler was awarded a Nobel Memorial Prize in 1982. The term is almost self-explanatory: industry commandeers policymaking against the public interest. Stigler's contribution coheres with the political philosophy for which his academic affiliation is eponymous: The

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[1] For my peer reviews of the four inter-sessional studies on DSI in 2018-2020, see <https://www.cbd.int/abs/DSI-peer/2019/Study1/JosephHenryVogel.pdf>, <https://www.cbd.int/abs/DSI-peer/2019/Study4/JosephHenryVogel.pdf>, <https://www.cbd.int/abs/DSI-peer/2019/Study2-3/JosephHenryVogel.pdf>. Peer review of the antecedent 2017 study on DSI can be found at <https://www.cbd.int/abs/DSI-peer/Vogel,%20UPR.pdf>, and that of the 2020 study on transboundary situations, at <https://www.cbd.int/abs/Art-10/Peer-review/Vogel.pdf>.

Chicago School [2]. Among its advocates was fellow Nobelist Frederich August von Hayek, whose ideology complemented Stigler's aversion to an expansive State. According to Hayek, the State lacks the capacity to process the torrent of information necessary for efficient regulation. Attempts to do so usurp market-based solutions and put society on "The Road to Serfdom" [3].

The Draft Report is replete with statistics which would support the Chicago-School critique. "By 2017 more than 25,000 authors at 3700 organisations located in 79 countries had contributed to the synthetic biology research..." (p.10). Among those research streams will be high-impact-low-probability (HILP) events. But just how high is the high impact? And how low is low probability? And what is the landscape of events? Answers would be contentious. The Draft Report speaks of the need for regulation to be "future-proof", as unanticipated developments will raise new issues that may eclipse those still being discussed by regulators (p. 12).

#### Mandatory Financial Security

The knowledge necessary to allow or prohibit Synbio endeavors requires a mechanism of control, be it enabled by the operators, the market or the State. The Draft Report treats liability and risk assessment extensively, but does not discuss mechanisms of financial security, which is discussed in the Draft Study on the NKLSP. Mechanisms include compulsory insurance, risk-sharing, risk-pooling, compensation funds, bonds and self-insurance (aka "going naked").

Because compulsory insurance would put the kibosh on a large swath of Synbio, lobbying will undoubtedly accompany investment in R&D [4]. The history of nuclear energy policy in the USA merits review [5]. Through regulatory capture, liability could be capped for worst-case scenarios. The capping shifts the costs of HILP events to society whenever the damages exceed the cap. A caveat is in order: uninsurable activities do not necessarily mean that the expected losses are greater than the discounted value of the premia paid. Risk assessment is a "public good" in the

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[2] See Filippo Maria Lancieri and Luigi Zingales, "Economic Regulation after George Stigler", ProMarket: Publication of The Stigler Center at the University of Chicago, 2021. <https://promarket.org/2021/04/14/economic-regulation-after-george-stigler/>.

[3] F.A. Hayek, *The Road to Serfdom*, Chicago: University of Chicago Press, 1944.

[4] Expenditure on lobbying is unconstrained in the non-Party, under *Citizens United v. Federal Election Commission*, 558 U.S. 310 (2010).

[5] Garrett Hardin critiqued mid-twentieth century nuclear-energy policy with insights that are eerily prescient for twenty-first century Synbio. See his capstone oeuvre *Living Within Limits*, New York: Oxford, 1993.

economic sense [6]. An efficiency argument can be made that the modeling of events be government-financed and placed in the public domain. Insurance ambiguity would thus be diminished and render economic many otherwise uninsurable activities. Is therefore compulsory insurance with government-financed risk assessment the solution to the HILP events of Synbio? The answer is nuanced.

Cognitive biases in personal risk assessment are common to all cultures. People tend to confuse the low probability of an event as if the expectation were also low (probability multiplied by the value of the event). The analysis of such uneconomic behavior earned the psychologist Daniel Kahneman the 2002 Nobel Memorial Prize in Economics. Non-rational patterns of risk perception justify seat belt laws, prohibitions of construction in floodplains, lugubrious images on cigarettes packages and so on. Insurers are not inanimate conglomerations. They are composed of people who may sort out in dominance hierarchies, where cognitive biases are amplified, almost invariably from top to bottom. One suspects that non-rational decisions will also afflict insurers and re-insurers, albeit much less so due to corporate checks and balances. So, the societal problem is not that some Synbio activities will be uninsurable, but that they will be mistakenly insured.

Should HILP events be uncapped and even one insurer liberally underwrite HILP events à la Hayek, liability would be limited through the insolvency of the insurer or re-insurer. Worries about regulations not being "future-proof" pale against those about an insurer being "judgement-proof". The State must intervene to impede the gung-ho insurer who, at the right price, never says "no". In other words, compulsory insurance cannot stand alone as the mechanism of control due to HILP events that hazard global catastrophes. This is one of many places where the State must "draw the line", to use Keynes's metaphor in response to Hayek's unbound enthusiasm for market-based solutions [7].

Compulsory insurance is thus a very large part of the solution, but not the whole solution. How did this issue not merit inclusion in the laboriously constructed Draft Report? Had economists been among the authors, perhaps they would have suggested "regulatory capture", which assumes that they themselves were not captured. A biographical sketch of the authors is essential within the Draft Report. In the 2017 Report, 44 members were identified and in the 2019 Report, some 38 [8]. Has the

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[6] "A good that is non-excludible and non-depletable (non-rivalrous)". *Britannica*. <https://www.britannica.com/topic/public-good-economics>

[7] J.M. Keynes, 'Letter to Hayek' (28 June 1944) in Vol. 27 of the *Collected Writings of John Maynard Keynes* (ed.), Donald Moggridge, London, 1980, p. 385.

[8] See, <https://www.cbd.int/doc/c/aa10/9160/6c3fcedf265dbee686715016/synbio-ahteg-2017-01-03-en.pdf> and <https://www.cbd.int/doc/c/2074/26e7/a135b1b57dabe8e8ed669324/synbio-ahteg-2019-01-03-en.pdf>

composition changed again? What was the contribution of each co-author? Such disclosure is now common practice in multi-authored scientific publications.

### Compulsory Insurance and Grey Goo

Risk assessment may bog down regulation for Synbio products that present no possibility of an HILP event. One imagines that the insurance premia for "cultured leather products" (p. 37) or "digital information storage using DNA molecules" (p. 39) could be easily incorporated into the cost structure of a firm. One sincerely hopes that this is also not true of engineered bacteria for "carbon recycling" (p. 35) with its attendant possibilities for the grey-goo scenarios of sci-fi. Because grey-goo is an existential threat, the Keynesian line should be drawn on all such applications of engineered gene drives.

The question of intentions must also be asked: What for? Do we risk global catastrophe to clean up an oil spill, knowing that the contaminants will eventually disperse? Do we risk it to sequester carbon, knowing that cost-effective alternatives go unexploited (e.g., subsidizing a vegetarian diet, public transport, re-forestation)? Other than nuclear war, only Synbio portends a man-made doomsday within our lifetimes. And like the nuclear threat, the possibility is so awful that the public prefers not to think about it. Cognitive dissonance is real. The wisdom of the Russell-Einstein Manifesto of 1955 seems apropos "All, equally, are in peril, and, if the peril is understood, there is hope that [all groups] may collectively avert it" [9].

The nonchalance of the Draft Report about gene drives morphs into hubris: "Unlike non-engineered gene drive organisms which can be limited in time and space and therefore provide data from small-scale tests that can be relevant to large-scale releases, the potential of engineered gene drive organisms to spread over large areas and landscapes, even from a limited release or well-isolated trials, means that risk assessors will need to consider models and forecasts in their assessments. However, as the development of engineered gene drive organisms near potential release, further ecological work will be essential to enhance model predictions (Sánchez et al., 2020)" (p. 58). G-d help us.

### Bounded Openness over Natural Information

Although the economics of uncertainty is not my area of specialization, the elisions of the Draft Report were sufficiently flagrant that even a non-specialist like myself could identify them. I will now focus where I can profess specialization: "access to genetic resources" and the "fair and equitable sharing of benefits arising from utilization" (ABS).

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[9] "The Russell-Einstein Manifesto", issued in London, 9 July 1955, <http://umich.edu/~pugwash/Manifesto.html>

Variance is as bedrock to economics as it is to biology. Just as risks vary across the landscape of Synbio, so too should the obligations for ABS. Many "BioBlocks" of Synbio have appeared in the published literature since the onset of molecular biology and others have been published in patents, long since expired. User resistance to any ABS obligation inheres to the perception of an ersatz clawback by Providers, who would be well advised to abandon such attempts. Common ground in ABS should be sought for genetic material not previously utilized in intellectual property.

The definition of the term "genetic material" in the CBD and NP employs "material" without defining what is "material". The AHTEG operational definition of Synbio does likewise: “[S]ynthetic biology is a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic *materials*, living organisms and biological systems” (Decision XIII/17) (p. 8). Most Users insist that "material" be interpreted as only tangible for the purposes of ABS. Do they also interpret "material" as only tangible in the operational definition of Synbio? If their interpretation shifts between the "silos" for ABS and biosafety, then good faith comes into question. If their interpretation does not shift, then the definition of Synbio loses all operability. "Genetic material" interpreted as only tangible suppresses the role of some 1700+ databases worldwide in the phenomenon defined.

A literature exists that resolves the contradiction by distinguishing natural from artificial information and rejecting the placeholder "digital sequence information" [10]. In reductionist terms, the object of access is natural information and any value added through R&D, artificial information [11]. The medium of natural information may take various forms for which the tangible (biological samples) and the digital are currently the most prevalent. The Sociedad Peruana de Derecho Ambiental (SPDA, Peruvian Society of Environmental Law) has suggested the following definition for Synbio, which is both broad and discriminating, while affording exclusionary criteria:

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[10] See trilogy of OP-EDs and references therein, published open-access in several languages from *Intellectual Property Watch*: "Ending Unauthorised Access to Genetic Resources (aka Biopiracy): Bounded Openness", 6 April 2018, <http://www.ip-watch.org/2018/04/06/ending-unauthorised-access-genetic-resources-aka-biopiracy-bounded-openness/> , "Not Just A Matter Of Matter: 'The Way Forward' For The UNCBD, NP And Half-Earth", 7 September 2018, <http://www.ip-watch.org/2018/09/07/not-just-matter-matter-way-forward-uncbd-np-half-earth/> , "The Global Multilateral Benefit-sharing Mechanism: Where will be the Bretton Woods of the 21st Century?", 5 October 2018, <http://www.ip-watch.org/2018/10/05/global-multilateral-benefit-sharing-mechanism-will-bretton-woods-21st-century/>

[11] See *Genetic Resources as Natural Information: Implications for the Convention on Biological Diversity and Nagoya Protocol*, Manuel Ruiz Muller, London, Routledge, 2015. Spanish translation, 2nd edition, in open access at [https://spda.org.pe/?wpfb\\_dl=4131](https://spda.org.pe/?wpfb_dl=4131)

Synthetic Biology: the extremely intensive use of artificial information in the manipulation of natural information [12].

One indicator of the intensity of artificial information would be extensive use of patented inventions [13]. Equal treatment of natural and artificial information implies that both enter the public domain when a patent expires. Should a commercial application arise that enjoys intellectual property protection for which the utilized natural information is not public domain, then equal treatment would mean that economic rents be shared among the countries of origin through a Global Multilateral Benefit-Sharing Mechanism (GMBSM), which is the title of Article 10 of the NP. The rents would vary by the class of utilization. Classification of certain endeavors as Synbio would thus facilitate negotiation of a royalty rate for that class [14]. The scant 50 lines on pages 92 and 93 (Sections 8.4 and 8.4.1) about ABS and the NP make no reference to this literature. The absence of any mention of the GMBSM speaks loudly.

Conclusion.

The narrative of this General Comment addresses the call to "focus on substantive matters rather than on editorial issues". The obligatory template biases peer reviews against identifying elisions. This peer review recommends that authors address substantively three issues: regulatory capture, mandatory financial mechanisms and bounded openness over natural information. A significant literature exists which throws light on the implications of the CBD and NP for Synbio, however the field is ultimately defined.

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[12] Sociedad Peruana de Derecho Ambiental 'Submitted view for the Updated report and synthesis of views in response to paragraph 7(b) of Decision XII/24; and Report of the Meeting of the Ad Hoc Technical Expert Group on Synthetic Biology', <http://bch.cbd.int/synbio/peer-review/2015-2016/>

[13] "One early example [of Synbio] is genetically modified 'golden rice'—actually developed before the term synthetic biology was widely used—for which more than 70 patent rights needed to be cleared". Berhold Rutz, "Synthetic biology and patents. A European perspective", *EMBO Reports* 2009 Aug; 10 (Suppl 1): S14–S17. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726002/#b13>

[14] Joseph Henry Vogel, Klaus Angerer, Manuel Ruiz Muller and Omar Oduardo-Sierra, "Bounded Openness as the Global Multilateral Benefit-Sharing Mechanism for the Nagoya Protocol". Pages 377-394 in Charles R. McManis and Burton Ong (eds) *Routledge Handbook on Biodiversity and the Law*, London, Routledge, 2018.

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