## Biotechnology Risk Assessment & Mitigation

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Opinions addressed herein are of the speaker's alone, and not representative of any government agency or institution.

### Challenge: The Pacing Problem

**Technology** Data **Future of Industry** Emergence Risk Data **Regulatory Challenges** 

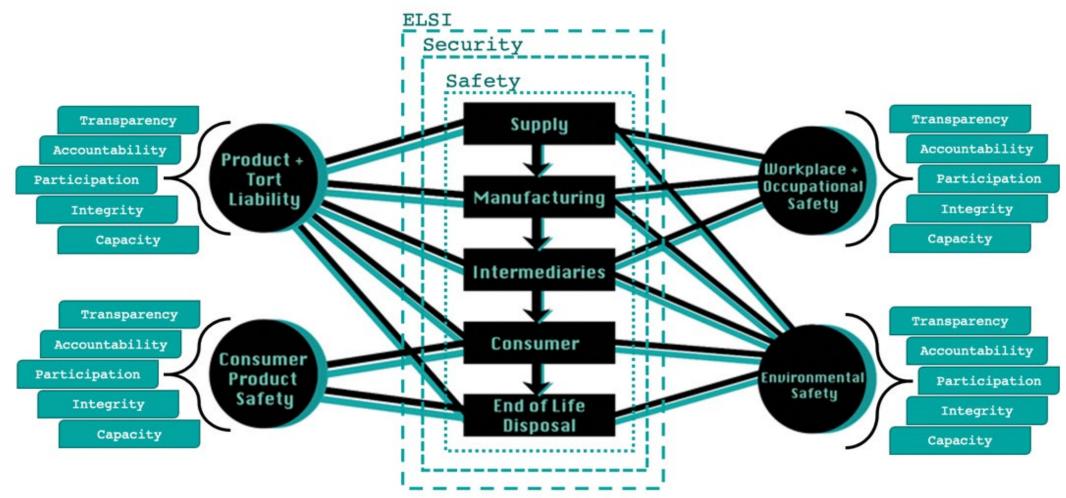
No matter how sophisticated health risk assessment becomes, a gap will always exist between new material introduction and risk characterization & mgmt.

- (1) Is the intervention reversible? What does recovery look like?
- (2) Is it containable?
- (3) Do countermeasures or treatments exist?
- (4) Does it work successfully?
- (5) Are the harms significant, even if briefly?
- (6) What can be quantified, and what is elusive?

Time

Trump, B. D., Keisler, J. M., Galaitsi, S. E., Palma-Oliveira, J. M., & Linkov, I. (2020).

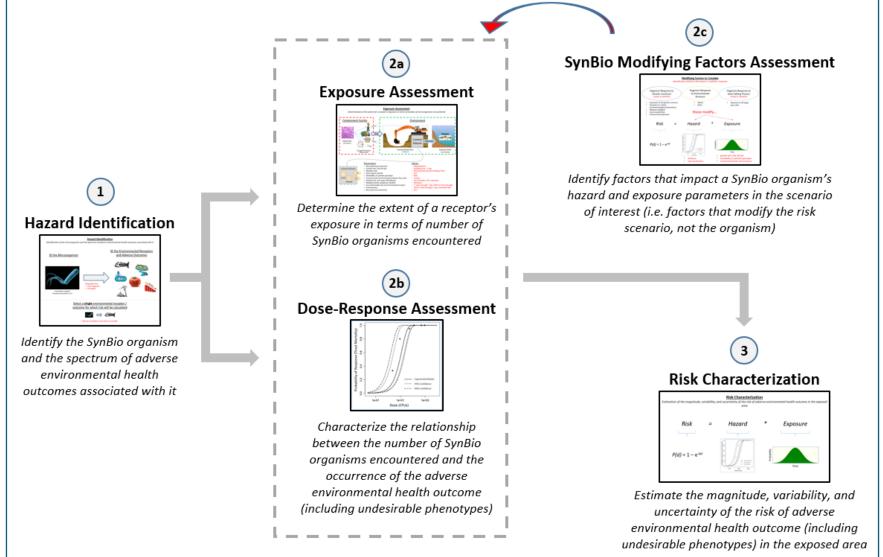
### Governance instruments/targets take many forms.

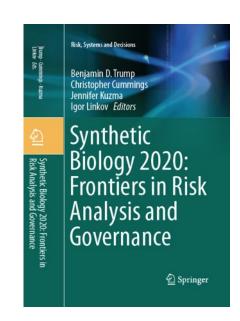


Trump, B. D., Hristozov, D., Malloy, T., & Linkov, I. (2018). Risk associated with engineered nanomaterials: Different tools for different ways to govern. *Nano Today*, *21*, 9-13.

Linkov, I., Trump, B. D., Anklam, E., Berube, D., Boisseasu, P., Cummings, C., ... & Vermeire, T. (2018). Comparative, collaborative, and integrative risk governance for emerging technologies. *Environment Systems and Decisions*, *38*, 170-176.

# Many Novel Materials Require Unique Additions or Modifications to Risk Analysis





Trump, B. D., Foran, C., Rycroft, T., Wood, M. D., Bandolin, N., Cains, M., ... & Hamilton, K. (2018). Development of community of practice to support quantitative risk assessment for synthetic biology products: contaminant bioremediation and invasive carp control as cases. Environment Systems and Decisions, 38(4), 517-527.

#### **Hypothetical Case - Dose Calculation**

Realistically, parameter values will be represented as <u>distributions</u> rather than point values. The calculated dose will be determined using Monte Carlo simulation and will be represented as a <u>distribution</u>.

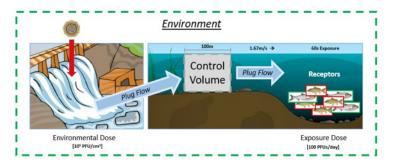
Contact

Surface Area

Encounter

Rate

(Interspecies)



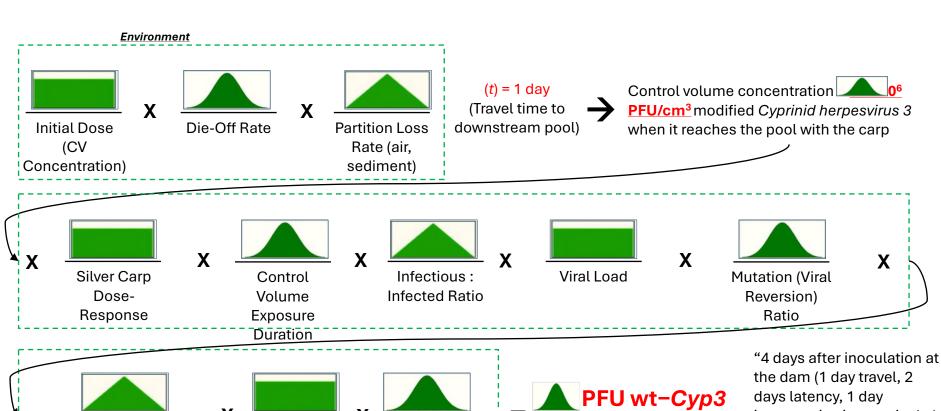
interspecies interaction), 1

Common Ca A dosed

dav"

with 100 PFU of wild type

Cyprinid herpesvirus 3 per



**Transmission** 

rate

(Transfer

Efficiency)

day

# Information Hazards – Some hints at early answers

- A1: WHEN DO INFORMATION HAZARDS MATTER?
- Rising significance of information as rate limiting factor on critical path to doing harm
- Falling significance of skill premiums, materials access, editing methods and other factors
- Information incontinence eg. cybersecurity, discovery and Freedom of Information Act
- Identification of info hazards best done with mixed teams of technologists and devious bastards
- A2. BASIC POSITIONS ON INFORMATION HAZARDS
- Focus 1: Malevolent Actors- States, terrorist organizations, lone wolves
  - Limit access to info that could be used to do harm
- Focus 2: Benign Naïve Actors Researchers and their Biosafety Officers
  - Provide access that could do harm to forestall unintended harms
- Focus 3: Political Actors officials, regulators, firms, civil society
  - Provide info needed to deliberate on info hazards, research funding, EHSS policy
- Focus 4: Researchers academic and industrial
  - Provide info needed to enable science and engineering advances
  - Identify safeguards for LLMs and machine learning



NATO Science for Peace and Security Series - C Environmental Security

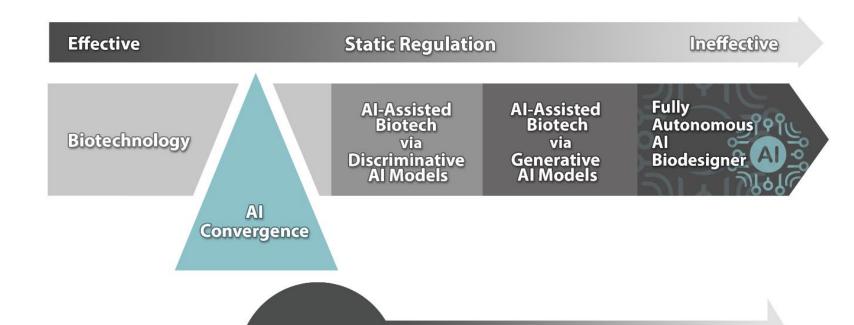
#### Emerging Threats of Synthetic Biology and Biotechnology

Addressing Security and Resilience Issues

Edited by Benjamin D. Trump Marie-Valentine Florin Edward Perkins Igor Linkov



Al adds unpredictability to the future of biotechnology development and proliferation



Adaptive Regulation

Vindman, C., Trump, B., Cummings, C., Smith, M., Titus, A. J., Oye, K., ... & Linkov, I. (2025). The convergence of AI and synthetic biology: the looming deluge. *Npj Biomedical Innovations*.

Gregory, F. D., & Trump, B. D. (2024). The Evolving Landscape of Biotechnology Research: Challenges and Opportunities in Acquisitions, Funding, Education, and Workforce Development for a Productive Bioeconomy. *Advanced Study Institute on NATO ASI on Quantum Nano-Photonics*, 25-50.

Predict Regulatory Need

Systemic ObservationFeedback/ Risk Analysis

# The next step: how to tie technology development and risk governance into strategic planning?

• Trump, B., Cummings, C., Klasa, K., Galaitsi, S., & Linkov, I. (2023). Governing biotechnology to provide safety and security and address ethical, legal, and social implications. Frontiers in genetics, 13, 1052371.

