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is only the view of the authors*

# **Resilience: Relevance for SynBio Risk Assessment**

**Igor Linkov, PhD**

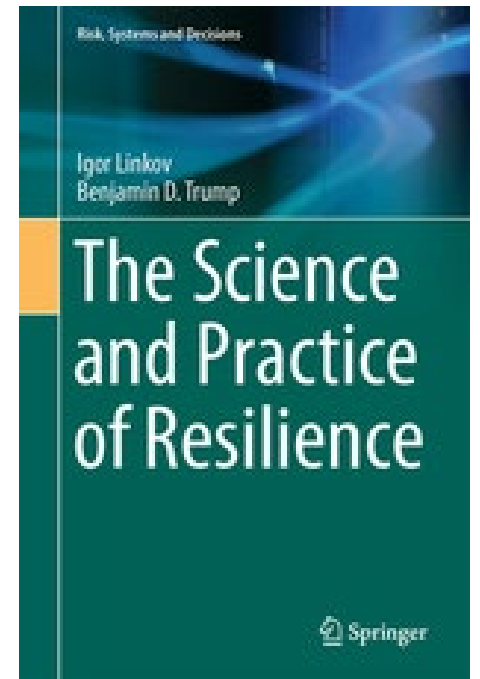
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R&D Center; US Army Corps of Engineers

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# Main Ideas

- Risk Assessment and Management in traditional framing is very difficult if not impossible for SynBio, **transition to Risk Governance and Resilience**
- Multi Criteria Decision Analysis as foundation for Risk Governance, **prevention and containment is not enough**
- Novel functions and properties require **resilience approaches to manage unknowns and emergent behaviors**
- Experience with Nano – do not reinvent the wheel and **Start Right from the beginning!**



**Risk** -- “a situation involving exposure to danger [threat].”

**Security** -- “the state of being free from danger or threat.”

**Resilience** -- “the capacity to recover quickly from difficulties.”

Definitions by Oxford Dictionary

### **Don't conflate risk and resilience**

'Risk' and 'resilience' are fundamentally different concepts that are often conflated. Yet maintaining the distinction is a policy necessity. Applying a risk-based approach to a problem that requires a resilience-based solution, or vice versa, can lead to investment in systems that do not produce the changes that

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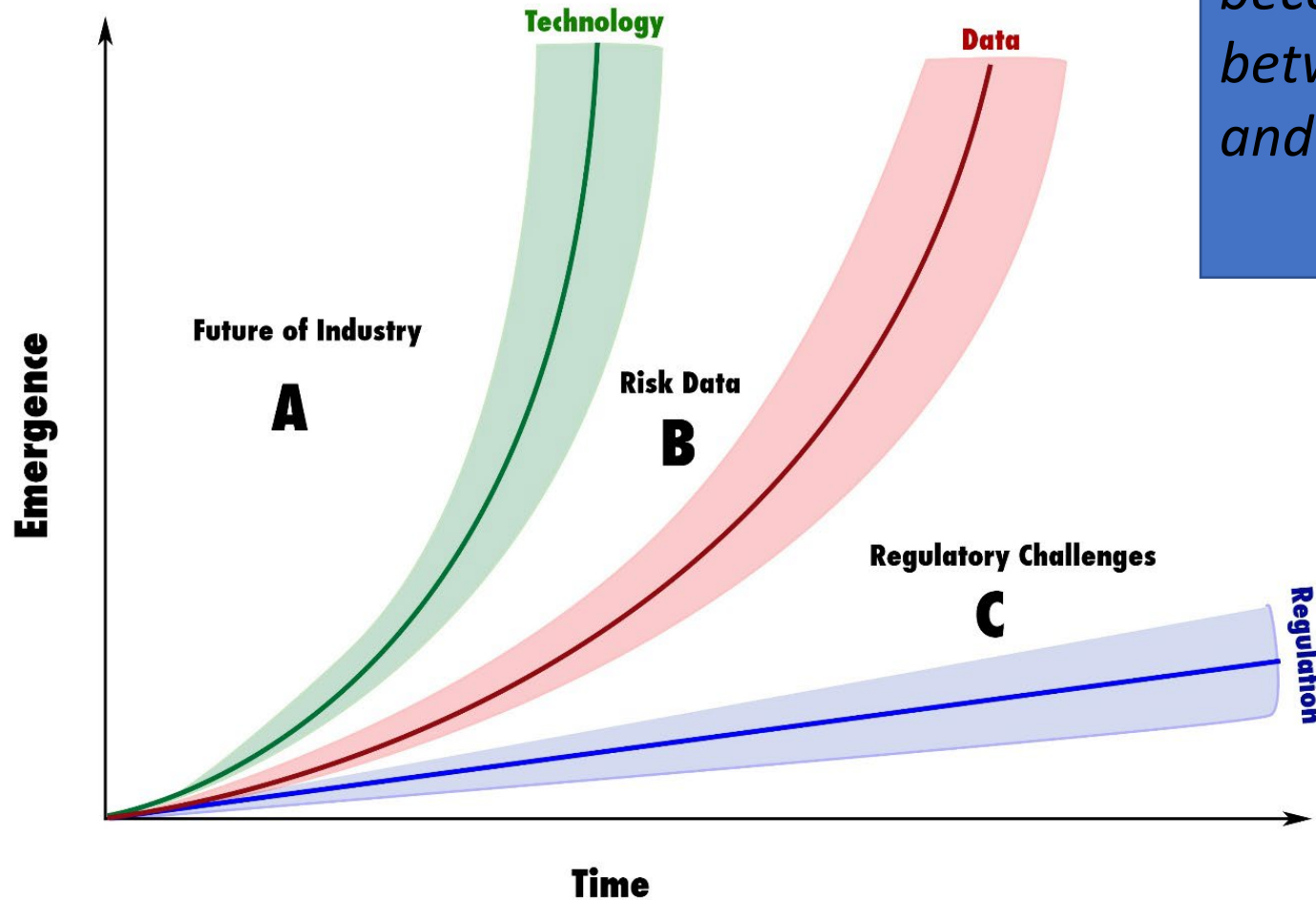
# Risk Assessment in Practice

$$Risk = Hazard \times Exposure \times Effects$$

- Requires specific knowledge and quantification of all three components
- Complexity of emerging materials makes Hazard assessment challenging
- Exposure assessment is difficult because of environmental transformations
- Effects may be unknown

# Challenge 1: The Pacing Problem

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



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Environmental Security

## Nanomaterials: Risks and Benefits

Edited by  
Igor Linkov  
Jeffery Stevens

2008

Springer



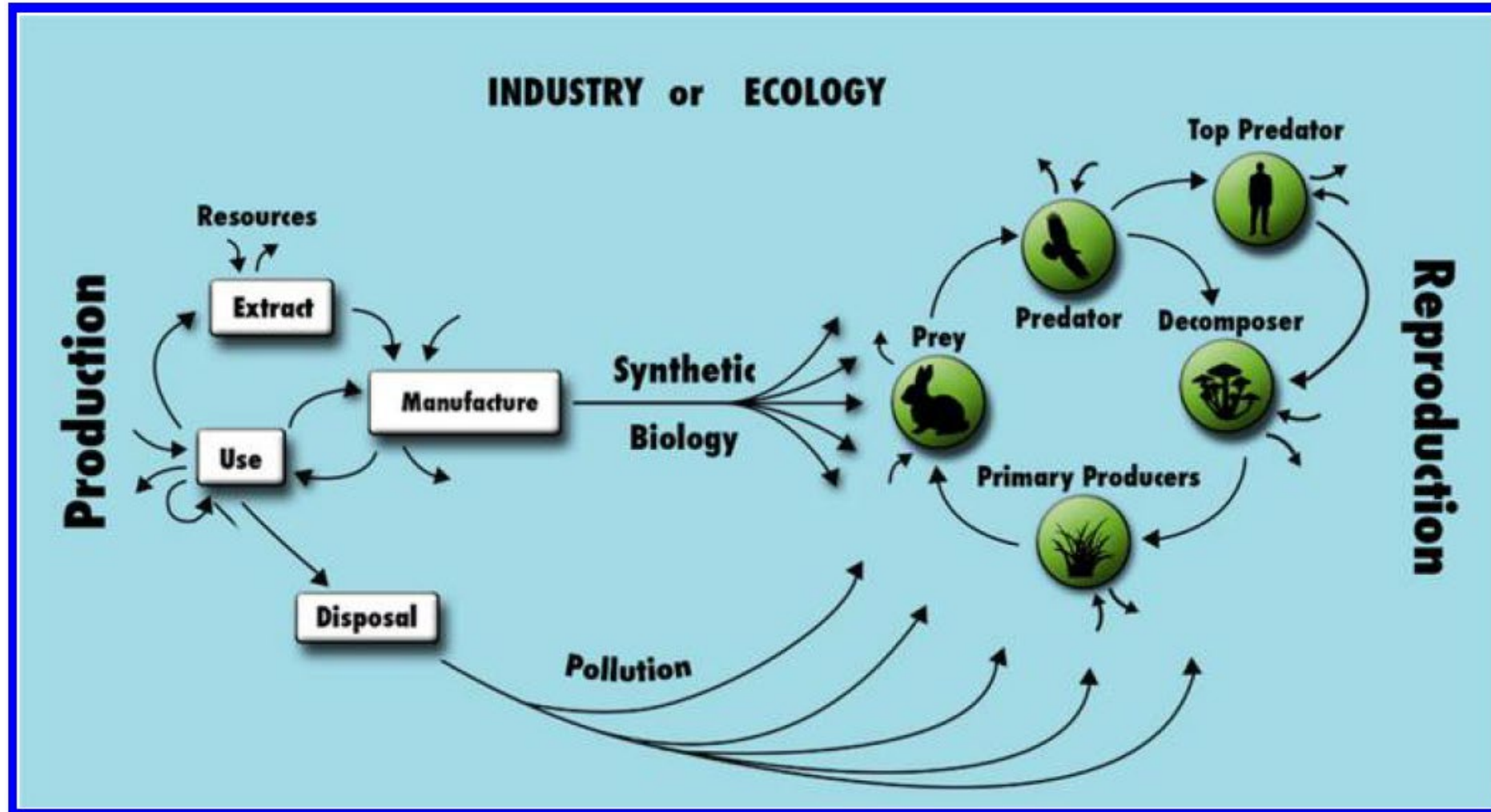
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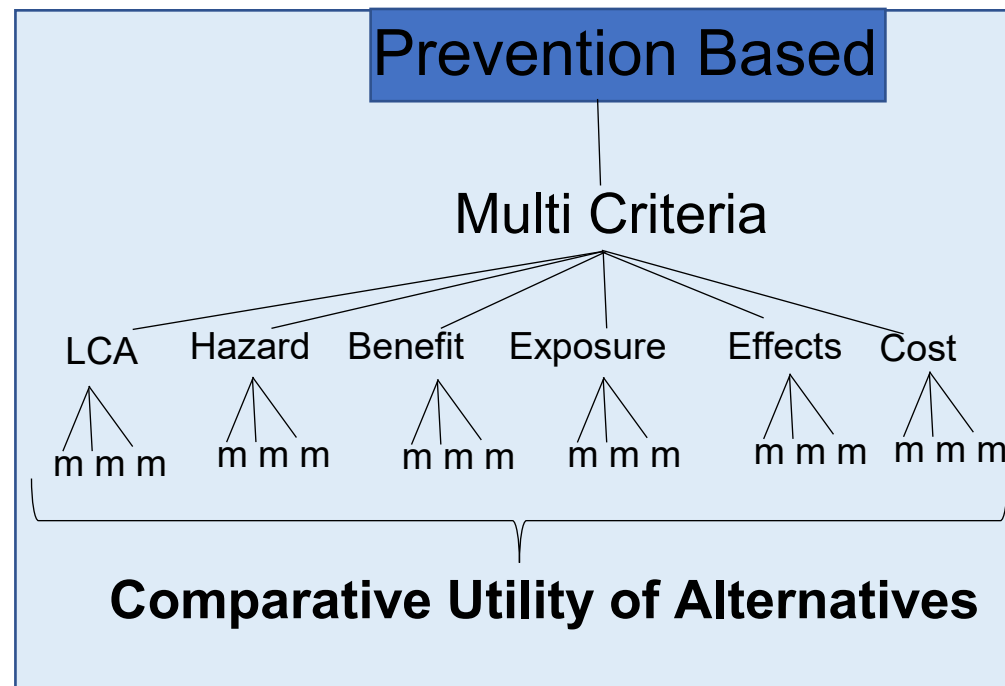
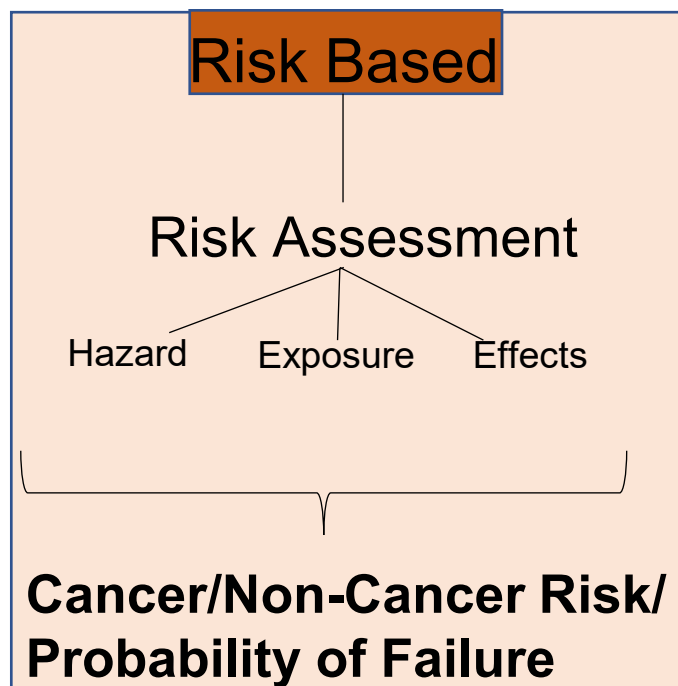
## Why Life Cycle Assessment Does Not Work for Synthetic Biology

Thomas P. Seager,<sup>†</sup> Benjamin D. Trump,<sup>‡</sup> Kelsey Poinsett-Jones,<sup>‡</sup> and Igor Linkov<sup>\*,‡,§</sup>

# Challenge 2 – from Industry to Ecology



# Is Risk Governance for Emerging Materials Possible?



Linkov, I., Trump, B. D., Anklaam, E., Berube, D., Boisseasu, P., Cummings, C., ... & Jensen, K. A. (2018). Comparative, collaborative, and integrative risk governance for emerging technologies. *Environment Systems and Decisions*, 38(2), 170-176.



# Implementation - Nano Prioritization/Grouping Tool for Consumer Product Safety Commission

## Cosmetic products

(improved cleansing and absorption)



## Food packaging

(reduce moisture & bacteria)



## Children's toys and blankets

(antimicrobial protection)



## Polymer composite materials

(lighter and more durable)



- Stakeholders need the ability to screen and prioritize a diverse array of nano-enabled consumer products in order to prioritize research into risks, triage reported safety concerns, and **allocate limited resources more efficiently**

Environmental  
Science  
Nano

PAPER



Cite this: *Environ. Sci.: Nano*, 2019, 6, 356

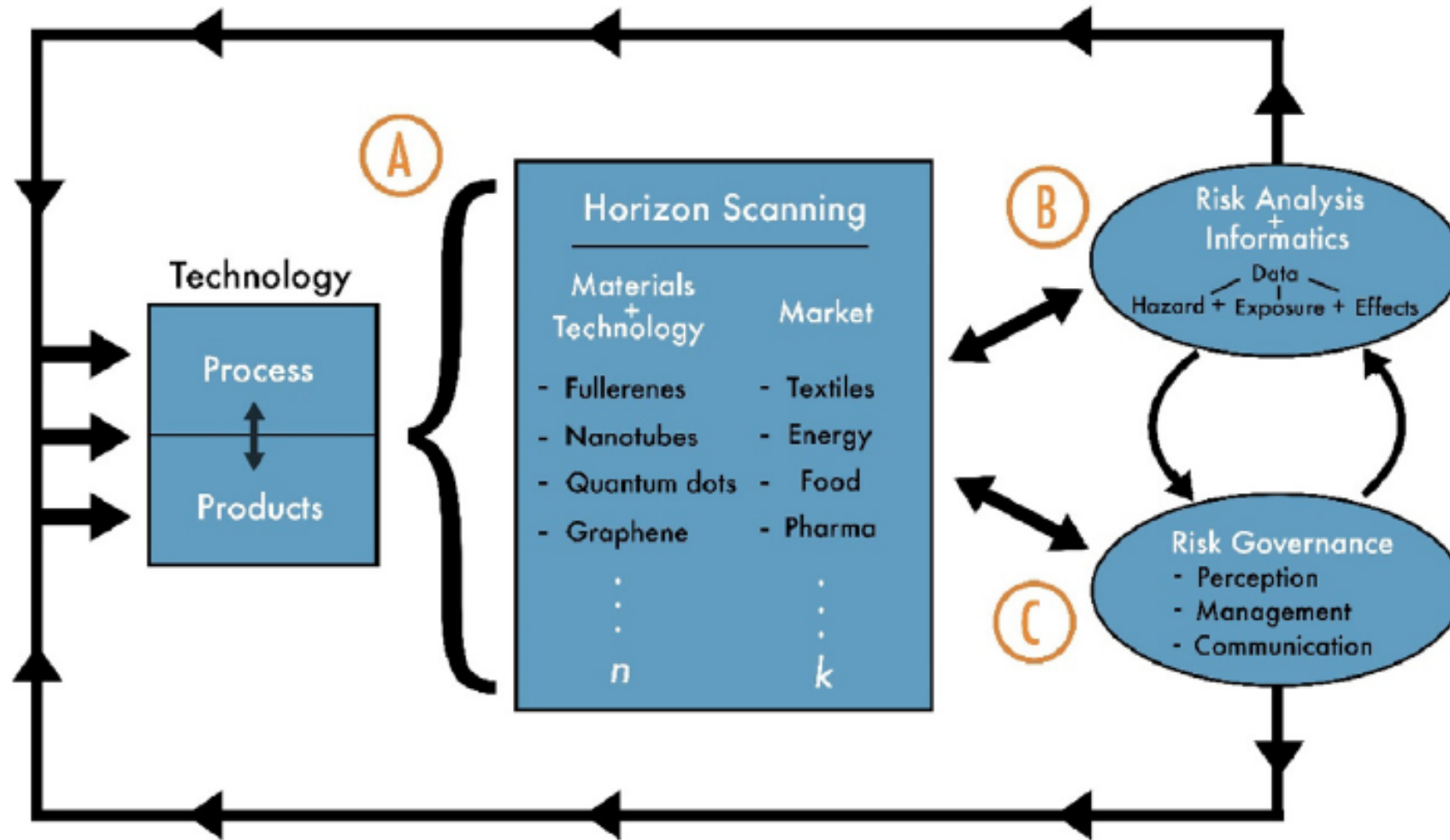
## A framework and pilot tool for the risk-based prioritization and grouping of nano-enabled consumer products†

Taylor Rycroft, <sup>a</sup> Sabrina Larkin, <sup>b</sup> Alexander Ganin, <sup>b</sup> Treye Thomas, <sup>c</sup> Joanna Matheson, <sup>c</sup> Tessa Van Grack, <sup>c</sup> Xinrong Chen, <sup>c</sup> Kenton Plourde, <sup>b</sup> Alan Kennedy <sup>d</sup> and Igor Linkov <sup>\*a</sup>





# Safety-by-Design



Nano Today 35 (2020) 100989

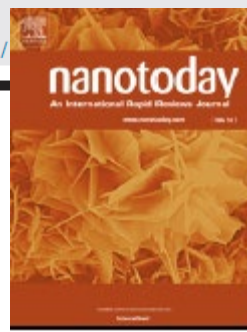
Full text lists available at [ScienceDirect](https://www.sciencedirect.com)

Nano Today

Full text available at [www.elsevier.com/locate/nanotoday](https://www.elsevier.com/locate/nanotoday)

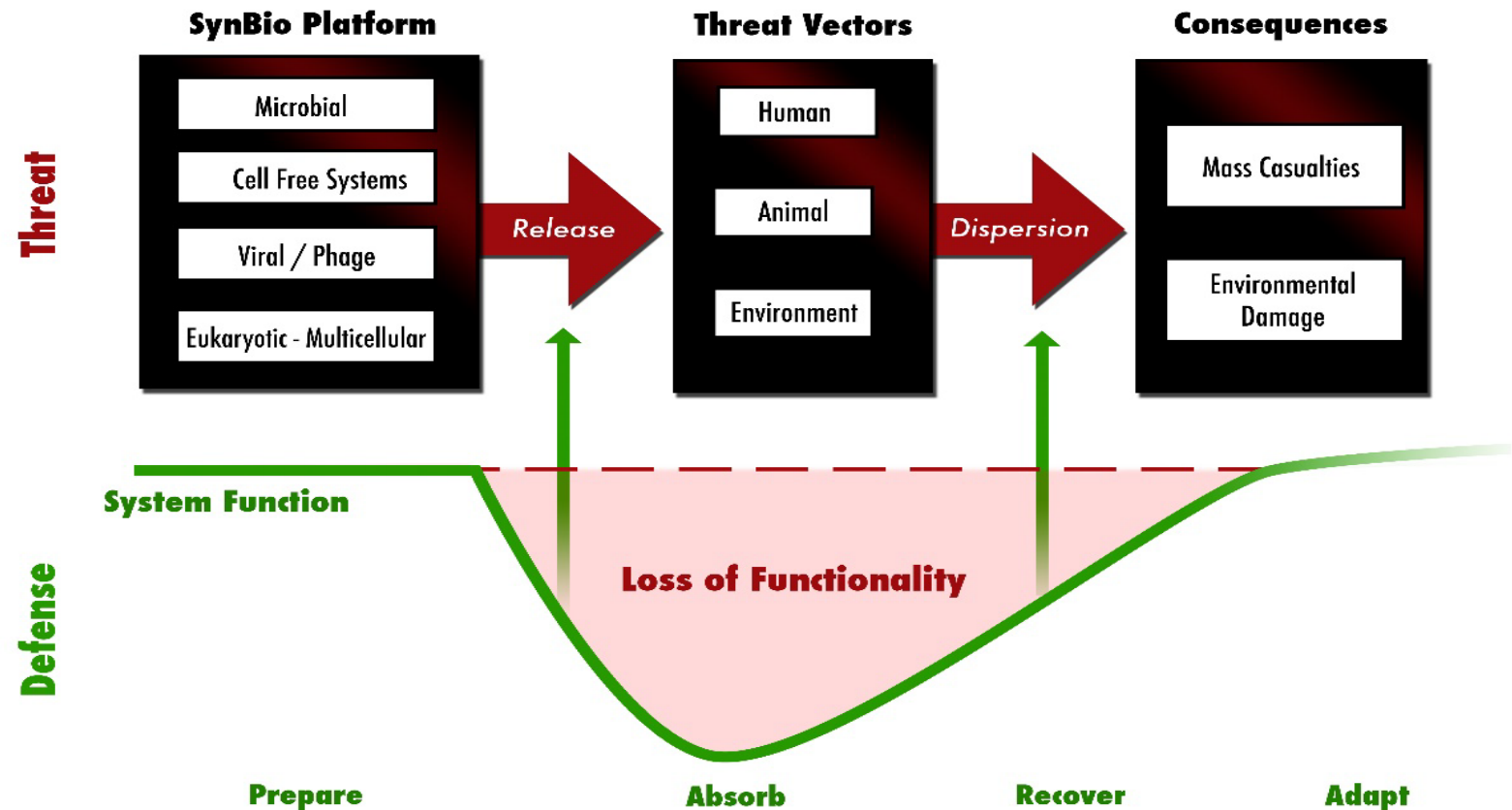
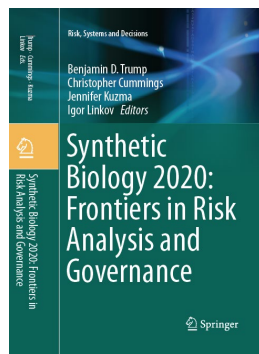
## Safety-by-design as a governance problem

Benjamin D. Trump<sup>a,\*</sup>, Jeffrey M. Keisler<sup>b</sup>, Stephanie E. Galaitsi<sup>a</sup>,  
José Manuel Palma-Oliveira<sup>c</sup>, Igor Linkov<sup>a,\*</sup>



# From Risk to Resilience – The Need for Recovery in Biosecurity

Framing the  
Dual-Use  
Problem:  
*Understanding  
the need for  
Resilience*

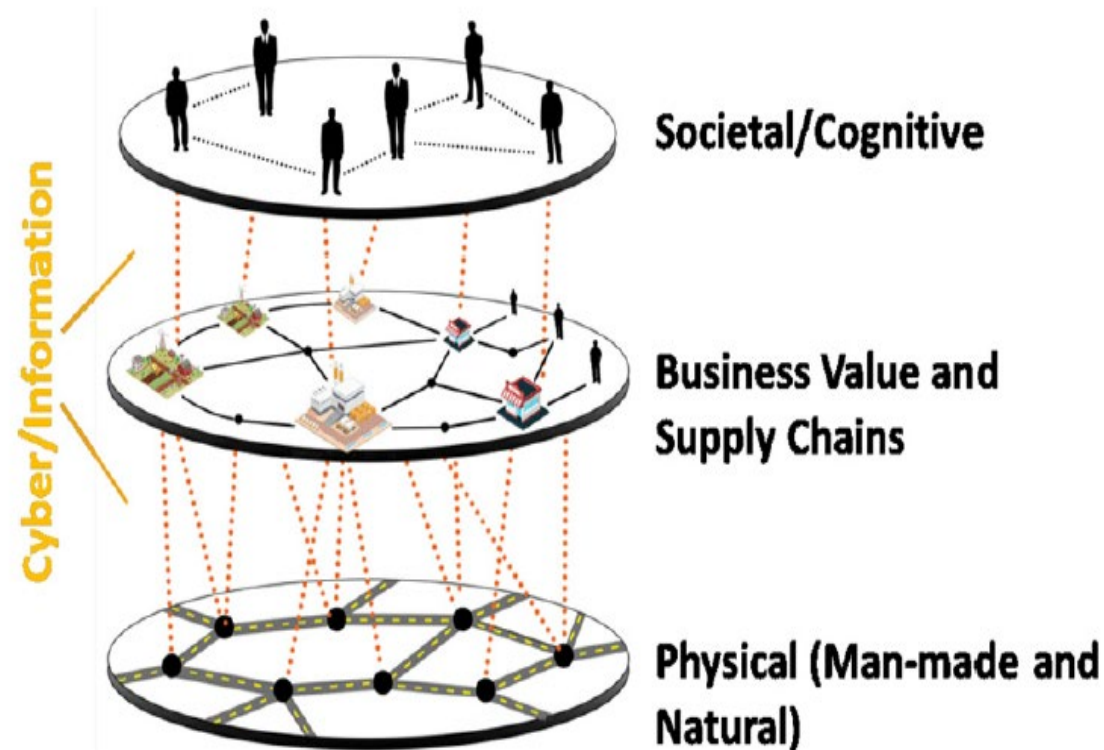
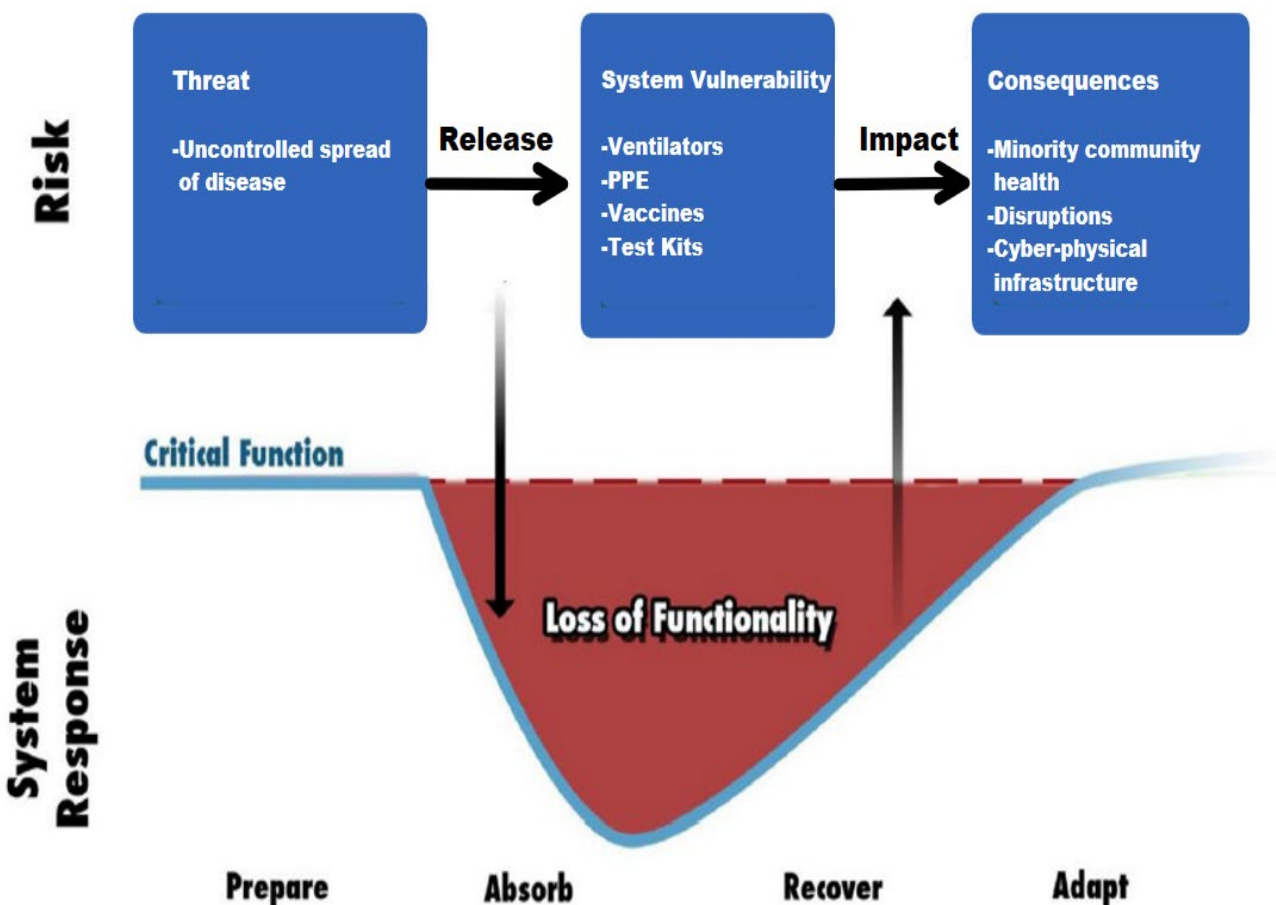


Trump, B., Cummings, C., Kuzma, J., and Linkov, I. (2020). *Synthetic Biology 2020: Frontiers in Risk Analysis and Governance*. Springer: New York, NY. DOI: 10.1007/978-3-030-27264-7

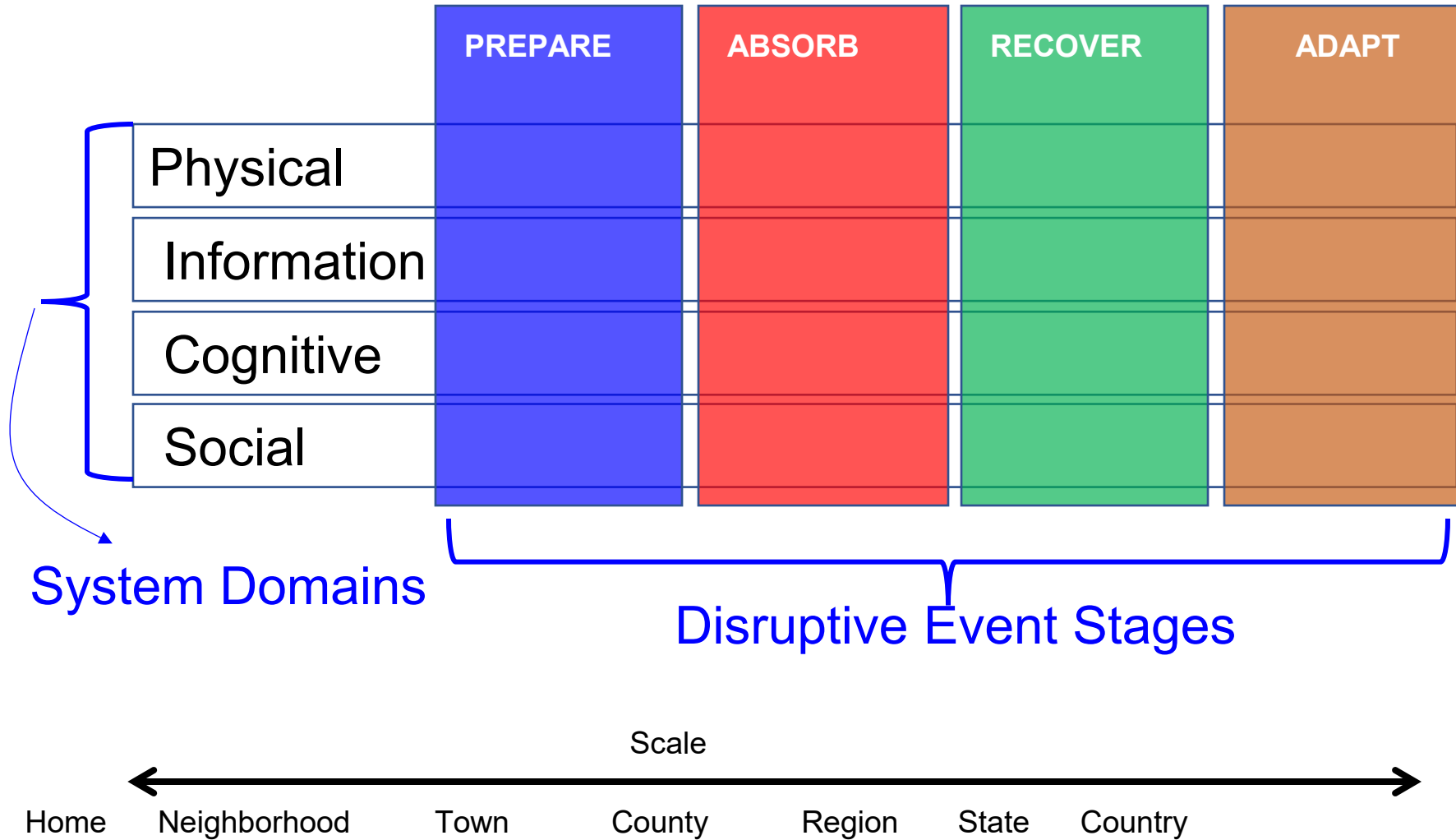
# Dealing with Systemic Threats

## Biosecurity Demands Resilience

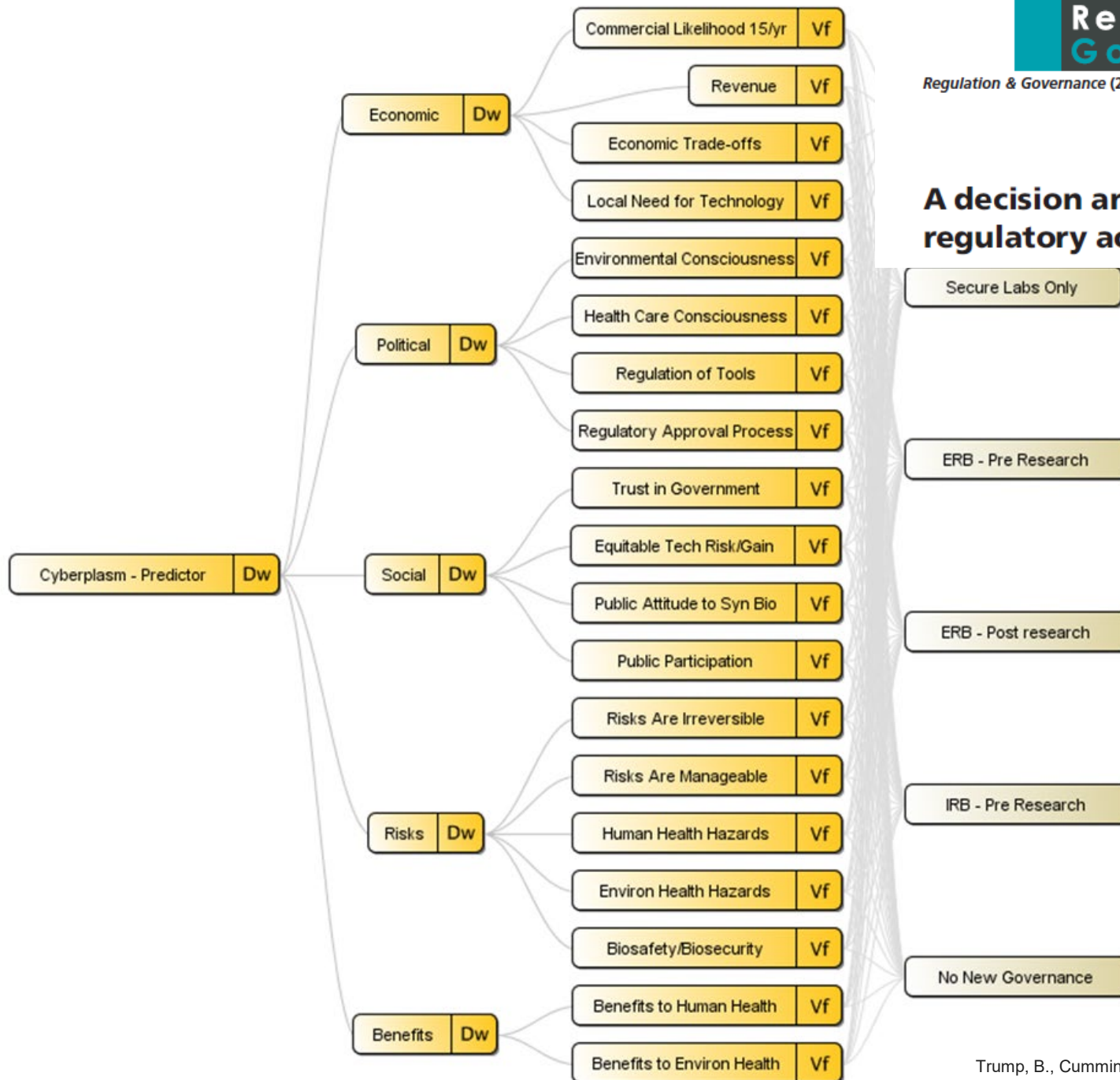
Benjamin D. Trump,\* Jeffrey M. Keisler, Kaitlin M. Volk, and Igor Linkov\*



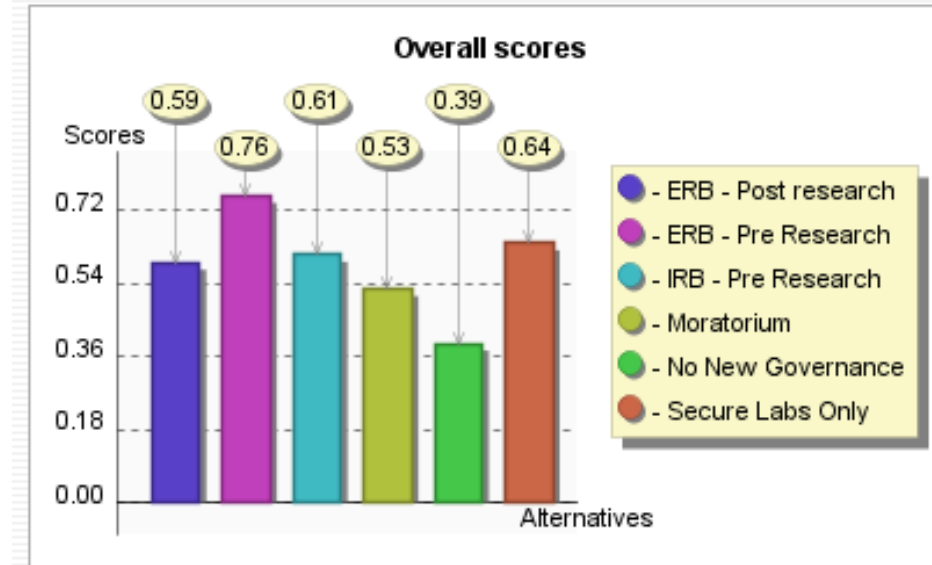
# Resilience Quantification – Resilience Matrix



## A decision analytic model to guide early-stage government regulatory action: Applications for synthetic biology



### Report (MAVT)



### Resulting values of alternatives

IRB - Pre Research score = 0.611

Moratorium score = 0.527

No New Governance score = 0.392

Secure Labs Only score = 0.640

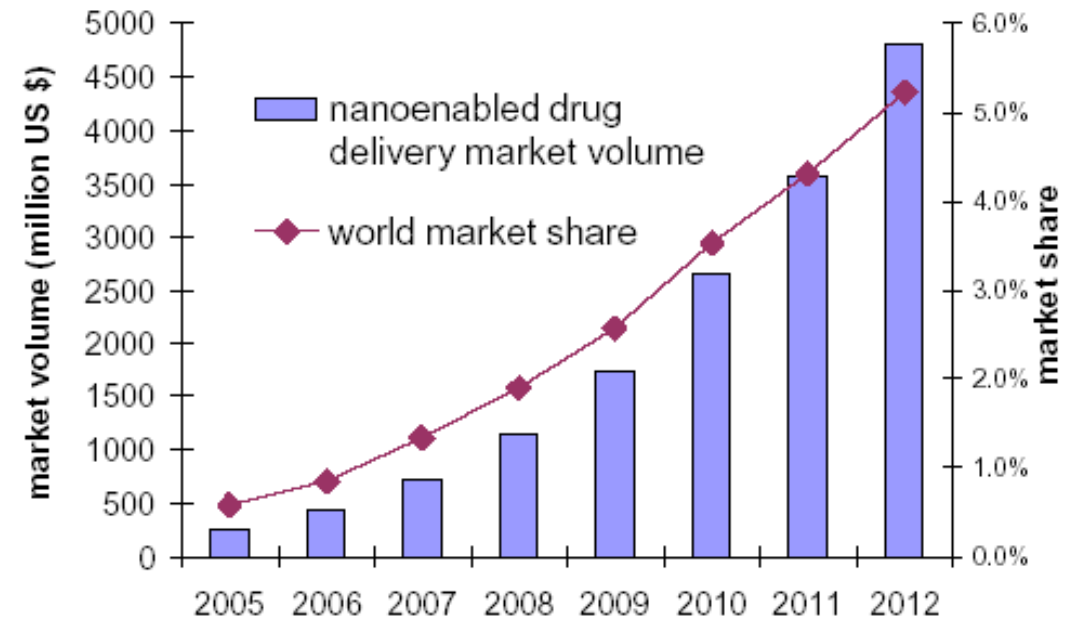


# Learning from Nano --Emerging Nanotech Market (*aka 2005, good old days...*)

Slide from my  
presentation  
in 2005

- Current State
  - R&D Surging – Global Nano R&D \$9 billion
  - Nano Patents to Date – 4,000 US Patents
  - Over \$32 Billion in Nano-products Sold in 2005
- Near Future
  - Estimated market of \$2.6 trillion by 2014
  - 2015 – 15% of Global Manufacturing will use nano

## Nano-enabled drug delivery market



Source: Moradi, 2005



December 2, 2005  
External Review Draft

**Slide from my  
presentation  
in 2005**

# **U.S. Environmental Protection Agency**

## **EXTERNAL REVIEW DRAFT**

### **Nanotechnology White Paper**

#### **Workgroup Co-Chairs**

**Jeff Morris**

Office of Research and Development

**Jim Willis**

Office of Prevention, Pesticides and  
Toxic Substances

#### **Science Policy Council Staff**

Kathryn Gallagher  
Office of the Science Advisor



# EPA Nanotechnology White Paper: Peer Review Panel Recommendations

- Develop a **“nano periodic table”** that defines a framework or a roadmap for assessing patterns and structure activity and physio-chemical properties.
- Complete **full in vivo characterization** of several key (1-3) nanomaterials.
- Determine **relevance of in vitro assays for predicting in vivo effects of nanomaterials** for both ecological and human health effects.
- Develop and utilize a framework to methodically identify potential releases of nanomaterials and assess their associated **risks through the complete product lifecycle**.
- Discuss the use **of multi-criteria decision analysis, value of information analysis, and adaptive management** that supplement a risk assessment framework which can be used to prioritize nanotechnology research needs.

Slide from my  
presentation  
in 2005

# EPA Nanotechnology White Paper: Peer Review Panel Summary

Slide from my  
presentation  
in 2005

- **Risk Assessment Challenges**
  - Current risk assessment experience is for chemicals and stable agents and not for engineered materials
  - Relation of pattern, structure-activity and physico-chemical properties of nanoparticles on toxicity and risk is widely unknown
  - Uncertainty in exposure assessment, risk characterization and dose-response is unprecedented
- **Regulatory Challenges**
  - Immediate regulatory need
  - Environmental evaluations and decisions are growing more complex and current RA paradigm may not be appropriate

# Main Ideas

- Risk Assessment and Management in traditional framing is very difficult if not impossible for SynBio, **transition to Risk Governance and Resilience**
- Multi Criteria Decision Analysis as foundation for Risk Governance, **prevention and containment is not enough**
- Novel functions and properties require **resilience approaches to manage unknowns and emergent behaviors**
- Experience with Nano – do not reinvent the wheel and **Start Right from the beginning!**



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Environmental Security

# Biotechnology and AI: Technological Convergence and Information Hazards

Edited by  
Christopher L. Cummings · Benjamin D. Trump ·  
Valentina Prado · Beth Ellinport · Igor Linkov

 Springer

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The NATO Science for Peace  
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Risk, Systems and Decisions

Benjamin D. Trump  
Christopher L. Cummings  
Jennifer Kuzma  
Igor Linkov *Editors*

# Synthetic Biology 2020: Frontiers in Risk Analysis and Governance

 Springer

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

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