Policy Landscape

Army Roundtable on Synthetic Biology

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PILLARS OF LIFE SCIENCE POLICY

These pillars have not largely changed – but the life sciences landscape has changed.

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Biosafety

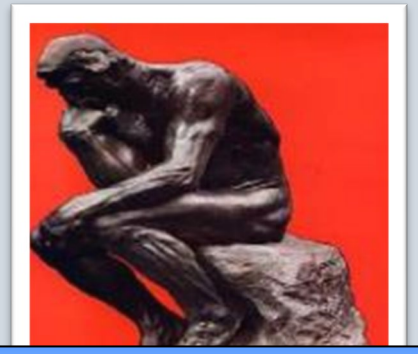
Accidental exposure to pathogens, toxins, or genetically engineered organisms that harms:

Laboratory workers
General public
Plants, animals
Environment
Materiel

Biosecurity

Deliberate misuse of technology to cause harm to:

Humans
Plants
Animals
Environment
Materiel
Economies



Societal Norms & Ethics

Controversial uses of technology:

Germline interventions
Enhancements
Genetically modified organisms
Harm to humans, plants, animals, environment, societies

US Life Sciences policy has been *reactive*

The iterative nature of policy creation AFTER negative events creates a patchwork that is not predictive or strategic.

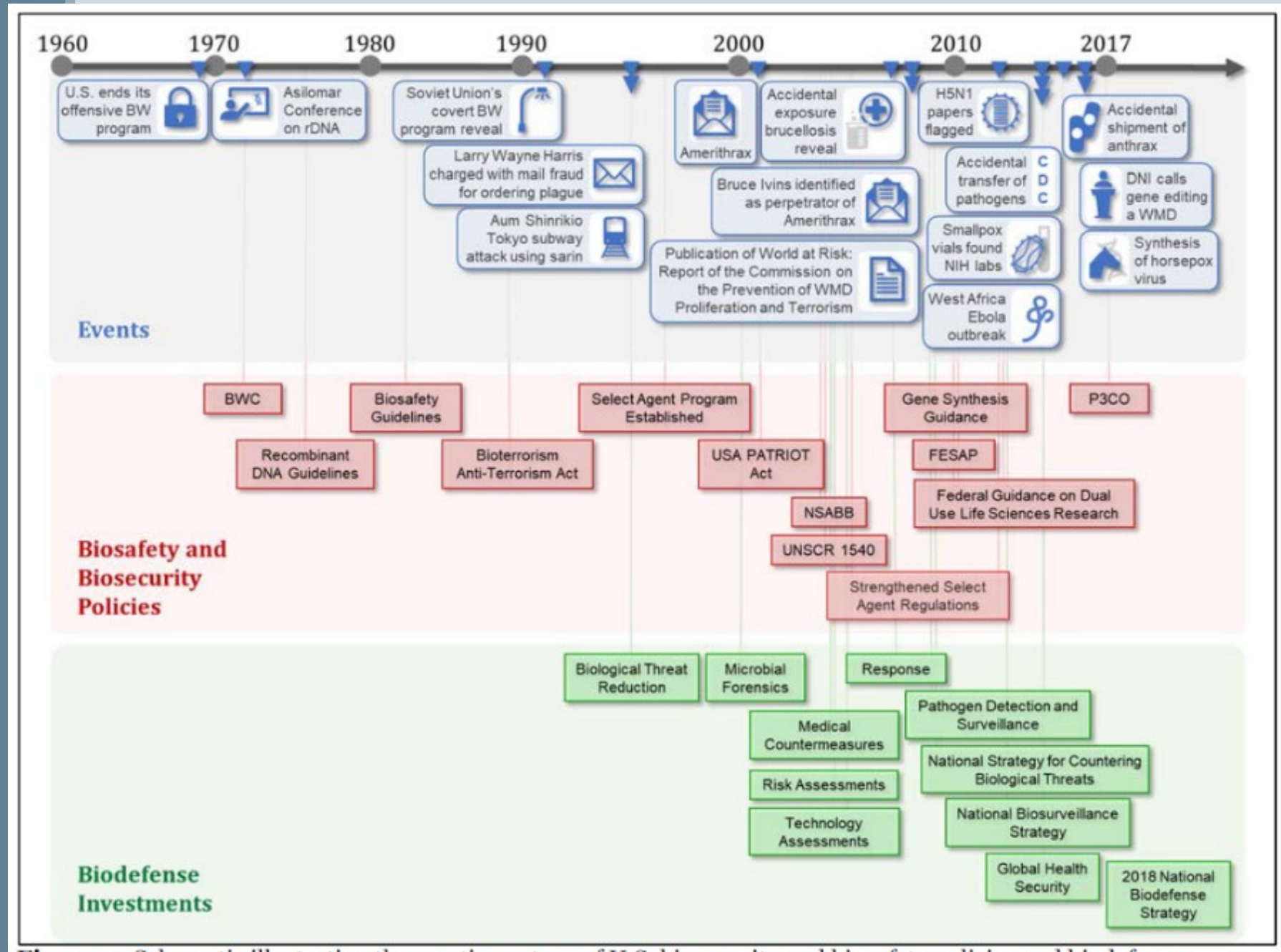
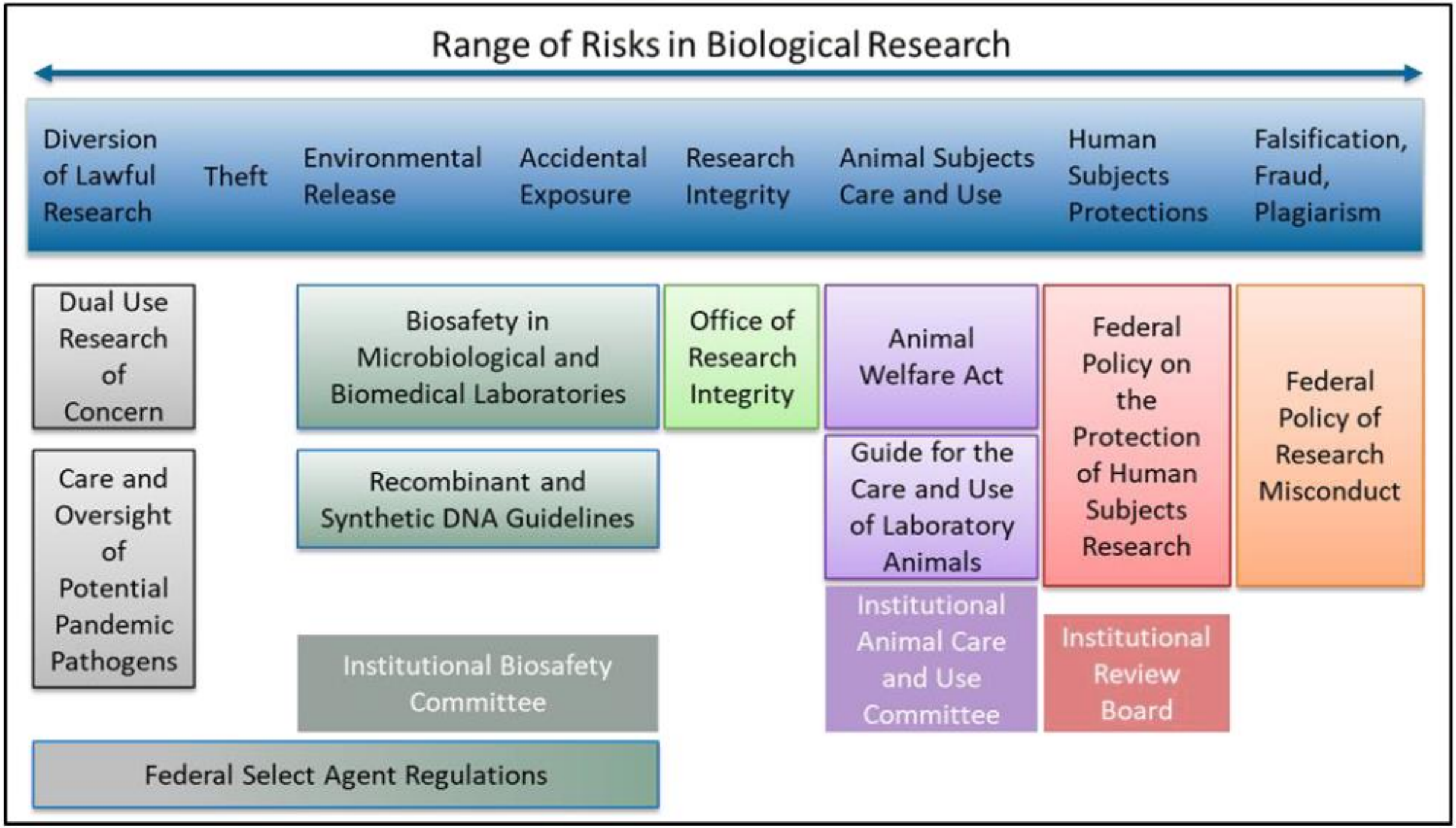


Figure 2. Schematic illustrating the reactive nature of U.S. biosecurity and biosafety policies and biodefense

Drivers of Life Sciences Policies and Governance


Range of Risks in Biological Research
Diversion of Lawful Research
Theft
Environmental Release
Accidental Exposure
Research Integrity
Animal Subjects Care and Use
Human Subjects Protections
Falsification, Fraud, Plagiarism
Dual Use Research of Concern
Care and Oversight of Potential Pandemic Pathogens
Biosafety in Microbiological and Biomedical Laboratories
Recombinant and Synthetic DNA Guidelines
Institutional Biosafety Committee
Federal Select Agent Regulations
Office of Research Integrity
Animal Welfare Act
Guide for the Care and Use of Laboratory Animals
Institutional Animal Care and Use Committee
Federal Policy on the Protection of Human Subjects Research
Institutional Review Board
Federal Policy of Research Misconduct

USDA FDA EPA United States Environmental Protection Agency

The Unified Website for Biotechnology Regulation

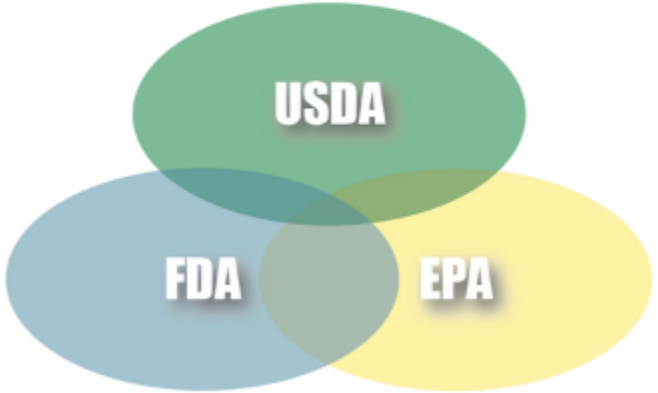
The U.S. Coordinated Framework for Biotechnology
biotechnology products. The goal of the Coordinate
predictability, coordination, and, efficiency of the bio

About the Coordinated Framework

History of the Coordinated Framework

In 1986, the White House Office of Science and Technology Policy (OSTP) published the U.S. Coordinated Framework for the Regulation of Biotechnology, describing the comprehensive federal regulatory policy for ensuring the safety of biotechnology products. The framework sought to protect health and the environment without impeding innovation.

In 1992, OSTP issued an update to the framework that set forth a risk-based, scientifically sound basis for the oversight of biotechnology products introduced into the environment or used for human or animal food. The update affirmed that federal oversight should focus on the characteristics of the product and the environment into which it is being introduced, not the process by which the product is created. A more recent update in 2017 is described in more detail below.



USDA SECURE Rule Paves Way for Agricultural Innovation

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Print

(Washington, D.C., May 14, 2020) U.S. Secretary of Agriculture Sonny Perdue today announced a final rule updating and modernizing the U.S. Department of Agriculture's (USDA) biotechnology regulations under the Plant Protection Act. The Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule will bring USDA's plant biotechnology regulations into the 21st century by removing duplicative and antiquated processes in

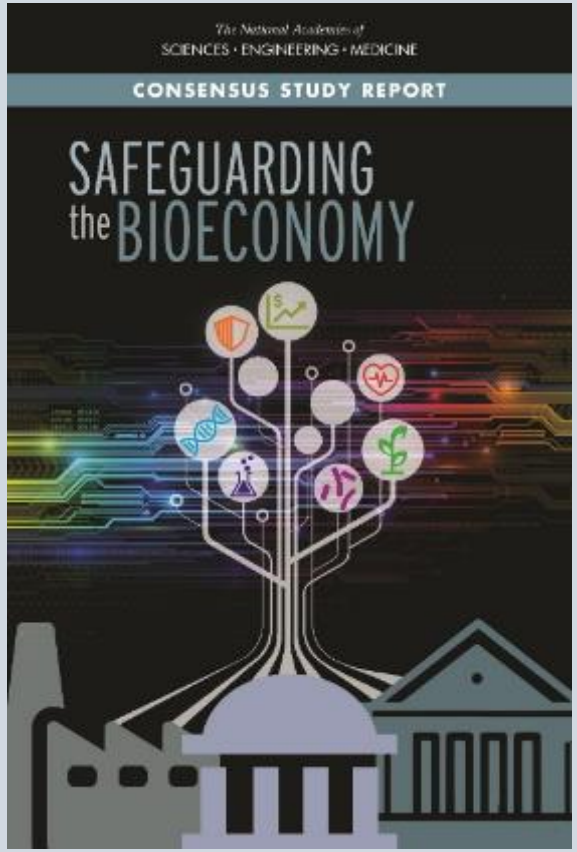
Now – we have emergence of a diverse Bioeconomy

Range of Risks in Biological Research

Diversion of Lawful Research	Theft	Environmental Release	Accidental Exposure	Research Integrity	Animal Subjects Care and Use	Human Subjects Protections	Falsification, Fraud, Plagiarism

Range of Risks Associated with Bioeconomy*

Product diversion/ tampering	**Theft, espionage, IP breach**	**Environmental release**	**Financial surety (foreign Investment)**	**Sabotage/ Critical Infrastructure concerns**	**Trade Barriers/ International data constraints**



***Many are subject to CYBER risks – generating the need for "digital biosecurity"**

Lack of Public Trust or Conflict with Public Values

- the safety, environmental, or land implications of the *use of genetic engineering in agriculture* or of the production of crops for biofuels;
- the consequences of the release or potential *release of genetically engineered organisms into the environment;*
- the *distribution of economic benefits* between producers and consumers, or among producers of different sizes;
- the distribution of economic benefits between those who generate economic value from genetic information and those who had *sovereignty over the specimens* from which that genetic information was originally obtained;
- *lack of confidence in government* regulatory bodies;
- the *price* of biotechnology-derived medical therapies;

the *ethics and propriety of modifying human DNA*;

- the ethics and propriety of engineering other living organisms;
- the application of biotechnology to human reproduction, including the *modification of DNA of future generations;*
- propagation of misinformation on the internet that can put public health at risk
- *violations of personal privacy* due to unauthorized release of one's own or one's relative's genetic information;
- the potential use of biotechnology by those *deliberately seeking to inflict harm.*

Lack of Public Trust or Conflict with Public Values

HUMAN HEALTH CONCERNS

CONCERNS FOR THE ENVIRONMENT

(weapons use)

Scenarios: HOW WILL THE ARMY USE SYNTHETIC BIOLOGY?*

Direct use in Humans	• Microbiome drinks, Food/MREs, gene therapy, genetic manipulation (transient or permanent), nano-bio Rx, Medical Countermeasures, etc.
Applied to humans	• Topical microbes, medical tattoos, skin grafts, uniforms of novel or living materials, eye drops, etc…
Employed Deployed	• Sensors (extrinsic or intrinsic to environments), biomaterials, coatings, Gene drives, terraforming, etc
Industry manufacture	• Synbio platforms, engineered organisms, etc.

*all of these will traverse R&D, Translation, Manufacturing, Scaling, Fielding, etc

Table 1
Regulatory Coverage of Synthetic Biology Across Cases (added to [25]).

Novel Health Risk	United States	European Union
Gene transfer	TSCA Section 5; PPA 7712, 7414	Directive 2001/18/EC
Mutation and Proliferation	TSCA Section 5	Directive 2001/18/EC
Ecosystem Health and Biodiversity	TSCA Section 5; PPA 7712, 7414	Directive 2001/18/EC; Directive 2015/412
Commercial Consumption	TSCA Section 5 (postmarket environmental review); FDCA Ch.5. (pre- and post-market human health review)	Regulation (EC) 1829/2003
Laboratory/Worker Safety	NIH Guidelines for Recombinant DNA Molecules; OSHA 1910.1200	Directive 2009/41/EC; Directive 2000/54/EC
Accidental Release of Premarket Material	NIH Guidelines for Rec Molecules	
Pharmaceutical Development	FDCA Chapter 5; NEPA Section 102 (for pest material)	
Import, Export, and Shipment	TSCA; FDCA Chapter 5	

BECOM

EBRC Engineering Biology Research Consortium

POLICY + INTERNATIONAL ENGAGEMENT

How will we use synthetic biology?

HOW INVASIVE is it? IS IT REVERSIBLE?

IS IT BEYOND THE KINDS OF THINGS HUMANS CAN NATURALLY DO?

IS IT A RISK/TARGET FOR AN ADVERSARY?

DOES IT COMPROMISE OTHER CAPABILITIES?

WHATS HAPPENS TO WARFIGHTERS WHEN THEY LEAVE THE FORCE?

WHAT ABOUT THOSE WHO ENTER THE FORCE WITH ALTERATIONS?

How will society treat those who are altered?

International Policy surrounding Synthetic Biology?

Focused on *sharing and economic benefits*

- Convention on Biological Diversity (CBD) & Nagoya Protocol;

Focused on biosecurity

- Biological Weapons Convention
- Australia Group
- IGSC/US DNA screening frameworks

The ABC's of ABS for the Nagoya Protocol

Access

- Must first get permission from the provider country, know as prior informed consent (PIC), unless otherwise determined by the provider country.

Benefit-sharing

- Will need to negotiate an agreement to share benefits resulting from the use of the genetic resources; shall be upon mutually agreed terms (MAT).

Compliance

- Parties shall take appropriate measures to ensure that genetic resources utilized within its jurisdiction have been accessed in accordance with PIC and MAT (an internationally recognized certificate of compliance).

Where else do these issues come up?

- **World Intellectual Property Organization (WIPO)**
  - Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
- **UN General Assembly (UNGA)**
  - Biodiversity Beyond National Jurisdiction (BBNJ) negotiations
- **Food and Agriculture Organization (FAO)**
  - Commission on Genetic Resources for Food and Agriculture
- **World Health Organization (WHO)**
  - Pandemic Influenza Preparedness (PIP) Framework
- **International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)**
  - Revised Standard Material Transfer Agreement
- **U.S. Trade agreements/negotiations (bilateral and multilateral)**

The Nagoya Protocol Learning Portal

LearnNagoya.com

- Key features:
  - Benefit sharing examples
  - Use cases
  - Curated resources
  - Guides and templates

What assists with Policy/Governance concerns or barriers?

"*Approaches to Risk and Benefit Assessment for Advances in the Life Sciences"* (submitted by the United States of America). Meeting of Experts on Review of developments in the field of science and technology related to the Convention. Geneva, 2019. https://undocs.org/en/bwc/msp/2019/mx.2/wp.3

Utilize a "toolkit" of Standards, Checklists, Risk Assessment Frameworks, Mitigation, monitoring, norms, guides, etc.

Transparency, Accountability, Participation,Integrity, Capacity*

*It's the governance, stupid!: TAPIC: a governance framework to strengthen decision making and implementation 2019 https://pubmed.ncbi.nlm.nih.gov/32045179/

thank you!

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