



Image credit: BBC Science Focus 2023

M3-F: Roundtable: Interdisciplinary Perspectives on the U.S. Executive Order on Biotechnology

1:30-3pm



Khara Grieger
Assist. Prof.
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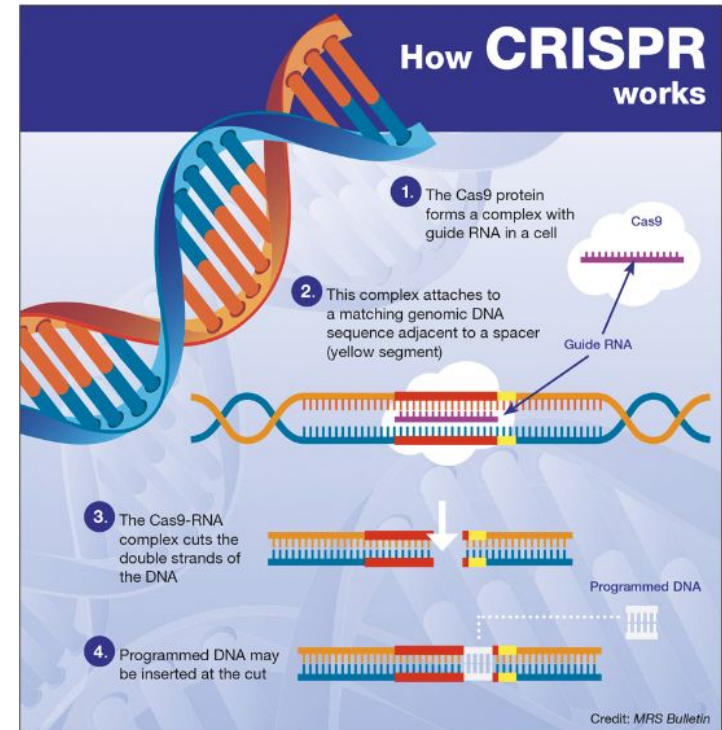
Nick Loschin
PhD student
NC State



Ilaria Cimadori
PhD student
Yale

Potential for biotechnology

- Biotechnology hold potential for more sustainable and resilient societies
- Biotech = range of techniques to modify or engineer living organisms
 - Genetic engineering and genome editing to insert or modify specific genes or gene sequences
- Innovation of agricultural biotechnologies may improve food quality and nutrition, enhance sustainable agriculture



Potential for biotechnology in food and agriculture

Purple tomato



Non-browning apples



Better tasting mustard greens



Faster-growing salmon



Heat-tolerant cattle



US Executive Order to Advance Biotech and Bioeconomy

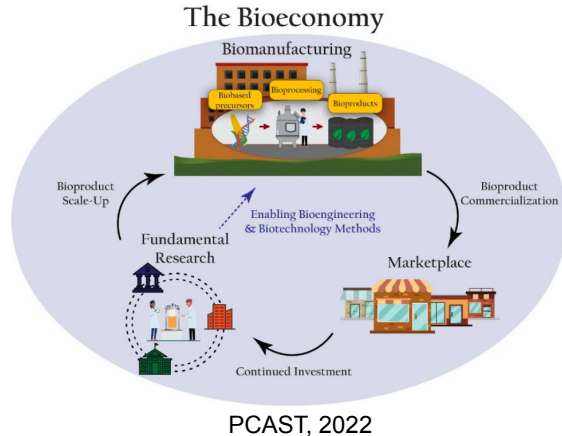
THE WHITE HOUSE



SEPTEMBER 12, 2022

Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy

THE WHITE HOUSE
BRIEFING ROOM
PRESIDENTIAL ACTIONS



- US strategic plan to promote biotech and bioeconomy
- Opens policy window for regulators to respond to stakeholder input to modify process, regulation, and oversight

US Executive Order to Advance Biotech and Bioeconomy

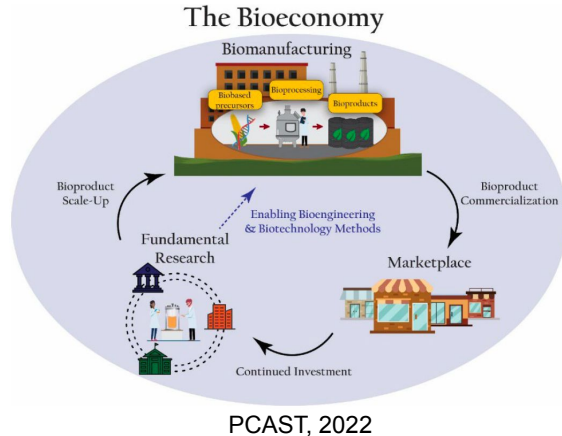
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SEPTEMBER 12, 2022

Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy

THE WHITE HOUSE | BRIEFING ROOM | PRESIDENTIAL ACTIONS



Sections:

1. Policy
2. Coordination
3. Harnessing Biotechnology and Biomanufacturing R&D to Further Societal Goals
4. Data for the Bioeconomy
5. Building a Vibrant Domestic Biomanufacturing Ecosystem
6. Biobased Products Procurement
7. Biotechnology and Biomanufacturing Workforce
8. Biotechnology Regulation Clarity and Efficiency
9. Reducing Risk by Advancing Biosafety and Biosecurity

US Executive Order to Advance Biotech and Bioeconomy

Section 8. Biotechnology Regulation Clarity and Efficiency

- Identify areas of confusion or gaps in current rules
- Clarify what each agency is responsible for
- Make a plan to improve rules, including updates/clarifying existing regulations or create new regs if needed
- Improve the website where developers can ask questions
- Review every 3 years and propose revisions as needed

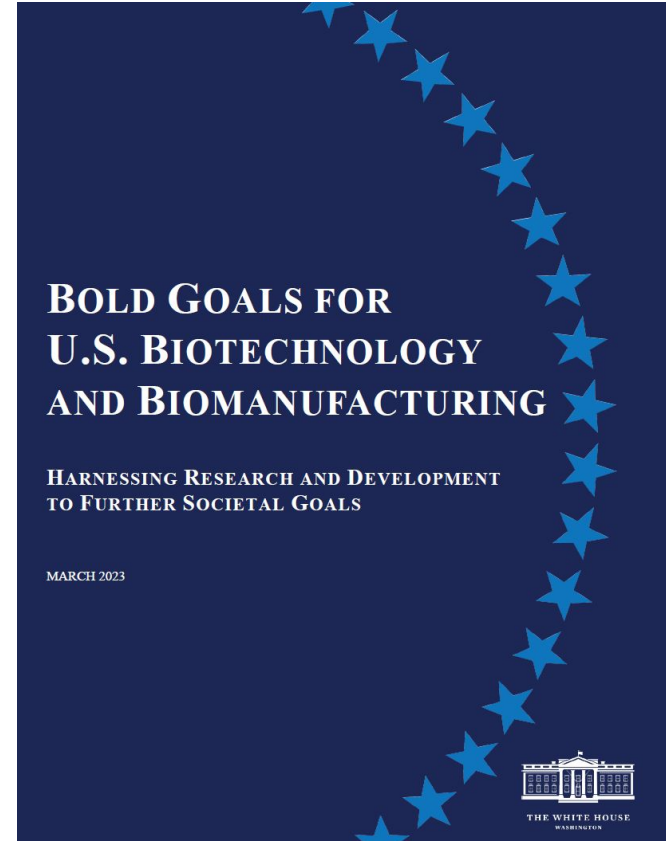
Section 9. Reducing Risk by Advancing Biosafety and Biosecurity

- Prioritize investments in research to support safe biotechnology and bioeconomy processes
- Create a plan for bio-safety and security, mainly for biological risks
- Funding to encourage and improve safety practices
- Review and report safety of biomanufacturing

US Executive Order to Advance Biotech and Bioeconomy

White House Report on Bold Goals

- Climate Change Solutions
- Food and Agriculture Innovation
- Supply Chain Resilience
- Human Health
- Cross-Cutting Advances



Roundtable: Interdisciplinary Perspectives on the U.S. Executive Order on Biotechnology

Goal: Discuss strengths and limitations of EO from range of perspectives

- Each panelists will present their perspectives, discuss impact on research, innovation, oversight of biotech in food and agriculture systems
- Open Q&A Discussion



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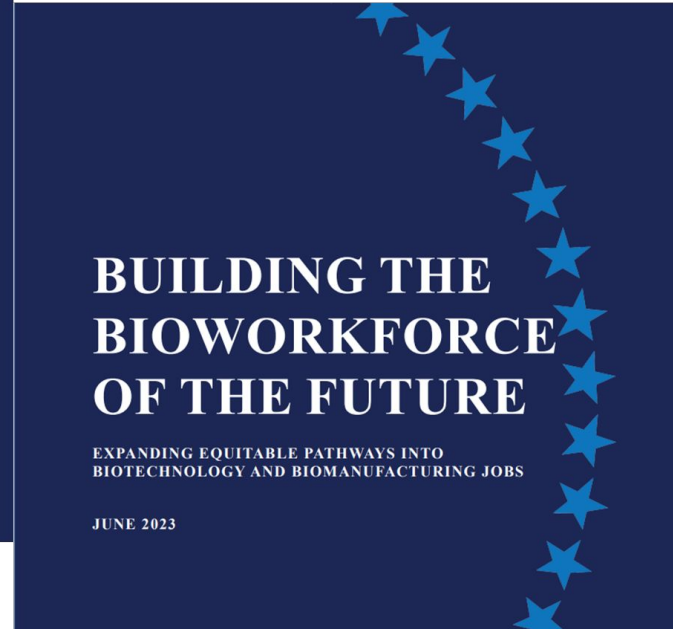
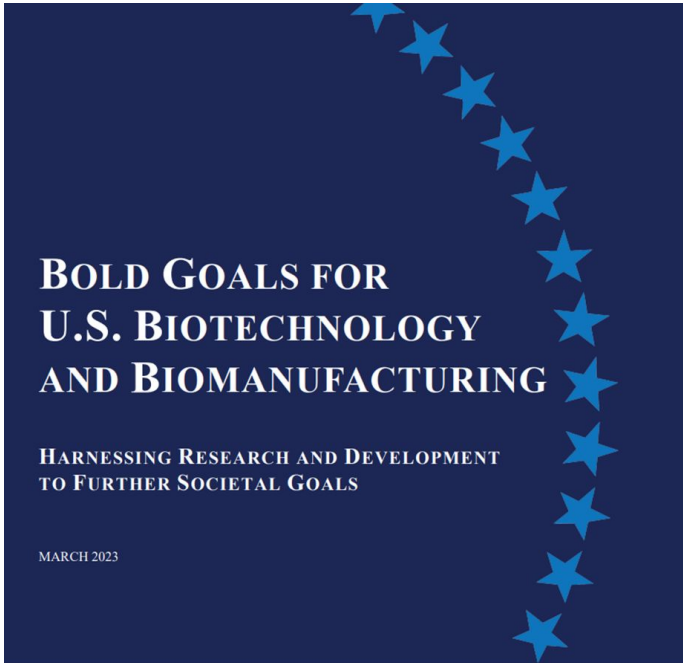


Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

- The Executive Order Update
- Bioeconomy as it relates to agriculture and food
 - Research, Development and Demonstration
 - Investments
 - Products and Markets
- USDA Biotech Regulation Update



Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA





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Biotechnology and Biomanufacturing in Food and Agriculture Innovation

USDA's bold goals center on three themes:

1. Improve sustainability while increasing productivity
 - Increase climate-smart feedstock and biofuel usage
 - Reduce nitrogen and methane emissions
 - Reduce food waste
2. Increase food nutrition, quality, and consumer choice
 - Enhance food nutrient density
 - Develop new food and feed sources
 - Reduce foodborne illness
3. Protect plants and animals against environmental stress
 - Detect and mitigate pests and pathogens
 - Improve plant and animal resilience to environmental stress





Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

EO Upcoming Deliverables

- Recommendations for bioeconomy-related revisions to NAICS and NAPCS
- Plan to support the resilience of the United States biomass supply chain for domestic biomanufacturing and biobased product manufacturing, while also advancing food security, environmental sustainability, and the needs of underserved communities.
- Biomanufacturing report
- Data for the bioeconomy



Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

USDA Activity Supporting the Bioeconomy in FY23



Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

USDA Bioeconomy Research and Development

- Research on plant, animal and microorganism genetics and genomics to improve productivity and resilience to pests, diseases, and climate change
 - Genetic engineering, gene editing, functional genomics, transcriptomics, proteomics, metabolomics, genetic resources, etc.
- Bioenergy research on the agronomic production of crops that can be used as dedicated feedstocks for bioenergy and use of agricultural wastes for energy production, such as manure digestion for biogas production
- Forestry research in the production, utilization, and protection of forestland
- Research into alternative proteins, including cell-cultured meat



Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

Examples of R&D Funded Projects

- RIPE (Realizing Increased Photosynthesis Efficiency) -- engineering crops to be more productive by improving photosynthesis.
- “Manureshed” management research program – examine the entire spectrum of manure production, distribution, and use. Innovative systems to turn byproducts into beneficial resource for crop producers
- Developing biobased methods to convert vegetable oils and compounds into products for the personal care market
- Establish a National Institute of Cellular Agriculture, which focuses on cell-cultured meat
- NIFA Bioproducts program: Funding to Soylei Innovations for a project that proposes to transform high oleic soybean oil into thermoplastic rubber for pavements



Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

Investment in Bioeconomy infrastructure, manufacturing capacity and product development

- Rural Development area has invested in different loan guarantee and grant programs
 - Higher Blends Infrastructure Incentive Program
 - Fertilizer Production Expansion Program -- renewable sources such as compost and animal waste
 - Rural Energy for America Program -- Biomass and Biogas projects
 - Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program (9003)
- USDA Forest Service funded projects to support innovation, market development, and new and expanded manufacturing capacity of wood-based products



Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

BioPreferred Program

- Identifies and seeks new markets for biobased products
- Spurs economic development, creates new jobs, increases the use of renewable agricultural resources, etc.
- Two major program elements:
 - Voluntary Labeling Program
 - A Federal Procurement Preference



*Skillcraft
Biobased Cleaner*



*Sink made from
plant-based resins*

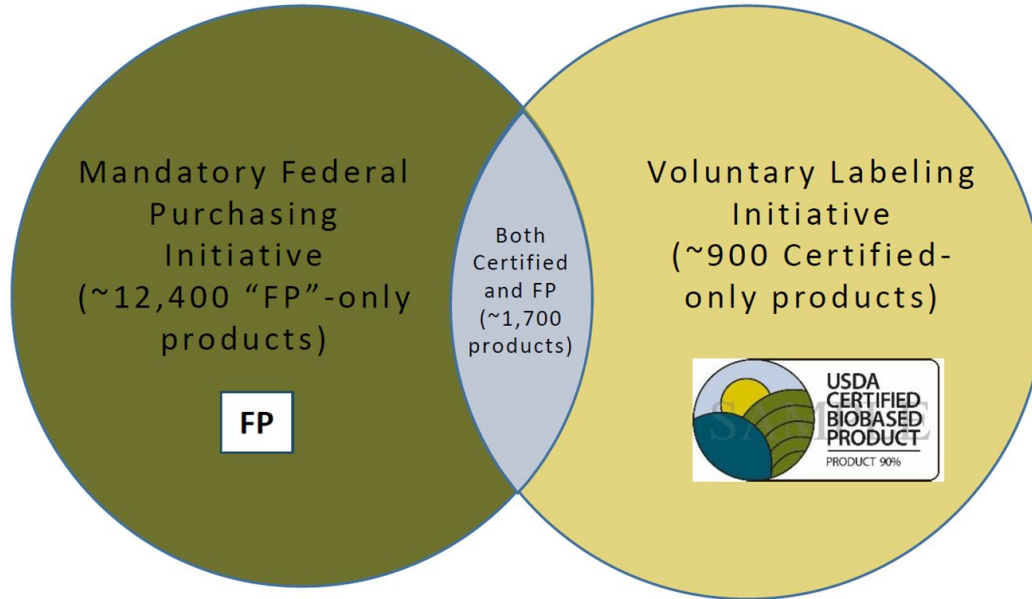
<https://www.biopreferred.gov/>

*Biobased linoleum made
from linseed oil, pine
rosins, wood flour*





Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA



In FY23, 1,456 new products were added to the BioPreferred Catalogue and 521 new companies are offering BioPreferred products.



Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

Ongoing



Explore Regulatory Process for Microbes



Streamline Regulatory Status Review Process and a Business Process Improvement Project for Permits



Multiyear release permit for annual plant species



Work with interagency partners to further harmonize roles, processes and requirements





Gregory Jaffe - Senior Advisor for Regulatory Affairs, Office of the Secretary, USDA

USDA Bioeconomy Goals

- Improve **food security**
- Strengthen **supply chains and increase competition**
- Reduce impacts of **climate change** and make agriculture more sustainable
- **Create jobs** across America, especially in rural communities

Christopher Cummings - Research Social Scientist, US Army Corp, NC State



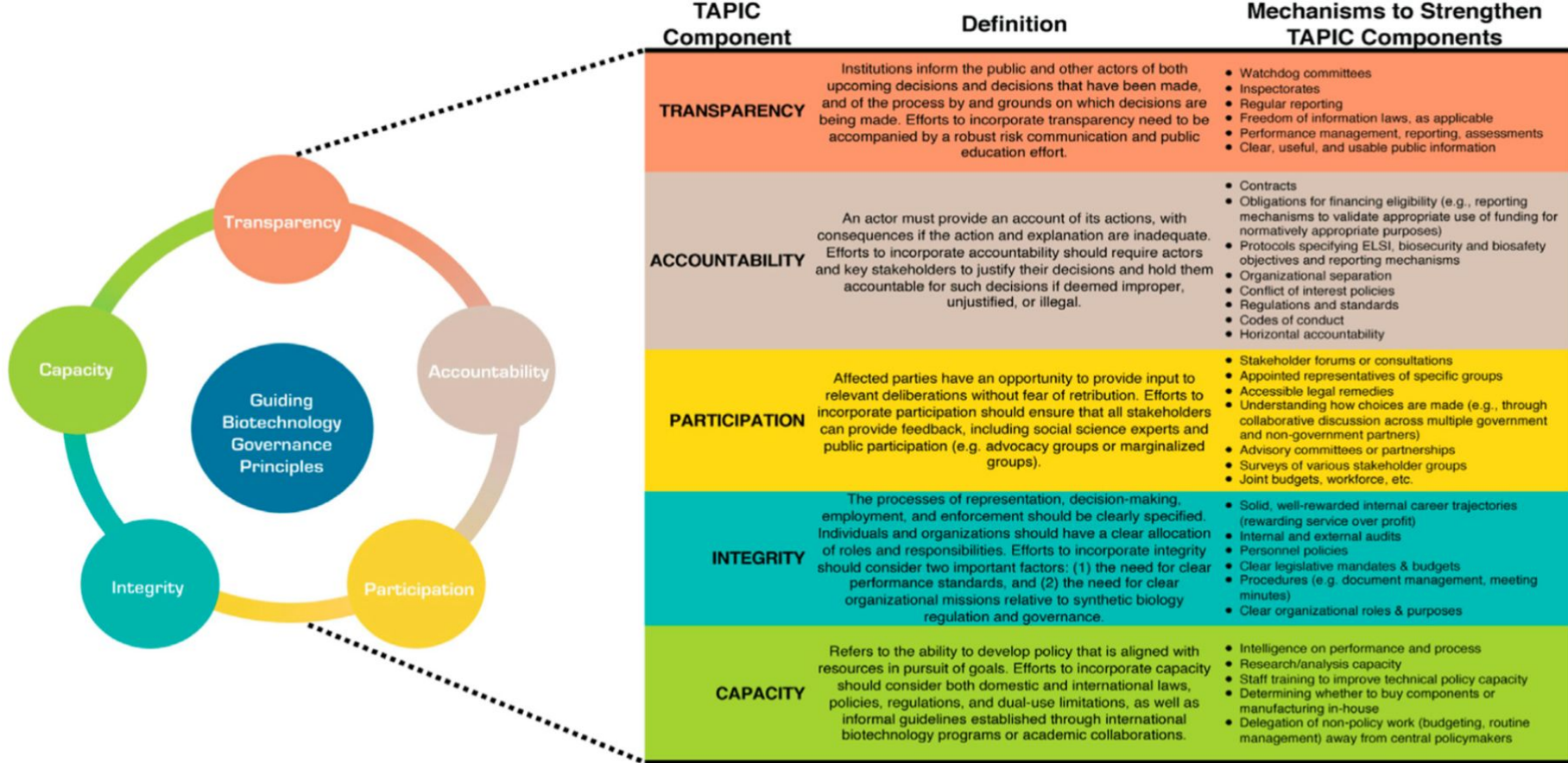
Biotechnology industry	Description of application
Industrial Biotechnology	Application of biotechnology for streamlined production and refinement of industrial materials (e.g., the development of enzymes as catalysts to produce, modify, or remediate specific chemical substances)
Environmental Biotechnology	Application of biotechnology capabilities to remediate contaminants in the environment, facilitate biodiversity and protection of at-risk species etc.
Medical Biotechnology	Application of biotechnology to foster new therapeutics, medical procedures, or medical devices for the advancement of human health
Agricultural Biotechnology	Application of biotechnology to amplify available crop production processes (e.g., engineering transgenic plants suitable for specific environments or consumption targets)
Marine Biotechnology	Application of biotechnology to engineer, improve, or utilize sea resources in a sustainable fashion (e.g., engineered algae for algal ethanol and oil byproducts)
Informatics	Synthesis of computational and biological sciences to better understand biological data, particularly in the field of genomics, to better understand the organizational principles of the genome

	Future Biotechnology Concerns	Suggested Solutions to Concerns
Biosafety	<ul style="list-style-type: none"> Short- and long-term human health risks Lack of clear benchmarks or metrics to evaluate hazard, exposure, effects Need for up-to-date biosafety training across all stages of product development Lack of proper classification of risk with emerging technologies Growing risk of information hazards 	<ul style="list-style-type: none"> Standardization of safety evaluations Develop tests, benchmarks, or metrics to characterize hazard, evaluate exposure scenarios, parameterize intended and unintended effects Create case-specific 'gold standard' assays and <i>In situ</i> testing methodologies Create remediation agents and therapeutics to mitigate or remove potentially harmful genetically modified agents Strict monitoring of research on gain-of-function and identification of possible information hazards
Biosecurity	<ul style="list-style-type: none"> Purposeful or negligent misuse Proprietary technology lost or stolen during manufacturing, use, and product end-of-life, leading to modification or misuse Development of new products or infrastructure that challenges status quo due to evolving implementation needs Misuse of technology or corruption of production systems 	<ul style="list-style-type: none"> Strong cybersecurity protocols Conduct continuous assessments and reflexive evaluations to identify emerging challenges in security needs Public and private oversight committees Material tracking capabilities and (e.g. cellular barcoding) Create clear guidelines for using kill switches Increased or improved vetting of personnel with access to potentially harmful organisms (i.e., select agent regulations)
Ethical Considerations	<ul style="list-style-type: none"> Lack of an informed public and affirmative consent regarding potential biological hazards and secondary/downstream risks Ethical opposition from specific public domains Erosion of public support for biotechnology development Environmental justice concerns Misinformation and negative media reporting of technology 	<ul style="list-style-type: none"> Establish adequate public voice in decision-making and governance Inclusion of bioethicists and at-risk communities and patient groups Ensure open and transparent communication streams with public regarding ongoing testing and evaluation of risk-based concerns
Legal Implications	<ul style="list-style-type: none"> Limited established legal oversight to guide approval of new products & extensive market approval timelines due to legal challenges Concerns related to patenting and proprietary ownership of innovative biotechnology products (especially among small businesses and joint development initiatives) Tort and liability concerns such as assigning duty of care and responsibility of product management and harm reduction 	<ul style="list-style-type: none"> Close loopholes in existing laws and address regulatory gaps Provide clear guidelines for risk and safety evaluations of novel biotechnologies Establish clear regulations for biotechnology products in pre-market and post-market review and oversight
Social Concerns	<ul style="list-style-type: none"> Disruptions to local economy and/or job markets Limited public knowledge of, understanding of, or approval of biotechnologies Equity issues among vulnerable, underrepresented, or marginalized populations Privacy concerns in how data is used, stored, or transferred 	<ul style="list-style-type: none"> Create product specific evaluation templates that considers potential sociocultural disruptions throughout product development process Ensure public engagement to incorporate diverse perspectives and ensure even distribution of product's public benefits Understand cultural norms and their impact on biotechnology development and adoption Transparent communication with public regarding intended use, safety protocols, and benefits of biotechnology Establishing robust risk transfer measures and duty-of-care protocols for individuals negatively affected by exposure to biotechnology products

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.

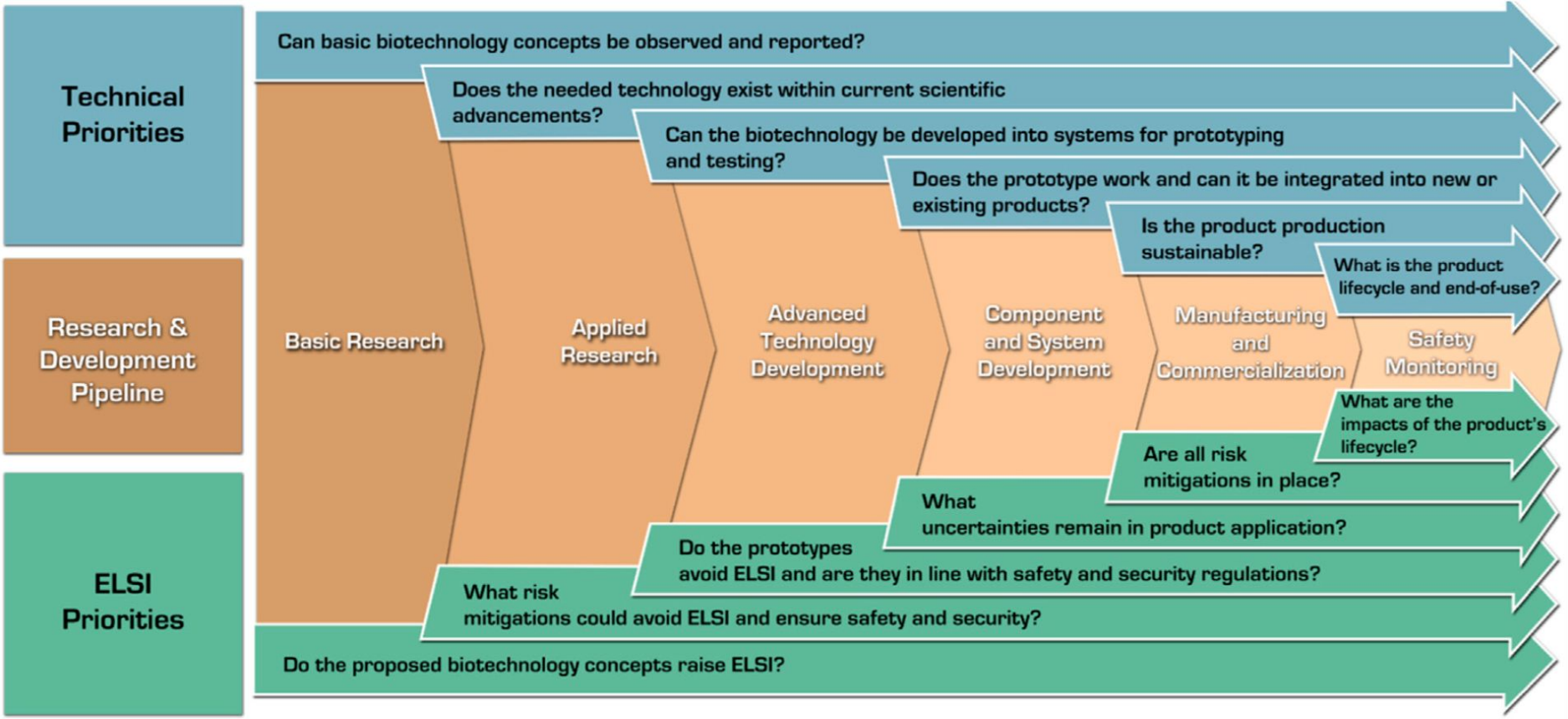
<https://doi.org/10.3389/fgene.2022.1052371>





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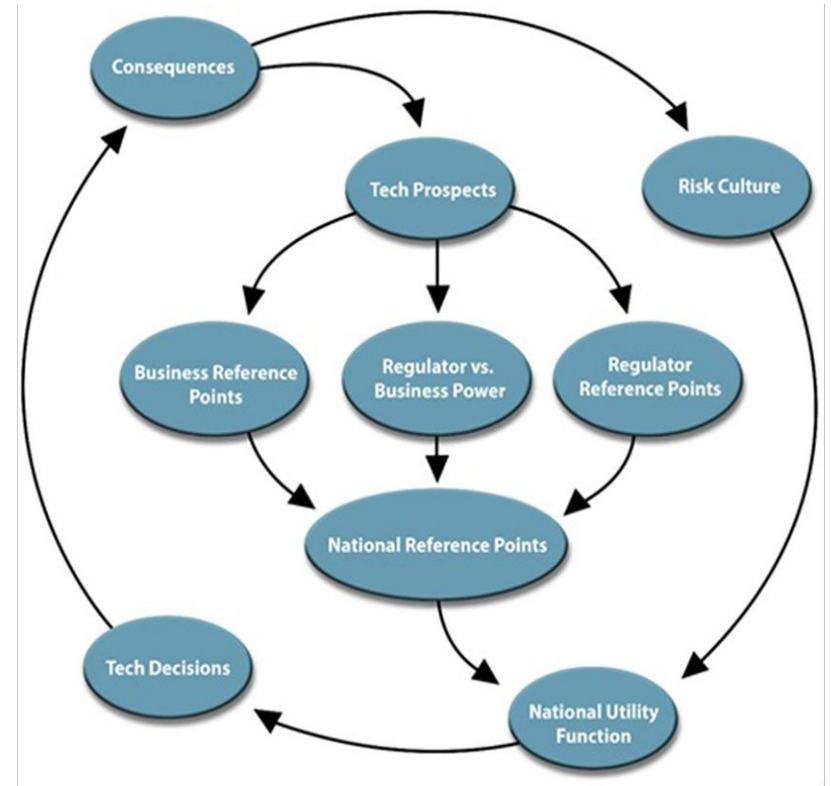




Trump, B., Cummings, C., Klasa, K., Galaitsi, S., & Linkov, I. (2023). Governing biotechnology to provide safety and security and address ethical, legal, and social implications. *Frontiers in Genetics*, 13, 1052371. <https://doi.org/10.3389/fgene.2022.1052371>



- Biotechnology advancements in the last two decades have led to a global divergence in technological modernization and capabilities.
- This divide has created significant international disparities in commercial and intellectual aspects of biotechnology.
- Prospect theory is employed to explore how risk culture contributes to this divide, offering insights into the future of biotech development and its impact on the global landscape.



Trump, B. D., Cummings, C. L., Loschin, N., Keisler, J. M., & Wells, E. M. (2023). The worsening divergence of biotechnology: the importance of risk culture. *Frontiers in Bioengineering and Biotechnology*, 11(2023), 1250298. <https://doi.org/10.3389/fbioe.2023.1250298>



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Where's the money? (adapted from CRS Report R47274)

<i>Agency</i>	<i>Millions \$</i>	<i>Purpose</i>
<u>Previously announced</u>		
USDA	\$500	sustainable fertilizer production
	\$32	wood innovation
	\$68	next gen research & ed
	\$200	BBB Regional Challenge investments (NH, VA, NC, OR, AK)
DOE	\$178	biotech R&D
<u>Future investments(as of Oct. 2022)</u>		
DHHS	\$40	Expand pharma biomanufacturing
DOD	\$270	(5 years) resilient supply chains
	\$1,000	(5 years) biomanufacturing industrial base
	\$200	(5 years) biosecurity & cybersecurity of biomanufacturing
DOE	\$100	Biofuels & biomass-produced chemicals
	\$60	'De-risk & scale up' biotech products & biorefineries
	\$20	Anticipate, assess & detect biological threats
USDA	\$10	Bio-product pilot program
NIST	\$14	Measuring bioeconomy
NSF	\$20	Biosciences data center

General questions I have:

- **How is EPA be involved?**
 - ◆ Climate change solutions are major area in Bold Goals report
 - ◆ Recent increase in social cost of carbon to \$190 per ton
- **How will socioeconomic & distributional impacts be evaluated?**
 - ◆ Some language in Bold Goals on investments in “equity-focused science” & environmental justice
 - ◆ ... but should be a part of measuring the bioeconomy
 - ◆ No NSF or NIFA support for social science research on bioeconomy?
 - ◆ Recent updates to Federal guidance on benefit-cost analysis
 - OMB Circulars A-4, A-94
 - New recommendations about how to evaluate distributional impacts
 - Modified discounting procedures

Nick Loschin - PhD student, NC State



- NSF-funded AgBioFEWS program, GES Center, NC State
- Furgurson, Loschin et al. 2023
- Building transparency and trust in regulation
 - Shared database ecosystem
 - Two-directional, authentic public engagement



 | Frontiers in Bioengineering and Biotechnology

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Seizing the policy moment in crop biotech regulation: an interdisciplinary response to the Executive Order on biotechnology

Jill Furgurson^{1,2*†}, Nick Loschin^{2,3†}, Eric Butoto^{2,4†}, Modesta Abugu^{2,5†}, Christopher J. Gillespie^{2,6†}, Rebekah Brown^{2,7†}, Greg Ferraro^{2,8†}, Nolan Speicher^{2,9†}, Ruthie Stokes^{2,10†}, Asa Budnick^{2,11†}, Katrina Geist^{2,12†}, Rex Alirigia^{1,2†}, Amaja Andrews^{2,12†} and Amanda Mainello^{2,6†}

Ilaria Cimadori - PhD student, Yale School of the Environment



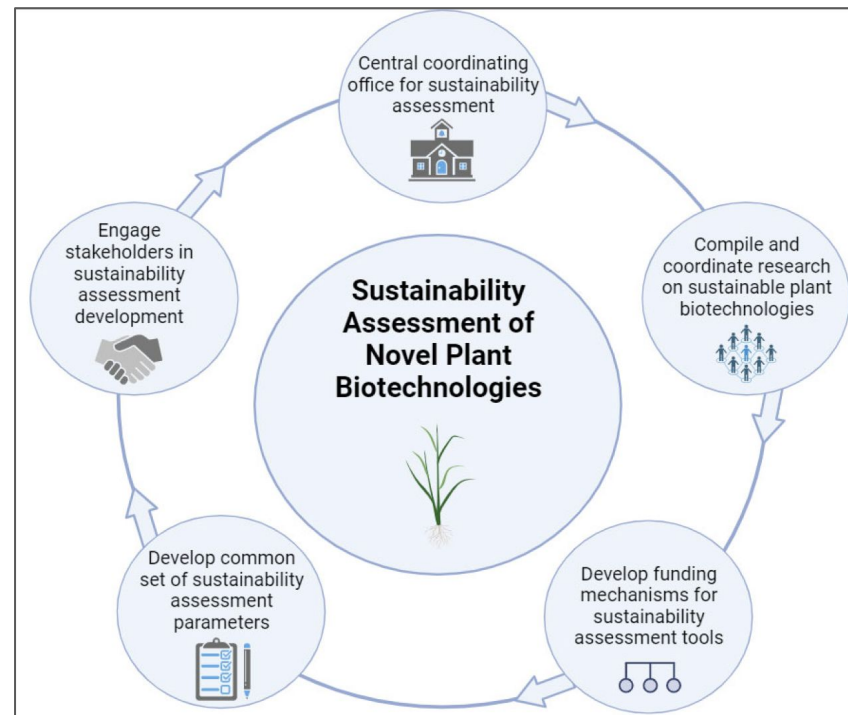
- Examining the global regulatory landscape of gene editing in animals, with a specific emphasis on its intersection with breeding practices and animal welfare.
- New FDA Animal and Veterinary Innovation Agenda (September 2023)



Khara Grieger - Assistant Professor, NC State



- Consensus on need for *sustainable* plant biotechnologies
- However, there is no harmonized or formalized set of assessment tools or parameters to measure sustainability
- “Bottom up” efforts by researchers will not be able to keep pace with innovation
- We call for formalized research programs that develop suite of tools and approaches to evaluate sustainability across range of parameters



Discussion



Discussion Questions

1. The EO aims to strike a balance between fostering innovation while also ensuring safety and sustainability. Does the EO strike the right balance?
 - What are the consequences of either overregulation or underregulation?

Discussion Questions

2. Is the EO flexible enough to handle new / novel biotechnologies as they continue to evolve?

- What mechanisms can be put in place to regularly review and update regulations as our understanding of biotechnologies evolves?

Discussion Questions

3. Does the EO align with other international frameworks for oversight of biotechnologies?

- Are there aspects or approaches in the EO that align or misalign with other frameworks? If so, which ones?

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Genetic Engineering and Society (GES) Center, NC State

