ITIF | INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

Prospects for Transatlantic Cooperation in Biotech Policy—A US Perspective

L. VAL GIDDINGS | MARCH 2022

There are multiple opportunities to advance solutions to major societal challenges by fostering transatlantic cooperation in biotech policy. But developing and applying them will require a return to science-based regulation that advances safety while enabling, not deterring innovation.

A WORLD OF BIOLOGICAL POSSIBILITIES

Mutual self-interest provides a strong basis for transatlantic cooperation in biotechnology based on shared recognition of its vast potential to provide solutions to some of civilization's most pressing problems. Thanks to explosive advances in our understanding of the many ways in which promiscuous nature has been manipulating DNA and RNA for the past billion years, it is widely anticipated that the 21st century will belong to biology.[1] We are now at the point where our ability to innovate is constrained less by technical capability than by the limits of our imaginations. Multiple laboratories and companies on both sides of the Atlantic (and throughout the world) are pursuing promising applications, and experience confirms progress would be accelerated by cooperative approaches. But there are some considerable challenges, especially in agricultural and industrial contexts.

The most important rate-limiting factor in our ability to harness biological innovations to the challenges of feeding the world, sustaining human and environmental health, and addressing climate change, is the burden imposed by ill-considered regulations. Unless this bottleneck can be unblocked, the enormous potential for transatlantic scientific cooperation will not yield the necessary fruits.

DIVERGENT REGULATORY PATHS: PRECAUTION VS. OPENNESS TO INNOVATION

Existing policies, legislation, and regulations do little or nothing to advance human or environmental safety.[2] Born out of understandable caution at the dawn of recombinant DNA technologies, today their most obvious impact is to obstruct and discourage research, development, and deployment of innovative solutions to various challenges.[3] This is so despite an abundant record of production and consumption of new biotech products with enviable records of improved safety, superior sustainability, and widespread beneficial economic impacts.[4] The benefits are so substantial that a pattern has emerged of farmers breaking the law to acquire and plant improved seeds in countries where governments have lagged in allowing access.[5]

It is one thing to implement policies and regulations ostensibly designed to ensure safety; it is quite another to ignore vast data and decades of experience around the world to maintain obsolete policies and regulations that add nothing to safety or sustainability, but only impede our ability to use the most innovative, precise, and safest tools to address our gravest challenges.[6]

In terms of regulatory policy and openness to biological innovations, the width of the Atlantic might be measured better in light years than miles or kilometers. As imperfect as regulations for the products of biotechnology are in North America, they are simply indefensible in Europe.[7]

The United States decided in 1986, after years of study and consultation, that no new laws were required to ensure the safety of crops and foods improved through biotechnology. This was based on the finding that they present no novel hazards, and foreseeable risks of their development and use fall into categories with which humans have considerable experience from millennia of conventional plant and animal breeding.[8] The United States therefore decided to regulate these novel products under existing authorities administered by the Department of Agriculture, the Food and Drug Administration, and Environmental Protection Agency.[9] While implementation of this policy, the "Coordinated Framework," has been far from perfect, it has been sufficiently predictable and science-based to enable an explosion of innovation, new product development, and commercial activity. Consequently, the United States has led the world to the present day wherein crops improved through biotechnology are now the global standard for quality seeds, delivering improved yields, safety, sustainability, and economic productivity around the world, with the lion's share of benefits accruing on behalf of small farmers in developing countries.[10] Europe took a different approach.

It is one thing to implement policies and regulations ostensibly designed to ensure safety; it is quite another to ignore vast data and decades of experience around the world to maintain obsolete policies and regulations that add nothing to safety or sustainability.

The European Union decided to regulate seeds improved through biotechnology as a novel class governed under new regulations specifically focused on an arbitrary category known as "GMOs" (for "genetically modified organisms"). The conceit was that because they represented gene combinations produced by mechanisms supposedly "not found in nature" (but actually ubiquitous) they must present novel hazards, even though none has ever been identified. These putatively novel hazards, despite the lack of any concrete manifestations, allegedly required dedicated, specific, "precautionary" regulations. The resulting regulatory regime proved so burdensome it led to the general collapse of agricultural biotechnology in Europe, which had played a leading role in its discovery and invention. Permissions for field trials proved almost impossible to obtain, products could not be developed and brought to market, academic labs abandoned the field, and the industry relocated most of its assets and activities to the Americas. And Europe became the world's largest importer of commodity foods improved through biotechnology, only recently surpassed by China.

OPPORTUNITY FOR TRANSATLANTIC COOPERATION

Many scientists in the EU (and around the world) knew from the beginning that this was the wrong approach, yet the EU pushed its model internationally, with aggressive diplomacy, leading to emulation by many countries in the developing world, with equally unhappy results to those seen in Europe.[11] But a growing number of scientists, policymakers, and even "green" NGOs that had originally opposed GMOs, now recognize the counterproductive results of this approach and are working to avoid repeating the same mistakes with gene editing. This shines a spotlight on the most important and potentially fruitful opportunity for transatlantic cooperation in

biotechnology: the revival of science-based regulatory regimes in which the degree of regulatory oversight is proportional to the hazards involved, and regulation that enables, rather than discourages the safe development of innovative products. A return to and reaffirmation of these first principles would provide fertile ground for cooperation and coordination globally. Regulatory reform (everywhere, not just in the EU and its emulators, though the need is greatest there) provides fertile ground for transatlantic cooperation and coordination. We have robust models of proven approaches.[12] Without such cooperation, other progress in developing and deploying innovative solutions through biotechnology will be impeded or foregone.

As to national security risks, just as with other risks, novelty attributable to biotechnology is elusive. One can do very nasty things with conventional bioweapons, and they are easily magnified with recombinant DNA techniques. At the same time, defensive capacities are also buttressed by biotechnology, as demonstrated by the rapid development of mRNA vaccines against SARS-CoV-2. There has been some good work done in this area, but this topic is worth exploring at greater depth. The OECD has a track record of thoughtful analyses with such topics. One possibility would be to build on that foundation by establishing a joint OECD/NATO working group to serve as a forum.

FURTHER READING

- Robert D. Atkinson, "Sectoral Policies to Drive Productivity Growth" (ITIF, October 12, 2021), https://itif.org/publications/2021/10/12/sectoral-policies-drive-productivity-growth.
- ITIF comments to the White House Office of Science and Technology Policy regarding its Notice of Request for Information for Bioeconomy (84 Federal Register 47561), October 15, 2019, http://www2.itif.org/2019-comments-ostp-bioeconomy.pdf.
- Robert D. Atkinson, "Computer Chips vs. Potato Chips: The Case for a U.S. Strategic-Industry Policy" (ITIF, January 2022), https://itif.org/publications/2022/01/03/computer-chips-vs-potato-chips-case-us-strategic-industry-policy.
- Robert D. Atkinson, "Weaving Strategic-Industry Competitiveness Into the Fabric of U.S. Economic Policy" (ITIF, February 2022), https://itif.org/publications/2022/02/07/weaving-strategic-industry-competitiveness-fabric-us-economic-policy.
- Office of Science and Technology Policy, "National Strategy for Modernizing the Regulatory System for Biotechnology Products," September, 2016, https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.
- Jyotsna L. Pandey, "Policy for Bioeconomic Growth," *BioScience*, 70(6):459-460 (June 2020), https://doi.org/10.1093/biosci/biaa049.

Acknowledgments

This publication was made possible in part by a grant from the U.S. Air Force to the Center for a New American Security (CNAS). It is based on a presentation delivered at a Hybrid Workshop on Transatlantic Cooperation in Biotechnology Policy organized and convened by CNAS on February 8, 2022, in Palo Alto, California. The statements made and views expressed are solely the responsibility of the author.

About the Author

L. Val Giddings (@prometheusgreen) is a senior fellow at ITIF. He has over three decades of experience in science and regulatory policy relating to biotechnology innovations in agriculture and biomedicine. His work at ITIF focuses on constraints inhibiting innovations in these areas, and remedies to those constraints. Giddings is also president and CEO of PrometheusAB, Inc., a consultancy focusing on regulatory compliance, media, and strategic planning for governments, multilateral organizations, and industry.

About ITIF

The Information Technology and Innovation Foundation (ITIF) is an independent, nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized by its peers in the think tank community as the global center of excellence for science and technology policy, ITIF's mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress.

For more information, visit itif.org.

ENDNOTES

1. Anne Glover, "The 21st Century: The Age of Biology," OECD Forum on Biotechnology (November 12, 2012), https://www.oecd.org/sti/emerging-tech/A%20Glover.pdf.
2. L. Val Giddings, "How the Biden Administration can accelerate prosperity by fixing agricultural-biotech regulations" (ITIF, March 2021), https://itif.org/publications/2021/03/31/how-biden-administration-can-accelerate-prosperity-fixing-agricultural.
3. James D. Watson and John Tooze, *The DNA Story: A Documentary History of Gene Cloning* (W.H. Freeman & Co., San Francisco, 1981), https://www.amazon.com/DNA-Story-Documentary-History-Cloning/dp/071671292X/; L. Val Giddings, "Biotech innovation: The low hanging fruit they missed in Glasgow," ITIF *Innovation Files*, November 29, 2021, https://itif.org/publications/2021/11/29/biotech-innovation-low-hanging-fruit-they-missed-glasgow.
4. Wilhelm Klümper and Matin Qaim, "A Meta-Analysis of the Impacts of Genetically Modified Crops," *PLOS One*, November 3, 2014, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111629; Graham Brookes and Peter Barfoot, "GM crop technology use 1996-2018: farm income and production impacts," *Biotechnology in Agriculture and the Food Chain* 11(4):242-261 (2020), https://www.tandfonline.com/doi/full/10.1080/21645698.2020.1779574; Alessandro Nicolia et al., "An overview of the last 10 years of genetically engineered crop safety research," *Critical Reviews in*

Biotechnology 34(1):77-88 (September 16, 2013), https://www.tandfonline.com/doi/abs/10.3109/07388551.2013.823595; Alison L. Van Eenennaam and A.E. Young, "Prevalence and impacts of genetically engineered feedstuffs on livestock populations," *Journal of Animal Science* 92(10):4255-78 (September, 2014) doi: https://doi.org/10.2527/jas.2014-8124; U.S. National Academies of Science, "Our work: Genetically-Engineered Crops: Past Experience and Future Prospects," (accessed March 7, 2022), https://www.nationalacademies.org/our-work/genetically-engineered-crops-past-experience-and-future-prospects.

5. T.V. Jayan and Radheshyam Jadhav, "Maharashtra farmers defy ban to plant GM cotton," *The Hindu Business Line*, June 10, 2019, https://www.thehindubusinessline.com/news/maharashtra-farmers-defy-ban-to-plant-gm-cotton/article27766300.ece; Shruti Rajagopalan, "The Impartial Spectator, Opinion: A farmer satyagraha for permission-less innovation," *Mint*, June 11, 2019, https://www.livemint.com/opinion/online-views/opinion-a-farmer-satyagraha-for-permission-less-innovation-1560192197896.html; L. Val Giddings, "Indian Farmers Launch Civil Disobedience Campaign to Secure Access to GM Seeds," ITIF *Innovation Files*, June 14, 2019, https://itif.org/publications/2019/06/14/indian-farmers-launch-civil-disobedience-campaign-secure-access-gm-seeds; Vishwa Mohan, "Tests confirm illegal cultivation of Bt Brinjal in Haryana district," *Times of India*, May 11, 2019, http://timesofindia.indiatimes.com/articleshow/69276147.cms; "Pro-GM seed movement spreads to 11 districts in Maharashtra, bail of Buldana farmer rejected," *Times of India*, June 25, 2019, http://timesofindia.indiatimes.com/articleshow/69932768.cms; Joseph Opoku Gakpo, "Ghana's scientists, farmers reject claim that GMO crops aren't needed," Cornell Alliance for Science (March 20, 2019), https://allianceforscience.cornell.edu/blog/2019/03/ghanas-scientists-farmers-reject-claim-gmo-crops-arent-needed/; John Agaba, "African farmers want GMO seeds to help weather climate change," Cornell Alliance for Science (March 12, 2019), https://allianceforscience.cornell.edu/blog/2019/03/african-farmers-want-gmo-seeds-help-weather-climate-change/.
6. Alison L. Van Eenennaam and A. E. Young, "Prevalence and impacts of genetically engineered feedstuffs on livestock populations," *Journal of Animal Science*, 92(10):4255–78 (October, 2014), doi: https://doi.org/10.2527/jas.2014-8124; Alessandro Nicolia et al., "An overview of the last 10 years of genetically engineered crop safety research," *Critical Reviews in Biotechnology*, 34(1):77–88 (September 16, 2013), https://doi.org/10.3109/07388551.2013.823595; Wilhelm Klümper and Matin Qaim, "A Meta-Analysis of the Impacts of Genetically Modified Crops," *PLOS One*, November 3, 2014, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111629; Si Quiero Transgenicos, "More than 280 scientific and technical institutions support the safety of GM crops," website accessed March 7, 2022, http://www.siquierotransgenicos.cl/2015/06/13/more-than-240-organizations-and-scientific-institutions-support-the-safety-of-gm-crops/; U.S. National Academies of Science, "Our work: Genetically-Engineered Crops: Past Experience and Future Prospects," accessed March 7, 2022, https://www.nationalacademies.org/our-work/genetically-engineered-crops-past-experience-and-future-prospects.
7. Philip Blenkinsop, "EU calls for rethink of GMO rules for gene-edited crops," *Reuters*, April 29. 2021, https://www.reuters.com/world/europe/eu-calls-rethink-gmo-rules-gene-edited-crops-2021-04-29/; Jonathan Jones, "GM regulation 'not fit for purpose', says Commons committee—and it's right," *The Conversation*, February 25, 2015, https://theconversation.com/gm-regulation-not-fit-for-purpose-says-commons-committee-and-its-right-38016.
8. Nina V. Fedoroff, "Food in a Future of 10 Billion," *Agriculture and Food Security*, 4 (11) (2015), https://agricultureandfoodsecurity.biomedcentral.com/articles/10.1186/s40066-015-0031-7; Noel Kingsbury, *Hybrid; The History and Science of Plant Breeding* (University of Chicago Press, November 15, 2011); Stephen Budiansky, *The Covenant of the Wild: Why Animals Chose Domestication* (Yale University Press, April 10, 1999); Tim Flannery, *The Future Eaters: An Ecological History of the Australasian Lands and People* (Grove Press, New York, 1994), ISBN 0-8021-3943-4.

9. U.S. Department of Agriculture, "The Unified Website for Biotechnology Regulation," accessed March 7, 2022, https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about/.
10. International Service for the Acquisition of Agri-Biotech Applications, "Brief 55: Global Status of Commercialized Biotech/GM Crops: 2019," November 30, 2020, https://www.isaaa.org/resources/publications/briefs/55/default.asp.
11. Margaret Karembu, "How European-Based NGOs Block Crop Biotechnology Adoption In Africa," Genetic Literacy Project (February 23, 2017), https://geneticliteracyproject.org/2017/02/23/european-based-ngos-block-crop-biotechnology-adoption-africa/; Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa* (Cambridge, MA: Harvard University Press, 2008), ISBN 13:978-0-674-02973-6; *Food Politics: What Everyone Needs to Know* (Oxford, U.K.: Oxford University Press, 2010), ISBN 978-0-19-538960-9; "Opinion: Europe Is Sinking Biotech—Again; Scientifically groundless regulations could undercut the potential of gene-edited crops, much as they have with GMOs," *The Scientist*, February 1, 2021, https://www.the-scientist.com/reading-frames/europe-is-sinking-biotechagain-68339; Jon Entine (ed.), *Let Them Eat Precaution*, AEI Press (Washington, D.C., 2006), ISBN 0-8447-4200-7.
12. International Plant Protection Convention (accessed March 7, 2022), https://www.ippc.int/en/about/overview/; World Trade Organization Agreement on Sanitary and Phytosanitary Measures (accessed March 7, 2022), https://www.wto.org/english/tratop_e/sps_e/sps_e.htm.