Biotechnology Innovation Organization

Dr Michelle McMurry-Heath

President & CEO

June 4, 2021

The Honorable Tom Vilsack
Secretary
U.S. Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

The Honorable Katherine Tai
Ambassador
Office of the U.S. Trade Representative
600 17th Street NW
Washington, DC 20508

Secretary Vilsack and Ambassador Tai:

Thank you for prioritizing agricultural innovation in your recent dialogues with international counterparts. As you seek to position agriculture as a solution to domestic and global climate and sustainability challenges, the United States must continue to address acute and systemic trade barriers to innovative biotechnology tools in important export markets. To fully leverage the potential of technology to address these challenges, a level-playing field globally will be essential.

BIO[1] represents over 1,000 members in a biotech ecosystem with a central mission – to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the agriculture, energy, health, and manufacturing sectors to improve the lives of people and the health of the planet. BIO is committed to speaking up for the millions of families around the globe who depend upon our success. We will drive a revolution that aims to cure patients, protect our climate, and nourish humanity.

BIO applauds the Administration for addressing the climate crisis,[2] including promotion of trade policies that work to protect the environment and achieve global alignment[3]. Initiatives such as USDA's *Climate-Smart Agriculture and Forestry Strategy*[4] and global efforts such as *Agriculture Innovation Mission for Climate* (AIM for Climate)[5] recognize agriculture's unique role in combatting climate change.

For over twenty years, the United States has successfully and safely led the world in the commercialization of biotechnology to enable more sustainable farming and industrial practices. These innovations reduce greenhouse gas emissions throughout agricultural supply chains, delivering environmentally friendly products and processes to the market and more nutritious offerings to all tables[6].

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[1] https://www.bio.org/
[2] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/executive-order-on-tackling-the-climate-crisis-at-home-and-abroad/
[3] https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/april/remarks-ambassador-katherine-tai-trade-policy-environment-and-climate-change
[4] https://www.usda.gov/sites/default/files/documents/climate-smart-ag-forestry-strategy-90-day-progress-report.pdf
[5] https://www.usda.gov/media/press-releases/2021/04/23/launching-agriculture-innovation-mission-climate
[6] https://www.bio.org/letters-testimony-comments/bio-submits-comments-usda-highlighting-biotechs-role-tackling-climate

As BIO highlighted in its comments[7] to USDA's *Climate-Smart Agriculture and Forestry Strategy*, biotech crops such as those that enable no-till practices have saved 27.1 billion kg of carbon dioxide. This is equivalent to taking 16.7 million cars off the road. And the development and deployment of gene editing and synthetic technology will play a vital role in making crops and livestock more resilient to pests, disease, and extreme weather variabilities caused by climate change. Gene editing enables this increased resilience while reducing the usage of agricultural inputs. The benefits of biotechnology go beyond the farm gate. Innovations on the farm foster the development and production of biobased products and renewable chemicals from biomass and waste feedstocks, which removed 12.7 million metric tons of carbon dioxide in 2016 alone.

Unfortunately, when major trading partners such as China, the European Union (EU), or Mexico, delay biotechnology risk assessments and approvals or intentionally malign technology, the global marketplace is reluctant to accept new technology due to potential impacts on global trade. The results are unfortunate, as producers in the United States and around the world are denied innovative tools to reduce emissions, sustainably increase production, and deploy climate-resilient technologies.

The following challenges represent significant barriers to sustainably address climate change.

- ***China:*** Despite agreeing to important systemic changes aimed at establishing a more science-based and timely biotech approval process as part of the U.S.-China Phase One Agreement, China has yet to demonstrate a commitment to fully implement the agreement. Specifically, China agreed to complete regulatory review of biotechnology products within two years, on average, and to limit the scope of the regulatory review to the product's intended use, i.e. feed or further processing. China has failed to address either issue. Addressing this systemic issue will be critical to ensuring China upholds its Phase One Agreement commitments and is fundamental to credible collaboration to address the climate crisis[8].

- ***European Union***: For the first time in decades, there appear to be opportunities emerging within Europe to enable innovation. Both the Farm to Fork strategy and the European Commission's recent study on *New Genomic Techniques*[9] point to the importance of innovation to achieving a more sustainable food system. However, significant risks remain as Europe's regulatory processes are fundamentally prejudiced to agricultural biotechnology. Nevertheless, we believe it is critical for the United States government to proactively engage with like-minded countries and chart a path forward with the EU to enable science-based regulations for biotechnology tools and expand sustainable agricultural practices to achieve our shared climate goals.

- ***Mexico***: More recent, but particularly worrisome, is Mexico's rapid dismantling of regulatory institutions and international commitments with respect to agricultural biotechnology. Despite recently confirming its commitment to North American trade through the U.S.-Mexico-Canada Agreement (USMCA), Mexico has become a major

[7] https://www.bio.org/letters-testimony-comments/bio-submits-comments-usda-highlighting-biotechs-role-tackling-climate
[8] https://www.state.gov/u-s-china-joint-statement-addressing-the-climate-crisis/
[9] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1985

barrier to introducing new agricultural biotechnology products within North America. At issue is the fact that COFEPRIS, Mexico's food and drug regulator, has not issued a new biotech trait approval since May 2018. During this time, the queue of biotech products has grown to 20, with nearly all products far exceeding Mexico's six-month statutory time limit. The Government of Mexico has offered no explanation for the delays nor provided any guidance to developers. We question Mexico's commitments to the USMCA and are highly concerned about the Government of Mexico's rejection of technology that has been proven to enhance the sustainability of agriculture.

Compounding matters, on December 31, 2020, President Andrés Manuel López-Obrador published a Decree attacking modern agricultural technologies, including biotechnology. Citing the precautionary principle, and unsupported environmental and public health claims, the Decree states the intention to phase out genetically modified corn for human consumption by 2024 and to revoke existing, and refrain from future, biotech approvals. Such actions, merely six months following USMCA ratification, are highly concerning and must be addressed at the highest levels of government.

Moreover, such regulatory practices increase the cost to commercialize new products, limiting the use of biotechnology beyond major commodity crops such as soybeans, corn, and cotton. New critical biotechnologies such as gene editing and synthetic biotech and the broader application of these technologies to plants, animals, and microbes will suffer a similar fate if unjustified regulatory barriers persist.

Harnessing the latest science to combat climate change will require a global strategy. One that addresses existing trade barriers in China, the EU, and Mexico and builds common ground on how these technologies can contribute to sustainable agricultural practices and the United Nation's Sustainable Development Goals. BIO urges the Administration to build a proactive trade policy agenda aimed at addressing existing barriers to biotechnology and facilitating regulatory approvals for critical climate technologies for agriculture.

Yours Sincerely,

Michelle McMurry-Heath, MD, PhD
President and Chief Executive Officer
Biotechnology Innovation Organization

cc. The Honorable Antony Blinken, United States Secretary of State
The Honorable John Kerry, United States Special Presidential Envoy for Climate
The Honorable Gina McCarthy, National Climate Advisor
Honorable Jake Sullivan, National Security Advisor