



Biotechnology Innovation Organization
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November 17, 2021

The Honorable Jim Costa
Chairman
Subcommittee on Livestock and
Foreign Agriculture
Committee on Agriculture
U.S. House of Representatives
Washington, DC 20515

The Honorable Dusty Johnson
Ranking Member
Subcommittee on Livestock and
Foreign Agriculture
Committee on Agriculture
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Costa, Ranking Member Johnson, and Members of the Subcommittee:

The Biotechnology Innovation Organization (BIO) is pleased to submit a statement for the record to the United States House of Representatives Committee on Agriculture Subcommittee on Livestock and Foreign Agriculture hearing entitled, *Trade Policy and Priorities*.

Introduction

BIO¹ 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.

Trade Policy and Priorities

BIO applauds the Subcommittee for examining trade policy and priorities to support agricultural producers, promote innovation, protect the environment and enable agriculture to combat climate change.

Because of bipartisan support, 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 tables².

¹ <https://www.bio.org/>

² <https://www.bio.org/letters-testimony-comments/bio-submits-comments-usda-highlighting-biotechs-role-tackling-climate>



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.

China

For more than a decade biotechnology regulatory policy in China has effectively limited U.S. farmer access to new biotechnology traits, and by extension worked counter to the interests of American farmers and American businesses. In response to these practices, the U.S. Government (USG) has repeatedly intervened with the Chinese government. As a result, China has made multiple commitments to implement a transparent, predictable, and science-based biotechnology risk assessment system, both informally during multiple bilateral meetings and formally through the Phase One Economic and Trade Agreement (Phase One Trade Agreement) signed by both countries in January 2020. To date, however, there is no evidence that China has followed through on these commitments, as the system continues to be opaque and protracted, averaging over eight years to secure an import approval for a biotech trait.

Chief among China's Phase One provisions is a commitment from China 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. Of particular concern is the fact that nearly two years following the signing of the Phase One Agreement, Chinese authorities have yet to articulate how they intend to implement commitments made to the USG. While there is anecdotal evidence to suggest that process changes may have been enacted, there has been no official communication to seed technology companies or the USG regarding China's path to compliance.

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*³ point to the importance of innovation to achieving a more sustainable food system. However, significant risks remain as Europe's regulatory processes

³ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1985



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. We applaud Secretary Vilsack's efforts to work with like-minded countries around the UN Food Systems Summit to launch the Coalition for Sustainable Productivity Growth.⁴ However, it is critical to also engage the European Commission to ensure that concrete measures are taken to enable a timely, predictable, and science-based approval process to enable innovation to fully address climate and food system challenges.

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 barrier to introducing new agricultural biotechnology products within North America.

At issue is the fact that COFEPRIS, Mexico's food and drug regulator, has been not maintained a science-based process for over three years. During this time, the queue of biotech products has grown to 25, 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, the Government of Mexico continues to make a series of troubling statements regarding imports of corn produced with biotechnology – explicitly stating that imports will be prohibited by 2024 and future approvals will be denied, and existing approvals will be revoked. The most recent example being a recent letter from Mexican President Andrés Manuel López Obrador to President Joe Biden⁵ that tied Mexico's actions on biotechnology to climate change commitments.

We appreciate U.S. Trade Representative Ambassador Katherine Tai and U.S. Department of Agriculture Secretary Tom Vilsack have actively engaged with the Mexican government on

⁴ <https://www.usda.gov/oce/sustainability/spg-coalition>

⁵ <https://www.gob.mx/presidencia/documentos/carta-al-presidente-de-estados-unidos-joseph-biden?idiom=es>



these issues, however, we are increasingly alarmed as the Government of Mexico has yet to acknowledge U.S. government intervention and articulate a path to compliance.

These actions are highly concerning and must be addressed at the highest levels of government.

Conclusion

A proactive trade agenda is needed to harness the latest science, enable U.S. producers to be competitive in a global market, sustainably increase production, and combat climate change. U.S. trade policy must be aimed at addressing existing barriers to biotechnology and facilitating regulatory approvals for critical technologies.

BIO is committed to working with the Subcommittee to address these barriers to foster the rapid development and deployment of agricultural biotechnology to help American agriculture meet the challenges of the 21st Century. We look forward to our continued partnership in this critical endeavor.

Sincerely,

A handwritten signature in black ink, appearing to read "Sarah Gallo". The signature is fluid and cursive, written over a white background.

Sarah Gallo
Vice President, Agriculture and Environment
Biotechnology Innovation Organization