



**Testimony of Dr. Michelle McMurry-Heath, MD, PhD
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**United States Senate Committee on Finance Hearing
*Implementation and Enforcement of the United States – Mexico – Canada
Agreement: One Year After Entry into Force***

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Chairman Wyden, Ranking Member Crapo, Members of the Committee, my name is Dr. Michelle McMurry-Heath. I am the President and CEO of the Biotechnology Innovation Organization (BIO). I am honored to testify before you for today's hearing, *Implementation and Enforcement of the United States – Mexico – Canada Agreement: One Year After Entry into Force* and address our industry's concerns around the implementation of the agricultural biotechnology provisions of the United States – Mexico – Canada Agreement or USMCA.

Introduction

BIO¹ represents 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 energy, agriculture, manufacturing, and health 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.

Biotech and Trade Policy

United States leadership in biotech innovation represents the cornerstone of the U.S. economy. Our industry is vital to U.S. national security, climate policy, pandemic preparedness, and provides a platform from which to exercise global leadership on key issues.

As the U.S. biotechnology industry has demonstrated in our response to COVID-19, the U.S. can lead the world in developing technologies that will solve health and economic crises. In record time, the U.S. biotechnology industry and its global partners launched highly effective vaccines and therapeutics to help the world begin to turn the corner on the pandemic. Like with COVID, American innovation in biosciences, coupled with the U.S. government's leadership, can similarly be unleashed to help address several other crises, including climate change and malnutrition.

¹ <https://www.bio.org/>



Executing thoughtful and creative trade strategies is among the most effective means to enhance global science-based collaboration while growing the U.S. bioeconomy. An open, global trading and investment system benefits innovators, researchers, patients, farmers, and consumers everywhere by establishing a level playing field for all. Trade agreements help to establish science-based regulatory systems that can promote the development of and access to disruptive and transformative biotechnologies that will be required to effectively confront serious public health, environmental, and nutritional challenges.

The U.S. must reassert its influence within the global trading system by leading efforts to place science and technology at the core of its global economic and strategic interests. This will require maintaining long-standing U.S. trade policy commitments to intellectual property (IP), which is critical to risk-taking and investment in pre-profit companies, who are at the heart of BIO's membership. It will also require modernizing U.S. trade policy to address novel issues such as the need to ensure enforceable digital trade rules that minimize restrictions on cross-border data flows and enable the international transfer of data needed to advance global biotechnology R&D efforts. It is also essential that we enhance our ability to proactively confront regulatory barriers in other countries that stifle the trade of transformative biotech innovations – barriers that not only do a disservice to global society by delaying their adoption but also have a chilling effect on future biotechnology investment.

Leveraging U.S. leadership in global trade to address these concerns will boost the American bioeconomy revolution, creating high-quality jobs and better position the United States to effectively confront and lead on big global challenges. We have an obligation – industry and government – to leverage American strengths and work collectively to remove barriers that restrict the development of the global biotech ecosystem.

Agricultural Biotechnology in the United States

The United States is the world's largest producer of biotechnology crops. With over 90 percent of corn, soybean and cotton acres produced with biotechnology crops², this technology is ubiquitous in American agriculture. The United States is also a major exporter of these crops. In the case of corn, Mexico is the United States largest international market, representing nearly 30 percent of total U.S. corn exports in 2020. If Mexico does not approve a new corn biotechnology product, U.S. corn farmers are reluctant to plant the product for fear of disrupting trade to Mexico. This means, in effect, that Mexico determines which technology U.S. farmers can use.

² <https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>



Biotechnology companies plan their commercial launches years in advance, preparing regulatory submissions in export markets, and consulting with value chain customers. When regulatory authorities in export destinations cease to function and shut off communication with companies, as in the current case of Mexico, it is impossible to predict with certainty when to launch a product in the United States. As a result, biotechnology companies often delay, affecting investments and future R&D.

In 2018, BIO and international partners conducted an extensive economic analysis of the impact of regulatory delays in China³. Like Mexico, China is a major importer of U.S. soybeans and corn. Without Chinese approval, the same scenario applies. The analysis showed that delays in China decreased U.S. farm income by \$5 billion and cost nearly 34,000 jobs between 2011 and 2016. Today China remains a major challenge, with approvals delayed by seven years on average, but through the US-China Phase One agreement there are continued efforts to address these systemic challenges.

USMCA

For agricultural biotechnology, USMCA represented a significant improvement on NAFTA for the agricultural biotechnology industry and the constituents it seeks to serve. Enhanced provisions for agricultural biotechnology set it apart from previous trade agreements. For these reasons BIO applauded the USMCA as a major step forward and as the basis for future agreements. Over the past year, however, we have noted both practical barriers to seamless implementation of USMCA as well as missed opportunities that stemmed from the process leading to U.S. approval of the agreement. Today, I hope to highlight these barriers and missed opportunities for your consideration in future discussions with our allies.

With respect to agricultural biotechnology, what exists on paper is a far cry from reality. USMCA is the first agreement to address agricultural biotechnology specifically. All three parties confirmed the importance of encouraging agricultural innovation and facilitating trade in products of agricultural biotechnology⁴. The provisions focus on ensuring trading partners have functional regulatory systems that promote transparency and cooperation. The intent of the provisions is to supplement the requirements of the Sanitary and Phytosanitary (SPS) Agreement, facilitate trade, and to proactively avoid unnecessary and costly trade disruption that can occur when regulatory approvals are delayed. Furthermore, the agreement established a committee to enhance cooperation and regulatory consistency on current and emerging agricultural biotechnologies, including genome editing. Unfortunately, the Government of Mexico's treatment of agricultural biotechnology is a stark example of how it has strayed in a matter of three years and how trade barriers actively restrict the development of new technologies.

³ <https://croplife.org/wp-content/uploads/2018/05/Impact-of-Delays-in-Chinese-Approvals-of-Biotech-Crops-05-18-FINAL-1.pdf>

⁴ https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/03_Agriculture.pdf



Regulatory Challenges for Innovative Agricultural Biotechnology Products in Mexico

Failure to Issue Biotech Import Approvals

Even before USMCA negotiations were completed, problems began to emerge. While Mexico never fully embraced the cultivation of agricultural biotechnology, it was a model trading partner. The Government of Mexico's food and drug regulatory authority (COFEPRIS) routinely processed new product applications within Mexico's statutory limit of six months. The process was largely transparent, science-based, and predictable. Since the election of President Andrés Manuel López Obrador, however, COFEPRIS has effectively shut down and Mexico's regulatory system has become nonfunctional.

For agricultural biotechnology specifically, Mexico has not granted a single approval since May 2018; meanwhile, the backlog of pending approvals has grown to 23. This affects all of BIO's agricultural members, covering a wide range of commodities: apples, canola, corn, cotton, potatoes, and soybeans. 20 of these have now exceeded the six-month statutory time limit for COFEPRIS to determine whether to issue a biotech import approval. During this time, Mexican regulators have provided no substantive communications with companies on the delays. It is also important to highlight that the products pending approval in Mexico are legal to grow in the United States as well as many other countries.

It is worth noting, these challenges are not unique to agricultural biotechnology. Similarly, for biopharmaceutical products, COFEPRIS has not issued a new approval since early 2019. The queue of pending approvals for new treatments and formulations, as well as pending applications to initiate clinical studies, number in the hundreds. There are dozens of new drugs that have been favorably reviewed by the New Molecules Committee and are awaiting approval. These pending applications have also exceeded the statutory time limit for COFEPRIS to issue a decision. Likewise, companies are still unable to meet directly with the regulator.

Decree to Ban Biotech Corn

Compounding the uncertainty caused by COFEPRIS's failure to issue a biotech import approval in over three years, the Government of Mexico published a decree on December 31, 2020, announcing the intention to phase-out the use of important agricultural technologies, including use of biotech corn for human consumption by 2024. In 2020, the U.S. exported \$2.7 billion of corn to Mexico. As a result, this decree could have a major impact on the U.S. agriculture industry and producers across the country. It is another unfortunate example of Mexico's waning adherence to our trade agreements.

Further, the decree raises the potential for existing biotech authorizations to be revoked and signals the government's intention to not grant approvals for future



biotech corn products. The announcements of these policy changes, which have far-reaching implications for North American agriculture, were issued with neither industry or trading partner consultation nor any demonstrable scientific rationale. They also incorrectly allege that biotech corn and modern agricultural practices harm the environment.

Economic impacts from the decree would not stop at the U.S. border. To date, the decree's application to imports of biotech corn for use as animal feed remains ambiguous. While the decree does not specify if the ban will apply to imports for animal feed, Mexican officials have issued competing statements. Regardless, the practicality of separating corn for feed from corn for human consumption is costly and creates supply chain challenges, not to mention increased risk of shipment rejections. Such uncertainty risks long-standing cross-border commercial relationships between suppliers in the United States and Mexican livestock producers who have mounting questions about their supply chains, economic well-being, and future of their domestic industries. What is more, enactment of the decree will be in direct violation of Mexico's commitments under USMCA and the World Trade Organization (WTO), as the decree is neither science nor risk-based and is out of step with international standards and norms.

Mexico's Lack of Regulatory Framework for Gene Edited Products

As existing biotechnology products await action in Mexico, we are highly concerned about the implications for emerging biotechnologies such as genome editing and synthetic biology. BIO members are actively leveraging genome editing techniques to help plants, animal and microbes become more resilient to pests, diseases, and extreme weather, and reduce usage of agricultural inputs. While the global regulatory landscape is emerging, several agricultural producing countries, including most of the Western Hemisphere, have established regulatory pathways for products derived through genome editing. Mexico stands out as the major exception.

USMCA's goal to enhance cooperation in emerging technologies among the three parties aimed to facilitate commercial availability and acceptance of biotech products. Lack of progress by Mexico is forcing biotechnology companies with robust pipelines of gene-edited products to make unenviable decisions- move forward with product development without the benefit of regulatory clarity in Mexico, or cease developing gene edited products that may be produced in, or traded with, Mexico.

Impact on Addressing Global Challenges

Mexico's actions are impeding global research and development, jeopardizing the potential of biotechnology to address myriad challenges related to climate change, sustainability, human nutrition, animal welfare, and worker safety. What was



intended in USMCA to invigorate investment in, and development of these technologies, is now threatened by the obstruction of one of its key signatories. Biotechnology crops positively impact food security, sustainability, and climate change solutions. For example, biotechnology crops:

- Reduced carbon dioxide emissions in 2016 by 27.1 billion kg, equivalent to taking 16.7 million cars off the road for one year.⁵
- Maintain yields in the face of drought, which has a direct bearing on improved food security and poverty alleviation.
- Combat global hunger and malnutrition by increasing the vitamin and mineral contents of plants. They also address the lack of fresh fruits and vegetables in food deserts in urban and rural communities. (Additional information available in the New York Times Magazine article, *Learning to Love GMOs*⁶.)
- Extend the shelf life of produce, cutting down on food waste, which creates eight percent of all global emissions.⁷

To learn more about how biotechnology can enable agriculture to be solution to climate change please see BIO's [Biotech Solutions for Climate Report](#) and BIO's [response](#) to U.S. Department of Agriculture's (USDA) *Request for Public Comment on the Executive Order on Tackling the Climate Crisis at Home and Abroad*⁸.

Resolving Mexico's Ag Biotech Regulatory Challenges

Mexico's failure to perform scientific regulatory assessments in over three years, its disregard for due process and transparency, and its decree to arbitrarily ban key technologies is a direct violation of both the letter and spirit of USMCA and commitments to the WTO. These actions require a strong response from the U.S. government

Mexico must resume the approval process for all agricultural biotechnology products and implement a science-based and predictable regulatory process going forward. It must immediately rescind its anti-USMCA decree banning the import of biotech corn and begin creating a gene editing framework that conforms with international norms and trade agreement commitments.

BIO appreciates the work of the U.S. Trade Representative (USTR) and USDA to date. Specifically, USTR Ambassador Katherine Tai calling for the immediate resumption of agricultural biotechnology product approvals in Mexico in her recent meetings with Mexico's Secretary of Economy, Tatiana Clouthier and Secretary of Agriculture and Rural Development, Victor Villalobos, and for USDA Secretary Tom Vilsack's efforts to engage and reinforce this message. This engagement builds on

⁵ <https://www.isaaa.org/resources/publications/briefs/54/executivesummary/default.asp>

⁶ <https://www.nytimes.com/2021/07/20/magazine/gmos.html>

⁷ http://www.fao.org/fileadmin/templates/nr/sustainability_pathways/docs/FWF_and_climate_change.pdf

⁸ <https://www.federalregister.gov/documents/2021/03/16/2021-05287/notice-of-request-for-public-comment-on-the-executive-order-on-tackling-the-climate-crisis-at-home>



numerous attempts by former USTR Ambassador Robert Lighthizer and USDA Secretary Sonny Perdue.

However, with little indication from Mexico that it will adhere to its USMCA commitments, BIO strongly urges USTR to begin taking enforcement action on Mexico's treatment of agriculture biotechnology. An enforcement case would at a minimum provide a framework and timeline to resolve the COFEPRIS-related delays in biotechnology approvals and the December 31, 2020, decree. Without a process, BIO and its members fear the Government of Mexico will continue the status quo, and possibly broaden the scope of the decree to additional agricultural products, which would compound the impact on U.S. trade and future innovation.

More broadly, if the United States does not enforce against Mexico's practices, BIO is concerned about the message this sends to current and future trading partners. The biotech sector has faced a host of challenges with Europe and China. Each time the U.S. government has aggressively engaged to protect American interests in advancing this critical technology. Taking enforcement action with Mexico on this issue is critical to protect economic growth and job creation and ensure science and American innovation can continue to thrive to solve society's biggest and most pressing challenges.

Missed Opportunity for Biopharmaceutical Innovation Incentives in USMCA

As negotiated, the USMCA represented a significant step towards advancing rules for intellectual property rights to support the modern biotechnology sector. However, while the final text advanced helpful rules for trade secrets, copyrights, and trademarks generally, important IP provisions for biopharmaceuticals that had been agreed to by Canada and Mexico were ultimately stripped from the agreement at the insistence of U.S. lawmakers.

Specifically, the removal of the agreement on 10 years of Regulatory Data Protection, as well as the elimination of patent and regulatory incentives for the study of important product improvements to existing medicines, represents an important, even historic lost opportunity to raise IP standards in key markets and create high-quality US jobs at no cost to North American patients and consumers. More importantly, stripping these provisions sent a global signal that the U.S. Government no longer appears willing to protect leading American innovation in the biopharmaceutical sector against appropriation by foreign competitors.

A more recent manifestation of such misguided antagonism to biopharmaceutical IP is the U.S. government's support for a global waiver of intellectual property rights relating to Covid-19 vaccines, which, however well-intentioned, will only serve as a harmful distraction from the urgent work that must be done to ameliorate global vaccine inequity.



BIO urges the U.S. Government to rethink its support for the proposed global waiver of IP rights that is currently pending in the WTO, and to increase its focus on effective policies to maximize the global availability and equitable distribution of COVID-19 vaccines and therapeutics. BIO's [COVID Global Strategy for Harnessing Access Reaching Everyone \(SHARE\) Program](#) and a [Declaration from Members of the World's Biotechnology Sector](#) provide solutions to ensure vaccines and treatments get to the patients in the world who most need them without undermining innovation.

Conclusion

In closing, a year after the United States, Mexico and Canada confirmed their commitment to North American trade, the biotech sector is faced with tremendous uncertainty. Companies are making decisions today about whether to proceed with launch plans or delay, potentially costing technology companies billions of dollars in foregone revenue and future investment. Similarly, U.S. farmers are facing increasing challenges related to climate change and sustainability, potentially without cutting edge biotechnology tools.

The U.S. government has been a consistent champion for this technology, defending against scientifically unjustified regulatory practices in Europe and China for decades. As one of the United States longest and most significant export markets, Mexico's dramatic policy reversal creates significant risk to the trade of U.S. agricultural products and the ability to leverage biotechnology going forward.