

REGULATORY CHALLENGES

Background

BIO members strive to enrich human health and wellbeing by bringing products to the market that are nutritious for consumers, environmentally sustainable, improve worker safety, enhance animal welfare, and increase farmer productivity and income. Because of the integration of the North American economies, enabled by the North American Free Trade Agreement (NAFTA) and recently confirmed through the United States-Mexico-Canada Agreement (USMCA), the agricultural markets of U.S. and Mexico are inseparably linked. Unfortunately, Mexico's treatment of innovative biotech products is undermining the development and deployment of technologies critical to sustainably feeding the world and addressing climate change.

To function properly, the U.S.-Mexico relationship must be underpinned by functioning laws and regulatory bodies. However, in recent years the Government of Mexico's food and drug regulatory authority (COFEPRIS) has eschewed its responsibilities by failing to assess and approve new drugs for human health and agricultural technologies – leaving Mexican citizens without a competent science-based regulatory authority to safeguard their interests.

The Government of Mexico's failure to fulfill its most basic responsibilities has jeopardized the commercial launch of new agricultural biotechnology products. These actions harm U.S. technology providers and farmers by undermining their efforts to use technology to address nutritional challenges, improve sustainability, and tackle climate change at home and abroad.

\$6 Billion

The United States exports roughly **\$20 billion in agricultural products** to Mexico on an annual basis, **nearly \$6 billion of which is biotech crops and derived products.**

Action is Needed

Mexico is obligated, like other trading partners, to scientific and process-related principles under USMCA and the World Trade Organization (WTO). Aside from similar biopharmaceutical regulatory challenges, there are currently two major regulatory challenges in Mexico that impede agricultural innovation, jeopardizing scientific and human progress:

- ❖ **Failure to Issue Biotech Import Approvals** – Up until 2018 the Mexican government's biotech import approval process was transparent, science-based, and predictable. The Lopez-Obrador administration ended this practice, as his government has failed to issue a biotech import approval since mid-2018. The impact of this failure to administer a functioning biotech regulatory system is that Mexico is now the rate-limiting step to the commercialization of new biotech products in North America.
- ❖ **Mexico's Lack of Regulatory Framework for Gene Edited Products** – Unlike most major agricultural production countries, Mexico has yet to develop a regulatory approach to gene edited agricultural products. As a result, life-science companies seeking to advance a pipeline of gene edited products must either 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. Mexico's failure to develop a gene editing framework impedes global research and development and jeopardizes the potential of this technology to address myriad challenges related to climate change, sustainability, human nutrition, animal welfare, and worker safety.

Recent Decree Further Undermines Agricultural Innovations

Compounding these regulatory challenges, Mexico has recently published a decree announcing the intention to phase-out the use of important agricultural technologies, including imports of biotech corn for human consumption by 2024. Further, the Decree raises the potential for *existing GMO 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 consultation nor scientific rationale.

Through this series of regulatory actions & omissions Mexico is:

- ❖ **Threatening market access for \$6 billion in annual food and agricultural exports to Mexico, and undermining Mexico's food security**, by failing to issue new biotech approvals and signaling the potential to revoke regulatory approvals for biotech corn products;
- ❖ **Violating the biotech provisions of USMCA's Agriculture chapter** whereby Mexico confirmed the importance of encouraging agricultural innovation by maintaining a science-based approval process and facilitating trade in products of agricultural biotechnology;
- ❖ **Disregarding its obligations under USMCA's Sanitary and Phytosanitary Measures chapter**, which requires that Parties' measures to ensure the life and health of humans, animals, and plants be based on scientific principles and not be applied in a manner which would constitute a disguised restriction on international trade; and,
- ❖ **Ignoring its broader international obligations** made under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

BIO asks the U.S. Government to use all possible bilateral and multilateral policy mechanisms and levers to work with Mexico to:

1

Approve all biotech products that have reached or exceeded the 6-month statutory timeline for review and implement a science-based and predictable regulatory process going forward.

2

Create a gene editing framework that conforms with international norms and standards; and

3

Immediately **rescind the recent decree.**