



UNDERSTANDING THE AGRICULTURAL BIOTECHNOLOGY PROVISIONS IN THE U.S.-MEXICO-CANADA AGREEMENT

INTRODUCTION

After several years of negotiation, the United States-Mexico-Canada Agreement (USMCA) entered into force on July 1, 2020.¹ The USMCA updated and in some respects significantly changed the original North America Free Trade Agreement (NAFTA) that had been in effect since January 1, 1994. With some important exceptions, including limits on excessive protections for foreign investment and strengthened labor and environmental protections,² many of the new provisions expand corporate rights in the name of trade liberalization and seek to narrow the scope of domestic regulation of all three signatory countries.

One of the new provisions, incorporated into the USMCA at the behest of the biotechnology industry and industrial agricultural conglomerates, is a section on “Agricultural Biotechnology.”³ There can be no doubt that the proponents of this section hoped to expand the use of biotechnology in agriculture in part by tying the hands of government regulators through trade disciplines. Nonetheless, the final text of the agreement does not restrict domestic policy choices in the manner agribusiness and its allies might wish. This Policy Brief analyzes the agricultural biotechnology provisions of the USMCA to understand what they may require of the parties to the agreement.

INDUSTRY ADVOCACY AND MEXICO’S BIOTECHNOLOGY POLICIES

The advocates for these provisions intended, in the words of Michelle McMurry-Heath, president and CEO of the lobby group Biotechnology Innovation Organization (BIO), “to proactively confront regulatory barriers in other countries that stifle the trade of transformative biotech innovations.”⁴ More specifically, BIO and pharmaceutical, seed and pesticide conglomerate Bayer/Monsanto, among other agribusiness interests, lobbied for these new trade provisions in their bid to reverse a series of regulatory policies and judicial decisions of the Mexican government.

In the past several years, Mexico’s government has sought to promote the biodiversity of Mexican corn varieties and reduce the use of the herbicide glyphosate to protect public health. Mexico has not issued any biotechnology food or feed product approvals since May 2018, with some applications pending at the health

agency COFEPRIS beyond the six-month deadline set out in Mexico's statute regulating biotechnology.⁵ Permits for planting herbicide-resistant cottonseed, which is the only genetically engineered crop allowed to be grown commercially in Mexico at this time, have also been delayed or denied by the Secretariat of Environment and Natural Resources (SEMARNAT) based on concerns about impacts on seed biodiversity and inadequate consultation with indigenous communities.⁶ On January 1, 2021, a Presidential Decree entered into force calling for a phase-out of glyphosate and genetically engineered corn by January 2024 and its replacement with "sustainable and culturally appropriate" alternatives.⁷ A 2021 decision by Mexico's highest court upheld the denial of a permit for a new corn variety developed by Bayer/Monsanto, preventing future imports. In its decision, the court found that cultivation of genetically modified corn poses a credible threat to Mexico's rich store of native corn biodiversity through uncontrolled cross-pollination.⁸

Mexico's regulatory actions have been roundly attacked by U.S. agribusiness, the U.S. Department of Agriculture and some politicians. For instance, Bayer has been making the case both publicly in the media and privately to government officials that Mexico's refusal to approve its new genetically engineered corn variety violates the agricultural biotechnology provisions of USMCA.⁹ These claims were repeated by BIO's McMurray-Heath in her testimony before the U.S. Senate; because of the USMCA agricultural biotechnology provisions, she averred, "Mexico must resume the approval process for all agricultural biotechnology products" and "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."¹⁰

Industry complaints about Mexico's permitting process have been echoed by members of Congress in several letters sent to both U.S. Department of Agriculture Secretary Tom Vilsack and U.S. Trade Representative Katherine Tai. A joint letter from Senate Finance Committee Chair Ron Wyden and ranking member Mike Crapo calls for the U.S. to "take enforcement steps if necessary" under the USMCA because, they claim, "Mexico has failed to properly consider or approve applications for innovative U.S. biotech products" and "announced its intention to eliminate biotech corn for human consumption by 2024, a troubling step that would adversely impact access to the largest U.S. export market for corn."¹¹

WHAT THE USMCA AGRICULTURAL BIOTECHNOLOGY PROVISIONS SAY

EXPANSIVE DEFINITION OF COVERED PRODUCTS. The USMCA is the first U.S. free trade agreement to include agricultural biotechnology provisions.¹² Covered products are broadly defined to encompass products created with newer genome editing and other genetic engineering techniques, which are identified in the text as "modern biotechnology." Article 3.12 expansively defines agricultural biotechnology as "technologies, including modern biotechnology, used for the deliberate manipulation of an organism to introduce, remove, or modify one or more heritable characteristics of a product for agriculture and aquaculture use and that are not technologies used in traditional breeding and selection." [emphasis added] The article defines "modern biotechnology" as "the application of: (a) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles; or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection."

Products created with any of these techniques are within the scope of the USMCA provisions. The expansive definition of agricultural biotechnology is significant because it covers all tariff lines for agricultural and food products in the World Customs Union's Harmonized Schedule including horticulture products and other "specialty crops." It also inserts into an enforceable international agreement longstanding U.S. regulatory doctrine that no matter how much a genome such as corn is altered in engineering, it is not materially different in composition, safety and other relevant parameters from conventionally grown corn-derived

food and feed currently on the market and thus not subject to formal risk assessment and safety reviews.¹³ This policy differs from that currently followed in the European Union and other countries.¹⁴

AUTHORIZATION NOT REQUIRED. The USMCA agricultural biotechnology text is heavy on procedural provisions and nonbinding language about promoting information exchanges, transparency and cooperation. There are few mandatory provisions, and none require approving applications to market agricultural biotechnology products. While the introductory paragraph of Article 3.14 states, “The Parties confirm the importance of encouraging agricultural innovation and facilitating trade in products of agricultural biotechnology,” this hortatory declaration is followed immediately by the unambiguous and unequivocal statement: “*This Section does not require a Party to mandate an authorization for a product of agricultural biotechnology to be on the market.*” [Art. 3.14.2, emphasis added]

Some procedural provisions are mandatory.

- **INFORMATION PUBLICLY AVAILABLE.** Information about how to apply for authorization of a covered product, risk assessments supporting a decision to authorize a product and a list of any agricultural biotechnology products that have been authorized are required to be made available to the public, and to the extent possible, accessible online. [Art. 3.14.3(a)-(c)]
- **YEAR-ROUND APPLICATION PROCESS.** The Parties are required to “encourage applicants to submit timely and concurrent applications to the Parties for authorization” [Art. 3.14.4(b)] and to “accept and review applications for the authorization, if required, of products of agricultural biotechnology on an ongoing basis year-round.” [Art. 3.14.4(b)(i)] This provision requires Canada, Mexico and the U.S. to accept and review applications to authorize agricultural biotechnology products throughout the year. It is notable that nothing here requires a decision on the application within a particular timeframe or indeed, that a decision be rendered.
- **A PROCESS TO CONSIDER NOVEL PRODUCTS.** The Parties are required to “adopt or maintain measures that allow the initiation of the domestic regulatory authorization process of a product not yet authorized in another country.” [Art.3.14(b)(ii)] This provision would prevent a party from linking an authorization decision or limiting acceptance of applications for authorization to only those products that have already been authorized in another country.
- **PREVIOUSLY AUTHORIZED PRODUCTS.** In contrast with the first-time and novel product authorization provisions, a party requiring reauthorization of a previously authorized product shall “take steps to help ensure that the review of the product is completed and a decision is made in a timely manner, and if possible, prior to expiration.” [Art.3.14.4(b)(iii)] This is the only reference in the agricultural biotechnology section to completing review of an application or to a timeframe for that review, and its application is limited to reauthorization decisions. The language encourages action (“help ensure”) rather than impose a hard-and-fast deadline.
- **COMMUNICATION.** The Parties are required to exchange information about “new and existing authorizations of products of agricultural biotechnology.” [Art.3.14.4(b)(iv)]

MANAGING LOW LEVEL CONTAMINATION. To the extent that the agricultural biotechnology section includes mandatory provisions, these primarily address avoiding and mitigating cross-contamination from imported genetically engineered products. “Low Level Presence Occurrence” (LLP) is defined as genetically engineered plant materials “which may on occasion be inadvertently present in food or feed in importing countries in which the food safety of the relevant recombinant DNA plant has not been determined.” [Art. 3.12]¹⁵ This section requires each party to “adopt or maintain policies or approaches designed to facilitate the management of any LLP Occurrence” [Art. 3.15.1] and lists several required or encouraged information

exchanges. The LLP occurrence provisions also impose on the importing party a requirement that the occurrence of the contamination “is managed without unnecessary delay” and that any measure taken to address the contamination is “appropriate” taking into account the risk. [Art. 3.15.3(c)-(d)]

COOPERATION ACTIVITIES. A Working Group for Cooperation on Agricultural Biotechnology is established, which is to meet at least annually to provide a forum for information exchanges and potential collaboration on approaches to managing LLP occurrences and regulation of agricultural biotechnology more generally. [Art. 3.16]

ENFORCEABILITY. The agricultural biotechnology provisions are subject to USMCA Chapter 31 on dispute settlement, which applies to the Chapter on Agriculture in its entirety.¹⁶ Because there are so few hard obligations set out in the agricultural biotechnology section of that chapter, the utility of the Chapter 31 dispute settlement mechanism is necessarily limited.

Article 31.2 lists three scenarios for invoking dispute settlement: (1) “avoidance or settlement of disputes between the Parties regarding the interpretation or application” of the USMCA [Art. 31.2.1(a)]; (2) “when a Party considers that an actual or proposed measure of another Party is or would be inconsistent with an obligation of this Agreement or that another Party has otherwise failed to carry out an obligation of this Agreement” [Art. 31.2.2(b)]; or (3) “when a Party considers that a benefit it could reasonably have expected to accrue to it under” the Agriculture chapter “is being nullified or impaired as a result of the application of a measure of another Party that is not inconsistent with this Agreement.” [Art. 31.2.3(c)]

A decision by a Party to deny an application for authorization of a product of agricultural biotechnology could not be contested under this paragraph. As discussed above, Agricultural Biotechnology Article 3.14.2 makes clear that there is no obligation of a Party to approve any application. For the same reason, there could not be a reasonable expectation by the applicant that approval is “a benefit that would accrue to it.” Likewise, a failure by a Party to act promptly (or at all) on a first-time application for authorization of a product of agricultural biotechnology would be difficult to contest, as there is no obligation to do so spelled out in the text of the agreement.

A complaint that a Party was refusing to accept any applications for authorization of a product of agricultural biotechnology, or limiting the submission of applications to a narrow window of time, would be on stronger ground as an “obligation.” As we have discussed, Agricultural Biotechnology Article 3.14.4(b) requires that a Party have a review process and accept applications throughout the year. Similarly, a complaint that a Party had failed to review a reauthorization application and issue a decision “in a timely manner” has support in the text. Even so, without hard and fast deadlines written into the agreement, “timeliness” would be subject to interpretation.

ARE CLAIMS THAT MEXICO IS VIOLATING THE AGRICULTURAL BIOTECHNOLOGY ARTICLE MERITED?

To succeed in an enforcement action against Mexico under this article, the U.S. would need to establish a specific obligation that Mexico failed to carry out or show that a benefit it could reasonably have expected to receive under the USMCA was “nullified or impaired” by Mexico’s actions. As a straightforward reading of the biotechnology article makes clear, there is no basis for an enforcement action to challenge Mexico’s decision not to authorize the new Bayer/Monsanto corn variety. The company could not reasonably expect authorization when the text of the USMCA unequivocally asserts in Article 3.14.2 that the section “does not require a Party to mandate an authorization for a product of agricultural biotechnology to be on the market.”

Additionally, while the Wyden-Crapo letter is free to call the decision by Mexico to phase out biotech corn for human consumption by 2024 a “troubling step” for U.S. exporters, Mexico retains its domestic policy-making authority to adopt nondiscriminatory health and environmental regulations even if there are trade impacts. The agricultural biotechnology article does not require Mexico to “immediately rescind” its decree phasing out importation of biotech corn, as the lobby group BIO demands.

Mexico retains authority to adopt and implement policies to protect the environment and public health, preserve and enhance biodiversity, and respect Indigenous communities and lifestyles. For example, Article 24.3.1 of the USMCA’s Environment Chapter recognizes “the sovereign right of each Party to establish its own levels of domestic environmental protection and its own environmental priorities, and to establish, adopt, or modify its environmental laws and policies accordingly.” Article 24.15 on Trade and Biodiversity mandates that each Party “shall promote and encourage the conservation and sustainable use of biological diversity, in accordance with its law or policy” [Art. 24.15.2] and includes a provision recognizing “the importance of respecting, preserving, and maintaining knowledge and practices of indigenous peoples and local communities embodying traditional lifestyles that contribute to the conservation and sustainable use of biological diversity.” [Art. 24.15.3]¹⁷

Complaints that Mexico has unreasonably delayed acting to approve or deny permits and marketing authorizations do raise process issues that could be addressed in consultations between the parties pursuant to the USMCA. Although the agricultural biotechnology article does not impose a specific timetable for regulatory decisions, there would be a reasonable expectation by U.S. companies that Mexico’s regulatory agencies would seek to meet the deadlines set out in Mexico’s applicable domestic law. There may be legitimate reasons for the delays that would be most appropriately explored in a consultation setting. For instance, after several years of appeals, Mexico’s Supreme Court issued a decision only in October 2021 upholding a 2013 injunction restricting cultivation of genetically modified corn. That case could be expected to set substantive ground rules for decisions by COFEPRIS to grant or deny marketing authorization. Pandemic-related delays may also be a factor.

CONCLUSION

The agricultural biotechnology article of the USMCA provides procedural guidance to government regulators but lacks substantive requirements that would provide a basis for overturning Mexico’s policies and permit decisions about genetically modified agricultural products. While industry lobbyists succeeded in convincing trade negotiators to include agricultural biotechnology provisions in the USMCA, they now misstate the scope and significance of the text that was agreed to by Canada, Mexico and the U.S. The parties to the USMCA retain considerable authority to enact and implement non-discriminatory agricultural, environmental and cultural policies that may affect the marketing and cultivation of agricultural biotechnology. Mexico’s actions align with that authority.



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ENDNOTES

1. While the agreement is known as USMCA in the United States, Canada officially named the agreement “CUSMA,” putting Canada first in the order of countries, and in Mexico the agreement is known as T-MEC (El Tratado entre México, Estados Unidos y Canadá).
2. An exception is USMCA’s Chapter 14 on investment, which limited the scope of the corporate arbitration system known as Investor State Dispute Settlement, and the Labor and Environment chapters, which were amended to include stronger enforcement provisions to address concerns raised by the U.S. Congress. The full USMCA text is posted here: <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between>.
3. Agriculture, Chapter 3, Section B, Article 3.12-16, https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/o3_Agriculture.pdf (accessed February 8, 2022).
4. Testimony of Dr. Michelle McMurry-Heath, President & CEO Biotechnology Innovation Organization (BIO), United States Senate Committee on Finance Hearing “Implementation and Enforcement of the United States – Mexico – Canada Agreement: One Year After Entry into Force,” July 27, 2021, <https://www.finance.senate.gov/imo/media/doc/2021.07.27%20SFC%20USMCA%20Hearing%20-%20McMurry-Heath%20Testimony.pdf> (accessed February 8, 2022).
5. U.S. Department of Agriculture, Global Agricultural Information Network. Agricultural Biotechnology Annual Country: Mexico. Report Number: MX2021-0087. October 20, 2021. https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Mexico%20City_Mexico_10-20-2021.pdf (accessed January 31, 2022).
6. U.S. Department of Agriculture, Global Agricultural Information Network. Cotton and Products Update. Report Number: MX2020-0045. March 01, 2021. https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Cotton%20and%20Products%20Update_Mexico%20City_Mexico_08-30-2020 (accessed February 7, 2022).
7. See e.g., Directive of December 31, 2020, https://www.dof.gob.mx/nota_detalle.php?codigo=5609365&fecha=31/12/2020 (accessed February 7, 2022).
8. “Mexico’s Highest Court Rejects Appeal of GM Corn Ban,” Food Tank, October 2021, <https://foodtank.com/news/2021/10/mexicos-highest-court-rejects-appeal-of-gm-corn-ban/> (accessed February 8, 2022); David Alire Garcia, Adriana Barrera, “Mexico denies permit for new GMO corn variety, first time ever,” October 8, 2021, Reuters, <https://www.reuters.com/article/mexico-grains-corn/mexico-denies-permit-for-new-gmo-corn-variety-first-time-ever-idUSKBN2GY1GL> (accessed February 8, 2022).
9. David Alire Garcia, “Bayer blasts ‘unscientific’ rejection by Mexican regulator of GMO corn permit,” Reuters, October 8, 2021, <https://www.reuters.com/world/americas/bayer-blasts-unscientific-rejection-by-mexican-regulator-gmo-corn-permit-2021-10-08/> (accessed February 8, 2022).
10. Ibid. See also letter from several agricultural trade organizations to USDA Secretary Tom Vilsack and U.S. Trade Representative Katherine Tai (March 22, 2021), https://www.nationalpotatocouncil.org/wp-content/uploads/2021/03/Vilsack_Tai-Letter_USDA-Mexico-issues_Final_210322.pdf (accessed February 10, 2022).
11. See e.g., Wyden, Crapo urge Tai to consider more USMCA enforcement actions, Inside U.S. Trade, January 12, 2022, <https://insidetrade.com/daily-news/wyden-crapo-urge-tai-consider-more-usmca-enforcement-actions>; letter posted at: <https://www.finance.senate.gov/chairmans-news/bipartisan-senate-finance-committee-leaders-wyden-and-crapo-ustr-must-enforce-usmca-to-ensure-benefits-for-american-workers-farmers-and-businesses>. The Wyden-Crapo letter also objected to Mexico’s food labeling policies, which are not addressed in this policy brief. For IATP’s analysis of food labeling complaints see “The Bully in the Lunchroom,” March 6, 2020, <https://www.iatp.org/documents/bully-lunchroom>.
12. Congressional Research Service. “Agricultural Biotechnology: Overview, Regulation, and Selected Policy Issues”. March 29, 2021. (p.35). <https://crsreports.congress.gov/product/pdf/R/R46737/3>. While not technically an FTA, the 2020 “Phase One” economic agreement with China also includes agricultural biotechnology provisions, albeit more narrowly defined. See, Annex 16 of the 2020 “Economic And Trade Agreement Between The Government Of The United States Of America And The Government Of The People’s Republic Of China” (known as the “Phase One Trade Agreement”), https://ustr.gov/sites/default/files/files/agreements/phase%20one%20agreement/Economic_And_Trade_Agreement_Between_The_United_States_And_China_Text.pdf.

13. See e.g., U.S. Department of Agriculture. Media Release. March 28, 2018. <https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation>. For more on these issues see “Food safety and GMOs in the ‘new NAFTA.’” Institute for Agriculture and Trade Policy. Steve Suppan. October 17, 2018, <https://www.iatp.org/documents/food-safety-and-gmos-new-nafta>.

14. Current EU policy is guided by a 2018 court decision. See, Court of Justice of the European Union. 25 July 2018. Judgment in Case C-528/16 Confédération paysanne and Others v Premier ministre and Ministre de l’Agriculture, de l’Agroalimentaire et de la Forêt. “Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive.” <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>. The European Commission has proposed changing EU legislation to limit regulatory oversight of GMOs, an action the French Council of State has requested be suspended until the Court of Justice publishes clarifications concerning the status of new GM techniques in EU law. “More than 80 organisations call on European Commission to wait for court’s clarifications on new GM Details.” GM Watch. February 8, 2022, <https://www.gmwatch.org/en/106-news/latest-news/19982-more-than-80-organisations-call-on-the-european-commission-to-wait-for-court-s-clarifications-on-new-gm> (accessed February 8, 2022).

15. The full definition is: “Low Level Presence (LLP) Occurrence means low levels of recombinant deoxyribonucleic acid (DNA) plant materials that have passed a food safety assessment according to the Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) in one or more countries, which may on occasion be inadvertently present in food or feed in importing countries in which the food safety of the relevant recombinant DNA plant has not been determined.”

16. USMCA Article 31, Dispute Settlement, <https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/31%20Dispute%20Settlement.pdf>.

17. USMCA Chapter 24, https://ustr.gov/sites/default/files/files/agreements/usmca/24_Environment.pdf.