MEXICO – MEASURES CONCERNING GENETICALLY ENGINEERED CORN

(MX-USA-2023-31-01)

INITIAL WRITTEN SUBMISSION OF THE UNITED STATES OF AMERICA

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TABLE OF ABBREVIATIONS

Abbreviation	Definition
2020 Corn Decree	*Decree establishing the actions that must be carried out by the agencies and entities that make up the Federal Public Administration, within the scope of its powers, to gradually replace the use, acquisition, distribution, promotion and importation of the chemical substance called glyphosate and of the agrochemicals used in our country that contain it as an active ingredient, for sustainable and culturally appropriate alternatives that allow maintaining production and are safe for human health, the biocultural diversity of the country and the environment*[1]
2023 Corn Decree or Decree	*Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn* [2]
AAAS	American Association for the Advancement of Science
AMS	Agricultural Marketing Service
ALOP	Appropriate level of protection
APHIS	Animal and Plant Health Inspection Service
Biosafety Law	*Biosafety Law of Genetically Modified Organisms* (Feb. 2005)
Biosafety Regulations	*Regulations to the Genetically Modified Organisms Biosafety Law* (2008)
CGIAR	Consortium of International Agricultural Research Centers
CIMMYT	International Maize and Wheat Improvement Center
Codex	Codex Alimentarius Commission

[1] The original Spanish text is titled: "*Decreto por el que se establecen las acciones que deberán realizar las dependencias y entidades que integran la Administración Pública Federal, en el ámbito de sus competencias, para sustituir gradualmente el uso, adquisición, distribución, promoción e importación de la sustancia química denominada glifosato y de los agroquímicos utilizados en nuestro país que lo contienen como ingrediente activo, por alternativas sostenibles y culturalmente adecuadas, que permitan mantener la producción y resulten seguras para la salud humana, la diversidad biocultural del país y el ambiente*."

[2] The original Spanish text is titled: "*Decreto por el que se Establecen Diversas Acciones en Materia de Glifosato y Maíz Genéticamente Modificado*."

Codex Guidelines	*Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*
Codex Principles	*Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*
COFEPRIS	Mexican Federal Commission for the Protection Against Sanitary Risks
DNA	Deoxyribonucleic acid
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
ERS	Economic Research Service
FAO	Food and Agriculture Organization of the United Nations
FAS	Foreign Agricultural Service
FDA	U.S. Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
GAIN	Global Agricultural Information Network
GATT 1994	*General Agreement on Tariffs and Trade 1994*
GE	Genetically engineered
GEOs	Genetically engineered organisms
GMOs	Genetically modified organisms
IPPC	*International Plant Protection Convention*
ISAA	International Service for the Acquisition of Agri-biotech Applications
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LMOs	Living modified organisms
Party	USMCA Party

PDP	Pesticide Data Program
SADER or SAGARPA	Mexican Secretariat of Agriculture
SALUD or SSA	Mexican Secretariat of Health
SHCP	Mexican Secretariat of Finance and Public Credit
SEMARNAT	Mexican Secretariat of the Environment
SPS	Sanitary and phytosanitary
SPS Agreement	*Agreement on the Application of Sanitary and Phytosanitary Measures*
USDA	U.S. Department of Agriculture
USMCA or Agreement	*United States-Mexico-Canada Agreement*
Vienna Convention	*Vienna Convention on the Law of Treaties* (1969)
WHO	World Health Organization
WTO	World Trade Organization

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USA-103	Secretariat of the IPPC, *Pest Risk Analysis for Quarantine Pests* (2017).
USA-104	Panel Reports, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R (adopted Nov. 21 2006).
USA-105	"Affect," *Oxford English Dictionary*, https://www.oed.com/view/Entry/3324?rskey=xMfh8h&result=4#eid.

Exhibit No.	Description
USA-106	"Trade," *Oxford English Dictionary*, https://www.oed.com/view/Entry/204274?rskey=xCv2qZ&result=1&isAdvanced=false#eid.
USA-107	U.S. Census Bureau Trade Data, "U.S. Agriculture Imports for Consumption from the World."
USA-108	Intentionally omitted
USA-109	Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R (adopted Nov. 6, 1998).
USA-110	"Base," *Oxford English Dictionary*, https://www.oed.com/view/Entry/15856?rskey=rbmMNE&result=3&isAdvanced=false#eid.
USA-111	Panel Report, *United States – Measures Affecting the Importation of Animals, Meat and Other Animal Products from Argentina*, WT/DS447/R (adopted Aug. 31, 2015).
USA-112	Panel Report, *India – Measures Concerning the Importation of Certain Agricultural Products*, WT/DS430/R (adopted June 19, 2015).
USA-113	Codex Alimentarius Commission ("Codex"), *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*.
USA-114	Codex, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*.
USA-115	Intentionally omitted
USA-116	"Nobel Prize Winners Endorse Agricultural Biotechnology," *Institute for Agriculture & Trade Policy* (Feb. 8, 2000), https://www.iatp.org/news/nobel-prize-winners-endorse-agricultural-biotechnology.
USA-117	Secretariat of the IPPC, *Framework for Pest Risk Analysis* (2007), https://www.ippc.int/static/media/files/publication/en/2016/01/ISPM_02_2007_En_2015-12-22_PostCPM10_InkAmReformatted.pdf.
USA-118	"Apply," *Oxford English Dictionary*, https://www.oed.com/view/Entry/9724?rskey=hXUug1&result=2&isAdvanced=false#eid.
USA-119	"Necessary," *Oxford English Dictionary*, https://www.oed.com/view/Entry/125629?redirectedFrom=necessary#eid.

Exhibit No.	Description
USA-120	Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R (adopted Jan. 10, 2001).
USA-121	Panel Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/R (adopted Dec. 17, 2010).
USA-122	Panel Report, *United States – Certain Measures Affecting Imports of Poultry from China*, WT/DS392/R (adopted Oct. 25, 2010).
USA-123	"Principle," *Oxford English Dictionary*, https://www.oed.com/dictionary/principle_n?tab=meaning_and_use#28387945.
USA-124	Intentionally omitted
USA-125	"Prohibition," *Oxford English Dictionary*, https://www.oed.com/view/Entry/152258?redirectedFrom=prohibition#eid.
USA-126	Panel Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/R (adopted Dec. 17, 2007).
USA-127	"Restriction," *Oxford English Dictionary*, https://www.oed.com/view/Entry/164022?redirectedFrom=restriction#eid.
USA-128	Panel Report, *India – Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, WT/DS90/R (adopted Sept. 22, 1999).
USA-129	Panel Report, *India – Measures Affecting the Automotive Sector*, WT/DS146/R, WT/DS175/R (adopted Apr. 5, 2002).
USA-130	Appellate Body Reports, *China – Measures Related to the Exportation of Various Raw Materials*, WT/DS394/AB/R, WT/DS395/AB/R, WT/DS398/AB/R (adopted Feb. 22, 2012).
USA-131	Appellate Body Reports, *Argentina – Measures Affecting the Importation of Goods*, WT/DS438/AB/R, WT/DS444/AB/R, WT/DS445/AB/R (adopted Jan. 26, 2015).
USA-132	"Importation," *Oxford English Dictionary*, https://www.oed.com/dictionary/importation_n?tab=meaning_and_use#875896.
USA-133	Intentionally omitted

Exhibit No.	Description
USA-134	Panel Report, *Indonesia – Importation of Horticultural Products, Animals and Animal Products*, WT/DS477/R, WT/DS478/R (adopted Nov. 22, 2017).
USA-135	Appellate Body Report, *Indonesia – Importation of Horticultural Products, Animals and Animal Products*, WT/DS477/AB/R, WT/DS478/AB/R (adopted Nov. 22, 2017).
USA-136	Intentionally omitted
USA-137	Codex, "Glossary of Terms," https://www.fao.org/fao-who-codexalimentarius/GSFA-online/Glossary.
USA-138	Codex, *Guidelines on the Application of Risk Assessment for Feed* (2013).
USA-139	WTO, *General Agreement on Tariffs and Trade 1994* (excerpt).

I. INTRODUCTION

1. For the past three decades, farmers around the world have been sowing and harvesting millions of acres of genetically engineered ("GE") corn for use in food products and animal feed. Over this time, an extensive body of scientific research has been developed, confirming the safety of GE corn—and GE crops more broadly—that have been commercialized for human and animal consumption.[3]

2. Historically, Mexico has been one of the countries with the most authorizations for importing and selling GE crops for use in human food and animal feed. Mexico has issued over 200 event authorizations across 11 different GE crops—alfalfa, canola, two types of cotton, corn, lemon, potato, rice, soybean, sugar beet, and tomato—and the number of authorizations for corn (scientific name, *Zea mays*) alone nearly equals the number of authorizations for the other ten GE crops combined.[4]

3. After permitting the importation and sale of GE corn in Mexico for decades without experiencing any adverse effects on human, animal, or plant life or health, and after recommitting to fair, open, and science-based trade under the *United States-Mexico-Canada Agreement* ("USMCA" or "Agreement"), Mexico suddenly and completely reversed its policy. There was no new science. There was no new risk assessment. There was only a change in government.

4. For more than four years, the United States has used the mechanisms available under the USMCA to urge Mexico to return to a science- and risk-based approach that is consistent with Mexico's obligations under the USMCA. Rather than bringing its measures into conformity, Mexico has continued to diverge from its USMCA obligations, most recently by issuing a Presidential decree on February 13, 2023, that (i) bans the use of GE corn in dough and tortillas, and (ii) instructs Mexican government agencies to gradually substitute—*i.e.*, restrict and eventually ban outright—the use of GE corn in all products for human consumption and for

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[3] *See, e.g.*, D. Norero, "More than 280 Scientific and Technical Institutions Support the Safety of GM crops," *Sí Quiero Transgénicos* ("*I Do Want GMOs*") (June 19, 2017), http://www.siquierotransgenicos.cl/2015/06/13/more-than-240-organizations-and-scientific-institutions-support-the-safety-of-gm-crops/ (summarizing the thousands of scientific studies and the 284 scientific and technical institutions around the world that have affirmed the safety of GE crops) (Exhibit USA-1).

[4] *See infra* Section II.D; *see also* U.S. Department of Agriculture Foreign Agricultural Service ("USDA FAS") & Global Agricultural Information Network ("GAIN"), "Agricultural Biotechnology Annual, Mexico," at 8, 11, 14 (Mar. 12. 2020), https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Mexico%20City_Mexico_10-20-2019 (Exhibit USA-2). As explained in Section II.D, Mexico approves GE products on the basis of specific "events" (*i.e.*, particular crop variety with one or more particular transgenes in specific locations on a chromosome). Mexico historically published a list of event authorizations but has not done so since 2020; accordingly, the United States learned of event authorizations since 2020 through confidential conversations with Mexico and applicant companies.

animal feed.[5] This decree, which restricts the importation of goods from another Party, is not predicated on science- or risk-based principles and contradicts the international standards, guidelines, and recommendations relevant to human, animal, and plant life and health.

5. Accordingly, for the reasons provided in this U.S. initial written submission, Mexico's measures concerning GE corn are inconsistent with several of Mexico's obligations under the Sanitary and Phytosanitary Measures Chapter ("SPS Chapter") as well as under the National Treatment and Market Access for Goods Chapter of the USMCA. The United States respectfully requests that the Panel find that Mexico's measures are inconsistent with Mexico's USMCA obligations.

II. STATEMENT OF FACTS

A. Products at Issue

6. Mexico is a critical export market for U.S. agricultural products, particularly corn and soybeans—and the United States similarly is a huge market for Mexican agricultural exports.[6] In 2022, the United States exported to Mexico $28.5 billion of agricultural goods, including $4.9 billion of corn and $4.5 billion of soybeans and soy products.[7] Mexico is the United States' second largest export market for corn, and corn is Mexico's largest agricultural import, by value, from the United States.[8]

7. The United States is also the largest producer of genetically engineered ("GE") crops in the world.[9] In 2022, U.S. farmers grew GE alfalfa, apples, canola, corn, cotton, papayas,

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[5] *See Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn* (Feb. 13, 2023) ("2023 Corn Decree") (Exhibit USA-3).

[6] *See* U.S. Census Bureau Trade Data, "U.S. Agriculture Imports for Consumption from the World" (Exhibit USA-107). In 2022, U.S. agricultural imports from Mexico totaled $43.3 billion, constituting the United States' largest supplier of imported agricultural products. As of 2022, Mexico had a $14.8 billion trade surplus with the United States in agricultural products.

[7] USDA FAS, "U.S. Trade with Mexico in 2022," https://www.fas.usda.gov/regions/mexico (Exhibit USA-4).

[8] *See* USDA, "U.S. Corn Exports in 2022," https://www.fas.usda.gov/data/commodities/corn#:~:text=Export%20Sales%20Announcement-,Export%20Sales%20to%20Mexico,delivery%20during%20MY%202023%2F2024 (Exhibit USA-5); USDA FAS & GAIN, "Retail Foods," at 2 (July 5, 2023), https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Retail%20Foods_Mexico%20City%20ATO_Mexico_MX2023-0033.pdf (Exhibit USA-6).

[9] *See* International Service for the Acquisition of Agri-biotech Applications ("ISAA"), "ISAAA Brief 55-2019: Executive Summary Biotech Crops Drive Socio-Economic Development and Sustainable Environment in the New Frontier" (2019), https://www.isaaa.org/resources/publications/briefs/55/executivesummary/pdf/B55-ExecSum-English.pdf (Exhibit USA-7).

potatoes, soybeans, sugar beets, and summer squash.[10] Corn, upland cotton, and soybeans are the predominant GE field crops in the United States and have been commercially available in the United States since the mid-1990s.[11] As of 2022, GE products accounted for 93 percent of corn, 95 percent of cotton, and 95 percent of soybeans planted in the United States.[12] Nearly all canola planted in the United States is also GE.[13]

8. As will be further explained in this initial submission, Mexico, in issuing its *Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn* ("2023 Corn Decree" or "Decree"), seeks to eliminate the importation and sale of GE corn for human consumption and animal feed, threatening billions of dollars of U.S. exports to Mexico and wholly undermining the commitments that Mexico made under the USMCA, without scientific basis.[14]

9. In the next section, the United States will explain the historical and scientific context in which genetic engineering was developed and will explain the benefits of the technology along with its established safety record. The United States will then explain the robust regulatory framework that the United States has in place for bringing GE products of agricultural biotechnology to market and Mexico's regime governing the importation and sale of GE products in Mexico.

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[10] *See* U.S. Food and Drug Administration ("FDA"), "GMO Crops in the U.S." (July 2022), https://www.fda.gov/media/135274/download (Exhibit USA-8). FDA uses the acronym "GMO" in certain materials for a public audience to facilitate accessibility, but FDA uses the more precise term ("GE") for regulatory purposes. *See also infra* Section II.B (explaining that "GE" organisms are a subset of "GMOs").

[11] USDA Economic Research Service ("ERS"), "Recent Trends in GE Adoption" (Sept. 14, 2022), https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption/ (Exhibit USA-9).

[12] USDA ERS, "Genetically Engineered Varieties of Corn, Upland Cotton, and Soybeans by State and for the United States, 2000-22" (Sept. 14, 2022), https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-u-s/ (Exhibit USA-10).

[13] *See* USDA ERS, "More than Half of Harvested U.S. Cropland Uses Seed Varieties with at least One Genetically Modified Trait" (last updated Aug. 7, 2023), https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=107037&cpid=email (Exhibit USA-11).

[14] *See* Trade Data Monitor, "United States Exports to Mexico, Commodity: 100590, Corn (Maize), Other than Seed Corn" (last accessed August 24, 2023) (Exhibit USA-12). The United States presently understands that HTS subheading 1005.90.4049 (Popcorn, Unpopped, Except Seed, Nesoi) is not within the scope of the 2023 Corn Decree and thus not within scope of this dispute.

B. Genetic Engineering

10. Genetic engineering is defined as the "manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques."[15] Products of genetic engineering are commonly referred to as genetically engineered ("GE") products or genetically engineered organisms ("GEOs").[16] The U.S. Department of Agriculture ("USDA") and other U.S. regulatory agencies consider GE products to be a subset of genetically modified organisms ("GMOs"), which are organisms produced through genetic modification, *i.e.*, "the production of heritable improvements in plants or animals for specific uses, via either genetic engineering or other more traditional methods."[17] Other countries, including Mexico, tend to use "genetically modified organism" or "GMO" to refer to GE products. However, such usage is imprecise, because virtually all modern crops are the product of genetic modification.[18]

11. Over the centuries, plants have been genetically modified through, among other methods, selective breeding,[19] grafting,[20] cross-breeding,[21] induced mutation,[22] and tissue culture.[23] Modern biotechnology continues the trend in developing ever more precise and effective methods for improving the productivity and functionality of plants, animals, and microorganisms. The phrase "GE products" or "biotech products," as used in this submission, refers to plant cultivars that have primarily been developed through recombinant deoxyribonucleic acid ("recombinant DNA") technology, the most advanced technique of genetic modification.

12. As scientists obtained greater understanding of the principles of genetics, they began to identify the specific biochemical and molecular mechanisms that operated within living

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[15] USDA, "Agricultural Biotechnology Glossary," https://www.usda.gov/topics/biotechnology/biotechnology-glossary (Exhibit USA-13).

[16] *Id.* (Exhibit USA-13).

[17] *Id.* (Exhibit USA-13).

[18] *Id.* (Exhibit USA-13); **Error! Main Document Only.***see also, e.g.*, T. V. Suslow et al., **Error! Main Document Only.**"Biotechnology Provides New Tools for Plant Breeding," *Agricultural Biotechnology in California Series*, at 14 (Mar. 2001), https://anrcatalog.ucanr.edu/pdf/8043.pdf (Exhibit USA-14). Therefore, this submission uses the term "GE products" or "biotech products" when referring to products of modern biotechnology.

[19] Genetic modification of plants began with the invention by early farmers of selective breeding techniques to obtain plants with improved traits and qualities. Selective breeding represents human's first successful modification, for the benefit of all succeeding generations, of the process of natural selection in plants. *See* T. V. Suslow, et al., "Biotechnology Provides New Tools for Plant Breeding," *Agricultural Biotechnology in California Series*, at 1-5 (Mar. 2001), https://anrcatalog.ucanr.edu/pdf/8043.pdf (Exhibit USA-14).

[20] Early agriculturalists also learned to use, in addition to selective breeding, the technique of grafting to improve genetically certain plants. Grafting was the first technique by which man inserted genes from one organism directly into another to achieve an improvement in plant performance. *Id.* (Exhibit USA-14).

organisms to give them their particular traits. Scientists learned that within the nucleus of every cell of all organisms there are molecular structures, which they called "genes," that are packaged in long chains called chromosomes on which most of the biochemical instructions that determine the organism's characteristics are encoded. Although there are thousands of unique genes on the chromosomes of each organism (a simple plant has approximately 20,000 genes, complex plants approximately 100,000), researchers learned that particular characteristics are determined by a discrete number—one or several—of those thousands of genes.[24]

13. During the past century, scientists also discovered that the basic genetic material in all living organisms is chemically similar. All DNA (deoxyribonucleic acid, the molecule that genes are made of) is a combination of just four chemical compounds distinguished by their distinctive bases—adenine, thymine, cytosine and guanine. The sequence in which these compounds appear on a particular gene is a biological code—instructions that the cell machinery follows in order to manufacture different proteins. The particular set of proteins produced in an organism—whether a plant, animal, or microorganism—direct the functions necessary for life and for the expression of specific traits. Because DNA is chemically the same in all living things, different organisms can read and interpret the information encoded on any gene.

14. Improved understanding of the biochemistry underlying the laws of genetics has allowed scientists to operate on a molecular level and to develop new "transgenic" techniques—*i.e.*, techniques in which a discrete number of genes (usually one or several) are transferred to an organism. The major difference between the traditional forms of genetic modification described

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[21] A number of technological advances in the genetic modification of crop plants have occurred since the end of the nineteenth century as the science of genetics developed based on the pioneering work of Gregor Mendel. In particular, the basic understanding of genetics that Mendel provided paved the way for the development of more powerful and more precise methods to improve plants. One such tool was the development of plant "hybridization," or "combination breeding." Plant hybridization involves crossing two plants of the same species in an effort to improve plant performance. This important method of genetic modification has permitted modern agriculturalists to create new cultivars that are more disease resistant, more uniform, and higher yielding. Virtually all modern crop plants incorporate characteristics—*e.g.*, disease resistance—that were acquired from wild species by virtue of such inter-species genetic transfers. *Id.* (Exhibit USA-14).

[22] In the late 1920s, researchers found that they could induce mutation by exposing plants or their embryos to radiation or chemical mutagens. These mutagens produce genetic changes that occasionally produce useful traits. However, researchers have no control over the number or kind of genetic changes made when they employ these techniques; the mutations are random and unpredictable. Its non-specific nature results in a low frequency of useful mutations. *Id.* (Exhibit USA-14).

[23] The last major type of genetic modification technique introduced prior to recombinant DNA technology was a tissue culture technique developed beginning in the 1940s. This technique involves culturing cells, embryos, or parts of plants in growth media in the laboratory until they can be moved to the field. The technique can speed the development cycle for new crops and greatly expand the number of plant cultivars that can be screened for useful traits. *Id.* (Exhibit USA-14).

[24] Corn, like humans, are diploid, meaning they have two sets of each chromosome and between 20,000 to 30,000 genes. Some plants are polyploids meaning they have more than two sets of chromosomes. For example, wheat is a polyploid with six sets of each chromosome and over 100,000 genes.

above and recombinant DNA technology does not lie in the basic strategy but in the much-improved efficiency and precision of the genetic transfer. In both cases, the goal is to improve a plant by introducing a particular trait or set of traits through the transfer of genes. Recombinant DNA technology permits scientists to accomplish this goal by transferring only those genes that are needed, without transferring unnecessary and potentially problematic genes that might be transferred using conventional breeding approaches.

15. In theory, any gene from any living organism can be transferred into another organism, giving that organism the ability to do something that it could not previously have done—*e.g.*, resist a particular disease or produce a vitamin it had not previously been able to produce. Some of the early applications of this knowledge and of transgenic technology have been dramatic and profound. For example, before the development of this technology, humans suffering from diabetes had to obtain insulin from the pancreases of pigs. Now, most insulin used in human therapy for diabetes can be produced in harmless bacteria that have incorporated human genes responsible for the production of insulin. The insulin is then purified from the bacteria and is indistinguishable from that produced in mammals.

16. Modern biotechnology, specifically genetic engineering, is used to alter seeds so that crops grown from them include more desirable traits than their conventional counterparts. The most common traits found in GE crops include resistance to certain insects, tolerance of specific herbicides used to control weeds, and resistance to plant viruses.[25] Other modifications have been created to enhance nutritional content, to better withstand the environmental conditions caused by climate change, or to improve aesthetic appearance.[26] Biotechnology companies are also developing GEOs with traits to decrease allergens or harmful toxins found in certain food plants and to enable the plant to detoxify pollutants in the soil through phytoremediation.[27]

17. The following sections will describe the benefits of modern biotechnology for human health and the environment, including higher agricultural output and lower utilization of agricultural chemicals, fertilizers, and water in commercial farming. As Nobel Laureate Norman Borlaug, who spent decades working at the International Maize and Wheat Improvement Center ("CIMMYT") in Mexico, presciently stated in 2000, meeting ever-increasing global food demand "cannot be accomplished unless farmers across the world have access to current high-

[25] USDA, "Biotechnology Frequently Asked Questions (FAQs)," https://www.usda.gov/topics/biotechnology/biotechnology-frequently-asked-questions-faqs (Exhibit USA-15); FDA, "How GMO Crops Impact Our World" (Apr. 19, 2023), https://www.fda.gov/food/agricultural-biotechnology/how-gmo-crops-impact-our-world (Exhibit USA-16).

[26] *Id.* (Exhibit USA-15; Exhibit USA-16).

[27] USDA, "Biotechnology Frequently Asked Questions (FAQs)," https://www.usda.gov/topics/biotechnology/biotechnology-frequently-asked-questions-faqs (Exhibit USA-15).

yielding crop production methods as well as new biotechnological breakthroughs that can increase the yields, dependability, and nutritional quality of our basic food crops."[28]

1. Increased Agricultural Output & More Secure Food Supply

18. Modern biotechnology can significantly increase agricultural output by protecting plants from factors that reduce yields, such as pests, diseases, spoilage, climate change, and extreme weather conditions. Up to 40 percent of global crop production is lost to pests annually.[29] The Food and Agriculture Organization of the United Nations ("FAO") has estimated that, each year, plant diseases cost the global economy over $220 billion, and invasive insects cost the global economy at least $70 billion.[30] Losses are particularly great in the developing world.

19. According to the FAO, food security exists when "all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences" and encompasses four dimensions—availability, access, utilization, and stability.[31] The effects of climate change—decreasing yields, unstable water supply, and emerging plant diseases—in addition to greater incidences of extreme weather events, have placed increasing pressure on the four dimensions of food security, especially for those in the developing world.[32] Moderate or severe food insecurity has been climbing globally since 2014.[33] Around 2.4 billion people in the world (29.6 percent) were moderately or severely food insecure

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[28] N. Borlaug, "Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry," 124 PLANT PHYSIOLOGY 487, 490 (Oct. 2000) (Exhibit USA-17); *see also* N. Borlaug, "Feeding a World of 10 Billion People: The Miracle Ahead," 38 IN VITRO CELLULAR & DEVELOPMENTAL BIOLOGY—PLANT 221, 223 (Mar.-Apr. 2002) ("I am hopeful that scientific breakthroughs—particularly from genetic engineering—will permit another 50% increase in yields over the next 35 years.") (Exhibit USA-18); R. Rajaram, "Norman Borlaug: The Man I Worked With and Knew," 49 REVIEW OF PHYTOPATHOLOGY 17, 24 (2011) ("Borlaug noted that there is no scientific evidence to substantiate that GM foods are inherently dangerous, pointing out that recombinant DNA has been used in pharmaceuticals for years. This issue is one of misguided public perception. He contended that rigorous procedures are in place to allay any societal concerns about GM crops."), https://www.annualreviews.org/doi/pdf/10.1146/annurev-phyto-072910-095308 (Exhibit USA-19).

[29] *See* Food and Agriculture Organization of the United Nations ("FAO"), "Climate Change Fans Spread of Pests and Threatens Plants and Crops, New FAO Study" (June 2, 2021), https://www.fao.org/news/story/en/item/1402920/icode/ (Exhibit USA-20); FAO, "New Standards to Curb the Global Spread of Plant Pests and Diseases" (Apr. 3, 2019), https://www.fao.org/news/story/en/item/1187738/icode/ (Exhibit USA-21).

[30] *Id.* (Exhibit USA-20; Exhibit USA-21).

[31] FAO, "Policy Brief: Food Security" (2006), https://www.fao.org/fileadmin/templates/faoitaly/documents/pdf/pdf_Food_Security_Cocept_Note.pdf (Exhibit USA-22).

[32] D. Fróna et al., "Economic Effects of Climate Change on Global Agricultural Production," 44 NATURE CONSERVATION 117 (2021), https://natureconservation.pensoft.net/article/64296/ (Exhibit USA-23).

[33] FAO et al., "The State of Food Security and Nutrition in the World 2021 – The World is at a Critical Juncture," https://www.fao.org/state-of-food-security-nutrition/2021/en/ (Exhibit USA-24).

in 2022, of which approximately 900 million (11.3 percent of the global population) were severely food insecure.[34]

20. Biotechnology is considered to be among the most cost-effective and environmentally sound methods of addressing this problem.[35] The report *Transgenic Plants and World Agriculture*, prepared by seven national and international academies of science, including the Mexican Academy of Sciences, concluded that modern biotechnology must play a role in addressing food insecurity globally.[36] More than 100 Nobel laureates—41 who won for Medicine, 25 for Physics, and 34 for Chemistry—have joined together to promote GE crops as a safe way to meet the demands of a growing global population and to speak out against misinformation regarding GE food products.[37]

21. GE crops were developed with the objective of lowering input and associated costs of production, reducing losses to pests, and providing more options amenable to the conservation of soil health and water quality.[38] The positive yield effects of using GE corn, particularly for

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[34] FAO et al., THE STATE OF FOOD SECURITY AND NUTRITION IN THE WORLD 2023, at xvi (2023), https://docs.wfp.org/api/documents/WFP-0000151116/download/?_ga=2.194322597.980502899.1691074600-310413755.1691074600 (Exhibit USA-25); *see* also World Health Organization ("WHO") "UN Report: Global hunger numbers rose to as many as 828 million in 2021" (June 7, 2022) https://www.who.int/news/item/06-07-2022-un-report--global-hunger-numbers-rose-to-as-many-as-828-million-in-2021#:~:text=Around%202.3%20billion%20people%20in,207%20million%20in%20two%20years (Exhibit USA-26).

[35] *See, e.g.*, M. Qaim, "Role of New Plant Breeding Technologies for Food Security and Sustainable Agricultural Development," 42 APPLIED ECONOMIC PERSPECTIVES AND POLICY 129 (Apr. 2020), https://doi.org/10.1002/aepp.13044 (Exhibit USA-27); M. Qaim, "The Economics of Genetically Modified Crops," 1 ANNUAL REVIEW OF RESOURCE ECONOMICS 665 (2009), https://www.annualreviews.org/doi/pdf/10.1146/annurev.resource.050708.144203 (Exhibit USA-28).

[36] *See* National Academy of Sciences, TRANSGENIC PLANTS AND WORLD AGRICULTURE, at 3 (July 2000), https://nap.nationalacademies.org/read/9889/ (excerpt) (hereinafter "National Academy of Sciences") (Exhibit USA-29). This report was jointly prepared on behalf of the Royal Society of London, the Brazilian Academy of Sciences, the Chinese Academy of Sciences, the Indian National Science Academy, the Mexican Academy of Sciences, the National Academy of Sciences of the United States, and the Third World Academy of Sciences; *see also* Pontifical Academy of Sciences, "Transgenic Plants for Food Security in the Context of Development," 27 NEW BIOTECHNOLOGY 645, 645-659 (Nov. 30, 2010), https://www.sciencedirect.com/journal/new-biotechnology/vol/27/issue/5 (Exhibit USA-30); L. Herrera-Estrella & A. Alvarez-Morales, "Genetically modified crops: hope for developing countries?" 2 EMBO REPORTS 255 (Apr. 2001), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1083872/ (authored by two scientist-academics affiliated with the Department of Genetic Engineering of Plants of the Polytechnic National Institute in Mexico) (Exhibit USA-31).

[37] N. Chokshi, "Stop Bashing G.M.O. Foods, More than 100 Novel Laureates Say," *New York Times* (June 30, 2016), https://www.nytimes.com/2016/07/01/us/stop-bashing-gmo-foods-more-than-100-nobel-laureates-say.html (Exhibit USA-32); "Laureates Letter Supporting Precision Agriculture," *Support Precision Agriculture* (June 29, 2016), https://supportprecisionagriculture.org/nobel-laureate-gmo-letter_rjr.html (Exhibit USA-33).

[38] *See* FDA, "Why Do Farmers in the U.S. Grow GMO Crops?" (Feb. 17, 2022), https://www.fda.gov/food/agricultural-biotechnology/why-do-farmers-us-grow-gmo-crops (Exhibit USA-35); *see*

farmers in developing countries, have added 595 million tons of corn to global production since the introduction of GE corn in the mid-1990s.[39]

22. A scientific analysis of 76 studies, representing 21 years of field data, found that GE corn has a significantly higher harvested yield than non-GE varieties.[40] Putting this science into practice, as just one example, a large-scale, multiannual project in Brazil provided smallholder farmers with GE corn seeds, and resulted in eight-fold increases in yield as well as sizable income increases.[41]

23. Modern biotechnology has had a significant impact on global gross farm income as a result of increased cost-savings and increased yields. Between 1996 and 2020, cumulative farm income gain for developing country farmers due to the use of GE crops was estimated to be $136.6 billion.[42] During this same time period, the total increase in farm income from the use of insect-resistant GE corn was $67.8 billion, with an increase in income of $3.7 billion in 2020 alone.[43] Yield gains from the use of insect-resistant GE corn were highest in developing

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also W. Klümper & M. Qaim, "A Meta-analysis of the Impacts of Genetically Modified Crops," 9 PLOS ONE 1 (Nov. 2014), https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0111629&type=printable (finding that the adoption of GE technology has reduced the use of pesticides by 37 percent, has increased yields by 22 percent, and has increased farmers' profits by 68 percent) (Exhibit USA-36); Biotechnology Committee of the Mexican Academy of Sciences, TRANSGENICS. MAJOR BENEFITS, ABSENCE OF HARMS AND MYTHS, at 337 (2017), http://coniunctus.amc.edu.mx/libros/TransgenicosCoordinadorFBolivar.pdf (excerpt) (presenting the same statistics) (hereinafter "Biotechnology Committee of the Mexican Academy of Sciences") (Exhibit USA-37).

[39] G. Brookes, "Farm Income and Production Impacts from the Use of Genetically Modified (GM) Crop Technology 1996-2020," 13 GM CROPS & FOOD 171, 176-179, 181-182 (2022), https://www.tandfonline.com/doi/pdf/10.1080/21645698.2022.2105626 (Exhibit USA-38).

[40] E. Pellegrino, S. Bedini, et al., "Impact of Genetically Engineered Maize on Agronomic, Environmental and Toxicological Traits: A Meta-Analysis of 21 Years of Field Data," SCIENTIFIC REPORTS (2018) (finding 5.6 to 24.5 percent higher yield), https://www.santannapisa.it/sites/default/files/pellegrino_et_al.2018.pdf (Exhibit USA-39); *see also See, e.g.*, E. Stokstad, "Genetically Modified Corn Produces 10% More than Similar Types," SCIENCE (Nov. 4, 2019), https://www.science.org/content/article/new-genetically-modified-corn-produces-10-more-similar-types (Exhibit USA-40); "Are GMOs Safe?," *Michigan State University AgBio Research*, (Aug. 15, 2018), https://www.canr.msu.edu/news/are-gmos-safe (Exhibit USA-41); FDA, "GMO Crops, Animal Food, and Beyond" (Aug. 3, 2022), https://www.fda.gov/food/agricultural-biotechnology/gmo-crops-animal-food-and-beyond (Exhibit USA-42).

[41] *See* "Prospera – A More Fertile Future," *Global Communities Brasil*, https://globalcommunitiesbrasil.org/prospera-o-futuro-mais-fertil/ (farmers going from an average production of 15 bags per hectare prior to GE seeds, to 120 bags per hectare, and reaching a record 191.73 bags per hectare) (Exhibit USA-43).

[42] G. Brookes, "Farm Income and Production Impacts from the Use of Genetically Modified (GM) Crop Technology 1996-2020," 13 GM CROPS & FOOD 171, 181 (2022), https://www.tandfonline.com/doi/pdf/10.1080/21645698.2022.2105626 (Exhibit USA-38).

[43] *Id.* at 178 (Exhibit USA-38).

countries, where the use of conventional pest control is often ineffective or unavailable.[44] The increase in gross farm income, particularly in developing countries where agriculture and local food production is the primary economic activity, bolsters food security for the most food insecure populations.[45]

24. In addition, by engineering resistance to insect damage, farmers have been able to use fewer pesticides while increasing harvested yields, thereby lowering the cost of food and increasing its availability for consumers.[46] According to studies, the lower cost of production and greater efficiency allows food producers to sell GE crops, including corn, at prices upwards of 30 percent lower than the cost to consumers of conventional crops,[47] further contributing to food security.

25. As Nobel Laureate Norman Borlaug urged in his article "Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry": "[W]e must [] speak unequivocally and convincingly to policy makers that global food insecurity will not disappear without new technology."[48]

2. Environmental Benefits

26. Modern biotechnology can also provide numerous environmental benefits. GE products that are resistant to insect pests require less insecticide to achieve a given level of protection than products that are not resistant to such pests, thereby reducing or eliminating the need for

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[44] *Id.* (Exhibit USA-38).

[45] *See, e.g.*, National Academy of Sciences, at 3-4 (Exhibit USA-29).

[46] FDA, "Why Do Farmers in the U.S. Grow GMO Crops?" (Feb. 17, 2022), https://www.fda.gov/food/agricultural-biotechnology/why-do-farmers-us-grow-gmo-crops (Exhibit USA-35); G. Brookes, "Genetically Modified (GM) Crop Use 1996–2020: Environmental Impacts Associated with Pesticide Use Change," 13 GM CROPS & FOOD – BIOTECHNOLOGY IN AGRICULTURE AND THE FOOD CHAIN 262 (2022), https://www.tandfonline.com/doi/epdf/10.1080/21645698.2022.2118497?needAccess=true&role=button (Exhibit USA-46).

[47] *See, e.g.*, F. Taheripour et al., "Evaluation of Economic, Land Use, and Land-use Emission Impacts of Substituting Non-GMO Crops for GMO in the United States," 9 AGBIOFORUM 156 (2016), https://agbioforum.org/wp-content/uploads/2021/02/AgBioForum-19-2-156.pdf (Exhibit USA-44); G. Brookes et al., "The Production and Price Impact of Biotech Crops," *Center for Agricultural and Rural Development, Iowa State University* (Jan. 2010), https://www.card.iastate.edu/products/publications/pdf/10wp503.pdf (Exhibit USA-45).

[48] N. Borlaug, "Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry," 124 PLANT PHYSIOLOGY 487, 489-490 (Oct. 2000) ("Genetic modification of crops is not some kind of witchcraft; rather, it is the progressive harnessing of the forces of nature to the benefit of feeding the human race. The genetic engineering of plants at the molecular level is just another step in humankind's deepening scientific journey into living genomes.") (Exhibit USA-17); *id.* at 489 ("[T]here has been no credible scientific evidence to suggest that the ingestion of transgenic products is injurious to human health or the environment. . . . [T]he most prestigious national academies of science, and now even the Vatican, have come out in support of genetic engineering to improve the quantity, quality, and availability of food supplies.") (Exhibit USA-17).

insecticides altogether.[49] Additionally, products that are genetically resistant to herbicides can increase the precision with which herbicides can be applied, thus reducing the amount of herbicide used.[50] Moreover, by engineering crops to tolerate particular herbicides with more benign environmental toxicology profiles than other alternatives available, farmers can reduce the amounts of more toxic products that would need to be used if the target herbicides could not be used.[51]

27. A recent study identified that, between 1996 and 2020, the widespread use of insect-resistant and herbicide-tolerant seed technology reduced pesticide application by 748.6 million kilograms (-7.2 percent) and, as a result, decreased the environmental impact associated with insecticide and herbicide use on these crops by 17.3 percent.[52]

28. In addition to reducing insecticide and herbicide use, GE crops, including GE corn, were developed to facilitate the practice of no-till agriculture, which minimizes disruptions to the soil microbial community; prevents run-off of soil, fertilizers, and pesticides into waterways; and increases soil water-holding capacity (and thus drought tolerance) by increasing soil water

[49] *See, e.g.*, E. D. Perry et al., "Genetically Engineered Crops and Pesticide Use in U.S. Maize and Soybeans," 2 SCIENCE ADVANCES 1 (Aug. 2016), https://www.science.org/doi/pdf/10.1126/sciadv.1600850 (finding that adopters of GE insect-resistant maize used 11.2 percent (0.013 kilogram per hectare) less insecticide than nonadopters) (Exhibit USA-47); National Academy of Sciences, at 6 (stating that "[t]he benefits from transgenic plants under study include decreased dependency on chemical insecticides") (Exhibit USA-29); s*ee also* ISAA, "Pocket K No 2: Plant Products of Biotechnology" (Mar. 2020), https://www.isaaa.org/resources/publications/pocketk/document/Doc-Pocket%20K2.pdf ("[Insect resistant] maize contains a built-in insecticidal protein from a naturally occurring soil microorganism (Bacillus thuringiensis ["Bt"]), which gives maize plants season-long protection from corn borers. This means most farmers do not have to spray insecticide to protect maize from harmful pests, which can cause significant damage and yield loss in many maize-planting areas. Bt maize also reduces toxin contamination arising from fungal attack on the damaged grain. The Bt protein has been used safely as an organic insect control agent for over 50 years.") (Exhibit USA-48).

[50] *See, e.g.*, FDA, "Why Do Farmers in the U.S. Grow GMO Crops?" (Feb. 17, 2022), https://www.fda.gov/food/agricultural-biotechnology/why-do-farmers-us-grow-gmo-crops (Exhibit USA-35).

[51] *See, e.g.*, A. R. Kniss, "Long-term Trends in the Intensity and Relative Toxicity of Herbicide Use," 8 NATURE COMMUNICATIONS 1 (2017), https://www.nature.com/articles/ncomms14865 (Exhibit USA-49).

[52] G. Brookes, "Genetically Modified (GM) Crop Use 1996–2020: Environmental Impacts Associated with Pesticide Use Change," 13 GM CROPS & FOOD – BIOTECHNOLOGY IN AGRICULTURE AND THE FOOD CHAIN 262 (2022), https://www.tandfonline.com/doi/epdf/10.1080/21645698.2022.2118497?needAccess=true&role=button (Exhibit USA-46).

percolation.[53] No-till agriculture, which minimizes soil disturbance, also promotes the retention of organic carbon and reduces fossil fuel consumption.[54]

29. Finally, biotech products and innovation are contributing to the reduction of water consumption in agriculture, reducing agriculture's impact on ecosystems while supporting a growing global population. Biotech developers are developing seeds that are more resilient in the face of floods or droughts, producing consistent yields even in unfavorable weather conditions.[55]

3. Proven Safety Record of Recombinant DNA Technology

30. The safety of biotech products has been widely confirmed by international institutions, such as the FAO and World Health Organization ("WHO"),[56] the Organization for Economic

[53] *See, e.g.*, S. Bertrand et al., "No-till Farming Improves Soil Health and Mitigates Climate Change," *Environmental and Energy Institute* (Mar. 28, 2022), https://www.eesi.org/articles/view/no-till-farming-improves-soil-health-and-mitigates-climate-change (Exhibit USA-50).

[54] *See, e.g., id.* (Exhibit USA-50); C. Sutherland et al., "Correlating Genetically Modified Crops, Glyphosate Use and Increased Carbon Sequestration," 13 SUSTAINABILITY 1 (Oct. 2021), https://www.mdpi.com/2071-1050/13/21/11679 ("The results quantify the transition from farmland being a net carbon emitter to being a net carbon sequesterer over the past 30 years. The removal of tillage and adoption of minimal soil disturbances has reduced the amount of carbon released from tillage and increased the sequestration of carbon through continuous crop production. Countries that ban genetically modified crops and are enacting legislation restricting glyphosate use are implementing policies that Canadian farm evidence indicates will not contribute to increasing agricultural sustainability.") (Exhibit USA-51); R. Lai et al., "Carbon Sequestration in Agricultural and Forest Soils," *Soil Science Society of America*, https://www.soils.org/files/science-policy/caucus/briefings/carbon-sequestration.pdf (last accessed Aug. 23, 2023) (Exhibit USA-52).

[55] *See, e.g.*, K. Nemali, C. Bonin, et al., "Physiological Responses Related to Increased Grain Yield Under Drought in the First Biotechnology-derived Drought-tolerant Maize," 38 PLANT, CELL & ENVIRONMENT 1683 (Sept. 2015), https://onlinelibrary.wiley.com/doi/epdf/10.1111/pce.12446 (showing drought-tolerant GE corn reduced transpiration by 17.5 percent under stress conditions, allowing for better moisture retention without additional irrigation) (Exhibit USA-53).

[56] *See, e.g.*, WHO, World Health Organization ("WHO"), "Food, Genetically Modified" (May 1, 2014), https://www.who.int/news-room/questions-and-answers/item/food-genetically-modified ("Since the first widespread commercialisation of GM produce 18 years ago there has been no evidence of ill effects linked to the consumption of any approved GM crop.") (Exhibit USA-54); FAO, "FAO GM Foods Platform" (2023), https://www.fao.org/food/food-safety-quality/gm-foods-platform/browse-information-by/commodity/commodity-details/en/?com=38949 (database of over 200 different GE corn events authorized around the world) (Exhibit USA-55).

Co-operation and Development,[57] national and international academies of science,[58] as well as independent scientists in the United States,[59] Africa,[60] Europe,[61] and the United Kingdom.[62] Indeed, Mexico's own Biotechnology Committee of the Mexican Academy of Sciences has emphatically underscored the safety of GE crops and has condemned the false narratives propagated in Mexican society, stating bluntly: "There is no single confirmed evidence of damage caused by the use of transgenic organisms; all cases of alleged damage to health,

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[57] *See* Organization for Economic Co-operation and Development, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles," at 10 (Jan. 1, 1993) https://www.oecd.org/science/biotrack/41036698.pdf (stating that modern biotechnology "does not inherently lead to foods that are less safe than those developed by conventional techniques") (Exhibit USA-56).

[58] *See* National Academy of Sciences, at 15-16 ("To date, over 30 million hectares of transgenic crops have been grown and no human health problem associated specifically with the ingestion of transgenic crops or their products have been identified.") (Exhibit USA-29).

[59] *See, e.g.*, National Academies of Sciences, Engineering, and Medicine, GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS (2016), at 19 https://nap.nationalacademies.org/read/23395 (excerpt) ("On the basis of its detailed examination of comparisons between currently commercialized GE and non-GE foods in compositional analysis, acute and chronic animal-toxicity tests, long-term data on health of livestock fed GE foods, and epidemiological data, the committee concluded that no differences have been found that implicate a higher risk to human health safety from these GE foods than from their non-GE counterparts.") (Exhibit USA-57); Society of Toxicology, "The Safety of Genetically Modified Foods Produced Through Biotechnology," 71 TOXICOLOGICAL SCIENCES 2 (2003) (stating, "[t]he available scientific evidence indicates that the potential adverse health effects arising from biotechnology-derived foods are not different in nature from those created by conventional breeding practices") (Exhibit USA-58); American Cancer Society, "Common Questions About Diet, Activity, and Cancer Risk" (last updated Dec. 5, 2022) https://www.cancer.org/content/dam/CRC/PDF/Public/6753.00.pdf (excerpt) ("[T]here is no evidence that foods now on the market that contain genetically engineered ingredients or the substances found in them are harmful to human health, or that they would either increase or decrease cancer risk. The World Health Organization, the American Medical Association, the National Academy of Sciences, and the American Association for the Advancement of Science have all taken the stance that current evidence suggests that foods containing genetically engineered ingredients are safe.") (Exhibit USA-59).

[60] J. A. Thomson, "The Role of Biotechnology for Agricultural Sustainability in Africa," 263 PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY B 905 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2610117/ (Exhibit USA-60); F. Wambugu, "Why Africa Needs Agricultural Biotech," NATURE, at 15-16 (July 1, 1999), https://www.nature.com/articles/21771 (Exhibit USA-61).

[61] *See, e.g.*, European Academies Science Advisory Council, "Planting the Future: Opportunities and Challenges for Using Crop Genetic Improvement Technologies for Sustainable Agriculture," at 5 (June 2013), https://easac.eu/fileadmin/PDF_s/reports_statements/Planting_the_Future/EASAC_Planting_the_Future_FULL_REPORT.pdf ("[T]he conclusion from the scientific literature is that there is no validated evidence to associate the first generation of GM crops, that have been cultivated for more than 15 years worldwide (and commercialisation was dependent on more than 20 years of prior art in plant sciences), with higher risks to the environment or for food and feed safety compared with conventional varieties of the same crop.") (Exhibit USA-62).

[62] *See, e.g.*, John Innes Centre, "Using Genetic Technologies in Plant and Microbial Science," https://www.jic.ac.uk/about-us/our-position-on/using-genetic-technologies-in-plant-and-microbial-science/ (last accessed July 11, 2023) (Exhibit USA-63); Royal Society, "Is it Safe to Eat GM Crops?" (May 2016), https://royalsociety.org/topics-policy/projects/gm-plants/is-it-safe-to-eat-gm-crops/ ("All reliable evidence produced to date shows that currently available GM food is at least as safe to eat as non-GM food.") (Exhibit USA-64).

environment and biodiversity are unfounded and entirely lacking in scientific rigor."[63] Referencing over 1,800 scientific articles as well as reports by scientific academies from around the world, the Mexican Academy of Sciences has emphasized that GEOs are "as safe as the so-called conventional ones and [] their consumption, for more than 20 years, has not caused any harm to the health of humans or animals (including the hundreds of millions in the United States and other countries, and the millions of Mexicans who have consumed and are consuming transgenic corn imported to meet the demand)."[64]

31. The scientific findings on the safety of GE agricultural products are confirmed by empirical evidence. For multiple decades, farmers in various parts of the world have been sowing and harvesting millions of acres of GE corn, soybeans, canola, potatoes, and cotton, all of which are used in the production of food products or animal feed. Among GE crops, corn has the highest number of evaluated or approved "events" (*i.e.*, a particular crop variety with one or more particular transgenes in specific locations on a chromosome[65]), most of which combine insect resistance and herbicide tolerance traits.[66] Recombinant DNA technology is now widely used to improve the functionality and yield of economically important plants around the world.

32. According to the International Service for the Acquisition of Agri-biotech Applications ("ISAA"), a not-for-profit international organization that shares the benefits of crop biotechnology to resource-poor farmers in developing countries,[67] farmers in 29 countries, including 24 developing nations, planted over 190 million hectares (469.5 million acres) of GE crops in 2019, the highest area of GE crop adoption since cultivation began in 1996.[68] As of

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[63] Biotechnology Committee of the Mexican Academy of Sciences, at 28 (Exhibit USA-37); *id.* at 24 ("This book, produced by the Biotechnology Committee of the Mexican Academy of Science (AMC), comprising 17 academic experts from various institutions and disciplines—among which seven National Science Award winners—explains why transgenic organisms have been developed as one of the most meaningful, best characterized tools for modern biotechnology, in order to contribute to solving problems and meeting demands.") (Exhibit USA-37); *id.* at 27 ("It is important for society and public opinion to realize that genetically modified organisms and their products have been used in many countries for over thirty-five years without damaging health or negatively impacting the environment or biodiversity.") (Exhibit USA-37).

[64] *Id.* at 18 (Exhibit USA-37).

[65] University of Nebraska, "Glossary of Terms," http://agbiosafety.unl.edu/glossary.htm (Exhibit USA-65).

[66] *See* FAO, "FAO GM Foods Platform" (2023), https://www.fao.org/food/food-safety-quality/gm-foods-platform/browse-information-by/commodity/commodity-details/en/?com=38949 (last accessed Oct. 13, 2023) (Exhibit USA-55).

[67] *See* ISAA, "ISAAC Inc. in Brief," https://www.isaaa.org/inbrief/default.asp (Exhibit USA-67).

[68] ISAA, "Brief 55 Executive Summary – Global Status of Commercialized Biotech/GM Crops in 2019: Biotech Crops Drive Socio-Economic Development and Sustainable Environment in the New Frontier," at 2 (Nov. 2020), https://www.isaaa.org/resources/publications/briefs/55/executivesummary/pdf/B55-ExecSum-English.pdf (Exhibit USA-68); *see also* Royal Society, "What GM crops currently begin grown and where?," (last updated May 2016) https://royalsociety.org/topics-policy/projects/gm-plants/what-gm-crops-are-currently-being-grown-and-where/ (Exhibit USA-69).

2019, GE corn was cultivated on 60.9 million hectares (approximately 150.5 million acres) globally, representing one-third of global corn production.[69]

33. The scientific community has resoundingly confirmed the safety and benefits of consuming GE crops, including corn.[70] As the cohort of 110 Nobel laureates—representing the fields of Chemistry, Physics, Medicine, and Economics—stated:[71]

> Scientific and regulatory agencies around the world have repeatedly and consistently found crops and foods improved through biotechnology to be as safe as, if not safer than those derived from any other method of production. There has never been a single confirmed case of a negative health outcome for humans or animals from their consumption. Their environmental impacts have been shown repeatedly to be less damaging to the environment, and a boon to global biodiversity.

34. In the decades since the first GE foods reached the market, no adverse health effects among consumers have been found. The American Association for the Advancement of Science ("AAAS") has unequivocally affirmed: "[T]he science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe."[72]

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[69] ISAA, "Pocket K No. 16: Biotech Crop Highlights in 2019" (updated May 2021), https://www.isaaa.org/resources/publications/pocketk/16/ (Exhibit USA-70).

[70] *See, e.g.*, R. A. Herman & W. D. Price, "Unintended Compositional Changes in Genetically Modified (GM) Crops: 20 Years of Research." 61 JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY 11695, 11697 (2013) ("Scores of publications and regulatory submissions have confirmed the compositional equivalence between GM crops and their conventional counterparts and their equivalent safety. Over the past 20 years, the U.S. FDA found all of the 148 transgenic events that they evaluated to be substantially equivalent to their conventional counterparts, as have the Japanese regulators for 189 submissions, with the latter including combined-trait products. Over 80 peer-reviewed publications also conclude this same compositional safety for GM crops [citing these studies]. These studies have spanned the crops of corn, soybean, cotton, canola, wheat, potato, alfalfa, rice, papaya, tomato, cabbage, pepper, raspberry, and a mushroom, and traits of herbicide tolerance, insect resistance, virus resistance, drought tolerance, cold tolerance, nutrient enhancement, and expression of protease inhibitors. In addition, numerous studies have found that variation resulting from traditional breeding and environmental factors dwarf any changes observed in the composition due to introducing a trait through transgenesis." (citations omitted)) (Exhibit USA-71).

[71] "Laureates Letter Supporting Precision Agriculture," *Support Precision Agriculture* (June 29, 2016), https://supportprecisionagriculture.org/nobel-laureate-gmo-letter_rjr.html (Exhibit USA-33).

[72] "Statement by the AAAS Board of Directors on Labeling of Genetically Modified Foods," *American Association for the Advancement of Science* (Oct. 20, 2012), https://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf (Exhibit USA-72).

35. The EU, after investing more than €300 million in research on the biosafety of GE products, reached a similar conclusion:[73]

> The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not *per se* more risky than e.g. conventional plant breeding technologies.

36. GE crops are the most extensively tested crops ever added to the global food supply.[74] The National Academies of Science, Engineering, and Medicine—after a review of 900 studies and other publications on GE crops and significant public engagement[75]—found no substantiated evidence of a difference in risks to human health between current commercially available GE crops and conventionally bred crops, nor did it find any valid cause-and-effect evidence of environmental issues from GE crops.[76]

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[73] European Commission, "A Decade of EU-Funded GMO Research," at 16 (2010) (Exhibit USA-66).

[74] "Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods," *American Association for the Advancement of Science* (Oct. 20, 2012), https://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf (Exhibit USA-72); M. Qaim, "Role of New Plant Breeding Technologies for Food Security and Sustainable Agricultural Development," 42 APPLIED ECONOMIC PERSPECTIVES AND POLICY 129, 137 (Apr. 2020), https://doi.org/10.1002/aepp.13044 ("For the approval of a new GMO, many years of molecular, biochemical, and environmental testing, as well as feeding trials, are required. Some precaution when dealing with new technologies is always advisable. But GMOs are not so new anymore; they have been widely used and consumed for 25 years without a single case of harm to human health or unexpected environmental effects. GMOs are the most highly regulated and tested foods in the world. Many crop varieties that are commonly used in conventional and organic agriculture would not have been approved if the same standards that are now used for GMOs had applied.") (Exhibit USA-27); *see also* Biotechnology Committee of the Mexican Academy of Sciences, at 28 ("There is solid scientific evidence published in international journals subject to strict evaluations (over 1,800 publications), and reports by the academies of sciences and medicine by various countries and communities including the United States and Europe . . . These documents show that transgenic cultivars have been extensively evaluated by omic science techniques both as plants and foods. . . . These are the reasons why transgenic plants are as safe as the conventional cultivars and its consumption for more than 20 years . . . have not caused any damage to human or damage to human or animal health.") (Exhibit USA-37).

[75] *See* "Genetically Engineered Crops: Experiences and Prospects – New Report," *National Academies of Sciences, Engineering, and Medicine* (May 2016), https://www.nationalacademies.org/news/2016/05/genetically-engineered-crops-experiences-and-prospects-new-report ("The committee examined almost 900 research and other publications on the development, use, and effects of genetically engineered characteristics in maize (corn), soybean, and cotton, which account for almost all commercial GE crops to date. In addition, the committee heard from 80 diverse speakers at three public meetings and 15 public webinars, and read more than 700 comments from members of the public to broaden its understanding of issues surrounding GE crops.") (Exhibit USA-73).

[76] *Id.* ("The committee carefully searched all available research studies for persuasive evidence of adverse health effects directly attributable to consumption of foods derived from GE crops but found none. Studies with animals and research on the chemical composition of GE foods currently on the market reveal no differences that would implicate a higher risk to human health and safety than from eating their non-GE counterparts.") (Exhibit USA-73); *see also* National Academies of Sciences, Engineering, and Medicine, GENETICALLY ENGINEERED CROPS:

37. At bottom, the United States is not aware of any credible evidence suggesting that human or animal consumption of commercialized GE corn is unsafe, and the scientific and academic community overwhelmingly agrees.[77]

C. U.S. Regulatory Framework for GE Products of Agricultural Biotechnology

38. The United States has a robust, multi-pronged regulatory framework to ensure that GE products of agricultural biotechnology are safe for human, plant, and animal life and health.[78] The U.S. Food and Drug Administration ("FDA"), the U.S. Environmental Protection Agency ("EPA"), and the USDA operate collectively, pursuant to the Coordinated Framework for the Regulation of Biotechnology, first established in 1986, to regulate GE plants.[79]

39. The FDA, under the *Food, Drug, and Cosmetic Act*, is primarily responsible for regulating most human and animal food, and requires that GE products and GE ingredients meet the same strict safety standards as all other foods. The FDA sets and enforces food safety standards that those who produce, process, store, ship, or sell food must follow, no matter how the foods are created.[80] All food and feed, whether imported or domestic and whether derived

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EXPERIENCES AND PROSPECTS (2016), https://nap.nationalacademies.org/read/23395 (finding no evidence that GE crops had contributed to an increase in the incidence of cancer, obesity, diabetes, kidney disease, autism, celiac disease, or food allergies) (Exhibit USA-57).

[77] *See, e.g.*, "Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods," *American Association for the Advancement of Science* (Oct. 20, 2012), https://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf ("There are occasional claims that feeding GM foods to animals causes aberrations ranging from digestive disorders, to sterility, tumors and premature death. Although such claims are often sensationalized and receive a great deal of media attention, none have stood up to rigorous scientific scrutiny.") (Exhibit USA-72); P. Marcelo, "Posts Share Retracted Study to Question Safety of GM Corn," *AP News* (Oct. 7, 2022), https://apnews.com/article/fact-checking-815454767964 (Cornell University's Director of the Cornell Agricultural Experiment Station and Associate Dean of the College of Agriculture and Life Sciences stating same) (Exhibit USA-74); Biotechnology Committee of the Mexican Academy of Sciences, at 28 ("[T]he book stresses that, to date, there is no single confirmed evidence of damage caused by the use of transgenic organisms; all cases of alleged damage to health, environment and biodiversity are unfounded and entirely lacking in scientific rigor. This is why the agencies in charge of food safety have not retired any present GMO product from the market.") (Exhibit USA-37).

[78] FDA, "How GMOs are Regulated in the United States" (July 2022), https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-united-states (Exhibit USA-75).

[79] USDA, "How the Federal Government Regulates Biotech Plants," https://www.usda.gov/topics/biotechnology/how-federal-government-regulates-biotech-plants (Exhibit USA-76).

[80] FDA, "How GMOs are Regulated in the United States" (July 2022), https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-united-states (Exhibit USA-75); *see also* FDA, "Food from New Plant Varieties" (Apr. 13, 2023), https://www.fda.gov/food/food-ingredients-packaging/food-new-plant-varieties (Exhibit USA-77); FDA, "Understanding New Plant Varieties" (May 12, 2023), https://www.fda.gov/food/food-new-plant-varieties/understanding-new-plant-varieties (Exhibit USA-78).

from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards.[81]

40. The USDA's Animal and Plant Health Inspection Service ("APHIS") protects agriculture in the United States against pests and disease. APHIS sets regulations to make sure GE plants are not harmful to other plants, and USDA's Biotechnology Regulatory Services implements these regulations.[82] When APHIS receives a request for a regulatory status review of a GE plant, APHIS will determine whether there is a plausible pathway by which the GE plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, would pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparators.[83]

41. Finally, the EPA, through a registration process, regulates the sale, distribution, and use of pesticides in order to protect human health and the environment, regardless of how the pesticide was made or its mode of action. The EPA, under the *Federal Insecticide, Fungicide and Rodenticide Act* ("FIFRA"), regulates the distribution, sale, use, and testing of pesticidal substances produced in plants and microbes.[84] The EPA also sets tolerance limits for residues of pesticides on and in food and animal feed.[85] "Pesticide residues" refer to the pesticides that may remain in or on food after they are applied to a food crop (whether GE or non-GE), and the use of pesticides is strictly controlled in the United States. By law, the EPA is responsible for regulating the pesticides that are used by growers to protect crops and for setting limits on the amount of pesticides that may remain in or on foods marketed in the United States. These limits on pesticides left on foods are called "tolerances." In the United States, tolerances are established by EPA based on crop residue trial data and an extensive risk assessment process that

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[81] USDA, "How the Federal Government Regulates Biotech Plants," https://www.usda.gov/topics/biotechnology/how-federal-government-regulates-biotech-plants (Exhibit USA-76); FDA, "Understanding New Plant Varieties" (May 12, 2023), https://www.fda.gov/food/food-new-plant-varieties/understanding-new-plant-varieties ("The FDA focuses on the safety and nutritional characteristics of foods and not the processes by which they are produced. This regulatory approach is supported by more than 25 years of experience in this area demonstrating that as a class, foods from genetically engineered plant varieties don't present different or greater safety concerns than their non-genetically engineered counterparts.") (Exhibit USA-78).

[82] FDA, "How GMOs are Regulated in the United States" (July 2022), https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-united-states (Exhibit USA-75); USDA Animal and Plant Health Inspection Service ("APHIS"), "Biotechnology Regulations" (last updated Apr. 13, 2023), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulations/biotechnology-regulations (Exhibit USA-79).

[83] *See* U.S. Code of Federal Regulations, Title 7, Part 340 ("Movement of Organisms Modified or Produced Through Genetic Engineering"), https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340 (Exhibit USA-80).

[84] *See* U.S. Environmental Protection Agency ("EPA"), "Summary of the Federal Insecticide, Fungicide, and Rodenticide Act" (last updated Sept. 12, 2022), https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act (Exhibit USA-81).

[85] *See* EPA, "Summary of the Federal Food, Drug, and Cosmetic Act" (last updated Sept. 12, 2022), https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act (Exhibit USA-82).

assesses the potential risks that the pesticide may pose to human health or the environment.[86] Both the USDA and the FDA maintain pesticide monitoring programs to execute ongoing monitoring of pesticide residues on both GE and non-GE crops and enforce EPA's regulation of pesticide use in human food and animal feed.

D. Mexico's Legal Regime Governing the Importation of the Products at Issue

42. Mexico's principal legal instruments governing the importation and sale of agricultural biotechnology products in Mexico are the *Biosafety Law of Genetically Modified Organisms* ("Biosafety Law") and its implementing regulations.[87] These instruments establish the conditions under which GE products of agricultural biotechnology can be imported into and sold in Mexico, including for human consumption and animal feed ("food or feed"). Mexico enacted the Biosafety Law in February of 2005. The Biosafety Law governs the safety of all GMOs obtained or produced through "modern biotechnology techniques" (*i.e.*, GEOs and GE products containing them) and the permissions needed for importation and sale of such products in Mexico.[88] The law provides that three authorities—the Secretariat of the Environment ("SEMARNAT"), the Secretariat of Agriculture ("SAGARPA" or "SADER"), and the Secretariat of Health ("SALUD" or "SSA")—share responsibility for the formulation of policies on GE products.[89] It provides that these authorities will establish and enforce the procedures for the safety and use in Mexico of GE products, with each having areas of primary responsibility.

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[86] *See* EPA, "Setting Tolerances for Pesticide Residues in Foods" (last updated May 11, 2023), https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods (Exhibit USA-83); EPA, "Overview of Risk Assessment in the Pesticide Program" (last updated Mar. 10, 2023), https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program (Exhibit USA-84).

[87] *See Law on Biosafety of Genetically Modified Organisms* (Feb. 2005) ("Biosafety Law"), https://conahcyt.mx/cibiogem/images/cibiogem/eng/Docs/Ing_LBOGM_P.pdf (Exhibit USA-85); *Regulations to the Genetically Modified Organisms Biosafety Law* (2008) ("Biosafety Regulations"), https://conahcyt.mx/cibiogem/images/cibiogem/eng/Docs/Ing_RLBOGMs_P.pdf (Exhibit USA-86). The Biosafety Law and Biosafety Regulations do not address, for example, the production or processing of medicines and pharmacological agents with GEOs. *See* Biosafety Law, art. 6(III) (Exhibit USA-85).

[88] *See* Biosafety Law, arts. 3(VI), 3(XXI), 4, 5, 7 (Exhibit USA-85). The Biosafety Law defines "genetically modified organism" as "[a]ny living organism, human beings exempted, having acquired a new genetic combination, originated through the specific use of modern biotechnological techniques defined in this Law, as long as the techniques used are the ones established in this Law or in the Mexican official norms derived from it." *See id.*, art. 3(XXI) (Exhibit USA-85). "Modern biotechnology" is defined in the Biosafety Law as "the application of *in vitro* techniques of nucleic acids, including recombinant deoxyribonucleic acid (DNA and RNA) and the direct injection of nucleic acids into cells and organelles, or the fusion of cells beyond the taxonomic family, exceeding the natural physiological barriers of reproduction or recombination; these are not techniques commonly used in traditional reproduction and selection, and are used to originate genetically modified organisms, and will be determined in the Mexican official norms derived from this Law." *See id.*, art. 3(VI) (Exhibit USA-85).

[89] *Id.*, arts. 10-16 (Exhibit USA-85).

43. The Biosafety Law divides GE product use into two categories: (i) release into the environment (*i.e.*, planting) and (ii) other uses, generally for human consumption or animal feed.[90] Importation and sale of GE products for planting requires a "license"; other uses require an "authorization."[91]

44. The Fifth Title of the Biosafety Law, titled "On the Protection of Human Health in Relation to GMOs," sets out the authorization requirements for GE products *not* intended for release into the environment.[92] These authorizations are issued with respect to specific events, meaning a particular crop variety that has one or more transgenes inserted in specific locations on a chromosome.[93] Therefore, developers of GE crops—most commonly, biotechnology companies—must submit for authorization any new GE crop variety that they wish to commercialize for food or feed use in the Mexican market.

45. SALUD is responsible for reviewing and approving these event authorization applications.[94] Applications must contain: (i) a "study of the possible risks that the use or consumption by humans of the determined GMO might have on human health"; and (ii) other requirements, as determined by regulations issued pursuant to the law.[95] According to the Biosafety Law, GE products "may be freely commercialized and imported for their trading," provided that the GE products are authorized by SALUD.[96] SALUD's decision to authorize or reject an application, pursuant to the law, must be "in accordance with the sustained scientific and technical identification of the possible risks the GMOs could originate."[97] SALUD "will issue its resolution once it has analyzed the information and documentation provided," and the resolution must be "in a founded and rational manner."[98]

46. In 2008 Mexico enacted the *Regulations to the Genetically Modified Organisms Biosafety Law* ("Biosafety Regulations").[99] The Biosafety Regulations reinforce that SALUD is responsible for evaluating applications for authorization of GE products for human or animal

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[90] *See id.*, arts. 32, 91 (further explaining that GE products for human consumption are also considered to be for animal consumption) (Exhibit USA-85).

[91] *See id.*, arts. 32, 91 (Exhibit USA-85).

[92] *See id.*, arts. 91-98 (Exhibit USA-85).

[93] University of Nebraska, "Glossary of Terms," http://agbiosafety.unl.edu/glossary.htm (Exhibit USA-65).

[94] Biosafety Law, arts. 94-97 (Exhibit USA-85).

[95] *Id.*, art. 92 (providing that, in subsequent regulations, SALUD would set the "guidelines, criteria, characteristics and requirements of the studies on the possible risks that GMOs might have on human health" that must accompany authorization applications) (Exhibit USA-85).

[96] *Id.*, art. 97 (Exhibit USA-85).

[97] *Id.*, art. 96 (Exhibit USA-85).

[98] *Id.*, art. 96 (Exhibit USA-85).

[99] Biosafety Regulations, art. 1 (Exhibit USA-86).

consumption in Mexico.[100] The Biosafety Regulations also elaborate on the Biosafety Law's requirement that event authorization applications must contain a "study of potential risks that the human use or consumption of the GMO in question may represent to human health."[101] Specifically, a risk assessment for a particular event must contain "scientific and technical information" about the product's safety, including:

- the recipient organism, including its history of safe use in foods;
- each gene donor organism, including its origin and history of use;
- the introduction and arrangement of genetic material;
- any marker genes[102];
- any potential side effects of genetic modifications;
- the expression of transgenes;[103]
- detection and identification methods of the GEO;
- if the GEO is to be used as a foodstuff, information about how changes introduced into the GEO may affect its properties as food or feed (interactions with the intestines, vitamin content, fat content, et cetera) and substantial equivalence studies applied to use and consumption conditions in Mexico;
- complete toxicity studies;
- complete allergenicity studies; and
- for "events with combinations of genes," information about parental events, which must be previously authorized.[104]

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[100] *Id.*, art. 23 (Exhibit USA-86).

[101] *Id.*, art. 31(I) (Exhibit USA-86).

[102] An event includes: 1) a promotor sequence, 2) a "payload" sequence (the part that confers, for example, the insect resistance or herbicide tolerance), 3) marker gene sequences (which do not confer any effects but are used to track the transgene and thus remain in the final product), and 4) a terminator sequence. The promotor sequence ensures that the payload gene is expressed in the plant, and the terminator sequence tells the plant when to stop translating the DNA.

[103] This element of the risk assessment refers to evidence that the transgene is expressed at a level sufficient to do what the developer intends the event to do. A non-expressed or under-expressed transgene would not provide added agronomical value.

[104] Biosafety Regulations, art. 31(I) (Exhibit USA-86). The United States understands this element of the risk assessment to refer to "stacked" trait products, which are typically developed through conventional cross-breeding of GE parental plants. *See, e.g.*, "Food Derived from GM Plants Containing Stacked Genes," *Food Standards Australia New Zealand* (Aug. 2019), https://www.foodstandards.gov.au/consumer/gmfood/stackedgene/Pages/default.aspx#:~:text=Gene%20stacking%2

47. The Biosafety Regulations also require proof of the event's authorization in its country of origin, or a statement about the non-existence of such condition, accompanied by evidence supporting the resolution of the application.[105]

48. Once an application is received, SALUD must assess the completeness of the application and request any additional information within 30 business days.[106] Once the 30 days have elapsed, SALUD may not reject the application on grounds of incompleteness.[107] SALUD must render a decision on an application within six months of receiving a complete application.[108]

49. Mexico's legal regime for GE products includes a penalty scheme for unauthorized use. A person is liable for an "administrative infraction" when the person, knowing a product is a GE product, performs "activities with [the product] without the respective license or authorization" or in a manner inconsistent with the terms and conditions in the respective license or authorization.[109] These infractions are punishable by a fine of 1,501 to 30,000 days of the general minimum salary in force in Mexico City.[110] Presenting false information or documentation to the competent authorities concerning the possible risks to human health arising from a GE product is punishable by a fine of 500 to 1,500 days of the general minimum salary in Mexico City.[111] Additional penalties, including suspension or revocation of the corresponding licenses and authorizations as well as "administrative arrest up to 36 hours" may also be issued for these infractions.[112]

1. Mexico's Application of the Biosafety Law and Regulations Prior to May 2018

50. In the dozen years following the promulgation of the Biosafety Law and the Biosafety Regulations, Mexico regularly reviewed and approved authorization applications for GE events for food and feed use in Mexico. The Mexican Federal Commission for the Protection Against Sanitary Risks ("COFEPRIS") is the department within SALUD that is responsible for reviewing

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0refers%20to%20the,at%20least%20two%20novel%20genes (Exhibit USA-87); L. Goodwin et al., "Stacked Trait Products are as Safe as Non-Genetically Modified (GM) Products Developed by Conventional Breeding Practices," 9 JOURNAL OF REGULATORY SCIENCE 22 (2021) https://croplife.org/wp-content/uploads/2021/01/Stacked-Traits-Goodwin-et-al.pdf (Exhibit USA-88).

[105] Biosafety Regulations, art. 31(II) (Exhibit USA-86).

[106] *Id.*, art. 28 (Exhibit USA-86).

[107] *Id.*, art. 30 (Exhibit USA-86).

[108] *Id.*, arts. 28-29, 32 (Exhibit USA-86); *see also* Biosafety Law, art. 95 (Exhibit USA-85).

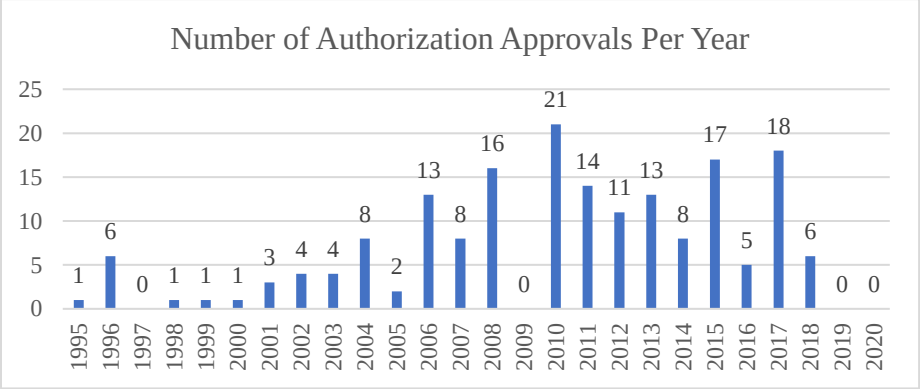
[109] Biosafety Law, art. 119(I)-(II) (Exhibit USA-85).

[110] *Id.*, art. 120(II) (Exhibit USA-85).

[111] *Id.*, arts. 119(V), 120(II) (Exhibit USA-85).

[112] *Id.*, art. 120(V)-(VI) ("Exhibit USA-85).

and approving such applications.[113] As shown in the graph below, from 2005, when the Biosafety Law was passed, through 2017, COFEPRIS granted an average of 11.2 authorizations per year. As of May 2018, there were 181 different events for which authorizations had been granted:[114]



51. The authorizations covered 11 different crops—alfalfa, canola, two types of cotton, corn, lemon, potato, rice, soybean, sugar beet, and tomato.[115] As depicted in the table below, half of the authorizations were for corn events:

Events Authorized in Mexico for Food or Feed[116]

Crop	Authorized Events
Alfalfa (M*edicago sativa*)	4
Canola (*Brassica napus)*	10
Cotton (*Gossypium hirsutum*)	30
Cotton (*Gossypium barbadense*)	6

[113] *See* USDA FAS & GAIN, "Agricultural Biotechnology Annual, Mexico," at 6 (Jan. 11, 2021), https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Mexico%20City_Mexico_10-20-2020 (Exhibit USA-89).

[114] *Id.* at 6, 10 (Exhibit USA-89); *see also* COFEPRIS, "Case-by-Case Safety Assessment List of Genetically Modified Organisms (GMOs)" (2018), https://conahcyt.mx/cibiogem/images/cibiogem/sistema_nacional/registro/lista-evaluacion-inocuidad-181-portal.pdf (Exhibit USA-90).

[115] USDA & GAIN, "Agricultural Biotechnology Annual, Mexico," at 14 (Mar. 12, 2020), https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Mexico%20City_Mexico_10-20-2019 (Exhibit USA-2).

[116] *Id*. (Exhibit USA-2).

Corn (*Zea mays*)	90
Lemon (*Citrus autantifolia*)	2
Potato (*Solamum tuberosum*)	6
Rice (*Oryza sativa*)	1
Soybean (*Glycine max*)	28
Sugar beet (*Beta vulgaris*)	1
Tomato (*Lycopersicon esculentum*)	3
Total	**181**

52. A USDA and Global Agricultural Information Network ("GAIN") report on Mexico's biotechnology policy described Mexico's authorization process prior to May 2018 as "relatively fast" and noted that "Mexico is one of the countries with the most authorizations for food and feed in the world."[117]

2. Application of the Biosafety Law and Regulations from May 2018 to Late 2022

53. In contrast to Mexico's authorization process prior to May 2018, Mexico did not issue a decision on any authorization application between May 15, 2018, and August 23, 2021,[118] despite the Biosafety Law's requirement that COFEPRIS render a decision on an application within six months.[119] During this period, a new presidential administration assumed office in Mexico and suggested, without providing further detail, a forthcoming "ban" on GE corn and imports of such products.[120] Then, on December 31, 2020, Mexico issued a presidential Decree ("2020 Corn Decree") directing authorities to revoke and abstain from granting authorizations to import GE corn for use "in the diets of Mexicans, until its total substitution on a date no later

[117] *Id.* (Exhibit USA-2).

[118] *See, e.g.*, COFEPRIS, "Case-by-Case Safety Assessment List of Genetically Modified Organisms (GMOs)" (2018), https://conahcyt.mx/cibiogem/images/cibiogem/sistema_nacional/registro/lista-evaluacion-inocuidad-181-portal.pdf (Exhibit USA-90).

[119] Biosafety Regulations, art. 32 (Exhibit USA-86); *see also* Biosafety Law, arts. 95 (Exhibit USA-85).

[120] *See, e.g.*, "AMLO's Government Pledges to Ban GMO Corn," *teleSUR* (Aug. 23, 2018), https://www.telesurenglish.net/news/AMLOs-Government-Pledges-to-Ban-GMO-Corn-20180823-0003.html (then-incoming Undersecretary of Agriculture for Food Self-sufficiency Víctor Suárez Carrera stating on August 23, 2018: "There is no possible doubt about the ban on transgenic corn.") (Exhibit USA-91).

than January 31, 2024."[121] Over the year and a half that followed, Mexico rejected authorization applications for certain GE corn events and GE events for certain other crops, notwithstanding that these events had been evaluated and lawfully marketed in the United States and other markets.

3. 2023 Corn Decree

54. Following this abrupt change in Mexico's policy in 2018, and for more than four years, the United States sought to engage with Mexico over concerns regarding Mexico's agricultural biotechnology measures, especially related to GE corn. On February 13, 2023—after the United States issued a formal written request to Mexico under Article 9.6.14 of the USMCA for "an explanation of the reasons for" and "pertinent relevant information regarding" Mexico's agricultural biotechnology measures, and a day before Mexico responded to that request—Mexico issued a new presidential Decree ("2023 Corn Decree" or "Decree") repealing the 2020 Corn Decree.[122] The 2023 Corn Decree went into effect the next day, *i.e.*, February 14, 2023.[123]

55. As relevant here, the 2023 Corn Decree identifies three categories of corn for consumption. First, it defines "corn for human consumption" as corn "intended for human consumption through nixtamalization or flour processing, which is the one carried out in the sector known as the dough and tortilla."[124] Second, the 2023 Corn Decree defines "genetically modified corn for industrial use for human consumption" as GE corn "which is intended for human consumption, before industrialization other than that indicated in the preceding section [on 'corn for human consumption']."[125] Thirdly, the Decree defines "genetically modified corn

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[121] *Decree by which the actions to be taken by the agencies and entities that comprise the Federal Public Administration, within the scope of their competencies, to gradually replace the use, acquisition, distribution, promotion and importation of the chemical substance called glyphosate and the agrochemicals used in our country that contain it as an active ingredient, with sustainable and culturally appropriate alternatives that allow production to be maintained and are safe for human health, the biocultural diversity of the country and the environment, are established*, art. 6 (Dec. 31, 2020), https://www.dof.gob.mx/nota_detalle.php?codigo=5609365&fecha=31/12/2020#gsc.tab=0 ("2020 Corn Decree"). ("2020 Corn Decree") (Exhibit USA-92).

[122] *See* 2023 Corn Decree (Exhibit USA-3).

[123] *Id*. (Exhibit USA-3).

[124] *Id.*, art. 2.III (Exhibit USA-3). The term "nixtamalization" refers to a specific process to prepare corn for making dough, in which dried kernels are cooked and steeped in an alkaline solution, usually water and food-grade lime (calcium hydroxide). *See* E. Orchardson, "What is Nixtamalization?," *CIMMYT* (Mar. 23, 2021), https://www.cimmyt.org/news/what-is-nixtamalization/ (Exhibit USA-93).

[125] 2023 Corn Decree, art. 2.IV (Exhibit USA-3). "Genetically modified," as defined in the 2023 Corn Decree, refers to "corn that has acquired a novel genetic combination, generated through the specific use of biotechnology techniques as defined in the applicable national and international regulations," herein referred to as genetic engineering. *See id.*, art. 2.II (Exhibit USA-3). Accordingly, "genetically modified corn for industrial use for human consumption" refers to certain GE corn.

for animal feed" as GE corn "intended for the livestock and aquaculture sector, for animal feed."[126]

56. According to the 2023 Corn Decree's preamble: "[T]he main purpose of [the Decree] is to protect the rights to health and a healthy environment, native corn, the milpa, biocultural wealth, peasant communities and gastronomic heritage; as well as to ensure nutritious, sufficient and quality diet."[127]

57. Article 6 provides that "[t]he biosafety authorities, within the scope of their competence . . . [s]hall revoke and refrain from issuing authorizations for the use of genetically modified corn grain for human consumption."[128] Thus, the 2023 Corn Decree requires the relevant regulators—defined in the Decree as SEMARNAT, SADER, and SALUD (in which COFEPRIS operates), as well as the Secretariat of Finance and Public Credit ("SHCP")[129]—to immediately "revoke and refrain from issuing" authorizations covering GE corn intended "for human consumption," *i.e.*, the dough and tortilla sector ("Tortilla Corn Ban").[130]

58. Article 7 of the Decree further provides:[131]

> The agencies and entities of the Federal Public Administration will carry out the appropriate actions in order to conduct the gradual substitution of genetically modified corn for animal feed and industrial use for human consumption.
>
> Until the substitution referred to in the preceding paragraph is achieved, [COFEPRIS] may issue authorizations of genetically modified corn for animal feed and industrial use for human consumption, being the responsibility of whoever uses it in Mexico that it does not have the destination foreseen in section III of the second article of this ordinance [*i.e.*, "corn for human consumption"].

Read together with Article VI, the Decree provides that it is the immediate responsibility of anyone using GE corn in Mexico to ensure it is not used for dough and tortillas. Further, with respect to GE corn for animal feed and for industrial use for human food, the 2023 Corn Decree

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[126] *Id.*, art. 2.V (Exhibit USA-3).

[127] *Id.*, Preamble, 14th Recital (Exhibit USA-3).

[128] *Id.*, art. 6 (Exhibit USA-3). The opening paragraph of the Decree cites, among other provisions, Articles 91-98 of the Biosafety Law, concerning GE event authorizations, as operating in tandem with the Decree.

[129] *Id.*, art. 2.I (Exhibit USA-3).

[130] For ease of reference, the United States refers to Mexico's ban on GE corn intended "for human consumption," as defined in the 2023 Corn Decree, as the Tortilla Corn Ban. However, the United States understands that this ban encompasses any food product that uses dough made through the process of nixtamalization (*e.g.*, tamales, tostadas, gorditas, totopos, et cetera).

[131] 2023 Corn Decree, art. 7 (Exhibit USA-3).

instructs the aforementioned regulators to carry out the "gradual substitution" of GE corn ("Substitution Instruction").

59. The gradual substitution, according to the Decree, "shall be carried out based on supply sufficiency criteria, consistent with the country's food self-sufficiency policies, in accordance with scientific principles and relevant international standards, guidelines or recommendations."[132] The Decree does not further define the criteria of availability in the supply; the policies of food self-sufficiency; or the scientific principles and relevant international standards, guidelines, or recommendations on which the gradual substitution should be based.

III. PROCEDURAL BACKGROUND

60. As explained above, on January 30, 2023, the United States sent a formal, written request to Mexico under Article 9.6.14 of the SPS Chapter of the USMCA, requesting "an explanation of the reasons for" and "pertinent relevant information regarding" certain Mexican measures concerning agricultural biotechnology, in particular the 2020 Corn Decree.

61. Mexico provided a written response on February 14, 2023. The response directed the United States to the 2023 Corn Decree that Mexico issued the day prior to sending its response, and did not provide further relevant information on or an explanation of the reasons for the 2020 Corn Decree, or the newly issued 2023 Corn Decree.

62. On March 6, 2023, the United States initiated, by written request, technical consultations with Mexico regarding Mexico's agricultural biotechnology measures, pursuant to Article 9.19.2 of the SPS Chapter of the USMCA. On March 30, 2023, the United States held technical consultations with Mexico in Mexico City; Canada observed the consultations.[133] The technical consultations did not resolve the matter.

63. On June 2, 2023, the United States requested consultations with Mexico pursuant to Articles 31.2 and 31.4 of the USMCA, with regard to certain Mexican measures that concern products of agricultural biotechnology. Pursuant to that request, the United States held consultations with Mexico in Mexico City on June 29, 2023. Canada participated in the consultations as a third Party, pursuant to Article 31.4.4 of the USMCA. The consulting Parties failed to resolve the matter.

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[132] 2023 Corn Decree, art. 8 (Exhibit USA-3).

[133] On March 7, 2023, Canada similarly requested technical consultations with Mexico regarding Mexico's agricultural biotechnology measures. Canada's technical consultations with Mexico were held on March 31, 2023, in Mexico City, and the United States observed these consultations.

64. Accordingly, on August 17, 2023, the United States requested the establishment of a panel, pursuant to Article 31.6.1(a) of the USMCA, with the terms of reference as set out in Article 31.7 of the USMCA.[134]

65. On August 23, 2023, pursuant to Article 31.9.1(a) of the USMCA, the Parties agreed to a panel comprised of three members. On September 22, 2023, the United States was selected by lot to choose the chair of the Panel, pursuant to Article 31.9.1(b) of the USMCA.[135] On September 27, 2023, the United States selected Christian Häberli, a citizen of Switzerland, as the Panel Chair. On October 12, 2023, pursuant to Article 31.9.1(d), the United States selected Hugo Perezcano Díaz, a citizen of Mexico, to serve as a member of the Panel. The United States agreed that Mexico could have an extension of time to select a U.S. citizen from the Roster of Panelists for Chapter 31 Dispute Settlement Panels. On October 18, 2023, Mexico selected Jean Kalicki, a U.S. citizen, to serve as a member of the Panel.

66. Per Article 18.1 of the Rules of Procedure for Chapter 31 (Dispute Settlement), the United States is filing this initial written submission on October 25, 2023, seven days after the date on which the last panelist was selected.

IV. TERMS OF REFERENCE, RULES OF INTERPRETATION, AND STANDARD OF REVIEW

67. Mexico and the United States have not decided on terms of reference for this dispute other than the terms of reference as set out in Article 31.7 of the USMCA. Accordingly, pursuant to Article 31.7, the terms of reference shall be for the Panel to:

a) examine, in the light of the relevant provisions of this Agreement, the matter referred to in the request for the establishment of a panel under Article 31.6 (Establishment of a Panel); and

b) make findings and determinations, and any jointly requested recommendations, together with its reasons therefor, as provided for in Article 31.17 (Panel Report).[136]

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[134] In the U.S. request for technical consultations and in the U.S. request for dispute settlement consultations concerning Mexico's biotechnology measures, the United States included certain measures concerning Mexico's rejections of GE event authorization applications and the resultant bans on products including those events. The United States has not included this set of measures in the request to establish the present panel but continues to evaluate and reserves the right to request a panel on this set of measures in the future.

[135] The Parties originally endeavored to select the Panel Chair by mutual agreement and agreed to extend the deadline under Article 31.9.1(b) of the *United States-Mexico-Canada Agreement* ("USMCA") to facilitate this effort. Unfortunately, the Parties were unable to reach mutual agreement and decided to proceed to selection by lot pursuant to Article 31.9.1(b) of the USMCA.

[136] USMCA, art. 31.7.1. In the U.S. request for establishment of a panel, the United States asserted that, pursuant to Article 31.2(c) of the USMCA, the United States had a reasonable expectation at the time the USMCA was

68. Article 31.13 of the USMCA describes the "function of panels" and the standard of review to be applied by panels. A panel's function is to make an objective assessment of the matter before it. In making that objective assessment whether a measure is inconsistent with the USMCA, Article 31.13.4 of the USMCA establishes that a dispute settlement panel shall interpret the USMCA "in accordance with customary rules of interpretation of public international law, as reflected in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties*" ("Vienna Convention").[137] Article 31 of the Vienna Convention provides that "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."

69. Furthermore, the findings, determinations, and recommendations of the Panel shall not add to or diminish the rights and obligations of the Parties under the Agreement.[138]

V. LEGAL DISCUSSION

A. Measures at Issue

70. The United States challenges the following two sets of measures, imposed by Mexico on GE corn:

(i) Tortilla Corn Ban: Mexico's ban on the importation and sale of GE corn for nixtamalization or flour production, which is reflected in the 2023 Corn Decree and operates in conjunction with Mexico's legal regime governing the importation and sale of GE food products other than for cultivation.[139]

(ii) Substitution Instruction: Mexico's instruction to gradually substitute GE corn used for human consumption other than for nixtamalization or flour production, and for animal feed, which is reflected in the 2023 Corn Decree and operates in conjunction with Mexico's legal regime governing the importation and sale of GE products other than for cultivation.[140]

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concluded that Mexico would not adopt the Tortilla Corn Ban or Substitution Instruction. Accordingly, the United States considers that a benefit it could reasonably have expected to accrue to it under Chapter 2 or Chapter 9 of the USMCA is being nullified or impaired as a result of the application of this measure. Pursuant to Article 31.7.2 of the USMCA, these claims of nullification or impairment shall be included in the terms of reference for this dispute.

[137] *Id.*, art. 31.13.4.

[138] *Id.*, art. 31.13.2.

[139] This legal regime governing the importation and sale of GE products other than for cultivation is set out in the Biosafety Law (Exhibit USA-85), in particular Articles 1-8, 91-98, and 119-122, and in the Biosafety Regulations (Exhibit USA-86), in particular Articles 1-4 and 23-32.

[140] This legal regime governing the importation and sale of GE products other than for cultivation is set out in the Biosafety Law (Exhibit USA-85), in particular Articles 1-8, 91-98, and 119-122, and in the Biosafety Regulations (Exhibit USA-86), in particular Articles 1-4 and 23-32.

71. Article 31.2 of the USMCA provides, in relevant part, that the USMCA dispute settlement provisions apply "when a Party considers that an actual or proposed measure of another Party is or would be inconsistent with an obligation of this Agreement." In this section, the United States further explains the contents of these measures and why these measures are properly within the Panel's terms of reference.

1. Tortilla Corn Ban

72. The Tortilla Corn Ban establishes an immediate ban on the importation and sale of GE corn for use in dough and tortillas. This ban is reflected in Articles 6 and 7 of the 2023 Corn Decree, in conjunction with Mexico's Biosafety Law and Biosafety Regulations governing the importation and sale of GE products in Mexico.

73. Article 6 of the 2023 Corn Decree requires Mexico's regulatory authorities to "revoke and refrain from granting authorizations for the use of genetically modified corn grain for human consumption."[141] As described above, the Decree is binding on federal agencies. The Decree provides that an agency's failure to comply with the Decree will carry "administrative liabilities" under Mexico's General Law of Administrative Responsibilities.[142] Thus, Mexico's government agencies—specifically, COFEPRIS, which administers the review of event authorization applications—is prohibited from authorizing any new GE corn events for dough and tortillas and is required to revoke any existing authorizations with respect to this use.

74. The United States is aware of at least 97 GE corn events that Mexico approved to date, all of which were approved for food or feed use (including use in dough and tortillas).[143] The 2023 Corn Decree requires revocation of existing authorizations that cover the use of GE corn in dough and tortillas.[144]

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[141] 2023 Corn Decree, art. 6 (Exhibit USA-3).

[142] *Id.*, art. 10 (Exhibit USA-3). Mexico's General Law of Administrative Responsibilities establishes the principles and obligations that govern the performance of public servants and establishes penalties for failing to satisfy those principles. The 2023 Corn Decree does not further define which provisions of the General Law of Administrative Responsibilities would be invoked should an agency fail to comply with the Decree.

[143] The Biosafety Law and the associated event authorization process concern, in relevant part, "GMOs destined for human usage or consumption, or the processing of foods for humans to be used in trading and imported for trading." *See* Biosafety Law, art. 5 (Exhibit USA-85). The Biosafety Law does not specifically address or provide for authorizations covering human consumption that are tailored based on intended end use, such as in dough or tortillas. To the contrary, Article 97 of the Biosafety Law provides that "GMOs authorized by [SALUD] may be freely commercialized and imported for their trading, as well as products containing such organisms and products derived from them." Mexico historically would publish a list of authorizations but has not done so since 2020; accordingly, the United States learned of authorizations since 2020 through confidential conversations with Mexico and applicant companies.

[144] *See* 2023 Corn Decree, art. 6 (Exhibit USA-3).

75. In addition, the Decree provides that COFEPRIS must "refrain from issuing" any future authorization applications for GE corn where the intended end use would be dough and tortillas.[145] Because an authorization is required to import and sell any GE corn event in Mexico, the 2023 Decree eliminates the only legal path to import GE corn into Mexico that contains new events, where such corn is intended for use in dough and tortillas.[146]

76. Additionally, Article 7 provides that it is the "responsibility" of "whoever uses [GE corn] in Mexico" to ensure that the corn is not used in dough or tortillas.[147] Thus, according to the 2023 Corn Decree, all persons transacting in or using GE corn in Mexico are responsible for ensuring, effective immediately, that GE corn is not used in dough or tortillas; this means dough and tortilla producers could not purchase and use GE corn imported from the United States even if the GE events contained therein have been authorized.

77. Official Mexican press statements concerning the 2023 Corn Decree confirm that the Decree sets out an immediate ban on the importation and sale of GE corn for use in dough and tortillas in Mexico. The Mexican Secretariat of Economy's own press statement, issued on the day that the Decree was released, stated: "The Decree bans the use of genetically modified corn for masa [dough] and tortilla."[148] The Mexican President has also enforced the Tortilla Corn Ban, making multiple public statements that the Mexican government has executed agreements with tortilla producers that prohibit the use of GE corn in their products.[149]

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[145] *Id.*, art. 6.II (Exhibit USA-3).

[146] Biosafety Law, arts. 97, 119 (Exhibit USA-85).

[147] 2023 Corn Decree, art. 7 (Exhibit USA-3).

[148] Mexican Secretariat of Economy, "The Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn is Published" (Feb. 13, 2023), https://www.gob.mx/se/prensa/se-publica-el-decreto-por-el-que-se-establecen-diversas-acciones-en-materia-de-glifosato-y-maiz-geneticamente-modificado#:~:text=Hoy%20en%20la%20edici%C3%B3n%20vespertina,2020%20sobre%20la%20misma%20materia (Exhibit USA-94).

[149] *See, e.g.*, "Stenographic Version of the Morning Press Conference of President Andrés Manuel López Obrador" (June 19, 2023), https://lopezobrador.org.mx/2023/06/19/version-estenografica-de-la-conferencia-de-prensa-matutina-del-presidente-andres-manuel-lopez-obrador-985/ (excerpt) (Exhibit USA-95). It should be noted that the excerpt erroneously suggests that Japan and the EU ban the importation of GE crops and food products. Japan does not permit the local cultivation of GE crops but has no such ban on the importation of GE crops or of foods made of GE ingredients. *See* USDA FAS & GAIN, "Agricultural Biotechnology Annual – Japan," at 2 (Nov. 14, 2022), https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Tokyo_Japan_JA2022-0092.pdf ("Japan is a major per-capita importer of food and feed produced using modern biotechnologies. The United States is the top exporter of genetically engineered (GE) products, namely grains and oilseeds, to Japan, but other major suppliers include Canada, Brazil, and Argentina. In Marketing Year (MY) 2020/2021, Japan imported 15.5 million metric tons of corn, 3.1 million tons of soybeans, and 3.4 million tons of canola. Japan also imports billions of dollars of processed foods that contain GE-derived oils, sugars, yeasts, enzymes, and additives.") (Exhibit USA-96). Likewise, in the EU, certain countries have elected not to permit the cultivation of GE crops but nevertheless permit the importation of GE products for use as food or feed.

2. Substitution Instruction

78. Mexico's Substitution Instruction legally mandates the "gradual substitution" of GE corn for animal feed and for human consumption other than dough and tortillas.[150] The Substitution Instruction is reflected in Articles 7 and 8 of the 2023 Corn Decree, in conjunction with Mexico's Biosafety Law and Biosafety Regulations governing the importation and sale of GE products in Mexico.

79. As with the Tortilla Corn Ban, the Substitution Instruction is binding on Mexico's federal agencies. Under Article 7, "[t]he agencies and entities of the Federal Public Administration"—defined in Article 2 as SEMARNAT, SADER, SALUD, and SHCP—are required to "carry out the appropriate actions in order to conduct the gradual substitution of genetically modified corn for animal feed and industrial use for human consumption."[151] The Decree states that, while the "substitution" is in progress, COFEPRIS "*may* issue authorizations" for GE corn to be used in animal feed and for human consumption other than dough and tortillas.[152] The language of the Decree indicates that once the substitution is completed, COFEPRIS will no longer issue authorizations to import or sell GE corn for animal feed or for human consumption other than dough and tortillas.[153]

80. Mexican statements in the press concerning the 2023 Corn Decree confirm this interpretation. Mexico's Secretariat of Economy stated in an official press statement on the day that the 2023 Corn Decree was released:[154]

> Regarding the use of GMO corn for fodder and the industry, the deadline to ban it is eliminated; its ban depends on there being sufficient supply. Working groups with the national and international private sectors will be set up to achieve an orderly transition.

81. Per Mexico's own statements, only the "deadline to ban" GE corn for animal feed and for human consumption other than dough and tortillas has been eliminated, but the direction to eliminate GE corn for these purposes and "achieve an orderly transition" remains and is legally binding.

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[150] *See* 2023 Corn Decree, arts. 7-8 (Exhibit USA-3).

[151] *Id.*, art. 7 (Exhibit USA-3).

[152] *Id.* (italics added) (Exhibit USA-3).

[153] *See id.* (Exhibit USA-3).

[154] Mexican Secretariat of Economy, "The Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn is Published" (Feb. 13, 2023), https://www.gob.mx/se/prensa/se-publica-el-decreto-por-el-que-se-establecen-diversas-acciones-en-materia-de-glifosato-y-maiz-geneticamente-modificado#:~:text=Hoy%20en%20la%20edici%C3%B3n%20vespertina,2020%20sobre%20la%20misma%20materia (Exhibit USA-94).

B. The Measures at Issue are Subject to the Obligations of the SPS Chapter of the USMCA.

82. The two sets of measures at issue are inconsistent with several provisions in the SPS Chapter of the USMCA. The United States first discusses the applicability of the SPS Chapter to the Tortilla Corn Ban and Substitution Instruction, respectively, and then details the specific provisions of the SPS Chapter that the two sets of measures breach.

1. The Obligations of the SPS Chapter Apply to the Tortilla Corn Ban.

83. The SPS Chapter of the USMCA sets out the Parties' obligations with respect to SPS measures. Article 9.2 ("Scope") provides that the SPS Chapter of the USMCA applies to "all sanitary and phytosanitary measures of a Party that may, directly or indirectly, affect trade between the Parties." Thus, the obligations of the SPS Chapter apply if two criteria are met: (i) the measure at issue is an SPS measure, and (ii) the measure may, directly or indirectly, affect international trade. The Tortilla Corn Ban meets both of these criteria.

a. The Tortilla Corn Ban is an SPS Measure.

84. Article 9.1 ("Definitions") of the SPS Chapter incorporates the definitions from Annex A of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement").[155] Annex A, paragraph 1 of the SPS Agreement defines the term "sanitary or phytosanitary measure" to mean:[156]

> Any measure applied:
>
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
>
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

[155] USMCA, art. 9.1.1 ("The definitions in Annex A of the SPS Agreement are incorporated into and made part of this Chapter, *mutatis mutandis*, except as otherwise provided for in paragraph 2.").

[156] World Trade Organization ("WTO"), *Agreement on the Application of Sanitary and Phytosanitary Measures*, Annex A, para. 1 (hereinafter "SPS Agreement") (Exhibit USA-34).

> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; [and] testing, inspection, certification and approval procedures . . . .

85. Thus, whether a measure constitutes an SPS measure under the USMCA depends on whether the measure is applied to accomplish one of the aims in Annex A, paragraphs 1(a)-(d) of the SPS Agreement.

86. The Tortilla Corn Ban on its own terms constitutes an SPS measure. The 2023 Corn Decree expressly states that "the main purpose" of the Decree includes "the rights to health and a healthy environment, native corn, . . . as well as to ensure nutritious, sufficient and quality diet."[157] Article 6 of the 2023 Corn Decree, which sets out the Tortilla Corn Ban, further establishes that the action is a "special measure" to "protect" "human health" and "native corn."[158]

87. Mexican government statements concerning the 2023 Corn Decree confirm that the Decree and the Tortilla Corn Ban specifically were adopted to protect both human health and native landraces of corn[159]—although neither the Decree nor Mexico's public statements have articulated what risks to human health or native corn have been identified or any underlying scientific support.

88. Shortly after the 2023 Corn Decree was published, the Mexican President said in a press conference: "[H]ealth is put first" and that "in the case of transgenic corn . . . we have, first, to take care of health and also to protect native corn varieties."[160] He added, in response to a question about the 2023 Corn Decree: "Food that may be harmful to health should not be allowed anywhere."[161]

89. Mexico's Secretary of the Economy asserted that the objectives of the Tortilla Corn Ban include preservation of native corn landraces in Mexico, by ensuring "continued preparation of

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[157] 2023 Corn Decree, Preamble, 14th Recital (Exhibit USA-3).

[158] *Id.*, art. 6 (Exhibit USA-3).

[159] "Landrace" is defined as "[a] locally developed breed of livestock or variety of a cereal or other crop plant." *See* "Landrace," *Oxford English Dictionary*, https://www.oed.com/dictionary/landrace_n?tab=meaning_and_use#39683737 (Exhibit USA-97).

[160] "Stenographic Version of the Morning Press Conference of President Andrés Manuel López Obrador" (Feb. 15, 2023), https://lopezobrador.org.mx/2023/02/15/version-estenografica-de-la-conferencia-de-prensa-matutina-del-presidente-andres-manuel-lopez-obrador-911/ (excerpt) (Exhibit USA-98).

[161] *Id*. (Exhibit USA-98).

the tortilla with native corn."[162] For avoidance of doubt, the Secretary publicly represented that the 2023 Corn Decree's provisions on GE corn are SPS measures, asserting that they are "consistent with the commitments undertaken in the USMCA, . . . all sanitary restrictions on trade must be based on scientific evidence."[163] The Mexican President has subsequently repeated Mexico's position that the 2023 Corn Decree's provisions on GE corn are consistent with the USMCA because "[n]o treaty in the world allows for the purchase or sale of goods that are harmful to health."[164]

90. Thus, the Tortilla Corn Ban is clearly applied for one or more of the purposes set forth in Annex A, paragraph 1 of the SPS Agreement, even though it is not a science-based measure that actually protects human health or native corn. More specifically, to the extent that Mexico instituted the Tortilla Corn Ban to address concerns that GE corn might cause an allergic reaction or ill health effects in people who consume it—*e.g.*, the presence of additives, contaminants, or toxins in foods containing GE corn products—such concerns fall within the definition of Annex A, paragraph 1(b), which covers measures applied to protect "human or animal life or health" from risks arising from "additives," "contaminants," or "toxins" in "foods, beverages or feedstuffs."[165]

91. To the extent Mexico instituted the Tortilla Corn Ban to address concerns that the intentional or unintentional transfer of GE traits to non-target organisms could directly or indirectly threaten plant life or health—*e.g.*, concerns that herbicide tolerance could be transferred from a GE variety to a native or wild variety—the ban would fall within the scope of Annex A, paragraph 1(a), which covers measures applied "to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms."[166]

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[162] Mexican Secretariat of Economy, "Secretariat of Economy and USTR Discuss the Corn Decree" (Feb. 27, 2023), https://www.gob.mx/se/prensa/secretaria-de-economia-y-ustr-dialogan-sobre-el-decreto-de-maiz (Exhibit USA-99).

[163] *Id.* (Exhibit USA-99).

[164] "Transcript of the Morning Press Conference of President Andrés Manuel López Obrador" (Mar. 7, 2023), https://lopezobrador.org.mx/2023/03/07/version-estenografica-de-la-conferencia-de-prensa-matutina-del-presidente-andres-manuel-lopez-obrador-924/ (excerpt) (Exhibit USA-100).

[165] *See, e.g.*, Codex Alimentarius Commission ("Codex"), "Glossary of Terms," https://www.fao.org/fao-who-codexalimentarius/GSFA-online/Glossary (defining "food additive" as "[a]ny substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities." (citation omitted)) (Exhibit USA-137).

[166] The SPS Agreement defines "pests" to include "weeds." *See* SPS Agreement, Annex A n.4 (Exhibit USA-34); *see also* "Pest," *Oxford English Dictionary*,

92. Accordingly, the Tortilla Corn Ban is plainly a "sanitary or phytosanitary" measure as defined in Annex A of the SPS Agreement. It is also worth noting that the definition of an SPS measure under the SPS Agreement does not require that a measure be enacted or applied *solely* for the purposes enumerated in the paragraphs of Annex A, paragraph 1.[167] A World Trade Organization ("WTO") report similarly explained that a measure that fulfills multiple purposes is nevertheless an SPS measure to the extent one of its purposes falls within the scope of the definition in Annex A, paragraph 1 of the SPS Agreement.[168] Because a clearly evidenced purpose of the Tortilla Corn Ban is to protect human health and plant health from the risks in subparagraphs (a) and (b), it constitutes an SPS measure under the SPS Chapter of the USMCA.

b. The Tortilla Corn Ban May Affect International Trade.

93. The Tortilla Corn Ban also "may, directly or indirectly, affect trade between the Parties" and, thus, meets the second requirement to fall within the scope of the USMCA's SPS Chapter.[169]

94. "Affect" means, as relevant, "to have an effect on, either materially or otherwise."[170] "Trade," as used in Article 9.2 of the USMCA, refers to "[t]he buying and selling of goods and commodities, esp. that conducted between nations on a large scale; commerce, traffic, business, originally carried out by means of travel or passage between trading parties."[171] Thus, a measure that has an effect on the buying or selling of goods between countries meets the second criterion of Article 9.2.

95. The Tortilla Corn Ban provides that no GE corn is permitted to enter Mexico or be sold

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https://www.oed.com/dictionary/pest_n?tab=meaning_and_use#31021226 (defining "pest" as a "person who or thing which is destructive, noxious, or troublesome" or "a plant that is an invasive weed") (Exhibit USA-101). The United States notes that the FAO's *International Plant Protection Convention* ("IPPC") of 1997 defines the term "pest" as "[a]ny species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products." *See* Secretariat of the IPPC, *International Plant Protection Convention*, art. II.1 (1997) (Exhibit USA-102). The definition of a pest, as contained in the International Standard for Phytosanitary Measures Number 11, *Pest Risk Analysis for Quarantine Pests*, suggests that the scope of the IPPC also extends to organisms that may directly or indirectly affect plants. *See* Secretariat of the IPPC, *Pest Risk Analysis for Quarantine Pests*, Annex 1 (2017) (Exhibit USA-103).

[167] *See* SPS Agreement, Annex A (Exhibit USA-34).

[168] *See* Panel Reports, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.166 (adopted Nov. 21 2006) (hereinafter "Panel Reports, *EC –Approval and Marketing of Biotech Products*") (Exhibit USA-104).

[169] USMCA, art. 9.2.

[170] "Affect," *Oxford English Dictionary*, https://www.oed.com/view/Entry/3324?rskey=xMfh8h&result=4#eid (Exhibit USA-105).

[171] "Trade," *Oxford English Dictionary*, https://www.oed.com/view/Entry/204274?rskey=xCv2qZ&result=1&isAdvanced=false#eid (Exhibit USA-106).

in Mexico for use in dough or tortillas.[172] COFEPRIS is obligated to revoke any existing authorizations that cover GE corn that could be used for these purposes (in effect, all GE corn event authorizations that the United States is aware of)[173] and, in the meantime, all persons dealing with GE corn are responsible for ensuring it is not used for these purposes.[174] Further, GE corn with events that have not yet been authorized in Mexico cannot be legally imported now or in the future for use in dough or tortillas, as long as the Decree is in effect.[175] Thus, the Tortilla Corn Ban prohibits GE corn imports into Mexico for certain purposes.

96. Because the Tortilla Corn Ban unequivocally is an SPS measure and may, directly or indirectly, affect international trade, the Tortilla Corn Ban is a measure subject to the SPS obligations of the USMCA.

2. The Obligations of the SPS Chapter Apply to the Substitution Instruction.

97. The Substitution Instruction also meets the two criteria of Article 9.2 ("Scope"), which provides that the obligations of the SPS Chapter apply where the measure at issue (i) is an SPS measure, and (ii) may, directly or indirectly, affect international trade.

a. The Substitution Instruction is an SPS Measure.

98. The Substitution Instruction constitutes an SPS measure, as defined by Annex A, paragraph 1 of the SPS Agreement, incorporated by reference into the SPS Chapter of the USMCA.[176]

99. As explained in Section II.D.3, the 2023 Corn Decree expressly states that "the main purpose" of the Decree includes "the rights to health and a healthy environment, native corn, . . . as well as to ensure nutritious, sufficient and quality diet."[177] Article 1 of the Decree reiterates that the purpose of the Decree is "to safeguard health."

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[172] 2023 Corn Decree, arts. 2.III, 6 (Exhibit USA-3).

[173] Mexico grants authorizations with respect to specific events (*i.e.*, insertion of a particular transgene into a specific location on a chromosome). Once events are authorized in major markets, the corn bred from the seeds containing them are typically comingled and not, in the course of bringing the corn to market, segregated by event. Because the Tortilla Corn Ban orders the elimination of all existing and future authorizations of GE corn events that cover use in dough and tortillas, the Tortilla Corn Ban in practice effectively reaches all authorizations that have been granted, which include use for human consumption.

[174] 2023 Corn Decree, arts. 6-7 (Exhibit USA-3).

[175] *Id.* (Exhibit USA-3); *see also* Biosafety Law, art. 97 (providing that only those GE products that have been authorized by COFEPRIS may be "freely commercialized and imported for their trading, as well as products containing such organisms and products derived from them") (Exhibit USA-85).

[176] USMCA, art. 9.1.1.

[177] 2023 Corn Decree, Preamble, 14th Recital (Exhibit USA-3).

100. The fact that the Substitution Instruction is directed at GE corn for animal feed and for other human consumption (not already covered by the Tortilla Corn Ban) further reinforces that the Substitution is directed at human, animal, or (as Mexico seems to assert through references to native corn) plant life or health, thereby meeting the definition of an SPS measure under Annex A, paragraphs 1(a) and 1(b), at a minimum.[178] The fact that the measure may serve more than one purpose does not alter its classification as an SPS measure.[179]

101. Similarly, Mexican officials' statements about the 2023 Corn Decree, linking the prohibitions and restrictions on GE corn to the protection of human health and native corn, also apply to the Substitution Instruction.[180]

102. Accordingly, the Substitution Instruction is also an SPS measure under the SPS Chapter of the USMCA.

b. The Substitution Instruction May Affect International Trade.

103. The Substitution Instruction also meets the second criterion required to constitute an SPS measure within the scope of the USMCA's SPS Chapter, because the Substitution Instruction "may, directly or indirectly, affect trade between the Parties."[181]

104. The Substitution Instruction expressly mandates that "[t]he agencies and entities of the Federal Public Administration will carry out the appropriate actions in order to conduct the gradual substitution of genetically modified corn for animal feed and industrial use for human

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[178] SPS Agreement, Annex A, para. 1(a) ("to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms") (Exhibit USA-34); *id.*, Annex A, para. 1(b) ("to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs") (Exhibit USA-34). Although the 2023 Corn Decree, and the Substitution Instruction specifically, do not appear to specify what, if any, risks to animal plant life or health are to be addressed through the gradual replacement of GE corn for animal feed, the measure, by being directed at animal feed could, "as applied," also fulfill Annex A, paragraphs 1(a) or 1(b), both of which include animal life or health.

[179] *See* SPS Agreement, Annex A (Exhibit USA-34); Panel Reports, *EC – Approval and Marketing of Biotech Products*, para. 7.166 (Exhibit USA-104).

[180] *See, e.g.*, "Stenographic Version of the Morning Press Conference of President Andrés Manuel López Obrador" (Feb. 15, 2023), https://lopezobrador.org.mx/2023/02/15/version-estenografica-de-la-conferencia-de-prensa-matutina-del-presidente-andres-manuel-lopez-obrador-911/ (President López Obrador remarking on the 2023 Corn Decree: "[I]n the case of transgenic corn . . . we have, first to take care of health and also protect the native varieties of corn.") (Exhibit USA-98); Mexican Secretariat of Economy, "Secretariat of Economy and USTR Discuss the Corn Decree" (Feb. 27, 2023), https://www.gob.mx/se/prensa/secretaria-de-economia-y-ustr-dialogan-sobre-el-decreto-de-maiz (Mexican Secretary of the Economy Buenrostro emphasizing that Mexico is the center of origin of maize (corn) and that the Decree seeks to preserve Mexico's 64 landraces of maize, noting that "all sanitary restrictions on trade must be based on scientific evidence, as expressly indicated in the Decree") (Exhibit USA-99).

[181] USMCA, art. 9.2.

consumption."[182] Should any relevant government agency in Mexico fail to comply with the provisions of the Decree, the Decree establishes that these agencies will be subject to administrative penalties.[183] Mexico's decision not to define the exact timing in which the gradual substitution will be carried out does not obviate the fact that this measure may or does affect international trade. The Decree specifies that, while the "substitution" is in progress, COFEPRIS "may" (but is not required to) grant authorizations for GE corn for animal feed and industrial use for human consumption, and further suggests that once the "substitution" is completed, COFEPRIS cannot do so.[184] The Secretariat of Economy has similarly stated that Mexico is establishing working groups "to achieve an orderly transition" away from GE corn.[185] Thus, both the Decree and official statements concerning the Substitution Instruction indicate that future trade in GE corn for animal feed and for industrial use for human consumption will be restricted or prohibited.

105. Mexico's Substitution Instruction affects not only future trade but also current trade, as seed developers and seed companies, farmers, and traders are unable to plan efficiently for subsequent growing seasons. In field crop industries, U.S. farmers and biotechnology companies view Mexican approval of new products as a precondition for U.S. farmers to plant the products. U.S. biotechnology companies will not commercialize a new GE product, and U.S. farmers will not begin growing it, until it is evaluated and can be lawfully marketed in the United States *and* in key export markets.[186] Mexico is a critical export market for U.S. corn. Therefore, Mexico's Substitution Instruction could have a significant chilling effect on the advancement of biotechnology and bringing new GE corn products to the global marketplace, at a time when biotechnology is a key component for navigating climate change, food insecurity, and an increasing global population. Accordingly, Mexico's disregard for the overwhelming scientific evidence demonstrating no human, animal, or plant life or health risk arising from GE corn, could have knock-on effects for the entire global food system by stifling innovation and imposing unjustifiable costs throughout the agricultural supply chain.

106. Even if Mexico were to define the timing in which the gradual substitution will be carried out—or were Mexico even to profess that complete substitution will never be attained—the measure, according to the plain text and as applied, is intended to restrict the importation of GE corn for animal feed and for industrial use for human consumption in Mexico. Clearly, the

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[182] 2023 Corn Decree, art. 7 (Exhibit USA-3).

[183] *Id.*, art. 10 (Exhibit USA-3).

[184] *Id.*, art. 7 (Exhibit USA-3).

[185] Mexican Secretariat of Economy, "The Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn is Published" (Feb. 13, 2023), https://www.gob.mx/se/prensa/se-publica-el-decreto-por-el-que-se-establecen-diversas-acciones-en-materia-de-glifosato-y-maiz-geneticamente-modificado#:~:text=Hoy%20en%20la%20edici%C3%B3n%20vespertina,2020%20sobre%20la%20misma%20materia (Exhibit USA-94).

[186] *See also* National Academies of Sciences, Engineering, Medicine, GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS, at 306-308 (2016), https://nap.nationalacademies.org/read/23395 (Exhibit USA-57).

Substitution Instruction may directly or indirectly affect trade between the Parties.[187]

107. Because the Substitution Instruction is an SPS measure and may affect international trade, the Substitution Instruction is a measure subject to the SPS obligations of the USMCA. In the sections that follow, the United States details the specific SPS obligations that both the Tortilla Corn Ban and the Substitution Instruction violate under the USMCA.

C. The Measures at Issue Are Not Based on Relevant International Standards, Guidelines, or Recommendations or on an Assessment, as Required under Article 9.6.3 of the USMCA.

108. A bedrock principle of the SPS Chapter of the USMCA is that any SPS measure must have a basis in science.[188] This requirement was intended to allow Parties to protect human, animal, or plant life or health while reducing potential abusive uses of SPS measures for non-legitimate purposes. Particularly critical in furthering the requirement that all SPS measures be based on science is the risk assessment requirement. The SPS Chapter requires that a Party first determine, through either a scientific risk assessment or adherence to an international standard, guideline, or recommendation, that a risk to human, animal, or plant life or health exists. If such a risk exists, then the Party may choose a measure that meets the level of protection that the Party considers appropriate to address that risk, provided that the measure is not otherwise inconsistent with the SPS Chapter.[189]

109. Article 9.6.3 of the USMCA specifically provides:

> Each Party shall base its sanitary and phytosanitary measures on relevant international standards, guidelines, or recommendations provided that doing so meets the Party's appropriate level of sanitary or phytosanitary protection (appropriate level of protection). If a sanitary or phytosanitary measure is not based on relevant international standards, guidelines, or recommendations, or if relevant international standards, guidelines, or recommendations do not exist, the Party shall ensure that its sanitary or phytosanitary measure is based on an assessment, as appropriate to the circumstances, of the risk to human, animal, or plant life or health.

110. Therefore, a Party must base its SPS measures on relevant international standards, guidelines, or recommendations—provided that such standards, guidelines, or recommendations exist and meet the Party's appropriate level of protection ("ALOP"). Otherwise, a Party

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[187] *See, e.g.*, Panel Reports, *EC – Approval and Marketing of Biotech Products* ("[I]t is not necessary to demonstrate that an SPS measure has an actual effect on trade. Article 1.1 merely requires that an SPS measure 'may, directly or indirectly, affect international trade.'") (Exhibit USA-104).

[188] *See* USMCA, art. 9.6.1 ("The Parties recognize the importance of ensuring that their respective sanitary and phytosanitary measures are based on scientific principles.").

[189] *See id.*, arts. 9.6.2-9.6.3.

nevertheless must ensure that its SPS measures are based on an appropriate risk assessment. In establishing the Tortilla Corn Ban and the Substitution Instruction, Mexico has not complied with this core obligation of the SPS Chapter.

1. The Tortilla Corn Ban is Inconsistent with Article 9.6.3 of the USMCA.

111. The Tortilla Corn Ban is not based on any relevant international standards, guidelines, or recommendations. In fact, Mexico has not even identified an ALOP that its ban is intended to achieve, much less established that it could not meet such an ALOP if it based its measures on relevant international standards, guidelines, or recommendations.[190] Furthermore, the Tortilla Corn Ban is not based on an appropriate risk assessment. Accordingly, the Tortilla Corn Ban is inconsistent with Article 9.6.3 of the USMCA.

112. As explained above in Section V.B.1.a, the text of the Tortilla Corn Ban and Mexico's official public statements confirm that the Tortilla Corn Ban was adopted to address purported risks to human or plant life or health. The sections that follow explain why this set of measures is not based on any relevant international standards, guidelines, or recommendations or on an assessment of the purported risks to humans or plants, respectively.

a. The Tortilla Corn Ban Is Not Based on Relevant International Standards, Guidelines, or Recommendations, or on an Assessment of the Risk to ***Human Life or Health.***

113. The Tortilla Corn Ban is not based on the international standards, guidelines, or recommendations relevant to human life or health, nor is this set of measures based on a risk assessment, contrary to the requirements of Article 9.6.3 of the USMCA.[191]

114. The ordinary meaning of "base" (as in "based on") is "to place on (also upon) a foundation, fundamental principle, or underlying basis."[192] Serving as a foundation or basis does not require that the standards, guidelines, or recommendations be copied entirely by the measure. Past WTO reports have similarly interpreted the phrase "based on" in the context of Article 3 of

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[190] The appropriate level of sanitary or phytosanitary protection, or "ALOP," as defined in the SPS Agreement and incorporated by reference into the SPS Chapter of the USMCA, is the "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." *See* SPS Agreement, Annex A, para. 5 (Exhibit USA-34); USMCA, art. 9.1.1; *see also* Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, para. 205 (adopted Nov. 6, 1998) (explaining that the SPS Agreement contains an implicit obligation for a Member to determine its ALOP) (Exhibit USA-109).

[191] The term "risk assessment," as applicable to food safety, is defined in Annex A of the SPS Agreement, incorporated by Article 9.1.1 of the USMCA, as "the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

[192] "Base," *Oxford English Dictionary*, https://www.oed.com/view/Entry/15856?rskey=rbmMNE&result=3&isAdvanced=false#eid (Exhibit USA-110).

the SPS Agreement and found that "based on" "does not require the wholesale adoption of the international standard, guideline or recommendation into the measure of the importing measure."[193] But logically, if a measure contradicts pertinent standards, guidelines, or recommendations, those cannot be understood as a foundation or underlying basis for the measure.[194]

115. Article 9.1 of the USMCA provides that "**relevant international standards, guidelines, or recommendations** means those defined in paragraph 3(a) through (c) of Annex A of the SPS Agreement and standards, guidelines, or recommendations of other international organizations as decided by the SPS Committee."

116. Paragraphs 3(a) through (c) of Annex A of the SPS Agreement define international standards, guidelines, and recommendations as follows:

> a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
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> b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics; [and]
>
> c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention[.]

117. When adopting an SPS measure concerned with food safety, the relevant standards, guidelines, or recommendations to consider are those of the Codex Alimentarius Commission ("Codex"), per Annex A, paragraph 3(a) of the SPS Agreement. However, Mexico has failed to follow the relevant Codex instruments in adopting the Tortilla Corn Ban.

118. Codex has established international standards that pertain to GE food products specifically. These international standards underscore the importance of conducting a risk

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[193] *See, e.g.*, Panel Report, *United States – Measures Affecting the Importation of Animals, Meat and Other Animal Products from Argentina*, WT/DS447/R, para. 7.239 (adopted Aug. 31, 2015) (hereinafter "Panel Report, *US – Animals*") (Exhibit USA-111).

[194] Where a measure, or aspect of a measure, contradicts an international standard or constitutes a "fundamental departure" from the international standard, the measure has been considered not "based on" that standard. *See* Panel Report, *India – Measures Concerning the Importation of Certain Agricultural Products*, WT/DS430/R, paras. 7.269, 7.271 (adopted June 19, 2015) (hereinafter "Panel Report, *India – Agricultural Products*") (Exhibit USA-112); Panel Report, *US – Animals*, para. 7.239 (Exhibit USA-111).

assessment before undertaking any risk management measures related to GE products. However, Mexico has failed to follow these Codex instruments, which constitute relevant international standards under Annex A, paragraph 3(a) of the SPS Agreement.

119. First, the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* ("Codex Principles") state that a risk analysis approach can be applied to foods derived from modern biotechnology and provide a framework for applying that approach with respect to the "safety and nutritional aspects" of GE foods.[195] The Codex Principles explain that a risk assessment includes a "safety assessment," which is designed to "identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity."[196] The safety assessment should include "a comparison between the food derived from modern biotechnology and its conventional counterpart," and should be performed on a case-by-case basis for the particular GE product.[197] In addition, the safety assessment should utilize information obtained from "a variety of sources, such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties."[198] The Codex Principles further state that the risk assessment should take into account "all available scientific data and information derived from different testing procedures, provided that the procedures are scientifically sound."[199] Any risk management measures for foods derived from biotechnology should be based on the risk assessment.[200] The Codex Principles emphasize that risk assessments should be based on "scientific data" and scientific principles.[201]

120. Second, the Codex *Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* ("Codex Guidelines") support the Codex Principles by providing guidelines for conducting risk assessments of "whole foods" (*i.e.*, assessments of all potential risks associated with a food rather than of discrete risks).[202] The Codex Guidelines further outline the safety assessment approach described in the Codex Principles' risk assessment

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[195] *See* Codex, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, sec. 1, para. 4 ("Codex Principles") (Exhibit USA-113); *id.*, sec. 2, para. 7 (Exhibit USA-113).

[196] *Id.*, sec. 3, para. 10 (Exhibit USA-113).

[197] *Id.*, sec. 3, paras. 10, 12 (Exhibit USA-113).

[198] *Id.*, sec. 3, para. 12 ("The data and information, based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques, should be of a quality and, as appropriate, of quantity that would withstand scientific peer review.") (Exhibit USA-113); *id.*, sec. 3, para. 14 (Exhibit USA-113).

[199] *Id.*, sec. 3, para. 15 (Exhibit USA-113).

[200] *Id.*, sec. 3, para. 16 (Exhibit USA-113); *see also* USMCA, art. 9.1.2 (defining "risk management" as "the weighing of policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate controls, which may include sanitary or phytosanitary measures").

[201] Codex Principles, sec. 3, paras. 12-15, 29-30 (Exhibit USA-113).

[202] Codex, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* ("Codex Guidelines"), sec. 1, para. 3 (Exhibit USA-114).

framework.[203] The Codex Guidelines explain that a food safety assessment for a GE product should be based on (i) a description of the recombinant-DNA plant; (ii) a description of the host plant and its use as a food; (iii) a description of the donor organisms; (iv) a description of the genetic modifications at issue; (v) a "comprehensive molecular and biochemical characterization of the genetic modification"; (vi) a safety assessment, including assessment of possible toxicity, possible allergenicity, and a compositional analysis of the recombinant-DNA plant designed to assess its nutritional content relative to conventional counterparts; and (vii) other considerations, including potential accumulation of pesticide residues and use of antibiotic resistance marker genes.[204] As with the Codex Principles, the Codex Guidelines provide that all data should be obtained "using sound scientific methods and analysed using appropriate statistical techniques."[205]

121. The Tortilla Corn Ban is not based on relevant international standards, guidelines, or recommendations relevant to food safety. The Tortilla Corn Ban is not the result of any risk assessment, let alone a credible risk assessment, as outlined in the Codex Guidelines and Principles. Further, Mexico's absolute prohibition on the use of GE corn in dough and tortilla products undermines the fundamental guidance of the Codex Principles and Guidelines, which provides that risk should be assessed on a case-by-case basis and any risk management measures should be based on the outcome of the risk assessment.[206]

122. Mexico has not conducted a product-specific (or even categorical) risk assessment of GE corn vis-à-vis their conventional counterparts that would justify the Tortilla Corn Ban at issue. To the contrary, after evaluating and approving over 90 different GE corn events for importation and sale in Mexico, Mexico has decided to prohibit any previously authorized GE corn events for use in dough and tortillas, without conducting a food safety assessment for any of these products or offering a risk assessment to justify the prohibition on their use in dough and tortillas specifically. Moreover, Mexico has prohibited all future GE corn events for use in dough and tortilla, regardless of what they might be, without any scientific evidence. The Tortilla Corn Ban contradicts the vast universe of scientific literature and testing that have confirmed that GE products, including GE corn, are safe for human consumption.[207] Even Mexico's own Biotechnology Committee of the Mexican Academy of Sciences has rejected the fallacious arguments that Mexico has put forward to justify the Tortilla Corn Ban, stating: "It is important

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[203] *Id.*, sec. 1, para. 5 (Exhibit USA-114).

[204] *Id.*, sec. 3, para. 18 (Exhibit USA-114); *id.*, secs. 4-5, paras. 22-59 (Exhibit USA-114).

[205] *Id.*, sec. 3, para. 20 (Exhibit USA-114).

[206] Codex Principles, sec. 3, paras. 12, 16 (Exhibit USA-113).

[207] *Supra* Section II.B.3; *see also* N. Chokshi, "Stop Bashing G.M.O. Foods, More than 100 Novel Laureates Say," *New York Times* (June 30, 2016), https://www.nytimes.com/2016/07/01/us/stop-bashing-gmo-foods-more-than-100-nobel-laureates-say.html (Exhibit USA-32); "Nobel Prize Winners Endorse Agricultural Biotechnology," *Institute for Agriculture & Trade Policy* (Feb. 8, 2000), https://www.iatp.org/news/nobel-prize-winners-endorse-agricultural-biotechnology (over 1,000 eminent scientists around the world endorsing agricultural biotechnology, including Nobel Prize winner James Watson, who co-discovered the structure of DNA) (Exhibit USA-116).

for society and public opinion to realize that genetically modified organisms and their products have been used in many countries for over thirty-five years without damaging health or negatively impacting the environment or biodiversity."[208]

123. Because Mexico did not base the Tortilla Corn Ban on international standards, guidelines, or recommendations relevant to human life or health, or on a risk assessment, the Tortilla Corn Ban is inconsistent with Article 9.6.3 of the USMCA.

b. The Tortilla Corn Ban Is Not Based on Relevant International Standards, Guidelines, or Recommendations, or on an Assessment of the Risk to ***Plant Life or Health.***

124. To the extent Mexico contends that the Tortilla Corn Ban is intended to protect plant life or health (notwithstanding that the measure is directed at food products: dough and tortillas), Mexico has failed to comply with the "international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention," as required under Annex A, paragraph 3(c) of the SPS Agreement, incorporated into the USMCA under Article 9.1.2. In addition, Mexico has not conducted an assessment of the risk to plant life or health resulting from the use of existing or future GE corn varieties in dough or tortillas.[209] Mexico therefore has contravened the obligations of Article 9.6.3 under the USMCA.

125. The *International Plant Protection Convention* ("IPPC") of 1997, produced by the Secretariat of the IPPC, provides that "phytosanitary measures should be technically justified, transparent and should not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade."[210] "Technically justified" is defined as "justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information."[211] The IPPC underscores that "[c]ontracting parties shall institute only phytosanitary measures that are technically justified, consistent with

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[208] Biotechnology Committee of the Mexican Academy of Sciences, at 27 (Exhibit USA-37).

[209] The SPS Agreement defines the applicable "risk assessment" relevant to plant health: "The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences." SPS Agreement, Annex A, para. 4 (Exhibit USA-34); USMCA, art. 9.1.1.

[210] Secretariat of the IPPC, *International Plant Protection Convention*, Preamble (1997), https://www.ippc.int/en/publications/131/ (Exhibit USA-102); *see also id.*, arts. VII.1-2 ("In order to minimize interference with international trade, . . . Contracting parties shall not, under their phytosanitary legislation, take any of the measures specified in paragraph 1 of this Article [e.g., "refuse entry or detain, or require treatment, destruction or removal from the territory of the contracting party, of plants, plant products and other regulated articles"] unless such measures are made necessary by phytosanitary considerations and are technically justified.") (Exhibit USA-102).

[211] *Id.*, art. II.1 (Exhibit USA-102).

the pest risk involved and represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances."[212]

126. The Secretariat of the IPPC has also published a *Framework for Pest Risk Analysis*, known as the "International Standard for Phytosanitary Measures 2" or "ISPM 2."[213] The ISPM 2 outlines three stages in the pest risk analysis process: (i) initiation, (ii) pest risk assessment, and (iii) pest risk management.[214] Initiation is the "identification of organisms and pathways that may be considered for pest risk assessment in relation to the identified [pest risk analysis] area," including determining whether an organism is a pest and the pathways of the pest.[215] The "pest risk assessment" includes an assessment of the introduction and spread of the pest and its economic impacts.[216] The "pest risk management" stage occurs once the pest risk assessment has concluded and "involves the identification of phytosanitary measures that (alone or in combination) reduce the risk to an acceptable level."[217]

127. The Secretariat of the IPPC has also issued specific standards related to pest risk analysis for living modified organisms ("LMOs"), which the Secretariat of the IPPC defines as "organisms that have been modified using techniques of modern biotechnology to express one or more new or altered traits."[218] According to these standards, also known as "ISPM 11," the pest risk assessment should be conducted on a case-by-case basis, just as with the Codex Principles.[219] "Evidence should be available to support the conclusion that the pest could become established or spread" in the assessed area, and "[t]here should be clear indications that the pest is likely to have an unacceptable economic impact" in the assessed area.[220] The risk management stage, at which point phytosanitary measures may be considered, should be based on "a quantitative or qualitative estimate of the probability of introduction of a pest or pests, and a corresponding quantitative or qualitative estimate of economic consequences (including

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[212] *Id.*, art. VII.2(g) (Exhibit USA-102).

[213] Secretariat of the IPPC, *Framework for Pest Risk Analysis* (2007), https://www.ippc.int/static/media/files/publication/en/2016/01/ISPM_02_2007_En_2015-12-22_PostCPM10_InkAmReformatted.pdf (Exhibit USA-117).

[214] *Id.*, Background (Exhibit USA-117).

[215] *Id.*, secs. 1-1.5 (Exhibit USA-117).

[216] *Id.*, sec. 2.2 (Exhibit USA-117).

[217] *Id.*, sec. 2.3 (Exhibit USA-117); *see also id.*, sec. 3.4 ("At the end of the PRA [pest risk analysis], evidence supporting the PRA, the proposed mitigations and uncertainties should preferably be communicated to stakeholders and other interested parties, including other contracting parties . . . .") (Exhibit USA-117).

[218] Secretariat of the IPPC, *Pest Risk Analysis for Quarantine Pests*, sec. 1 (2017), https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_11_2013_En_2017-05-25_PostCPM12_InkAm.pdf (Exhibit USA-103).

[219] *Id.*, sec 2 (Exhibit USA-103).

[220] *Id.*, secs. 2.1.14-2.1.1.5 (Exhibit USA-103).

environmental consequences)."[221] The whole process, from initiation to pest risk management, should be documented, "so that when a review or a dispute arises, the sources of information and rationale used in reaching the management decision can be clearly demonstrated."[222] Any risk management measures that are implemented should be chosen based on their effectiveness in reducing the probability of introduction of the pest, but "should not be more trade restrictive than necessary," and "[i]f different phytosanitary measures with the same effect are identified, they should be accepted as alternatives."[223]

128. Importantly, the ISPM 11 emphasizes that "prohibit[ing] the importation of the relevant commodities . . . should be viewed as a measure of last resort" and should be employed only "[i]f no satisfactory measure to reduce risk to an acceptable level can be found."[224] Therefore, a ban on the importation of a commodity perceived as a pest or as a vector for a pest should only be employed where, following a well-documented risk assessment, it is determined that the measure is necessary (albeit not more trade restrictive than necessary) and no other measure would be equally if not more effective.[225]

129. The Tortilla Corn Ban flatly contradicts the relevant international standards, guidelines, and recommendations set out by the Secretariat of the IPPC with respect to plant health, applicable pursuant Annex A, paragraph 3(c) of the SPS Agreement. Not only has Mexico failed to conduct a pest risk analysis before instituting the Tortilla Corn Ban, but Mexico has chosen the severe approach of completely banning the importation and sale of all existing and yet-to-be-developed GE corn for certain end uses.

130. Even if there were no such relevant international standards, guidelines, or recommendations, Article 9.6.3 of the USMCA would still have required Mexico to conduct a risk assessment prior to issuing the Tortilla Corn Ban. However, again, Mexico did not conduct a risk assessment as the basis for the Tortilla Corn Ban.

131. In sum, Mexico cannot establish that the Tortilla Corn Ban is "based on" the international standards, guidelines, or recommendations relevant to plant life or health, as Mexico did not follow the pest risk analysis process outlined by the Secretariat of the IPPC. Mexico did not conduct any type of risk assessment as the basis for the Tortilla Corn Ban, nor would any valid risk assessment have justified such a measure. Accordingly, the Tortilla Corn Ban is inconsistent with Article 9.6.3 of the USMCA.

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[221] *Id.*, sec. 2.5 (Exhibit USA-103).

[222] *Id.*, sec. 4.1 (Exhibit USA-103).

[223] *Id.*, sec. 3.4 (Exhibit USA-103).

[224] *Id.*, sec. 3.4.6 (Exhibit USA-103).

[225] *See also* USMCA, art. 9.1.2 (defining "risk management" as "the weighing of policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate controls, which may include sanitary or phytosanitary measures").

2. The Substitution Instruction is Inconsistent with Article 9.6.3 of the USMCA.

132. Like the Tortilla Corn Ban, Mexico's Substitution Instruction is not based on international standards, guidelines, or recommendations, nor is it based on an assessment, as appropriate to the circumstances, of the risk to human, animal, or plant life or health. As a result, the Substitution Instruction is inconsistent with Article 9.6.3 of the USMCA.

a. The Substitution Instruction Is Not Based on Relevant International Standards, Guidelines, or Recommendations, or on an Assessment of the Risk to ***Human Life or Health****.*

133. The Substitution Instruction appears to be directed, at least in part, at protecting human life or health, through its provision to gradually substitute GE corn for industrial use for human consumption, as defined in the 2023 Corn Decree.[226] Therefore, Mexico should have based the Substitution Instruction on the relevant Codex standards, guidelines, and recommendations for food safety, as defined in Annex A, paragraph 3(a) of the SPS Agreement, incorporated into the USMCA by Article 9.1.2. However, the Substitution Instruction contradicts the Codex guidance, such that it cannot be deemed "based on" relevant international standards, guidelines, or recommendations for food safety.[227]

134. The Substitution Instruction is not based on the Codex Principles, because the Substitution Instruction is not based on any risk assessment.[228] In addition, the Substitution Instruction contradicts both the Codex Principles and the Codex Guidelines, because it does not take a case-by-case approach to assessing risk (instead seeking to ban GE corn writ large)[229] and is not based on "all available scientific data" or scientifically sound procedures.[230]

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[226] *See* 2023 Corn Decree, arts. 2.IV, 7-8 (Exhibit USA-3).

[227] *See* Panel Report, *India – Agricultural Products*, paras. 7.269, 7.271 ("[W]here an SPS measure and the relevant international standard contradict each other, it cannot properly be concluded that the SPS measure is 'based on' that international standard. . . . India's AI measures amount to a 'fundamental departure' from the Terrestrial Code.") (Exhibit USA-112); Panel Report, *US – Animals*, para. 7.239 (Exhibit USA-111).

[228] Codex Principles, sec. 3, para. 10 (Exhibit USA-113).

[229] *Id.*, sec. 3, para. 12 (Exhibit USA-113); Codex Guidelines, sec. 3, para. 18; secs. 4-5, paras. 22-59 (Exhibit USA-114).

[230] *See* Codex Principles, sec. 3, paras. 12-15, 29-30 (Exhibit USA-113); Codex Guidelines, sec. 3, para. 20 (Exhibit USA-114). Further, to the extent Mexico's gradual substitution of GE corn in *animal feed* is predicated on a purported risk to human life or health resulting from consumption of meat derived from animals fed GE corn feed, the relevant international standards, guidelines, and recommendations would include the Codex *Guidelines on the Application of Risk Assessment for Feed*, which "address[es] the potential risks to human health associated with the presence of hazards in the feed of food-producing animals and the subsequent transfer of hazards to edible products." *See* Codex, *Guidelines on the Application of Risk Assessment for Feed* (2013) (Exhibit USA-138). However, Mexico completely departed from these guidelines by failing to conduct a risk assessment prior to

135. To the contrary, the scientific literature on existing GE products—and the exhaustive testing of these products—overwhelmingly confirm that these products, including GE corn, are safe.[231] Mexico's own Biotechnology Committee of the Mexican Academy of Sciences—comprised of seventeen experts from various Mexican academic and scientific institutions, including seven National Science Award winners—has reinforced the safety of GE corn and debunked the justifications that Mexico is now advancing.[232] As the Biotechnology Committee of the Mexican Academy of Sciences has explained, GEOs are one of the "most meaningful tools . . . for modern biotechnology, in order to contribute to solving problems and meeting demands," and "all cases of alleged damage to health, environment and biodiversity are unfounded and entirely lacking in scientific rigor."[233] Nevertheless, Mexico has elected to ignore the voluminous scientific literature in issuing the Substitution Instruction, contrary to what the Codex Principles and Guidelines require.

136. Even in the absence of relevant international standards, guidelines, or recommendations in the form of Codex Guidelines and Principles—or if Mexico could not meet some defined ALOP (which does not exist here) by basing the measure on such international standards, guidelines, or recommendations—Article 9.6.3 of the USMCA would still have required Mexico to conduct a risk assessment prior to issuing the Substitution Instruction. Mexico failed to conduct a risk assessment in relation to the Substitution Instruction prior to issuing the 2023 Corn Decree, let alone one that would conform to the definition of "risk assessment" provided in Annex A of the SPS Agreement, as incorporated into the USMCA.[234]

137. Article 8 of the 2023 Corn Decree, which addresses the Substitution Instruction, reinforces that Mexico has not carried out a risk assessment. Article 8 provides that, at an undefined time in the future, "relevant scientific studies will be carried out, for which [COFEPRIS] will integrate a joint research protocol . . . on the consumption of genetically modified corn and the possible damages to health."[235] This stated intent to potentially establish a

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establishing the Substitution Instruction. *Id.* (providing that any "risk management" should take into account the "risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices") (Exhibit USA-138).

[231] *Supra* Section II.B.3; *see also* N. Chokshi, "Stop Bashing G.M.O. Foods, More than 100 Novel Laureates Say," *New York Times* (June 30, 2016), https://www.nytimes.com/2016/07/01/us/stop-bashing-gmo-foods-more-than-100-nobel-laureates-say.html (Exhibit USA-32); "Nobel Prize Winners Endorse Agricultural Biotechnology," *Institute for Agriculture & Trade Policy* (Feb. 8, 2000), https://www.iatp.org/news/nobel-prize-winners-endorse-agricultural-biotechnology (over 1,000 eminent scientists around the world endorsing agricultural biotechnology, including Nobel Prize winner James Watson, who co-discovered the structure of DNA) (Exhibit USA-116).

[232] Biotechnology Committee of the Mexican Academy of Sciences, at 24 (Exhibit USA-37).

[233] *Id.* at 27-28 (Exhibit USA-37).

[234] SPS Agreement, Annex A, para. 4 ("the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs") (Exhibit USA-34); USMCA, Art. 9.1.1.

[235] 2023 Corn Decree, art. 8 (Exhibit USA-3).

post hoc rationalization for a measure is directly at odds with all of the relevant international guidance for food safety, as recognized by the SPS Agreement and the USMCA, and contradicts the very text of Article 9.6.3, which requires that an SPS measure be "based on" any such risk assessment.

138. Thus, the Substitution Instruction does not comply with the USMCA requirement under Article 9.6.3 that a Party base its SPS measures on relevant international standards, guidelines, or recommendations, or on an assessment of the risk to human life or health.

b. The Substitution Instruction Is Not Based on Relevant International Standards, Guidelines, or Recommendations, or on an Assessment of the Risk to ***Plant Life or Health****.*

139. To the extent Mexico contends that the Substitution Instruction is intended to protect plant life or health (notwithstanding that the measure is directed at animal feed and industrial use for human consumption), Mexico has failed to comply with the relevant IPPC international standards, guidelines, and recommendations issued by the Secretariat of the IPPC, as required under Annex A, paragraph 3(c) of the SPS Agreement, incorporated into the USMCA under Article 9.1.2. Mexico also did not conduct a relevant risk assessment concerning plant life or health prior to establishing the Substitution Instruction, inconsistent with Mexico's obligations under Article 9.6.3 of the USMCA.

140. First, the Substitution Instruction does not conform to the international standards, guidelines, or recommendations published by the Secretariat of the IPPC. As explained in Section V.C.1.b, the IPPC of 1997 establishes that phytosanitary measures should be, among other things, "technically justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information,"[236] and the measures should be the "least trade restrictive measures available."[237]

141. However, there is no indication that Mexico has completed any scientific analysis that would render the Substitution Instruction "technically justified." Mexico has not conducted a pest risk analysis related to GE corn collectively or on a product-specific basis; according to the Secretariat of the IPPC's *Framework for Pest Risk Analysis*, also known as the "International Standard for Phytosanitary Measures 2" or "ISPM 2," such an analysis would have included an identification of the organisms and pathways under consideration, determining whether the organisms are indeed pests, and assessing their introduction and spread, along with the economic

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[236] Secretariat of the IPPC, *International Plant Protection Convention*, art. II.1 (1997), https://www.ippc.int/en/publications/131/ (Exhibit USA-102).

[237] *Id.*, VII.2(g) ("Contracting parties shall institute only phytosanitary measures that are technically justified, consistent with the pest risk involved and represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances.") (Exhibit USA-102).

impacts—none of which Mexico completed.[238] Mexico also did not conduct any comparable scientific evaluation that might legitimately substitute a pest risk analysis consistent with the IPPC of 1997.[239] Moreover, Mexico has banned all future GE corn events for use in animal feed and industrial use for human consumption, regardless of what those future events might be.

142. The Substitution Instruction also squarely contradicts the Secretariat of the IPPC's guidance to establish SPS measures that are necessary given the scientific evidence and risks. In fact, the IPPC of 1997 provides that "[i]n order to minimize interference with international trade, . . . [c]ontracting parties shall not, under their phytosanitary legislation, take any of the measures specified in paragraph 1 of this Article [e.g., "refuse entry or detain, or require treatment, destruction or removal from the territory of the contracting party, of plants, plant products and other regulated articles"] unless such measures are made necessary by phytosanitary considerations and are technically justified."[240] Instead, Mexico, without conducting any risk analysis, has instituted the most restrictive risk management measure available—an elimination of GE corn from the market—which the Secretariat of the IPPC has stated should be used only as a "last resort" and only "[i]f no satisfactory measure to reduce risk to an acceptable level can be found."[241]

143. Not only has Mexico failed to base the Substitution Instruction on the relevant international standards, guidelines, or recommendations, but also has failed to base the Substitution Instruction on a "risk assessment," as defined by the SPS Agreement, Annex A: "The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences."[242] There is no evidence in the public record that the Substitution Instruction is based on any risk assessment whatsoever, which is reinforced by Article 8 of the Decree, indicating that "relevant scientific studies" will be conducted at some point in the future. Further, there is no indication that these "relevant scientific studies" would even relate to plant life or health, because the Substitution Instruction requires that these studies focus on "the *consumption* of genetically

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[238] Secretariat of the IPPC, *Framework for Pest Risk Analysis* (2007), secs. 1-1.5, 2.2. https://www.ippc.int/static/media/files/publication/en/2016/01/ISPM_02_2007_En_2015-12-22_PostCPM10_InkAmReformatted.pdf (Exhibit USA-117).

[239] *See* Secretariat of the IPPC, *International Plant Protection Convention*, art. II.1 (1997), https://www.ippc.int/en/publications/131/ (defining "technically justified" as "justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information") (Exhibit USA-102).

[240] *Id.*, arts. VII.1-2 (Exhibit USA-102).

[241] Secretariat of the IPPC, *Pest Risk Analysis for Quarantine Pests*, sec. 3.4.6 (2017), https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_11_2013_En_2017-05-25_PostCPM12_InkAm.pdf (Exhibit USA-103).

[242] SPS Agreement, Annex A, para. 4 (Exhibit USA-34); USMCA, art. 9.1.1.

modified corn and the possible damages to health."[243]

144. For these reasons, Mexico's Substitution Instruction is not based on relevant international standards, guidelines, or recommendations or on an assessment, as appropriate to the circumstances, of the risk to plant life or health, despite Mexico purporting, among other things, to protect native corn through this set of measures.

145. Taken together, the Substitution Instruction is not "based on" relevant international standards, guidelines, or recommendations, or on an assessment, as required under Article 9.6.3 of the USMCA.

D. The Measures at Issue are SPS Measures that are Applied Beyond the Extent Necessary to Protect Human, Animal, or Plant Life or Health, Inconsistent with Article 9.6.6(a) of the USMCA.

146. Article 9.6.6(a) of USMCA provides: "Each Party shall ensure that its sanitary and phytosanitary measures . . . are applied only to the extent necessary to protect human, animal, or plant life or health."[244]

147. However, the Tortilla Corn Ban and Substitution Instruction go well beyond that which is necessary to protect human, animal, or plant life or health, contravening Article 9.6.6(a).

1. The Tortilla Corn Ban is Inconsistent with Article 9.6.6(a) of the USMCA.

148. Pursuant to Article 9.6.6(a) of the USMCA, an SPS measure may only be applied to the extent necessary to protect human, animal, or plant life or health. The word "necessary" means "indispensable, vital, essential; requisite."[245] In similar contexts in the WTO agreements, the word "necessary" has been interpreted to mean "significantly closer to the pole of

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[243] 2023 Corn Decree, art. 8 (italics added) (Exhibit USA-3); *see also* Mexican Secretariat of Economy, "The Decree Establishing Various Actions Regarding Glyphosate and Genetically Modified Corn is Published" (Feb. 13, 2023), https://www.gob.mx/se/prensa/se-publica-el-decreto-por-el-que-se-establecen-diversas-acciones-en-materia-de-glifosato-y-maiz-geneticamente-modificado#:~:text=Hoy%20en%20la%20edici%C3%B3n%20vespertina,2020%20sobre%20la%20misma%20materia (explaining that Article VIII, regarding the Substitution Instruction, "explicitly established that Cofepris will carry out scientific research studies regarding the possible impacts on people's health of GMO corn." (underline added)) (Exhibit USA-94).

[244] Article 9.6.6(a) concerns how SPS measures are "applied." "Apply" means, as relevant, "to bring (a rule, a test, a principle, etc.) into contact with facts; to bring to bear practically; to put into practical operation." "Apply," *Oxford English Dictionary*, https://www.oed.com/view/Entry/9724?rskey=hXUug1&result=2&isAdvanced=false#eid (Exhibit USA-118).

[245] "Necessary," *Oxford English Dictionary*, https://www.oed.com/view/Entry/125629?redirectedFrom=necessary#eid (Exhibit USA-119).

'indispensable' than to the opposite pole of simply 'making a contribution to' [its objective]."[246] Here, the Tortilla Corn Ban cannot be found to meet any of these definitions of "necessary."

a. The Tortilla Corn Ban is Applied Beyond the Extent Necessary to Protect ***Human Life or Health****.*

149. The United States is not aware that the Tortilla Corn Ban makes *any* contribution to human health, let alone an "indispensable" contribution to human health so as to render the ban "necessary."[247] This is because there is no scientific evidence of a risk to human health from previously authorized GE corn events. As discussed, the Tortilla Corn Ban is not based on international standards, guidelines, or recommendations; in addition, the Tortilla Corn Ban is not based on any risk assessment that would suggest that the GE corn events authorized for importation and sale in Mexico for use other than cultivation are intrinsically hazardous to human health.[248] Indeed, it is simply not logical, nor scientifically sound, for a Party to contend that its measure is "necessary" to protect human, animal, or plant life or health where that Party has conducted no risk assessment that actually establishes a risk. Moreover, it is illogical and unscientific to claim that it is necessary to ban all future GE corn events before such events have been developed.

150. Instead, there is no evidence that Mexico's Tortilla Corn Ban is "necessary" to protect human health, and it is therefore inconsistent with Article 9.6.6(a) of the USMCA.

b. The Tortilla Corn Ban is Applied Beyond the Extent Necessary to Protect ***Plant Life or Health.***

151. To the extent Mexico contends that the Tortilla Corn Ban is intended to protect plant life or health, this set of measures is similarly not "necessary" to protect against such risks. First and foremost, it is not at all apparent how a ban on the use of GE corn in dough and tortillas—that is, for human consumption—has any relation to the protection of plant life or health.

152. There is also no credible scientific evidence that GE corn imports for dough and tortillas are affecting or could negatively affect native Mexican corn varieties. The Tortilla Corn Ban is not based on international standards, guidelines, or recommendations relevant to plant health or on any risk assessment that would suggest that the GE corn events that have been authorized for importation and sale in Mexico for use other than cultivation present a risk to plant life or health

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[246] *See* Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, para. 161 (adopted Jan. 10, 2001) (Exhibit USA-120).

[247] *See* "Necessary," *Oxford English Dictionary*, https://www.oed.com/view/Entry/125629?redirectedFrom=necessary#eid (Exhibit USA-119); Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, para. 161 (adopted Jan. 10, 2001) (Exhibit USA-120).

[248] *See supra* Section V.C.1.a.

or that any products including those events are hazardous to plant life or health.[249] Again, a Party cannot reasonably contend that its measure is "necessary" to protect plant life or health where that Party has not conducted a scientifically sound risk assessment to identify and assess the potential risk. That position is supported by the Secretariat of the IPPC, which has emphasized that any pest risk management measures must be based on the underlying risk assessment, and "prohibit[ing] the importation of the relevant commodities . . . should be viewed as a measure of last resort," only "[i]f no satisfactory measure to reduce risk to an acceptable level can be found."[250]

153. For these reasons, the Tortilla Corn Ban is an SPS measure that is applied beyond the extent necessary to protect human, animal, or plant life or health, and is therefore inconsistent with Article 9.6.6(a) of the USMCA.

2. The Substitution Instruction is Inconsistent with Article 9.6.6(a) of the USMCA.

154. For reasons similar to those presented with respect to the Tortilla Corn, the Substitution Instruction contravenes Article 9.6.6(a) of the USMCA, because it is an SPS measure that is applied beyond the extent necessary to protect human, animal, or plant life or health.

*a. The Substitution Instruction is Applied Beyond the Extent Necessary to Protect **Human Life or Health.***

155. The Substitution Instruction is not "necessary" to protect human health, because it is not "indispensable" or "essential" to mitigate against any human health risk.[251] The Substitution Instruction is not based on any international standards, guidelines, or recommendations or on a risk assessment that would suggest that the GE corn events that have been authorized for importation and sale in Mexico for use other than cultivation are intrinsically hazardous to human health or that any products including those events are hazardous to human health.[252] Similarly, it is illogical and unscientific to claim that it is necessary to ban all future possible GE corn events that may be imported and sold in Mexico for uses other than cultivation before such events have even been developed.

156. There is no foundation upon which Mexico can contend that the Substitution Instruction is "necessary" where it has failed to heed the relevant international standards, guidelines, or

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[249] *See supra* Section V.C.1.b.

[250] Secretariat of the IPPC, *Pest Risk Analysis for Quarantine Pests*, sec. 3.4.6 (2017), https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_11_2013_En_2017-05-25_PostCPM12_InkAm.pdf (Exhibit USA-103).

[251] Necessary," *Oxford English Dictionary*, https://www.oed.com/view/Entry/125629?redirectedFrom=necessary#eid (defining "necessary" as "indispensable, vital, essential; requisite") (Exhibit USA-119).

[252] *See supra* Section V.C.2.a.

recommendations and failed to conduct a risk assessment to identify and assess any relevant risk. Indeed, the 2023 Corn Decree provides that COFEPRIS is to conduct, at some unfixed point in the future, "the relevant scientific studies on the consumption of genetically modified corn and the possible damages to health," such that Mexico has no basis to contend that the Substitution Instruction is "necessary" to protect against these yet-to-be-identified risks to human health.[253]

157. Mexico's Substitution Instruction is not "necessary" to protect human health, and it is therefore inconsistent with Article 9.6.6(a) of the USMCA.

b. The Substitution Instruction is Applied Beyond the Extent Necessary to Protect ***Plant Life or Health.***

158. As for protecting plant life or health, the Substitution Instruction is not "necessary" to protect against any such risks either. Fundamentally, a ban on the use of GE corn in animal feed and for industrial use for human consumption is not rationally related to the protection of plant life or health.

159. In any event, Mexico has not based the Substitution Instruction on international standards, guidelines, or recommendations relevant to plant health or on any risk assessment that has found that the GE corn events that have been historically authorized for importation and sale in Mexico for use other than cultivation present a risk to plant life or health.[254] To the extent that Mexico were able to identify and technically justify a risk to plant life or health resulting from the use of GE corn for animal feed or industrial use for human consumption, such findings would need to be based on a risk assessment, and any ban on such end uses should only be considered as a "last resort," consistent with the relevant international standards, guidelines, and recommendations of the Secretariat of the IPPC.[255] However, Mexico has not produced a risk assessment to justify the Substitution Instruction, let alone demonstrated that there is "no other satisfactory measure to reduce risk to an acceptable level," as established under the ISPM 11 of the Secretariat of the IPPC.[256]

160. Mexico's Substitution Instruction is applied beyond the extent necessary to protect plant life or health, just as it is applied beyond the extent necessary to protect human or animal life or health. The Substitution Instruct is therefore inconsistent with Article 9.6.6(a) of the USMCA.

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[253] *See* 2023 Corn Decree, art. 8 (Exhibit USA-3).

[254] *See supra* Section V.C.2.b.

[255] Secretariat of the IPPC, *Pest Risk Analysis for Quarantine Pests*, sec. 3.4.6 (2017), https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_11_2013_En_2017-05-25_PostCPM12_InkAm.pdf (Exhibit USA-103).

[256] *Id.* (Exhibit USA-103).

E. The Measures at Issue Are Not Based on Relevant Scientific Principles, Inconsistent with Article 9.6.6(b) of the USMCA.

161. Article 9.6.6 (b) of the USMCA provides, in relevant part:

> Each Party shall ensure that its sanitary and phytosanitary measures . . . are based on relevant scientific principles, taking into account relevant factors, including, if appropriate, different geographic conditions."[257]

Mexico's Tortilla Corn Ban and Substitution Instruction are inconsistent with this USMCA obligation, because these sets of measures are not based on any relevant scientific principles.

1. The Tortilla Corn Ban is Inconsistent with Article 9.6.6(b) of the USMCA.

162. Both the SPS Chapter of the USMCA and the WTO's SPS Agreement provide that any SPS measure must be based on "scientific principles."

163. The dictionary definition of "principles," as relevant, is "[a] general law or rule adopted or professed as a guide to action; a settled ground or basis of conduct or practice."[258] As discussed above in the context of Article 9.6.3, the generally accepted "rules" and "grounds" or "guide to action" on which the development of SPS measures is based are the Codex standards, guidelines, and recommendations in the context of food safety, and the Secretariat of the IPPC's standards, guidelines, and recommendations in the context of plant health.[259] These relevant standards, guidelines, and recommendations all prescribe that a scientifically sound risk assessment should be performed and undergird any SPS measure that is enacted. However, as established in Section V.C.1, the Tortilla Corn Ban is not based on international standards, guidelines, or recommendations or on a risk assessment. Indeed, there is nothing in the 2023 Corn Decree that would indicate that the Tortilla Corn Ban is based on any scientific evidence at all, and the United States is not aware of any such evidence.

164. WTO panels, in assessing this requirement, have similarly explained that where a Party has failed to conduct a risk assessment, it may be presumed that the Party's measure is not based on scientific principles.[260] As WTO panels have reasoned, "[a]ny SPS measure must be based on

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[257] USMCA, art. 9.6.6(b).

[258] "Principle," *Oxford English Dictionary*, https://www.oed.com/dictionary/principle_n?tab=meaning_and_use#28387945 (Exhibit USA-123).

[259] *See supra* Section V.C.

[260] *See* Panel Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/R, paras. 7.472, 7.510, 7.779, 7887, 7.905, 7.1308 (adopted Dec. 17, 2010) (hereinafter "Panel Report, *Australia – Apples*") (Exhibit USA-121); Panel Report, *United States – Certain Measures Affecting Imports of Poultry from China*, WT/DS392/R, para. 7.201 (adopted Oct. 25, 2010) (hereinafter "Panel Report, *US – Poultry (China)*") (Exhibit USA-122).

a risk assessment, which, in turn, must be based on scientific evidence."[261]

165. Because the Tortilla Corn Ban is not based on scientific principles, the Tortilla Corn Ban is inconsistent with Article 9.6.6(b) of the USMCA.

2. The Substitution Instruction is Inconsistent with Article 9.6.6(b) of the USMCA.

166. Similarly, the Substitution Instruction is not based on relevant scientific principles and therefore is inconsistent with Article 9.6.6(b) of the USMCA.

167. The Substitution Instruction was developed without any basis in a risk assessment or on relevant international standards, guidelines, or recommendations.[262] The 2023 Corn Decree does not indicate that the Substitution Instruction is based on any scientific evidence whatsoever, and the United States is not aware of any credible evidence that would justify this sweeping set of measures that will reduce and ultimately eliminate GE corn for use in animal feed and for industrial use for human consumption.

168. Not based on any scientific principles, the Substitution Instruction is inconsistent with Article 9.6.6(b) of the USMCA.

F. Mexico Did Not Conduct Risk Assessments or Risk Management in a Manner that is Documented and Provided to Other Parties for an Opportunity to Comment, as Required by Article 9.6.7 of the USMCA.

169. As discussed above, Mexico did not conduct a risk assessment as the basis for the 2023 Corn Decree. However, even if Mexico had conducted risk assessments on which the Tortilla Corn Ban and Substitution Instruction were based, these measures would still be inconsistent with Article 9.6.7 of the USMCA, because the United States received no opportunity to comment on the risk assessments or the resulting risk management.

1. The Tortilla Corn Ban is Inconsistent with Article 9.6.7 of the USMCA.

170. Under Article 9.6.7 of the USMCA, "[a] Party shall conduct its risk assessment and risk management with respect to a sanitary or phytosanitary regulation within the scope of Annex B of the SPS Agreement in a manner that is documented and provides the other Parties and persons of the Parties an opportunity to comment, in a manner to be determined by that Party."

171. Annex B of the SPS Agreement defines SPS "regulations" as "[s]anitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally."[263]

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[261] *See* Panel Report, *Australia – Apples*, paras. 7.214 (Exhibit USA-121).

[262] *See supra* Section V.C.2.

[263] SPS Agreement, Annex B n.5 (Exhibit USA-34).

The Tortilla Corn Ban is part of the 2023 Corn Decree (*i.e.*, a decree), which applies generally. Furthermore, as explained in Section V.B.1, the Tortilla Corn Ban constitutes an SPS measure. Therefore, Article 9.6.7 of the USMCA applies to the Tortilla Corn Ban.

172. The USMCA incorporates the SPS Agreement's definition of "risk assessment,"[264] and the SPS Chapter of the USMCA defines "risk management" as "the weighing of policy alternatives in light of the results of [a] risk assessment and, if required, selecting and implementing appropriate controls, which may include sanitary or phytosanitary measures."[265] Thus, any risk management measures should be undertaken only upon consideration "of the results of [a] risk assessment" and may or may not include SPS measures.[266]

173. The United States was not provided an opportunity to comment on any such risk assessment or risk management prior to the issuance of the Tortilla Corn Ban. Moreover, Mexico did not document its risk assessment or risk management. As a result, the Tortilla Corn Ban is inconsistent with Article 9.6.7 of the USMCA.

2. The Substitution Instruction is Inconsistent with Article 9.6.7 of the USMCA.

174. The Substitution Instruction is inconsistent with Article 9.6.7 of the USMCA, because Mexico did not provide the United States with an opportunity to comment on any risk assessment or the resulting risk management.

175. Like the Tortilla Corn Ban, the Substitution Instruction constitutes "a sanitary or phytosanitary regulation within the scope of Annex B of the SPS Agreement" and therefore is subject to Article 9.6.7 of the USMCA. Specifically, the Substitution Instruction is part of the 2023 Corn Decree—*i.e.*, a decree that applies generally—which constitutes a "regulation within the scope of Annex B of the SPS Agreement."[267] In addition, the Substitution Instruction constitutes an SPS measure.[268] Therefore, the obligations of Article 9.6.7 apply to the Substitution Instruction.

176. However, the United States was not presented with an opportunity to comment on any risk assessment or risk management prior to Mexico's issuance of the Substitution Instruction. Moreover, Mexico did not document its risk assessment or risk management. Accordingly, the Substitution Instruction also is inconsistent with Article 9.6.7 of the USMCA.

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[264] USMCA, art. 9.1.1; SPS Agreement, Annex A, para. 4 (Exhibit USA-34).

[265] USMCA, art. 9.1.2.

[266] *Id*.

[267] *See* SPS Agreement, Annex B n.5 (defining SPS "regulations" to include "laws, decrees or ordinances which are applicable generally") (Exhibit USA-34).

[268] *See supra* Section II.D.3.

G. Mexico Failed to Conduct Risk Assessments that Took Into Account the Available Relevant Scientific Evidence, the Relevant Guidance of the WTO SPS Committee, or the Relevant International Standards, Guidelines, and Recommendations, Contrary to Article 9.6.8 of the USMCA.

177. Even if Mexico had conducted a risk assessment to evaluate the potential adverse effects to human, animal, or plant life or health arising from the use of GE corn in dough and tortillas (as relevant to the Tortilla Corn Ban) or the use of GE corn in animal feed and industrial use for human consumption (as relevant to the Substitution Instruction), Article 9.6.8 of the USMCA would still require such risk assessments, and any associated risk management, to "take into account… the relevant international standards, guidelines, and recommendations of the relevant international organization" and "the available relevant scientific evidence," which was not the case here.[269]

1. The Tortilla Corn Ban is Inconsistent with Article 9.6.8 of the USMCA.

178. Article 9.6.8 of the USMCA provides:

> In conducting its risk assessment and risk management, each Party shall:
>
> (a) ensure that each risk assessment it conducts is appropriate to the circumstances of the risk to human, animal, or plant life or health, and takes into account the available relevant scientific evidence, including qualitative and quantitative data and information; and
>
> (b) take into account relevant guidance of the WTO SPS Committee and the relevant international standards, guidelines, and recommendations of the relevant international organization.

179. As noted repeatedly above, Mexico did not base any aspect of the 2023 Corn Decree on a risk assessment. And Mexico certainly did not conduct a risk assessment that took into account the available relevant scientific evidence or the relevant international standards, guidelines and recommendations of the relevant international organizations.

180. As detailed in Section V.C.1, the Tortilla Corn Ban is plainly at odds with the applicable international standards, guidelines, and recommendations of Codex and the Secretariat of the IPPC, which establish that a risk assessment should be based on "scientific data"[270] and use

[269] USMCA, art. 9.6.8.

[270] *See* Codex Principles, sec. 3, paras. 12-15, 29-30 (Exhibit USA-113).

"sound scientific methods,"[271] and the resulting SPS measure should be "technically justified."[272] The Tortilla Corn Ban also contradicts the extensive scientific literature affirming that dietary consumption of GE corn is safe for both humans and the environment. Any risk assessment therefore cannot have taken into account the relevant scientific evidence demonstrating the safety of GE corn, including those events previously authorized by Mexico itself.

181. Accordingly, the Tortilla Corn Ban is inconsistent with Article 9.6.8 of the USMCA.

2. The Substitution Instruction is Inconsistent with Article 9.6.8 of the USMCA.

182. Even if Mexico had conducted a risk assessment to evaluate the potential adverse effects to human, animal, or plant life or health arising from the use of GE corn in animal feed and industrial use for human consumption, the risk assessment would not meet the criteria set out in Article 9.6.8.

183. Again, as detailed in Section V.C.2, Mexico has not taken into account the international standards, guidelines, and recommendations of Codex or the Secretariat of the IPPC, relevant to assessing potential risks to human or plant life or health, respectively. Furthermore, Mexico has not taken into account the available relevant scientific evidence that demonstrates that consuming GE corn presents no adverse effects to human, animal, or plant life or health.[273] Indeed, there is no scientific evidence of a risk from GE corn in animal feed and industrial use for human consumption, and any risk assessment cannot have taken into account the abundant evidence of safety.

184. For these reasons, Mexico has acted inconsistently with Article 9.6.8 of the USMCA.

H. The Measures at Issue are More Trade-Restrictive Than Required to Achieve a Defined Level of Protection, in Breach of Article 9.6.10 of the USMCA.

185. The Tortilla Corn Ban and Substitution Instruction are inconsistent with Article 9.6.10 of the USMCA because these sets of measures are more trade-restrictive than required to achieve an ALOP that Mexico has determined to be appropriate.

186. Article 9.6.10 of the USMCA provides:

> Without prejudice to Article 9.4 (General Provisions), each Party shall select a sanitary or phytosanitary measure that is not more trade restrictive than required

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[271] *See* Codex Guidelines, sec. 3, para. 20 (Exhibit USA-114).

[272] *See* Secretariat of the IPPC, *International Plant Protection Convention*, arts. II.1, VII.2 (1997), https://www.ippc.int/en/publications/131/ (Exhibit USA-102).

[273] *See supra* Section II.B.3.

> to achieve the level of protection that the Party has determined to be appropriate. For greater certainty, a sanitary or phytosanitary measure is not more trade restrictive than required unless there is another option that is reasonably available, taking into account technical and economic feasibility, that achieves the Party's appropriate level of protection and is significantly less restrictive to trade.

187. The second sentence of Article 9.6.10 clarifies that a measure is not consistent with Article 9.6.10 if there is an alternative measure that (i) is reasonably available, taking into account technical and economic feasibility, (ii) achieves the Party's ALOP, and (iii) is significantly less trade-restrictive than the measure at issue. Annex A of the SPS Agreement, incorporated as relevant here into the USMCA, defines "appropriate level of sanitary or phytosanitary protection" as "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal, or plant life or health within its territory."[274]

1. The Tortilla Corn Ban is Inconsistent with Article 9.6.10 of the USMCA.

188. Mexico has not publicly defined any particular ALOP it seeks to achieve through the Tortilla Corn Ban.[275] And there is no credible scientific evidence establishing any health risks posed by human consumption of GE corn in dough and tortillas. Therefore, whatever ALOP Mexico might have set, the Tortilla Corn Ban would be more trade-restrictive than is necessary to meet it.

189. Similarly, to the extent the Tortilla Corn Ban is intended to protect plant life or health, Mexico would have needed to determine the risk to plant life or health, establish an ALOP, and then tailored the measure to not be more trade restrictive than necessary while meeting that ALOP. There is no plausible ALOP related to plant life or health that would require a blanket prohibition on importation of GE corn for dough and tortillas, as evident from the safe consumption and use of GE corn for years in Mexico and around the world.

190. At bottom, because the Tortilla Corn Ban does not achieve any ALOP, a reasonably available, less trade-restrictive alternative would be to withdraw it altogether.

2. The Substitution Instruction is Inconsistent with Article 9.6.10 of the USMCA.

191. Similarly, Mexico's Substitution Instruction is inconsistent with Article 9.6.10 of the USMCA, because this set of measures is more trade-restrictive than required to achieve any

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[274] USMCA, art. 9.1.1 ("The definitions in Annex A of the SPS Agreement are incorporated into and made part of this Chapter, *mutatis mutandis*, except as otherwise provided for in paragraph 2.").

[275] *See also* Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, para. 205 (adopted Nov. 6, 1998) (evaluating language similar to Article 9.6.10 of the USMCA, and explaining that the SPS Agreement contains an implicit obligation for a Member to determine its ALOP) (Exhibit USA-109).

purported ALOP.

192. Again, Mexico has not publicly defined any particular ALOP it seeks to achieve with this set of measures. There is no credible evidence establishing that human (or animal) consumption of GE corn presents a different or greater risk to health than consumption of non-GE corn. Indeed, Mexico appears to acknowledge there is no material difference, as any COFEPRIS authorization of a GE corn event, including recent COFEPRIS authorizations, must be predicated on finding that the GE corn event is substantially equivalent to its conventional counterpart, and take into account the "use and consumption conditions in Mexico."[276] Therefore, whatever ALOP Mexico might have set, the Substitution Instruction would be more trade-restrictive than is necessary to meet it.

193. To the extent the Substitution Instruction is intended to protect plant life or health (*e.g.*, Mexico's native corn landraces), Mexico would have needed to have credible scientific evidence establishing a risk to plant health or life posed by the use of GE corn in animal feed or industrial use for human consumption, establish an ALOP, and then tailored the measure to not be more trade restrictive than necessary while meeting that ALOP. There is no plausible ALOP related to plant life or health that would require a phase-out and ultimate prohibition on the importation of GE corn for animal feed and industrial use for human consumption. Even if the Substitution Instruction contributed to a yet-to-be-defined ALOP, there certainly would be less trade-restrictive alternatives readily available for Mexico to utilize.

194. For these reasons, the Substitution Instruction is inconsistent with Article 9.6.10 of the USMCA.

I. The Measures at Issue are Also Inconsistent with the National Treatment and Market Access for Goods Chapter of the USMCA.

195. In addition to the claims under the SPS Chapter, laid out above, the Tortilla Corn Ban and the Substitution Instruction are inconsistent with Chapter 2 of the USMCA. Chapter 2 of the USMCA (National Treatment and Market Access for Goods) "applies to trade in goods of a Party."[277]

196. In particular, Article 2.11 of the USMCA provides in relevant part:

> Except as otherwise provided in this Agreement, no Party shall adopt or maintain any prohibition or restriction on the importation of any good of another Party or on the exportation or sale for export of any good destined for the territory of another Party,

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[276] *See* Biosafety Regulations, art. 31.I.j.5 (providing that the substantial equivalence studies, submitted by applicants, must include information on the content of true proteins and amino acids; the composition of total lipids, carbohydrates, and vitamins; the presence of any antinutritional constituents; stability during storage, in particular degrading of nutrients; et cetera.) (Exhibit USA-86).

[277] USMCA, art. 2.2.

> except in accordance with Article XI of the [General Agreement on Tariffs and Trade ("GATT")] 1994, including its interpretative notes, and to this end Article XI of the GATT 1994 and its interpretative notes are incorporated into and made a part of this Agreement, *mutatis mutandis*.

197. Thus, Article 2.11 sets out three elements to determine whether the measures at issue are inconsistent with the provision: (i) the measure is a "prohibition or restriction" on importation, (ii) the measure is not "in accordance with Article XI of the GATT 1994," and (3) the measure is not "otherwise provided" for in the USMCA.

198. The sections that follow detail how the Tortilla Corn Ban and Substitution Instruction, respectively, meet these three elements and thus are inconsistent with Article 2.11 of the USMCA.

1. The Tortilla Corn Ban Constitutes a Prohibition or Restriction on the Importation of a Good of Another Party that is Inconsistent with Article 2.11 of the USMCA.

199. The Tortilla Corn Ban is inconsistent with Article 2.11 of the USMCA, because this set of measures (i) constitutes a "prohibition or restriction" on importation, (ii) is not "in accordance with Article XI of the GATT 1994," and (iii) is not "otherwise provided" for in the USMCA.

a. The Tortilla Corn Ban Constitutes a "Prohibition or Restriction" on Importation.

200. The Tortilla Corn Ban constitutes a "prohibition or restriction" on importation for purposes of Article 2.11 of the USMCA.

201. The ordinary meaning of "prohibition," as used in Article 2.11, is "[t]he outlawing of the trading or importation of a specific commodity; a legal ban of this sort."[278] The ordinary meaning of "restriction," as relevant to acts of importation or exportation, is "a limitation on action; a limiting condition or regulation."[279] Thus, the ordinary meaning encompasses anything that imposes a "limitation" or a "limiting condition" on importation.

202. Finally, the ordinary meaning of "importation," as relevant to Article 2.11 of the USMCA, concerns the "action or practice of importing . . . goods."[280] Thus, the definition of

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[278] "Prohibition," *Oxford English Dictionary*, https://www.oed.com/view/Entry/152258?redirectedFrom=prohibition#eid (Exhibit USA-125).

[279] "Restriction," *Oxford English Dictionary*, https://www.oed.com/view/Entry/164022?redirectedFrom=restriction#eid (Exhibit USA-127).

[280] "Importation," *Oxford English Dictionary*, https://www.oed.com/dictionary/importation_n?tab=meaning_and_use#875896 ("The action or practice of

"importation" suggests that showing a measure constitutes a "restriction on the importation" of a good does not require a showing that trade levels have been affected but rather that the measure places a limitation on the process of importation.

203. In WTO dispute settlement, panels have interpreted similar language in Article XI:1 of the GATT 1994 ("[n]o prohibitions or restrictions . . . on the importation of any product of the territory of any [Member]"). WTO panels have interpreted "prohibition" on importation to mean that "Members shall not forbid the importation of any product of any other Member into their markets."[281] As for the word "restriction" in Article XI:1 of the GATT 1994, WTO panels have found that "[t]he scope of the term 'restriction' is . . . broad, as seen in its ordinary meaning"[282] and that "any form of limitation imposed on, or in relation to importation constitutes a restriction on importation within the meaning of Article XI:1."[283]

204. Mexico's Tortilla Corn Ban constitutes, at a minimum, a "restriction" under Article 2.11 of the USMCA. The Tortilla Corn Ban provides that Mexico's "biosafety authorities . . . shall revoke and refrain from issuing authorizations for the use of genetically modified corn grain for human consumption."[284] Moreover, effective immediately, it is the "responsibility of whoever uses [GE corn] in Mexico [to ensure] that it does not have the destination foreseen in [the Tortilla Corn Ban]."[285]

205. Consequently, the Tortilla Corn Ban provides that, effective immediately, COFEPRIS must revoke any authorizations of GE corn events that cover "human consumption," as defined in the Decree to cover use in dough and tortillas; further, GE corn with events not already authorized for importation and commercialization for "human consumption" cannot legally be

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importing a commodity, merchandise, goods, etc., from another country or territory for use or resale in the domestic market.") (Exhibit USA-132).

[281] *See* Panel Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/R, para. 7.11 (adopted Dec. 17, 2007) (Exhibit USA-126); Panel Report, *US – Poultry (China)*, para. 7.454 (quoting same) (Exhibit USA-122).

[282] Panel Report, *India – Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, WT/DS90/R, para. 5.128 (adopted Sept. 22, 1999) (hereinafter "Panel Report, *India – Quantitative Restrictions*") (Exhibit USA-128).

[283] Panel Report, *India – Measures Affecting the Automotive Sector*, WT/DS146/R, WT/DS175/R, para. 7.265 (adopted Apr. 5, 2002) (original emphasis omitted) (Exhibit USA-129); *see also* Appellate Body Reports, *China – Measures Related to the Exportation of Various Raw Materials*, WT/DS394/AB/R, WT/DS395/AB/R, WT/DS398/AB/R, para. 319 (adopted Feb. 22, 2012) (finding that "restriction" refers to "'[a] thing which restricts someone or something, a limitation on action, a limiting condition or regulation,' and thus refers generally to something that has a limiting effect" (quoting *Shorter Oxford English Dictionary*, 6th edn, W.R. Trumble, A. Stevenson (eds) (Oxford University Press, 2007), Vol. 2, p. 2553)) (Exhibit USA-130); Appellate Body Reports, *Argentina – Measures Affecting the Importation of Goods*, WT/DS438/AB/R, WT/DS444/AB/R, WT/DS445/AB/R, para. 5.217 (adopted Jan. 26, 2015) (quoting same) (Exhibit USA-131).

[284] 2023 Corn Decree, art. 6.II (Exhibit USA-3).

[285] *Id.*, art. 7 (Exhibit USA-3).

imported for that purpose. Moreover, anyone using GE corn in Mexico must ensure that it is not used for "human consumption," as defined in the 2023 Corn Decree. Accordingly, there is no legal path for GE corn to be imported or sold in Mexico for use in dough and tortillas, pursuant to the Tortilla Corn Ban.

206. The Tortilla Corn Ban establishes that GE corn cannot be imported or sold in Mexico for a specified purpose and thereby imposes a "limitation" or a "limiting condition" on importation. WTO panels interpreting Article XI of the GATT 1994 have concluded that bans on the importation of products for certain purposes are "restrictions" under Article XI:1.[286] Similarly here, the Tortilla Corn Ban constitutes a "restriction" on importation under Article 2.11 of the USMCA.

b. The Tortilla Corn Ban Is Not "In Accordance with Article XI of the GATT 1994."

207. The Tortilla Corn Ban also meets the second element required to show inconsistency with Article 2.11 of the USMCA, in that the Tortilla Corn Ban is not "in accordance with Article XI of the GATT 1194."

208. Article 2.11 of the USMCA incorporates by reference Article XI of the GATT 1994 and provides that any measure "in accordance with Article XI of the GATT 1994, including its interpretative notes" is not inconsistent with Article 2.11. Article XI:1 of the GATT 1994 reflects an obligation similar to the one provided under Article 2.11 of the USMCA. Article XI:1 states, in relevant part:

> No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party . . . .

209. Article XI:2 sets out three categories of measures that are exempted from the scope of Article XI:1, namely: (a) export prohibitions or restrictions temporarily applied to prevent or relieve critical shortages, (b) import and export prohibitions or restrictions "necessary to the application of standards or regulations for the classification, grading or marketing of commodities in international trade," and (c) import restrictions on agricultural or fisheries products necessary to the enforcement of certain governmental measures.[287] The interpretive

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[286] Panel Report, *India – Quantitative Restrictions*, para. 5.142 (finding that an "actual user" requirement was a "restriction" inconsistent with Article XI:1, because it "preclude[d] imports of products for resale by intermediaries, i.e. distribution to consumers who are unable to import directly for their own immediate use is restricted") (Exhibit USA-128); *see also* Panel Report, *Indonesia – Importation of Horticultural Products, Animals and Animal Products*, WT/DS477/R, WT/DS478/R, paras. 7.198-7.199 (adopted Nov. 22, 2017) (Exhibit USA-134).

[287] WTO, *General Agreement on Tariffs and Trade 1994*, art. XI:2 (hereinafter "GATT 1994") (excerpt) (Exhibit USA-139). Article XI:2(c), pertaining to "[i]mport restrictions on any agricultural or fisheries product," provides

notes to Article XI concern Article XI:2 specifically.[288]

210. The Tortilla Corn Ban is a "restriction[] . . . on the importation of any product of" the United States under Article XI:1 of the GATT 1994 for the same reasons it constitutes a "restriction on the importation of any good of [the United States]" under Article 2.11 of the USMCA, as addressed in the previous section.[289] Further, the Tortilla Corn Ban does not constitute a duty, tax, or charge, all of which are carved out from Article XI:1, nor does the Tortilla Corn Ban fall within the categories of measures exempted by Article XI:2 of the GATT 1994. Thus, the Tortilla Corn Ban is not in accordance with Article XI of the GATT 1994.

c. The Tortilla Corn Ban Is Not "Otherwise Provided" For in the USMCA.

211. Finally, the Tortilla Corn Ban is an import restriction that is not "otherwise provided" for in the USMCA and therefore is inconsistent with Article 2.11.

212. The first clause of paragraph 1 of Article 2.11 provides that the prohibition on adopting or maintaining import and export restrictions is applicable "[e]xcept as otherwise provided in this Agreement."

213. However, there is no provision of the USMCA that shields the Tortilla Corn Ban from the obligations of Article 2.11. For example, Article 2.11.7 of the USMCA provides that paragraphs 1 to 6 of Article 2.11 do not apply to the measures listed in Annex 2-A, titled "Exceptions to Article 2.3 (National Treatment) and Article 2.11 (Import and Export Restrictions)."[290] However, the Tortilla Corn Ban does not fall under any of the measures that Mexico exempted in Annex 2-A.[291]

214. Because the Tortilla Corn Ban is not otherwise provided for in the USMCA and constitutes an import restriction that is not adopted or maintained in accordance with Article XI of the GATT 1994, the Tortilla Corn Ban is inconsistent with Article 2.11 of the USMCA.

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that such restrictions must be necessary to enforce government measures that operate, *inter alia*, "to restrict the quantities of the like domestic product" or "to remove a temporary surplus of the like domestic product." Even if Article XI:2(c) were relevant to the situation here, which it is not, this subparagraph was rendered inoperative with respect to agricultural products by Articles 4.2 and 21.1 of the WTO's *Agreement on Agriculture* and, consequently, is not available to justify the challenged measures. *See* Appellate Body Report, *Indonesia – Importation of Horticultural Products, Animals and Animal Products*, WT/DS477/AB/R, WT/DS478/AB/R, paras. 5.79-5.85 (adopted Nov. 22, 2017) (Exhibit USA-135).

[288] *See* GATT 1994, Annex I, ad art. XI (Exhibit USA-139).

[289] *See supra* Section V.I.1.a.

[290] *See* USMCA, art. 2.11.7.

[291] *See id.*, Annex 2-A, art. 2.A.3 (referring, *inter alia*, to "prohibitions or restrictions on the importation into Mexico of used tyres, used apparel, non-originating used vehicles, and used chassis equipped with vehicle").

2. The Substitution Instruction Constitutes a Prohibition or Restriction on the Importation of a Good of Another Party that is Inconsistent with Article 2.11 of the USMCA.

215. The Substitution Instruction is inconsistent with Article 2.11 of the USMCA, because this set of measures (i) constitutes a "prohibition or restriction" on importation, (ii) is not "in accordance with Article XI of the GATT 1994," and (iii) is not "otherwise provided" for in the USMCA.

a. The Substitution Instruction Constitutes a "Prohibition or Restriction" on Importation.

216. Mexico's Substitution Instruction, like the Tortilla Corn Ban, constitutes a "restriction" on importation under Article 2.11 of the USMCA.[292]

217. The Substitution Instruction mandates that the relevant government agencies "will carry out the appropriate actions in order to conduct the gradual substitution of genetically modified corn for animal feed and industrial use for human consumption."[293] The 2023 Corn Decree underscores that government enforcement of the Substitution Instruction is mandatory: "Non-compliance with the provisions of this Decree by [these agencies] shall give rise to the corresponding administrative liabilities."[294]

218. The Substitution Instruction is a use restriction, restricting imports of GE corn for animal feed or industrial use for human consumption. Both the gradual phase-out and the completed substitution place a "limiting condition" on importation for certain (broad) uses, and therefore constitute a "restriction" under the ordinary meaning of "prohibition or restriction" on importation for purposes of Article 2.11.[295]

219. Accordingly, the Substitution Instruction constitutes a restriction on importation of a good under Article 2.11 of the USMCA.

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[292] *See supra* Section V.I.1.a (explaining the ordinary meanings of "prohibition," "restriction," and "importation," relevant to Article 2.11 of the USMCA).

[293] 2023 Corn Decree, art. 7 (Exhibit USA-3).

[294] *Id.*, art. 10 (Exhibit USA-3).

[295] *See* Panel Report, *India – Quantitative Restrictions*, para. 5.142 (finding that certain use requirements constitute a "restriction" inconsistent with Article XI:1 of the GATT 1994) (Exhibit USA-128); Panel Report, *Indonesia – Importation of Horticultural Products, Animals and Animal Products*, WT/DS477/R, WT/DS478/R, paras. 7.198-7.199 (adopted Nov. 22, 2017) (same) (Exhibit USA-134); *supra* Section V.I.1.a (explaining the ordinary meanings of "prohibition," "restriction," and "importation," relevant to Article 2.11 of the USMCA).

b. The Substitution Instruction Is Not "In Accordance with Article XI of the GATT 1994."

220. The Substitution Instruction is not "in accordance with Article XI of the GATT 1994."

221. As explained in Section V.I.1.b, Article 2.11 of the USMCA incorporates by reference Article XI of the GATT 1994 and provides that any measure "in accordance with Article XI of the GATT 1994, including its interpretative notes" is not inconsistent with Article 2.11.

222. However, like the Tortilla Corn Ban, the Substitution Instruction constitutes a prohibited "restriction[] . . . on the importation of any product of" the United States under Article XI:1 of the GATT 1994 for the same reasons the Substitution Instruction constitutes a "restriction on the importation of any good of [the United States]" under USMCA Article 2.11.[296] The Substitution Instruction is not a duty, tax, or charge, all of which are exempted from the obligation of Article XI:1 of the GATT 1994.[297] Nor does the Substitution Instruction fall under one of the categories of prohibitions or restrictions that are exempted under Article XI:2 of the GATT 1994. Thus, the Substitution Instruction is not in accordance with Article XI of the GATT 1994.

c. The Substitution Instruction Is Not "Otherwise Provided" For in the USMCA.

223. Finally, the Substitution Instruction is an import restriction that is not "otherwise provided" for in the USMCA and therefore is inconsistent with Article 2.11.

224. As explained in the context of the Tortilla Corn Ban, there is no provision of the USMCA that would obviate the application of Article 2.11 to the Substitution Instruction. The Substitution Instruction does not fall within the measures listed in Annex 2-A, which lists Mexico's designated exceptions to Article 2.11.[298]

225. Because no other provision of the USMCA provides for the adoption or maintenance of the Substitution Instruction, this set of measures constitutes an import restriction that is inconsistent with Article 2.11 of the USMCA.

VI. CONCLUSION

226. For the reasons set out above, Mexico's agricultural biotechnology measures concerning GE corn are inconsistent with the commitments that Mexico made in the USMCA. The United

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[296] *See supra* Sections V.I.1.b, V.I.2.a.

[297] *See* GATT 1994, art. XI:1 ("No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party . . . .") (Exhibit USA-139).

[298] *See* USMCA, art. 2.11.7; *id.*, Annex A, art. 2.A.3.

States respectfully requests that the Panel make findings of breach with respect to both the Tortilla Corn Ban and the Substitution Instruction, which the United States challenges in this dispute. Specifically, the United States requests that the Panel find that:

(1) The Tortilla Corn Ban is inconsistent with the following provisions of the USMCA:

a. Article 9.6.3 because the measure is not based on relevant international standards, guidelines, or recommendations or on an appropriate risk assessment;

b. Article 9.6.6(a) because the measure is not applied only to the extent necessary to protect human, animal, or plant life or health;

c. Article 9.6.6(b) because the measure is not based on relevant scientific principles, taking into account relevant factors;

d. To the extent Mexico conducted a risk assessment, Article 9.6.7 because Mexico did not conduct a risk assessment or risk management with respect to an SPS regulation in a manner that is documented and provides the other Parties an opportunity to comment;

e. To the extent Mexico conducted a risk assessment, Article 9.6.8 because any such risk assessment did not take into account the available relevant scientific evidence, the relevant guidance of the WTO SPS Committee, or the relevant international standards, guidelines, and recommendations;

f. Article 9.6.10 because Mexico did not select an SPS measure not more trade restrictive than required to achieve the level of protection that the Party has determined to be appropriate; and

g. Article 2.11 because Mexico adopted or maintains a prohibition or restriction on the importation of a good of another Party.

(2) The Substitution Instruction is inconsistent with the following provisions of the USMCA:

a. Article 9.6.3 because the measure is not based on relevant international standards, guidelines, or recommendations or on an appropriate risk assessment;

b. Article 9.6.6(a) because the measure is not applied only to the extent necessary to protect human, animal, or plant life or health;

c. Article 9.6.6(b) because the measure is not based on relevant scientific principles, taking into account relevant factors;

d. To the extent Mexico conducted a risk assessment, Article 9.6.7 because Mexico did not conduct a risk assessment or risk management with respect to an SPS regulation in a manner that is documented and provides the other Parties an opportunity to comment;

e. To the extent Mexico conducted a risk assessment, Article 9.6.8 because any such risk assessment did not take into account the available relevant scientific evidence, the relevant guidance of the WTO SPS Committee, or the relevant international standards, guidelines, and recommendations;

f. Article 9.6.10 because Mexico did not select an SPS measure not more trade restrictive than required to achieve the level of protection that the Party has determined to be appropriate; and

g. Article 2.11 because Mexico adopted or maintains a prohibition or restriction on the importation of a good of another Party.